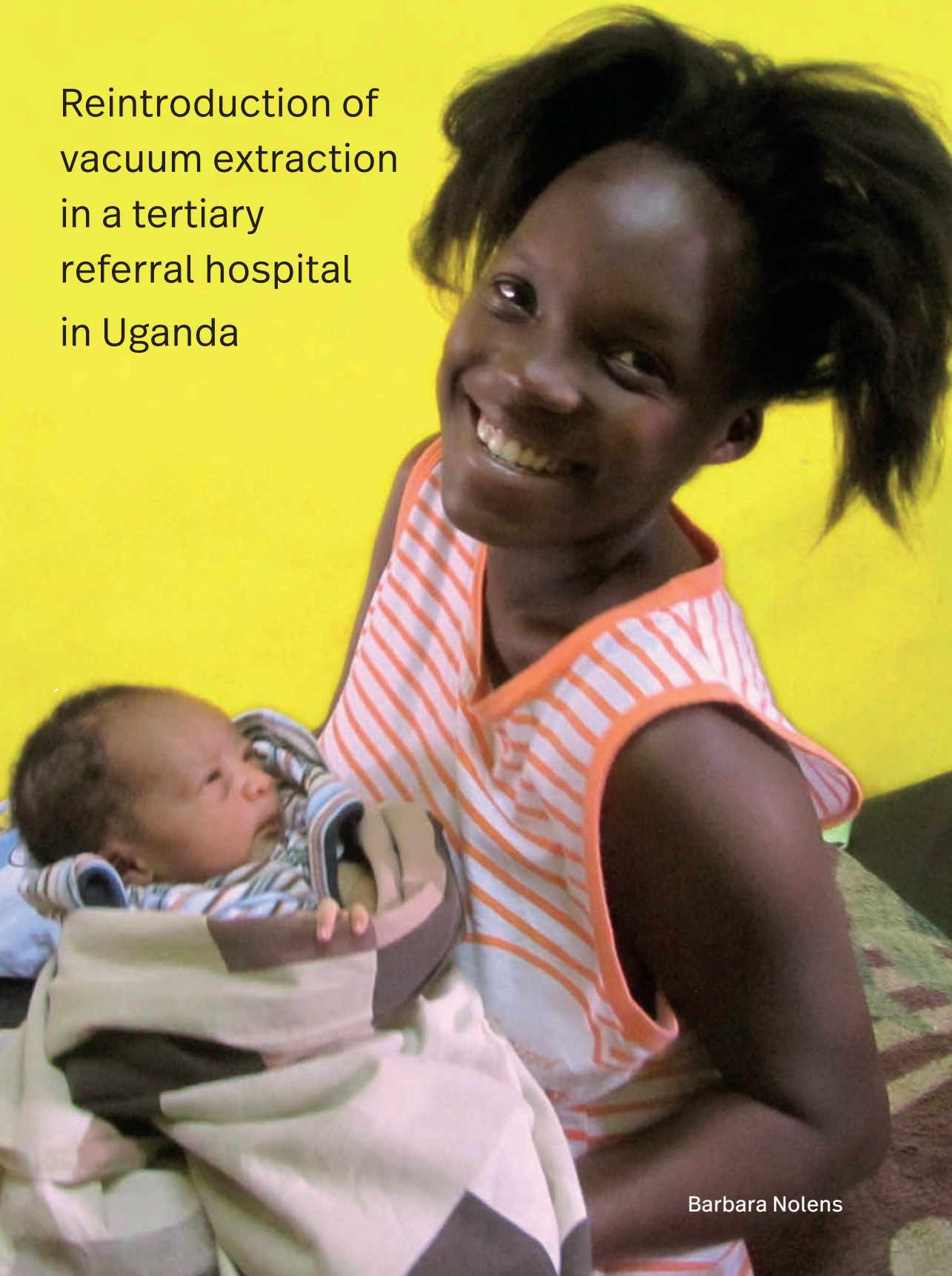
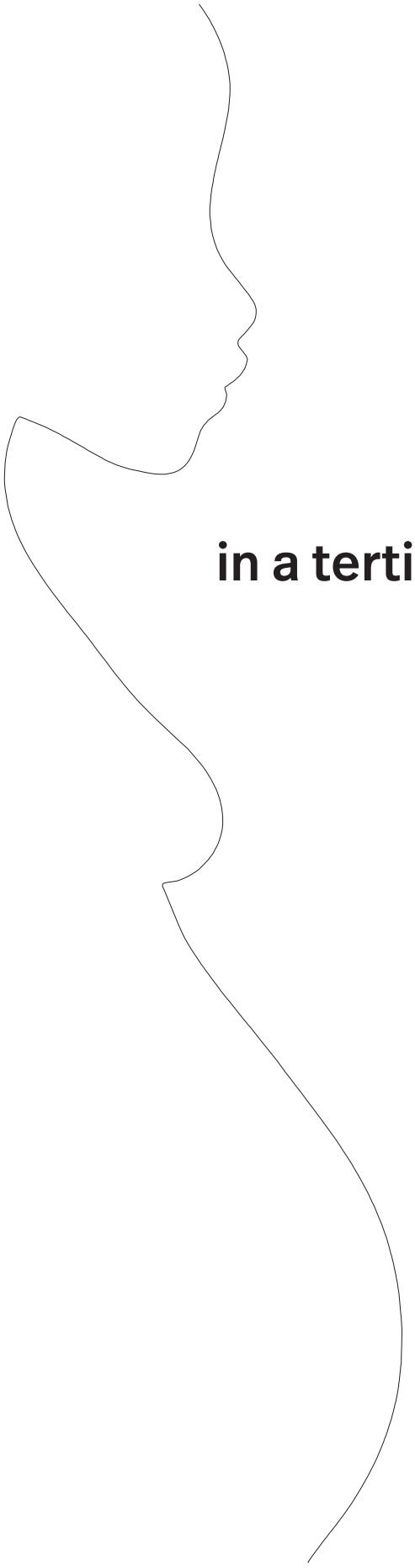
Reintroduction of vacuum extraction in a tertiary referral hospital in Uganda



Barbara Nolens



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Barbara Nolens

Colofon

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Reintroduction of vacuum extraction in a tertiary referral hospital in Uganda

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Barbara Johanna Nolens – van der Horst
geboren te Enschede

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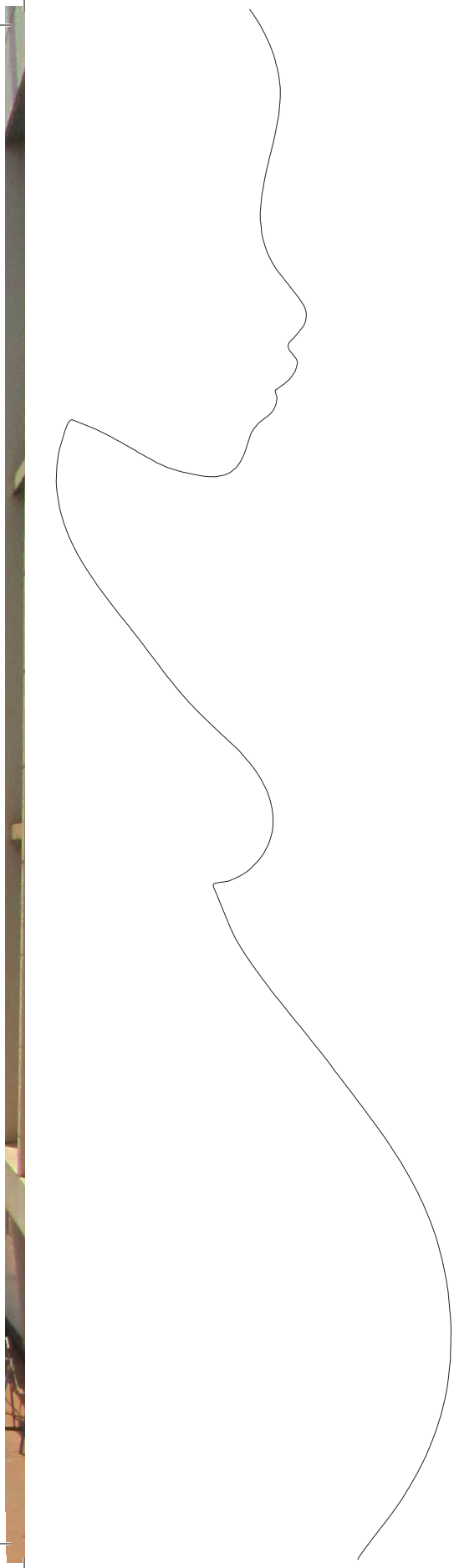

CHAPTER 1

General introduction

Vacuum extraction is a method to assist a woman to give birth vaginally, using a vacuum device. The device, known as a vacuum extractor, uses a cup that attaches to the baby's head with suction. It is used in the second stage of labour if there has been inadequate progress, if the woman is exhausted or if fetal or maternal distress is suspected. While the woman pushes, the health professional assists by pulling, usually during one to four contractions. Vacuum extraction is considered safe for mother and baby if the correct technique is applied.[1-4] Alternative management options are forceps birth and caesarean section. In this thesis we explore the use and outcome of vacuum extraction compared to caesarean section during the second stage of labour in the setting of a tertiary referral hospital in Uganda.

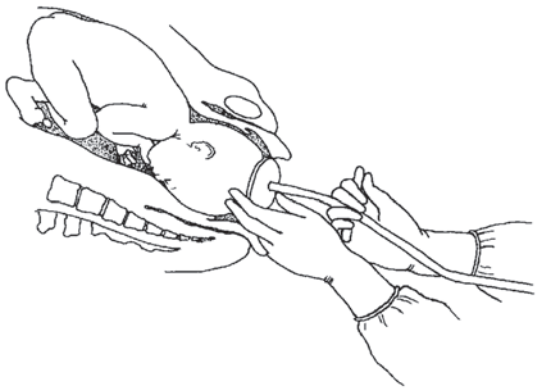

Figure 1 | Vacuum extraction with Malmström vacuum extractor[1]

Background and justification

Observations from a Dutch obstetrician in Mulago hospital, Uganda

From 2012 to 2015 I had the privilege to work as an obstetrician in Mulago hospital, the large tertiary referral and university teaching hospital for Makerere University in Kampala, Uganda. The hospital has one of the busiest labour wards in the world, with up to 33 000 births per year, equivalent to 90 per day. Most women give birth on main labour ward, the ward for women with medium- to high-risk pregnancies (Table 1). In this labour ward, work was very different from what I was used to in the Netherlands. Vacuum extraction was hardly ever used. Of all births, 0.6% were by vacuum extraction compared to 10.5% in the Dutch hospital where I had worked previously. The caesarean section rate was relatively high at 28.2% of births, compared to 20.6% in the Dutch hospital. Forceps was used in less than 0.1% in both hospitals (data for 2012 from Mulago hospital, records department and Canisius-Wilhelmina hospital, annual report 2012). Fetal monitoring during labour was by intermittent auscultation with Pinard fetoscope.

Table 1 | Key data Mulago hospital 2012[a]

Total number of beds (entire hospital)	2 700
Total births 2012	33 231
- Births on main labour ward (study site)	24 530
- Births on low risk maternity ward (managed by midwives)	6 754
- Births on private ward	1 947
Staff	
Nurse-midwives	43
Consultant obstetricians	46
Residents in obstetrics and gynaecology	45
Intern doctors	20
Characteristics main labour ward (medium and high risk)[b]	
Caesarean section rate (%)	28.2
Vacuum extraction rate (%)	0.6
Maternal mortality ratio (MMR) per 100 000 births	799
MMR caused by intrapartum complications	264
Stillbirths per 1000 births	57
Intrapartum stillbirths per 1000 births	34
Perinatal mortality rate per 1000 births	91

[a] *From Mulago hospital records department*
[b] *Data from May-October 2012*

In Mulago hospital, most women with prolonged second stage of labour or fetal distress during the second stage of labour were taken to the operating theatre for caesarean section. The theatre was situated next to main labour ward and consisted of two operating rooms. It was accessible 24 hours per day. However, due to the limited capacity of the theatre compared to the overwhelming number of women, the operating rooms were constantly occupied and waiting time for emergency caesarean section could be hours.

This had devastating consequences: intrauterine fetal death (IUFD), uterine rupture and neonatal brain damage caused by birth asphyxia.[5-7] Every day, there were on average four IUFD's and one woman with uterine rupture (data from Mulago hospital records department). Also, some women had complications directly resulting from surgery, such as haemorrhage, sepsis or complications from anaesthesia.[8] It was not uncommon that a woman died during or shortly after caesarean section. These adverse outcomes are comparable to figures from other hospitals in similar settings.[9,10] Infrequent use of vacuum extraction and use of caesarean section rather than vacuum extraction for prolonged second stage of labour are two observations present in many hospitals in sub-Saharan Africa.[11-13]

Watching women and neonates die, knowing that some would have survived in different circumstances, made me sad and frustrated. The plan of (re)implementing vacuum extraction arose and resulted in this thesis.

Setting

Uganda

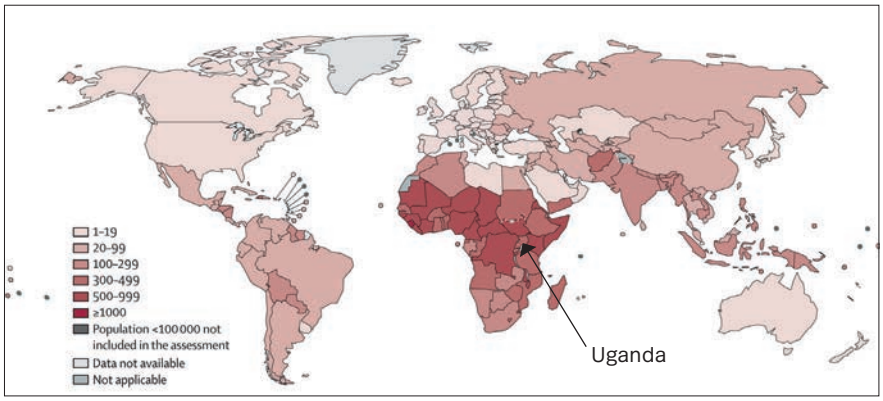

Figure 2 | Global maternal mortality ratios per 100 000 live births[14]

The studies in this thesis took place in Kampala, the capital of Uganda. Uganda is a landlocked country in east-Africa surrounded by Kenya, Tanzania, Rwanda, Democratic Republic of the Congo and South-Sudan. Uganda is 5.7 times the size of the Netherlands, with 2.4 times the number of inhabitants. It is a low-income country with a GDP of 27 billion USD compared to 758 billion USD of the Netherlands (2015). In 2015, health expenditure per capita was 40 USD (5.7% of GDP) in Uganda and 4660 USD (10.4% of GDP) in the Netherlands[15]. Some important maternal health related indicators are shown in Table 2 and Figure 2.

Table 2 | Health related data for Uganda and the Netherlands[a,15-22]

	Uganda	Netherlands
Total population (million)	38.2	16.9
Life expectancy at birth (years, female)	62	83
Total live births per year (million)	1.69	0.17
Total fertility rate	5.4	1.7
MMR per 100 000 live births	336	5
Stillbirths per 1000 live births[b]	16.5	2.2
NMR per 1000 live births[c]	24.1	2.0
Physician density per 1000 population	0.1	3.4
Nurse and midwife density per 1000 population	0.6	10.4
Antenatal care at least four visits (%)	60	100
Skilled birth attendance (%)	74	100
Live birth in health facility (%)	73	86
Caesarean section rate (population) (%)	6.2	17.4
Assisted vaginal birth rate (population) (%)	Unknown	8.4

MMR: Maternal mortality ratio; NMR: neonatal mortality rate
[a] Data from 2015 (during studies in Mulago hospital) or from period including 2015
[b] Uganda: Stillbirths per 1000 live births (≥28 wk), Netherlands: Stillbirths per 1000 total births (≥28 wk)
[c] Uganda: NMR per 1000 live births (≥28 wk), Netherlands: NMR per 1000 live births (≥24 wk)

Ugandan healthcare system

Mulago hospital in Kampala is Uganda's national referral hospital. In addition, there are 13 regional referral hospitals and 35 district hospitals. Besides these government hospitals, there are private hospitals and many small clinics that provide different levels of healthcare. In government hospitals, maternity care is free of charge. However, women commonly have to buy their own medication and medical supplies.[23]

Mulago hospital and training of obstetricians

Mulago hospital is the university teaching hospital for Makerere University and the main training centre for specialist obstetricians in the country. Key data for the maternity unit of the hospital are presented in Table 1. Each year, 20 new specialist obstetricians graduate from this university hospital. There are six other hospitals offering post graduate specialty training (Master of Medicine programme, MMed) for obstetrics and gynaecology, with one to six obstetricians graduating per year. MMed for obstetrics and gynaecology takes three years of mainly on-job training. Training fees are usually paid by the regional hospital sending one of their medical doctors for MMed training to Mulago with the agreement that, once specialised, this doctor serves the regional hospital for at least another two years.

Because of its unique training position, obstetric skills training programmes in Mulago hospital results in the dissemination of these obstetric skills to other parts of the country

and beyond, as some newly trained specialists are from countries like South-Sudan, Democratic Republic of the Congo, Rwanda and Sierra Leone.

History of vacuum extraction in Mulago hospital

Vacuum extraction was introduced in Mulago hospital in 1962, according to a publication by Donald Gebbie, a Scottish obstetrician who worked in the hospital from 1964 to 1967.[24] At that time, vacuum extraction was combined with symphysiotomy in 11.0-17.5% of vacuum extractions to prevent caesarean section (in symphysiotomy the joint of the pubic bones is widened by an incision, increasing pelvic in- and outlet, for the fetal head to pass). Gebbie warned for "the dangers inherent in performing caesarean section in Southern Uganda", describing increased risk of uterine rupture in subsequent pregnancies with high perinatal and maternal mortality rates. Annual reports and Gebbie's paper show that, after its introduction in 1962, vacuum extraction was used in 1.3-4.9% of births in 1962-1972 (Figure 3 and 4). Caesarean section rates were 4.8-7.3% during this period. After 1972, no annual reports are available, possibly because of civil and political turmoil in the country and the hospital that followed after the military coup by Idi Amin in 1971. Before the start of the programme, hospital data from 2004-2012 showed that vacuum extraction was used in 0.1-0.6% of all births in the main labour ward. Use of forceps was not recorded. Caesarean section rate in the main labour ward continued to rise, from 22.0% in 2004 to 28.2% in 2012.

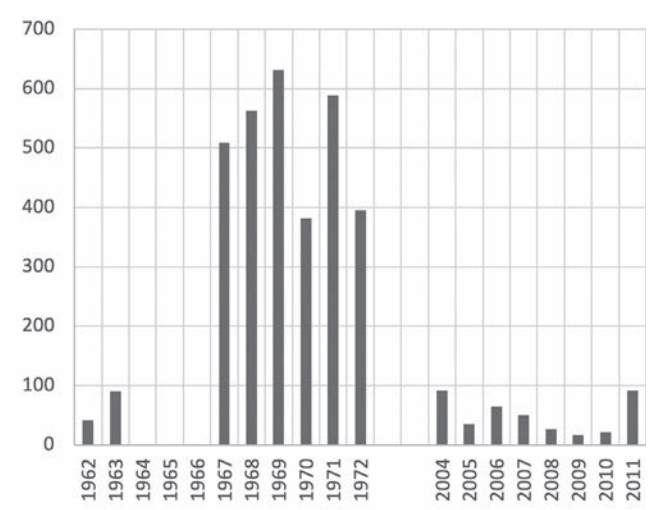

Figure 3 | Vacuum extractions per year in Mulago hospital 1962-2011

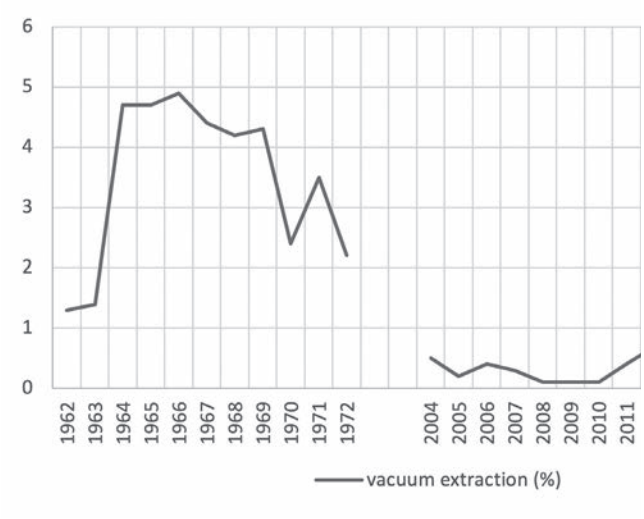

Figure 4| Vacuum extraction rates (%) in Mulago hospital 1962-2011

Assisted vaginal birth

Risks of caesarean section compared to (assisted) vaginal birth

A summary of risks of caesarean section compared to (assisted) vaginal birth is presented in Table 3.

Many of the complications described in the first paragraph could probably have been prevented if vacuum extraction had been used more frequently, rather than resorting to caesarean section.[25] An important advantage of vacuum extraction is that it avoids abdominal surgery.

In the absence of advanced monitoring systems and safety procedures, Surgery and anaesthesia carry higher risks in Mulago hospital compared to high-income settings.[26,27]

Severe haemorrhage, for instance, is more frequent after caesarean section than after vaginal birth and can be life threatening, since blood for transfusion is not always available.[28,29] Post-operative infections are a common complication of surgery, especially in low-and middle-income countries (LMIC) and may result in life threatening sepsis.[30] Sepsis and haemorrhage are main causes of maternal death in Mulago hospital and important causes of global maternal mortality.[31]

A recent systematic review and meta-analysis of 2.9 million women who gave birth by caesarean section in LMIC showed that in sub-Saharan Africa 11 out of 1000 women who

had given birth by caesarean section died.[9] Causes of death during or after caesarean section were haemorrhage (32%), sepsis (22%), pre-eclampsia (19%) and complications from anaesthesia (14%). The risk of maternal death during or after second-stage caesarean section was 12.3 times increased compared to caesarean section during the first stage of labour (OR 12.3; 95%CI 2.9-52.5).[9]

Another study in three sub-Saharan African countries showed that per 1000 caesarean sections 14 to 15 women died, compared to one woman per 1000 vaginal births.[10] In the same study, stillbirths and neonatal deaths were substantially more frequent after caesarean section compared to vaginal birth (Table 3). A study analysing perinatal outcome of 14 179 vacuum extractions in Papua New Guinea showed a perinatal mortality rate of 0.75% after vacuum extraction.[32]

Smaller studies analysing outcome of vacuum extraction in low-income countries showed reassuring maternal and perinatal outcome.[33-39] Adverse outcome after caesarean section could partly be due to underlying obstetric and pre-existing risk-factors and possibly late presentation to hospital, but it is assumed that the quality of surgery and anaesthesia played an important role.[9,10,26] Caesarean section can be a life-saving intervention when medically indicated, but especially in the second stage of labour and in low-resource settings, the intervention is associated with maternal and perinatal death.[9,10] Use of vacuum extraction would decrease risks of surgery and anaesthesia.

There are more reasons to prevent caesarean section. Caesarean section in the index pregnancy increases risk of several complications in subsequent pregnancies (Table 3). Some of these risks are life-threatening, especially when undiagnosed due to absence of ultrasound technology (abnormal placentation), when subsequent births happen outside hospital or without adequate monitoring (uterine rupture), or when there is not enough blood for transfusion (in case of haemorrhage, due to abnormal placentation or uterine rupture). In Uganda, with a fertility rate of 5 to 6 births per woman, uterine scars are challenged many times.[16] Of all births, 27% take place outside health facilities and without skilled birth attendants.[16] Women with a uterine scar may decide to give birth at home for several reasons: they are not aware of the risks; have financial constraints; have had a bad birth experience in hospital previously; or they simply do not want another caesarean section.[40-42]

Table 3 | Comparison of maternal and perinatal risks per mode of birth

	(Second-stage) caesarean section	(Assisted) vaginal birth	OR (95%CI)	Mode of birth
Maternal complications in % of births (studies in sub-Saharan Africa)				
Maternal death[9]	1.09			CS
Maternal death[10]	1.47	0.09	13.6 (9.3-19.9)	CS vs VB
PPH[10]	6.1	3.0	1.9 (0.9-4.0)	CS vs VB
Infection[10]	3.9	0.4	8.7 (4.4-17.2)	CS vs VB
Hysterectomy[10]	1.7	0.1	15.0 (6.6-33.9)	CS vs VB
Severe maternal outcome[43]	26.26	6.57	5.06[a] (4.26-6.02)	EMCS vs AVB
Perinatal complications in % of births (studies in sub-Saharan Africa)				
Perinatal death[9]	10.04			CS
Perinatal death[32]		0.75		Vacuum extraction
Stillbirth[9]	8.25			CS
Stillbirth[10]	10.78	2.10	5.6 (4.3-7.1)	CS vs VB
Neonatal death[10]	4.78	1.59	3.2 (2.4-4.2)	CS vs VB
Perinatal complications in % of births (studies in high-resource settings)				
Severe perinatal outcome[44]	0.66-1.80	0.86-1.78		SSCS vs vacuum
Neurological complication[45]	0.44	0.45	0.96[a] (0.76-1.22)	CS vs vacuum
HIV-transmission in % of births (studies in high-resource settings)				
HIV-transmission[46]		0.45		AVB
HIV-transmission[47]	16.2	18.3	0.86[a] (0.65-1.15)	EMCS vs AVB
Complications in subsequent pregnancy after previous CS in % of births (studies in high-resource settings)				
Uterine rupture[48]	0.94	0.30		previous CS vs all births
Placenta praevia[49]	0.44	0.27	1.47 (1.41-1.52)	Previous CS vs VB
Abnormally invasive placenta[50]	1.15	0.13	4.66 (3.02-7.18)	Previous CS vs VB
Placental abruption[49]	0.68	0.48	1.40 (1.36-1.45)	Previous CS vs VB
Spontaneous preterm birth[51] <32w[51]	0.9	0.4	2.25[a] (1.73-2.92)	Previous SSCS vs AVB

OR: odds ratio; CS: caesarean section; VB: vaginal birth; PPH: postpartum haemorrhage; EMCS: emergency or intrapartum caesarean section; AVB: assisted vaginal birth; SSCS: second-stage caesarean section

[a] *unadjusted OR, calculated from data in paper*

(Reference, 1st author) Type of study and important features

(9, Sobhy) Systematic review and meta-analysis 1990-2017 of outcome of CS in LMIC. Data used here is from countries in sub-Saharan Africa.
(10, Harrison) Prospective population-based study 2010-2015. Data used here is from DRC, Zambia, Kenya. CS (n=1440) vs VB (n=104 273). RR from paper.
(32, Mola) Retrospective facility-based study (1977-2015) in Papua New Guinea. Vacuum extraction (n=14 179).
(43, Souza) Multicountry facility-based survey 2004-2008. Data used here is from Algeria, Angola, DRC, Kenya, Niger, Nigeria and Uganda. EMCS (n=7396) vs AVB (n=2298). Severe maternal outcome: death, admission to ICU, blood transfusion, hysterectomy.
(44, Muraca) Population-based retrospective cohort study 2003-2013 in Canada. Second-stage CS (n=15 034) vs vacuum extraction (n=24 851). Severe neonatal outcome: convulsions, intubation, intracranial laceration or haemorrhage, skull fracture, severe injury to nervous system, long bone injury, subgaleal haemorrhage, injury to liver or spleen.
(45, Werner) Retrospective cohort study 1995-2003 in US. CS (n=87 059) vs vacuum extraction (n=18 024). Neurological complications: convulsions, intraventricular haemorrhage, subdural haemorrhage.
(46, Peters) Population based study in UK and Ireland, 2008-2016. HIV-transmission in AVB (n=222, including vacuum extraction (n=76), 80-90% of women had achieved viral suppression. HIV-transmission in 1/222 AVB, other risk factors than mode of birth for this HIV-transmission described in paper (non-adherence to medication, breastfeeding).
(47, HIV-group) Meta-analysis of studies from North America and Europe in 1982-1996. 83% of women was not on adequate antiretroviral therapy. EMCS (n=895) vs AVB (n=520).
(48, Hofmeyr) Systematic review 1990-2002 of prevalence of uterine rupture. 0.94% is the global figure, for LMIC it is 1.4% (after previous CS).
(49, Yang) Retrospective cohort study 1995-2000 in US. Outcome of second birth after first birth by CS (n=742 832) or VB (n=4 403 910).
(50, Iacovelli) Systematic review and meta-analysis of worldwide studies in 2000-2017. Previous CS (n=80 458) vs no previous CS (n=575 710).
(51, Wood) Retrospective cohort study 1992-2014 in Canada. Outcome of second birth after previous second-stage CS (n=8607) or AVB (n=44 991).

Common misconceptions about vacuum extraction

The idea of reimplementing vacuum extraction in Mulago hospital was discussed with Ugandan colleagues. Their reactions were diverse. Some were enthusiastic, others were worried about potential complications of vacuum extraction, despite the literature described in Table 3. They were concerned that vacuum extraction would cause neonatal brain damage, obstetric fistulas and vertical HIV-transmission. These concerns are described elsewhere as well.[11] Studies about HIV-transmission and neurological complications were from high-income settings.[44-47] Would vacuum extraction be safe in the setting of Mulago hospital?

- *Is vacuum extraction causing brain damage?*
  Birth asphyxia and subsequent brain damage is quite prevalent in Uganda.[52,53] When birth of an asphyxiated neonate occurred after vacuum extraction, brain damage would wrongly be attributed to vacuum extraction rather than asphyxia. Some parents (and health professionals) assumed that the vacuum cup or traction force caused the damage. However, from studies in high-income countries we know that brain damage resulting from vacuum extraction is very rare.[44,45,54]

- *Is vacuum extraction causing obstetric fistula?*
  Similarly, obstetric fistula after vacuum extraction was mentioned as possible severe complication by concerned colleagues. Obstetric fistula (an opening between urinary bladder or rectum and vagina, causing urine- or faecal incontinence with important social consequences) is a complication of severely prolonged obstructed labour.[55-56] In this condition, maternal bladder or bowel and vaginal tissues have been compressed too long between the fetal head and the maternal bony pelvis, leading to pressure necrosis. If birth in obstructed labour is assisted by vacuum extraction, parents (and health professionals) may incorrectly assume that it is the vacuum cup that caused the fistula rather than the pressure necrosis from obstructed labour.
  Caesarean section is hardly ever mentioned as cause of fistula, but a study analysing 5959 women undergoing fistula repair in 11 countries showed that 13.2% of fistulas were iatrogenic, based on type of fistula and obstetric history (for example no history of obstructed labour). The majority of iatrogenic fistulas were after caesarean section.[55,56]

- *Is vacuum extraction causing vertical HIV-transmission?*
  Concerns with regard to vertical HIV-transmission in case of vacuum extraction are described as a reason for not performing the procedure.[12] In 2012, 10% of women who gave birth in Mulago hospital were HIV-positive. It is therefore a relevant question what to do in case of prolonged second stage or fetal distress during the second stage of labour in presence of a positive or unknown HIV-status. Since 2013, Uganda is one of the countries where the so-called 'option B+ HIV-programme' has been implemented.

This programme aims to initiate all HIV-positive women on life-long antiretroviral therapy from the moment they test positive.[57] In Mulago hospital all women who came for antenatal visits were tested. If they were HIV-positive, antiretroviral therapy was started. Women with unknown HIV-status at the moment of admission to the labour ward were tested and treatment was started when the test was positive. Viral load was usually not known.

In a study from the UK and Ireland including 251 neonates born by vacuum extraction or forceps, one infant in 222 infants (0.45%) with known HIV-status had acquired HIV at the age of 18 months. Of these 222 infants, 73 were born by vacuum extraction and 149 by forceps. Neonates were born between 2008 and 2016 and 80-90% of their mothers had achieved viral suppression by the time of birth. It is not stated whether the infected neonate was born by vacuum extraction or forceps. The authors state that there were other significant risk factors, apart from birth, that could have contributed to this transmission (maternal adherence to therapy and possible breastfeeding).[46]

A meta-analysis of studies conducted before 1999 about risk of HIV-transmission in different modes of birth showed no statistically significant difference in HIV-transmission between a group of mother-child pairs after assisted vaginal birth (vacuum extraction or forceps, n=520) and non-elective caesarean section (n=895). HIV-transmission rate was 16.2% in the non-elective caesarean section group and 18.3% in the assisted vaginal birth group (OR 0.86 95%CI 0.65-1.15).[47] In this meta-analysis vacuum extraction and forceps birth were combined for analysis and 83% of women was not on adequate antiretroviral therapy.

The RCOG guideline states: "Blood-borne viral infections of the mother are not a contraindication to operative vaginal delivery."[3] The British HIV Association guideline (2019) indicates that when viral load is suppressed the most appropriate instrument should be used in assisted vaginal birth, consistent with national obstetric guidelines and there is no preference for forceps or vacuum extraction. Intrapartum caesarean section is not recommended as a strategy to prevent HIV-transmission.[58]

It was interesting to hear the dilemmas that health professionals considered in using vacuum extraction in the setting of Mulago hospital. These dilemmas had never occurred to me whilst working in a high-income country where access to hospitals was easy, maternal and fetal monitoring during labour strict and timely intervention almost always possible. In such setting, obstetric fistulas did not occur, perinatal death or brain damage due to birth asphyxia were rare and vacuum extraction was not blamed for any of these adverse outcomes.

It became clear that apart from organising skills training and providing equipment, we needed to investigate whether vacuum extraction was not only safe for mother and neonate in high-income settings, but also in settings like Mulago hospital with different morbidity and mortality figures and circumstances.

Differences in use of assisted vaginal birth

- *Use of assisted vaginal birth in the Netherlands*
  In the Netherlands, it is uncommon to perform caesarean section when a woman is in the second stage of labour and the fetal head has engaged into the maternal pelvis to the level of the ischial spines (station 0) or lower. In this situation, most Dutch obstetricians would perform assisted vaginal birth, where vacuum extraction is generally preferred over forceps extraction. Vacuum extraction is considered safe for mother and neonate; it is faster than caesarean section; it does not have the disadvantages of caesarean section; and mother and neonate may go home the same day.[1-4] For these reasons, assisted vaginal birth is used frequently: 8.4% of all births in the Netherlands in 2015 were by assisted vaginal birth.[17] Hospital based percentages for obstetric interventions are a little higher, since 28.9% of births in the Netherlands are attended by a midwife at home or in a midwifery-led maternity unit (where assisted vaginal birth is not performed).[18] Different types of hospitals (tertiary referral hospital or other) may have different percentages as well.

My current place of work, Canisius-Wilhelmina hospital in Nijmegen, a Dutch hospital with 1500-1700 births per year, has the following figures for 2012-2015: of all 6403 births, 11.2% were assisted vaginal births (>99% vacuum extraction) and 19.7% caesarean sections. Of all births, 12.8% (821/6403) occurred with a second-stage intervention. And of all second-stage interventions, 87.5% (718/821) were assisted vaginal births and only 12.5% (103/821) caesarean sections (Table 4). This means that 7 out of 8 second-stage interventions were assisted vaginal births and only 1 out of 8 was a caesarean section.

Of all births, 1.6% (103/6403) were second-stage caesarean sections in women with a term cephalic singleton. If all assisted vaginal births would have been caesarean sections instead, the caesarean section rate would be 31.0% instead of 19.7%, illustrating the impact assisted vaginal birth-use has on caesarean section rates (unpublished data from hospital birth registry).

Table 4 | Second-stage intervention in Canisius-Wilhelmina hospital, the Netherlands[a] (Total births: 6403)

	n (%)
Second-stage intervention: CS + AVB	821 (12.8)
- Successful AVB	718/821 (87.5)
- Second stage CS (incl. failed AVB)	103/821 (12.5)
AVB as % of total births	718/6403 (11.2)
Second-stage CS as % of total births	103/6403 (1.6)
Failed vacuum extraction and subsequent CS	38/718 (5.3)

CS: caesarean section; AVB: assisted vaginal birth
[a] 2012-2015

- *Use of assisted vaginal birth worldwide*
  Use of assisted vaginal birth varies widely between countries as shown in Table 5 and 6. In Europe, this varies between 0.5% of all births in Romania to 15.1% in Ireland and Spain (Table 5).[17] For all births in Europe included in the Euro Peristat report (n=3.6 million), the average assisted vaginal birth rate was 8.4%. Of countries with known assisted vaginal birth rates, 18 out of 29 countries use assisted vaginal birth in more than 5% of births. Use of caesarean section varied from 16.1% in Iceland to 56.9% in Cyprus. A survey in six African countries revealed that assisted vaginal birth was used in 0.2% of institutional births in Congo-Brazzaville to 1.2% in Niger (Table 6). In 47% of 1728 sub-Saharan hospitals in 27 countries assisted vaginal birth had not been used in the three months prior to the survey. Assisted vaginal birth was the most frequently missing basic emergency obstetric care signal function in 35 out of 40 country assessments in Africa, Asia, Latin America and the Caribbean.[11]

Vacuum extraction instruments

- *Vacuum extraction cups and pumps*
  Many different types of vacuum extraction instruments exist, and these have different advantages and disadvantages (Table 7). In the setting of Mulago hospital, with 70 births per day on main labour ward, the ideal vacuum extractor should be: affordable; durable; only need one operator; easy to sterilise; and many vacuum extractors should be ready to use at all times. As can be seen from the table, such a vacuum extractor does not yet exist.

Table 5 | Caesarean section and AVB rates in Europe in 2015, population based[17]

Country	total births	AVB (%)	CS (%)	AVB/CS
Ireland	65912	15.1	31.3	0.48
Spain[a]	385478	15.1	24.6	0.61
UK: England[a]	632784	13.0	27.0	0.48
UK: Scotland[b]	54273	12.2	32.5	0.38
France (2016, survey)[b]	13301	12.1	20.2	0.60
UK: Northern Ireland	24540	12.0	29.9	0.40
Luxembourg	6861	11.2	32.7	0.34
UK: Wales	32128	10.9	26.1	0.42
Switzerland (2014)[b]	81969	10.8	34.2	0.32
Norway	59930	10.2	16.5	0.62
Belgium	121185	9.5	21.3	0.45
Finland	55759	9.2	16.4	0.56
Netherlands	165295	8.4	17.4	0.48
Iceland	4091	7.6	16.1	0.47
Austria	83884	7.2	29.7	0.24
Germany	728496	6.8	32.2	0.21
Denmark	57847	6.4	21.6	0.30
Sweden (2014)	115710	6.0	18.3	0.33
Estonia	13961	4.2	19.5	0.22
Malta	4453	4.2	32.0	0.13
Cyprus	9422	3.7	56.9	0.07
Italy	480217	3.5	35.4	0.10
Slovenia	20336	2.8	21.2	0.13
Czech Republic[a]	111162	2.7	26.1	0.10
Latvia	21826	2.4	22.0	0.11
Slovakia	55824	2.1	31.1	0.07
Lithuania	29019	1.9	21.9	0.09
Croatia	37428	1.4	21.6	0.06
Romania	153746	0.5	46.9	0.01
Bulgaria (2014)[c]	62912	-	43.0	-
Hungary[c]	92098	-	39.0	-
Poland (2014)[c]	376709	-	42.2	-
Portugal[a,c]	83957	-	32.9	-
Greece	-	-	-	-

AVB: assisted vaginal birth; CS: caesarean section

[a] *N=number of mothers instead of births*

[b] *Missing information: in Switzerland 185 CS with unknown mode of onset are excluded, in France 3. In Scotland 181 vaginal births with unknown mode of birth (assisted or not) are excluded.*

[c] *Bulgaria, Hungary, Portugal and Poland: no data on assisted vaginal birth*

Table 6 | Institutional caesarean section and AVB rates in six African countries and WHO global survey [11,43,59]

Country (year)	AVB (%)	CS (%)	AVB/CS
Niger (2010)	1.2	5.9	0.20
Mozambique (2012)	1.1	4.2	0.26
Senegal (2012/2013)	0.6	4.4	0.14
Zambia (2015)	0.6	5.0	0.12
Ghana (2010)	0.5	12.3	0.04
Congo-Brazzaville (2012)	0.2	6.9	0.03
WHO Global Survey Africa	3.0	8.8	0.34
WHO Global survey	2.6	25.7	0.10

AVB: assisted vaginal birth; CS: caesarean section

Table 7 | Vacuum extraction instruments[60-62]

Advantages	Figure 5 (page 22)	High traction force possible	Lower risk of skin lacerations	Can be used in OP position	Sterilisation in autoclave	Consists of few parts	No electricity needed (pump)	Only one operator needed	Indication of costs (euro)
Cup (re-usable)									
Malmström (stainless steel)	A,B	+		+/-	+				150
Bird (stainless steel)	A, C	+		+	+	+			140
Flexible cup (soft plastic)	A		+		+	+			170
Pump									
Handpump (bicycle type)	D						+		80[a]
Mityvac® handpump	F					+	+	+/-	180
Egar Device	E					+	+		NA
Electrical pump	-							+/-	2000
Handheld all in one device									
Kiwi-Omnicup® (single use)	G	+		+		+	+	+	40
re-usable Kiwi-Omnicup	H	+		+	+		+	+	NA
Mystic II® (single use)	I	+				+	+	+	40

NA: not applicable, not (yet) for sale

[a] Bicycle type handpump 80-630 euro depending on manufacturer

Figure 5 | Vacuum extraction instruments
A: From left to right: Flexible cup, Malmstrom cup, Bird cup; B: Malmstrom cup; C: Bird cup; D: Bicycle type handpump with Bird cup; E: Egar pump with Bird cup; F: Mityvac handpump; G: Kiwi-Omnicup (single use); H: Kiwi-Omnicup re-usable (can be sterilised in autoclave); I: Mystic vacuum extractor (single use) Pictures by the author. Figure F and I from from Mityvac and Mystic II brochure.[67]

- **Re-use of Kiwi-Omnicup® vacuum extractors**
  During this research project, Kiwi-Omnicup vacuum extractors, designed for single use, were re-used. This practice is common in many hospitals in low-income countries but has never been published. Kiwi-Omnicup vacuum extractors were re-used in Mulago hospital to ensure availability of ready-to-use vacuum extractors at all times and to ensure affordability. Together with the hospital hygiene department a protocol for high-level disinfection of Kiwi-Omnicup vacuum extractors with Cidex OPA® was designed. Cidex OPA (ortho-phthalaldehyde) is a solution for high-level disinfection of flexible endoscopes and other medical devices that cannot be sterilised by autoclave. It provides broad-spectrum activity against bacteria, mycobacteria, fungi and viruses, including HIV and Hepatitis B and C.[63,64] It is safe to use for health professionals.[65]

Three midwives were trained and responsible for high-level disinfection. Samples for culture taken from disinfected Kiwi-Omnicup vacuum extractors were negative for pathogens.

A re-usable hand pump vacuum extractor (bicycle type) with flexible cups and Bird cups was available as well, so that operators could choose which instrument to use. Sterilisation of flexible cups and Bird cups was by autoclave, once a day.

Problem statement and programme

Problem statement

Although, according to international guidelines, vacuum extraction is the first-choice obstetrical intervention for prolonged second stage of labour or fetal distress during the second stage of labour, it is hardly used in Mulago hospital and many other parts of the world.[1-4,11,17] Women with an indication for assisted vaginal birth have caesarean section instead (Mulago hospital, personal observation). Caesarean section, compared to assisted vaginal birth, has increased risks of maternal and perinatal complications, including maternal and perinatal death (Table 3). Apart from lack of training and functioning equipment, misconceptions about the safety of vacuum extraction seem to hinder its use.[11] Indeed, outcome after vacuum extraction in the setting of Mulago hospital may often be unfavourable because of the high overall perinatal mortality (all modes of birth combined, Table 1). This could make interpretation of results after (re) implementation of vacuum extraction difficult. Therefore, the following programme was designed:

A programme for (re)introducing vacuum extraction in Mulago hospital

"The Mulago hospital vacuum extraction interest group" was formed, consisting of two Ugandan obstetricians, who had experienced the benefits of vacuum extraction elsewhere or in the past, together with a Ugandan paediatrician and two Dutch obstetricians (the authors of chapter 2). We designed a programme that aimed at increasing the use of vacuum extraction to reduce the numbers of second-stage caesarean section and its complications. The programme consisted of developing a Mulago hospital guideline for the use of vacuum extraction, skills training and supply of equipment. The vacuum extraction guideline is available online.[66] We planned to monitor vacuum extraction use and outcomes of vacuum extraction compared to second-stage caesarean section.

It turned out to be challenging to raise funding for the project. Re-implementing vacuum extraction was seen as a good idea, but neither innovative, nor a "golden bullet". Was it not already one of the seven signal functions of basic emergency obstetric care? Furthermore, it was suggested by possible funders that the study design should be

a randomised trial, where women with an indication for vacuum extraction would be randomly assigned to vacuum extraction or caesarean section. We were of the opinion that this would not be ethical (Table 3) and decided that a prospective cohort study with a control group (second-stage caesarean section) was the best possible way to evaluate outcomes of vacuum extraction in our setting.

Aim of thesis and research questions

Aim of thesis

The aim of this thesis is to investigate whether vacuum extraction can be re-introduced in a high-volume tertiary referral hospital in Uganda and what the effects are of the re-introduction. We hypothesised that when vacuum extraction would be used more frequently, it would have a positive effect on maternal and perinatal outcome.

Research questions

Research question		Chapter
1	What is the impact of a programme aiming to increase the use of vacuum extraction in Mulago hospital on vacuum extraction incidence and maternal and perinatal outcome?	2
2	Which factors were causing the low utilisation of vacuum extraction in Mulago hospital?	3
3	What are health professionals' perspectives regarding vacuum extraction in Mulago hospital?	3
4	What are maternal and perinatal outcomes of vacuum extraction in this setting, compared to second-stage caesarean section?	4
5	What are women-centred outcomes of vacuum extraction, such as birthing experience, quality of life, experience of pain, sexual activity and dyspareunia in this setting, compared to second-stage caesarean section?	5
6	Do women in Mulago hospital consider vacuum extraction an acceptable intervention?	6

Timeline and methods of studies in this thesis

Table 8 | Timeline and methods of vacuum extraction studies resulting in thesis

Period	Activity and methods	Chapter
May-November 2012	Baseline data before implementation were (retrospectively) collected (overall data from hospital registers): - Vacuum extraction rate - Maternal and perinatal outcome	2
November 2012	Start of implementation: - Supply of vacuum extraction equipment - Use of RCOG guideline while developing Mulago guideline - Guideline for high-level disinfection of Kiwi-Omnicup® vacuum extractors - Training of staff	2
November 2012-February 2013	Weekly training of staff	2
November 2012-May 2014	Audit (18 months) Follow-up data (overall data from hospital registers): - Vacuum extraction rate - Maternal and perinatal outcome	2
February 2013 onwards	Training of staff according to curriculum	
July 2013	Mulago guideline for vacuum extraction approved by staff	
November 2013-May 2014	Retrospective pilot study of maternal and perinatal outcome after vacuum extraction (n=342). This is a more detailed subgroup analysis of women who gave birth by vacuum extraction during the last six months of the 18 months follow-up after implementation of the programme	2
February 2014	Survey staff: Recommendations and perspectives about vacuum extraction (questionnaires)	3
November 2014-July 2015	Prospective cohort study of vacuum extraction (n=358) versus second-stage caesarean section (n=425) - Maternal and perinatal outcome (from medical records and follow-up visits) - Birthing experience, quality of life, experience of pain, dyspareunia (interviews) - Women's recommendations for mode of birth (interviews)	4,5,6
January 2016	Six months follow-up of prospective cohort study vacuum extraction versus second-stage caesarean section completed	4,5,6
Presentation of results		
Between September 2013 and June 2017 results of the studies were presented at nine international conferences as well as during several department and morning meetings in Mulago hospital.		

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Kiwi

CHAPTER 2

Audit of a programme to increase the use of vacuum extraction in Mulago hospital, Uganda

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BMC Pregnancy Childbirth 2016; 16: 258

Abstract

Background

Prolonged second stage of labour is a major cause of perinatal and maternal morbidity and mortality in low-income countries. Vacuum extraction is a proven effective intervention, hardly used in Africa. Many authors and organisations recommend (re)introduction of vacuum extraction, but successful implementation has not been reported. In 2012, a programme to increase the use of vacuum extraction was implemented in Mulago hospital, Uganda. The programme consisted of development of a vacuum extraction guideline, supply of equipment and training of staff. The objective of this study was to investigate the impact of the programme.

Methods

Audit of a quality improvement intervention with before and after measurement of outcome parameters. Setting: Mulago hospital, the national referral hospital for Uganda with approximately 33 000 births per year. It is the university teaching hospital for Makerere University and most of the countries doctors and midwives are trained here. Data was collected from hospital registers and medical files for a period of two years. Main outcome measures were vacuum extraction rate, intrapartum stillbirth, neonatal death, uterine rupture, maternal death and decision-to-birth interval.

Results

Mode of birth and outcome of 12 143 births before and 34 894 births after implementation of the programme were analysed. The vacuum extraction rate increased from 0.6 to 2.4% of births ($P<0.01$) and was still rising after 18 months. There was a decline in intrapartum stillbirths from 34 to 26 per 1000 births (-23.6%, $P<0.01$) and women with uterine rupture from 1.1 to 0.8 per 100 births (-25.5%, $P<0.01$). Decision-to-birth interval for vacuum extraction was four hours shorter than for caesarean section.

Conclusions

A programme to increase the use of vacuum extraction was successful in a high-volume university hospital in sub-Saharan Africa. The use of vacuum extraction increased. An association with improved maternal and perinatal outcome is strongly suggested. We recommend broad implementation of vacuum extraction, whereby university hospitals like Mulago hospital can play an important role. To support implementation, we recommend further research into outcome of vacuum extraction and into vacuum extraction devices for low-income countries. Such studies are now in progress at Mulago hospital.

Background

With 293 000 maternal deaths and 5.3 million stillbirths and neonatal deaths per year, global maternal and perinatal mortality rates have decreased since 1990, but far below targets and the numbers are still alarming.[1-3] Worldwide approximately 800 women and 14 500 babies die every day because of complications of pregnancy and childbirth. Intrapartum complications are responsible for more than one third of these deaths.[1-3] Many complications are preventable or treatable with known evidence-based interventions.[2,4-6] An important cause of maternal and perinatal morbidity and mortality is prolonged second stage of labour and its complications such as haemorrhage, sepsis, uterine rupture, obstetric fistula and birth asphyxia.[1,5,7] Vacuum extraction is one of the evidence-based interventions that can prevent complications by shortening the second stage of labour.[8-11] It also prevents women from having a caesarean section with its increased risk of maternal and perinatal morbidity and mortality in the index and subsequent pregnancies compared to (assisted) vaginal birth.[12-15] Use of vacuum extraction varies widely between countries and hospitals. In 31 European countries, rates of assisted vaginal birth varied between 0.5 and 16.4%.[16] In the Netherlands 9%, in the UK 6% and in the US 3% of births are by vacuum extraction.[17-19] While some decades ago vacuum extraction was still widely practiced in low-income countries (LIC), nowadays it is hardly used, with some exceptions.[20-27] Many authors and organisations, including the World Health Organization, recommend the use of vacuum extraction.[4,5,20,21,28-30] But successful implementation has not been reported. Reasons mentioned for the infrequent use of vacuum extraction are lack of skilled operators, equipment and training opportunities and beliefs of health care providers concerning trauma to the neonate and HIV-transmission.[20-22,24-28] Fear of litigation and financial incentives may also play a role.[16] In 2012, a programme to increase the use of vacuum extraction was implemented in Mulago hospital, Uganda. The programme consisted of development of a vacuum extraction guideline, supply of equipment and training of staff. The objective of this study was to investigate the impact of the programme.

Methods

The study design is audit of a quality improvement intervention with before and after measurement of outcome parameters. The setting is Mulago hospital in Kampala. This is the national referral hospital in Uganda and the university teaching hospital for Makerere University. It is Uganda's main training facility for doctors and midwives. Every year 100 midwives, 140 doctors and 20 specialists in obstetrics & gynaecology graduate here. With approximately 33 000 births per year, it has one of the busiest maternity units in the world. The study was performed in the labour ward for women with medium to high-risk pregnancies, where maternity services are free of charge. Every month approximately 2000 women give birth in this ward, many of them after referral because of complications. Women come mainly from Kampala and surroundings, but some have to travel for a day

to reach this hospital. There is an obstetric high-care unit where care is given to women with severe complications, such as uterine rupture, severe haemorrhage, sepsis and eclampsia. There is a neonatology unit where care is given to neonates with severe morbidity, such as prematurity and birth asphyxia.

Together with Mulago hospital's obstetricians and the Hospital Hygiene department, standard operating procedures (SOP) for the use of vacuum extraction and sterilisation of Kiwi vacuum extractors (Clinical Innovations, USA) were developed.[31,32] Used Kiwi vacuum extractors (type OmniCup) were donated by several hospitals in the Netherlands and sterilised according to the SOP. Sterilisation was repeated after every use. Training took place in the hospital. All 45 residents (in training to become specialists in obstetrics & gynaecology) were trained in small groups of four to six doctors in the week before they had a duty-week on labour ward. Training was provided by the first author and consisted of discussion of the SOP on vacuum extraction and sterilisation, watching the World Health Organization Reproductive Health Library video on vacuum extraction and skills training on mannequins.[33] They had on the job supervision in the week after the training. After completion of this programme with a duration of four months, training continued according to the existing curriculum complemented with the new SOP on vacuum extraction. It consisted of a yearly theory- and a yearly skills training session per year group for all residents and medical students in their last year, provided by Mulago hospital's specialists (six theory and six skills training sessions during 18 months follow-up). Data was collected for a baseline period of six months before- and a follow-up period of 18 months after implementation. The follow-up period started at the time of implementation. To investigate uptake and success rate of vacuum extraction, information on the following outcome measures was collected from the registers of labour ward and the obstetric operating theatre: successful vacuum extraction and failed vacuum extraction. Successful vacuum extraction was defined as birth by vacuum extraction, irrespective of maternal or perinatal complications. Failed vacuum extraction was defined as an attempted vacuum extraction whereby the procedure was abandoned, usually because the stopping criteria were met. Stopping criteria were: the fetus head is not born or about to be born after three traction-aided contractions; the vacuum pops off three times or 20 min have passed after application of the cup.[31] To investigate the impact on perinatal outcome, information on the following outcome measures was collected for all births on the medium to high-risk labour ward during the study period: intrapartum stillbirth, macerated stillbirth, neonatal death with birthweight of ≥2.5 kg, admission to the neonatology unit with birthweight of ≥2.5 kg and total perinatal deaths. In Mulago hospital the gestational age is often not known. We used low birthweight (<2.5 kg) as a proxy for preterm birth. Outcome for neonates with birthweight ≥2.5 kg was investigated separately, because most vacuum extractions are done in this group. Total perinatal deaths was defined as all stillbirths plus all neonatal deaths during admission. This included low birthweight stillbirths and low birthweight neonatal deaths.

To measure maternal outcome, information on the following outcome measures was collected: uterine rupture, admission to obstetric high-care unit and maternal death. Data were obtained from the records department and the registers of the labour ward, obstetric high-care unit, obstetric operating theatre and neonatology unit. In addition to this, medical files of those women who had vacuum extraction during the last six months of the study were investigated for maternal and perinatal outcome and decision-to-birth interval (DBI). DBI was defined as time between doctors' decision to do a vacuum extraction (as noted in file) and time of birth. Data was entered into MS Excel 2013 and imported into Statistical Package of the Social Sciences (SPSS) 22.0 for analysis. Observations before and after implementation of the programme were compared. Results are reported in numbers and proportions. The chi-square test was used for comparison of the categorical variables. *P*-values <0.05 were considered statistically significant.

Ethical permission to conduct this study was obtained from the Mulago hospital Research and Ethics Committee (refnr: MREC 489) and the Uganda National Council for Science and Technology (refnr: HS1752).

Results

Overall outcome

During the two-year study period from May 2012 to May 2014, 47 037 births were registered on the medium to high-risk labour ward: 12 143 in the baseline period and 34 894 in the follow-up period. The use of vacuum extraction increased from 0.6% to a maximum of 3.7% and stabilised at 2.4% of all births on this ward (Figure 1 and 2). In the first six months after implementation vacuum extraction was used in 1.9%, in the next six months 2.1% and the last six months 2.4% of births. The vacuum extraction rate in the total follow-up period was 2.1% (Table 1). In the 18 months after implementation 805 vacuum extractions were performed with 63 failures (8.5%).

Total perinatal mortality decreased from 91 per 1000 births in the baseline period to 84 per 1000 births in the follow-up period (P<0.05). This was mainly a result of a decrease in intrapartum stillbirths from 34 per 1000 to 26 per 1000 births, a decrease of 23.6% (P<0.01). Admission of term neonates to the neonatology unit, however, increased with 14.4% (P<0.01) from 87 to 100 per 1000 births (Table 1, Figure 2). Decrease in intrapartum stillbirths was most notable in the last six months of the study with 24 per 1000 births, a decrease of 28.7%, when the vacuum extraction rate was at its highest (Figure 2). The macerated stillbirth rate did not change (Figure 2).

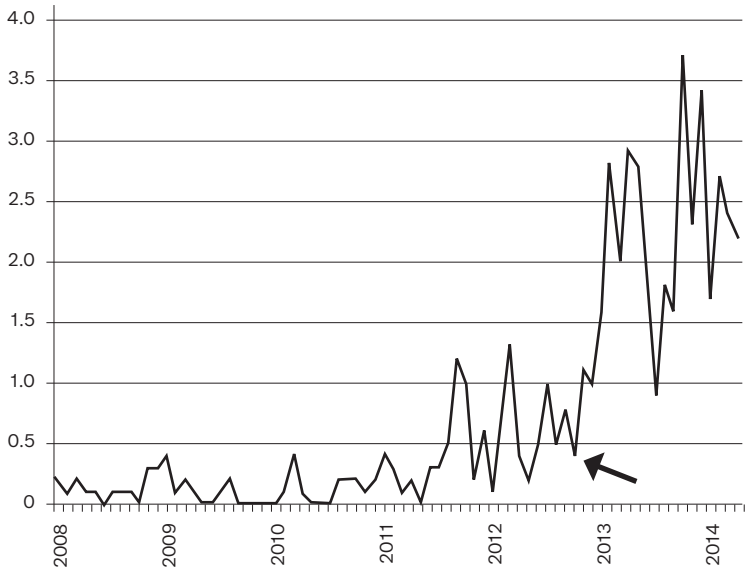

Figure 1 | Monthly vacuum extractions as percentage of all births, January 2008-April 2014. Arrow: start of programme in November 2012

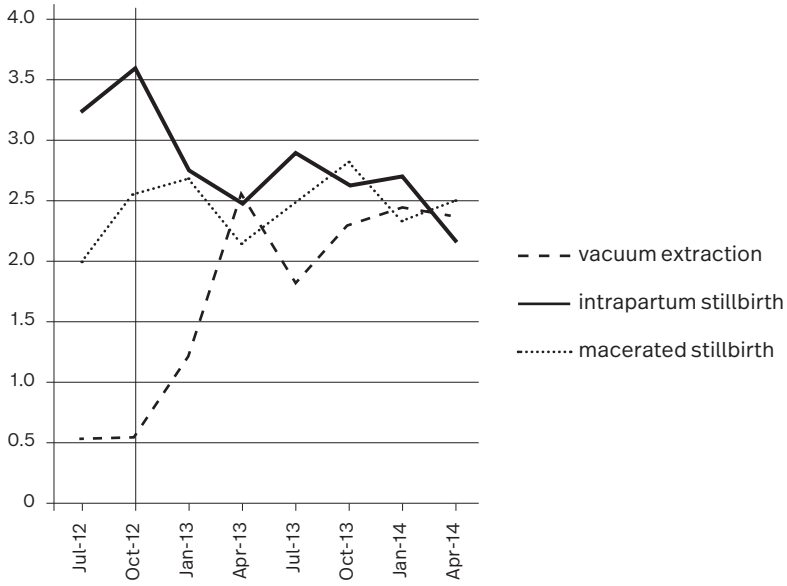

Figure 2 | Vacuum extractions, intrapartum stillbirths and macerated stillbirths as percentage of all births. Percentages are calculated per period of three months. Vertical line: start of programme

Table 1 | Maternal and perinatal outcome in Mulago hospital medium to high-risk labour ward in baseline and follow-up period

	Baseline		**Follow-up**		**Impact**	**P-value**
Duration	6 months		18 months			
Total births	12143		34894			
	n	(%)	n	(%)		
Vacuum extraction	68	(0.6)	742	(2.1)	+280%	<0.01
Caesarean section	3427	(28.2)	10550	(30.2)	+7.1%	<0.01
Caesarean section for obstructed labour	729	(6.0)	2106	(6.0)	0%	0.90
Maternal outcome						
Ruptured uterus	133	(1.1)	287	(0.8)	-25.5%	<0.01
Admissions to obstetric high-care unit[a]	228	(1.9)	629	(1.8)	-4.3%	0.59
Maternal deaths	**n**	**(per 100 000)**	**n**	**(per 100 000)**		
Maternal death due to intrapartum complication	32	(264)	82	(235)	-11.0%	0.58
Maternal death due to hypertensive disorder	13	(107)	48	(138)	+29.0%	0.42
Maternal death due to abortion	22	(181)	65	(186)	+2.8%	0.91
All maternal deaths	97	(799)	254	(728)	-8.8%	0.43
Perinatal outcome	**n**	**(‰)**	**n**	**(‰)**		
Total perinatal death	1112	(91)	2946	(84)	-7.7%	0.02
Macerated stillbirth	278	(23)	877	(25)	+ 9.6%	0.17
Intrapartum stillbirth	417	(34)	914	(26)	-23.6%	<0.01
"Term" neonatal death	156	(13)	482	(14)	+7.8%	0.43
"Term" admissions to neonatology unit	1060	(87)	3482	(100)	+14.4%	<0.01

Definitions used in this study:
Total perinatal death: stillbirths + neonatal deaths during admission
Stillbirth: neonate born with no signs of life at or after 28 weeks gestation or with a birthweight of 1 kg or more
Neonatal death: death during admission after live birth
"Term": birthweight of 2.5 kg or more
[a] *for intrapartum complication*

Maternal deaths from intrapartum complications, such as haemorrhage, sepsis, uterine rupture and obstructed labour showed a downward trend from 264 to 235 per 100 000 births (-11.0%), but this did not reach statistical significance. Admissions to the obstetric high-care unit for intrapartum complications showed a downward trend as well. The number of women with ruptured uterus decreased by 25.5% (P<0.01). Maternal deaths from abortions and hypertensive disorders remained the same or increased (Table 1).

Outcome of vacuum extraction

During the last six months of the study, 342 vacuum extractions were attempted of which 32 failed (9.4%). Mean DBI for (attempted) vacuum extraction was 34 min. After exclusion of 15 women with intra uterine fetal death before vacuum extraction and one woman with unknown outcome, perinatal outcome of 326 (attempted) vacuum extractions could be analysed, 296 vacuum extractions and 30 failed vacuum extractions. The perinatal mortality rate was 19/326 (58 per 1000 births) for all attempted vacuum extractions with a live fetus at time of decision for intervention. It was documented in 35% of files that emergency caesarean section was planned initially. However, while the woman was waiting for caesarean section the planned mode of birth changed to vacuum extraction due to various reasons (different findings on examination, more experienced doctor, fetal distress, no theatre space available). Vacuum extraction was successful in 93.3% of women initially scheduled for caesarean section, comparable to women not scheduled for caesarean section.

Discussion

Increased use of vacuum extraction

After implementation of a programme to increase the use of vacuum extraction in Mulago hospital Uganda, the use of this intervention rose rapidly. Within a few months it became a routine procedure that was used daily. After 18 months, at the end of the study period, more than 800 vacuum extractions had been performed and the vacuum extraction rate was still rising. This study shows that implementation is possible in a high-volume university hospital in a LIC and that vacuum extraction is accepted by health care providers. What is needed is training and equipment. This might sound straight forward and many authors and organisations advise implementation of vacuum extraction to LIC.[4,5,20,21,28-30] But to our knowledge successful projects of this size have not yet been published. A key to success might be involving major university hospitals. Our approach of incorporating the programme into the medical curriculum of a national referral and university hospital where the majority of doctors and midwives for the country are trained had several benefits: The programme was efficient in training many health care providers in a relatively short period of time. Many women could benefit from the procedure and trainees did get enough exposure. Doctors and midwives trained in this institution took their knowledge and skills to all parts of the country. Furthermore, senior specialists who are lecturers at the country's major medical university and opinion leaders about medical practice in the country, were consulted and supported the programme. Nevertheless, regular (in-service) training, updates and skills and drills sessions for all health care providers attending childbirth in smaller health units is needed as well.

Increased use of vacuum extraction, as seen in our study, might not only lead to better maternal and perinatal outcome, but in a high fertility environment like Uganda, it could have a huge impact on future healthcare costs by reducing the number of second-stage caesarean sections.

Improved perinatal and maternal outcome

In settings where fetal monitoring is adequate and timely access to the operating theatre for caesarean section is guaranteed, increasing the vacuum extraction rate (and decreasing the caesarean section rate) would probably result in better maternal outcome but might not have a measurable effect on perinatal outcome. In LIC where access to the operating theatre is often delayed, timely intervention by vacuum extraction might have a major effect on perinatal outcome as well.

In this study we observed that, while the vacuum extraction rate increased, perinatal mortality decreased. Although this observational study cannot prove causality, an association is strongly suggested. An important factor is DBI. Mean DBI for (attempted) vacuum extraction was 34 minutes. Mean DBI for caesarean section in the second stage of labour was four hours and 38 minutes in Mulago hospital (Unpublished data from ongoing study in Mulago hospital by the same authors). Although theatre is functioning 24 hours per day, demand caused by the overwhelming number of births exceeds its maximum capacity. Vacuum extraction shortens the second stage of labour in women with an indication for intervention with four hours. Fetuses that otherwise would have died from birth asphyxia during this waiting time have now probably survived. This results in a shift from intrapartum stillbirths to live births. Some of these neonates however, would need admission to the neonatology unit. This might explain the increase of admissions to that unit. Perinatal mortality after (attempted) vacuum extraction on a live fetus is 58.3 per 1000 in this study. Interpretation of this outcome is difficult, because literature on outcome of vacuum extraction in sub-Saharan Africa is scarce.[22,23,27] Birth asphyxia is probably the major cause of perinatal death, rather than complications from the vacuum extraction procedure. More research is needed into outcome of vacuum extraction in LIC, especially because concern about trauma to the neonate is often mentioned as a reason for not doing vacuum extraction (Unpublished data from ongoing study in Mulago hospital by the same authors).

Uterine rupture is a severe complication of labour with a high risk of maternal and perinatal mortality. In LIC its prevalence ranges from 0.1 to 2.9% of births.[34-36] The number of women who sustained uterine rupture in Mulago hospital decreased after implementation of the programme. This might also be explained by the shorter DBI for vacuum extraction compared to caesarean section. The downward trends in admissions to the obstetric high care unit and maternal deaths from intrapartum complications may be a result of the shorter DBI as well. Prevention of difficult caesarean sections with a deeply impacted fetal head might have had a positive effect.

Vacuum extraction device

During this study Kiwi-vacuum extractors, designed for single use, were re-used. This is done in many hospitals in LIC but has never been published. Re-use of Kiwi vacuum extractors is done in Mulago hospital to ensure availability of ready-to-use vacuum extractors at all times and to keep costs low. Kiwi-vacuum extractors are always complete, ready to use and can be operated by one person. Because of this, the procedure can be performed quickly, without losing time looking for an assistant or missing parts. We are of the opinion that Kiwi-vacuum extractors can safely be re-used if a rigorous infection control protocol is in place. Together with the Hospital Hygiene Department we designed a SOP for sterilisation of Kiwi vacuum extractors.[32] The programme, including the re-use of Kiwi vacuum extractors, was approved by the Mulago hospital Research and Ethics Committee and the Uganda National Council for Science and Technology.

We acknowledge that re-using a devise that is designed for single use is not ideal. Problems we encountered during this study were: temporarily unavailability of Cidex, so that sterilisation and re-use was not possible and problems with creating a vacuum after 3-5 times of use. On the other hand, the user-friendliness of the Kiwi vacuum extractor might have contributed to the fast uptake of the intervention. However, now that vacuum extraction is a routine intervention in Mulago hospital, we have re- introduced other types of vacuum extractors as well (Bird and flexible-cup with different types of pumps) and we are investigating what type would be the most helpful in terms of user-friendliness, patient-friendliness, safety, effectivity and costs in our setting. So far, we have not found the ideal vacuum extractor. We would recommend the development of an affordable user-friendly vacuum extractor or making the existing Kiwi device affordable as single-use instrument for LIC.

Failure rate

In the literature failure rates of 5.6 to 34% are described.[23,37-39] Although the 8.5% failure rate in this study is in the lower range of what is described elsewhere, failed vacuum extractions are a cause for concern. If a difficult procedure is expected, trial of vacuum extraction in theatre with everything in place for caesarean section in case of failure is advisable.

Limitations

A limitation of the study is the design with before and after measurements. Although it seems plausible, it cannot prove that the increased vacuum extraction rate has caused better maternal and perinatal outcome. Randomisation was not considered ethical, because vacuum extraction was not new to Mulago hospital and because vacuum extraction is a known effective intervention elsewhere. Randomisation in the setting of Mulago hospital would mean that half of the women would have to wait for an extra four

hours for caesarean section. During this waiting time they would be at risk of developing uterine rupture and/or intrapartum stillbirth. They would have a high-risk operation and a uterine scar with an increased risk of complications in next pregnancies, while a vacuum extraction would have been possible there and then.

During the study period there was no other ongoing intervention in Mulago hospital that may have accounted for the observed outcome.

Conclusions

A programme to increase the use of vacuum extraction was successful in a high-volume university hospital in sub-Saharan Africa. The use of vacuum extraction increased. An association with improved maternal and perinatal outcome is strongly suggested. The much shorter decision-to-birth interval for vacuum extraction compared to caesarean section probably plays an important role. We recommend broad implementation of vacuum extraction, whereby university hospitals like Mulago hospital can play an important role. To support implementation, we recommend further research into (long term) outcome of vacuum extraction and into vacuum extraction devices for low-income countries. Such studies are now in progress at Mulago hospital.

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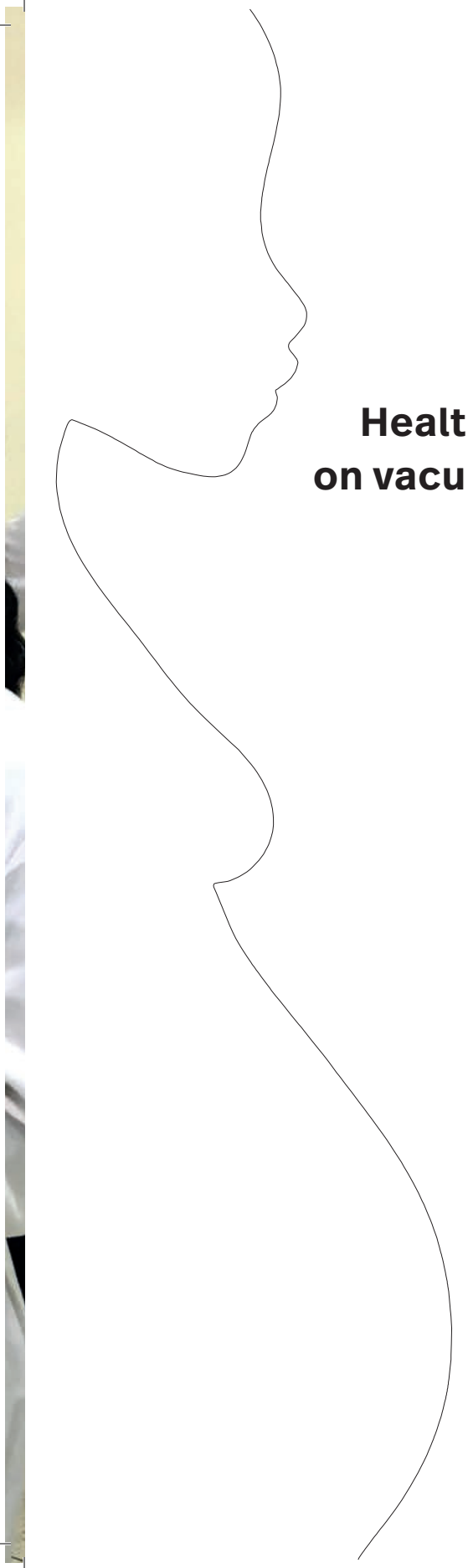

CHAPTER 3

Health workers' perspectives on vacuum extraction in Mulago hospital, Uganda

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Submitted

Abstract

Objective

To explore perceptions of health workers regarding the use of vacuum extraction.

Methods

A cross-sectional survey among midwives, residents and consultant obstetricians in Mulago hospital, Uganda, was performed. It was composed of questions pertaining to vacuum extraction, addressing reasons for low use, recommendations to increase use, preferred mode of birth in case of prolonged second stage for oneself or one's relative, views about who is suited to perform the procedure and contraindications.

Results

Eighty-three of 134 (61.9%) participants returned the survey. The most frequent reasons for low use of vacuum extraction were lack of training (60/83, 72.3%) and equipment (59/83, 71.1%) and concern about neonatal trauma (29/83, 34.9%) or HIV-transmission (27/83, 32.5%). Skills training and improved supply of equipment were recommended. Most participants (57/83, 68.8%) chose vacuum extraction over caesarean section as hypothetical mode of birth for themselves or a relative in case of prolonged second stage of labour. Opinions about contraindications varied. There was a tendency to cite contraindications not identified as such in international guidelines (big baby, caput succedaneum, moulding). Midwives, residents, interns and consultant obstetricians with appropriate training were generally all considered suited to perform vacuum extraction.

Conclusions

Health workers generally conveyed a positive attitude towards vacuum extraction, despite some perceived barriers, often unsupported by evidence. Organisation of skills training, supply of equipment and focus on knowledge of indications are essential to increase its use.

Introduction

Vacuum extraction is a procedure assisting a woman to give birth vaginally when the second stage of labour is prolonged or needs to be shortened because of suspected fetal or maternal distress.[1] It can be life-saving and improve maternal and fetal outcomes.[2,3] It also has significant advantages over caesarean section, including the reduction of complications associated with surgery, reduced delay between decision for intervention and birth, faster recovery, lower health care costs and avoiding complications related to uterine scars in subsequent pregnancies – an important aspect, particularly in low resource areas with high fertility rates.[2,4,5]

Despite these advantages, vacuum extraction has been under-utilised in low-and-middle-income countries (LMIC) in recent years, as compared to many high-income countries.[6,7] Furthermore, rising caesarean section rates and increasing proportions of caesarean sections unsupported by medical indications are also present in LMIC.[7,8] These unwarranted caesarean sections are part of the growing concern for excessive or inappropriate use of obstetric interventions.[9]

As one of the interventions to counteract this trend, a programme aiming to increase use of vacuum extraction in Mulago hospital, Uganda, was introduced in November 2012. Part of this programme was to assess health workers' perspectives on the intervention.

Common reasons for low vacuum extraction use in LMIC in the literature are lack of appropriate equipment, lack of skilled staff and training, low detection rate of indications for vacuum extraction, and concerns held by health care providers as well as national health institutions regarding potential harm to the neonate and increases in mother-to-child transmission of HIV.[5,7,8,10]

In this paper, we report outcomes of a survey distributed to health workers in the obstetric department of Mulago hospital in Uganda. The aim was to obtain a better understanding of the underlying reasons for low use of vacuum extraction by assessing personal opinions, recommendations and preferences.

Methods

Study design

A cross-sectional study was conducted, using a semi-structured questionnaire filled by Mulago hospital's maternity unit staff. This study was part of a larger implementation programme with the aim to re-introduce vacuum extraction, including audit of the impact of this programme on vacuum extraction use, clinical outcomes and women's experiences regarding vacuum extraction. Detailed methods and outcomes of these aspects of the programme were described elsewhere.[3,11,12,13]

Setting and participants

Mulago hospital is the national referral hospital of Uganda and the university teaching hospital for Makerere University, situated in the capital city, Kampala. It is a government hospital with 2700 beds and more than 31 000 births annually. The programme aiming to re-introduce vacuum extraction started in November 2012 consisted of developing a local vacuum extraction guideline, supply of equipment and training of staff.[11] During the programme, all residents in training to become obstetricians (45) were trained in small groups and received on-the-job supervision. Several presentations about the vacuum extraction guideline were given to the entire department staff (consultant obstetricians, midwives, residents, interns) during morning report meetings. Use of vacuum extraction increased from 0.6% to 2.4% of births over the 15-month time frame between November 2012 and February 2014, when a survey was done to assess health workers' opinions about vacuum extraction, and their recommendations to achieve additional increases in the use of vacuum extraction.

In February 2014, medical staff consisted of 43 nurse-midwives, 46 obstetricians and 45 residents in training. A convenience sample was used, consisting of all staff working in the department of obstetrics at the time of the survey. The survey was developed by the second author, based on what was found in literature regarding reasons for low use of vacuum extraction, international guidelines and the Mulago hospital vacuum extraction guideline.[1,10,14-16] After obtaining verbal consent, participants were asked to complete the survey anonymously. The questions from the survey are represented below. The answers to the questions were entered into Excel version 15.3 and analysed with SPSS version 24. The answers to the questions were translated into counts and percentages.

Survey questions

What were the reasons for the low vacuum extraction rate in Mulago hospital before the start of the programme?
(multiple choice + "other reason, specify", more than one reason possible)

What are your recommendations to increase vacuum extraction use?
(open question)

What would be your preferred mode of birth in case of prolonged second stage of labour? (or for your partner/sister in case of male health worker)
(vacuum extraction or caesarean section)

What would you consider (relative) contraindications for vacuum extraction?
(multiple choice)

Who should be entitled to perform vacuum extraction after being trained
(multiple choice)

Ethical clearance

Ethical permission to conduct this study was obtained from the Mulago Research and Ethics Committee (refnr: MREC 489).

Results

In total, 83/134 (61.9%) participants returned the questionnaires, including 22/43 nurse-midwives, 32/45 residents in training and 29/46 consultant obstetricians.

Reasons for (previously) low vacuum extraction use

The most frequently mentioned reasons for low vacuum extraction use before the start of the programme were lack of vacuum extraction skills amongst doctors and midwives (60/83, 72.3%,), no vacuum extractor available (59/83, 71.1%), not enough opportunities for practice and training of staff (30/83, 36.1%), concerns of trauma to the neonate (29/83, 34.9%) and concerns related to mother to child transmission of HIV (27/83, 32.5%) (Table 1).

Concerns regarding trauma to the neonate were more frequently reported by midwives (13/22, 59.1%) as compared to obstetricians (4/29, 13.8%). The majority of consultant obstetricians (15/29, 51.7%) reported concerns about HIV-transmission, as compared to 8/32 (25.0%) of residents and 6/22 (27.3%) of midwives.

Table 1 | Reasons for (previously) low vacuum extraction use

Reason	Mentioned by N(%) of health workers
	All (N=83)
Lack of skilled staff	60 (72.3)
No vacuum extractor available	59 (71.1)
No training opportunities	30 (36.1)
Concern trauma to neonate	29 (34.9)
Concern HIV-transmission	27 (32.5)
No vacuum extraction if caesarean section is possible	4 (4.8)
Caesarean section safer for mother	3 (3.6)
Vacuum extraction should be done by specialist	3 (3.6)
Vacuum extraction is obsolete	0 (0.0)
Other	7 (8.4)

Recommendations to increase vacuum extraction use

The most frequently reported suggestions for increasing the use of vacuum extraction were organising more skills training (61/83, 73.5%) and increase the availability of equipment (38/83, 45.9%) (Table 2). It was furthermore suggested by a few participants (3/83, 3.6%) to raise awareness about the procedure.

Table 2 | Recommendations to increase the use of vacuum extraction

Option	Mentioned by N(%) of health workers
	All (N=83)
Vacuum extraction skills training	61 (73.5)
Increase availability of equipment	38 (45.9)
Supervision and feedback	7 (8.4)
Present evidence	5 (6.0)
Need for local protocol	4 (4.8)
Raise awareness	3 (3.6)
No recommendation	32 (16.9)

Preference of health worker for herself or his partner/sister

In the event of a prolonged second stage of labour, 57/83 (68.8%) would choose vacuum extraction as preferred mode of birth, compared to 21/83 (25.3%) who would choose caesarean section (Table 3). Especially consultant obstetricians preferred vacuum extraction over caesarean section (25/29, 86.2%). On the other hand, many midwives were in favour of caesarean section (9/22, 40.9%).

Table 3 | Preferred mode of birth of health worker for oneself or family member

Option			Mentioned by N(%) of health workers	
	Midwife (22)	Resident (32)	Obstetrician (29)	All (N=83)
Vacuum extraction	13 (59.1)	19 (59.4)	25 (86.2)	57 (68.8)
Caesarean section	9 (40.9)	11 (34.4)	1 (3.4)	21 (25.3)
No preference	0 (0.0)	2 (6.3)	3 (10.3)	5 (6.0)

Contra-indications for using vacuum extraction

Face and brow presentations were perceived by the majority of the participants as absolute contra-indications and also considered as such in international guidelines (Table 4).[1]

Table 4 | Contraindications according to health workers in Mulago hospital

(Contra)Indication	Mentioned by N(%) of health workers		
	Absolute contra-indication	Relative contra-indication	Blanc
Face presentation	73 (87.9)	4 (4.8)	6 (7.2)
Brow presentation	66 (79.5)	10 (12.0)	5 (6.0)
Big baby	42 (50.6)	33 (39.6)	3 (3.6)
Previous caesarean section	33 (39.8)	40 (48.2)	3 (3.6)
HIV without medication	28 (33.7)	39 (46.9)	2 (2.4)
HIV with ART	7 (8.3)	38 (45.8)	6 (7.2)
Caput succedaneum	25 (30.1)	41 (49.4)	7 (8.4)
IUFD	22 (26.5)	16 (19.3)	5 (6.0)
Occiput posterior	17 (20.5)	38 (45.8)	8 (9.6)
Moulding	10 (12.1)	45 (54.2)	12 (14.5)

IUFD: intra-uterine fetal death; ART: antiretroviral therapy

Big baby, moulding and caput succedaneum were perceived as absolute contra-indications by 42/83 (50.6%), 25/83 (30.1%) and 10/83 (12.1%) of the health workers, respectively. Few participants (7/83, 8.3%) perceived a woman with HIV receiving antiretroviral therapy as an absolute contra-indication for vacuum extraction. When it concerned a woman not receiving antiretroviral therapy, 28/83 (33.7%) considered this an absolute contra-indication.

Who should be allowed to perform vacuum extraction?

When asked which type of health worker would be suited to perform vacuum extraction, obstetricians were unanimous (32/32, 100%) that obstetricians, residents and interns should be entitled to perform it. Overall, the majority found that obstetricians, residents, midwives and interns would be suited to perform vacuum extraction after having received appropriate training (Table 5).

Table 5 | Who should be entitled to perform vacuum extraction

Type of health worker	Mentioned by N(%) of health workers
	All (N=83)
Obstetrician	76 (91.6)
Residents	81 (97.6)
Interns	61 (73.5)
Midwives	60 (72.3)
Nurses	15 (18.1)
Blanc	0 (0.0)

Comments mentioned by participants:

Category	Reasons for low use	Suggestions to increase use
Logistical organisation	"Vacuum extraction should be performed if caesarean section is available in case of failed attempt"	"Decongest (operating) theatre, so that it is ready in case of failed vacuum"
	"Simply because donation of vacuum extractors was irregular"	"Provide vacuum sets and make them available for use and provide regular periodic training for all doctors in the department"
	"Satisfactory resuscitation of babies not guaranteed in labour ward"	
Implementation	"Low number of cases for vacuum extraction on the day of duty"	"Do hands-on training to increase confidence of health workers to do this procedure"
	"There are few indications for vacuum extraction"	
Perception	"Attitude towards vacuum extraction: people just don't want to do it."	"Perform evidence-based studies on vacuum extraction in Uganda and present evidence of success"
		"Sensitise mothers about this procedure"
		"Increase knowledge, train medical workers and dispense myths about the risks for the babies"

Discussion

Main findings

The most frequently reported reasons for previous low use of vacuum extraction are lack of skills among health workers, lack of available equipment and insufficient opportunities for training and practice. Concerns related to neonatal trauma and HIV-transmission were also reported. Recommendations to increase use of vacuum extraction included providing additional training and guaranteed supply of equipment. Most participants chose vacuum extraction over caesarean section when asked about their personal preferred mode of birth. The majority of health workers agreed that consultant obstetricians, residents and midwives should be entitled to perform vacuum extraction.

Interpretation

Results from other studies, including the ones performed in the context of the implementation programme in Mulago hospital, revealed that frequent periodic training sessions and supply of equipment can reverse the trend of low vacuum extraction use with improvement of neonatal and maternal outcomes.[2,3,12,17,18] As a matter of fact, before the start of the programme, trainings were limited and vacuum extractors scarce.

Despite a generally open attitude, a substantial part of participants expressed concerns regarding vacuum extraction as a mode of birth. Apparent concerns regarding trauma to the neonate were mentioned. However, outcomes of severe neonatal trauma and brain damage were investigated in the same hospital and revealed that neonatal trauma was infrequent and not more frequent after vacuum extraction compared to second-stage caesarean section.[3] This is consistent with other studies from high-income and low-income countries that show reassuring outcomes after vacuum extraction, especially when compared to caesarean section.[19-27]

Another concern was vertical HIV-transmission. A meta-analysis conducted in the era before antiretroviral treatment was introduced revealed that there is no significant difference in transmission risk between a second-stage caesarean section and assisted vaginal birth.[28] A more recent study stated that vertical transmission risk was very low in women on antiretroviral therapy with suppressed viral load.[29] Furthermore, it is unlikely that second-stage caesarean section provides a better protection for HIV-transmission compared to vacuum extraction, especially considering the delay between the decision to perform a caesarean section and actual birth.[28,29] Decision on mode of birth in HIV-positive women should be based on risks and benefits, depending on the underlying risks associated with disease stage, antiretroviral treatment and local capacity to manage potential complications.[30]

There were also suggestions to raise awareness about benefits of vacuum extraction through presenting local outcomes in order to sensitise not only health workers, but also women. Since September 2013, outcomes from studies performed in Mulago hospital have been presented in the hospital itself as well as during various conferences. Studying interventions in a local context can indeed help health workers understand benefits and inform them about safety. In this way, beliefs about potential harm can be addressed, discussed and adjusted.

Big baby, moulding and caput succedaneum were perceived as relative and absolute contra-indications by an important number of participants, whilst in international guidelines these are not described as such.[1,31] Non-recognition of indications or wrongly assumed contraindications may be an additional reason for low use of vacuum extraction.[7]

In Uganda, obstructed labour is not a rare event and is sometimes diagnosed at a late stage with severe caput succedaneum and moulding.[32] This might have contributed to the misconception that caput and moulding are pathological findings indicative of cephalo-pelvic disproportion and that caesarean section is the only possible intervention in case these are present. Concerns about cephalo-pelvic disproportion is hence probably the reason that "Big baby" is seen as a contraindication. However, estimating fetal weight by abdominal palpation is unreliable. The best way to find out if vaginal birth is possible is trial of labour with adequate contractions. When cephalo-pelvic disproportion is present, descent of the fetal head does not take place. In the event of prolonged labour or fetal distress in the second stage of labour, vacuum extraction could be tried, provided the bony part of the fetal head has engaged to the level of the ischial spines (station 0) and if per abdominal palpation not more than 1/5th of the fetal head is palpable above the pubic bone, irrespective whether caput succedaneum or moulding are present. When a difficult vacuum extraction is expected (severe caput succedaneum and/or moulding, fetal head not reaching beyond station 0), trial of vacuum extraction with the operation theatre available and ready could be considered.

Furthermore, scarred uterus, occipito-posterior position, an HIV-positive woman on antiretroviral therapy or intra-uterine fetal death are not considered contraindications for vacuum extraction in international guidelines, contrary to the opinion of a substantial part of the participants.[1,31] The diverse answers to these questions reveal that there is a lack of clarity of guidelines and reluctance to use vacuum extraction. In May 2013, a local guideline on vacuum extraction was designed by Ugandan obstetricians and international members of the research group, based on the RCOG guideline and adapted to the local context. This protocol was presented to the department (midwives, residents and consultant obstetricians) in May and July 2013 and approved by the department in July 2013. The guideline was distributed to all staff and posters were placed in the labour ward. The survey, however, revealed that not all participants agreed or were aware of the protocol. Together with reporting local outcomes, continuous training and supervision may help to improve adherence to the guideline. Finally, the majority of participants was of the opinion that a wide range of trained health workers can perform vacuum extraction, including interns and midwives. This reflects an open approach towards the expansion of skills among all health workers.

Strengths and limitations

In the dynamic process of re-introducing vacuum extraction, a survey obviously only represents a snapshot of opinions at a certain point in time. However, we believe that this survey provides a fair representation of the stance of health workers on vacuum extraction at the time, which is important in the context of implementing an intervention programme. Furthermore, to our knowledge, health workers' opinion on this obstetric intervention has not been studied before.

The response rate was relatively low and could indicate that there is a chance of selection bias, with participants more acquainted with the procedure being perhaps more likely to return the survey. Furthermore, there is a chance of recall bias considered that some of the questions referred to the period before the start of the re-introduction programme.

Nevertheless, the outcomes of this study complements outcomes of previous publications on this topic and may encourage further implementation of training programmes on vacuum extraction in Mulago hospital as well as other hospitals in LMIC.[7,8,10]

Conclusion

Health workers' perspectives on vacuum extraction demonstrate their willingness to learn more about maternal and neonatal outcomes of vacuum extraction and translate them into practice with the support of skills training, supervision and feedback.

Most participants would prefer the use of vacuum extraction over caesarean section for themselves or family members. Outcomes suggest that there is room to expand the knowledge on medical indications which could promote use of vacuum extraction.

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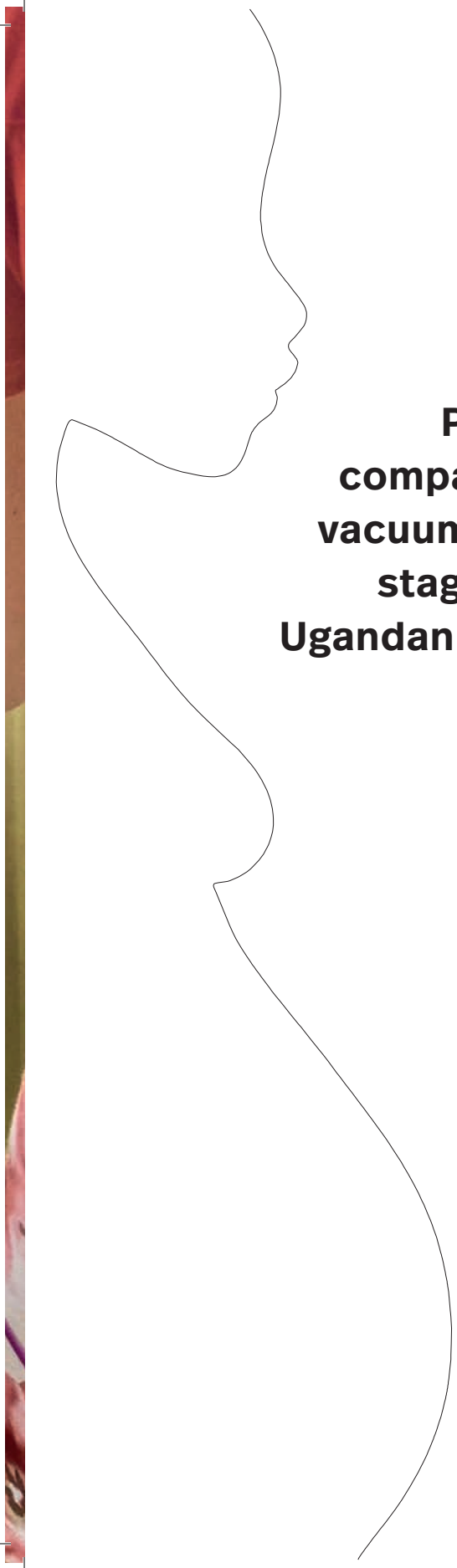

CHAPTER 4

Prospective cohort study comparing outcomes between vacuum extraction and second-stage caesarean section at a Ugandan tertiary referral hospital

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Abstract

Objective

To compare maternal and perinatal outcomes between vacuum extraction and second-stage caesarean section.

Methods

The present observational cohort study was conducted among women with term vertex singleton pregnancies who underwent vacuum extraction or second-stage caesarean section at Mulago national referral hospital, Kampala, Uganda, between November 25th, 2014, and July 8th, 2015. Severe maternal outcomes (mortality, uterine rupture, hysterectomy, re-laparotomy) and perinatal outcomes (mortality, trauma, low Apgar score, convulsions) were compared between initial mode of birth.

Results

Among 13 152 births, 358 women who underwent vacuum extraction and 425 women who underwent second-stage caesarean section were enrolled in the study. No maternal deaths occurred after vacuum extraction versus five deaths from complications of second-stage caesarean section. Vacuum extraction was associated with less severe maternal outcomes compared with second-stage caesarean section: 3/358 (0.8%) versus 18/425 (4.2%); adjusted OR 0.24, 95%CI 0.07-0.84. Fetal death during the decision-to-birth interval was also less common in the vacuum extraction group: 3/347 (0.9%) versus 18/410 (4.4%); adjusted OR 0.24, 95%CI 0.07-0.84. However, the perinatal mortality rate did not differ between the vacuum extraction and caesarean section groups: 29/347 (8.4%) versus 45/410 (11.0%) respectively; adjusted OR 0.83, 95%CI 0.49-1.41. One infant in each group exhibited neurodevelopmental anomalies at six months.

Conclusions

Vacuum extraction had better maternal outcomes and equivalent perinatal outcomes compared with second-stage caesarean section. These findings encourage re-introduction of vacuum extraction.

Introduction

With 275 288 maternal deaths, 2.1 million stillbirths, and 2.0 million early neonatal deaths recorded worldwide in 2015, maternal and perinatal mortality are global health priorities.[1,2] Most maternal and perinatal deaths occur in low-income and middle-income countries (LMIC).[1,2]

Vacuum extraction is an evidence-based intervention that is used to shorten the second stage of labour. Indications for this approach include fetal distress, prolonged second stage of labour, maternal exhaustion, or the need to avoid expulsive efforts among women with conditions such as heart failure or severe anaemia.[3,4] Although vacuum extraction can reduce maternal mortality from haemorrhage and sepsis, as well as perinatal mortality from birth asphyxia, use of this method has almost disappeared from obstetric practice in many LMIC.[5-8] One study found that assisted vaginal birth was not used in almost half of 1728 sub-Saharan African hospitals, with usage rates below 1% in the remaining centres.[6] Reasons for this deficit include lack of functioning equipment, lack of trained personnel, staff perceptions regarding trauma to the fetus, and fear of mother-to-child transmission of HIV.[6–8] Consequently, many women in LMIC undergo avoidable caesarean section.[9]

The use of caesarean section, especially when performed during the second stage of labour, increases the risks of haemorrhage and infection, which are two of the main drivers of global maternal mortality.[10–12] In addition, a scarred uterus is a risk factor for uterine rupture and abnormally invasive placenta in subsequent pregnancies.[13] These risks are particularly high in low-resource settings, where many births happen outside healthcare facilities; access to safe surgery and anaesthesia cannot be taken for granted; blood for transfusion is in short supply; and fertility rates are high.[14,15] Therefore, it is crucial that unnecessary caesarean section is avoided.[16–18]

Published literature regarding outcomes of vacuum extraction among LMIC is scarce. Most studies lack follow-up, and vacuum extraction was not compared with alternative management options.[19–21] In 2012, vacuum extraction was reimplemented in the main tertiary hospital in Uganda (Mulago national referral hospital, Kampala). This initiative led to declines in intrapartum stillbirths and uterine ruptures of 24% and 26%, respectively.[7]

The use of vacuum extraction was hypothesised to reduce maternal morbidity, perinatal morbidity, and the decision-to-birth interval (DBI) when compared with second-stage caesarean section.[12] The aim of the present study was to test this hypothesis among pregnant women attending Mulago national referral hospital.

Materials and methods

The present prospective observational cohort study was conducted among women undergoing vacuum extraction or second-stage caesarean section in the main labour ward of Mulago national referral hospital between November 25th, 2014, and July 8th, 2015. Women with a term singleton pregnancy in vertex presentation who gave birth by vacuum extraction or second-stage caesarean section at the study centre were included, as were those who developed a ruptured uterus while in the second stage of labour and waiting for the intervention. Women who experienced a ruptured uterus before the decision for intervention (vacuum extraction or caesarean section) were excluded. Women who experienced intrauterine fetal death (IUFD) before the decision for intervention were excluded from the analysis of perinatal outcomes. Ethical approval for the present study was obtained from the Mulago national referral hospital Research and Ethics Committee (MREC 489) and the Uganda National Council for Science and Technology, Kampala, Uganda (HS1752). Women provided written informed consent for their participation.

Mulago hospital is a university teaching and government hospital with 2700 beds and greater than 31 000 births recorded annually. It is the main training centre for midwives, medical doctors, and obstetricians in the country. The maternity unit has an operating theatre, which is accessible 24 hours per day. Vacuum extraction and caesarean section are performed by residents (50 trainee obstetricians at the centre, with 5-7 on labour wards) with or without supervision, depending on experience, and specialist obstetricians (40 at the centre, with 1-3 on labour wards). All doctors are trained in performing vacuum extraction and caesarean section; however, caesarean section is undertaken more frequently than vacuum extraction (approximately 20 caesarean sections per day compared with one or two vacuum extractions per day at the study centre). Although vacuum extraction is used regularly, and the hospital has a protocol with indications, the decision regarding mode of birth depends not only on clinical factors but also on the doctor's personal preference and expertise, as well as the availability of theatre and vacuum equipment. Many women undergoing caesarean section at Mulago hospital could be eligible for vacuum extraction.[7,12]

The vacuum equipment used at this centre comprises Kiwi vacuum extractors (Clinical Innovations, South Murray, Utah, USA), Bird and silicone cups, with hand and foot pumps. Forceps are available, but rarely used, as is the case in many hospitals in LMIC.[6] Spinal anaesthesia during caesarean section is provided by anaesthetic nurses or anaesthesiologists. An obstetric high dependency unit is available where women are monitored and given oxygen when needed. The hospital has a general intensive care unit, with mechanical ventilation. There is a blood bank; however, the availability of blood for transfusion is limited. Fetal monitoring occurs using a Pinard fetoscope or handheld doppler machine. The neonatology ward has incubators, phototherapy, and continuous positive airway pressure, but no mechanical ventilation. Most women come from

Kampala and the surrounding area, although some have travelled for a day to attend the hospital. Maternity services are free of charge, except in the private ward.

Within 24 hours of birth, a member of the research team identified women with vacuum extraction from the delivery book. Women who underwent caesarean section were identified from the theatre register and their medical records examined to identify those who had a fully dilated cervix at the time of decision for caesarean section. Eligible women were asked to participate in the present study on the day after birth.

Data were extracted from the participants' medical records. Indications for caesarean section and vacuum extraction were classified as "delay", "fetal distress", "maternal", and "other" (Table S1). Women were interviewed using structured questionnaires (File S1). Data were extracted from medical records and the admission, discharge, and mortality registers for neonates admitted to the neonatology unit. Follow-up consultations occurred at six weeks and six months after birth. During these visits, women were interviewed using semi-structured questionnaires (File S1). Neonates were weighed and assessed according to the neurodevelopmental scoring chart of Van Wiechen.[22] Verbal autopsy forms were used to determine the cause of any neonatal deaths that occurred after hospital discharge.[23] Women who missed the postnatal consultations were interviewed by telephone using the same questionnaire; however, questions about HIV-status were omitted for reasons of privacy.

The primary maternal outcomes were death and a composite of severe maternal outcomes, defined as death, uterine rupture, hysterectomy, or relaparotomy (Table S1). Secondary maternal outcomes were postpartum haemorrhage (PPH), infection, genital tract injury, and duration of hospital admission.

Primary perinatal outcomes were death after the decision for a second stage intervention and a composite severe perinatal outcome, which was defined as death, severe birth trauma, convulsions, or a 5-minute Apgar score below four. Secondary outcomes were admission to the neonatology unit, duration of admission, and diagnosis. Outcomes assessed during follow-up were neonatal or infant death after discharge, and neurodevelopment anomalies.

Sample size calculations are shown in Table S2. Failed vacuum extraction with subsequent caesarean section (or forceps) was analysed as part of the outcome of vacuum extraction, as this was the intended mode of birth. The data were collated using Excel 2013 (Microsoft, Redmond, WA, USA) and analysed using SPSS version 24 (IBM, Armonk, NY, USA). Baseline characteristics were reported as numbers with percentages, with P-values calculated using a two-sided chi-square test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. Outcome parameters were reported as numbers with percentages, P-values, unadjusted (univariate) odds ratios (OR) and, for primary outcomes, adjusted (multivariate) OR with 95% confidence

intervals (95%CI). A multivariate logistic regression model to calculate adjusted OR (aOR) was constructed to adjust for potential confounders. Factors were tested one by one, stratified for mode of birth, and included in the multivariate model based on differences in distribution and the strongest potential for confounding. The number needed to treat (NNT) was calculated for maternal death and the composite severe maternal outcome. A P-value of less than 0.05 was considered to be statistically significant.

Results

Among the 13 152 births recorded during the present study period, 369 (2.8%) women with a term vertex singleton underwent (trial of) vacuum extraction and 429 (3.3%) women with a term vertex singleton underwent second-stage caesarean section. The inclusion process is outlined in Figure 1. The vacuum extraction and caesarean section groups used to analyse maternal outcomes comprised 358 and 425 women, respectively. In all, 36 (9.5%) women experienced a failed vacuum extraction: 35 of these women gave birth by caesarean section and one by forceps. These 36 women were analysed in the vacuum extraction group. Women who experienced IUFD before the decision to intervene were excluded from the analysis of perinatal outcomes. Therefore, the vacuum extraction and caesarean section groups used to analyse perinatal outcomes comprised 347 and 410 women, respectively.

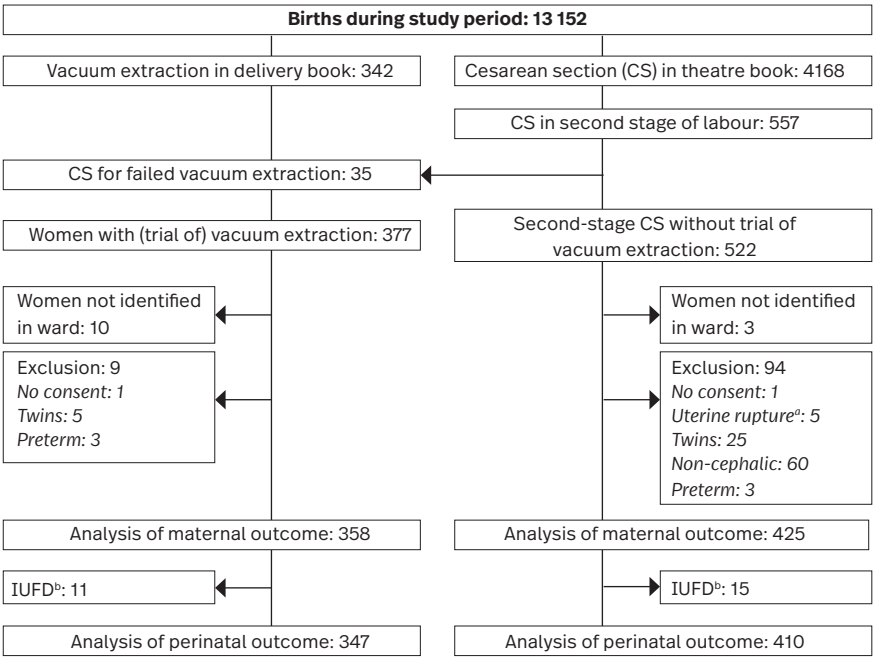

Figure 1 | Inclusion process
CS, caesarean section; IUFD, intrauterine fetal death; [a]Uterine rupture before decision to do second-stage CS; [b]Intrauterine fetal death before decision to do vacuum extraction or caesarean section

Baseline characteristics of the participants are shown in Table 1. More women in the caesarean section group had a previous caesarean section, gave birth to a neonate weighing more than 4000g, were in second stage of labour on admission, and had indication delay, fetal distress or impending uterine rupture. There were non-significant trends toward greater numbers of nulliparous women and women with HIV in the vacuum extraction group. Baseline data with the missing data included as a proportion are presented in Table S3.

Table 1 | Baseline characteristics of the participants[a,b]

	(Trial of) Vacuum extraction (n=358)	Second-stage caesarean section (n=425)	P-value[c]
Maternal			
Nulliparous	201/352 (57.1)	215/425 (50.6)	0.070
Age<20 years	84/353 (23.8)	91/424 (21.5)	0.438
Education ≤ 6 years	86/349 (24.6)	105/413 (25.4)	0.804
Previous caesarean section	38/351 (10.8)	102/425 (24.0)	<0.001
HIV-positive status	36/296 (12.2)	30/364 (8.2)	0.095
Eclampsia	2/358 (0.6)	4/425 (0.9)	0.693
Neonatal			
Intrauterine fetal death[d]	11/358 (3.1)	15/425 (3.5)	0.722
Male sex	198/354 (55.9)	232/422 (55.0)	0.790
Birthweight >4000 g	10/353 (2.8)	32/420 (7.6)	0.003
Labour and delivery factors[e]			
Referral	153/349 (43.8)	208/423 (49.2)	0.139
In second stage of labour at hospital admission	138/349 (39.5)	203/425 (47.8)	0.022
Indication			
Delay	248/333 (74.5)	363/424 (85.6)	<0.001
Fetal distress	34/333 (10.2)	90/424 (21.2)	<0.001
Maternal	54/333 (16.2)	49/424 (11.6)	0.063
Other	14/333 (4.2)	3/424 (0.7)	0.001
Impending uterine rupture	2/358 (0.6)	12/425 (2.8)	0.017
Placental abruption	2/358 (0.6)	2/425 (0.5)	>0.99
Cord prolapse	3/358 (0.8)	3/425 (0.7)	>0.99

[a] Values are given as number/number of women or neonates with available data for this characteristic (percentage) unless indicated otherwise.
[b] Missing data are specified in Table S3.
[c] P-values were calculated using a two-sided chi-square test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was P<0.05.
[d] Occurred before the decision to perform second-stage cesarean delivery or vacuum extraction.
[e] More than one indication could apply.

Table 2 | Maternal outcome at hospital discharge.[a,b]

Outcome	(Trial of) vacuum extraction (n=358)	Second-stage caesarean section(n=425)	OR	(95%CI)[c]	P-value[d]
Maternal mortality	0	5 (1.2)	NA	NA	0.066
Severe maternal outcome[e]	3 (0.8)	18 (4.2)	0.19	(0.06-0.65)	0.003
Postpartum haemorrhage					
Blood loss documented	307 (85.8)	350 (82.4)	1.29	(0.88-1.90)	0.197
Volume, mL					
≥500	22/307 (7.2)	210/350 (60.0)	0.05	(0.03-0.08)	<0.001
≥1000	3/307 (1.0)	10/350 (2.9)	0.34	(0.09-1.23)	0.098
Blood transfusion	3 (0.8)	4 (0.9)	0.89	(0.20-4.00)	>0.99
Urogenital tract injury					
Uterine rupture	2 (0.6)	8 (1.9)	0.29	(0.06-1.39)	0.100
Cervical tear	3 (0.8)	0	NA	NA	0.095
Anal sphincter rupture	3 (0.8)	0	NA	NA	0.095
Operation during hospital admission					
Hysterectomy	1 (0.3)	4 (0.9)	0.30	(0.03-2.65)	0.383
Re-laparotomy[f]	3 (0.8)	5 (1.2)	0.71	(0.17-2.99)	0.733
Hospital stay					
Date of discharge documented	231 (64.5)	289 (68.0)	0.86	(0.64-1.15)	0.305
Length of stay, days					
0-2	186/231 (80.5)	60/289 (20.8)	15.78	(10.24-24.31)	<0.001
>5	12/231 (5.2)	38/289 (13.1)	0.36	(0.18-0.71)	0.002

OR, odds ratio; CI, confidence interval; NA, not applicable

[a] Values are given as number (percentage) unless indicated otherwise.

[b] More than one adverse event could apply.

[c] OR and 95%CI were calculated using univariate logistic regression analysis. Calculations of adjusted OR are shown in Table S5.

[d] P-values were calculated using a two-sided chi-square test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was P<0.05.

[e] Death, uterine rupture, hysterectomy, or relaparotomy.

[f] Relaparotomy after caesarean section or laparotomy after vacuum extraction.

Maternal outcomes at hospital discharge are shown in Table 2. In all, 5 (1.2%) maternal deaths during the first six weeks after birth were found for the caesarean section group; however, no maternal deaths were recorded in the vacuum extraction group. The difference in maternal mortality between the groups was not significant (P=0.066). Deaths in the caesarean section group occurred among women who underwent the procedure for prolonged labour. The causes of death were complete spinal block with cardiac arrest (n=4) and complete spinal block with hypoxic brain damage (n=1). Contributing factors were PPH, infection, and aspiration pneumonia (Table S4). One woman in the vacuum extraction group died five months after birth following an episode of fever; however, this event was unlikely to be related to mode of birth.

Table 3 | Maternal infection and urogenital tract injury at six weeks follow-up[a,b]

Maternal outcomes	(Trial of) vacuum extraction (n=284)	Second-stage caesarean section (n=365)	OR	(95%CI)[c]	P-value[d]
Infection					
Total infections	10 (3.5)	58 (15.9)	0.19	(0.10-0.39)	<0.001
Wound infection[e]	6 (2.1)	43 (11.8)	0.16	(0.07-0.39)	<0.001
Sepsis and/or fever	5 (1.8)	21 (5.8)	0.29	(0.11-0.79)	0.010
Wound dehiscence or burst abdomen	2 (0.7)	8 (2.2)	0.32	(0.07-1.50)	0.127
Peritonitis or pelvic abscess	0	2 (0.5)	NA	NA	0.507
Urogenital tract injury					
Obstetric fistula[f]	1 (0.4)	4 (1.1)	0.32	(0.04-2.87)	0.393
Urine incontinence ≥ 6 weeks	6 (2.1)	9 (2.5)	0.85	(0.30-2.43)	0.766
Faecal incontinence ≥ 6 weeks	0	0	NA	NA	
Surgical intervention[g]					
Obstetric fistula repair	1 (0.4)	4 (1.1)	0.32	(0.04-2.87)	0.393
Wound closure and/or drainage of pus	1 (0.4)	5 (1.4)	0.23	(0.03-2.00)	0.239
Laparotomy for pelvic abscess	0	1 (0.3)	NA	NA	>0.99

CS, cesarean section; OR, odds ratio; CI, confidence interval; NA, not applicable
[a] Values are given as number (percentage) unless indicated otherwise.
[b] More than one adverse event could apply.
[c] ORs and 95%CIs were calculated using univariate logistic regression analysis.
[d] P values calculated using a two-sided chi-square test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was P<0.05.
[e] Infection of the operation wound or perineum.
[f] Obstetric fistula in the vacuum extraction group occurred following failed vacuum extraction and subsequent caesarean delivery.
[g] These operations were performed on re-admission and are not included in Table 2.

As shown in Table 2, the composite severe maternal outcome was recorded among 3 of 358 (0.8%) women after vacuum extraction and 18 of 425 (4.2%) women after caesarean section (OR 0.19, 95%CI 0.06–0.65). The aOR was 0.24 (95%CI 0.07–0.84) (Table S5). The NNT to prevent one severe maternal adverse event during or after second-stage caesarean section was 28 (95%CI 17–69) patients. The NNT to prevent one maternal death was 85 (95%CI 45–661). Among women with relevant data available, blood loss of at least 500 mL was more frequent in the caesarean section group (P<0.001), blood loss of at least 1000 mL did not differ (P=0.098), and number of blood transfusions did not differ (*P*>0.99). Hospital stay was shortened after vacuum extraction, with a duration of 0–2 days more common in the vacuum extraction group (P<0.001) and a duration of longer than 5 days more common in the caesarean section group (P=0.001) (Table 2). Maternal follow-up rates at six weeks after birth were 79% for the vacuum extraction group and 87% for the caesarean section group (Fig. S1). Maternal infection and urogenital tract injuries that had occurred after vacuum extraction or caesarean section and were reported at the 6 week follow-up consultation are shown in Table 3. Infection had occurred among 10 (3.5%) women after vacuum extraction and 58 (15.9%) women after caesarean section; the OR was 0.19 (95%CI 0.10–0.39; P<0.001). An obstetric fistula after failed vacuum extraction and subsequent caesarean section was recorded in 1 (0.4%) woman, and 4 women (1.1%)

developed an obstetric fistula after caesarean section (P=0.393). Urine incontinence was present in 6 women (2.1%) after vacuum extraction and in 9 women (2.5%) after caesarean section (P=0.766).

Table 4 | Perinatal outcomes[a,b]

Outcome	(Trial of) vacuum extraction (n=347)	Second-stage caesarean section (n=410)	OR	(95%CI)[c]	P-value[d]
Perinatal death	29 (8.4)	45 (11.0)	0.74	(0.45-1.21)	0.227
Severe perinatal outcome[e]	45 (13.0)	55 (13.4)	0.96	(0.63-1.47)	0.857
Timing of death					
During DBI	3 (0.9)	18 (4.4)	0.19	(0.06-0.65)	0.003
Early neonatal period[f]	26 (7.5)	27 (6.6)	1.15	(0.66-2.01)	0.626
DBI					
Documented	225 (64.8)	364 (88.8)	0.23	(0.16-0.34)	<0.001
Duration>60 min	66/225 (29.3)	298/364 (81.9)	0.09	(0.06-0.14)	<0.001
Adverse events among surviving neonates[g]	318	365			
Birth asphyxia	41 (12.9)	40 (11.0)	1.20	(0.76–1.91)	0.435
Convulsions	11 (3.5)	7 (1.9)	1.83	(0.70–4.79)	0.210
Sepsis and/or fever	14 (4.4)	14 (3.8)	1.16	(0.54–2.46)	0.709
Jaundice	8 (2.5)	7 (1.9)	1.32	(0.47–3.68)	0.595
Feeding difficulties	4 (1.3)	2 (0.5)	2.31	(0.42–12.71)	0.425
Breathing difficulties	17 (5.3)	15 (4.1)	1.32	(0.65–2.68)	0.446
Continuous positive airway pressure administered	10 (3.1)	5 (1.4)	2.34	(0.79–6.91)	0.114
Severe trauma[h]	4 (1.3)	2 (0.5)	2.31	(0.42–12.71)	0.425
Minor trauma[i]	5 (1.6)	2 (0.5)	2.90	(0.56–15.05)	0.260
All trauma	9 (2.8)	4 (1.1)	2.63	(0.80–8.62)	0.098
5-min Apgar score among surviving neonates					
<7	18/314 (5.7)	19/362 (5.2)	1.10	(0.57-2.13)	0.783
<4	2/314 (0.6)	3/362 (0.8)	0.77	(0.13-4.62)	>0.99
Admission to neonatology unit among surviving neonates					
Total no. of admissions	80 (25.2)	69 (18.9)	1.44	(1.00-2.08)	0.048
Duration of admissions, days					
>2	42/315 (13.3)	45/361 (12.5)	1.08	(0.69-1.70)	0.737
>7	11/315 (3.5)	12/361 (3.3)	1.05	(0.46-2.42)	0.904

OR, odds ratio; CI, confidence interval; DBI, decision-to-birth interval.

[a] Values are given as number (percentage) unless indicated otherwise.

[b] Outcomes assessed at hospital discharge or 1 wk after admission to the neonatology unit.

[c] OR and 95%CI were calculated using univariate logistic regression analysis. Calculations of adjusted OR are presented in Tables S6, S7, and S10.

[d] P-values were calculated using a two-sided chi-square test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was P<0.05.

[e] Perinatal death, severe trauma, 5-min Apgar score<4, or convulsions.

[f] In the first week after delivery.

[g] More than one adverse event could apply.

[h] Intraventricular, intracerebral, or subgaleal hemorrhage; facial palsy; or dislocation of a leg.

[i] Cephalohematoma or fracture of clavicula.

As shown in Table 4, perinatal death was recorded in similar numbers of neonates in the vacuum extraction and caesarean section groups (OR 0.74, 95%CI 0.45–1.21; P=0.227); the aOR was 0.83 (95%CI 0.49–1.41; P=0.483) (Table S6). The composite severe perinatal outcome was also recorded at a similar rate in both groups (OR 0.96, 95%CI 0.63–1.47; P=0.857); the aOR was 1.04 (95%CI 0.66–1.66; P=0.854) (Table S7).

Neonates were admitted to the neonatology unit more frequently following vacuum extraction than following caesarean section (P=0.048) (Table 4). Admissions to the neonatology unit for longer than 2 days were comparable between the groups (P=0.737), indicating that the "extra admissions" after vacuum extraction were usually for a short period. Severe neonatal trauma was infrequent and occurred after six vacuum extractions versus three caesarean sections (Table S8).

At 6-month follow-up, two (out of six) infants that had experienced severe trauma after vacuum extraction had died, whereas four had developed normally (three according to examination during follow-up visit using the scoring chart of Van Wiechen[22] and one (who had dislocation of a leg) according to maternal report by telephone) (Table S8). After caesarean section, one (out of three) infant had died, one was lost to follow-up, and one showed developmental anomalies suggestive of brain damage (Table S8). Among the 74 perinatal deaths that occurred during admission (regardless of mode of birth), 68 (91.9%) had birth asphyxia as the only identifiable cause of death (Table S9).

DBI data are outlined in Table 4. The median DBIs were 25 minutes for successful vacuum extraction; 97 minutes for failed vacuum extraction; and 144 minutes for second-stage caesarean section. During the DBI, 3 (0.9%) fetal deaths occurred in the vacuum extraction group compared with 18 (4.4%) in the caesarean section group (OR 0.19, 95%CI 0.06–0.65; P=0.003). The aOR was 0.24 (95%CI 0.07–0.84; P=0.025) (Table S10). Neonatal and infant follow-up rates were 82% after vacuum extraction and 89% after caesarean section. The rates at six months were 79% and 83%, respectively (Figure S2).

After six months, 39 of 347 (11.2%) infants in the vacuum extraction group and 51 of 410 (12.4%) infants in the caesarean section group had died; the OR was 0.89 (95%CI 0.57–1.39). However, some deaths could have been missed owing to loss of participants to follow-up. At six-month follow-up, 131 infants in the vacuum extraction group and 107 infants in the caesarean section group were examined. In each group, one infant showed developmental anomalies suggestive of brain damage. Tests for HIV-infection were recorded for 14 infants among the mothers with HIV who had attended the six-month follow-up consultation; 10 in the vacuum extraction group and four in the caesarean section group. All of these infants had negative HIV polymerase chain reaction test results at six weeks after birth. The mothers of these infants had received antiretroviral therapy during pregnancy.

Of the 140 study participants with one or more previous caesarean sections, 65 (46.4%) were admitted to hospital during the second stage of labour. Of the 33 women with two or more previous caesarean sections, 23 (69.7%) were in the second stage of labour on admission; of these patients, two gave birth by vacuum extraction and 21 underwent caesarean section. Of the 358 women who underwent vacuum extraction, 79 (22.1%) had been expected to undergo second-stage caesarean section; however, while waiting for theatre space, vacuum extraction was performed instead. Among these 79 women, 1 (1.3%) experienced a severe maternal outcome (uterine rupture) and vacuum extraction was successful among 73 (92.4%). Among 76 viable fetuses, 6 (7.9%) neonatal deaths occurred; no other severe perinatal complications were recorded among these participants. Maternal and perinatal outcomes among women who had undergone vacuum extraction after initially being scheduled for second-stage caesarean section were comparable to those of the vacuum extraction group as a whole.

Discussion

The present study found fewer maternal complications after vacuum extraction than after second-stage caesarean section, whereas perinatal outcomes were comparable for the two groups. Severe neonatal trauma and brain damage were infrequent regardless of the mode of birth. The risk of severe maternal complications -including death- during or after second-stage caesarean section was one per 24 women.

The present findings from Uganda were consistent with those from high-income countries, indicating that vacuum extraction is a safe intervention and that second-stage caesarean section carries an increased risk of maternal adverse events.[3,5,12] Indeed, one study found maternal and neonatal mortality to be higher following caesarean section compared with vaginal birth, especially in African countries.[24]

The present study found no maternal deaths after vacuum extraction but five after second-stage caesarean section. Although this observation did not reach statistical significance, it is suggested here that this is highly relevant and probably not random. Anaesthetic adverse events played an important role in this study (Table S4). All five women who died were suspected to have had hypoxia following complete spinal block, some in addition to other adverse events (sepsis, PPH). These maternal deaths following complete spinal block show that improvement in the quality of anaesthetic care is needed and that preventing unnecessary surgery is of utmost importance.[14]

A strength of the present study was the setting; namely, the largest teaching hospital in Uganda, which records a high number of births each year. Almost all eligible women were included, thereby minimising selection bias. The present findings could be generalised to many hospitals among LMIC, where access to safe surgery, anaesthesia, and blood for transfusion is limited, and infection rates are high. The duration of follow-up added value

to the present study by showing that almost all infants that attended the six-months postnatal consultation had developed normally, including those with initial severe neonatal trauma.

A potential limitation of the present study was the observational design; however, a randomised trial would have been unethical owing to the exposure of many more participants to the increased risks of surgery and a lengthened waiting time, with increased risk of birth asphyxia and adverse maternal outcomes.[6,24] Consequently, the current results must be interpreted with caution. For example, the group of women who underwent second-stage caesarean section could have had high risk profiles. Previous caesarean section, fetal weight greater than 4000g, and being in the second stage of labour at hospital admission were all risk factors for undergoing caesarean section and potential risk factors for an unfavourable outcome. Multivariate regression models were therefore constructed to adjust for potential confounders. Mode of birth was an independent risk factor for severe maternal outcomes and fetal death during DBI in all models.

The rate of women who experienced successful vacuum extractions while waiting for caesarean section was high. The rate of second-stage caesarean section for term singletons in vertex presentation was 3.3% of all births at the study site and this is high compared with 1.0% in other studies.[12,25] The vacuum extraction rate at the study site (2.8%) was low compared with the literature.[12,25,26] Consequently, it is suggested that many women in the second-stage caesarean section group would probably have qualified for vacuum extraction and that it was not only women with a higher risk profile who underwent caesarean section.

Although no data were missing for the primary outcome measures, incomplete documentation was a limitation of the present study. This deficit could have led to information bias. The fact that a considerable number of follow-up contacts occurred by telephone could have caused selection bias, in particular regarding HIV-transmission as this aspect was not addressed in the telephone interviews. However, the HIV-related outcome indicated that vacuum extraction among women with HIV was safe, particularly for those receiving antiretroviral therapy. The present study was underpowered to draw generalisable conclusions about perinatal mortality owing to the sample size calculation being based on groups with a large difference in perinatal mortality.

In the present study, nearly half of the women with a previous caesarean section arrived at the hospital during the second stage of labour. This observation suggests that many women with scarred uteri attempted to give birth outside hospitals. Birth asphyxia, rather than trauma, was the main cause of perinatal mortality. This finding calls for action to improve the quality of monitoring during labour, to prevent birth asphyxia. In all, 33 women had both IUFD and second-stage caesarean section. The occurence of IUFD had been diagnosed before caesarean section was planned among 15 women. One of these

15 women died and two sustained uterine rupture during DBI. A timely vacuum extraction or destructive operation could possibly have prevented these adverse outcomes.

In conclusion, it is of utmost importance that unnecessary second-stage caesarean section is prevented whenever possible, and particularly in areas where the risks associated with caesarean section are high. Reintroduction of vacuum extraction is an important strategy to limit unnecessary caesarean sections, reduce DBI, and prevent maternal and perinatal mortality and morbidity.

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Supporting information

Additional supporting information can be found below (S4 and S8) and online through the original open access publication: Nolens B, Namiiro F, Lule J, Van den Akker T, Van Roosmalen J, Byamugisha J. Prospective cohort study comparing outcomes of vacuum extraction and second-stage cesarean delivery at a Ugandan tertiary referral hospital. Int J Gynaecol Obstet 2018; 142: 28–36.

Figure S1 | Flowchart of maternal follow-up.
Figure S2 | Flowchart of perinatal, neonatal and infant follow-up.
Table S1 | Definitions of the maternal and perinatal outcome measures and indications for intervention.
Table S2 | Sample size calculations.
Table S3 | Baseline characteristics with missing data specified.
Table S4 | Suspected causes of maternal death.
Table S5 | Regression analysis for severe maternal outcomes.
Table S6 | Regression analysis for perinatal death.
Table S7 | Regression analysis for severe perinatal outcomes.
Table S8 | Severe neonatal trauma and outcomes at six months after birth.
Table S9 | Causes of perinatal, neonatal, or infant death.
Table S10 | Regression analysis for fetal death in decision-to-birth interval (DBI).
File S1 | Questionnaires used at inclusion and during follow-up

Table S4 | Suspected causes of maternal death.

1	Cardiac arrest during caesarean section, suspected from hypoxia caused by complete spinal block. Successful resuscitation but died eight days after birth on intensive care unit from respiratory insufficiency.
2	Cardiac arrest during caesarean section. Severe (intrauterine) infection or complete spinal block suggested as cause. Resuscitation failed. Died during caesarean section.
3	Breathing difficulties and convulsions during caesarean section, suspected from hypoxia caused by complete spinal block. Had normal blood pressure before operation. Unconscious after caesarean section. Needed intensive care unit admission for respiratory insufficiency, but no bed available. Died two days after birth from respiratory insufficiency and suspected hypoxic brain damage.
4	Cardiac arrest and convulsions during caesarean section, suspected from hypoxia caused by complete spinal block. Successful resuscitation. Was initially well but became respiratory insufficient after caesarean section from suspected aspiration pneumonia. Needed intensive care unit admission for respiratory insufficiency but no bed available. Died 19 hours after birth.
5	Cardiac arrest during caesarean section, suspected from hypoxia caused by complete spinal block. Successful resuscitation. Severe vaginal haemorrhage directly after caesarean section and relaparotomy. Unconscious after operation. Two times cardiac arrest after operation and died five hours after birth at intensive care unit.

Table S8 | Severe neonatal trauma and outcome at six months after birth.

	Mode of birth	Indication	Trauma	AS[a]	NU[b]	Other diagnosis or treatment	Outcome
1	Failed vacuum, forceps	Prolonged labour	Suspected ICH	6-8	1d	Anaemia, blood transfusion	END day 1
2	Vacuum extraction	Borderline pelvis	Head injury	7-9	1d	Suspected birth asphyxia	END day 1
3	Failed vacuum, CS	Prolonged labour	IVH (USS), cephalo-haematoma	7-8	8d	Brain oedema, anaemia, blood transfusion	Normal development at six months follow-up visit
4	Failed vacuum, CS	Fetal distress	Dislocation of leg	x-6	2d	From reversed breech extraction at CS	Normal development at six months according to mother on phone
5	Vacuum extraction	Maternal exhaustion	Suspected ICH	6-9	6d	HIE grade 2, Hb 14g/dl, small scalp laceration, phenobarbitone treatment given	Normal development at six months follow-up visit
6	Vacuum extraction	Prolonged labour	Subgaleal haemorrhage	5-6	4d	Jaundice, phototherapy, CPAP (Hb 16g/dl)	Normal development at six months follow-up visit
7	Second-stage CS	Prolonged labour	Suspected ICH	4-5	5d	Severe birth asphyxia, HIE grade 3, anaemia	END day 5, MD day 2[c]
8	Second-stage CS	Prolonged labour	Facial palsy	1-3	17d	Severe birth asphyxia, NEC, HIE grade 2, CPAP	Underweight but normal development at six weeks, loss to follow-up at six months.
9	Second-stage CS	Prolonged labour	IVH (USS)	6-8	8d	HIE grade 3, convulsions, phototherapy, phenobarbitone treatment given	Abnormal development, suggestive of brain damage at six months follow-up visit

AS, Apgar score; NU, neonatology unit; ICH, intracerebral haemorrhage; END, early neonatal death (in first week after birth); CS, caesarean section; IVH, intraventricular haemorrhage; USS, on ultrasound scan; HIE, hypoxic-ischemic encephalopathy; CPAP, continuous positive airway pressure; Hb, haemoglobin; MD, maternal death; NEC, necrotising enterocolitis.

[a] *Apgar score at 1 and 5 minutes.*

[b] *Days on neonatology unit.*

[c] *Maternal death due to anaesthetic complication (complete spinal block) and respiratory insufficiency.*

CHAPTER 5

Birthing experience and quality of life after vacuum extraction and second-stage caesarean section: a prospective cohort study in Uganda

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Abstract

Objective

To assess perceptions of women undergoing vacuum extraction or second-stage caesarean section in a tertiary referral hospital in sub-Saharan Africa.

Methods

Prospective cohort study, with six months follow-up, of women who gave birth to a term singleton in cephalic presentation by vacuum extraction (n=289) or second-stage caesarean section (n=357) between 25th of November 2014 and 8th of July 2015, in Mulago hospital, Uganda. Excluded were women who had failed vacuum extraction, severe birth complications and those whose neonates had died. Outcome measures were birthing experience satisfaction, physical component summary (PCS) and mental component summary (MCS) of the SF-12 quality-of-life questionnaire, pain scores and dyspareunia.

Results

One day after vacuum extraction, 63.7% (181/284) of women were feeling well versus 48.1% (167/347) after caesarean section (OR 1.89; 95%CI 1.37–2.61) and mean pain sores were 2.70 versus 3.87 (P<0.001). In both groups, more than 90% of women were satisfied with their birthing experience. At six weeks, in vacuum extraction versus caesarean section, mean pain sores were 0.40 versus 0.89 (P<0.001); mean PCS was 48.67 versus 44.03 (P<0.001); mean MCS was 52.80 versus 51.23 (P=0.203); 40% (70/175) versus 28.3% (70/247) of women had resumed sexual intercourse (OR 1.69; 95%CI 1.12–2.54) and 21.4% (15/70) versus 28.6% (20/70) had dyspareunia (OR 0.68; 95%CI 0.32–1.47). No differences were found at six months after birth.

Conclusions

One day and six weeks after birth, outcomes were better in women who had vacuum extraction. At six months, outcomes were similar. To promote quick recovery, vacuum extraction should be the first intervention considered in the second stage of labour.

Introduction

Increased use of vacuum extraction or other modes of assisted vaginal birth could potentially prevent many maternal deaths caused by complications of prolonged labour or unsafe caesarean section and a large proportion of stillbirths and neonatal deaths in sub-Saharan Africa.[1-8]

Indications for vacuum extraction are prolonged second stage of labour, fetal distress, maternal exhaustion or the need to avoid expulsive efforts in maternal conditions such as severe anaemia or heart failure.[9-12] Use of vacuum and forceps-assisted vaginal birth varies from more than 10% in northern Europe to less than 1% in many places in sub-Saharan Africa.[2,13] In many sub-Saharan African countries, surgery carries higher risks due to unsafe anaesthesia and unavailability of blood for transfusion.[6,14,15] A uterine scar may lead to uterine rupture and abnormal or invasive placentation in a subsequent pregnancy.[16] Women with a uterine scar may not be aware of these risks and try to give birth at home.[6] Recent publications suggest that caesarean section in the second stage of labour increases the risk of spontaneous preterm birth in the next pregnancy.[17,18] Therefore, particularly in these settings, preventing caesarean section is important: this view is supported by WHO and other international reproductive health and maternity care leaders.[19-21] Thus, vacuum extraction, the simplest method of assisted vaginal birth, was re-introduced in the main teaching hospital in Uganda in 2012.[9] After re-introduction, clinical maternal and perinatal outcome improved significantly with considerably fewer intrapartum stillbirths and uterine ruptures.[3]

In addition to clinical outcomes, birthing experience, pain, ability to work and pain-free sexual intercourse are also very important birth outcomes, particularly from a woman's perspective (and influencing her decision on where to give birth the next time). These outcomes, in women who had assisted vaginal births, have only been studied in high-income settings.[22-29]

The aim of this study was to assess how vacuum extraction was experienced by women after its re-introduction in a tertiary referral hospital in sub-Saharan Africa, using women-centred outcomes such as birthing experience satisfaction; pain one day after birth; and quality of life, pain and dyspareunia six weeks and six months after birth. Outcome is compared with outcome after second-stage caesarean section, which is another intervention in case of delay or failure to progress in the second stage of labour.

This study was part of a larger study that also investigated clinical maternal and perinatal outcome after vacuum extraction and second-stage caesarean section.[6] Vacuum extraction (including failed vacuum extraction and subsequent caesarean section) had better maternal outcomes than caesarean section and equivalent perinatal outcomes. The odds ratio for severe maternal complications after vacuum extraction versus second-stage caesarean section was 0.24 (95%CI 0.07–0.84). The odds ratio for perinatal death was 0.83 (95%CI 0.49-1.41).

Methods

Participants

This was an observational, prospective cohort study, comparing women-centred outcomes after vacuum extraction and second-stage caesarean section. The study was conducted in the main labour ward of Mulago national referral hospital, Kampala, Uganda. The inclusion period was from 25th of November 2014 to 8th of July 2015, and women were interviewed one day, six weeks and six months after birth. Included were women who gave birth to a term singleton in cephalic presentation by vacuum extraction or second-stage caesarean section and who consented to being included. Excluded were women who had a failed vacuum extraction followed by caesarean section due to the inability to ascribe outcomes to either procedure, and women who had severe complications (defined as maternal death, uterine rupture, re-laparotomy, obstetric fistula and eclampsia) or perinatal death that had occurred before the moment of inclusion at one day after birth (Figure 1). Women whose neonates had died before six-week or six-month follow-up were excluded from analysis of outcome at that time-point. Clinical outcome of women and neonates excluded here is described elsewhere.[6] Vacuum extraction was compared to second-stage caesarean section as the alternative treatment option. Forceps was hardly used in this hospital (fewer than five times during the study period).

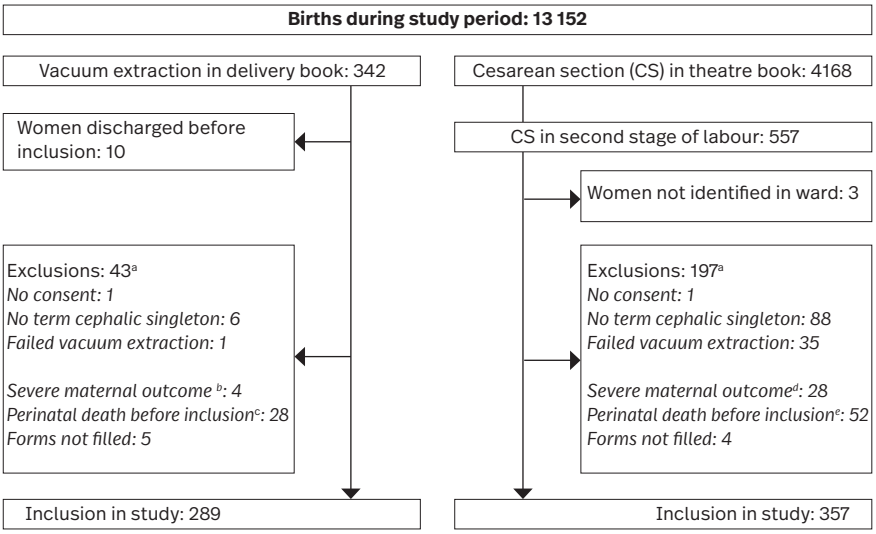

Figure 1 | Inclusion process

CS, ceasarean section; IUFD, intrauterine fetal death

[a] *More than one exclusion criterion could apply*

[b] *Ruptured uterus and re-laparotomy (2), eclampsia (2)*

[c] *IUFD on admission (10), IUFD in waiting time or during vacuum extraction (3), neonatal death on day one (15)*

[d] *Maternal death (5), ruptured uterus (13: 5 on admission, 8 in waiting time for CS), re-laparotomy (5), eclampsia (4), obstetric fistula (4)*

[e] *IUFD on admission (15), IUFD in waiting time or during CS (18), neonatal death on day one (19)*

Setting

Mulago hospital is the national referral and main teaching hospital of Uganda. It is a government hospital with 2700 beds and more than 31 000 births annually, with the capital Kampala and surroundings as catchment area. Maternity services are free of charge. Vacuum extraction was by Kiwi vacuum extractor (Clinical Innovations, South Murray, Utah, US) or Bird and silicone cups with hand and foot pumps. Regional analgesia during labour or assisted vaginal birth was not used.

Episiotomy for vacuum extraction was not routinely performed. If performed, local lidocaine infiltration was used, if available. Caesarean section was by lower abdominal transverse incision (Pfannenstiel, Joel-Cohen or modification) or subumbilical midline incision. Caesarean section was most often performed under spinal anaesthesia. Post-vacuum analgesia was by paracetamol and NSAIDs. Post-caesarean section analgesia was by pethidine, tramadol, paracetamol and NSAID's, when available. Women were normally discharged at the first day after vacuum extraction or the third day after caesarean section.

Inclusion process

On the first day after birth, women who had given birth by vacuum extraction were identified from the hospital's birth register by a member of the research team. Women who had had a caesarean section were identified from the operating theatre register. To identify those women who had been in the second stage of labour during caesarean section, their medical records were examined. Women who fulfilled the inclusion criteria were asked to participate in the study on the first day after birth. After obtaining written informed consent, the woman was interviewed by a trained research assistant in either English or Luganda, which are the most commonly spoken languages in Kampala. Baseline characteristics were extracted from the medical records.

Birthing experience interview

The birthing experience assessment consisted of a short interview, based on four questions, each with four fixed response options. Questions addressed how women had experienced giving birth (Appendix S1). A numeric pain rating scale (NPRS, scale 0–10) was filled.[30]

Follow-up

Postnatal consultations took place six weeks and six months after birth. During these visits, women were interviewed using structured questionnaires (Appendix S2). The questionnaires consisted of the SF-12v1 questions, pain scores (NPRS 0–10) and a question concerning dyspareunia.[30-32] Women who missed postnatal consultations were

interviewed over the phone, using the same questionnaire, from which SF-12 questions were excluded. Therefore, groups with analysis of SF12-questions are smaller.

SF-12 questionnaire

The Short Form 12 (SF-12) questionnaire contains 12 items and is based on the original SF-36 Health Survey.[30,31] It is a norm-based generic measure to assess health-related quality of life, widely used and psychometrically robust.[31] SF-12 measures general physical and mental health status and is not specific for age, disease or health condition. It assesses eight physical and mental health dimensions: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional health problems and mental health. From these eight dimensions, a physical component summary (PCS) and mental component summary (MCS) are calculated. The tool is designed such that mean PCS and MCS (in the US population) are 50 with a standard deviation (SD) of 10. High scores indicate better subjective health functioning (PCS) and emotional wellbeing (MCS). The SF-12 questionnaire is used worldwide and has been translated in more than 100 languages.[31,33]

Outcome measures

Outcome measures were birthing experience satisfaction (based on the answers from the interview at the first day after birth), quality of life (mean PCS and MCS scores from the SF-12 questionnaire and answers per question at six weeks and six months after birth); pain during the procedure and at one day, six weeks and six months after birth (using mean and stratified pain scores; 0: no pain; 1–4: mild pain; 5–7: moderate pain; 8–10: severe pain); percentage of women who reported they had resumed sexual intercourse at six weeks and six months, and percentage of women with dyspareunia at these timepoints.

Analysis

Baseline characteristics are reported in counts and percentages with P-values comparing vacuum extraction to second-stage caesarean section. Outcome parameters are reported as means with standard deviations (SD) and P-values or counts with percentages and odds ratios (OR) with 95% confidence intervals (CI). P-values were calculated with two-sided Chi-square (or two-sided Fisher's exact test where total events were <10). Differences in means between groups were calculated using independent t-tests. Data were entered in Microsoft Excel, and SPSS version 24 was used for data analysis.

Sample size

A convenience sample was used, as this study was part of a larger study including clinical outcome after vacuum extraction and second-stage caesarean section.[6] The sample size for that study was based on expected differences in perinatal deaths per mode of birth.

Handling of missing data

Percentages were calculated by dividing the number of women with a certain characteristic or outcome parameter by the number of women with a valid response for that characteristic or outcome parameter at each timepoint. Therefore, the denominator in the fractions may differ slightly per characteristic or outcome parameter. In the tables, the total number of participating women and the number of women with a valid response per characteristic or outcome parameter are shown. The number of women with missing data can be calculated by subtracting the number with valid responses from the total number.

Analysis was performed for included women at one day, six weeks and six months after birth. Groups were not exactly the same at six weeks and six months. Some women came for either the six-week or the six-month consultation, but not for both.

Ethical clearance

Ethical permission to conduct this study was obtained from the Mulago hospital Research and Ethics Committee (refnr: MREC 489) and the Uganda National Council for Science and Technology (refnr: HS1752).

Results

During the study period, 289 women were enrolled after vacuum extraction and 357 women after second-stage caesarean section (Figure 1). More women who had given birth by vacuum extraction were nulliparous or had their neonates admitted to the neonatology unit, but these findings did not reach statistical significance (Table 1).

After six weeks, losses to follow-up were 29.8% (86/289) for vacuum extraction and 23.2% (83/357) for caesarean section. Thirteen women who had given birth by vacuum extraction, and ten women who had had caesarean section were excluded because the neonate had died in the time elapsed between one day and six weeks postpartum. One woman who had had vacuum extraction was excluded because the neonate was found to have a serious congenital syndrome and died after five months. After six months, losses to follow-up were 31.5% (91/289) for vacuum extraction and 28.3% (101/357) for caesarean section. In both groups, one woman was excluded because the neonate had died.

Table 1 | Baseline characteristics

	Vacuum extraction (289)		Second-stage caesarean section (357)		
	n/N [a]	(%)	n/N [a]	(%)	*P*-value
Pre-labour characteristics					
Nulliparous	156/283	(55.1)	173/357	(48.5)	0.094
Maternal age<20 years	65/284	(22.9)	74/356	(20.8)	0.522
Mean age	23.5 (284)	(SD 5.21)	24.0 (356)	(SD 5.21)	0.191
Education ≤ 6 years	64/284	(22.5)	89/352	(25.3)	0.420
Formally employed	111/284	(39.1)	154/352	(43.8)	0.235
HIV-positive	28/240	(11.7)	28/309	(9.1)	0.317
Labour and postpartum characteristics					
More than three hours in second stage	78/287	(27.2)	118/357	(33.1)	0.107
5-min Apgar score below seven	18/286	(6.3)	21/354	(5.9)	0.849
Neonate in neonatology unit at time of interview	59/289	(20.4)	53/357	(14.8)	0.063
Perineal status					
Perineal status known	262/289	(90.7)	NA	NA	NA
- intact	89/262	(34.0)	NA	NA	NA
- episiotomy	94/262	(35.9)	NA	NA	NA
- 1st or 2nd degree tear	78/262	(29.8)	NA	NA	NA
- 3rd degree tear	2/262	(0.8)	NA	NA	NA
Type of incision					
Incision known	NA	NA	345/357	(96.7)	NA
- Pfannenstiel	NA	NA	308/345	(89.3)	NA
- Midline	NA	NA	37/345	(10.7)	NA
Anaesthesia					
Anaesthesia known	NA	NA	349/357	(97.8)	NA
- Spinal	NA	NA	340/349	(97.4)	NA
- General	NA	NA	9/349	(2.6)	NA
Exclusive breastfeeding at six weeks					
Kind of feeding known	186/189	(98.4)	256/264	(97.0)	0.325
Exclusive breastfeeding	166/186	(89.2)	231/256	(90.2)	0.735

SD, standard deviation; NA, not applicable
[a] In n/N, n is the number of women with this characteristic and N is the number of women with known data for this variable.

Birthing experience

One day after birth, women were feeling significantly better if they had given birth by vacuum extraction than by caesarean section (Table 2). After either intervention, more than 90% of women were satisfied with their birthing experience, although more than 50% had been very concerned about their baby. Compared to caesarean section, more women reportedly had been 'very scared' during vacuum extraction (Table 2).

Table 2 | Birthing experience

	Vacuum extraction (289)		Second-stage caesarean section (357)		OR	(95%CI)
Are you/were you:	n/N [a]	(%)	n/N [a]	(%)		
Feeling well [b]	181/284	(63.7)	167/347	(48.1)	1.89	(1.37-2.61)
Satisfied about birth [c]	257/282	(91.1)	332/355	(93.5)	0.71	(0.40-1.28)
Very scared during birth [d]	46/287	(16.0)	25/357	(7.0)	2.54	(1.52-4.24)
Very concerned about baby [e]	169/287	(58.9)	185/357	(51.8)	1.33	(0.97-1.82)

OR, odds ratio; CI, confidence interval
[a] In n/N, n is the number of women with this characteristic and N is the number of women with valid responses for this variable.[b] "very good" or "normal"; [c] "very much" or "yes"; [d] "very scared" or "afraid of dying"; [e] "very concerned" or "afraid the baby would die" (Answers from questionnaire, Appendix S1)

Pain

Women experienced more pain during vacuum extraction than during caesarean section, but they reported less pain in the first 24 hours after birth (Table 3). One day after vacuum extraction 91.6% (263/287) of women had no pain or mild pain (NPRS 0–4), versus 62.6% (223/356) after caesarean section (OR 6.54; 95%CI 4.09–10.46). Women experienced more pain at one day after subumbilical midline incision than lower transverse incision: mean pain score 4.41 versus 3.78 (P=0.038). Perineal status (intact, episiotomy, tear) had no influence on pain scores during the procedure, or one day after birth in women who gave birth vaginally.

At six weeks after birth, women who had given birth by vacuum extraction had lower mean pain scores than women who had given birth by caesarean section (Table 3). At six-week follow-up, no pain (NPRS 0) was reported by 76.2% (144/189) of women after vacuum extraction, compared to 55.5% (146/264) after caesarean section (OR 2.56; 95%CI 1.70–3.88). Of women who had given birth by vacuum extraction, 3.4% (4/119) had had 'severe' or 'very severe' pain in the four weeks prior to the follow-up visit, versus 17.1% (21/123) after caesarean section (OR 0.17; 95%CI 0.06–0.51) and for 50% (56/112) versus 73.6% (89/121) pain had interfered with daily activities ('normal work, including both work outside the home and house- work')(OR 0.36; 95%CI 0.21–0.62) (Appendix S3).

Table 3 | Pain scores

	Mean	SD	Mean	SD	P-value
One day after birth	**Vacuum extraction (289)[a]**		**Second-stage caesarean section (357)[a]**		
Pain during intervention	5.35 (287)[b]	3.79	0.35 (357)[b]	0.93	<0.001
Pain first 24 hours	2.70 (287)[b]	1.34	3.87 (356)[b]	1.75	<0.001
Six weeks after birth	**Vacuum extraction (189)[a]**		**Second-stage caesarean section (264)[a]**		
Pain abdominal/vaginal	0.40 (189)[b]	0.84	0.89 (262)[b]	1.21	<0.001
Six months after birth	**Vacuum extraction (186)[a]**		**Second-stage caesarean section (245)[a]**		
Pain abdominal/vaginal	0.28 (185)[b]	1.06	0.27 (244)[b]	0.72	0.952

SD, Standard deviation;
[a] Number of women that was interviewed per time point; [b] Number of valid responses

Six months after birth, there was no significant difference in pain scores between both groups. Mean pain scores were 0.28 and 0.27 after vacuum extraction and caesarean section, respectively (Table 3). After vacuum extraction, 89.2% (165/185) of women reported no pain at all versus 85.2% (208/244) after caesarean section. In 8.8% (10/113) of women after vacuum extraction, pain had interfered 'moderately' to 'extremely' with daily activities in the four weeks prior to the consultation, versus 10.6% (11/104) in women after caesarean section (difference not statistically significant).

Quality of life

During the six-week follow-up visit, the SF-12 questionnaire was completed by 112 women after vacuum extraction and 121 women after caesarean section. At the six-month follow-up visit, the questionnaire was completed by 113 and 104 women, respectively.

Six weeks after birth the physical component summary (PCS), measured with the SF-12 questionnaire, was better after vacuum extraction than after caesarean section (Table 4). The mental component summary (MCS) was comparably good. After six months, PCS and MCS had improved and were comparable between both groups.

At six weeks, all 12 questions of the SF-12 questionnaire had better scores after vacuum extraction, seven of them statistically significant (Appendix S3). Six weeks after vacuum extraction, fewer women reported that they 'accomplished less work than they would like' as a result of their physical health, compared to after caesarean section (31/112 (27.8%) versus 57/121 (47.1%), OR 0.43; 95%CI 0.25–0.74). Similarly, fewer women reported that they 'accomplished less work than they would like' as a result of emotional problems after vacuum extraction compared to after caesarean section (16/112 (14.3%) versus 32/121 (26.4%), OR 0.46; 96% CI 0.24-0.90) (Appendix S3).

Table 4 | Quality of life

	Mean	SD	Mean	SD	P-value
Six weeks after birth	**Vacuum extraction (112)**		**Second-stage caesarean section (121)**		
PCS	48.67	7.31	44.03	9.15	<0.001
MCS	52.80	8.94	51.23	9.78	0.203
Six months after birth	**Vacuum extraction (113)**		**Second-stage caesarean section (104)**		
PCS	52.42	6.52	52.43	6.33	0.993
MCS	54.41	7.28	52.99	8.02	0.173

SD, Standard deviation; PCS, physical component summary; MCS, mental component summary

Table 5 | Dyspareunia

	n	(%)	n	(%)	OR	(95%CI)	P-value
Sexual activity at six weeks after birth	**Vacuum extraction (189)**		**Second-stage caesarean section (264)**				
Resumed	70/175	(40.0)	70/247	(28.3)	1.69	(1.12-2.54)	0.012
Painful when resumed	15/70	(21.4)	20/70	(28.6)	0.68	(0.32-1.47)	0.329
No comment, excluded from analysis	14/189	(7.4)	17/264	(6.4)			0.687
Sexual activity at six months after birth	**Vacuum extraction (186)**		**Second-stage caesarean section (245)**				
Resumed	177/185	(95.7)	229/242	(94.6)	1.26	(0.51-3.10)	0.620
Painful when resumed	16/177	(9.0)	12/229	(5.2)	1.80	(0.83-3.90)	0.134
No comment, excluded from analysis	1/186	(0.5)	3/245	(1.2)			0.637

OR, odds ratio; CI, confidence interval

Dyspareunia

At six weeks follow-up, more women reported to have resumed sexual intercourse after vacuum extraction than after caesarean section (Table 5). At six months, almost all women had resumed sexual intercourse in both groups. Dyspareunia decreased over time and was comparably low for the groups at six weeks and six months after birth.

Discussion

Main findings

This study shows that women-centred outcomes, such as pain scores, quality of life and absence of dyspareunia, were better in the first six weeks postpartum in women who had given birth by vacuum extraction than in women who had given birth by second-stage caesarean section. Six months after birth outcomes were similar. More than ninety percent of women who had given birth by vacuum extraction were satisfied about their birthing experience.

Other findings

Similar to women after second-stage caesarean section, more than half of the women after vacuum extraction reported to have been 'very concerned' about their baby during the intervention. Information about the procedure and its safety for mother and neonate to women undergoing vacuum extraction is needed to prevent anxiety and concern. Debriefing after birth might reduce fear in future pregnancies.[22]

Understandably, pain scores during vacuum extraction were higher than during caesarean section, as spinal or general anaesthesia were used during caesarean section. Pain scores during vacuum extraction in our study are comparable to pain scores during spontaneous vaginal birth reported in the literature.[34] Pain was, however, significantly worse after caesarean section at one day and six weeks after birth. The latter was also found in a study in the US, where, in the first two months after birth 68% of women experienced significant pain after assisted vaginal birth and 79% after caesarean section. Six months after birth, these percentages had decreased to 2% after assisted vaginal birth and 18% after caesarean section.[23]

Although mean PCS scores were better after vacuum extraction, we did not find differences in mean MCS scores of the SF-12 quality-of-life questionnaire per mode of birth. These findings were similar in a Norwegian study.[24] In a study from the UK, however, women who gave birth by forceps or unplanned caesarean section had a higher risk of reduced postnatal health and wellbeing (including increased risk of post traumatic stress syndrome following forceps birth), while outcomes after vacuum extraction were comparable to those after spontaneous birth.[25] A study from Sweden reported better quality of life five years after assisted vaginal birth compared to emergency caesarean section.[26]

At six weeks after birth, pain, body weakness and emotional problems interfered significantly less with daily activities after vacuum extraction than caesarean section (Appendix S3). This could be of particular importance in a setting where many women are self-employed and do not have a paid maternity leave, while their family is depending on their income.

Reports on dyspareunia after different modes of birth give a wide range of results. In a study from Germany, 13.9% of women had dyspareunia six months after assisted vaginal birth versus 3.4% after caesarean section.[27] In a study from Australia, 59.5% of women had dyspareunia at six months after vacuum extraction and 40.6% after emergency caesarean section. At 18 months, these percentages were 28.9% and 29.3% in that study.[28]

Another study from Australia reported that at 12 months after birth, sexual function had returned to early pregnancy levels, irrespective of mode of birth.[29]

Strengths and limitations

Strengths of this study are its prospective design and follow-up to six months after birth, use of validated questionnaires and large number of participants. Nearly all eligible women were included, preventing selection bias (Figure 1). Follow-up at one day, six weeks and six months prevented recall bias. This study is the only study known to us about this subject in sub-Saharan Africa and the only study performed just after the reintroduction of vacuum extraction in a maternity care service.

Limitations of the study were its observational design, which may have introduced bias. However, not statistically different, nulliparity or admission of the neonate to the neonatology unit were somewhat more frequent in the vacuum extraction group and this may have introduced bias. But the absence of this bias would probably have resulted in even larger differences in favour of vacuum extraction. Excluding women with a neonate in the neonatology unit at the time of birthing experience interview did not have an effect on the results. Losses to follow-up may have caused bias but these were comparable between both groups and comparable to losses to follow-up in other studies.[22,24,26-29] Recruitment from a single hospital compromises generalisability, but the situation in many resource-constrained high-volume hospitals in sub-Saharan Africa is likely to be similar.

Interpretation and implications

This study is the first study describing how vacuum extraction was experienced by women after its re-introduction in a hospital in sub-Saharan Africa. The major contribution is that it shows that aside from medical reasons to prevent caesarean section, there are several reasons in favour of vacuum extraction instead of caesarean section from the women's point of view. Main reasons are pain, quality of life and ability to perform daily activities in the first six weeks after birth.

Conclusion

Women-centred outcomes, such as pain scores and quality of life, were better in the first six weeks postpartum in women who had given birth by vacuum extraction, compared to women who had given birth by second-stage caesarean section. Six months after birth outcomes were similar. Our findings suggest that women, even if they are not acquainted with the procedure, are satisfied with their birthing experience after vacuum extraction. These findings, in combination with medical reasons, support the use of vacuum extraction as first intervention to be considered in the second stage of labour to prevent complications and promote quick recovery.

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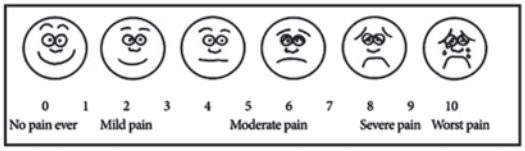
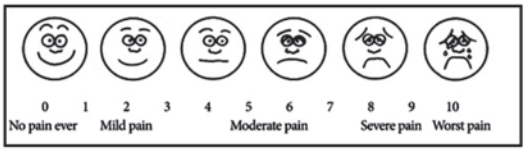
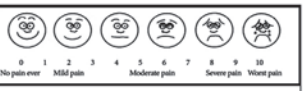
Supporting information

Additional Supporting Information can be found below and on the next pages:

Appendix S1 | Questionnaire day one

1	How are you feeling? *Owulire otya?*	very good *bulungi nnyo*	normal *nga bulijjo*	not well sibulungi	bad *bubi*
2	Are you satisfied about your birth? *Oli mumativu mu ngeri gyózaddemu?*	not at all *tewali wadde*	no *nedda*	yes *yee*	very much *nnyo ddala*
3	Were you scared during the vacuum extraction/caesarean section? *Watya nga basikayo omwana oba nga balongoosa?*	no *nedda*	a little scared *satyo nnyo*	very scared *natya nnyo*	afraid of dying *ntya okufa*
4	Were you concerned about the baby? *Wafaayo nnyo ku omwana?*	no *nedda*	a little concerned *nafaayo katono*	very concerned *nafaayo nnyo*	afraid the baby would die *natya nti omwana ayinza okufa*
5	Did you experience pain during the vacuum extraction/caesarean section? Indicate how much, circle the number: *Wawulira obulumi nga basikayo oba bakulongoosa?*  				
6	Did you experience pain after the vacuum extraction/caesarean section (first 24-hours)? *Wawulira obulumi oluvannyuma lw'okusikayo omwana, oba nga bamaze okulongoosamu omwana?*  				

Appendix S2 | Questionnaire six weeks and six months

							
					0 No pain ever 1 2 Mild pain 3 4 5 Moderate pain 6 7 8 Severe pain 9 10 Worst pain		
1	**Do you still have abdominal/vaginal pain?**	No	Yes				
2	**Is having sexual intercourse painful?**	No	Yes		Not resumed yet		
3	**How much pain have you had during the past four weeks?**	None	Very mild	Mild	Moderate	Severe	Very severe
SF1	**In general, would you say your health is:**	Excellent		Very Good	Good	Fair	Poor
The following items are about activities you might do during a typical day.							
SF2	**Does your health now limit you in moderate activities, such as moving a table (pushing a vacuum cleaner, bowling or playing golf)?**	Yes, limited a lot		Yes, limited a little		No, not limited at all	
SF3	**Does your health now limit you in climbing several flights of stairs?**	Yes, limited a lot		Yes, limited a little		No, not limited at all	
During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?							
SF4	**Accomplished less than you would like**	No	Yes				
SF5	**Were limited in the kind of work or other activities**	No	Yes				
During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?							
SF6	**Accomplished less than you would like**	No	Yes				
SF7	**Didn't do work as carefully as usual**	No	Yes				
SF8	**During the past four weeks, how much did pain interfere with your normal work (including both work outside the house and housework)?**	Not at all		A little bit	Moderately	Quite a bit	Extremely
These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the answer that comes closest to the way you have been feeling. How much time during the past four weeks:							
SF9	**Have you felt calm and peaceful?**	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
SF10	**Did you have a lot of energy?**	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
SF11	**Have you felt downhearted and blue?**	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
SF12	**During the past four weeks, how much of the time has your physical heath or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
If follow-up was on phone, only the first two questions were asked							

Appendix S3 | SF-12 interview at six weeks after birth, outcome per question

	Vacuum extraction (112)		Second-stage caesarean section (121)			P-value
	n	(%)	n	(%)	OR[a] (95%CI)	
1. In general, would you say your health is:						
Excellent (1)	21	(18.8)	11	(9.1)		
Very good (2)	44	(39.3)	36	(29.8)		
Good (3)	37	(33.0)	63	(52.1)		
Fair (4)	10	(8.9)	10	(8.3)		
Poor (5)	0	(0)	1	(0.8)		
Mean (SD)	2.32	(0.88)	2.62	(0.80)		0.007
The following items are about activities you might do during a typical day.						
2. Does your health now limit you in moderate activities, such as moving a table (pushing a vacuum cleaner, bowling or playing golf)?						
Yes, limited a lot (1)	6	(5.4)	17	(14.0)		
Yes, limited a little (2)	19	(17.0)	40	(33.1)		
No, not limited at all (3)	87	(77.7)	64	(52.9)		
Mean (SD)	2.72	(0.56)	2.39	(0.72)		<0.001
3. Does your health now limit you in climbing several flights of stairs?						
Yes, limited a lot (1)	6	(5.4)	8	(6.6)		
Yes, limited a little (2)	22	(19.6)	23	(19.0)		
No, not limited at all (3)	84	(75.0)	90	(74.4)		
Mean (SD)	2.70	(0.57)	2.68	(0.60)		0.806
During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?						
4. Accomplished less than you would like						
No (1)	81	(72.3)	64	(52.9)		
Yes (2)	31	(27.7)	57	(47.1)	0.43 (0.25-0.74)	
Mean (SD)	1.28	(0.45)	1.47	(0.50)		0.002
5. Were limited in the kind of work or other activities						
No (1)	80	(71.4)	62	(51.2)		
Yes (2)	32	(28.6)	59	(48.8)		
Mean (SD)	1.29	(0.45)	1.49	(0.50)		0.002
During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?						
6. Accomplished less than you would like						
No (1)	96	(85.7)	89	(73.6)		
Yes (2)	16	(14.3)	32	(26.4)	0.46 (0.24-0.90)	
Mean (SD)	1.14	(0.35)	1.26	(0.44)		0.022
7. Didn't do work as carefully as usual						
No (1)	100	(89.3)	90	(74.4)		
Yes (2)	12	(10.7)	31	(25.6)	0.35 (0.17-0.72)	
Mean (SD)	1.11	(0.31)	1.26	(0.44)		0.003

Continued on next page

Appendix S3 | continued

8. During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?						
Not at all (1)	56	(50.0)	32	(26.4)		
There was interference (a little bit to extremely)	56	(50.0)	89	(73.6)	0.36 (0.21-0.62)	
- A little bit (2)	35	(31.3)	45	(37.2)		
- Moderately (3)	14	(12.5)	23	(19.0)		
- Quite a bit (4)	7	(6.3)	14	(11.6)		
- Extremely (5)	0	(0)	7	(5.8)		
Mean (SD)	1.75	(0.91)	2.33	(1.16)		<0.001
These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the answer that comes closest to the way you have been feeling. How much time during the past four weeks:						
9. Have you felt calm and peaceful?						
All the time (1)	56	(50.0)	51	(42.1)		
Most of the time (2)	25	(22.3)	31	(25.6)		
A good bit of the time (3)	4	(3.6)	9	(7.4)		
Some of the time (4)	14	(12.5)	16	(13.2)		
A little of the time (5)	7	(6.3)	8	(6.6)		
None of the time (6)	6	(5.4)	6	(5.0)		
Mean (SD)	2.19	(1.56)	2.31	(1.53)		0.533
10. Did you have a lot of energy?						
All the time (1)	52	(46.4)	42	(34.7)		
Most of the time (2)	21	(18.8)	26	(21.5)		
A good bit of the time (3)	9	(8.0)	15	(12.4)		
Some of the time (4)	17	(15.2)	21	(17.4)		
A little of the time (5)	10	(8.9)	9	(7.4)		
None of the time (6)	3	(2.7)	8	(6.6)		
Mean (SD)	2.29	(1.52)	2.61	(1.59)		0.123
11. Have you felt downhearted and blue?						
All the time (1)	4	(3.6)	7	(5.8)		
Most of the time (2)	5	(4.5)	6	(5.0)		
A good bit of the time (3)	3	(2.7)	6	(5.0)		
Some of the time (4)	12	(10.7)	10	(8.3)		
A little of the time (5)	19	(17.0)	30	(24.8)		
None of the time (6)	69	(61.6)	62	(51.2)		
Mean (SD)	5.18	(1.34)	4.95	(1.48)		0.219
12. During the past four weeks, how much of the time has your physical heath or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?						
All the time (1)	23	(20.5)	29	(24.0)		
Most of the time (2)	9	(8.0)	5	(4.1)		
Some of the time (3)	8	(7.1)	11	(9.1)		
A little of the time (4)	17	(15.2)	29	(24.0)		
None of the time (5)	55	(49.1)	47	(38.8)		
Mean (SD)	3.64	(1.62)	3.50	(1.60)		0.487

CHAPTER 6

Women's recommendations: vacuum extraction or caesarean section for prolonged second stage of labour, a prospective cohort study in Uganda

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Abstract

Objectives

To investigate what women who have experienced vacuum extraction or second-stage caesarean section would recommend as mode of birth in case of prolonged second stage of labour.

Methods

A prospective cohort study was conducted in a tertiary referral hospital in Uganda. Between November 2014 and July 2015, women with a term singleton in vertex presentation who had undergone vacuum extraction or second-stage caesarean section were included. The first day and six months after birth women were asked what they would recommend to a friend: vacuum extraction or caesarean section and why. Outcome measures were: proportions of women choosing vacuum extraction versus caesarean section and reasons for choosing this mode of birth.

Results

The first day after birth, 293/318 (92.1%) women who had undergone vacuum extraction and 176/409 (43.0%) women who had undergone caesarean section recommended vacuum extraction. Of women who had given birth by caesarean section in a previous pregnancy and had vacuum extraction this time, 31/32 (96.9%) recommended vacuum extraction. Six months after birth findings were comparable. Less pain, shorter recovery period, avoiding surgery and the presumed relative safety of vacuum extraction to the mother were the main reasons for preferring vacuum extraction. Main reasons to opt for caesarean section were having experienced caesarean section without problems, caesarean section presumed as being safer for the neonate, caesarean section being the only option the woman was aware of, as well as the concern that vacuum extraction would fail.

Conclusion

Most women would recommend vacuum extraction over caesarean section in case of prolonged second stage of labour.

Introduction

Prolonged second stage of labour is an important cause of maternal and perinatal morbidity and mortality in low- and middle-income countries (LMIC).[1-6] Interventions aiming to end prolonged second stage of labour are assisted vaginal birth (vacuum extraction and forceps) and caesarean section.[1,7-9] Although caesarean section can be a lifesaving procedure and must be available when indicated, the operation may also cause maternal and perinatal morbidity and mortality. Performing caesarean section without strict indication is therefore a major cause of concern.[3,10,11] Assisted vaginal birth has many advantages over caesarean section, especially in LMIC, where the risks of surgery are substantial.[10,12] Performing assisted vaginal birth avoids the risks related to anaesthesia and reduces risk of surgery-related bleeding and infection.[13-15] In addition, delay between decision and birth may be reduced and thereby the risk of uterine rupture or intrauterine fetal death during waiting time.[15] Furthermore, the procedure does not result in a uterine scar, with an increased risk of uterine rupture, placenta previa or abnormal invasive placenta in a next pregnancy. This is a particular advantage in settings where many women give birth outside hospital and where these complications are truly life-threatening.[16] The fertility rate in LMIC is often high (5.8 per woman in Uganda during the study period) meaning that, when the first birth is by caesarean section, many 'trials of labour' or repeat caesarean sections are likely to follow. Other long-term complications of caesarean section, or complications causing long-term morbidity, are increased risk of preterm birth in subsequent pregnancies and iatrogenic obstetric fistula.[17,18] Recovery time after assisted vaginal birth is substantially shorter compared to caesarean section and assisted vaginal birth is less costly.[10,19] Therefore, assisted vaginal birth was included as one of the seven signal functions of basic emergency obstetric care and one of the nine signal functions of comprehensive emergency obstetric care (together with caesarean section). Vacuum extraction is recommended as an important management option for prolonged second stage of labour to avoid caesarean section and associated maternal and perinatal morbidity and mortality.[15,20-22]

Despite its advantages, assisted vaginal birth is hardly used in many LMIC (<1% of institutional births), which is very different from many high-income European countries that often have frequencies above 15%.[23-26] A cross-sectional health facility assessment in 40 countries in Latin America, sub-Saharan Africa and Asia revealed that reasons for not using assisted vaginal birth were equipment related; lack of staff training; issues with authorisation of human resources and the perception amongst staff that no women with an indication for assisted vaginal birth had presented to the health facility.[23] Failing to resort to assisted vaginal birth could be a major impediment to the reduction of medically non-indicated caesarean sections and maternal and perinatal morbidity and mortality in LMIC.[3,22] Authorities have declared vacuum extraction the method of choice in modern obstetrics because of its safety for woman and fetus.[9,23] Several projects have been implemented intending to increase the use of vacuum extraction in LMIC, with promising results.[27-30] It is not known, however, whether women find vacuum

extraction an acceptable mode of birth, especially in settings where the procedure is uncommon. Studies about women's preferences for mode of birth have only investigated whether women preferred (elective) caesarean section or spontaneous vaginal birth. In those studies, most women preferred vaginal birth above caesarean section.[31-35] The preference of women in case of prolonged second stage of labour has not been studied.

The objective of this study was to investigate what women, who have undergone vacuum extraction or second-stage caesarean section, would recommend to their friends in case of prolonged second stage of labour and why.

Methods

Study design

A prospective cohort study, consisting of interviews with women who gave birth by vacuum extraction or second-stage caesarean section. Interviews were conducted on the first day and six months after birth. This study was part of a larger study on clinical and woman-centred outcomes of vacuum extraction and second-stage caesarean section in Mulago hospital, Uganda. Detailed methods and outcomes were described elsewhere.[15,19]

Setting

Mulago hospital is the national referral and main teaching hospital of Uganda, situated in the capital city, Kampala. It is a government hospital with 2700 beds and more than 31 000 births annually. The study was conducted in the main labour ward. Medical care in this ward is free of charge. However, due to shortages women sometimes have to buy medical items outside the hospital (e.g. drugs and urinary catheters). During the study period, the vacuum extraction rate in this ward was 2.6% and the caesarean section rate 31.7%. Caesarean section during the second stage of labour in a term singleton pregnancy in vertex presentation occurred to 3.3% of all women. Of women with a term cephalic singleton who had a second stage intervention, 42% had vacuum extraction, 4% had failed vacuum extraction followed by caesarean section and 54% had caesarean section without trial of vacuum extraction.[15]

Participants and period of recruitment

Between 25 November 2014 and 8 July 2015, women with a term, singleton in vertex presentation who had undergone vacuum extraction or caesarean section in the second stage of labour were included, after providing a written informed consent.

Outcome measures and method of assessment

Outcome measures were: proportions of women recommending vacuum extraction and caesarean section on the first day and six months after birth, stratified by mode of birth (vacuum extraction, failed vacuum extraction followed by caesarean section or second-stage caesarean section without trial of vacuum extraction).

Since unfavourable clinical outcome could influence women's preferences, outcome measures were calculated for all women and also after exclusion of women with unfavourable maternal or perinatal outcome at the moment of interview, defined as: neonate had died before interview, severe maternal complications (re-laparotomy, hysterectomy and obstetric fistula). Additional outcome measures were reasons for choosing vacuum extraction or caesarean section and frequencies (in percentages), in which those reasons were mentioned, stratified by mode of birth. For reasons of interpretation, clinical information is described when relevant. Method of data collection of clinical outcomes was described elsewhere.[15]

On the first day after birth, women were asked what they would recommend to a friend who would need an intervention for prolonged second stage of labour: vacuum extraction or caesarean section (closed question). During a six months follow-up visit or phone call, women were asked what they would recommend to a friend, as well as why they would recommend the chosen mode of birth (open question). Interviews were conducted by trained research assistants who were not performing vacuum extraction or caesarean section themselves. The answers to the open question about why they would recommend the chosen mode of birth were literally recorded into a database by the research assistants.

More than one reason per woman was possible. During analysis, reasons given by the women were categorised into 'main reasons' (mentioned 15 times or more) and 'other reasons' (mentioned less than 15 times). This resulted in five main reasons for choosing vacuum extraction and five main reasons for choosing caesarean section.

Statistical methods

Baseline characteristics are reported in counts and percentages with P-values comparing vacuum extraction to caesarean section without trial of vacuum extraction. Outcome parameters are reported as counts with percentages. P-values were calculated with two-sided chi-square. Data were entered in Microsoft Excel and SPSS version 24 was used for data analysis. $P<0.05$ was considered statistically significant.

Study size

A convenience sample was used, since this study was part of a larger study including clinical and woman-centred outcome after vacuum extraction and second-stage caesarean section.[15] Sample size for that study was based on expected differences in perinatal death per mode of birth. Missing data per baseline characteristic or outcome parameter varied from 0% to 3.1% and are shown in the tables. Loss to follow-up is described in Results section.

Ethical permission

Ethical permission to conduct this study was obtained from the Mulago hospital Research and Ethics Committee (refnr: MREC 489) and the Uganda National Council for Science and Technology (ref HS1752).

Results

Of 783 eligible women, 759 (96.9%) participated in the study. Three hundred and eighteen women had vacuum extraction, 32 women had caesarean section after failed vacuum extraction and 409 women had second-stage caesarean section without trial of vacuum extraction (Figure 1). One day after birth, 317 (99.7%) women after vacuum extraction, 401 (98.0%) women after second-stage caesarean section without trial of vacuum extraction and 32 (100%) women after failed vacuum extraction and subsequent caesarean section had a complete intake interview. Six months after birth, 178 (56.0%) women after vacuum extraction, 226 (55.3%) women after caesarean section without trial of vacuum extraction and 22 (68.8%) women after failed vacuum extraction and subsequent caesarean section could be interviewed.

Table 1 shows socio-demographic characteristics. Ninety-nine of 409 (24.2%) women who had caesarean section without trial of vacuum extraction had a previous caesarean section versus 32/318 (10.1%) women who had vacuum extraction (P<0.001). Other characteristics were not statistically different between the groups. During the interview on the first day after birth, the majority of women who had vacuum extraction (293/318; 92.1%) would recommend this procedure. Almost half of women who had caesarean section (176/409; 43.0%) would recommend vacuum extraction rather than caesarean section (Table 2).

When women with unfavourable outcome were excluded, these figures did not change (Table S1). Of 32 women who had experienced caesarean section in a previous pregnancy and vacuum extraction during this study, 31 women (96.9%) would recommend vacuum extraction to a friend rather than caesarean section. During the follow-up interview at six months after birth, the answers were similar to those on the first day after birth (Table 2).

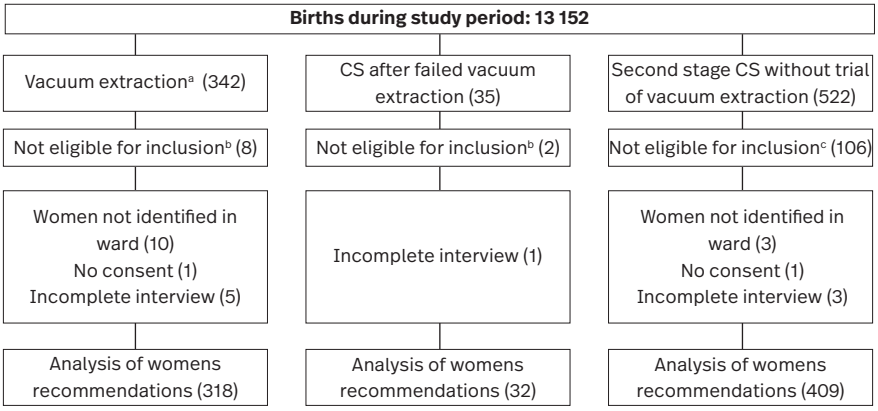

Figure 1 | Inclusion process

CS, caesarean section

[a] One woman had failed vacuum extraction and subsequent forceps delivery (analysed in vacuum extraction group).

[b] One of the following exclusion criteria (more than one could apply): Uterine rupture (2), twin and/or preterm birth (8).

[c] One of the following exclusion criteria (more than one could apply): Maternal death (6), uterine rupture (13), twin, preterm and/or non-vertex presentation (88).

Table 1 | Characteristics of participants

Mode of birth	**Vacuum extraction (318)**	**CS without trial of vacuum extraction (409)**	**CS after failed vacuum extraction (32)**
Parity	n (%)	n (%)	n (%)
Nulliparous	175 (55.0)	207 (50.6)	22 (68.8)
Parous	137 (43.1)	202 (49.4)	10 (31.3)
Missing data	6 (1.9)	0 (0)	0 (0)
Previous CS			
Yes	32 (10.1)	99 (24.2)	5 (15.6)
No	279 (87.7)	310 (75.8)	27 (84.4)
Missing data	7 (2.2)	0 (0)	0 (0)
Education			
None	3 (0.9)	9 (2.2)	1 (3.1)
1-6 years	76 (23.9)	91 (22.2)	5 (15.6)
7-12 years	209 (65.7)	271 (66.3)	22 (68.8)
>12 years	25 (7.9)	32 (7.8)	4 (12.5)
Missing data	5 (1.6)	6 (1.5)	0 (0)
Occupation			
Employed	117 (36.8)	170 (41.6)	15 (46.9)
Student	3 (0.9)	5 (1.2)	0 (0)
Unemployed	191 (60.1)	228 (55.7)	16 (50.0)
Missing data	7 (2.2)	6 (1.5)	1 (3.1)
Age			
Mean age	23.3 (SD 5.2)	23.9 (SD 5.3)	23.4 (SD 5.3)
<20 years	78 (24.5)	88 (21.5)	5 (15.6)
≥20 years	235 (73.9)	320 (78.2)	27 (84.4)
Missing data	5 (1.6)	1 (0.2)	0 (0)

CS: Caesarean section

Table 2 | Women's recommendations in case of second stage intervention

Mode of birth	Vacuum extraction		CS without trial of vacuum extraction		CS after failed vacuum extraction	
Recommendation on first day after birth	**n (318)**	**(%)**	**n (409)**	**(%)**	**n (32)**	**(%)**
Vacuum extraction	293	(92.1)	176	(43.0)	14	(43.8)
Caesarean section	24	(7.5)	225	(55.0)	18	(56.3)
Missing data	1	(0.3)	8	(2.0)	0	(0)
Recommendation at six months after birth	**n (178)**	**(%)**	**n (226)**	**(%)**	**n (22)**	**(%)**
Vacuum extraction	160	(89.9)	100	(44.2)	9	(40.9)
Caesarean section	14	(7.9)	123	(54.4)	13	(59.1)
No preference	4	(2.2)	3	(1.3)	0	(0)

CS: caesarean section

Main reasons for recommending vacuum extraction

Reasons why women would recommend vacuum extraction are shown in Table 3. Less pain was the most important reason for recommending vacuum extraction, especially in women who had experienced caesarean section and would recommend vacuum extraction. A short recovery period, avoiding surgery, the presumption that vacuum extraction is safer for the mother and having experienced vacuum extraction without problems were other frequently mentioned reasons.

Table 3 | Reasons for recommending vacuum extraction or caesarean section at six months after birth

Mode of birth	Vacuum extraction (178)		CS without trial of vacuum extraction (226)		CS after failed vacuum extraction (22)		All women (426)	
Women who recommended vacuum extraction	**n(160)**	**(%)[a]**	**n (100)**	**(%)[a]**	**n(9)**	**(%)[a]**	**n(269)**	**(%)[a]**
Reasons for recommending vacuum extraction								
Less pain during/after vacuum extraction	50	(31.3)	54	(54.0)	6	(66.7)	110	(40.9)
Short recovery, no limitations	28	(17.5)	14	(14.0)	3	(33.3)	45	(16.7)
Vacuum extraction is like normal delivery/no operation or scar	27	(16.9)	13	(13.0)	0	(0.0)	40	(14.9)
Vacuum extraction is safer for mother	20	(12.5)	17	(17.0)	0	(0.0)	37	(13.8)
I had no problems with vacuum extraction	28	(17.5)	0	(0.0)	0	(0.0)	28	(10.4)
Other reason	28	(17.5)	8	(8.0)	0	(0.0)	36	(13.4)
Women who recommended CS	**n(14)**	**(%)[a]**	**n(123)**	**(%)[a]**	**n(13)**	**(%)[a]**	**n(150)**	**(%)[a]**
Reasons for recommending CS								
I had no problems with CS	0	(0.0)	44	(35.8)	2	(15.4)	46	(30.7)
CS is safer for baby	8	(57.1)	30	(24.4)	2	(15.4)	40	(26.7)
CS is the only option I know	0	(0.0)	21	(17.1)	0	(0.0)	21	(14.0)
Vacuum extraction may fail	0	(0.0)	12	(9.8)	9	(69.2)	21	(14.0)
CS is safer for mother	2	(14.3)	18	(14.6)	0	(0.0)	20	(13.3)
Other reason[b]	9	(64.3)	20	(16.3)	2	(15.4)	31	(20.7)
Women who did not make a choice	**4/178**	**(2.2)[c]**	**3/226**	**(1.3)[c]**	**0/22**	**(0.0)[c]**	**7/426**	**(1.6)[c]**

CS: caesarean section

[a] women who gave this reason as percentage of women who recommended this mode of birth per mode of birth group (more than one reason per woman possible).

[b] Other reasons for recommending vacuum extraction: vacuum extraction is easier/ less complicated (12); CS is scary (10); vacuum extraction saves lives (5); vacuum delivery is faster (4); vacuum extraction is safer for baby (3); I've heard bad stories about CS (1); concern about sexual activity after CS (1). Other reasons for recommending CS: CS saves lives (11); vacuum extraction is scary (8); CS is faster (5); less pain during/after CS (3); good care after CS (2); the ones helping you have no experience in vacuum extraction (1)

[c] percentage of women who did not make a choice per mode of birth group

Quotes that illustrate reasons for recommending vacuum extraction are shown below:

"I would advise vacuum extraction to a friend, because I have experienced both and caesarean section was too painful compared to vacuum. I had caesarean section on my first born and it was terrible. But now (after vacuum extraction) I am very OK."
23-year-old housewife, now P2, gave birth to 3.1 kg girl by vacuum extraction.

"After vacuum extraction you can work. After caesarean section it may take six months."
19-year-old businesswoman, now P1, gave birth to 3.1 kg boy by vacuum extraction.

"I would recommend vacuum extraction because I recovered so fast compared to my friends who were cut."
19-year-old businesswoman, now P1, gave birth to 3.1 kg girl by vacuum extraction.

"Vacuum extraction seems normal, while with caesarean section one is cut open."
17-year-old bar attendant, now P1, gave birth to 2.5 kg girl by vacuum extraction.

"Vacuum extraction prevents operation and is not so painful."
30-year-old restaurant attendant, now P3, gave birth to 3.7 kg girl by caesarean section.

"One does not have to go through the trauma of (operating) theatre."
22-year-old housewife, now P1, gave birth to 3.5 kg girl by vacuum extraction.

"Caesarean section is total deformity."
19-year-old hairdresser, now P1, gave birth to 3.0 kg boy by caesarean section.

"Vacuum extraction saved me and my baby. Some people die during caesarean section."
30-year-old housewife, now P4, gave birth to 4.0 kg boy by vacuum extraction.

Main reasons for recommending caesarean section

The most frequently mentioned reasons for choosing caesarean section were: having experienced caesarean section without problems; caesarean section presumed as being safer for the neonate; caesarean section being the only option the woman was aware of, concern that vacuum extraction may fail and caesarean section presumed as being safer for the mother:

"I would recommend caesarean section, because I don't know vacuum extraction."
20-year-old hairdresser, now P1, gave birth to 2.9 kg girl by caesarean section.

"I don't know vacuum extraction; the baby might get damage to the head."
Housewife, now P1, gave birth to 3.7 kg boy by caesarean section.

"Vacuum extraction may fail and when they take you to (operating) theatre it's too late."
18-year-old businesswoman, now P1, gave birth to 3.1 kg boy by caesarean section.

"I had failed vacuum and it was very painful."
20-year-old hairdresser, now P2, gave birth to 3.6 kg boy by caesarean section after failed trial of vacuum extraction. Neonate was in neonatology unit for 11 days for suspected birth asphyxia, but showed normal development at six months after birth.

"Caesarean section can save baby and mother. In the process of vacuum extraction, one can die, mother or baby."
34-year-old hairdresser, now P3, gave birth to 4.2 kg girl by caesarean section.

Other reasons for recommending vacuum extraction or caesarean section

Some women recommended vacuum extraction but were concerned about trauma to the neonate as well. Other women were rather concerned about perinatal outcome after caesarean section:

"I would recommend vacuum extraction, but only if there is an assurance that the baby's brain will not be damaged."
20-year-old trader, now P2, had one previous caesarean section and gave birth to 3.0 kg boy by vacuum extraction. Neonate had no signs of brain damage at birth (Apgar score 8-9) or at six months follow-up.

"Maybe vacuum extraction saves babies' lives, since it is faster."
34-year-old businesswoman, now P4, had one previous caesarean section. Gave birth to a stillborn 3.0 kg boy by (repeat) caesarean section. Intrauterine fetal death occurred during waiting time for caesarean section.

"When babies are born vaginally, they breathe better."
30-year-old housewife, now P5, gave birth to 4.0 kg boy by caesarean section.

Vacuum extraction perceived as being scary was mentioned by eight women:

"I witnessed vacuum extraction and it was horrible."
19-year-old housewife, now P1, gave birth to 2.7 kg boy by caesarean section.

One woman mentioned:
"The ones helping you have no experience in vacuum extraction."
35-year-old housewife, now P2, had one previous caesarean section, gave birth to 2.8 kg boy by (repeat)caesarean section.

The (higher) costs of caesarean section were mentioned by one woman:

"If financially stable they can do caesarean section, but if not, they should do vacuum."
26-year-old housewife, now P3, gave birth to 3.2 kg girl by vacuum extraction.

Six months after birth, only eight out of 161 (5.0%) women who had given birth by vacuum extraction with good outcome (neonate alive and no severe maternal complications) recommended caesarean section, while 78 out of 193 (40.4%) women who had undergone caesarean section with good outcome would recommend vacuum extraction to a friend. Reasons for recommending caesarean section after having experienced vacuum extraction with good outcome were (with number of women who mentioned this reason in brackets) pain during vacuum extraction (2); 'My baby had to go to neonatology unit' (1) (The neonate was in the neonatology unit for suspected birth asphyxia and showed normal development at six months after birth.); 'It felt bad to see my baby's head swollen' (1) (Subgaleal haemorrhage was suspected. The neonate had phototherapy and showed normal development at six months after birth.); Vacuum extraction was scary (2); Complications after vacuum extraction (1) (Mother and neonate went home after 1 day, no complications noted at discharge and at six months follow-up.)

Discussion

The vast majority of women who had experienced vacuum extraction would recommend this mode of birth above caesarean section in case of prolonged labour. Nearly half of the women who experienced caesarean section would also recommend vacuum extraction. Main reasons for choosing vacuum extraction were experiencing less pain, having a shorter recovery period, avoiding surgery and vacuum extraction being presumed as being safer for the mother. Main reasons for recommending caesarean section were having experienced caesarean section without problems, caesarean section presumed as being safer for the neonate, caesarean section being the only option the woman was aware of and concern that vacuum extraction may fail.

These results show that most women perceive vacuum extraction as an acceptable intervention for prolonged second stage of labour. In case they had experienced the procedure, they clearly preferred this intervention above caesarean section. These results are in line with previous findings from the same setting: 91% of the women after vacuum extraction were satisfied about their birthing experience.[19] A study from Argentina found that only 6% of the healthy pregnant nulliparous women (without indication for caesarean section) in the public sector preferred caesarean section above vaginal birth.[33] In a study from Italy, 94% of the parous women without previous caesarean section would prefer to have a vaginal birth in a next pregnancy compared to 60% of the parous women with a previous caesarean section.[34] Reasons for preferring

vaginal birth in that study were not wanting to be separated from the neonate, shorter hospital stay and faster postpartum recovery.

Reasons for choosing vacuum extraction in our study are supported by results of studies in the same setting: after vacuum extraction, compared to after caesarean section, pain scores were lower up to six weeks after birth and more women were able to work at six weeks after birth.[19] Vacuum extraction was indeed safer for the mother: risk of severe maternal complications (maternal death, uterine rupture while waiting for procedure, hysterectomy and re-laparotomy) was 0.8% (3/358) in women who had had (trial of) vacuum extraction as compared to 4.2% (18/425) in women who had undergone second-stage caesarean section. During or after caesarean section 5/425 (1.2%) of women died, none (0/358) after (trial of) vacuum extraction.[15]

'Vacuum extraction is like normal birth' or 'I do not want an operation or scar' were important reasons to choose vacuum extraction. This might be of particular importance to women in countries where having had caesarean section is seen as abnormal, 'a significant subtraction from womanhood' or even as 'the devil's work' or 'a sign of marital infidelity'.[31,36]

An important reason for recommending caesarean section is the belief that caesarean section is safer for the neonate. However, this is not supported by publications from Uganda and the United States.[15,37] In our setting (Uganda), a study of clinical outcome of 757 neonates after either second-stage caesarean section or (trial of) vacuum extraction showed that perinatal outcome and outcome at six months after birth was comparable. Occurrence of perinatal death was 45/410 (11.0%) in the caesarean section group and 29/347 (8.4%) in the vacuum extraction group (P=0.227). Occurrence of intra uterine fetal death during waiting time for caesarean section was 18/410 (4.4%) and for vacuum extraction 3/347 (0.9%, P=0.003).[15]

It is clear that many women are not aware of the risks and benefits of vacuum extraction versus caesarean section. This is an important knowledge gap for pregnant women and possibly for health care providers in this setting. In the situation of prolonged second stage with a clear indication for a vacuum extraction, this option should be promoted as the option of first choice. Women will have to be explained risks and benefits of vacuum extraction, also in relation to caesarean section, and should be asked to provide consent.

Other reported reasons for choosing caesarean section, such as having experienced caesarean section without problems and caesarean section being the only option a woman was aware of, would probably be mentioned less often if women had been better informed.

The reason 'Vacuum extraction may fail' is indeed a realistic concern. In this cohort the failure rate was 9.1% (32/350, Figure 1), comparable to failure rates elsewhere.[9]

Interestingly, 14/32 (43.8%) of the women after failed vacuum extraction would still recommend vacuum extraction. Training and adhering to clinical guidelines are important in keeping failure rates as low as possible.

Although most women in our study would recommend vacuum extraction above caesarean section, vacuum extraction is not always a realistic management option. In some areas, neither caesarean section nor vacuum extraction is available, while in other areas vacuum extraction is not available and caesarean section rates are alarmingly high.[11,23,25] Such situations clearly represent a missed opportunity. Inexperience or inadequate skills in performing vacuum extraction have been associated with greater frequency of caesarean section use.[22] Implementation programmes aiming at increasing the use of vacuum extraction by training of staff, supply of equipment, development of guidelines, audit of indications for caesarean section and vacuum extraction have shown to be effective.[21,27-30] More such programmes are needed to ensure that women who have an indication for vacuum extraction benefit from the procedure.

Strengths and limitations

A strength of this study is that it addresses an important knowledge gap. Nearly all eligible women accepted to be included, minimising selection bias. An additional strength is that not only women who had experienced vacuum extraction, but also women who had undergone second-stage caesarean section or who had had a failed trial of vacuum extraction were interviewed. Some women in this study may have felt that they should give a response in favour of the care option they received, although 44% of the women after caesarean section recommended vacuum extraction. Only interviewing women after vacuum extraction would give results that would be difficult to interpret.

Eventual bias is expected to be in the same direction for the different groups and is not expected to change the conclusions of the study. The observational design comes with obvious limitations. The baseline characteristic 'previous caesarean section' was more frequent in women who had given birth by caesarean section, and this might have introduced bias. Losses to follow-up at six months are a limitation and could have introduced additional bias, although losses to follow-up were comparable between the different groups. Although participants were from different socioeconomic backgrounds and educational levels, the study was performed in a single health facility in an urban setting. Findings may be generalisable to similar settings, but repetition of our study in other similar and different settings must be encouraged.

In conclusion, the majority of women in this tertiary referral centre in Uganda, would recommend vacuum extraction over caesarean section in case of prolonged second stage of labour.

These findings are in line with literature that vacuum extraction should be the procedure of choice in prolonged second stage of labour to avoid caesarean section, unless a clear contraindication is present. Implementation programmes are much needed to make vacuum extraction a realistic management option for all women requiring this procedure.

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Supporting information

Additional supporting information can be found below:

Table S1 | Women's recommendations in case of second stage intervention, selection: good maternal and perinatal outcome[a]

Mode of birth	**Vacuum extraction (289)**		**CS without trial of vacuum extraction (362)**		**CS after failed vacuum extraction (28)**	
Recommendation on first day after birth	**n=289**	**(%)**	**n=362**	**(%)**	**n=28**	**(%)**
Vacuum extraction	271	(93.8)	154	(42.5)	13	(46.4)
Caesarean section	17	(5.9)	201	(55.5)	15	(53.6)
Missing data	1	(0.3)	7	(1.9)	0	(0.0)
Recommendation at six months after birth	**n=161**		**n=193**		**n=17**	
Vacuum extraction	151	(93.8)	78	(40.4)	8	(47.1)
Caesarean section	8	(5.0)	112	(58.0)	9	(52.9)
No preference	2	(1.2)	3	(1.6)	0	(0.0)

[a] *Women with unfavourable outcome were excluded. This was defined as neonate had died before interview, severe maternal complications (re-laparotomy, hysterectomy, obstetric fistula)*
When outcome in Table 2 is compared to outcome in this table, using P-values, all P-values are ≥ 0.05

CHAPTER 7

Use of assisted vaginal birth to reduce unnecessary caesarean sections and improve maternal and perinatal outcomes

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Far too many birth-related maternal and perinatal deaths still occur in low-income and middle-income countries. Prolonged labour is a common cause of stillbirths, maternal deaths, and lifelong disabilities.[1-3] Prolonged second stage of labour is a common indication for caesarean section; however, many of these caesarean sections could be prevented by the use of assisted vaginal birth, with vacuum extraction being the method of first choice.[1-3] Compared with caesarean section, vacuum extraction is associated with a lower risk of infection and haemorrhage, and shorter decision-to-birth interval and therefore lower rates of birth asphyxia, intrapartum stillbirths, and severe maternal morbidity.[2,3] Caesarean section is also associated with increased risks of pregnancy-related hysterectomy and, in future pregnancies, abnormal placentation and uterine rupture.[4] Furthermore, caesarean section usually means slower physical and mental maternal recovery and higher health service costs as compared with assisted vaginal birth.[4-6] When indications align, such as prolonged second stage of labour or fetal distress during the second stage of labour, use of vacuum extraction can lead to a reduction of unnecessary caesarean sections, an issue discussed at length in a 2018 Lancet Series on caesarean sections.[4,5]

Risk reduction associated with assisted vaginal birth is larger in settings where safe surgery and anaesthesia cannot be taken for granted and where fertility rates are high.[2,7] Studies in low-income and middle- income countries have shown that fewer than 1% of institutional births were by assisted vaginal birth compared with up to 16.4% in northwest Europe.[1,8] This difference is largely because obstetric skills required for assisted vaginal birth have disappeared from many of the areas where these skills are most needed and could potentially have the highest beneficial effect. WHO states that skilled attendants at primary care levels should be able to do vacuum extraction as one of the basic obstetric functions. Inexperience with, or inadequate skills required for assisted vaginal birth have been associated with a greater frequency of caesarean section use.[5] Other reported obstacles to assisted vaginal birth are a paucity of functioning equipment and exaggerated fear of scalp and brain injury for the neonate. Additionally, unjustified fear of mother-to-child transmission of HIV, policies forbidding available professional cadres such as midwives to do assisted vaginal birth, and fear of litigation also play a role.[1-3,5]

At the same time, studies evaluating the re-introduction of vacuum extraction in several low-income and middle-income countries have revealed promising results.[8-10] A 2018 study showed that it was feasible to re-introduce vacuum extraction in 15 health facilities in Tanzania with adequate training and supervision of staff.[9] In the main referral hospital in Kampala, Uganda, a programme was implemented in 2012, consisting of the development of a guideline, supply of equipment, and training of staff. Among all births, vacuum extraction use rose from 0.6% to 3.7%. This was accompanied by a 23.6% ($P<0.01$) decrease in intrapartum stillbirths and a 25.5% ($P<0.01$) decrease of uterine rupture.[8] Remarkably, mean decision-to-birth interval for vacuum extraction was 34 minutes versus 4 hours and 38 minutes for caesarean section: this reduction in time was the most likely explanation for the significant decrease ($P<0.01$) in intrapartum deaths from birth

asphyxia. Increased use of vacuum extraction also reduced the waiting time for women who really needed caesarean section, which in turn led to a reduction of uterine rupture and improved outcome for these women and neonates.[2,8] In a cohort of 289 women who had vacuum-assisted vaginal birth in this hospital, 257 (91%) were satisfied with their birthing experience.[6] Similarly, a series of interventions (training of staff, monitoring and evaluation, audit, and constructive feedback) were implemented in Mozambique in 2015. These interventions reversed the underutilisation of vacuum extraction, and led to a substantial reduction of maternal mortality and stillbirths.[10] A 2018 report from Papua New Guinea documented four decades of audit in a large public hospital, where a focus on maintaining obstetric skills, including the use of vacuum extraction, has been associated with low perinatal mortality and caesarean sections.[11]

Re-introduction of vacuum extraction in low-income and middle-income countries can play a major role in the prevention of mortality and morbidity related to prolonged labour and the reduction of unnecessary caesarean section in the second stage of labour. It is therefore of utmost importance to promote and support international and institutional efforts to work towards the re-introduction of vacuum extraction through intervention programmes.

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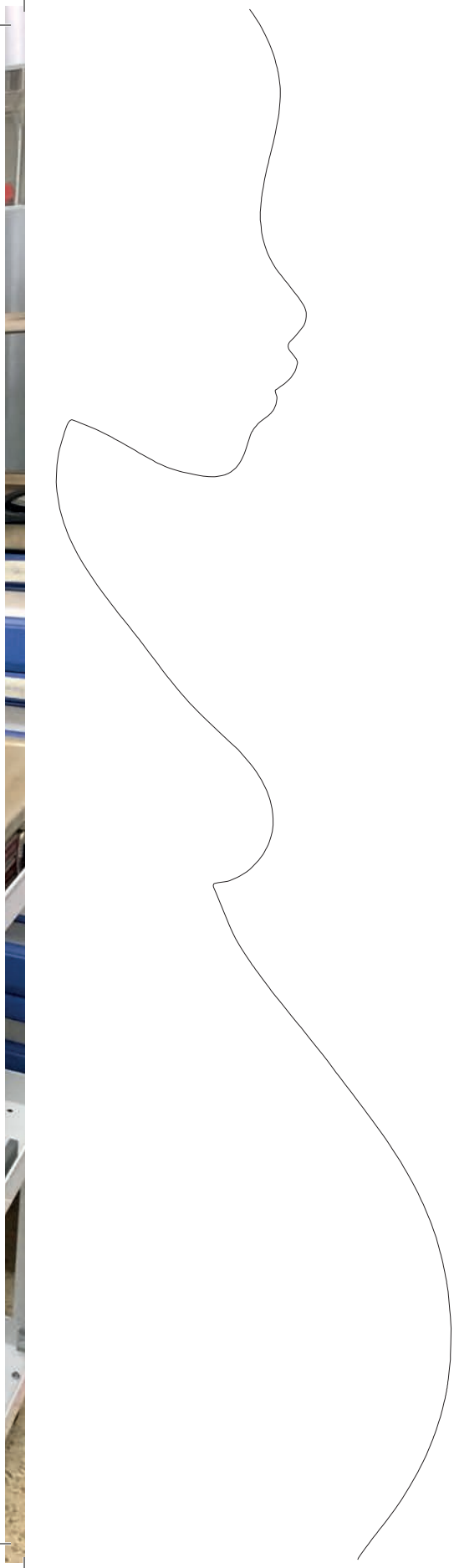

CHAPTER 8

General discussion

Main findings

In this thesis, implementation of a programme to increase use of vacuum extraction in Mulago hospital, Uganda was described. Maternal and perinatal outcome of vacuum extraction were addressed and compared to second-stage caesarean section. Perspectives of women who gave birth by vacuum extraction or second-stage caesarean section and opinions of Mulago hospital's maternity unit staff were studied. Here, findings are summarised per research question and put into broader perspective. A summary of quantitative outcomes is presented in Table 1.

1 **What is the impact of a programme aiming to increase the use of vacuum extraction in Mulago hospital on vacuum extraction incidence and maternal and perinatal outcome?**
After providing equipment and training of staff, use of vacuum extraction increased from 0.6% to 2.4% of births and an association with improved maternal and perinatal outcome was strongly suggested. The shorter decision-to-birth interval for vacuum extraction compared to caesarean section probably played an important role (chapter 2).

2 **Which factors were causing the low utilisation of vacuum extraction in Mulago hospital?**
Lack of functioning equipment and vacuum extraction skills, as well as concerns related to neonatal outcome, were factors contributing to low utilisation. Indications for use of vacuum extraction were not always recognised and contraindications incorrectly assumed (chapter 3).

3 **What are health professionals' perspectives regarding vacuum extraction in Mulago hospital?**
Most health professionals would prefer vacuum extraction over caesarean section for themselves or a relative in case of prolonged labour. This reflects a positive attitude towards vacuum extraction (chapter 3).

4 **What are maternal and perinatal outcomes of vacuum extraction in this setting, compared to second-stage caesarean section?**
In a prospective cohort study of 783 women who gave birth by vacuum extraction (n=358) or second-stage caesarean section (n=425), substantially fewer severe maternal complications and maternal deaths occurred after vacuum extraction compared to caesarean section. Perinatal outcomes were comparable for both modes of birth (chapter 4).

5 **What are women-centred outcomes of vacuum extraction, such as birthing experience, quality of life, experience of pain, sexual activity and dyspareunia in this setting, compared to second-stage caesarean section?**

The majority of women were satisfied with their birthing experience after vacuum extraction. Up to six weeks after birth, quality of life was better; experience of pain reduced and resumption to sexual activity occurred earlier after vacuum extraction compared to caesarean section. There was no difference in dyspareunia. At six-month follow-up, no differences between the groups existed anymore (chapter 5).

6 **Do women in Mulago hospital consider vacuum extraction an acceptable intervention?**
The majority of women recommend vacuum extraction over caesarean section in case of prolonged second stage of labour (chapter 6). Similarly, most women were satisfied with their birthing experience after vacuum extraction (chapter 5). Based on these findings, vacuum extraction seems to be an acceptable intervention to women in this setting.

Discussion

Vacuum extraction rate in international perspective

Compared to European population-based assisted vaginal birth rates of, for example, 15.1% in Spain, 13.0% in France and 8.4% in the Netherlands, the use of vacuum extraction in Mulago hospital was still low with 2.4% of all births at 18 months after onset of the programme, despite equipment becoming available (chapter 2).[1] Factors contributing to this low vacuum extraction rate in Mulago hospital compared to high-income settings could be differences in maternal characteristics with higher mean parity (fertility rate 5.4 in Uganda), unavailability of epidural analgesia and unavailability of monitoring by cardiotocography (CTG).[2-4] In Europe, routine use of CTG monitoring may lead to increased detection (and sometimes "over detection" by false positive CTG findings) of fetal distress and increased use of interventions such as vacuum extraction and caesarean section.[3] In contrast, due to limited fetal monitoring in Mulago hospital and other low-income settings, fetal distress is often not diagnosed.[5] Improved fetal monitoring (either by Pinard fetoscope or handheld doppler), during the second stage of labour, and timely intervention by vacuum extraction could possibly lead to increased vacuum extraction use and better perinatal outcome.[6]

Other contributing factors for the low vacuum extraction rate were reluctance to use vacuum extraction (chapter 3); not recognizing indications or incorrectly presumed contraindications (chapter 3) and, not reaching the second stage of labour because of caesarean section during the first stage of labour (chapter 4, Figure 1: 27.5% of all women gave birth by caesarean section before the second stage of labour was reached, 4.2% of all women gave birth by caesarean section in the second stage of labour). Audit of indications for caesarean sections was not part of the studies in this thesis, but studies from similar settings show that caesarean section is frequently used for dubious indications. This includes, for example, caesarean section for prolonged labour, while less invasive measures such as rupture of membranes, augmentation with oxytocin and – if in second stage – vacuum extraction, have not been tried.[7]

Table 1 | Summary of quantitative outcomes of chapter 2, 4, 5 and 6

Summary of impact of programme to increase use of vacuum extraction (chapter 2)			
	Baseline (reference)	**18 months follow-up**	**OR (95%CI) or P-value[a]**
Vacuum extraction per 100 births	0.6	2.1	3.86 (3.01-4.95)
CS for prolonged labour per 100 CS	23.1	20.0	0.92 (0.84-1.01)
Intrapartum stillbirth per 1000 births	34.3	26.2	0.76 (0.67-0.85)
Term neonate admissions to neonatology unit per 1000 births	87.3	99.8	1.16 (1.08-1.25)
Occurrence of uterine rupture per 1000 births	11.0	8.2	0.75 (0.61-0.92)
Maternal deaths from intrapartum complication per 100 000 live births	280	248	0.89 (0.59-1.33)

Summary of outcomes of vacuum extraction compared to second-stage caesarean section (chapter 4-6)					
	Vacuum extraction		**Caesarean section[b]**		
Maternal outcome[c]	**n**	**(%)**	**n**	**(%)**	
Maternal death	0/358	(0)	5/425	(1.2)	P=0.066
Severe maternal outcome[d]	3/358	(0.8)	18/425	(4.2)	0.19 (0.06-0.65)
Hospital admission max 2 days	186/231	(80.5)	60/289	(20.8)	15.78 (10.24-24.31)
Perinatal outcome[c]					
Perinatal death	29/347	(8.4)	45/410	(11.0)	0.74 (0.45-1.21)
Severe perinatal outcome[e]	45/ 347	(13.0)	55/410	(13.4)	0.96 (0.63-1.47)
IUFD during DBI	3/347	(0.9)	18/410	(4.4)	0.19 (0.06-0.65)
Early neonatal death	26/347	(7.5)	27/410	(6.6)	1.15 (0.66-2.01)
Admission to neonatology[f]	80/318	(25.2)	69/365	(18.9)	1.44 (1.00-2.08)
Birthing experience and quality of life[g]					
Satisfied about birth	257/282	(91.1)	332/366	(93.5)	0.71 (0.40-1.28)
Very scared during birth	46/287	(16.0)	25/357	(7.0)	2.54 (1.52-4.24)
Very concerned about baby	169/287	(58.9)	185/357	(51.8)	1.33 (0.97-1.82)
Pain[g]	**Mean**	**(SD)**	**Mean**	**(SD)**	
Pain during intervention (0-10)[h] (n=287 and 357)	5.4	(3.8)	0.4	(0.9)	P<0.001
Pain in first 24 hours after birth (n=287 and 356)	2.7	(1.3)	3.9	(1.8)	P<0.001
Pain at six weeks follow-up (n=189 and 262)	0.4	(0.8)	0.9	(1.2)	P<0.001
Physical (PQoL) and mental (MQoL) quality of life (by SF-12)[g]					
PQol at six w (n=112 and 121)	48.7	(7.3)	44.0	(9.1)	P<0.001
MQoL at six w (n=112 and 121)	52.8	(8.9)	51.2	(9.8)	P=0.203
Sexual activity[g]	**n**	**(%)**	**n**	**(%)**	
Resumed at six weeks follow-up	70/175	(40.0)	70/247	(28.3)	1.69 (1.12-2.54)
Painful when resumed (six weeks)	15/70	(21.4)	20/70	(28.6)	0.68 (0.32-1.47)
Resumed at six months follow-up	177/185	(95.7)	229/242	(94.6)	1.26 (0.51-3.10)
Painful when resumed (six months)	16/177	(9.0)	12/229	(5.2)	1.80 (0.38-3.90)
Women's recommendations at six months after birth[i]					
Vacuum extraction	160/178	(89.9)	100/226	(44.2)	P<0.001
Caesarean section	14/178	(7.9)	123/226	(54.4)	P<0.001
No preference	4/178	(2.2)	3/226	(1.3)	P=0.704

OR: Odds Ratio; CI: Confidence Interval; CS: caesarean section; IUFD: intra uterine fetal death; DBI: decision-to-birth interval
[a] P-value when OR not possible; [b] second-stage caesarean section; [c] inclusions and exclusions are described in chapter 4; [d] maternal death, uterine rupture, hysterectomy, re-laparotomy; [e] perinatal death, severe trauma, 5-min AS <4, convulsions; [f] surviving neonates; [g] inclusions and exclusions are described in chapter 5; [h] mean; [i] inclusions and exclusions are described in chapter 6, similar results on first day after birth

In Table 2, second stage interventions in Mulago hospital are compared to those in the Dutch Canisius-Wilhelmina hospital.

Table 2 | Second stage intervention in Mulago hospital (chapter 4) and CWZ (General introduction)

	Mulago hospital Total births: 13152[a]	**CWZ Total births: 6403**[b]
	n (%)	n (%)
Second stage intervention: CS + AVB	899 (6.8)	821 (12.8)
- Successful AVB	342/899 (38.0)	718/821 (87.5)
- Second stage CS (incl. failed AVB)	557/899 (62.0)	103/821 (12.5)
AVB as % of total births	342/13152 (2.6)	718/6403 (11.2)
Second stage CS[c] as % of total births	429/13152 (3.3)	103/6403 (1.6)
Failed vacuum extraction[d]	35/377 (9.3)	38/718 (5.3)

CWZ: Canisius-Wilhelmina hospital; CS: caesarean section; AVB: assisted vaginal birth
[a] November 2014-July 2015; [b] 2012-2015, unpublished data from hospital birth registry; [c] in women with term cephalic singleton; [d] and subsequent CS

The proportion of women who had a second stage intervention is lower in Mulago hospital: 6.8% versus 12.8% in the Dutch hospital. Of women who had a second stage intervention, 38.0% of women gave birth by vacuum extraction in Mulago hospital compared to 87.5% in the Dutch hospital. Roughly, this could suggest that more than half of the women in Mulago hospital who were eligible for vacuum extraction gave birth by caesarean section instead. This is also reflected in the percentage of all births by second-stage caesarean section in the two hospitals: in women with a term cephalic singleton 3.3% of births in Mulago hospital were second-stage caesarean sections and this was 1.6% in Canisius-Wilhelmina hospital. Other studies from high-income countries, where vacuum extraction is routinely used, show similarly low percentages of second-stage caesarean sections.[8,9] But, such interpretations have to be made with caution, since other factors may also play a role. For instance, Ugandan women may come to hospital only in case vaginal birth was not achieved after trying to give birth outside hospital for a long period of time or following a long journey. This would imply that only women with truly obstructed labour due to cephalopelvic disproportion would turn up in hospital. In the cohort study (chapter 4), 341/774 (44.1%) women were in the second stage of labour upon reaching the hospital.

To summarise, there is still room for improvement of several issues: fetal monitoring; recognition of indications; and removing unjustified reluctance to use vacuum extraction. Because, like hypothesised, our findings indicate that vacuum extraction is safer than caesarean section in the second stage of labour, also in the Ugandan setting (Table 1).

Maternal outcome

Adverse maternal outcomes such as uterine rupture and maternal death due to intrapartum complications decreased while use of vacuum extraction increased (chapter 2). Maternal outcome was substantially better after vacuum extraction than after second-stage caesarean section (chapter 4 and 5). These findings are supported by other studies indicating that (assisted) vaginal birth has better maternal outcome compared to caesarean section, especially in low-income settings.[10-12]

Five maternal deaths (5/425, 1.2%) from anaesthetic complications during caesarean section indicate how dangerous surgery in low-income settings may be. Improvement in the quality of anaesthetic care is needed and preventing unnecessary surgery very important.[13-15]

Some health professionals in Mulago hospital were concerned about vacuum extraction causing obstetric fistula. At six-week follow-up, an obstetric fistula had occurred in four women out of 365 women after second-stage caesarean section. No fistula had occurred after successful vacuum extraction (n=255) and one had occurred after failed vacuum extraction with subsequent caesarean section (n=29) (chapter 4). The aetiology of obstetric fistulas, as discussed in the introduction, makes it unlikely for vacuum extraction to be the cause.[16,17]

In addition to clinical outcomes, birthing experience, ability to work and pain-free sexual intercourse are important outcomes as well (chapter 5). These women-centred outcomes are likely to influence women in deciding where to give birth next time. A short recovery period and being able to work are of particular importance in a setting where many women are self-employed and do not have a paid maternity leave, while their family is depending on their income. Although maternity services are free of charge in the public sector in Uganda, time away from work due to obstetric interventions, such as caesarean section, may still cause serious financial problems to the family.[18]

Women-centred outcomes had only been studied in high-income countries before the emerging of this thesis.[19-26] Our findings indicate that women-centred outcomes were generally better after vacuum extraction compared to caesarean section and this is in line with studies from high-income settings (chapter 5).[19-26] These findings support the use of vacuum extraction to prevent caesarean section and promote quick recovery.

Perinatal outcome

After re-implementing vacuum extraction, overall perinatal outcome improved, and particularly the number of intrapartum stillbirths declined (chapter 2). This may be due to the much shorter decision-to-birth interval in case of vacuum extraction compared to caesarean section. Results from the cohort study (chapter 4) confirmed this hypothesis: waiting time for caesarean section was much longer than for vacuum extraction and

intra-uterine fetal death during this period more frequent in the caesarean section group. Our findings did not support the concerns related to vacuum extraction causing neonatal brain damage, which were present among some health professionals. Severe neonatal trauma was rare in both groups and there was no difference in the occurrence of neonatal brain damage between the groups (chapter 4). This is supported by literature both from high- and low-income countries.[27-35]

The importance of a control group when investigating outcome of vacuum extraction becomes clear when outcome of vacuum extraction versus second-stage caesarean section is compared to perinatal outcome after all modes of birth in the hospital (Table 3). Without knowing perinatal outcome of second-stage caesarean section, outcome of vacuum extraction would seem unfavourable compared to background perinatal mortality for term neonates.

Outcome of vacuum extraction in the setting of Mulago hospital should not be compared to outcome in high-income settings. As mentioned previously, improving fetal monitoring and timely interventions (vacuum extraction if in second stage and fetal head at least at station 0) are needed to improve perinatal outcome, since 92% of perinatal deaths in our cohort were caused by birth asphyxia (chapter 4).

Table 3 | Perinatal outcome of different modes of birth compared to outcome after all modes of birth combined in Mulago hospital (Data from chapter 2 and 4)

	All modes of birth	**Vacuum extraction**	**Second-stage caesarean section**
Intrapartum stillbirths + term neonatal deaths[a]	40/1000 (1396/34 894)		
Perinatal mortality[b]		84/1000 (29/347)	110/1000 (45/410)

[a] data from chapter 2, period after implementation of programme; [b] data from chapter 4

Vertical HIV-transmission

Concerns with regard to vertical HIV-transmission in case of vacuum extraction were mentioned by health professionals as a reason for not performing the procedure (chapter 3). Such concerns have been described previously[36].

HIV-related outcomes from the cohort study were as follows (chapter 4): Of 84.3% of women in the study HIV-status was known and 10.0% of those women were HIV-positive. As described in the general introduction, HIV-positive pregnant women started antiretroviral therapy according to the so-called 'option B+ HIV-programme', a programme aiming to initiate all HIV-positive women on life-long antiretroviral therapy from the moment they test positive.[37] After excluding stillbirths and neonatal deaths, there were 24 neonates of HIV-positive mothers who had given birth by vacuum extraction.

Seven neonates were lost to follow-up (29.2%) and one neonate died unexpectedly at home after nine days (the death, according to the mother, was sudden without the child being ill beforehand). Ten mothers came for a six-month follow-up visit: all ten infants had negative PCR tests six weeks after birth. Six women had six-month follow-up over the phone and HIV-status was not discussed (per study protocol). All six infants were doing well.

In the caesarean section group, there were 25 neonates of HIV-positive mothers alive at discharge. Ten neonates were lost to follow-up (40.0%). One infant died from fever after four months (information from follow-up over the phone, HIV-status not discussed). Five mothers came for a six-month follow-up visit: Four infants were tested and had negative PCR tests six weeks after birth. One infant was not tested. Nine mothers had six-month follow-up over the phone and HIV-status was not discussed. All nine infants were doing well. In conclusion: 14 infants were tested and negative, ten after vacuum extraction and four after caesarean section.

In case an HIV-positive woman has an indication for vacuum extraction, the health professional has to weigh risks and benefits of caesarean section versus vacuum extraction for woman and fetus. It is unknown whether vacuum extraction for prolonged second stage of labour increases or decreases risk of vertical transmission of HIV, but differences – if at all present – are likely to be small.[38] In general, birth by elective caesarean section reduces transmission of HIV in women with a high viral load.[39] However, caesarean section for prolonged second stage of labour is a different situation. The fetus has been in the birth canal and membranes have been ruptured for a long period of time. Waiting for caesarean section will prolong this period and might therefore even increase risk of transmission of HIV. Caesarean section is associated with increased maternal morbidity and mortality and women with high viral load are probably at an even higher risk of complications from caesarean section. In case of fetal distress, the fetus might benefit from the short decision-to-birth interval for vacuum extraction. Vacuum extraction can cause lacerations to the fetal scalp and hereby theoretically increase transmission of HIV, especially in women with a high viral load. There are no studies that have confirmed this theory.

As described in the general introduction, a study about HIV-transmission in women on antiretroviral treatment who gave birth by vacuum extraction or forceps showed 0.45% transmission.[40] An older review about HIV-transmission (most women not on antiretroviral treatment) showed no difference in HIV-transmission between assisted vaginal birth and intrapartum caesarean section.[39] The RCOG guideline states: “Blood-borne viral infections of the mother are not a contraindication to operative vaginal delivery.”[41] The British HIV Association guideline (2019) indicates that when viral load is suppressed the most appropriate instrument should be used in assisted vaginal birth, consistent with national obstetric guidelines and there is no preference of forceps or vacuum extractor. Intrapartum caesarean section is not recommended as a strategy to prevent HIV-transmission.[42]

Mode of birth preferred by women and health professionals

The vast majority of women who had experienced vacuum extraction would recommend this mode of birth over caesarean section in case of prolonged labour. Similarly, the majority of health professionals working in Mulago hospital's maternity unit would prefer vacuum extraction over caesarean section in case of prolonged labour. These results reflect that most women and most health professionals perceive vacuum extraction as an acceptable intervention, despite the procedure being new to them. Other studies about women's preferences for mode of birth have only investigated whether women preferred (elective) caesarean section or spontaneous vaginal birth. In those studies, most women preferred vaginal birth over caesarean section.[43-48] Caesarean section on maternal request is relatively uncommon and unlikely to be the reason for rising caesarean section rates in our setting.[49] However, a substantial part of women who gave birth by caesarean section would recommend caesarean section for prolonged labour. From the reasons they gave for choosing caesarean section, it became clear that many of them are not aware of the risks and benefits of vacuum extraction versus caesarean section. This is an important knowledge gap for pregnant women and should be addressed.

Methodological and ethical considerations

As presented in the introduction, a prospective cohort with a control group was chosen as the best possible way to evaluate outcomes of vacuum extraction in the study setting. Second-stage caesarean section was considered the best group for comparison, because this was the standard treatment before re-introduction of vacuum extraction. We hypothesised that still quite a number of women who would be eligible for vacuum extraction were going to have caesarean section, due to inexperience or reluctance of health professionals to use vacuum extraction and the procedure being new to them. Therefore, we expected that the groups of women (who underwent vacuum extraction and second-stage caesarean section) would be comparable.

A randomised trial would have been the gold standard for comparing outcomes of vacuum extraction to those of second-stage caesarean section, but we were of the opinion that this would not be ethical. We thought that if a woman has an indication and is eligible for vacuum extraction, she should have vacuum extraction. Randomising her between vacuum extraction and caesarean section would place her at risk of an unnecessary caesarean section, with an (expected) increased risk of morbidity and mortality and, in this setting, waiting time that could potentially lead to intrauterine fetal death for instance. Such a randomised trial has never been conducted in high-income countries either.

Because of the observational design our results must be interpreted with caution. For example, the group of women who underwent second-stage caesarean section could have had a higher risk profile. However, our findings indicated that a high proportion of

women with a second-stage intervention had caesarean section and that the vacuum extraction rate was still low (Table 2). Furthermore, a substantial part of women waiting for emergency caesarean section finally gave birth by vacuum extraction (chapter 4). Multivariate regression models to adjust for potential confounders showed that mode of birth was an independent risk factor for severe maternal complications and fetal death during waiting time in all models (chapter 4). Consequently, it seems justified to state that many women who gave birth by caesarean section would probably have qualified for vacuum extraction.

For future research into effects of implementation of vacuum extraction, a step-wedge cluster randomised trial could possibly combine benefits of stepwise implementation of vacuum extraction to several hospitals and generate even more robust data. In such a design several hospitals are randomised for timing of implementation. Over a certain period of time, implementation takes place in all hospitals and outcome data per hospital are analysed in such a way that coincidence of results can be excluded.[50]

Conclusion

Our studies showed that (re)implementation of vacuum extraction in a high-volume university hospital in a low-income country was successful. What was mainly needed was knowledge and skills training and provision of equipment. Health professionals generally had a positive attitude towards vacuum extraction and women preferred the intervention over caesarean section. Maternal outcome of vacuum extraction was substantially better than that of caesarean section. Decision-to-birth interval was shorter for vacuum extraction compared to caesarean section and intrauterine fetal death during waiting time for intervention higher in births by caesarean section. Severe neonatal trauma and brain damage were infrequent regardless of the mode of birth. Overall perinatal outcome was comparable. As vacuum extraction prevents women to have a uterine scar, long-term reproductive outcomes after vacuum extraction are expected to be better (less uterine rupture, less abnormal placentation) compared to caesarean section.

Future perspectives

From large studies in high-income countries where vacuum extraction is frequently used, we know the intervention is safe and prevents second-stage caesarean sections. Our studies have added information about outcome of vacuum extraction and perspectives of women and health professionals in a low-resource setting. All outcomes point in the same direction: vacuum extraction should be used much more frequently in settings where it is underused, especially where caesarean section is a relatively dangerous alternative.

Large scale implementation of vacuum extraction

Rollout of programmes to (re)implement vacuum extraction in low-income countries is much needed. Policy makers and funders should be made aware that (re)implementing vacuum extraction, amongst other basic emergency obstetric and newborn care functions is of utmost importance (Table 4). It will almost certainly have more impact than inventing (high tech) "golden bullets" and will definitely be more cost-effective. With what we know about maternal care and the interventions we have developed so far, most European countries have maternal mortality ratios below 6 per 100 000 live births, while in many sub-Saharan countries ratios remain above 300 per 100 000.[1,51] This is not only due to poverty and lack of high-tech interventions. In many hospitals basic obstetric care, including vacuum extraction, is simply not available. Reducing maternal mortality will need a holistic approach including obvious measures such as poverty reduction, better infrastructure, education and non-medical interventions such as maternity waiting homes and more respectful maternity care with an option of having a birth companion in the delivery room.[52,53] But, as long as a good functioning health system is not in place and basic obstetric care is not available in health facilities, the majority of maternal and perinatal deaths will not be prevented.

Table 4 | Basic and comprehensive emergency obstetric and neonatal care [54]

Basic emergency obstetric and neonatal care	
1	Parental antibiotics
2	(Parental) uterotonics
3	Parental anticonvulsants
4	Manual removal of placenta
5	Removal of retained products of conception
6	Assisted vaginal delivery
7	Newborn resuscitation (bag and mask)
Comprehensive emergency obstetric and neonatal care	
	all of the above, and:
8	Surgery
9	Blood transfusion

Participation of consultant obstetricians

Looking back and based on chapter 3, it seems that the Mulago guideline for vacuum extraction was not well known to many health professionals in Mulago hospital, despite several presentations for doctors and midwives. In our programme we focussed on training and on the job supervision of residents. These training sessions for residents were well attended (chapter 2). Consultant obstetricians were invited for training and presentations, but not all of them participated. Some consultants were too busy; some already knew how to use vacuum extraction or had other reasons for not attending. Vacuum extraction skills training had to compete with many other activities in this very

busy hospital. Active involvement of more Mulago hospital consultant obstetricians is needed to make the programme sustainable.

During the programme, midwives were invited to attend presentations about vacuum extraction but were not supposed to perform vacuum extractions. In this tertiary referral hospital opinions about task shifting were diverse. It was decided to train doctors first, since doctors are the ones who have to supervise others in case difficulties arise. In the setting of Mulago hospital there are doctors available when vacuum extraction needs to be performed. Smaller hospitals and health centres may not have doctors and it is important that midwives and clinical officers can perform vacuum extraction as well.

In Mulago hospital too, it could be beneficial if midwives could perform vacuum extraction, to reduce decision-to-birth-interval further and reduce the workload for doctors. A next step could therefore be training of midwives.

Vacuum extraction initiatives

Other studies evaluating re-introduction of vacuum extraction in several low-and middle-income countries have showed promising results. Examples include a study in Tanzania that showed that it was feasible to re-introduce vacuum extraction in fifteen health facilities.[55] A series of interventions in Mozambique (training of staff, accreditation, monitoring and evaluation, audit and constructive feedback), reversed the underutilisation of vacuum extraction and led to significant reduction of maternal mortality and stillbirths.[56] A recent report from Papua New Guinea documents four decades of audit in a large public maternity, where a focus on maintaining obstetrical skills, including use of vacuum extraction, has been associated with relatively low perinatal mortality and low caesarean section rates.[57]

Examples of ongoing and future programmes and research are:

- *The EgAr device vacuum delivery project in Brikama district hospital, the Gambia*. A midwife has developed a simplified and locally produced vacuum extractor pump (the EgAr device, described in the general introduction) which can be used with any type of vacuum extraction cup. The programme consists of evaluating use and outcome of the EgAr device and vacuum extraction skills training of midwives. The programme is ongoing.[58]
- *Improving emergency obstetric care through retraining of vacuum extraction – an intervention study in Dar es Salaam, Tanzania* (Uppsala-Muhimbili Collaboration). A programme planned to start in January 2020 with the purpose of training 150 health professionals, in order to increase the use of vacuum extraction and improve maternal and perinatal outcome in Muhimbili hospital, Dar es Salaam, Tanzania.
- *The Partoma project in Stone Town, Zanzibar*. The project consisted of implementation of locally tailored labour management guidelines and quarterly training sessions (including vacuum extraction skills training) in Mnazi Mmoja hospital, Stone Town,

Zanzibar. Vacuum extraction use increased from 0.3 to 1.2% of births. Stillbirth rate decreased from 59 to 39 per 1000 total births, primarily due to a reduction of intra-hospital stillbirths.[6] This programme is ongoing.

- Vacuum extraction skills training is part of the obstetric lifesaving skills training in *Gondar, Ethiopia* (programme by the Working party on international safe motherhood and reproductive health, the Netherlands) and in *Tonkolili, Sierra Leone* (programme by Capacare). These programmes are currently ongoing.[59,60]
- *Training for Life*. A programme consisting of simulation-based team training in obstetric emergencies. Vacuum extraction is one of the skills in the programme. It followed after our programme in Mulago hospital and rollout to 12 hospitals in Uganda is planned in 2020. The programme has started in the Maternal and Child hospital Shijiazhuang (China) as well.[61]
- *Reproductive outcome in women five years after vacuum extraction compared to after second-stage caesarean section in Mulago hospital, Uganda*. Five year follow-up of the women and neonates in the cohort of chapter 4, 5 and 6. Outcome parameters are: Mode of birth and maternal and perinatal outcome in subsequent pregnancies. The study is the MMed thesis of one of the residents in Mulago hospital and will start early 2020.

Vacuum extraction equipment

The following vacuum equipment is available in Mulago hospital (chapter 4): Kiwi-Omnicup® vacuum extractors (sterilised in Cidex-OPA® and re-used), handpump with Bird cup or flexible cup, electric pump with Bird cup or flexible cup. A team of three dedicated midwives is responsible for sterilising the equipment and availability in the ward. The electrical pump often has technical problems, the Kiwi-Omnicups (designed for single use) stop functioning after 3-5 times of use and Cidex-OPA is expensive, the handpump is sometimes not creating vacuum because of air leakage and requires two operators (one performing the assisted vaginal birth, one pumping to create vacuum).

Very effective user-friendly vacuum extraction equipment exists (for example Kiwi-Omnicup) and should be made affordable for hospitals and health centres in low-income countries. Or, if some people feel the need of inventing a “golden bullet”: Invention of a handheld one-piece vacuum extractor that can be sterilised in an autoclave and re-used would be helpful.

Recommendations

For women and their partners or birth companions

- If health professionals propose to perform caesarean section, ask for explanation. Is the caesarean section really needed and why? Would vacuum extraction be an option?

- Information about risks and benefits of vacuum extraction and caesarean section should be made available to women and their partners. Options could be: posters in hospitals and health centres; information in newspapers and magazines; radio and social media.

For midwives, doctors and other clinicians

- If you do not know how to perform vacuum extraction yet: find opportunities for learning the procedure. Perhaps you can visit a hospital or health centre where they use vacuum extraction and learn the procedure there or follow a good basic emergency obstetric and newborn care course.
- Check your workplace for a functioning vacuum extractor or convince your hospital administrator that you need such equipment.
- Regular audit of indications for caesarean section (for example once a week during morning meeting) is important to help creating awareness that caesarean sections can often be prevented by adequate management of first and second stages of labour.

For Mulago hospital doctors, midwives and administration

- More awareness of the Mulago hospital guideline for vacuum extraction is needed. This may be achieved through refresher courses for all health professionals (midwives, residents, consultants), posters in labour ward, focus group discussions to update the guideline and reach consensus, distribution of the guideline through email and online availability of the guideline.
- Change the curriculum, in such a way that it is obligatory for residents to have performed at least 20 vacuum extractions, of which the first 5-10 under supervision, before graduating as specialists. With the number of births per year in Mulago hospital, this should be possible.
- For residents: ensure that you will be able to do vacuum extractions in the hospital where you are going to work after your specialty training and teach midwives and clinicians how to use it as well.
- Administration: ensure that vacuum extraction equipment is available at all times.
- Mulago hospital could function as a "train the trainer hub" and train health professionals from other hospitals or health centres to become vacuum extraction trainers in their own place of work in and beyond Uganda.

For researchers

- Outcome of vacuum extraction in low-and middle-income countries should be published and shared to generate more evidence of the benefits of vacuum extraction in these settings.
- For research into implementation of vacuum extraction step-wedge cluster randomised trials could be a study design generating robust data without randomising

women to unnecessary caesarean section (as discussed in "methodological and ethical considerations").[50]

- For implementation programmes, it is advisable to involve teaching hospitals and the Ministry of Health when designing a programme, in order to include vacuum extraction into the general curricula of health professionals.

- Other interesting topics for research could be: long term follow-up, including future reproductive outcome after vacuum extraction compared to second-stage caesarean section and preferred/best functioning vacuum extraction instrument in low-income settings.

For inventors/technicians

- There is need for an affordable and easy-to-use vacuum extractor that can be sterilised in an autoclave.

For national associations of obstetricians and gynaecologists

- Ensure that a national guideline on the use of vacuum extraction is in place and available on the association's website.
- Consider a national guideline on indications for caesarean section if not yet in place.

For health initiative funders

- Institutional and international programmes aiming to increase use of vacuum extraction in low-and middle-income countries should be supported.

For university hospitals, medical universities and schools of midwifery

- Ensure that vacuum extraction is part of the curriculum of all doctors and midwives.

For ministries of health and other policy makers

- Allow midwives to perform vacuum extraction.

For all

- For all women in the world, who need an intervention in the second stage of labour with the fetal head at least at station 0, vacuum extraction should be the mode of birth of first choice, unless there is a contra-indication. Adhering to this recommendation will decrease caesarean section use in the second stage of labour and decrease

maternal complications including maternal death while no negative effects on neonatal outcome are expected.

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5C. 45 1h to 1h 05 2015

LS 24hr Report 31-1/6/15

Specialist

Admissions: 72

Deliveries

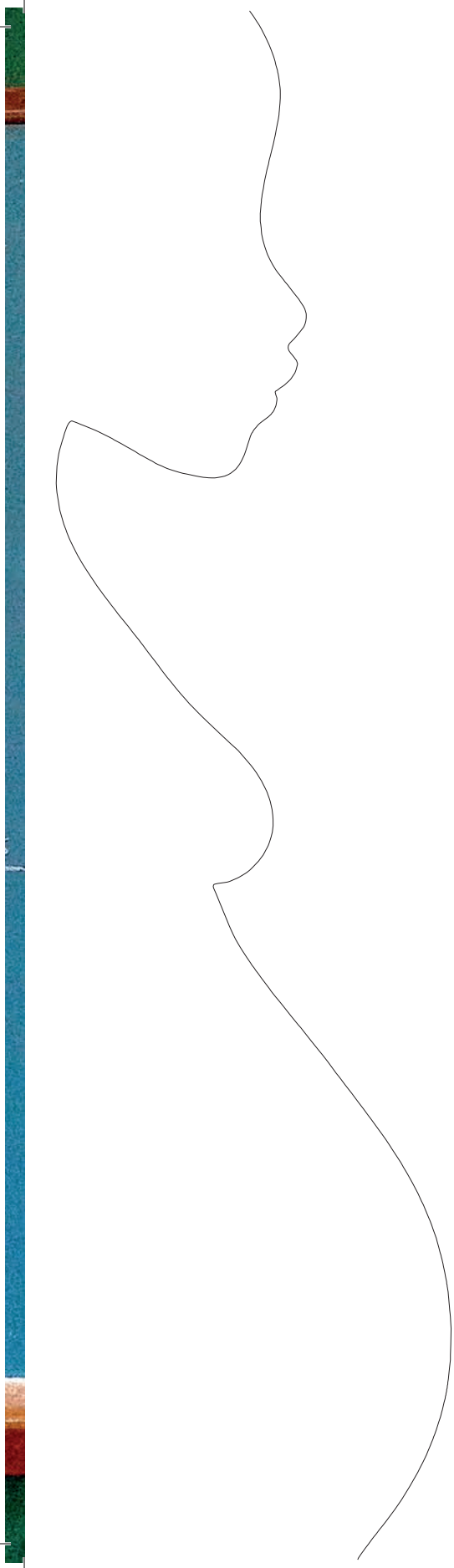
SVD - 41
C/S < Day - 11
night - 13

Laboratorny 00
Mustiple 04
Breech 00
Vaccum 08

Other categories

MSB - 00
FSB - 02
MD - 0
BBA - 1

HDU: 3
Severe PET: 1
Mild PET: 8 < 2 IUFD
6 Mild PET



CHAPTER 9

Epilogue

What happened after the end of the programme?

In January 2016, the last women came for follow-up visit and the re-implementation programme ended. Supply of equipment continued and three midwives have since been responsible for high-level disinfection. Vacuum extraction training is still present in the continuous professional training curriculum (once a year per year group) with two extra vacuum extraction training sessions per year (by the author) for residents and others who are interested.

Mulago hospital midwives continued monitoring the use of vacuum extraction. After the end of the research project the vacuum extraction rate declined from 1.9% in 2015 to 1.4% in 2016. In 2017 and 2018 it stabilised at 1.7% of births (438 and 401 vacuum extractions in 2017 and 2018 respectively) (Figure 1 and 2).

From a positive perspective, this means that vacuum extraction is still routinely used, and that many vacuum extractions continue to be performed. Residents do get (in-service) training and exposure and the vacuum extraction rate has stabilised three years after the end of the programme. Another positive finding was that residents after graduating took their skills to their new work places and continued using vacuum extraction. Some of them even brought their skills to neighbouring countries.

From a critical point of view, it is clear that the vacuum extraction rate in Mulago hospital is still low and that probably still many women who are eligible for vacuum extraction give birth by caesarean section instead (or have a delayed spontaneous vaginal birth with unfavourable neonatal or maternal outcome). So, ample room for improvement remains, as discussed in the recommendations of chapter 8.

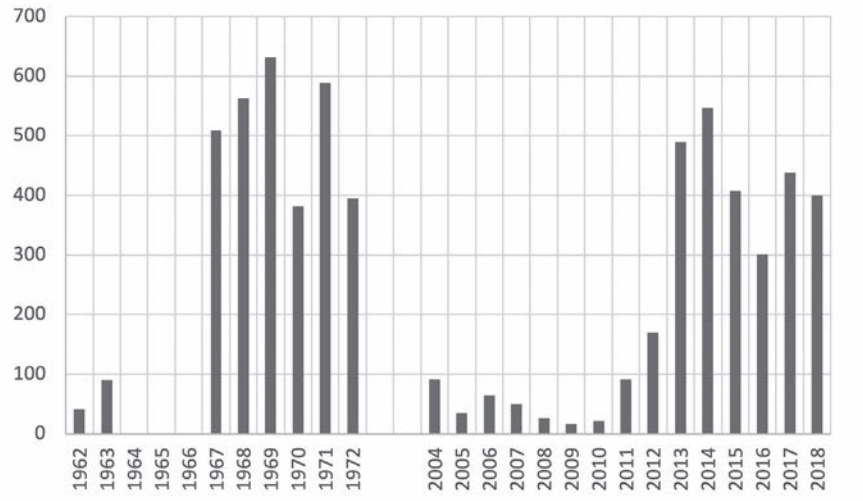


Figure 1 | Vacuum extractions per year in Mulago hospital 1962-2018

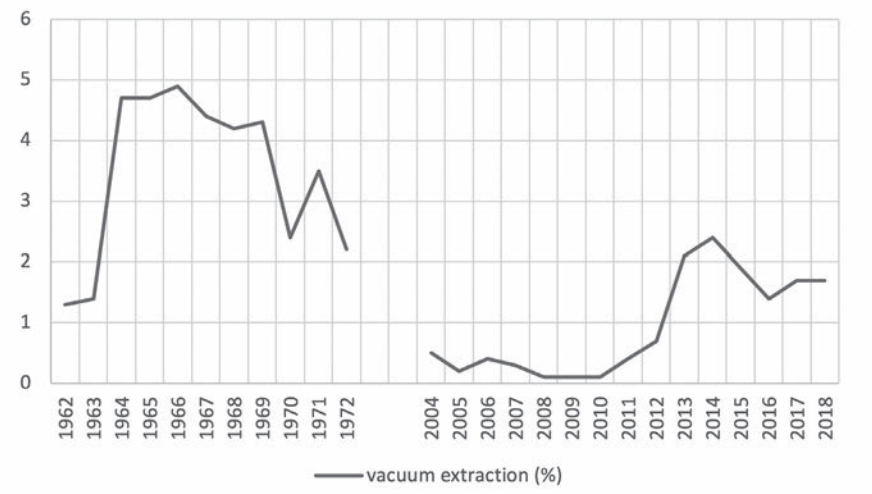


Figure 2 | Vacuum extraction rates (%) in Mulago hospital 1962-2018

The scientific aim of this thesis was to investigate whether vacuum extraction could be re-introduced in a high-volume tertiary referral hospital in Uganda and what the effects were of the re-introduction. The underlying intention was to improve maternal and perinatal outcome. We hypothesised that when vacuum extraction would be used more frequently, it could have a positive effect on these outcomes by preventing difficult second-stage caesarean sections. We hoped to prevent severe maternal complications, maternal deaths and perinatal complications.

A rough calculation with data from this thesis gives the following results:

1 Since the start of the programme in November 2012 up to the moment of writing (June 2019) 2814 births in Mulago hospital were by vacuum extraction. Assuming that all these vacuum extractions have prevented second-stage caesarean sections:
   a 2814 women would have gone home the same day, and back to work within a few weeks;
   b 2814 families would not have been confronted with the costs of caesarean section;
   c many resources in the hospital would have been saved, or used for other women; and
   d 2814 women would, without an uterine scar, have less risk during subsequent pregnancies.

   There are of course confounders, biases and perhaps some women would have given birth vaginally while awaiting caesarean section.
2 Total costs of the programme, including the studies, was 15 000 euro and this was mainly used to cover transportation costs of participating women and for research assistants. Implementation of the programme was possible on a low budget, because training and supervision were incorporated in the routine work schedule of trainers and trainees and Kiwi-Omnicups® were re-used, as described in the introduction.

3 The number of vacuum extractions needed to prevent one severe maternal complication from caesarean section (maternal death, uterine rupture in waiting time for caesarean section, hysterectomy, re-laparotomy) was 28, the number needed to prevent one maternal death was 85 (chapter 4). Assuming that all vacuum extractions have prevented second-stage caesarean sections, 101 severe maternal complications have been prevented, including 33 maternal deaths, since the start of the programme and in Mulago hospital alone.

Mulago hospital is one busy hospital with, still, a low vacuum extraction rate. Imagine the impact of a wider introduction of vacuum extraction, especially in low-income countries.

Summary

Far too many birth-related maternal and perinatal deaths still occur in low-income countries. Prolonged labour is a common cause of maternal and perinatal morbidity and mortality.[1-3] In many hospitals in the world, prolonged second stage of labour results in a (technically difficult) second-stage caesarean section with a high risk of complications, such as haemorrhage, sepsis or complications from anaesthesia. Especially in low-income countries, these complications can be life-threatening.[3] Many caesarean sections could be prevented by use of assisted vaginal birth, with vacuum extraction being the method of first choice.[4]

In Mulago hospital, the national referral hospital in Uganda, vacuum extraction was hardly used. Therefore, a programme to increase the use of vacuum extraction in this hospital was developed. The programme consisted of supply of equipment, training of staff and development of a local guideline for the use of vacuum extraction. The studies evaluating the impact of the programme resulted in this thesis.

Chapter 1 presents background information about Uganda, Mulago hospital, vacuum extraction and caesarean section. The six research questions, that form the basis of this thesis are introduced:

1 What is the impact of a programme aiming to increase the use of vacuum extraction in Mulago hospital on vacuum extraction incidence and maternal and perinatal outcome?
2 Which factors were causing the low utilisation of vacuum extraction in Mulago hospital?
3 What are health professionals' perspectives regarding vacuum extraction in Mulago hospital?
4 What are maternal and perinatal outcomes of vacuum extraction in this setting, compared to second-stage caesarean section?
5 What are women-centred outcomes of vacuum extraction, such as birthing experience, quality of life, experience of pain, sexual activity and dyspareunia in this setting, compared to second-stage caesarean section?
6 Do women in Mulago hospital consider vacuum extraction an acceptable intervention?

In **chapter 2** the implementation of the programme is described. Measurement of mode of birth, maternal and perinatal outcome before (n=12 143 births) and after (n=34 894 births) implementation was used to answer the first research question:
What is the impact of a programme aiming to increase the use of vacuum extraction in Mulago hospital on vacuum extraction incidence and maternal and perinatal outcome?

Following the training of staff and the introduction of equipment, use of vacuum extraction increased from 0.6% to 2.4% of births and an association with improved maternal and perinatal outcome was strongly suggested. The shorter decision-to-birth interval for vacuum extraction compared to caesarean section probably played an important role.

In **chapter 3**, research questions 2 and 3 are addressed, using a survey that was returned by 83 staff members of Mulago hospitals maternity unit.
Which factors were causing the low utilisation of vacuum extraction in Mulago hospital?
Lack of functioning equipment and vacuum extraction skills, as well as concerns related to neonatal outcome were factors contributing to low utilisation. Indications for use of vacuum extraction were not always recognised and contraindications incorrectly assumed.
What are health professionals' perspectives regarding vacuum extraction in Mulago hospital?
Most health professionals would prefer vacuum extraction over caesarean section for themselves or a relative in case of prolonged labour. This reflects a positive attitude towards vacuum extraction.

Chapter 4 presents the results of a prospective cohort study with six months follow-up that was conducted to answer research question 4:
What are maternal and perinatal outcomes of vacuum extraction in this setting, compared to second-stage caesarean section?
In a prospective cohort study of 783 women who gave birth by vacuum extraction (n=358) or second-stage caesarean section (n=425), substantially fewer severe maternal complications and maternal deaths occurred after vacuum extraction compared to caesarean section. Perinatal outcomes were comparable for both modes of birth.

Chapter 5 answers research question 5 about women-centred outcomes. Women in the cohort of chapter 4 were interviewed on the first day, six weeks and six months after birth.
What are women-centred outcomes of vacuum extraction, such as birthing experience, quality of life, experience of pain, sexual activity and dyspareunia in this setting, compared to second-stage caesarean section?
The majority of women were satisfied with their birthing experience after vacuum extraction. Up to six weeks after birth quality of life was better; experience of pain reduced and resumption to sexual activity occurred earlier after vacuum extraction compared to caesarean section. There was no difference in dyspareunia. At six-month follow-up, no differences between the groups existed anymore.

In **chapter 6** the women from the cohort in chapter 4 give their recommendations, answering research question 6.
Do women in Mulago hospital consider vacuum extraction an acceptable intervention?
The majority of women recommend vacuum extraction over caesarean section in case of prolonged second stage of labour. Based on these findings, and the findings in chapter 5, vacuum extraction seems to be an acceptable intervention to women in this setting.

Chapter 7 consists of a commentary in Lancet Global Health entitled '*Use of assisted vaginal birth to reduce unnecessary caesarean sections and improve maternal and perinatal outcomes*'. It was written by eight international obstetricians and global health specialists. The message of the commentary is: Re-introduction of vacuum extraction in low-income countries can play a major role in the prevention of mortality and morbidity related to prolonged labour and the reduction of unnecessary caesarean section in the second stage of labour. Broad re-introduction of vacuum extraction is recommended.

Chapter 8 is the general discussion of the thesis. The findings of all previous chapters are summarised and put into broader perspective. The chapter ends with the conclusion and recommendations of this thesis.

Conclusion

Our studies showed that (re)implementation of vacuum extraction in a high-volume university hospital in a low-income country was successful. What was mainly needed was skills training and provision of equipment. Health professionals generally had a positive attitude towards vacuum extraction and women preferred the intervention over caesarean section. Maternal outcome of vacuum extraction was substantially better than that of caesarean section. Decision-to-birth interval was shorter for vacuum extraction compared to caesarean section and intrauterine fetal death during waiting time for intervention higher in births by caesarean section. Severe neonatal trauma and brain damage were infrequent regardless to the mode of birth. Overall perinatal outcome was comparable. As vacuum extraction prevents women from having a uterine scar, long-term reproductive outcomes after vacuum extraction are expected to be better compared to caesarean section: less uterine rupture, less abnormal placentation, resulting in less maternal morbidity and mortality from haemorrhage and better perinatal outcome.

Recommendations

For all women in the world, who need an intervention in the second stage of labour with the fetal head at least at station 0, vacuum extraction should be the mode of birth of first choice, unless there is a contra-indication. Adhering to this recommendation will decrease caesarean section use in the second stage of labour and decrease maternal complications including maternal death while no negative effects on neonatal outcome are expected. It is therefore of utmost importance to initiate, promote and support international and institutional efforts to work towards the re-implementation of vacuum extraction.

In **chapter 9**, the epilogue, is described what happened in Mulago hospital after the end of the studies. It presents a rough calculation of how many severe complications might have been prevented since the start of the programme.

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2 Pattinson RC, Vannevel V, Barnard D, et al. Failure to perform assisted deliveries is resulting in an increased neonatal and maternal morbidity and mortality: an expert opinion. S Afr Med J 2018; 108: 75–78.
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Samenvatting

Er overlijden nog veel te veel vrouwen en baby's tijdens of vlak na de bevalling, vooral in lage inkomenslanden. Een belangrijke oorzaak van maternale en perinatale morbiditeit en mortaliteit is een niet vorderende baring.[1-3] Wereldwijd leidt in veel ziekenhuizen een niet vorderende uitdrijving tot een (technisch moeilijke) sectio bij volledige ontsluiting, met een hoog risico op complicaties zoals veel bloedverlies, sepsis of complicaties van de anesthesie. Vooral in lage inkomenslanden kunnen deze complicaties levensbedreigend zijn.[3] Veel sectio's zouden voorkomen kunnen worden als een kunstverlossing uitgevoerd zou worden, waarbij vacuümextractie de voorkeur heeft.[4]

In Mulago hospital, een groot derdelijns universiteitsziekenhuis in Oeganda, werd vacuümextractie nauwelijks gebruikt. Er werd een programma ontwikkeld om het gebruik van vacuümextractie te doen toenemen. Het programma bestond uit het verstrekken van vacuümextractors, training van het personeel en het ontwikkelen van een lokaal protocol voor het gebruik van vacuümextractie. De studies die werden uitgevoerd om het effect van het programma te meten resulteerden in dit proefschrift.

In **hoofdstuk 1** wordt achtergrond informatie gegeven over Oeganda, Mulago hospital, vacuümextractie en de sectio caesarea. Ook worden de zes onderzoeksvragen gepresenteerd, die de basis vormden voor dit proefschrift:

1 Wat is het effect van het programma -met als doel het gebruik van vacuümextractie te doen toenemen in Mulago hospital- op het gebruik van vacuümextractie en op maternale en perinatale uitkomsten?
2 Welke factoren veroorzaakten dat vacuümextractie zo weinig gebruikt werd in Mulago hospital?
3 Wat vinden artsen en verloskundigen in Mulago hospital van vacuümextractie?
4 Wat zijn de maternale en perinatale uitkomsten van vacuümextractie in dit ziekenhuis, vergeleken met uitkomsten na sectio bij volledige ontsluiting?
5 Wat zijn de zijn de effecten van vacuümextractie op de moeder, zoals tevredenheid over de bevalling, kwaliteit van leven, pijnbeleving, seksueel functioneren en dyspareunie, vergeleken met uitkomsten na sectio bij volledige ontsluiting?
6 Vinden vrouwen in Mulago hospital vacuümextractie een acceptabele interventie?

In **hoofdstuk 2** wordt de implementatie van het programma beschreven. Om de eerste onderzoeksvraag te beantwoorden werden de wijze van bevallen en maternale en perinatale uitkomsten van 12 143 geboorten voor de start van het programma vergeleken met 34 894 geboorten na de start van het programma:
Wat is het effect van het programma -met als doel het gebruik van vacuümextractie te doen toenemen in Mulago hospital- op het gebruik van vacuümextractie en op maternale en perinatale uitkomsten?

Na het verstrekken van vacuümextractors en het trainen van het personeel nam het gebruik van vacuümextractie toe van 0.6% naar 2.4% van alle geboorten en er was een sterk vermoeden op een associatie met verbeterde maternale en perinatale uitkomsten. De kortere tijdsduur tussen besluit tot interventie en geboortetijdstip speelde waarschijnlijk een belangrijke rol.

In **hoofdstuk 3** worden onderzoeksvraag 2 en 3 onderzocht, middels een vragenlijst die door 83 personeelsleden van de verloskunde afdeling van Mulago hospital werden ingevuld.
Welke factoren veroorzaakten dat vacuümextractie zo weinig gebruikt werd in Mulago hospital?
Een tekort aan functionerende vacuümextractors en een gebrek aan vaardigheden op het gebied van vacuümextractie, maar ook bezorgdheid over neonatale uitkomsten waren factoren die bijdroegen aan het spaarzame gebruik van vacuümextractie. Indicaties voor vacuümextractie werden niet altijd herkend en contra-indicaties ten onrechte verondersteld.
Wat vinden artsen en verloskundigen in Mulago hospital van vacuümextractie?
In het geval van niet vorderende uitdrijving zouden de meeste artsen en verloskundigen vacuümextractie boven een sectio verkiezen voor zichzelf of een familielid. Dit weerspiegelt een positieve houding tegenover vacuümextractie.

In **hoofdstuk 4** worden de uitkomsten van een prospectieve cohort studie met zes maanden follow-up gepresenteerd, die werd uitgevoerd om onderzoeksvraag 4 te beantwoorden:
Wat zijn de maternale en perinatale uitkomsten van vacuümextractie in dit ziekenhuis, vergeleken met uitkomsten na sectio bij volledige ontsluiting?
In een prospectief cohort van 783 vrouwen die bevielen met behulp van vacuümextractie (358) of sectio bij volledige ontsluiting (425), werden substantieel minder maternale complicaties -inclusief maternale sterfte- gezien na vacuümextractie vergeleken met na een sectio. Perinatale uitkomsten waren vergelijkbaar voor de groepen.

Hoofdstuk 5 beantwoordt onderzoeksvraag 5 over effecten van vacuümextractie op de moeder. Vrouwen in het cohort van hoofdstuk 4 werden geïnterviewd op de eerste dag, zes weken en zes maanden na de bevalling.
Wat zijn de effecten van vacuümextractie op de moeder, zoals tevredenheid over de bevalling, kwaliteit van leven, pijnbeleving, seksueel functioneren en dyspareunie, vergeleken met uitkomsten na sectio bij volledige ontsluiting?
De meerderheid van de vrouwen was tevreden over haar bevalling na vacuümextractie. Tot zes weken na de bevalling was de kwaliteit van leven beter; pijn was minder en vrouwen die met behulp van vacuümextractie waren bevallen, werden sneller weer seksueel actief dan vrouwen die een sectio hadden gehad. Er was geen verschil in dyspareunie. Na zes maanden follow-up was er geen verschil meer tussen de groepen.

In **hoofdstuk 6** geven de vrouwen uit het cohort van hoofdstuk 4 hun advies over de manier van bevallen bij niet vorderende uitdrijving. Hiermee geven zij een antwoord op onderzoeksvraag 6:
Vinden vrouwen in Mulago hospital vacuümextractie een acceptabele interventie?
De meerderheid van de vrouwen raadt vacuümextractie aan in het geval van niet vorderende uitdrijving. Gebaseerd op deze bevindingen en de bevindingen uit hoofdstuk 5, lijkt vacuümextractie een acceptabele interventie voor vrouwen in dit ziekenhuis.

Hoofdstuk 7 is een commentaar getiteld: "*Het gebruik van de kunstverlossing om onnodige sectio's te voorkomen en maternale en perinatale uitkomsten te verbeteren*." Het is geschreven door acht internationale obstetrici en 'global-health' specialisten. De boodschap van het commentaar is: re-introductie van vacuümextractie in lage inkomenslanden kan een belangrijke rol spelen in de preventie van mortaliteit en morbiditeit gerelateerd aan niet vorderende baring en het terugdringen van onnodige sectio's bij volledige ontsluiting. Grootschalige introductie van vacuümextractie wordt aangeraden.

Hoofdstuk 8 is de algemene discussie van dit proefschrift. De bevindingen van alle voorgaande hoofdstukken worden samengevat en in een breder perspectief bediscussieerd. Het hoofdstuk eindigt met de **conclusie** en **aanbevelingen**.

Conclusie
Onze studies laten zien dat (re)implementatie van vacuümextractie in een groot universiteitsziekenhuis in Oeganda succesvol was. Wat vooral nodig was waren vaardigheidstraining en vacuümextractors. Artsen en verloskundigen hadden over het algemeen een positieve houding tegenover vacuümextractie en vrouwen raadden vacuümextractie meer aan dan een sectio. Maternale uitkomsten na vacuümextractie waren substantieel beter dan na een sectio. De tijd tussen de beslissing tot interventie en geboortetijdstip was korter voor vacuümextractie vergeleken met sectio en foetale sterfte tijdens de wachttijd voor de interventie was hoger voor een sectio. Ernstig neonataal trauma en hersenschade kwam zelden voor, onafhankelijk van de manier van bevallen. Perinatale uitkomsten waren vergelijkbaar. Omdat vacuümextractie een litteken in de uterus voorkomt, is de verwachting dat lange termijn uitkomsten gunstiger zijn na vacuümextractie dan na sectio: minder uterusrupturen, minder abnormale placentatie en daardoor minder maternale morbiditeit en mortaliteit door bloedingen en betere perinatale uitkomsten.

Aanbevelingen
Voor alle vrouwen ter wereld, die een interventie nodig hebben tijdens de uitdrijvingsfase van de bevalling en waarbij het foetale hoofd is ingedaald tot minimaal Hodge 3, zou vacuümextractie de eerste keus interventie moeten zijn, tenzij er een contra-indicatie is. Dit zal het gebruik van sectio bij volledige ontsluiting doen afnemen, alsmede maternale complicaties, inclusief maternale sterfte, terwijl er geen negatief effect wordt

verwacht op neonatale uitkomsten. Het is daarom belangrijk om projecten gericht op re-implementatie van vacuümextractie te starten, te promoten en te ondersteunen.

In **hoofdstuk 9**, epiloog, wordt beschreven wat er in Mulago hospital gebeurde nadat de studies waren afgelopen. Ook wordt een ruwe schatting gemaakt van het aantal ernstige complicaties dat mogelijk voorkomen is sinds de start van het programma.

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Weebale nnyo!

Weebale nnyo! Thank you! Heel erg bedankt! Participating women in the studies; inspirators, supervisors and co-authors: Jos van Roosmalen, Thomas van den Akker, John Lule, Josaphat Byamugisha, Flavia Namiiro, Sulphine Twinomuhangi, Manuela Capelle, Glen Mola, Arfang Faye; research assistants: Tamar, Editor, Margareth, Mary, Rose, Regina, Christine, Ronald, Hadijah; 5-year follow-up study: Assen Kamwesigye, Jolly Beyeza, Herbert Kayiga; Mulago directorate of Obstetrics and Gynaecology: lecturers and consultants, with special thanks to Annettee Nakimuli, Eveline Nabunya, Peter Ntuyo, Imelda Namagembe, Eve Nakabembe, Felicia Lester, Mulago midwives; Mulago SHO's, with special thanks to vacuum extraction champions: Neema Nassolo, Irene Chebet, James Nabaasa, John Bosco Nsubuga, Muteke Kasereka, Joshua Ssebuliba, and many others; Mulago records department: Joseph, Joseph, Pheabarah; Mulago Maureen and "Teddy"; Stichting Mulago Mama: Maaike Hoekstra, Bertho Nieboer, Irma Baltes, Marlieke Klene; Mulago visitors: Cecile, Anneke, Caroline, Madeleine, Evelien, Anne, Andrea; Training for Life; paranymphs: John Lule, Maaike Hoekstra; leescommissie: Jelle Stekelenburg, Guid Oei, Griet Vandenberghe, Hanneke de Vries, Fedde Scheele; statistics: Ina Mulder; funding: Otto Kranendonkfonds, Stichting Mulago Mama, werkgroep Safe Motherhood; Kiwi's: Kiwi-sparende ziekenhuizen, Ross McQuivey; Uganda B&B: Maurits, Anneke, Stijn, Sjoerd, SolarNow; Inspiration: PhD-nerd friends, Tienke, Abera, Anke, Wouter, Rob, Steffie, Kim, Marieke, Tanneke, Andrea, Lachmi, Manuela, Fleur, Holland-house friends; CWZ maatjes: Daniela, Chantal, Jackie, Karin, Cathelijne, Inge, Marc, Jan en oud maatjes Jan, Ton; vacuümextractie onderzoek CWZ: Lotte Hamel; CWZ arts-assistenten, verloskundigen, verpleegkundigen en andere collega's; lieve familie: papa, mama, Jan-Paul, Sabine, Hester, Tommie, Sofie, Olivia, Floris, Juliette, Philine; en lieve schoonfamilie: Betty, Wim, Elvira, Jan-Philip, Jeroen, Lian, Roderick, Philine, Friso; extended family: Els, Fidel, Dagmar, Thymen, Fleur, Gijs, Maaike, Ed, Floor, Sara; mijn lieve thuis: Willem, Thijs, Floortje, Bas

Curriculum Vitae

Als eerste kind van Yvonne Bugter en Paul van der Horst werd Barbara geboren op 20 februari 1973 te Enschede. Volgens haar moeder was het een spontane en vooral ook onverwachte thuisbevalling, na een zwangerschap van 33 weken. Barbara werd per ambulance naar het ziekenhuis gebracht en haar vader ging er op de brommer achteraan. De kersverse moeder werd thuis achtergelaten.

Samen met haar broertje Jan-Paul en zusje Sabine groeide Barbara op in Borculo. Zij behaalde het eindexamen VWO aan de Rijks scholengemeenschap te Lochem. Vervolgens studeerde zij vanaf 1991 Geneeskunde aan de Rijksuniversiteit Groningen. Op de eerste dag in deze studentenstad ontmoette ze haar huidige echtgenoot, Willem Nolens. Na coschappen in het Medisch Spectrum Twente en stages in Zuid-Afrika en Zambia, slaagde ze in 1998 cum laude voor haar artsexamen.

Na het afsluitende coschap verloskunde en gynaecologie in het University teaching hospital in Lusaka, Zambia, wist Barbara wat zij wilde gaan doen: tropenarts worden en zich inzetten voor 'Safe motherhood'. Van 1998 tot 2001 volgde ze de opleiding tot tropenarts (chirurgie in het Meander medisch centrum Amersfoort; kindergeneeskunde in het St. Elisabeth hospitaal, Curaçao, verloskunde/gynaecologie in het Maasstad ziekenhuis, Rotterdam).

Hierna vertrokken Willem en Barbara naar Accra, Ghana waar zij drie jaar werkten, Barbara in Ridge hospital en een verloskunde kliniek van het Leger des heils. In 2005 begon Barbara aan de opleiding tot gynaecoloog (Catharina ziekenhuis, Eindhoven; Radboudumc en Canisius-Wilhelmina ziekenhuis, Nijmegen).

In 2012 werd de opleiding tot gynaecoloog afgerond en vertrok het gezin Nolens, inmiddels uitgebreid met Thijs (2002), Floortje (2004) en Bas (2007) naar Kampala, Oeganda. De periode in Mulago hospital (2012-2015) staat beschreven in dit proefschrift.

Sinds haar terugkeer in Nederland (juli 2015) werkt Barbara als gynaecoloog in het Canisius-Wilhelmina ziekenhuis te Nijmegen en als promovendus aan de Vrije universiteit, Amsterdam. Ze woont met haar gezin, hond, 7 kippen en 60 000 bijen in Millingen aan de Rijn.

The Safe Motherhood Series

The Dutch Working Party 'International Safe Motherhood and Reproductive Health' aims to contribute to improvement of the reproductive health status of women around the globe, in particular by collaborating with local health workers (http://www.safemotherhood.nl). The Working Party is part of both the Dutch Society of Obstetrics and Gynaecology (NVOG) and the Dutch Society for International Health and Tropical Medicine (NVTG). The activities that are undertaken under the umbrella of the Working Party can be grouped into four pillars: education, patient care, research and advocacy.

Research activities are undertaken by (medical) students, Medical Doctors International Health and Tropical Medicine and many others. Some research activities develop into PhD-trajectories. PhD- candidates all over the world, Dutch and non-Dutch, work on finding locally acceptable and achievable ways to improve the quality of maternal health services, supervised by different members of the Working Party. Professor Jos van Roosmalen initiated the Safe Motherhood Series, which started in 1995.

The Safe Motherhood Series

- Safe motherhood: The role of oral (methyl)ergometrin in the prevention of postpartum haemorrhage. (Akosua N.J.A. de Groot), Nijmegen, 1995
- Safe motherhood: Perinatal assessment in rural Tanzania. (Gijs E.L. Walraven), Nijmegen, 1995
- Safe motherhood: Confidential enquiries into Maternal Deaths in the Netherlands, 1983-1992. (Nico W.E. Schuitemaker), Leiden, 1998
- Safe motherhood: Confidential enquiries into Maternal Deaths in Surinam. (Ashok S. Mungra), Leiden, 1999
- Safe motherhood: Reproductive health matters in rural Ghana. (Diederike W. Geelhoed), Leiden, 2003
- Safe Motherhood: Vaginal birth after caesarean section in Zimbabwe and The Netherlands (Wilbert A. Spaans), Amsterdam AMC, 2004
- Safe Motherhood and Health systems research: Health care seeking behaviour and utilisation of health services in Kalabo District (Jelle Stekelenburg), VU University Medical Centre, Amsterdam, 2004
- Safe Motherhood. Enhancing survival of mothers and their newborns in Tanzania (Godfrey Mbaruku), Karolinska Institute, Stockholm, Sweden, 2005
- Safe Motherhood. Beyond the numbers: confidential enquiries into maternal deaths in Accra- Ghana (Afisah Yakubu Zakariah, Accra, Ghana), Vrije Universiteit Brussel, Belgie, 2008
- Safe Motherhood. Severe maternal morbidity in the Netherlands: the LEMMoN study (Joost Zwart), Leiden University Medical Centre, the Netherlands, 2009
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- Delay in Safe Motherhood (Luc van Lonkhuijzen), University Medical Centre Groningen, the Netherlands, 2011
- Safe Motherhood: Medical Mirrors: Maternal care in a Malawian district (Thomas van den Akker), VU University Medical Centre, Amsterdam, the Netherlands, 2012

- Safe Motherhood: Leading change in the maternal health care system in Tanzania: application of operations research (Angelo Nyamtema, Ifakara, Tanzania), VU University Medical Center, Amsterdam, the Netherlands, 2012
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- Safe Motherhood:Re-introduction of vacuum extraction in a tertiary referral hospital in Uganda (Barbara Nolens), VU University Amsterdam

Pictures

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Cover
Mother and baby in Mulago hospital

Chapter 1
Mulago hospital

Chapter 2
Residents attending vacuum extraction skills training

Chapter 3
Residents attending vacuum extraction skills training

Chapter 4
Infant is weighed during follow-up visit

Chapter 5
One of the research assistants with her baby

Chapter 6
Mother and baby at follow-up visit

Chapter 7
Midwives attending vacuum extraction skills training

Chapter 8
Trolley with on top Bird cups, flexible cups and tubing in sterile box, middle: electrical vacuum pump, bottom: Kiwi-Omnicup vacuum extractors (in sterile box, normally covered).

Chapter 9
Morning report in Mulago hospital. There were 41 vaginal births, 24 caesarean sections and eight women who gave birth by vacuum extraction in the past 24 hours.