Reintroduction of vacuum extraction in a tertiary referral hospital in Uganda

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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.

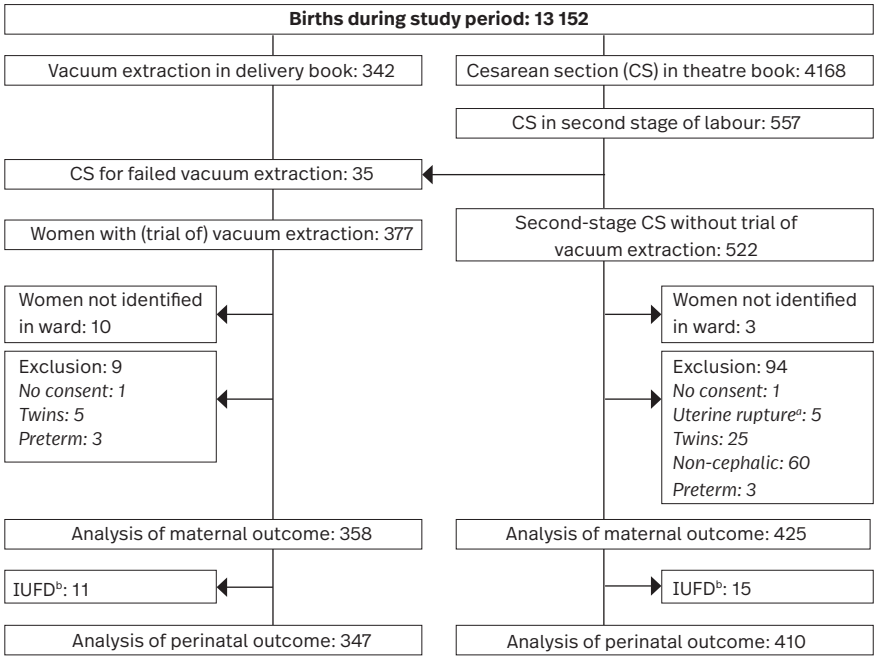

Figure 1 | Inclusion process
CS, caesarean section; IUFD, intrauterine fetal death; [a]Uterine rupture before decision to do second-stage CS; [b]Intrauterine fetal death before decision to do vacuum extraction or caesarean section

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.*