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

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Abstract

Objective: To compare maternal and perinatal outcomes between vacuum extraction and second-stage cesarean delivery (SSCD).

Methods: The present observational cohort study was conducted among women with term vertex singleton pregnancies who underwent vacuum extraction or SSCD at Mulago National Referral Hospital, Kampala, Uganda, between November 25, 2014, and July 8, 2015. Severe maternal outcomes (mortality, uterine rupture, hysterectomy, re-laparotomy) and perinatal outcomes (mortality, trauma, low Apgar score, convulsions) were compared between initial delivery mode.

Results: Among 13 152 deliveries, 358 women who underwent vacuum extraction and 425 women who underwent SSCD were enrolled in the study. No maternal deaths occurred after vacuum extraction versus five deaths from complications of SSCD. Vacuum extraction was associated with less severe maternal outcomes compared with SSCD (3 [0.8%] vs 18 [4.2%]; adjusted odds ratio [aOR] 0.24, 95% confidence interval [CI] 0.07–0.84). Fetal death during the decision-to-delivery interval was also less common in the vacuum extraction group (3 [0.9%] vs 18 [4.4%]; aOR 0.24, 95% CI 0.07–0.84); however, the perinatal mortality rate did not differ between the vacuum extraction and SSCD groups (29 [8.4%] vs 45 [11.0%], respectively; aOR 0.83, 95% CI 0.49–1.41). One infant in each group exhibited neurodevelopmental anomalies at 6 months.

Conclusion: Vacuum extraction had better maternal outcomes and equivalent perinatal outcomes compared with SSCD. These findings encourage re-introduction of vacuum extraction.

KEYWORDS

Cesarean delivery; Instrumental delivery; Maternal morbidity; Maternal mortality; Neonatal morbidity; Perinatal mortality; Vacuum extraction; Ventouse delivery

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1 | 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 (LMICs).^{1,2}

Vacuum extraction is an evidence-based intervention that is used to shorten the second stage of labor. Indications for this approach include fetal distress, prolonged second stage of labor, maternal exhaustion, or the need to avoid expulsive efforts among women with conditions such as heart failure or severe anemia.^{3,4} Although vacuum extraction can reduce maternal mortality from hemorrhage and sepsis—as well as perinatal mortality from birth asphyxia—use of this method has almost disappeared from obstetric practice in many LMICs.^{5–8} One study⁶ found that instrumental vaginal delivery was not used in almost half of 1728 Sub-Saharan African hospitals, with usage rates below 1% in the remaining centers. 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 LMICs undergo avoidable cesarean delivery.⁹

The use of cesarean delivery, especially when performed during the second stage of labor, increases the risks of hemorrhage 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 deliveries happen outside healthcare facilities; access to safe surgery and anesthesia 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 cesarean delivery is avoided.^{16–18}

Published literature regarding outcomes of vacuum extraction among LMICs 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 hypothesized to reduce maternal morbidity, perinatal morbidity, and the decision-to-delivery interval (DDI) when compared with second-stage cesarean delivery (SSCD).¹² The aim of the present study was to test this hypothesis among pregnant women attending Mulago National Referral Hospital.

2 | MATERIALS AND METHODS

The present prospective observational cohort study was conducted among women undergoing vacuum extraction or SSCD in the main labor ward of Mulago National Referral Hospital between November 25, 2014, and July 8, 2015. Women with a term singleton pregnancy in vertex presentation who delivered by vacuum extraction or SSCD at the study center were included, as were those who developed a ruptured uterus while in the second stage of labor and waiting for the intervention. Women

who experienced a ruptured uterus before the decision for intervention (vacuum extraction or SSCD) 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 National Referral Hospital is a university teaching and government hospital with 2700 beds and greater than 31 000 deliveries recorded annually. It is the main training center for midwives, medical doctors, and obstetricians in the country. The maternity unit has an operating theater, which is accessible 24 hours per day. Vacuum extraction and cesarean delivery are performed by residents (50 trainee obstetricians at the center, with 5–7 on labor wards) with or without supervision, depending on experience, and specialist obstetricians (40 at the center, with 1–3 on labor wards). All doctors are trained in performing vacuum extraction and cesarean delivery; however, cesarean delivery is undertaken more frequently than vacuum extraction (approximately 20 cesarean deliveries per day compared with one or two vacuum extractions per day at the study center). Although vacuum extraction is used regularly, and the hospital has a protocol with indications, the decision regarding mode of delivery depends not only on clinical factors but also on the doctor's personal preference and expertise, as well as the availability of theater and vacuum equipment. Many women undergoing cesarean delivery at Mulago National Referral Hospital could be eligible for vacuum extraction.^{7,12}

The vacuum equipment used at this center 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 LMICs.⁶ Spinal anesthesia during cesarean delivery is provided by anesthetic nurses or anesthesiologists. An obstetric high dependency unit is available where women are monitored and given oxygen. 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. Delivery is free of charge, except in the private ward.

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

Data were extracted from the participants' medical records. Indications for SSCD and vacuum extraction were classified as "delay", "fetal distress", "maternal", and "other" (Table S1). The women were also 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 6 weeks and 6 months after delivery. During these visits, women were interviewed using semistructured 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 hemorrhage (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 cesarean (or forceps) delivery was analyzed as part of the outcome of vacuum extraction, as this was the intended mode of delivery.

The data were collated using Excel 2013 (Microsoft, Redmond, WA, USA) and analyzed using SPSS version 24 (IBM, Armonk, NY, USA). Baseline characteristics were reported as numbers with percentages, with *P* values calculated using a two-sided χ^2 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 (ORs) and, for primary outcomes, adjusted (multivariate) ORs with 95% confidence intervals (CIs). A multivariate logistic regression model to calculate adjusted ORs (aORs) was constructed to adjust for potential confounders. Factors were tested one by one, stratified for mode of delivery, 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.

3 | RESULTS

Among the 13 152 deliveries 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 SSCD. The inclusion process is outlined in Figure 1. The vacuum extraction and SSCD groups used to analyze maternal outcomes comprised 358 and 425 women, respectively.

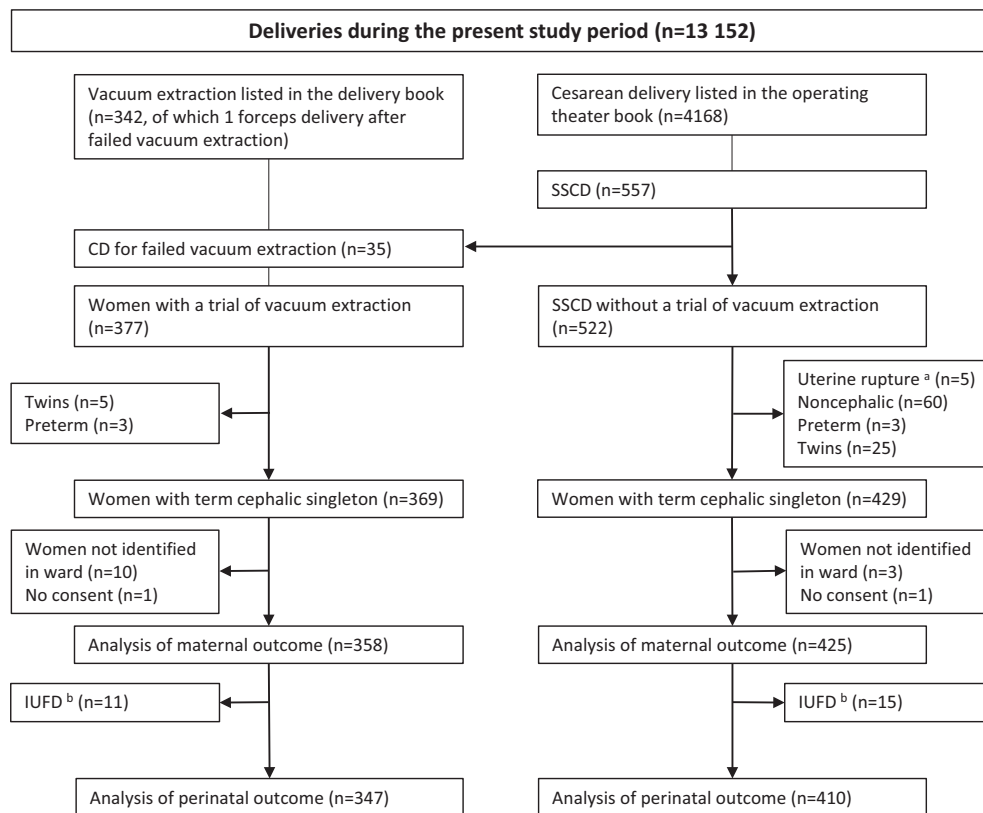


FIGURE 1 Flowchart of the study participation. Abbreviations: CD, cesarean delivery; SSCD, second stage cesarean delivery; IUFD, intrauterine fetal death. ^a Uterine rupture occurred before the decision to perform SSCD. ^b IUFD occurred before the decision to perform vacuum extraction or second-stage cesarean delivery.

In all, 36 (9.5%) women experienced a failed vacuum extraction: 35 of these women delivered by cesarean delivery and one by forceps. These 36 women were analyzed 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 SSCD groups used to analyze perinatal outcomes comprised 347 and 410 women, respectively.

Baseline characteristics of the participants are shown in Table 1. More women in the SSCD group had a previous cesarean delivery, delivered a neonate weighing more than 4000 g, were in second stage of labor 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.

Maternal outcomes at hospital discharge are shown in Table 2. In all, 5 (1.2%) maternal deaths during the first 6 weeks after delivery were found for the SSCD 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 SSCD group occurred among women who underwent the procedure for prolonged labor. 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 5 months after delivery following an episode of fever; however, this event was unlikely to be related to mode of delivery.

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 SSCD (OR 0.19, 95% CI 0.06–0.65). The aOR was 0.24 (95% CI 0.07–0.84; $P=0.026$) (Table S5). The NNT to prevent one severe maternal adverse event during or after SSCD 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 SSCD 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 SSCD group ($P=0.001$) (Table 2).

TABLE 1 Baseline characteristics of the participants.^{a,b}

Characteristic	Vacuum extraction (n=358)	Second-stage cesarean delivery (n=425)	P value ^c
Maternal			
Nulliparous	201/352 (57.1)	215/425 (50.6)	0.070
Age <20 y	84/353 (23.8)	91/424 (21.5)	0.438
Education ≤6 y	86/349 (24.6)	105/413 (25.4)	0.804
Previous cesarean delivery	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
Delivery weight >4000 g	10/353 (2.8)	32/420 (7.6)	0.003
Labor and delivery factors^e			
Referral	153/349 (43.8)	208/423 (49.2)	0.139
In second stage of labor 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

^aValues are given as number/number of women or neonates with available data for this characteristic (percentage) unless indicated otherwise.

^bMissing data are specified in Table S3.

^cP values were calculated using a two-sided χ^2 test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was $P<0.05$.

^dOccurred before the decision to perform second-stage cesarean delivery or vacuum extraction.

^eMore than one indication could apply.

Maternal follow-up rates at 6 weeks after delivery were 79% for the vacuum extraction group and 87% for the SSCD group (Fig. S1). Maternal infection and urogenital tract injuries that had occurred after vacuum extraction or SSCD 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 SSCD; the OR was 0.19 (95% CI 0.10–0.39; $P < 0.001$). An obstetric fistula after failed vacuum extraction and subsequent cesarean delivery was recorded in 1 (0.4%) woman, and 4 women (1.1%) developed an obstetric fistula after SSCD ($P = 0.393$). Urine incontinence was present in 6 women (2.1%) after vacuum extraction and in 9 women (2.5%) after SSCD ($P = 0.766$).

As shown in Table 4, perinatal death was recorded in similar numbers of neonates in the vacuum extraction and SSCD 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 SSCD ($P = 0.048$) (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 in SSCD (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 Wiechen²²) and one (who had dislocation of a leg) according to maternal report by telephone (Table S8). After SSCD, 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 delivery), 68 (91.9%) had birth asphyxia as the only identifiable cause of death (Table S9).

DDI data are outlined in Table 4. The median DDIs were 25 minutes for successful vacuum extraction; 97 minutes for failed vacuum extraction; and 144 minutes for SSCD. During the DDI, 3 (0.9%) fetal deaths occurred in the vacuum extraction group compared with 18 (4.4%) in the SSCD 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).

TABLE 2 Maternal outcome at hospital discharge.^{a,b}

Outcome	Vacuum extraction (n=358)	Second-stage cesarean delivery (n=425)	OR (95% CI) ^c	P value ^d
Maternal mortality	0	5 (1.2)	NA	0.066
Severe maternal outcome ^e	3 (0.8)	18 (4.2)	0.19 (0.06–0.65)	0.003
Postpartum hemorrhage				
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	0.095
Anal sphincter rupture	3 (0.8)	0	NA	0.095
Operation during hospital admission				
Hysterectomy	1 (0.3)	4 (0.9)	0.30 (0.03–2.65)	0.383
Relaparotomy ^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, d				
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

Abbreviations: OR, odds ratio; CI, confidence interval; NA, not applicable.

^aValues are given as number (percentage) unless indicated otherwise.

^bMore than one adverse event could apply.

^cORs and 95% CIs were calculated using univariate logistic regression analysis. Calculations of adjusted OR's are shown in Table S5.

^dP values were calculated using a two-sided χ^2 test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was $P < 0.05$.

^eDeath, uterine rupture, hysterectomy, or relaparotomy.

^fRelaparotomy after cesarean delivery or laparotomy after vacuum extraction.

TABLE 3 Maternal infection and urogenital tract injury at 6 wk of follow-up.^{a,b}

Outcome	Vacuum extraction (n=284)	Second-stage cesarean delivery (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	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 wk	6 (2.1)	9 (2.5)	0.85 (0.30–2.43)	0.766
Fecal incontinence ≥6 wk	0	0	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	>0.99

Abbreviations: OR, odds ratio; CI, confidence interval; NA, not applicable.

^aValues are given as number (percentage) unless indicated otherwise.

^bMore than one adverse event could apply.

^cORs and 95% CIs were calculated using univariate logistic regression analysis.

^dP values calculated using a two-sided χ^2 test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was $P < 0.05$.

^eInfection of the operation wound or perineum.

^fObstetric fistula in the vacuum extraction group occurred following failed vacuum extraction and subsequent cesarean delivery.

^gThese operations were performed on re-admission and are not included in Table 2.

As shown in Figure S2, neonatal and infant follow-up rates were 82% after vacuum extraction and 89% after SSCD. The rates at 6 months were 79% and 83%, respectively.

After 6 months, 39 of 347 (11.2%) infants in the vacuum extraction group and 51 of 410 (12.4%) infants in the SSCD 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 6-month follow-up, 131 infants in the vacuum extraction group and 107 infants in the SSCD 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 6-month follow-up consultation; 10 in the vacuum extraction group and four in the SSCD group. All of these infants had negative HIV polymerase chain reaction test results at 6 weeks after delivery. The mothers of these infants had received antiretroviral therapy during pregnancy.

Of the 140 study participants with one or more previous cesarean deliveries, 65 (46.4%) were admitted to hospital during the second stage of labor. Of the 33 women with two or more previous cesarean deliveries, 23 (69.7%) were in the second stage of labor on admission; of these patients, two delivered by vacuum extraction and 21 underwent SSCD. Of the 358 women who underwent vacuum extraction, 79 (22.1%) had been expected to undergo SSCD; however, while waiting for theater 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 SSCD were comparable to those of the vacuum extraction group as a whole.

4 | DISCUSSION

The present study found fewer maternal complications after vacuum extraction than after SSCD, whereas perinatal outcomes were comparable for the two groups. Severe neonatal trauma and brain damage were infrequent regardless of the mode of delivery. The risk of severe maternal complications—including death—during or after SSCD 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 SSCD carries an increased risk of maternal adverse events.^{3,5,12} Indeed, one study found maternal and neonatal mortality to be higher following cesarean delivery compared with vaginal, especially in African countries.²⁴

The present study found no maternal deaths after vacuum extraction but five after SSCD. Although this observation did not reach statistical significance, it is suggested here that this is highly relevant and probably not random. Anesthetic adverse events played an important role in this study (Table S4). All five women who died were

TABLE 4 Perinatal outcomes.^{a,b}

Outcome	Vacuum extraction (n=347)	Second-stage cesarean delivery (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 DDI	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
DDI				
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				
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 admission, d				
>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

Abbreviations: OR, odds ratio; CI, confidence interval; DDI, decision-to-delivery interval.

^aValues are given as number (percentage) unless indicated otherwise.

^bOutcomes assessed at hospital discharge or 1 wk after admission to the neonatology unit.

^cORs and 95% CIs were calculated using univariate logistic regression analysis. Calculations of adjusted ORs are presented in Tables S6, S7, and S10.

^dP values were calculated using a two-sided χ^2 test. However, a two-sided Fisher exact test was used for outcomes recorded fewer than 10 times. The cut-off for statistical significance was $P < 0.05$.

^ePerinatal death, severe trauma, 5-min Apgar score <4, or convulsions.

^fIn the first week after delivery.

^gMore than one adverse event could apply.

^hIntraventricular, intracerebral, or subgaleal hemorrhage; facial palsy; or dislocation of a leg.

ⁱCephalohematoma or fracture of clavicle.

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 anesthetic care is needed and that preventing unnecessary surgery is of the 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 deliveries each year. Almost all eligible women were included, thereby minimizing selection bias. The present findings could be generalized to many hospitals among LMICs, where access to safe surgery, anesthesia, 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 6-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 randomized 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 SSCD could have had high risk profiles. Previous cesarean delivery, fetal weight greater than 4000 g, and being in the second stage of labor at hospital admission were all risk factors for undergoing cesarean delivery and potential risk factors for an unfavorable outcome. Multivariate regression models were therefore constructed to adjust for potential confounders. Mode of delivery was an independent risk factor for severe maternal outcomes and fetal death during DDI in all models.

The rate of women who experienced successful vacuum extractions while waiting for cesarean delivery was high. The rate of SSCD for term singletons in vertex presentation was 3.3% of all deliveries 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 SSCD group would probably have qualified for vacuum extraction and that it was not only women with a higher risk profile who underwent cesarean delivery.

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 status 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 generalizable 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 cesarean delivery arrived at the hospital during the second stage of labor. This observation suggests that many women with scarred uteri attempted to deliver outside of 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 labor, to prevent birth asphyxia. In all, 33 women had both IUFD and SSCD. The development of IUFD had been diagnosed before SSCD was planned among 15 women. One of these 15 women died and two sustained uterine rupture during DDI. A timely vacuum extraction or destructive operation could possibly have prevented these adverse outcomes.

In conclusion, it is of utmost importance that unnecessary SSCD is prevented whenever possible, and particularly in areas where the risks associated with cesarean delivery are high. Reintroduction of vacuum extraction is an important strategy to limit unnecessary cesarean delivery, reduce DDI, and prevent maternal and perinatal mortality and morbidity.

AUTHOR CONTRIBUTIONS

BN contributed to the design of the study, collection, analysis, and interpretation of the data, and writing the manuscript. FN contributed to the design of the study, collection and interpretation of the data, and revising the manuscript. JL and JB contributed to the design

of the study, interpretation of the data, and revising the manuscript. TvdA contributed to the interpretation of the data and revising the manuscript. JvR contributed to the design of the study, analysis and interpretation of the data, and revising the manuscript. All authors approved publication of the article.

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CONFLICTS OF INTEREST

BN serves on an advisory committee for the development of a new vacuum extractor product by Clinical Innovations (South Murray, UT, USA). This company had no role in either the present study or the content of the manuscript. The authors have no other conflicts of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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 6 months after birth.

Table S9. Causes of perinatal, neonatal, or infant death.

Table S10. Regression analysis for fetal death in decision to delivery interval (DDI).

File S1. Questionnaires used at inclusion and during follow-up.