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Single Blade Forceps versus Manual Delivery of Fetal Head during Cesarean Section: A randomized controlled trial

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ABSTRACT

Objectives: We aimed to compare the efficacy of single blade forceps versus manual delivery during cesarean section vis-à-vis time to deliver the fetal head and maternal and neonatal outcomes.

Materials and Methods: One hundred and forty-four pregnant women were randomly assigned to single blade forceps or manual delivery. The women were term, singleton, cephalic presentation, undergoing a low transverse cesarean section under spinal anesthesia. The primary outcome was time to deliver the fetal head. The secondary outcomes included operative time, maternal outcomes (unintended excision of uterine incision, uterine vessels injury), neonatal outcomes (Apgar scores at 5 and 10 min, oxygen need for resuscitation, and neonatal injury), and surgeon satisfaction.

Results: Baseline characteristics were comparable between groups except for the type of skin incision. Median time to delivery of the fetal head using single blade forceps was statistically shorter than using the manual delivery (24.50 s (interquartile range (IQR), 10.50 - 41.50) vs. 45.00 s (IQR, 19.50 - 92.00), $p < 0.001$). Similar results occurred for operative time, maternal outcomes, neonatal outcomes, and surgeon satisfaction. Minor neonatal injury was 9.72% in the single blade forceps group.

Conclusion: Using single blade forceps shortened the delivery of the fetal head during cesarean section without serious maternal and neonatal complications. Minor neonatal injury was more common in the single blade forceps group than the manual delivery group.

Keywords: single blade forceps, manual delivery, time to delivery of fetal head, cesarean section.

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การใช้คีมข้างเดียวเทียบกับการใช้มือในการช่วยคลอดศีรษะทารกระหว่างการผ่าตัดคลอด: การทดลองแบบสุ่ม

รัตน์ศักดิ์ ตั้งเทอดชนะกิจ, อุษณีย์ สังคมกำแหง, ธนนิตย์ สังคมกำแหง

บทคัดย่อ

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิผลการช่วยคลอดศีรษะทารกในการผ่าตัดคลอดระหว่างการใช้คีมข้างเดียวหรือการใช้มือในเรื่องระยะเวลาการคลอด ภาวะแทรกซ้อนมารดาและทารก*

วัสดุและวิธีการ: *สตรีตั้งครรภ์เดี่ยวครบกำหนดที่มีส่วนนำของทารกเป็นศีรษะ ได้รับการผ่าตัดคลอดโดยระงับความรู้สึกด้วยการฉีดยาชาเข้าช่องไขสันหลัง จำนวน 144 คน ถูกสุ่มเป็นสองกลุ่มคือใช้คีมข้างเดียวช่วยคลอด เปรียบเทียบกับการใช้มือช่วยคลอด ผลลัพธ์หลักคือระยะเวลาที่ใช้ในการคลอดศีรษะทารก ผลลัพธ์รองคือระยะเวลาในการผ่าตัดคลอด ภาวะแทรกซ้อนมารดา (การฉีกขาดมดลูกเพิ่มเติมจากรอยผ่าตัด, การบาดเจ็บของหลอดเลือดที่มาเลี้ยงมดลูก) ผลต่อทารก (การประเมินสภาวะทารกแรกเกิดที่ 5 และ 10 นาที การใช้ออกซิเจนในทารก การบาดเจ็บขณะช่วยคลอดทารก) และความพึงพอใจของแพทย์ผู้ผ่าตัด*

ผลการศึกษา: *ลักษณะทางประชากรศาสตร์ไม่แตกต่างกันระหว่างกลุ่มยกเว้นชนิดของแผลผ่าตัดที่ผิวหนัง ค่ามัธยฐานของระยะเวลาในการช่วยคลอดศีรษะทารกในกลุ่มใช้คีมข้างเดียวน้อยกว่าในกลุ่มใช้มือช่วยคลอดอย่างมีนัยสำคัญทางสถิติ (กลุ่มคีมข้างเดียว 24.50 วินาที (interquartile range (IQR), 10.50-41.50), กลุ่มมือ 45.00 วินาที (IQR, 19.50-92.00), $p < 0.001$) และไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของระยะเวลาในการผ่าตัดคลอด ภาวะแทรกซ้อนมารดา ผลต่อทารกและความพึงพอใจของแพทย์ผู้ผ่าตัด การบาดเจ็บเล็กน้อยในทารกพบได้ร้อยละ 9.72 ในกลุ่มที่ใช้คีมข้างเดียวช่วยคลอด*

สรุป: *การใช้คีมข้างเดียว ลดระยะเวลาในการช่วยคลอดศีรษะทารกระหว่างการผ่าตัดคลอดได้อย่างมีนัยสำคัญทางสถิติเมื่อเทียบกับการใช้มือช่วยคลอด โดยไม่พบภาวะแทรกซ้อนที่อันตรายต่อมารดาและทารกโดยการบาดเจ็บเล็กน้อยต่อทารกพบในกลุ่มที่ใช้คีมข้างเดียวมากกว่าการใช้มือช่วยคลอด*

คำสำคัญ: *การใช้คีมข้างเดียว, การใช้มือช่วยคลอด, ระยะเวลาในการคลอดศีรษะทารก, การผ่าตัดคลอด*

Introduction

Cesarean section is a major obstetric surgical procedure used to deliver a viable fetus and placenta through an incision in the abdominal and uterine walls[1-2]. The procedure is often performed when vaginal delivery would be harmful to the mother or fetus. In the USA, the rate of cesarean section decreased from 31.9% in 2018 to 31.7% in 2019[3]. By comparison, the rate in Thailand rose from 15.2% in 1990 to 58% in 2019[4-6].

Typically, cesarean delivery of the fetal head in cephalic presentation is by manual extraction using the hand slipped into the uterine cavity between the pubic symphysis and the fetal head. The head is gently elevated with palm and fingers through the incision then modest pressure is applied to the transabdominal fundus to deliver the fetal head[7]. The most challenging aspect is fetal head extraction through the uterine incision, which can be problematic in about 10% of cases[8-9]. Prolonged uterine manipulation and fetal head compression during a difficult delivery can induce neonatal hypoxia due to minimization of uteroplacental blood flow[10-11]. Uterine fetal head delivery intervals of greater than 3 min are associated with fetal hypoxia, fetal acidosis, and a low Apgar score[11-14]. In addition, surgeons may encounter problems when using their hand to deliver the fetal head if the size of the hand results in unintended extension (tearing) of the uterine incision[15-16]. Several techniques can thus facilitate safe delivery for the mother and child of the fetal head in cesarean section (viz., forceps extraction or vacuum extraction)[17].

The effectiveness and safety of techniques to deliver the fetal head during cesarean section have been reported. Vacuum extraction of the fetal head may harm the fetus due to scalp abrasions, retinal hemorrhages, jaundice, and cephalhematomas[15]. By comparison, double-blade forceps delivery of the fetal head might harm the fetus due to scalp injury[9]. Wahab and Abolouz reported that single blade forceps delivery of the fetal head did not differ from double blade forceps or manual delivery; in terms of uterine extension, uterine vessel injury, or additional stitches needed for repair[18]. There is inconclusive evidence with respect to the comparative efficacy of single blade forceps versus manual delivery of the fetal head during cesarean section. The current study thus focused on single blade forceps for assisted fetal head delivery during cesarean section.

The purpose of the current study was to compare two methods of cesarean fetal head delivery: single blade forceps versus manual delivery. The primary outcome was time to deliver the fetal head. The secondary outcomes were operative time, adverse maternal outcomes (unintended extension of uterine incision, uterine vessels injury, additional stitches to repair injury, uterine incision hematoma), neonatal outcomes (birth weight, Apgar scores at 5 and 10 min, oxygen needed for resuscitation, and neonatal injury), and surgeon satisfaction.

Materials and Methods

The current randomized controlled study was performed at Khon Kaen Hospital (Thailand) and was approved by the Khon Kaen Hospital Institute Review Board for Human Research (KEF63009). The study included pregnant women 18 and over, term, singleton, cephalic presentation undergoing elective low transverse cesarean section under spinal anesthesia with intrathecal spinal morphine. Exclusion criteria were cesarean section with indications, including: non-reassuring fetal heart rate, fetal distress, maternal obstetric complications (pregnancy-associated hypertension, antepartum hemorrhage, placenta previa, placental abruption, ruptured vasa previa, and uterine rupture), major fetal structural anomalies[19], death fetus in utero, uterine anomalies, and deeply engaged fetal head. The latter refers to a condition in which cesarean delivery of the fetal head requires a disimpaction technique including abdomino-vaginal approach or push technique, and in such cases manual or single blade forceps cannot be used to assist in extraction of fetal head[9].

The presentation, position, and engagement of the fetus were verified and recorded before the operation. Women who met the eligibility criteria were

enrolled. Participants were then informed about the study and reassured regarding expertise and confidentiality. Computer software was used to generate a list with group allocation using sealed opaque envelopes. Block of four randomization was applied using a 1:1 ratio. All participants who joined the study signed informed consent at the labor room or obstetric wards, and were randomized into two groups at the operating room prior to surgery by a nurse.

The first group underwent assisted extraction of the fetal head using single forceps (Simpson-Braun 36 cm, 14 ¼"). The second group underwent manual-assisted extraction of the fetal head. In order to close the gap in delivery experience, all residents and staff who performed cesarean section were instructed how to use single blade forceps to deliver a fetal head.

All pregnant women underwent a standard, routine, preoperative evaluation, including laboratory testing (complete blood count (2 ml) at labor room or obstetrics ward) and antibiotic prophylaxis for cesarean section, as per the standing order approved by the Ethics Committee and staff of the Obstetric and Gynecologic Department, Khon Kaen Hospital.

The operation followed surgical safety protocols and was initiated with an appropriate Pfannenstiel or low midline skin incision with a scalpel. The subcutaneous incision and rectus sheath was opened and extended with scissors or electrocautery. The peritoneum was opened, and pelvic organs identified. The bladder was gently separated from the lower uterine segment with dissection of the vesicouterine flap. The lower uterine segment was opened by scalpel, and then an incision made to the fetal membrane in order to deliver the fetal head. The delivery of the fetal head was accomplished by single blade forceps or manually with proper transabdominal fundal pressure by surgeon assistance.

The on-duty nurse measured the time to delivery of the fetal head using a stopwatch (ZSD-Stopwatch ZSD-013 (Black)). The timing started after applying the single blade forceps (or when manual extraction began) until full delivery of the fetal head.

For the single blade forceps group, if the fetal head was left occiput anterior (LOA), left occiput transverse (LOT), left occiput posterior (LOP), the left handle of the forceps was placed between the fetal head and the surgeon's dominant hand, and the cephalic curve was placed along the left side of the fetal head. If the fetal head was right occiput anterior (ROA), right occiput transverse (ROT), or right occiput posterior (ROP), the right handle of the forceps was placed between the fetal head and the surgeon's dominant hand, and the cephalic curve was placed along the right side of the fetal head. Finally, if the fetal head was occiput anterior (OA) or occiput posterior (OP), the surgeon rotated the fetal head to LOA, LOT, LOP, ROA, ROT, or ROP and applied as above.

The other group was the manual-assisted extraction of the fetal head. First, the surgeon's dominant hand slipped into the lower segment of the uterine cavity between the pubic symphysis, and the fetal head was gently elevated with palm and fingers through the incision.

If the delivery of the fetal head took more than three minutes, the surgeon applied double blade forceps to assist delivery. The rest of the operation followed the method of a standard cesarean section. During the operation, the following were recorded: time to deliver the fetal head, operative time, maternal outcomes (unintended extension of uterine incision, uterine vessel injury, additional stitches to repair injury, uterine incision hematoma, and difference in maternal hemoglobin), neonatal outcomes (birth weight, Apgar scores at 5 and 10 min, oxygen need for resuscitation and neonatal injury), and surgeon satisfaction. After the cesarean section, all women received standard postoperative care. Blood work included: postoperative complete blood count (2 ml) 24-h[20] at the obstetrics ward.

The sample size was calculated by two independent means using the mean time to deliver the fetal head from a pilot study (n = 30). The time to deliver the fetal head in the single blade forceps group was 25.40 ± 19.84 s vs. 44.33 ± 50.19 s in the control group. We set the type I error at 0.05 with a power of 80%. The calculation of sample size was 64 per group. When combined with dropout rate of 10%, 144 participants (72 in each group) were recruited. This research was conducted on an intention-to-treat basis and statistics were calculated using Stata version 12. The student

t-test and Mann-Whitney U test were used to analyze the between-group continuous variables. The Chi-square and Fisher's exact test were used to analyze the categorical variables. Descriptive statistics included means, standard deviations (SDs), or medians, and interquartile ranges (IQRs). Differences were considered statistically significant when the p value was < 0.05.

Results

Two hundred and fifty-six women were counseled for participation in the study. Excluded from the study were 112 women due to (a) refusal to participate (n = 77); (b) maternal obstetric complications including pregnancy-associated hypertension (n = 21), placenta previa (n = 1), or placental abruption (n = 1); (c) non-reassuring fetal heart rate (n = 8); or (d) deeply engaged fetal head (n = 4).

One hundred forty-four women were randomized into the single-blade forceps and manual delivery groups. In the single blade forceps group, one woman did not undergo the intervention as a random assignment in accordance with fetal face presentation. Meanwhile, 72 women in the manual delivery group received an intervention by random allocation. Six women in the single blade forceps group and eight women in the manual delivery group received the double blade forceps intervention to deliver the fetal head. None of the patients in either group withdrew from the study. Each group included 72 women in the final analysis (Fig. 1).

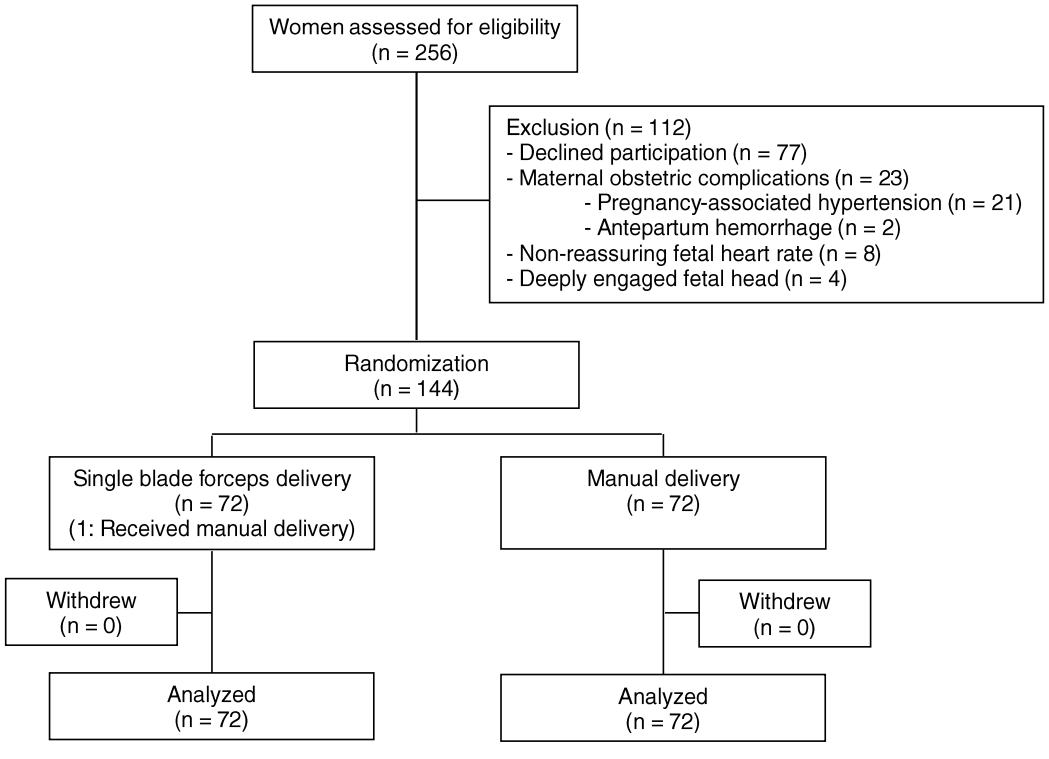

Fig. 1. Study flow.

Baseline characteristics were similar between groups, namely: maternal characteristics (age, gestational age, body mass index, parity, preoperative hemoglobin), surgical characteristics (indication of cesarean section, surgeon status), and neonatal characteristics (fetal head status) (Table 1). The exception was skin incision, where the proportion of Pfannenstiel incisions to low midline incisions was significantly greater in the single blade forceps group than the manual delivery group (p = 0.02).

Table 1. Baseline characteristics.

Characteristic	Single blade forceps delivery (n = 72)	Manual delivery (n = 72)	p value
Maternal characteristics			
Age (years), mean ± SD	29.85 ± 5.74	30.31 ± 5.34	0.62
Gestational age (weeks), mean ± SD	38.79 ± 0.80	38.78 ± 0.82	0.92
BMI (kg/m^2), mean ± SD	29.58 ± 4.17	29.72 ± 5.36	0.86
Parity, n (%)			0.37
Nulliparous	25 (34.72)	20 (27.78)	
Multiparous	47 (65.28)	52 (72.22)	
Pre-operative hemoglobin (g/dL), mean ± SD	12.03 ± 1.21	12.26 ± 1.13	0.24
Surgical characteristics			
Indication of cesarean section, n (%)			0.87
Previous cesarean section	36 (50.00)	39 (54.17)	
Cephalopelvic disproportion	28 (38.89)	25 (34.72)	
Others	8 (11.11)	8 (11.11)	
Skin incision, n (%)			0.02
Pfannenstiel	56 (77.78)	43 (59.72)	
Low midline	16 (22.22)	29 (40.28)	
Surgeon status, n (%)			0.85
Resident 1	5 (6.94)	4 (5.56)	
Resident 2	15 (20.83)	17 (23.61)	
Resident 3	11 (15.28)	14 (19.44)	
Staff	41 (56.95)	37 (51.39)	
Neonatal characteristics			
Fetal head status, n (%)			0.15
Head float	18 (25.00)	26 (36.11)	
Head engage	54 (75.00)	46 (63.89)	

BMI: body mass index, SD: standard deviation, n: number of patients

Time to delivery of the fetal head was the principal consequence and estimated at a median of 24.50 s (IQR, 10.50-41.50) in the single blade forceps category compared with 45.00 s (IQR, 19.50-92.00) in the manual category ($p < 0.001$). The secondary outcomes were not statistically different between the single blade forceps and manual delivery groups-namely, operative time (48.35 ± 17.62 min vs. 48.88 ± 18.89 min, p = 0.86); unintended extension of uterine incision (3 (4.17%) vs. 1 (1.39%), p = 0.31); uterine vessel injury (1 (1.39%) vs. 2 (2.78%), p = 0.56); additional stitch to repair injury (10 (13.89%) vs. (7 (9.72%), p = 0.44); hematoma at uterine incision (2 (2.78%) vs. 1 (1.39%), p = 0.56); proportion of surgeon satisfaction (69 (95.83%) vs. 66 (91.67%), p = 0.30); and, maternal hemoglobin change from preoperative to postoperative day 1 (median 0.80 g/dL (IQR, 0.07-1.30) vs. 0.90 g/dL (IQR, 0.40-1.70, p = 0.14). Neonatal outcomes had no remarkable differences between the single blade forceps and manual delivery groups-namely, birth weight; Apgar scores at 5 min or Apgar scores at 10 min; and, oxygen

therapy in newborns (equally both groups: 69 neonates did not use supplemental oxygen, 1 neonate used oxygen mask, tube, or oxygen box, 2 neonates used positive pressure ventilation). The 7 neonatal injuries included a mild degree of redness of the cheeks and chin and were found only in the single blade forceps group (9.72%) (Table 2). There were no serious neonatal injuries in either group.

Table 2. Primary and secondary outcomes.

Outcome	Single blade forceps (n = 72)	Manual delivery (n = 72)	p value
Primary outcome			
Time to delivery of fetal head (s), median (IQR)	24.50 (10.50 - 41.50)	45.00 (19.50 - 92.00)	< 0.001
Secondary outcomes			
Maternal outcomes			
Operative time (min), mean ± SD	48.35 ± 17.62	48.88 ± 18.89	0.86
Change in maternal hemoglobin between preoperative and postoperative day 1 (g/dL), median (IQR)	0.80 (0.07-1.30)	0.90 (0.40-1.70)	0.14
Adverse maternal outcomes			
Unintended extension of uterine incision, n (%)	3 (4.17)	1 (1.39)	0.31
Uterine vessel injury, n (%)	1 (1.39)	2 (2.78)	0.56
Additional stitch to repair injury, n (%)	10 (13.89)	7 (9.72)	0.44
Hematoma at uterine incision, n (%)	2 (2.78)	1 (1.39)	0.56
Neonatal outcomes			
Birth weight (grams), mean ± SD	3,230.69 ± 465.23	3,206.67 ± 407.87	0.74
Apgar scores at 5 min, n (%)			NA
Apgar scores < 7	0 (0)	1 (1.39)	
Apgar scores ≥ 7	72 (100.00)	71 (98.61)	
Apgar scores at 10 min, n (%)			NA
Apgar scores ≥ 7	72 (100.00)	72 (100.00)	
Minor neonatal injury, n %)	7 (9.72)	0 (0)	0.01
Surgeon satisfaction, n (%)	69 (95.83)	66 (91.67)	0.30

IQR: interquartile range, SD: standard deviation, n: number of patients

Discussion

Single blade forceps significantly shortened delivery of the fetal head during cesarean section (24.50 s (IQR, 10.50-41.50) vs. 45.00 s (IQR, 19.50-92.00), p < 0.001). Secondary outcomes were not significantly different between groups-namely, operative time, maternal outcomes (unintended extension of uterine incision, uterine vessels injury, additional stitch to repair injury, uterine incision hematoma), neonatal outcomes (birth weight, Apgar scores at 5 and 10 min, oxygen need for resuscitation), or surgeon satisfaction. The rate of minor neonatal injury was 9.72% in the single blade forceps group.

To our knowledge, no study has compared time to deliver the fetal head during cesarean section using single blade forceps versus manual delivery. Wahab and Abolouz did compare manual, single blade forceps and double blades forceps, and the primary outcome was discomfort or pain during fetal head delivery[18]. They did not, however, evaluate time to deliver of fetal

head in their study[18]. The respective median time in the single blade forceps category vs. the manual delivery category was 24.50 vs. 45.00 s: the difference being statistically but not clinically significant. The type of skin incision affected the time to deliver the fetal head because (a) the Pfannenstiel (transverse) skin incision provided less operating space (exposure) than the low midline (vertical) skin incision[21], and (b) the latter was predominately used in the single blade forceps group. Importantly, delivery of the fetal head was faster in the single blade forceps group than the manual delivery group. The fact that the single blade forceps reduced the time to delivery by about 20.5 s might have decreased adverse outcomes (i.e., blood loss from a uterine incision).

The primary outcome was consistent with Swain et al[22] who compared time to deliver the fetal head between the vacuum, double forceps, and manual methods. The double forceps-assisted delivery was shorter than the manual group as reported by Swain et al[22] in contrast to Bofill et al[23] who found that the manual group was faster than the double forceps group. The double forceps and vacuum-assisted delivery methods produced similar results according to Swain et al[22] To contrast, Bofill et al[23]observed that the vacuum-assisted method was faster than the double forceps delivery method. According to both research teams, the vacuum-assisted delivery method was faster than the manual method.

The secondary outcomes were operative time, adverse maternal outcomes (i.e., unintended extension of the uterine incision, uterine vessel injury, additional stitches to repair injury, and uterine incision hematoma), and neonatal outcomes (i.e., birth weight, Apgar scores at 5 and 10 min, oxygen need for resuscitation, and neonatal injury). The secondary outcomes were similar between groups, except for neonatal injury. The finding was consistent with Wahab et al who reported no significant differences for delivery of the fetal head between the single blade forceps and manual delivery methods vis-à-vis uterine extension, uterine vessel injury, or additional stitches to repair injury[18]. Similarly, Bofill et al reported no significant difference between the vacuum, forceps, and manual methods vis-à-vis uterine incision extension, post-operative hemoglobin, and hemoglobin drop[23]. Swain et al summarized that the manual method resulted in greater extension of the uterine incision than the forceps and vacuum methods, and that there was no significant difference in estimated blood loss between the manual and vacuum methods, even though the forceps method was hypothesized to have greater blood loss.

Mild neonatal injuries (e.g., red lesion) only occurred in the single blade forceps group (n = 7; 9.72%). There were no serious injuries in either group, as also reported by Swain et al[22] and Bofill et al[23]. Swain et al described 300 at-term cases of cesarean section presenting with a high floating fetal head. The study-assessing the three methods: forceps, vacuum, and manual extraction)- revealed that 2 of 100 cases in the forceps group had a minor scalp injury[22]. Meanwhile, Bofill et al reported that use of instruments (forceps or vacuum), at the time of an elective repeat cesarean section in 44 women, permitted a delivery that was as safe for the mother and infant and easy and effective for the mother and physician as traditional manual delivery[23]. There were also no serious neonatal injuries: the Apgar scores at 5 min was comparable to Swain et al with no significant difference between groups[22].

The strengths of the current study were that (a) it was a randomized controlled trial, thereby reducing confounding factors between groups; (b) none of the patients lost to follow-up; and (c) the sample size was adequate. The limitations were that (a) it was not possible to mask the surgeons and nurses to the allocation of the use of single blade forceps, and (b) we did not measure blood loss during the cesarean section.

Conclusion

Single blade forceps was an alternative method to manual delivery with a shortened time to deliver the fetal head during cesarean section with non-significant complications. Minor neonatal injury was more common in the single blade forceps group than the manual delivery group.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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