Original Article

Maternal and Fetal Effect of Misgav Ladach Cesarean Section in Nigerian Women: A Randomized Control Study

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Abstract

Background: The poor utilisation of the Misgav-Ladach (ML) caesarean section method in our environment despite its proven advantage has been attributed to several factors including its non-evaluation. A well designed and conducted trial is needed to provide evidence to convince clinician of its advantage over Pfannenstiel based methods. **Aim:** To evaluate the outcome of ML based caesarean section among Nigerian women. **Subjects and Methods:** Randomised controlled open label study of 323 women undergoing primary caesarean section in Lagos Nigeria. The women were randomised to either ML method or Pfannenstiel based (PB) caesarean section technique using computer generated random numbers. **Results:** The mean duration of surgery ($P < 0.001$), time to first bowel motion ($P = 0.01$) and ambulation ($P < 0.001$) were significantly shorter in the ML group compared to PB group. Postoperative anaemia ($P < 0.01$), analgesic needs ($P = 0.02$), extra suture use, estimated blood loss ($P < 0.01$) and post-operative complications ($P = 0.001$) were significantly lower in the ML group compared to PB group. Though the mean hospital stay was shorter (5.8 days) in the ML group as against 6.0 days, the difference was not significant statistically ($P = 0.17$). Of the fetal outcome measures compared, it was only in the fetal extraction time that there was significant difference between the two groups ($P = 0.001$). The mean fetal extraction time was 162 sec in ML group compared to 273 sec in the PB group. **Conclusions:** This study confirmed the already established benefit of ML techniques in Nigerian women, as it relates to the postoperative outcomes, duration of surgery, and fetal extraction time. The technique is recommended to clinicians as its superior maternal and fetal outcome and cost saving advantage makes it appropriate for use in poor resource setting.

Keywords: Cesarean section, Maternal and neonatal morbidity, Misgav Ladach

Introduction

Cesarean section is the most common intraperitoneal surgical procedure in obstetric practice; accounting for about 10-35% of all deliveries.[1-4] Over the years there has been a wider recognition of the desire to reduce cesarean section related morbidity and mortality through the modification of some steps of the procedure.[5,6] The Pfannenstiel based (PB) cesarean section technique has been widely accepted and used despite lack of evidence establishing its advantage over order techniques.[6-9] Given that the operation is conducted so frequently, any attempt to reduce risks associated with it (even with relatively modest alterations in the surgical procedure for a particular outcome) is likely to yield significant benefits in terms of costs and better health outcomes for women.[10,11]

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Michael Stark of Misgav Ladach hospital in Jerusalem introduced a novel technique of cesarean section by putting together modification of the various steps in traditional cesarean section.[7,12-15] This new technique was the result of a critical analysis of each surgical step in order to obtain an essentially less traumatic, easy, and quick to perform operation.[5,16] The new technique is now referred to as Misgav Ladach (ML) cesarean section.[17,18]

Meta-analysis of several randomized controlled trials comparing the ML technique, PB technique and lower midline techniques by two Cochrane reviews showed that ML technique is associated with shorter operating time, shorter time from skin incision to birth of baby, less blood loss, fewer analgesic injections, shorter time to oral intake postoperatively, and less fever.[19]

While it is tempting to adopt ML technique in our setting based on the above reviews without further evaluation, it should be noted that all the previous studies comparing the technique were in women from other race and settings.[7,12-15] In our setting unlike in Europe and North America, pelvic infection, adhesions, and uterine fibroid are common findings which may influence the outcome of the ML-based technique.[1]

In addition, the relative tensile strength of the tissues of the Negroid woman and surgical skill of junior obstetric staff on call when most of the cesarean section cases occur may influence the outcome.[1] A more pragmatic way will be to evaluate the ML technique in the new setting. This may also be the reason for its limited application among obstetricians.[5]

This study was, therefore, designed to determine the effect of the ML technique on maternal and infant outcome of operation time, blood loss, wound healing, analgesic use, fetal extraction time, Apgar score, neonatal admission, and deaths among Nigerian women.

Subjects and Methods

The study was conducted in two multidisciplinary proprietary hospitals in Lagos Nigeria over a 48-month period (January 2003-December 2008). Approval from the study was obtained from the research committees of the hospitals which also double as ethics committee. All consenting patients undergoing primary cesarean section in the hospitals that met the inclusion criteria during this period were enrolled into the study. They were randomized into either of two arms of Misgav Ladach method of cesarean section (ML) and Pfannenstiel based Cesarean section method (PB) using computer-generated random numbers. Randomization was hospital based and performed once the decision was made to deliver by cesarean section. Excluded from the study were cases of antepartum hemorrhage, prolonged obstructed labor, chorioamnionitis, preoperative hemoglobin less than 10 g/dl, prolonged premature rupture of membrane and clinically palpable uterine fibroid because the research committees of both hospitals gave their exclusion as condition for approval. Blood loss estimation was by visual inspection by the attending anesthetists. Only surgeons trained and experienced in the two techniques participated in the study.

Sample size

The sample size expression $n = 1/d2 \times Z2pq$ was used to determine the minimum number of subjects to be included in each arm of the study; where Z is the value of the Z score corresponding to the level of confidence; P is the estimated proportion of participants with any unfavorable outcome, $q = 1 - p$ and d is the tolerable error margin in our estimate. At 95% level of confidence, $Z = 1.96$ and $P = 0.10$, and error margin of 5%, a sample size of 138 was determined. We increased the sample size to at least 152 during the study period in anticipation of nonresponse or withdrawal of consent and the fact that we expected at least 10% of the total sample size in any cell generated in contingency tables. In all 323 women were recruited from the two sites.

Operative technique

Common postoperative procedures

Oxytocics were administered after delivery of baby and placenta in all cases and continued for at least six hours postsurgery. Wound dressing were removed on the third postoperative day, and stitches removed on the fifth postoperative day. The urinary catheter was removed on first postoperative day except otherwise stated by the attending surgeon. Extended prophylactic antibiotics of Clauvinic acid potentiated amoxicillin and Metronidazole were used in all cases. Pentazocine 30 mg 6 h were given to all women for the first 24 h and thereafter on request. Pentazocine was replaced with cap ibuprofen for four days.

Data collection

Information on age, weight at delivery, height, parity, gestational age at delivery, indications for surgery, operation time, fetal extraction time, blood loss (estimate of the attending Anesthetists), postoperative analgesia requirements, number of extra sutures used, blood transfusion, postoperative anemia, puerperal morbidities, duration of hospital stay, time of bowel motion and ambulation after surgery, neonatal outcome, and any other postoperative complication observed were collected prospectively and entered into case report form designed for the study.

Data analysis

The information collected on the case report forms were entered and analyzed using excel enhanced with Megstat. Comparisons were made between the two groups using Chi square with Yates corrections, Fischer's exact test and student's *t*-test as appropriate. The odd risk ratio at 95% confidence interval was obtained was appropriate. A P value <0.05 was considered significant.

Case definitions

Postoperative morbidity

The occurrence of one or more of the following conditions: Wound infection, endometritis, febrile morbidity, postoperative anemia, blood transfusion, and urinary traction infection.

Surgical steps	Misgav Ladach method[7,17]	Pfannenstiel based method[5,6]
Abdominal wall incision and entry	Joel-Cohen technique	Pfannenstiel incision
Packing	Omitted	Two large-taped gauze swabs are used to pack the lateral recesses of the wound
Lower segment entry	Superficial transverse incision is made through the visceral peritoneum about 1 cm above the bladder limit with the scalpel. The transverse incision is extended far enough to allow for delivery of the baby. The cut visceral peritoneum is pushed down with two fingers. A small transverse incision is made on the lower uterine segment with the scalpel. Using the thumbs, the incision is extended on either side to allow for the delivery of the baby	Visceral peritoneum overlying the uterus is grasped with forceps just above the superior margins of the bladder and incised with Metzenbaum scissors. The peritoneum is undermined laterally with the scissors and incised to the left and right of midline. The lower peritoneal flap thus formed is lifted up with forceps and by finger pressure with the other hand is stripped downwards for about 5 cm together with the incorporated bladder; the separation must extend well out to both sides. Using scissors snips the upper flap is freed for some distance if possible. Following the creation of bladder flap, a bladder blade is placed to keep the bladder out of the operative field. A Richardson retractor is placed superiorly to facilitate adequate exposure. The lower uterine segment is then incised with a scalpel in the midline just below the former area of attachment of the bladder peritoneal reflection. Having opened into the uterus, the operator extends the incision laterally by means of curved scissors; while doing this he uses the forefinger of the opposite hand as an elevator
Delivery of placenta	Manual removal	Controlled cord traction
Repair of the uterus	Uterus is exteriorized and repaired in one layer with continuous locked with chromic catgut # 1 taken big bites from both edges to secure hemostasis	The uterus is repaired within the peritoneal cavity in two layers with chromic catgut # 1. The first layer is by continuous locked stitch. The second layer is then placed imbricating the first. The loose visceral peritoneum above and below the exposed lower uterine segment is now brought together with continuous chromic catgut # 2-0
Closure of the anterior abdominal wall	The visceral and parietal peritoneum is left unstitched. The omentum is used to cover the repaired uterine wall. The fascia is repaired with continuous chromic catgut # 1. The skin is closed with subcuticular nylon # 0	The anterior abdominal wall in layers with continuous chromic catgut # 0 stitch to peritoneum, continuous chromic catgut # 1 stitch to the anterior rectus sheath. The subcutaneous layer is closed with interrupted plain catgut # 2-0 stitches. The skin is closed with subcuticular nylon # 0
Oral feeding and ambulation	Oral fluids are started six hours after surgery	Oral fluids are commenced with the return of normal bowel sound

Wound infection

The presence of one or more of the following; seriosangious/purulent discharge, induration, erythema, and/or pain and obvious wound dehiscence (partial or total).

Endometritis

The occurrence of at least two of the following; fever, soft and tender uterus, foul smelling lochia, cervical motion tenderness, and culture of pathogenic organism from the endocervical swab.

Febrile morbidity

The rise of temperature to 38°C on at least two occasions 4 h apart, excluding the first 24 h after surgery in the absence of known operative or nonoperative site infection.

Fetal extraction time

The total time elapsed between skin incisions and clamping of the umbilical cord.

Operation time

The total time elapsed between skin incision and the last skin stitch.

Prolonged hospital stay

Hospital stay greater than fifth postoperative day.

Results

During the period of study, 323 consenting women undergoing primary cesarean section in the two hospitals met the inclusion criteria and were thus randomized into either of the two arms. Though the ratio of case enrolled in the two hospitals was in the ratio 9:1 there were no statistically significant difference in characteristics of patients, indications for cesarean section and type of cesarean section (P = 0.23; 95% CI: 0.21-13.7). After randomization, four women randomized to ML group withdrew their consent and were thus excluded from the study. The groups' allocation was thus 157 in the ML group and 162 in the PB group.

The sociodemographic characteristics of the women are shown in Table 1 and are comparable.

Table 2 shows the comparison of maternal outcome between the two groups. The mean duration of surgery in the ML group of 29.6 (7.5) min was significantly shorter than 37.4 (10.8) min in the PB group ($P < 0.001$; OR: 7.1; CI: 4.7-11.8). The estimated blood loss was also significantly lower in the ML group (553.6 mls) compared to 734.9 mls in the PB group ($P < 0.01$; OR: 5.1; CI: 4.3-7.7). The number of cases of postoperative anemia was significantly more in the PB group than in the ML group ($P < 0.01$; OR: 2.87; CI: 1.4-6.4). Although more women were transfused with blood in the PB group (5.3%) for postpartum hemorrhage compared to 2.0% in the ML group, the difference was not statistically significant ($P = 0.38$). The mean extra analgesic requirement by the women postsurgery was less in the ML group (2.3 (1.0)) compared to 3.1 (1.3) in the women in the PB group ($P = 0.02$). There was also statistically significant difference between the two groups with respect to the time of first bowel motion ($P = 0.01$; OR: 4.0; CI: 2.6-3.4) and the time of first mobilization ($P < 0.001$; OR: 6.2; CI: 4.7-8.3). The mean time of first bowel motion was 26.2 (5.6) h in the ML group compared to 39.5 (9.4) h in the PB group. The mean postoperative time at mobilization was 22.5 (6.2) h in ML group as against 34.3 (8.9) h in than PB group. Eighteen (8.1%) women in the PB group had postoperative morbidities of anemia, wound infection, febrile morbidity, blood transfusion, and puerperal sepsis compared to seven (3.4%) women in ML group. The differences were statistically significant at $P = 0.001$ (OR: 3.3; CI: 1.6-6.8). The mean hospital stay was shorter (5.8 days) in the ML group as against 6.0 days; however, this difference was not significant statistically ($P = 0.17$).

Table 3 showed the neonatal outcome in the two groups. It was only in the fetal extraction time that there was a statistically significant difference between the two groups ($P = 0.001$). The mean fetal extraction time was 162 s in ML group compared to 273 s in the PB group (CI: 2.7-7.8). The other parameters compared were number of babies with Apgar score less than 7 at 1 min, neonatal admission and neonatal death.

Table 1: Sociodemographic characteristics, type of anesthesia, and reasons for cesarean among the study groups

Characteristics, type and reason for cesarean section	ML group *N*=157 (%)	PB group *N*=162 (%)	*P* value	95% confidence interval
Mean maternal age	27.9 (4.9)	28.0 (5.4)	0.75	0.91-1.19
Parity	1.4 (1.5)	1.3 (1.6)	0.14	0.02-1.23
Mean parity				
0-2	89 (56.7)	93 (57.4)		
3-5	57 (36.3)	57 (35.2)	0.97	0.32-3.8
≥5	11 (7.0)	12 (7.4)		
Mean body mass index	24.5 (5.5)	24.2 (4.4)	0.48	0.54-4.5
Gestational age at delivery	38.0 (2.1)	38.1 (2.0)	0.13	0.12-5.7
Type of anesthesia				
General anesthesia	101 (64.3)	105 (64.8)	0.98	0.60-1.59
Spinal anesthesia	56 (35.7)	57 (35.2)		
Indications for cesarean section				
Cephalopelvic disproportion	46 (29.3)	48 (29.6)	0.79	1.0-9.1
Persistent fetal distress	19 (12.1)	21 (13.0)		
Abnormal lie/malposition	17 (10.8)	13 (08.02)		
Severe PIH	27 (17.2)	22 (13.6)		
Bad obstetric history	13 (08.3)	19 (11.7)		
IVF pregnancy	26 (16.6)	32 (19.8)		
PMTCT	9 (05.7)	07 (04.3)		
Type of procedure				
Emergency	92 (58.6)	91 (56.2)	0.11	0.69-1.76
Elective	65 (41.4)	71 (43.8)		

PIH: Pregnancy induced hypertension, IVF: *In vitro* fertilization, PMTCT: Prevention of mother to child transmission of HIV

Discussion

Our study evaluate the maternal and short-term fetal outcome of two cesarean techniques of Misgav Ladach and Pfannenstiel based methods, with aim of proving the reported advantage of ML technique among Nigerian women. We were able to show the advantage of ML technique over PB technique in operation time, blood loss, hemoglobin levels postsurgery, time to first bowel motion, ambulation time, and postoperative morbidity like previous study in Refs. 13, 15, and 17. The mean operation time ($P < 0.001$), estimated blood loss ($P = 0.002$), time to first bowel motion ($P = 0.01$), and mean postoperative mobilization time ($P < 0.001$) were significantly shorter among the ML arm compared to PB arm. Also among the ML arm, the rate of postoperative morbidity of 8.2% was signifantly lower than rate 22.8% among the PB arm ($P = 0.001$). However, no difference was found between the techniques as it relates to the number of women that were transfused ($P = 0.69$), requiring extra stitch to control bleeding ($P = 0.38$), or stayed more than six days in the hospital ($P = 0.14$).

The finding above confirms the theoretical basis of Misgav Ladach technique of close relation between tissue trauma and morbidity and supports the assertion that the introduction of ML technique removes the unnecessary step in PB technique including the reduction of CS related morbidity.[7,13,15,17] Every unnecessary surgical step increases tissue damage and inflammatory response, with a consequent rise in hemorrhage and infection risk.[7] This study in addition excludes any expected effect of race and environment on the outcome of the new technique.

Among the fetal outcome parameters of mean fetal extraction time, Apgar score, neonatal admission, and death rates evaluated in the study, it was only in fetal extraction time that ML technique was found to confer significant advantage over PB technique. The mean fetal extraction time of 162 (5.1) s among the ML group was significantly lower than 273 (7.1) s in the PB group ($P = 0.001$; CI: 2.7–7.8). This finding supports the previous reports by Darj,[7] Ferrari,[16] and Franchi[9] which

Table 2: Comparison of maternal outcome in the two groups

Outcome variable	ML group *N*=157 (%)	PB group *N*=162 (%)	*P* value	OR (95%) confidence interval
Mean operation time (minutes)	29.6 (7.5)	37.4 (10.8)	<0.001	7.1 (4.7-11.8)
Estimated blood loss (mls)	553.6 (259.5)	734.9 (333.5)	0.02	5.1 (4.3-7.7)
Extra stitch to control bleeding				
Not required	128 (81.5)	139 (85.8)	0.38	0.73 (0.39-1.38)
Required	29 (18.5)	23 (14.2)		
Women transfused				
Not transfused	149 (94.9)	151 (93.2)	0.69	1.69 (0.49-3.82)
Transfused	8 (5.1)	11 (6.8)		
Hemoglobin levels postpartum				
≥10g/dl	145 (92.4)	130 (80.2)	0.03	2.97 (1.40-6.40)
<10 g/dl	12 (7.6)	32 (19.8)		
Mean time of first bowel motion (hours)	26.5 (4.2)	34.5 (6.7)	0.01	4.0 (2.6-13.4)
Mean postoperative mobilization time (hours)	22.5 (5.2)	34.3 (7.6)	<0.001	6.2 (4.7-8.3)
Postoperative morbidities				
No	144 (91.7)	125 (77.2)		
Yes	13 (8.2)	37 (22.8)	0.001	3.28 (1.60-6.83)
Mean hospital stay	5.3 (1.2)	5.9 (1.9)	0.14	0.58 (0.19-1.35)

Table 3: Comparison of fetal outcome in the two groups

Outcome variable	ML group *N*=157 (%)	PB group *N*=162 (%)	*P* value	OR (95% confidence interval)
Mean fetal extraction time (minutes)	162 (5.1)	273 (7.1)	0.001	3.1 (2.7-7.8)
Apgar score at 1 min				
Greater or equal to 7	128 (81.5)	139 (85.8)	0.38	0.73 (0.39-1.38)
Less than 7	29 (18.5)	23 (14.2)		
Neonatal admission				
Admitted	149 (94.9)	151 (93.2)	0.69	1.69 (0.49-3.82)
Not admitted	8 (5.1)	11 (6.8)		
Neonatal death				
Yes	148 (94.4)	154 (95.1)	0.95	0.85 (0.29-2.49)
No	9 (7.6)	8 (4.9)		

reported short fetal extraction time in ML technique compared to PB technique. Our study further confirms the conclusion of Carlo Dani and colleague who stated that though ML technique shortens fetal extraction time, it does not influence short-term outcome of the newborn infants.[13] It is therefore reasonable to believe that neonatal outcome depends more on other factors such as chronic hypoxia, delayed decision to intervention interval and pre-existing condition, than on the cesarean section.[9,20]

This study has shown the superiority of ML technique over PB techniques in Nigerian women like their counterparts elsewhere and is therefore recommended for routine cesarean section both for emergency and elective cases. Though this study was a randomized control study which provides grade A evidence, it has some limitation that may impact on its external validity. The restriction of the study sites to Lagos and the exclusion of complicated cases as requested by the research committees make its generalizability difficult. When these limitations are viewed within the context and aim of the study, which is to evaluate what, is already established in other climes, the limitations are, therefore, not enough to invalidate the study. However, more evaluation of the techniques in the other zones of Nigeria and in high risk case is recommended.

Conclusion

This study has confirmed the already established benefit of ML techniques in Nigerian women as it relates to the postoperative outcomes, duration of surgery, and fetal extraction time. It is therefore recommended to clinicans as its superior maternal and fetal outcome and cost saving advantage makes it appropriate for use in low resource setting like ours.

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