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RANDOMISED CONTROL TRIAL ON IMMEDIATE POST-OPERATIVE OUTCOMES ON PATIENTS DONE EITHER CLOSURE OR NON-CLOSURE OF PERITONEUM AT CAESAREAN DELIVERY AT THE KENYATTA NATIONAL HOSPITAL
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ABSTRACT

***Objectives*: To assess effects of non-closure as compared to closure of the peritoneum at caesarean delivery on the intra-operative and early post-operative outcomes.**
***Design*: Randomised controlled trial.**
***Setting*: Kenyatta National Hospital (KNH), Nairobi, Kenya.**
***Subjects*: One hundred and thirty (130) women undergoing first elective or emergency caesarean delivery.**
***Main outcome measure*: Primary outcome measures were operation time, number of sutures used, post-operative pain, febrile morbidity, wound dehiscence and hospital stay.**
***Results*: The mean duration of Caesarean Section (CS) was 42.8 minutes ± SD12.5. The closure group took longer than non-closure group (45.7±15Vs. 39.6 ±8, P<0.05). The number of sutures used was on average were 4.7 ± SD 0.8, the closure group more compared with the non-closure group (5.2 ±0.7 Vs. 4.2 ±0.7, p<0.05). Post-operative pain was generally not a problem to the patients with a mean Visual analogue score of 1.4 ± SD 1.0 on a scale of 0-10. The non-closure group however indicated slightly more pain (1.5± SD0.93) compared with the closure group (1.2 ±1.1), but this difference was not significant. The adverse outcomes like febrile morbidity and wound complications at Caesarean section were rare and not different whether peritoneum was closed or not during Caesarean section.**
***Conclusion*: Non-closure of peritoneum during CS took less time (42.8± SD 8) and number of sutures used (4.2±0.7) can result in cost savings. There were no statistically significant differences in post-operative pain scores, febrile morbidity, wound complications and length of hospital stay. Obstetricians and Medical institutions should consider adoption of non-closure of peritoneum at Caesarean delivery as part of the standard operating procedures.**

INTRODUCTION

An increase in the incidence of Caesarean delivery has been observed in both developing and developed countries over the last 20 years. As the operation is conducted so frequently, any attempt to reduce morbidity, even with relatively modest differences for a particular outcome, is likely to have significant benefits in terms of costs and health benefits for women. Caesarean delivery is one of the most frequently performed surgical procedures worldwide accounting for up to 70% of the deliveries depending on the facility assessed and the country involved. In general, rates around the world are about 5% to over 20% of all deliveries (1). At Kenyatta National Hospital the Caesarean delivery rate is 30-40% (2).

There are many possible ways of performing Caesarean delivery and operative techniques used for Caesarean delivery vary. The techniques used may depend on many factors including the clinical situation and the preference of the operator. Some of these techniques like closure versus non-closure of peritoneum need to be evaluated through studies to establish the scientific basis.

Closure of the peritoneum at Caesarean delivery has been a part of the standard procedure.

Cited reasons for closure of the peritoneum include restoration of anatomy and re-approximation of tissues, reduction of infection by re-establishing an anatomical barrier, reduction of wound dehiscence, reducing haemorrhage, minimisation of adhesion and continuation of what was thought as standard (3, 4). However, some studies have indicated that closure of the peritoneum is non beneficial to the client and is expensive (5,6,8). The objective of the study was to evaluate clinical outcome and cost effectiveness of closure and open technique in the closure of the peritoneum.

The study could help develop standard operating procedures and the development of National guidelines in regards to Caesarean delivery.

MATERIALS AND METHODS

The study was conducted at Kenyatta National Hospital, Nairobi, Kenya.

The study population consisted of patients undergoing first Caesarean delivery either electively or as an emergency at the hospital. They were admitted in the labour ward and later followed up at the general post natal wards

The sample size, n, was calculated with variables from a similar study done by Hull *et al*. Based on the formula used, the sample size was calculated to be 61 subjects for each group.

This was a randomised controlled clinical trial comparing closure versus non-closure of both visceral and parietal peritoneum at first Caesarean delivery. Computer generated random numbers generated the randomisation sequence. The Pfannestiel incision was used on the abdomen in both groups. The intervention group (non-closure group) consisted of 65 women randomised to have both the visceral and parietal peritoneum left unsutured. The control group (closure group) had 65 women randomised to have both the visceral and parietal peritoneum closed using a continuous absorbable suture (Vicryl).

Data collection was done using a pre-tested and structured questionnaire administered at the time of recruitment by the principal investigator or research assistant. This was done immediately after the operation by the surgeon, again on the third postoperative day and on discharge from hospital.

Statistical analyses were performed using SPSS statistical software (version…Chicago, IL, USA). The significance level was defined as $P<0.05$.

RESULTS

One hundred and twenty nine (129) patients were evaluated and data submitted for analysis out of the 130 recruited for the study. One of the patients was excluded because she had to undergo an exploratory laparotomy after the caesarean section for internal haemorrhage. Two hundred Caesarean deliveries were performed during the study period

Table 1
Socio-demographic characteristics

		Method		
Characteristic	Overall n (%)	Closure n (%)	Non Closure n (%)	P-value
Age				
15-24	35 (27.1)	19 (28.4)	16 (25.8)	0.370
25-34	78 (60.5)	40 (59.7)	38 (61.3)	0.426
35-44	15 (11.6)	7 (10.4)	8 (12.9)	0.329
45+	1 (0.8)	1 (1.5)	0 (0)	0.156
Total	129 (100)	67 (100)	62 (100)	
Marital status				
Single	21 (16.3)	8 (11.9)	13 (21)	0.081
Married	103 (79.8)	55 (82.1)	48 (77.4)	
Divorced	5 (3.9)	4 (6.0)	1 (1.6)	0.092
Total	129 (100)	67 (100)	62 (100)	
Education				
None	1 (0.8)	1 (1.5)	0 (.0)	0.156
Primary school	52 (40.3)	25 (37.3)	27 (43.5)	0.236
Secondary school	54 (41.9)	31 (46.3)	23 (37.1)	0.144

University/college	22 (17.1)	10 (14.9)	12 (19.4)	0.249
Total	129 (100)	67 (100)	62 (100)	
Parity after current birth				
1	61 (47.3)	31 (46.3)	30 (48.4)	0.405
2+	68 (52.7)	36 (53.7)	32 (51.6)	0.405
Total	129 (100)	67 (100)	62 (100)	

Most of study subjects (60.5%, Table 1) were aged between 25 and 34 years, were married (79.8%), had an education of secondary level (41.9%, Table 1) and were primiparas (61%, Table 1) after current delivery. The baseline characteristics were similar in both groups.

Table 2
Pre-operative and intra operative findings at caesarean delivery

Characteristic	Overall n (%)	Method		
		Closure n (%)	Non Closure n (%)	P value
Indication for CS				
CPD	12 (9.3)	8 (11.9)	4 (6.5)	0.142
Non reassuring fetal status	57 (44.2)	30 (44.8)	27 (43.5)	0.441
P.E.T/eclampsia	11 (8.5)	6 (9)	5 (8.1)	0.427
Placenta previa	6 (4.7)	2 (3)	4 (6.5)	0.176
Malposition/ malpresentation	16 (12.4)	9 (13.4)	7 (11.3)	0.358
Prolonged labour	10 (7.8)	6 (9)	4 (6.5)	0.297
PMTCT of HIV positive	11 (8.5)	5 (7.5)	6 (9.7)	0.328
Other	6 (4.7)	1 (1.5)	5 (8.1)	
Total	129 (100)	67 (100)	62 (100)	
Timing of CS				
Elective	9 (7)	5 (7.5)	4 (6.5)	0.411
Emergency	120 (93)	62 (92.5)	58 (93.5)	
Total	129 (100)	67 (100)	62 (100)	
Foul liquor (N=129)	8 (6.2)	5 (7.5)	3 (4.8)	0.231
Complications at CS				
None	124 (96.1)	65 (97)	59 (95.2)	0.299
Difficulty in achieving haemostasis	2 (1.6)	2 (3)	0 (0)	
Deeply impacted head	3 (2.3)	0 (0)	3 (4.8)	
Total	129 (100)	67 (100)	62 (100)	
Uterine tears at CS (N=129)	9 (7)	5 (7.5)	4 (6.5)	0.411

The most common indication for the CS was Non reassuring foetal status (44.2%) followed by malposition/malpresentation. Most Caesarean sections were done as emergencies (93%). Most of the study subjects had had membranes ruptured less than two hours before the operation (50.4%). Only 6.2%, (see Table 2) of the subjects had foul smelling liquor and there were no statistical differences in the two groups. There were no complications intra-operatively in the majority of the study subjects (96.1%) and only 9 (7%) had uterine tears. Peri-Caesarian section factors were not different in the two groups being compared.

Table 3
Outcome of the ceasarean delivery

Outcome	Overall N=129	Method	Closure N=67	Non Closure N=62	95% CI of difference/OR	P-value
Mean duration of CS (min)	42.8	45.7	39.6	1.9 – 10.3	0.005	
Mean no. of sutures used	4.7	5.2	4.2	0.7 – 1.3	0.000	
Mean V.A.S.	1.4	1.2	1.5	–0.2 – 0.2	0.180	
Mean duration of hospital stay (days)	4.2	4.1	4.2	–0.3 – 0.1	0.341	
Fever 3rd post-op day	0 (0%)	0 (0%)	0 (0%)	0.6-2.4 (OR)	1.000	
Mild to discomforting pain 3rd post-op	81(62.8%)	41(61.2%)	40(64.5%)	-	0.697	
Wound infection 3rd post-op day	1 (0.8%)	1 (1.5%)	0 (0%)	-	1.000	
Burst abdomen	0 (0%)	0 (0%)	0 (0%)	-	1.000	
Wound dehiscence	0 (0%)	0 (0%)	0 (0%)	-	1.000	

The mean duration of CS was 42.8 minutes ± SD12.5. The closure group took longer than non-closure group (45.7±15 Vs. 39.6 ±8, P<0.05, Table 3). The number of sutures used on average were 4.7 ± SD 0.8, the closure group more compared with the non-closure group (5.2 ±0.7 Vs. 4.2 ±0.7, p<0.05, table 3). Post-operative pain was generally not a problem to the patients with a mean Visual analogue score table 3of 1.4 ± SD 1.0 on a scale of 0-10. The non-closure group however indicated slightly more pain (1.5±0.93) compared with the closure group (1.2 ±1.1), but this difference was not statistically significant. The adverse outcomes like febrile morbidity and wound complications at Caesarean section were rare and not different whether peritoneum was closed or not during Caesarean section.

DISCUSSION

There was no statistical difference among the socio-demographic characteristic for both groups. Non-closure of peritoneum during CS took less time and fewer sutures were used and these can result in cost savings.

Overall, the mean duration of Caesarean section was 42.8 minutes. However, the closure of peritoneum group had a statistically significant longer duration of Caesarean section (45.7 minutes) compared with the non-closure group (39.6 minutes<0.05)). This can be explained by the fact that the step of closure of both peritoneums was omitted. These findings are in keeping with the findings of similar studies done by Nagale (6) and Hull (20) who found the average operating time was shorter for the open than the closed group. Four trials involving 1194 women (5, 7) included in a Cochrane systematic review (9) showed that non-closure of the peritoneum during Caesarean section saved operating time.

However, post-operative pain was generally not a problem to the patients in both groups with a mean Visual analogue score of 1.4 ± SD 1.0 on a scale of 0-10. The non-closure group however indicated slightly more pain (1.5± 0.93) compared with the closure group (1.2 ±1.1), but this difference was not statistically significant. The scores were noted to be low for both groups. It is likely that the patients were conservative in the interpretation of pain due to cultural influence. The Cochrane systematic review by Wilkinson *et al.* (9) showed that there were no statistically significant differences in analgesic requirements. Hull *et al.* (5) found no major difference though these patients whose peritoneum was left open were later found to require fewer doses of oral analgesics (P<0.2).

The adverse outcomes at Caesarean section were rare and not different whether peritoneum was closed or not during Caesarean section. Only one (0.8%) of the study subjects who had closure of peritoneum had wound infection on the third post-operative day. No fever, burst abdomen and wound dehiscence occurred in any of the study subjects. The Cochrane systematic review by Wilkinson *et al.* (9) showed that there were no statistically significant differences in postoperative morbidity. However, there was a consistent, although non-significant, trend for improved immediate postoperative outcome if the peritoneum was not closed. Harold *et al*. (10) failed to demonstrate any difference between healing of laparotomy wounds with peritoneum sutured or left open in 326 randomised patients. Naegele *et al* (6) In a prospective trial demonstrated that both temperature ≥ 38 ºC for more than two postoperative days and daily average temperature values during the first

post-operative week were significantly higher with closure of peritoneum ($p<0.001$).

The post-operative hospital stay in both groups had an average of 4·2 days, with no statistical difference in both the closed (4·1 days) and non-closure groups (4·2 days). Wilkinson *et al*. (9) showed that there were no statistically significant differences in the length of hospital stay. However, Naegele *et al* (6), in a prospective trial found that postoperative hospitalisation was significantly longer in the closed group (7.9 ±1.8 days) than in the open group (7.2 ±1.6days) ($p < 0.001$).

The number of sutures used on average was 4.7 and were statistically significant ($p<0.05$) more for the closure group (5.2) compared with the non-closure group (4.2). This translates to saving one suture length for every Caesarean section done. Other cost analysis studies that have been done to determine possible savings with omission of peritoneal closure were performed in two randomised trials (7, 8). Pietrantoni *et al.* (7), in a trial which involved 248 women and was reported in 1991 and Grundsell *et al*. (8) in 1998, found it as more cost effective in the number of sutures saved when open method was performed.

In conclusion, non-closure of peritoneum during CS took less time (42.8 ± SD 8) and fewer sutures were used (4.2 ±0.7) and these can result in cost savings. There were no statistically significant differences in post-operative pain scores, febrile morbidity, wound complications and length of hospital stay.

It is recommended that Obstetricians and Medical institutions should consider adoption of non-closure of peritoneum at Caesarean delivery as part of the standard operating procedures.

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