Caesarean deliveries by Pfannenstiel versus Joel-Cohen incision: A randomised controlled trial

Joel-Cohen insizyona karşılık Pfannenstiel insizyon ile Sezaryen doğumlar: Bir randomize kontrollü çalışma

Wessam Magdy Abuelghar¹, Gasser El-bishry¹, Lamiaa H. Emam²

¹Department of Obstetrics and Gynecology, Ain Shams University, Cairo, Eygpt ²Department of Obstetrics and Gynecology, Ghamra Hospital, Cairo, Eygpt

Abstract

Objective: This study was designed to compare the Pfannenstiel versus Joel-Cohen incisions during caesarean deliveries.

Material and Methods: Women undergoing caesarean deliveries (n=153) were randomly assigned to the conventional Pfannenstiel or the Joel-Cohen incision. The outcome measures included postoperative pain, requirement for analgesics, operative time and other postoperative data.

Results: Maternal age, parity, gestational age and indications for caesarean delivery were similar across groups. Total operative time, postoperative recovery duration, time to get out of bed, to walk straight without support, to detect audible intestinal sounds and to pass gases or stools were shorter in the Joel-Cohen group. Postoperative haematocrit decreases and estimated intraoperative blood loss were similar between the two techniques. Moderate and severe pain at 6, 12 and 18 hours postoperatively was less frequent after the Joel-Cohen technique.

Conclusion: Joel-Cohen incision in the non-scarred abdomen may provide a faster technique for caesarean section with less postoperative pain and probably early postoperative recovery in our circumstances. (J Turkish-German Gynecol Assoc 2013; 14: 194-200)

 Key words: Caesarean, deliveries, Pfannenstiel, Joel-Cohen, incision

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Özet

Amaç: Bu çalışma sezaryen doğumlar sırasında Joel-Cohen insizyona karşılık Pfannenstiel insizyonu kıyaslamak için tasarlandı.

Gereç ve Yöntemler: Sezaryen doğuma giden kadınlar (n=153) randomize olarak geleneksel Pfannenstiel veya Joel-Cohen insizyon grubuna ayrıldı. Akıbet ölçümlerine postoperatif ağrı, analjezik gereksinimi, operasyon süresi ve diğer postoperatif veriler dahildi.

Bulgular: Maternal yaş, parite, gestasyonel yaş ve sezaryen doğum endikasyonları gruplar arasında benzerdi. Toplam operasyon süresi, postoperatif iyileşme süresi, yataktan çıkma, destek olmaksızın düz yürüme, duyulabilir bağırsak seslerini saptama ve gaz veya gaita çıkarma zamanı Joel-Cohen grubunda daha kısa idi. Postoperatif hematokrit azalması ve tahmini intraoperatif kan kaybı iki teknik arasında benzerdi. Postoperatif 6., 12. ve 18. saatte orta ve şiddetli ağrı Joel-Cohen tekniği sonrası daha az sıklıkta oldu.

Sonuç: Skar olmayan karında Joel-Cohen insizyon, bizim koşullarımızda Sezaryen kesisi için daha az postoperatif ağrı ve muhtemelen postoperatif erken iyileşme ile daha hızlı bir teknik sağlayabilir. (J Turkish-German Gynecol Assoc 2013; 14: 194-200)

Anahtar kelimeler: Sezaryen, doğumlar, Pfannenstiel, Joel-Cohen, insizyon Geliş Tarihi: 29 Haziran 2013 Kabul Tarihi: 07 Ağustos 2013

Introduction

Caesarean section is the most common major abdominal operation performed on women in developed and developing countries; thus, any useful refinement in the operative technique is likely to yield substantial benefits. The surgical technique for caesarean delivery has changed over time, and from surgeon to surgeon, and these changes involve both uterine and skin incisions (1). Rates of caesarean section vary between countries and health services from 3.5% in Africa to 29.2% in Latin America and the Caribbean (2).

There are many possible ways to perform a caesarean section: 77% of Obstetricians use a Pfannenstiel incision for urgent or emergency caesarean sections, 55% use single-layer closure of the uterine incision, 37% use double-layer closure, while 11% use single-layer closure only in women undergoing concomitant sterilisation (3). The Pfannenstiel

incision is a transverse skin incision, two finger-breadths above the symphysis pubis, which is extended in the direction of the anterior superior iliac spine (ASIS) and ends 2-3 cm medial to ASIS on both sides (4). In the Joel-Cohen Incision, the skin incision is placed 3 cm above the original Pfannestiel incision, the subcutaneous tissue is incised only in the three most medial centimetres, and the lateral tissue is separated manually, before the fascia is divided bluntly with both index fingers inserted in the deep fascial space created by the knife. Then, the abdomen is opened bluntly with fingers, the uterine cavity is incised and the incision is extended laterally by 2 fingers. In both techniques, after delivery of the baby, the placenta is delivered spontaneously (5). The modified Joel Cohen technique is a very attractive surgical option due to its simplicity and its claimed advantages; it is faster to perform, causes less blood loss, less postoperative pain, shorter



hospital stay, less postoperative infection, is more economic, and saves more staff time and utilises less anaesthesia (6). This study was designed to compare the Pfannenstiel versus Joel-Cohen incisions during caesarean deliveries.

Material and Methods

This comparative study was carried out over one year from January 2012 to January 2013. One hundred and fifty three (153) women were included in this study after informed consent was taken and the study was approved by the institute ethical committee. One hundred and twenty eight (128) women were finally (25 were lost during follow-up, Figure. 1) included in this study and randomly assigned to either the conventional Pfannenstiel or the Joel-Cohen incisions during caesarean delivery according to the different obstetric indications. Exclusion criteria included (1) women having experienced previous abdominal operations, (2) women who had received a previous caesarean section, (3) women with any disease that could affect post-operative recovery (cardiac, diabetes mellitus, preeclampsia), and (4) patients who were complicated with unilateral or bilateral extension of the uterine incision during caesarean section.

All recruited women were subjected to history taking, general, obstetric examinations and preoperative investigations according to the hospital labour ward protocol, in particular preoperative haemoglobin and haematocrit analysis.

All caesarean section were done under spinal anaesthesia, by a lecturer of the causality (denoted as someone who had passed the residency program 3 years previously and had at least 3 years of experience as an assistant lecturer, with an MD degree), and were assisted by a registrar of the causality.



Figure 1. The flow chart of the study design

Randomisation was performed using a computer-generated list of random numbers; the allocation sequence was concealed from the researcher enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes, which were kept with the labour ward nurse. The envelopes were opened only after the enrolled participants had completed all of the baseline assessments and it was time to allocate the intervention. Once the decision regarding caesarean delivery was taken and after transferring the patient to the operating room, the patient was blinded to the method until a few minutes before the operation where the numbered randomisation envelopes were placed in the preparation room of the obstetric theatre and were consecutively picked by the anaesthetist for each caesarean delivery. The results of randomisation (whether 1 or 2) were known only to the single obstetrician who performed the operation (physicians, nursing staff and the patient were unaware of the randomisation results).

Group 1: The Joel-Cohen abdominal incision was used. This was a straight transverse incision through the skin only, 3 cm below the level of the anterior superior iliac spines (higher than the Pfannenstiel incision). The subcutaneous tissues were opened only in the middle 3 cm. The fascia was incised transversely in the midline then extended laterally with blunt finger dissection; finger dissection was used to separate the rectus muscles vertically and laterally and to open the peritoneum. All layers of the abdominal wall were stretched manually to the extent of the skin incision. The bladder was reflected inferiorly. The myometrium was incised transversely in the midline, without breaching the amniotic sac, then opened and extended laterally with finger dissection.

Group 2: A Pfannenstiel abdominal incision was used. The skin and rectus sheath were opened transversely using sharp dissection. The rectus sheath was dissected free from the underlying rectus abdominus muscles. The peritoneum was opened longitudinally using sharp dissection. The uterus was opened with a transverse lower segment incision. The uterine incision was closed with two layers of continuous sutures and both peritoneal layers were closed with continuous sutures. The fascia was closed with continuous or interrupted sutures. The skin was closed with interrupted or continuous sutures.

Before surgery in both groups, the pubic hair was removed from

the operative field using a razor, and a urinary catheter was introduced before surgery and removed after mobilisation. All patients received the same dose of prophylactic antibiotics, were transferred to the same post-operative ward, received the same medication and were nursed by well-trained nursing staff (the nursing staff were unaware to which group each patient was allocated). Primary outcome measures included postoperative pain using

a visual analogue scale (VAS) in the 1st 6th, 12th and 18th hours postoperative; VAS is represented by a 100 mm line with one end labelled as (no pain) and the other as (worst possible pain), in which the patient was asked to put a mark on the line representing the severity of pain she felt (7), (Figure 2).

Secondary outcome measures were operative time (time from skin incision to skin closure), delivery time (time from skin incision to delivery of the baby), delivery to closure time (time from delivery of the baby to closure of skin), the amount of blood loss during caesarean section (which was estimated by the amount of the blood in the suction bottle), postoperative haemoglobin (Hb) & haematocrit drop and postoperative febrile morbidities. Also, secondary outcome measures were the times from the end of caesarean section to getting out from bed and to walking straight without support, time to detecting audible intestinal sounds and to passing gases or stool, and length of postoperative hospital stay.

The same preoperative antibiotics and postoperative analgesics (Pethidine 50 mg IM on request) were given to both groups. Post-operative follow-up was done one week after the caesarean delivery.

Sample size justification

The required sample size was calculated using G* Power software version 3.17 for sample size calculation (*Heinrich Heine Universität; Düsseldorf; Germany), setting the primary outcome as the proportion of patients with severe or very severe pain after surgery as scored on the visual analogue scale (VAS), the α -error probability at 0.05, power (1- β error probability) at 0.95 %, and effective sample size (w) at 0.25.

The effective size (w) was calculated as follows: $w=\sqrt{X^2/N}$ where X² is the chi-square test and N is the total sample size. The number of participants needed to produce a statistically acceptable figure was 63 patients in each study group.



Figure 2. Visual analogue scale (VAS) for pain assessment

Statistical analysis

Data were collected, tabulated and then statistically analysed using the Statistical Package for Social Sciences (SPSS) computer software version 15. Numerical variables were presented as mean and standard deviation (\pm SD), while categorical variables were presented as number and percentage. Chi-square test (X^2) was used for comparison between groups with regard to qualitative variables. The Student t-test and Mann-Whitney U-test were used for comparison between groups as regard quantitative variables. Relative risks were calculated with respect to intraoperative and postoperative events in both groups, with the corresponding 95% confidence interval (CI). A difference with a p value <0.05 was considered statistically significant.

Results

The mean age of the studied population was 26.64 ± 3.66 years (range: 20–35 years), the mean gestational age at caesarean section was 38.82 ± 1.3 weeks (range: 35.14-42 weeks) and the mean parity was 1 (range: 0-4). There were no significant differences between the Joel Cohen group and Pfannenstiel group regarding mean age (26.75 ± 3.7 versus 26.53 ± 3.65 , respective-

Table 1. Mean age, parity and gestational age of the two studied groups

Variables	Group 1 (Joel Cohen Incision) (Number=64)	Group 2 (Pfannenstiel Incision) (Number=64)	p value
Age (years) Mean±SD (range)	26.75±3.7 (20-35)	26.53±3.65 (20-35)	0.74**
Parity Mean±SD (range)	1±1.2 (0-4)	1±1.5 (0-3)	0.80**
Gestational age (Weeks) Mean±SD (range)	38.86±1.4 (38-41)	38.78±1.2 (38.5-40.5)	0.73**
**: Non-significant			

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ly), mean parity (1 ± 1.2 versus 1 ± 1.5 , respectively) and mean gestational age (38.86 ± 1.4 versus 38.78 ± 1.2 , respectively) (p>0.5; Chi-square test); Table 1.

Also, there was no significant difference between the two studied groups regarding indications for caesarean section (p>0.5; Chi-square test); Table 2.

The mean VAS score at 6, 12 and 18 hours postoperative were significantly lower in the Joel-Cohen group (52.8 ± 13.0 , 31.5 ± 12.8 and 16.3 ± 6.9 , respectively) compared to the Pfannenstiel group (67.5 ± 12.1 , 43.7 ± 15.4 and 23.1 ± 9.5 , respectively), (p<0.001; independent-samples Student t test); Table 3.

The number of analgesic doses consumed postoperatively was significantly lower in the Joel-Cohen group compared to the Pfannenstiel group (2.4 ± 0.8 versus 3.0 ± 0.8 , respectively), (p<0.001, independent-samples Student t test); Table 3.

Risk analysis was performed to compare the risk of severe pain 6 and 12 hours postoperative in both of the studied groups; the odds and relative risk ratios of severe pain 6 hours postoperative were 0.18 (95%CI 0.08 to 0.38) and 0.43 (95%CI 0.29 to 0.65), respectively, and the risk of severe pain 6 hours postoperative was 0.31 in the Joel-Cohen group compared to 0.72 in the Pfannenstiel group. The Joel-Cohen incision was significantly associated with an absolute risk reduction of severe pain 6 hours postoperative compared to the Pfannenstiel group of 0.41 (95%CI 0.25 to 0.56), (p<0.05); Table 4.

The odds and relative risk ratios of severe pain 12 hours postoperative were 0.15 (95%CI 0.04 to 0.54) and 0.19 (95%CI 0.06 to 0.61), respectively, and the risk of severe pain 12 hours postoperative was 0.05 in the Joel-Cohen group compared to 0.25 in the Pfannenstiel group. The Joel-Cohen incision was significantly associated with an absolute risk reduction of severe pain 12 hours postoperative of 0.20 compared to the Pfannenstiel group (95%CI 0.09 to 0.32), (p<0.05); Table 5.

The secondary outcomes such as total operative time, incisionto-delivery and delivery-to-closure times were significantly shorter in the Joel Cohen group (22.36 ± 2.45 , 2.88 ± 1.12 and 17.86 ± 2.34 minutes, respectively) compared to the Pfannenstiel group (31.59 ± 2.88 , 3.75 ± 1.22 and 24.59 ± 2.51 minutes, respectively), (p<0.05; Independent Student's *t*-Test). Also, time to get

Indications for caesarean sections	Group 1 (Joel Cohen Incision) (Number=64)	Group 2 (Pfannenstiel Incision) (Number=64)	p value
Poor progress of labour and CPD	18 (28.1%)	17 (26.5%)	0.88**
Failed induction of labour	9 (14.1%)	10 (15.6%)	0.83**
Malpresentation	8 (12.5%)	6 (9.4%)	0.01**
Foetal distress	5 (6.3%)	5 (4.7%)	1.00**
Oligohydramnios	6 (9.4%)	9 (14.1%)	0.46**
Foetal macrosomia	6 (9.4%)	4 (6.3%)	0.54**
Multiple pregnancy	7 (10.9%)	7 (10.9%)	1.00**
Infertility	1 (1.6%)	2 (3.1%)	0.56**
Pulsating cord prolapse	3 (4.7%)	4 (6.3%)	0.71**
Previous repair of complete perineal tear	1 (1.6%)	0 (0%)	0.22**
**: Non-significant; CPD: Cephalo-pelvic disproportion	1		

out of bed, to walk straight without support, to detect audible intestinal sounds and to pass gas were significantly shorter in the Joel-Cohen group $(4.92 \pm 1.06, 7.28 \pm 1.25, 4.82 \pm 0.74 \text{ and} 9.34 \pm 1.83$ hours, respectively) compared to the Pfannenstiel group $(7.13 \pm 1.13, 9.53 \pm 1.46, 6.16 \pm 0.71 \text{ and } 12.14 \pm 2.37 \text{ hours}$,

respectively), (p<0.05; Independent Student's *t*-Test); Table 6. There was no significant difference between the Joel Cohen and Pfannenstiel groups regarding postoperative haemoglobin decrease (0.35 ± 0.26 versus 0.34 ± 0.21 g/dL, respectively) and haematocrit decrease (0.67 ± 0.29 versus 0.47 ± 0.35 g/dL, respectively), (p>0.05; Independent Student's *t*-Test). The number of patients with a hospital stay of 0-24 hours was 40 (62.5%) in the Joel Cohen group and 44 (68.8%) in the Pfannenstiel

Table 3. Postoperative pain scores and analgesic consumption in the two studied groups

Variables	Group 1 (Joel Cohen Incision) (Number=64)	Group 2 (Pfannenstiel Incision) (Number=64)	p value				
VAS at 6 hours postoperative Mean±SD	52.8 ± 13.0	67.5±12.1	<0.001*				
VAS at 12 hours postoperative Mean±SD	31.5±12.8	43.7±15.4	<0.001*				
VAS at 18 hours postoperative Mean±SD	16.3±6.9	23.1 ± 9.5	<0.001*				
Analgesic doses used postoperative Mean±SD	2.4 ± 0.8	3.0 ± 0.8	<0.001*				
*: Significant; VAS: Visual analogue score							

group (statistically insignificant), while the number of patients with a hospital stay of 24-28 hours was 24 (37.5%) in the Joel Cohen group and 20 (68.8%) in the Pfannenstiel group (statistically insignificant), (p>0.05; Chi-Squared Test); Table 6.

Discussion

Caesarean section is a common practice and each institute should study and evaluate the best evidence tailored to its staff and facilities. Caesarean section morbidity is closely related to the precision of opening and closing the abdomen and uterine wall. The modified Joel Cohen technique is a very attractive surgical option due to its simplicity and its claimed advantages. It has already been applied in many parts of the world as it provides more benefits as it is faster to perform, and results in less blood loss, less postoperative pain, earlier ambulation and a shorter hospital stay (6).

This study was designed to compare the Pfannenstiel versus Joel-Cohen incisions during caesarean deliveries, especially in settings with a high flow of patients, as our tertiary referral centre. Several studies have stated that the Joel-Cohen incision at caesarean delivery is a faster method of delivery than both Pfannenstiel incision and mid-line longitudinal incision (8-11). In this study, the total operative time, and incision-to-delivery and delivery-to-closure times in this study were significantly shorter in the Joel Cohen group compared to the Pfannenstiel group. Song & colleagues concluded that the Joel-Cohen incision at caesarean section reduces the operative time, blood loss and postoperative hospital stay (12). Also, the operative time was significantly shorter in the Joel-Cohen technique compared to the Pfannenstiel technique in the studies by Darj et al. (13) and Wallin et al. (14) and the modified Joel Cohen technique

Table 4. Odds, risk ratios and risk reduction of severe pain 6 hours postoperative in both studied groups

Variables	Value
Odds ratio of severe pain 6 hours postoperative	0.18 (95% CI 0.08 to 0.38)
Relative risk ratio of severe pain 6 hours postoperative	0.43 (95% CI 0.29 to 0.65)
Risk of severe pain 6 hours postoperative in Joel-Cohen group	0.31
Risk of severe pain 6 hours postoperative in Pfannenstiel group	0.72
Absolute risk reduction of severe pain 6 hours postoperative by Joel-Cohen technique	0.41 (95% CI 0.25 to 0.56)
Significance level	p<0.0001
*: Significant; VAS: Visual analogue score	

Table 5. Odds, risk ratios and risk reduction of severe pain 12 hours postoperative in both studied groups

Variables	Value
Odds ratio of severe pain 12 hours postoperative	0.15 (95% CI 0.04 to 0.54)
Relative risk ratio of severe pain 12 hours postoperative	0.19 (95% CI 0.06 to 0.61)
Risk of severe pain 12 hours postoperative in Joel-Cohen group	0.05
Risk of severe pain 12 hours postoperative in Pfannenstiel group	0.25
Absolute risk reduction of severe pain 12 hours postoperative by Joel-Cohen technique	0.20 (95% CI 0.09 to 0.32)
Significance level	p<0.0001
*: Significant; VAS: Visual analogue score	

Table	6.	The	second	arv	outcome	in	the	two	studied	groups
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	Group 1 (Joel Cohen Incision) (Number=64)	Group 2 (Pfannenstiel Incision) (Number=64)	p value
Total Operative Time (minutes) Mean±SD (range)	22.36±2.45 (20-32)	31.59±2.88 (25-36)	<0.001*
Incision-to-delivery time (minutes) Mean±SD (range)	2.88±1.12 (2-5)	3.75±1.22 (2-9)	<0.001*
Delivery-to-closure time (minutes) Mean±SD (range)	7.86±2.34 (12-25)	24.59±2.51 (20-30)	<0.001*
Postoperative haemoglobin drop (g/dL) Mean±SD (range)	0.35±0.26 (0.1-1.4)	0.34±0.21 (0-1.1)	0.734**
Postoperative haematocrit drop (%) Mean±SD (range)	0.67±0.29 (0-10.3)	0.47±0.35 (0-2)	0.099**
Postoperative temperature ≥38°C Number (%)	7 (10.9%)	15 (23.4%)	0.061**
Time to get out from bed (hours) Mean±SD (range)	4.92±1.06 (4-7)	7.13±1.13 (5-10)	<0.001*
Time to walk straight without support (hours) Mean±SD (range)	7.28±1.25 (5-10)	9.53±1.46 (7-13)	<0.001*
Time to detect audible intestinal sounds (hours) Mean±SD (range)	4.82±0.74 (4-6.5)	6.16±0.71 (5-7.7)	<0.001*
Time to pass gases or stool (hours) Mean±SD (range)	9.34±1.83 (7-13)	12.14±2.37 (8-18)	<0.001*
Postoperative hospital stay			
0-24 hours	40 (62.5%)	44 (68.8%)	0.457**
24- 48 hours	24 (37.5%)	20 (31.2%)	
*Significant ** Non-significant			

was recommended by the Royal College of Obstetricians and Gynecology in cases of urgent caesarean delivery due to its speed, non-closure of the pelvic peritoneum and non-closure of subcutaneous tissue (15).

The primary outcome of this study was focused on postoperative pain after caesarean delivery using the visual analogue scale (VAS) in first 6, 12 and 18 hours postoperative. The mean VAS score at 6, 12 and 18 hours postoperative were significantly lower in the Joel-Cohen group (52.8 ± 13.0 , 31.5 ± 12.8 and 16.3 ± 6.9 , respectively) compared to the Pfannenstiel group (67.5 ± 12.1 , 43.7 ± 15.4 and 23.1 ± 9.5 , respectively). The number of analgesic doses consumed postoperatively was significantly less in the Joel-Cohen group compared to the Pfannenstiel group (2.4 ± 0.8 versus 3.0 ± 0.8 , respectively).

Also, Darj et al. (13) and Ferrari et al. (16) concluded that the postoperative pain was significantly greater in the Pfannenstiel technique compared to the modified Joel Cohen technique due to extensive tissue trauma and increased inflammatory response in the Pfannenstiel technique.

Risk analysis was performed to compare the risk of severe 6 and 12 hours postoperative pain in both of the studied groups; the Joel-Cohen technique was significantly associated with an absolute risk reduction of severe postoperative pain after 6 hours [0.41 (95% CI 0.25 to 0.56)] and 12 hours [0.20 (95% CI 0.09 to 0.32)] compared to the Pfannenstiel technique. A large Cochrane systemic

review was done to evaluate the Joel-Cohen and Pfannenstiel techniques during caesarean deliveries and concluded that the postoperative pain and number of analgesics needed were lower in the Joel Cohen technique compared with the Pfannenstiel technique (17, 18).

Although this study and randomised controlled trials concluded that the time to get out of bed, to walk straight without support, to detect audible intestinal sounds and to pass gases were significantly shorter in the Joel-Cohen group compared to the Pfannenstiel group (6, 9, 19), the Cochrane systemic review concluded that there was no significant difference between the Joel-Cohen and Pfannenstiel techniques regarding time to return of bowel function, time to mobilisation and/or time to the start of breastfeeding (17, 18).

There was no significant difference in this study between the Joel Cohen group and the Pfannenstiel group regarding the postoperative hospital stay, while, Moreira et al. (6) and Popiela et al. (20), concluded that the postoperative hospital stay was significantly shorter in the modified Joel Cohen technique compared to the Pfannenstiel technique.

There was no significant difference in this study between the Joel Cohen group and the Pfannenstiel group regarding the postoperative haemoglobin and/or haematocrit decreases and no blood transfusion or serious complications were recorded; Darj et al. (13) and Wallin et al. (14) concluded that blood loss was less with the Joel Cohen procedure (448 & 250 mL, respectively) compared to the Pfannenstiel procedure (608 & 200 mL, respectively) due to the short operative time and minimal tissue trauma (13, 14).

The Cochrane systemic review (three trials) reported less blood loss with the Joel-Cohen technique compared to the Pfannenstiel technique and reported more blood transfusion with the Pfannenstiel compared with the Joel-Cohen technique; also, the Cochrane review stated that "the three trials do not provide information on mortality and serious or longterm morbidity such as morbidly adherent placenta and scar rupture" (17, 18).

The limitations of this study include a lack of long-term followup, and the fact that women with previous abdominal surgery, women with medical disorders and/or women receiving general anaesthesia were not included in this study.

Based on limitations of this study and Cochrane reviews, further trials with long-term follow-up are needed to provide information on mortality and/or long-term morbidity, such as morbidly adherent placenta and scar rupture after both techniques of caesarean deliveries.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Ain Shams University Maternity Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author contributions: Concept – G.E.B., W.M.A.; Design – W.M.A.; Supervision – W.M.A., G.E.B.; Resource – W.M.A., G.E.B.; Materials – W.M.A.; Data Collection&/or Processing – W.M.A.; Analysis&/or Interpretation– W.M.A.; Literature Search – W.M.A., L.H.E.; Writing – W.M.A., L.H.E.; Critical Reviews – W.M.A., L.H.E.

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