

## *Introduction*

The most common major abdominal operation done on women is caesarean section. Over the past century delivery by Caesarean section has been increased in both developed and developing countries (*Thomas et al., 2001*).

Global estimates indicate a caesarean section rate of 15% worldwide, ranging from 3.5% in Africa to 29.2% in Latin America and the Caribbean (*Betran 2007*).

As with other surgical procedures, there is no one standard surgical technique for caesarean delivery. The wide variation in surgical techniques in practice depends on many factors including the clinical situation and the preference of the operator. Various abdominal incisions have been used for Cesarean delivery. They include vertical incision (midline and para median) and transverse incision (Pfannenstiel, Maylard, Cherney and Joel-Cohen) (*Mathai 2007*).

The transverse suprapubic skin incision is the most common technique used for caesarean delivery in the developed world as well as majority of developing countries. The Pfannenstiel incision and Joel-Cohen abdominal incision are the commonly followed lower abdominal incisions in Caesarean section.

Pfannenstiel introduced the Pfannenstiel incision in 1900 (*Stark et al., 1995*). It is a horizontal incision about 2cm above pubic symphysis.

Professor Joel-Cohen introduced an incision for abdominal hysterectomy in 1954, and obstetricians have since used this widely to perform caesarean section (*Stark 1994*).

The incision is a straight horizontal incision, being positioned slightly higher than the Pfannenstiel, about 3cm below the line joining the anterior superior iliac spines.

In an attempt to simplify the surgical procedure and minimize the tissue damage, the Joel-Cohen method was modified by Stark and coworkers (*Holmgren 1999*) at Misgav-Ladach General Hospital in Jerusalem, leading to a unique improvement of the modified Misgav-Ladach method (*Kulas et al., 2008*).

The main features of the modified Misgav-Ladach technique for caesarean section were documented to be the transverse incision using Joel-Cohen incision for opening the abdomen, suturing the hysterotomy in one layer and nonclosure of the visceral and parietal peritoneum (*Stark et al., 1995*).

## *Research Hypothesis*

The modified Misgav-Ladach and Pfannenstiel-Kerr techniques in cases with only one previous caesarean section for the total operation time and operation related morbidity.

The modified Misgav-Ladach technique is not superior to Pfannenstiel-Kerr technique in reducing total operation time and operation related morbidity of caesarean section in women with previous one caesarean delivery.

## *Methodology*

Pregnant women will be enrolled according to the following criteria:

**Inclusion criteria:**

- Gestational age is 37 weeks or more.
- Previous one caesarean section with transverse abdominal incision but could have previous vaginal deliveries.
- Absence of uterine contractions.

**Exclusion criteria:**

- Previous other abdominal operations.
- Two or more previous caesarean section.
- Known severe anaemia.
- Bleeding disorders.
- Intrapartum febrile illness.
- Placenta previa.
- Abruption placentae.
- Severe preeclampsia.
- Multiple pregnancies.
- Antibiotic use in the previous two weeks.

Patients will be recruited from Ain Shams Maternity University Hospital.

All participants will provide written informed consent at the time of enrollment.

Participants will be randomized to one of 2 groups:

- Group 1: intervention group who will undergo caesarean section by modified Misgav-Ladach technique.
- Group 2: control group who will undergo caesarean section by Pfannenstiel-Kerr technique.

### **Study design:**

This is a randomized controlled trial.

Random sequence is computer generated and allocation concealment will be carried out by a computer based sealed opaque envelope method. The operation type printed on identical sheets of paper will be put into identical, consecutively numbered sealed opaque envelopes by a nonparticipating colleague. Immediately before the incision of the skin, responsible nurse will open the envelope.

All operations will be performed by two experienced surgeons each of whom performed at least 80 first time and 20 repeat caesarean sections using both techniques well documented in the literature and antibiotic prophylaxis will be

given to all patients according to the protocol guidelines of Ain Shams Maternity University Hospital at the time of the study.

### **The surgical methods:**

#### **The modified Misgav-Ladach method:**

- The skin is incised through the same transverse skin incision.
- The subcutaneous tissue and the anterior rectus sheath are opened a few centimeters only in the midline. Both the fascia and subcutaneous tissue are rapidly divided by blunt finger dissection.
- The rectus muscles are separated by finger traction.
- The peritoneum is opened by blunt dissection in a transverse direction and the opening is widened by traction in a transverse direction.
- After that the visceral peritoneum is opened and the uterus is sharply opened in the superficial layers; and deeper layers are opened and extended bluntly.
- The fetus is delivered and the placenta is removed manually.
- The uterus is exteriorized and the myometrial incision is closed with a single-layer locking continuous suture.

- The peritoneal layers are not sutured. The fascia is sutured with a continuous suture. The subcutaneous tissue is not sutured unless more than 2 cm thickness and the skin is closed with one intracutaneously running suture, all with VicrylA suture material.

### **The Pfannenstiel-Kerr method:**

- In the Pfannenstiel method the skin is incised through the same transverse skin incision. The subcutaneous tissue is incised and sharply divided with scissors.
- The fascia is transversely incised 15 cm and separated from the underlying muscles by blunt and sharp dissection.
- Once the fascia is dissected, rectus muscles are separated with finger dissection.
- The parietal peritoneum is sharply opened in vertical direction and the visceral peritoneum is then opened.
- After that the uterus is sharply opened in the superficial layers; and deeper layers are opened and extended bluntly.
- The fetus is delivered and the placenta is removed manually.
- The uterus is exteriorized and the incision is closed by double-layer continuous suture.

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- Both the visceral and parietal peritoneum is closed continuously. The fascia is then closed with a continuous suture. The subcutaneous tissue is not sutured unless more than 2 cm thickness and the skin is closed by one intracutaneously running suture, all with VicrylA suture material.

### **Outcomes:**

The primary outcomes will be:

1. The total operative time
2. Time until delivery of neonate (extraction time)
3. Apgar score
4. Blood loss
5. The number of used sutures

The secondary outcomes are defined to be:

1. Wound seroma.
2. Wound infection.
3. Wound disruption.
4. Time of bowel restitution.
5. Need for analgesics in the first 6 hours, total analgesic dose in the first twenty four hours.

6. The score obtained on Visual Analog Scale (VAS) at 6 and 24 h of the operation.
7. Postoperative febrile morbidity.
8. Endometritis.
9. Time to mobilization.
10. Time to oral intake.
11. Time to breastfeeding initiation.

Extraction time is defined as the interval from skin incision to the clamping of the umbilical cord, while the total operative time is defined as the time from skin incision to the end of the skin closure (*Franchi et al., 2002*).

Total operation and extraction times are recorded by an independent person using time chronometer.

Blood loss is evaluated by the difference in hemoglobin levels and haematocrit value before and after the operation.

Pain will be assessed by subjective scoring on visual analog scale indicating the severity of pain.

Febrile morbidity is defined as axillary temperature more than 38°C persisting for more than 48 hours.

Postpartum endometritis is diagnosed when a purulent vaginal discharge accompanied by uterine tenderness and/or an axillary temperature above 38°C occur.

### **Sample size justification:**

On the basis of a previously published article the total operation time by traditional Pfannenstiel-Kerr technique of caesarean section was about 33 minutes (*Franchi et al., 2002*) and our aim is to reduce the total operative time by modified Misgav-Ladach method to 17 minutes so we have to include 126 women in each arm of our randomized trial to detect such difference at 80% power and type I error 0.05 using PS Power and Sample Size Program version 3.0.43 and to nullify the attrition error we will add 13 patients so the total sample size will be 265 subjects.

### **Data analysis:**

- Data will be analyzed using IBM SPSS, version 21.0.
- Description of continuous variables will be performed in the form of mean, standard deviation (SD).
- Description of dichotomous data will be performed in the form of numbers and percent.
- Analysis of continuous variables will be performed using independent student's t test and Mean difference and 95% CI.

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- Analysis of dichotomous data will be performed using Fisher's exact test and risk ratio [RR] and their 95% CI
- Significance level is set at 0.05.
- Confidence interval:
- The confidence interval will be calculated according to the results.

### **Ethical considerations:**

IRB approval:

The clinical research study will be conducted in accordance with the current IRB-approved clinical protocol; ICH GCP Guidelines; and relevant policies, requirements, and regulations of the Ain Shams University.

### **Consent procedure:**

The Investigator will make certain that an appropriate informed consent process is in place to ensure that potential research subjects, or their authorized representatives, are fully informed about the nature and objectives of the clinical study, the potential risks and benefits of study participation, and their rights as research subjects. The Investigator will obtain the written, signed informed consent of each subject, or the subject's authorized representative, prior to performing any

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study-specific procedures on the subject. The Investigator will retain the original signed informed consent form.

### **Subject confidentiality:**

All laboratory specimens, evaluation forms, reports, video recordings, and other records that leave the site will not include unique personal data to maintain subject confidentiality.

### **Funding:**

The study will be funded internally.

## *References*

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**PS Power and Sample Size Program:** PS version 3.0.43.

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## References

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**Stark M, Chaavkin V, Kupfersztain C et al:** Evaluation of combinations of procedures in Caesarean section. International J Gynecol Obstet and 1995; 48: 273-6.

**Stark M, Finkel A:** The comparison between the Joel Cohen and Pfannenstiel incisions in Caesarean section. European J Obstet Gynecol Reprod Biol 1994; 53: 121-2.

## *Review of Literature*

### **Chapter I (Caesarean Section)**

**I- Introduction**

**II- Historical background**

**III- Epidemiology**

**IV- Planned caesarean section**

**V- Repeat caesarean section**

**VI- Indications:**

1. Indisputable indications.
2. Generally accepted indications.
3. Marginal indications.

**VII- Classification of urgency**

**VIII- Complications**