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Prospective, Randomized, Comparative Study of Misgav Ladach versus Traditional Cesarean Section at Nazareth Hospital, Kenya

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Abstract. Cesarean section (CS) is the commonest major operation carried out in many low income countries. A new technique for CS, called the Misgav Ladach procedure, was evaluated in a randomized trial in Nazareth Hospital (Kiambu District, Kenya). A total of 160 patients were assigned to the Misgav Ladach procedure ($n = 80$) or to the traditional CS as performed in most rural hospitals in low income countries ($n = 80$). The two groups were analyzed by operating time, presence of infection and febrile morbidity, grade of postoperative pain, starting of fluid and solid alimentation, and development of incisional hernia and hypertrophic scar. The operating time of the Misgav Ladach procedure was significantly shorter. 20.4 (SD 6.1) minutes versus 30.4 (SD 6.1) minutes ($p < 0.001$). A total of 5 wound infections (6.2%) were seen with the Misgav Ladach procedure versus 16 (20.0%) in the control group ($p = 0.01$). The number of analgesic doses required during the postoperative period were significantly less in the Misgav Ladach group: 1.3 (SD 0.6) versus 1.9 (SD 0.7) ampuls of pethidine ($p < 0.001$) and 15.1 (SD 2.0) versus 16.4 (SD 1.8) tablets of ibuprofen ($p < 0.001$). Incisional pain was significantly less in the Misgav Ladach group: Visual Analogue Scale score 3.0 (SD 1.5) versus 4.9 (SD 2.0), $p < 0.01$. The patients in the Misgav Ladach group began drinking fluids voluntarily [19.1 (SD 4.5) hours versus 20.6 (SD 4.0) hours; $p = 0.01$] and eating solid food [41.2 (SD 9.3) hours versus 46.1 (SD 9.0) hours; $p < 0.01$] significantly before than those in the control group. At the 6-week follow-up, the presence of hypertrophic scar was significantly associated with the traditional procedure (2.1% vs. 48.8%; $p < 0.001$). We conclude that the Misgav Ladach operation should become the standard method for performing CS in low income countries, particularly in rural hospitals.

Cesarean section (CS) is a common operation performed as an elective or an emergency procedure. Countless variations of the procedure have been introduced since the first CS was carried out. Some have concerned seemingly small details of the operation, whereas others have presented major breakthroughs, (e.g., the incision proposed by Pfannenstiel at the turn of the century that has become the standard in Western countries). In contrast, in many hospitals of low income countries CS is still traditionally performed with a longitudinal, subumbilical, midline laparotomy, with double layers of sutures on the uterine wall and with suturing of all layers (visceral and parietal peritoneum, fascia, subcutaneous, skin) to close the abdomen.

During the last decade, Stark and colleagues developed in Misgav Ladach Hospital in Jerusalem a new CS technique [1] in which the abdomen is opened using the transverse cut of the Joel-Cohen method [2]. Other distinctive features of the Misgav Ladach method include single-layer closure of the uterus and nonclosure of the peritoneal layers. Although none of these details is common practice for CS as it is actually practiced, they were demonstrated to be safe and efficacious in many studies [3–9]. Moreover, in preliminary reports from high income countries the Misgav Ladach method has been compared with the traditional Pfannenstiel method [10, 11], showing some advantages, such as less bleeding [1, 11], shorter operative duration saving theater and staff time [3, 11], less postoperative pain [10, 11], fewer postoperative infections and less febrile morbidity [10], early bowel function resumption [12], and less danger of peritoneal adhesions [1, 10, 13]. There are other advantages associated with the Misgav Ladach method for CS as well. It is easy to learn and to perform (even by nonsurgeon or nonobstetrician doctors), the strong scar wound reduces the risk of incisional hernia (major disability in women with heavy workloads), and fewer theater materials (i.e., sutures and instruments) are used. Moreover, there is early ambulation (with reduced risk of thrombosis and early start on breast-feeding), early discharge home, and a lower incidence of hypertrophic scar or keloids [14].

These advantages are important, particularly in low income countries. CS is the most common major operation carried out in eastern Africa. It has been estimated that 20 to 30 CSs are currently performed annually in a population of 100,000, although there is actually a need for 200 to 250 annually [15, 16]. The problem of this unmet need in the population living in rural areas of developing countries is due to the facts that in these areas doctors are scarce, distances between hospitals are large, and transport is rarely readily available. These considerations explain the fact that many obstetric and gynecologic conditions in rural settings are managed by non-specialist doctors (in particular general surgeons, when available) [17] and has motivated the health ministries of some countries to delegate CS performance to staff

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not formally trained as medical doctors [18]. Thus any improvement in CS should produce benefits to the reproductive health of the communities of low income countries, where the incidence of operative deliveries is high and sometimes delegated to nonmedical staff.

For these reasons we carried out a prospective, randomized study to compare the Misgav Ladach technique for CS with the traditional procedure as done in low income countries, mostly in the hospitals of rural areas. The aim of the study is to determine the safety of the technique by observing any complications arising intraoperatively and postoperatively and to evaluate its efficacy in comparison with the traditional method by noting the operating time, the presence of infection and febrile morbidity, the degree of postoperative pain, the time of starting fluid and solid alimentation, the development of incisional hernia, and the outgrowth of hypertrophic scar and keloids.

Patients and Methods

Study Site (Geographic) and Participating Surgeons

The study was performed in Nazareth Hospital (Kiambu District, Kenya), a 200-bed rural hospital sited 30 km from Nairobi, with a good standards of diagnostic and therapeutic facilities and a busy maternity ward. The study was carried out with the participation of two surgeons who agreed to standardize the two procedures. One of them (L.A.), who was already familiar with the Misgav Ladach technique, during a teaching/pilot phase taught the other surgeon (R.B.) this procedure until he was satisfied the latter could carry out the operation well. Both surgeons were already well familiar and expert with the traditional method of carrying out CS. Patients operated on during the teaching/pilot phase were not included in the study, but the data collected were used to calculate the sample size. This phase consisted of 50 patients and lasted 40 days.

Study Population and Preoperative Protocol

All patients who underwent CS performed by the two surgeons (emergency or elective, with any indication) from March 17, 1997 to July 27, 1997 were included in the study to attain the 160 CSs established by the sample size calculation. The exclusion criteria were uterine rupture with prolonged obstructed labor ($>$ 24 hours) or with fetal death or the need for a cesarean hysterectomy.

The patients were informed about the nature and purposes of the trial, and informed consent to participate to the randomization was obtained. They were free to withdraw from the study whenever they wished without any obligation. No incentives were given to the patients regarding participation in the study or the follow-up. All the medical information obtained from the patients was kept confidentially among the research scientists conducting the study.

Certain data were collected preoperatively, such as age, weight, marital status, education, gestational age (in weeks), gravidity, parity, number of abortions, previous cesarean section (PCS), rupture of membranes (in hours), degree of cervical opening (in centimters), number of cervical examination(s) performed prior to the operation, emergency procedure (versus elective), and indication for CS.

Concerning the marital status the patients were defined as single (when not married, divorced, or widowed) or married. The educational level was defined as "low" for patients who were illiterate or had a primary school diploma and "high" for those who had a secondary school diploma or more education.

Gestational age was calculated considering the last menstrual period (according to the patient) and the upper uterine level by palpation. The status was defined as an emergency when CS became immediately necessary because of maternal or fetal compromise, even if it was not considered life-threatening to the mother or the fetus. Elective CS was that performed at a time convenient to the patient and the medical and midwifery staff.

Indications for CS were formulated by the obstetrician in the ward and were grouped in the following categories: (1) fetal distress; (2) cephalopelvic disproportion (CPD) and one PCS with CPD; (3) more than one PCS; (4) maternal complications (placenta praevia, severe preeclampsia, eclampsia); (5) fetal malpresentations and cord prolapse; (6) failure of induction.

Randomization and Record Keeping

Randomization was obtained through an alternate assignment to the two procedures, closely following the inclusion/exclusion criteria. After completion of surgery, all details were recorded on a paper form kept with the patient's notes and later stored in a computer database.

Preoperative Management

The same antibiotic prophylaxis was given to all patients in the Misgav Ladach and traditional groups. They received a single dose of ampicillin 3 g plus metronidazole 500 mg intravenously immediately before operation. Ampicillin was chosen for its low cost, broad spectrum, sufficient half-life, and high wound concentration and metronidazole for its anaerobic activity and long half-life [19, 20]. No antibiotic prophylaxis was given after operation. This regimen has been proved effective for reducing the infectious morbidity rate in rural hospitals in developing countries [21].

The type of anesthesia, either general or spinal anesthesia (2%, hyperbaric lignocaine 2 ml) was chosen by the anesthetist independently of the surgeon's preference. All the patients were operated on in the supine position with a wedge placed under the right buttock to prevent the supine hypotensive syndrome. The instrument sets were the same for both procedures: one scalpel, two pairs of scissors (one straight, one curved), one Doyen mobile retractor, four artery forceps, three Green Armytage forceps, one needle-holder, two Durante dissecting forceps.

Surgical Procedures

Misgav Ladach Procedure. The principal elements of the Misgav Ladach CS are the following: (1) the Joel-Cohen method for opening the abdomen; (2) suturing the lower uterine segment incision in one layer of catgut chromic no. 2 in continued locked suture; and (3) nonclosure of both the visceral and parietal peritoneal layers. The technical details and operative steps used for the Misgav Ladach technique are exactly those described by Stark [1].

Traditional Procedure. The usual CS procedure in developing countries, mostly in rural hospitals, consists of subumbilical longitudinal laparotomy, closing the uterus in two layers of catgut chromic no. 2 in continued locked suture, and closing both peritoneal layers with continued sutures of plain catgut no. 2/0. The other technical details were common to the two procedures.

Duration of operation, complications during the operation, gender and weight of the baby, and the Apgar score (at 1 and 5 minutes) were collected as intraoperative data and recorded on the trial form. Operating time was measured from the first skin incision to the last skin suture placement for both techniques. A stillbirth was defined as any infant delivered after the 28th week of pregnancy who does not breathe or show any sign of life. Perinatal death was defined as a stillbirth or neonatal death during the first week of life.

Postoperative Management

During the immediate postoperative period the vital signs were monitored by the recovery room nurse until the patient was fully awake and stable; blood pressure and pulse were then monitored in the ward hourly for 6 hours and then on a daily basis. Body temperature was recorded twice a day (6 a.m. and 2 p.m., and further in case of need). The urinary catheter was removed when the patient was fully awake and stable.

Postoperative analgesia was given at the discretion of the patient. During the first postoperative day (24 hours) pethidine 100 mg IM 8 hourly was administered only if the dose was requested by the patient; beginning on the second day oral analgesia (ibuprofen 400 mg three times a day) was given only on the patient's request.

Saline 0.9% alternating with 5% dextrose, for a total of 3000 ml of intravenous fluids over 24 hours, were given until the patient requested them to be discontinued. She was then allowed to take oral fluids (even during the first postoperative day). Solid diet was allowed from the 18th postoperative hour at the patient's request. The advantages of starting alimentation with fluid and solid food early after CS are well documented in the literature [22–24].

Early mobilization of the patient was practiced 12 hours after surgery in the case of general anesthesia and 24 hours after surgery if spinal anesthesia was given. The supine position for the first 24 hours after spinal anesthesia was maintained to avoid a postdural puncture headache (PDPH). Although the efficacy of this measure as prophylaxis of PDPH is under debate [25], we did not want change a practice already established in our hospital.

The surgical wound was exposed on the third postoperative day and painted with gentian violet 1% solution. Gentian violet was chosen because is inexpensive and easily available in Kenya; it leaves a dry film on the wound, and it does not stain the skin of black patients. The daily dressing was continued only for infected wounds. Alternate stitches were removed on the sixth postoperative day and the remainder on the seventh day when the patients were discharged if no complications arose [26].

A surgical review after 6 weeks (or earlier, in case of need) in the outpatient department was proposed and planned for each patient who participated to the study. This length of time for the follow-up was chosen to coincide with immunization of the newborn.

Parameters

The following indicators were chosen to compare the postoperative outcome between the two procedures.

1. Febrile morbidity (defined as body temperature over 38°C on 2 days, excluding the first 24 hours.)
2. Eventual need and use of postoperative antibiotics.
3. Presence and grade of a wound infection. Using the definitions of Cruse [27], surgical wounds are considered "uninfected" if they heal per primum without discharge; "definitely infected" if pus is discharged, even if organisms are not cultured from the purulent material; and "possibly infected" if they are inflamed without discharge or draining of culture-positive serous fluid. Wound infections were also graded according to the classification of Karl et al. [28]: grade 1, superficial infection (cellulitis with minimal purulent exudate); grade 2, deep infection (cellulitis with moderate purulent infection); grade 3, infection throughout the wound with or without dehiscence.
4. Doses of analgesics required (number).
5. Evaluation of the pain grade at the 30th postoperative hour (±6 hours) with a Visual Analogue Scale (VAS) graduated from 0 to 10.
6. Postoperative day on which the patients spontaneously began to drink fluids (from the first postoperative day on) and to eat solid food (from the 18th postoperative hour on).
7. Postoperative day on which the patients were discharged (from the 7th day on).
8. Presence of any complications (particularly incisional hernia and hypertrophic scar or keloids) at the 6-week follow-up. Hypertrophic scar, which usually appears within weeks of the causative injury and in colored peoples precedes keloid formation, was defined as raised lesions in the surgical scar that stay within the boundaries of the wound (keloids, by contrast, are defined as scars in the skin that grow beyond the confines of the original wound) [29].

Points 1, 2, and 3 were used to compare the infectious morbidity in the two groups, points 4 and 5 the postoperative pain, point 6 the paralytic ileus, point 7 the presence of early postoperative complications, and point 8 the presence of late complications.

Approval and Ethical Consideration

This study was conducted under a protocol approved by the Scientific and Ethical Committee of Kenya Medical Research Institute (KEMRI no. 461–1997). In a series of studies already conducted on the Misgav Ladach procedure, although only in high income countries, the new method was shown to be safe and more efficacious than the Pfannenstiel procedure [1, 3, 10, 11].

Analysis

The sample size of 80 patients for each group has been calculated by Epitable of Epi Info, Version 6.02 software package (Centers for Disease Control and Prevention, Atlanta, GA, USA, 1994) to reach a confidence level of 95% with a power of 80%, through a pilot study with 50 nonrandomized patients, described before, that has demonstrated the percentage of some of the outcomes that were under study. The statistical analysis was carried out using Epi Info Analysis. Differences between proportions were tested using

Table 1. Baseline features of the randomized patients.

Parameter	Misgav Ladach CS (n = 80)	Traditional CS (n = 80)	p
Surgeon: L.A./R.B.	46/34	48/32	0.74*
Age (years), mean [SD]	27.6 [4.2]	27.0 [4.3]	0.26***
Weight (kg), mean [SD]	72.6 [13.8]	69.8 [13.1]	0.25***
Marital status: single/married	2/78	6/74	0.27**
Education: low/high	24/56	22/58	0.72*
Gestational age (weeks), mean [SD]	38.4 [1.7]	38.0 [1.8]	0.26***
Gravidity, mean [SD]	2.5 [1.1]	2.8 [1.9]	0.99***
Parity, mean [SD]	1.3 [1.1]	1.3 [1.5]	0.60***
Previous abortion, yes/no	15/65	18/62	0.55*
Presence of PCS, yes/no	41/39	38/42	0.63*
Labor length (hours), mean [SD]	5.4 [8.0]	4.3 [6.8]	0.60***
Membrane rupture (hours), mean [SD]	2.6 [4.8]	2.2 [4.6]	0.74***
Cervical dilatation (cm), mean [SD]	1.7 [2.8]	1.3 [2.3]	0.65***
Cervical examinations (no.), mean [SD]	1.2 [1.8]	0.8 [1.3]	0.46***
Emergency/elective CS	42/38	42/38	0.87*
Indications for CS			
Fetal distress	12	16	
CPD and one PCS with CPD	25	22	
More than one PCS	13	11	0.96*
Maternal complications	8	9	
Fetal malpresentation and cord prolapse	14	14	
Failed induction	8	8	
General/spinal anesthesia	55/25	63/17	0.15*
Single/twin pregnancy	78/2	74/6	0.27**
Newborn gender,[a] female/male	32/46	37/37	0.26*
Newborn weight (kg),[a] mean [SD]	3.2 [0.6]	3.1 [0.6]	0.62***

PCS: previous cesarean section; CPD: cephalopelvic disproportion.
[a]Single pregnancies only.
*Chi-square; **Fisher exact test, ***Mann-Whitney U-test.

the chi-square or Fisher's exact test (where appropriate) and differences between means using the Mann-Whitney U-test.

Results

During the study period (March 17, 1997 to July 27, 1997) at Nazareth Hospital we managed 1024 deliveries (mean 9.9 deliveries daily). Among them, 242 (23.6%) were cesarean deliveries, 161 of which were performed by the two surgeons (L.A. and R.B.) carrying out the study. All but one of CSs performed by the two surgeons were included in the study. The reason for exclusion in that case was the need for cesarean hysterectomy due to an unrepairable right lateral laceration of the lower uterine segment in a multipara with a fibromatous uterus during a CS performed with the traditional procedure. Hence 160 eligible patients were randomized. There were no statistically significant differences between the groups (Table 1).

The intraoperative complications are as follows. Strong adhesions due to PCS were found during the operation in three patients (3.8%) with the Misgav Ladach procedure and in three patients who underwent the traditional procedure. Extra stitches were needed owing to continuous bleeding from any of the corners of the uterine incision in four cases (5.0%) using the traditional CS and in two (2.5%) with the Misgav Ladach CS. During another two Misgav Ladach procedures some extra stitches were added to the single layer uterine suture because of bleeding from the edges of the uterine incision. In three other Misgav Ladach cases, closure of the uterine incision was performed with two locked continuous sutures and suture of the visceral peritoneal layer because of excessive bleeding in two patients and uterine rupture with an alive newborn in the other.

The data for the indicators used to compare the postoperative outcome between the two procedures are reported in Table 2. The traditional CS procedure took significantly longer than the Misgav Ladach procedure. There were three stillbirths among the 168 babies (1.8%) delivered during the 160 CSs under study: two were in single pregnancies in the Misgav Ladach CS group due to fetal asphyxia and one in a twin pregnancy in the traditional CS procedure group due to an anencephalic baby. During the perinatal period (the first week) there were four deaths among the 165 remaining newborns (2.4%): one in the Misgav Ladach group and three in the traditional procedure group, all due to prematurity.

Regarding the infectious morbidity, it must be pointed out that although there were no significant differences in febrile morbidity or use of postoperative antibiotics in the two groups wound infections complicated the postoperative course of 16 (20.0%) patients in the group with the traditional procedure versus 5 (6.2%) with the Misgav Ladach procedure (p = 0.01). According to the classification of Karl et al. [28], among the 16 infected wounds in the group operated with the traditional method eight were grade 1 and eight grade 2. In the Misgav Ladach group there were four of grade 1 and one of grade 2. None in either group was grade 3. Concerning the use of postoperative antibiotic treatment, it must be clarified that in eight patients (four in each CS group) the antibiotic was a continuation of a therapy started before the operation for various reasons (respiratory tract infection in two, membrane leak in four, skin infection and cervicitis in one each). Thus the antibiotic treatment was started after the operation in

Table 2. Comparative intraoperative, postoperative, and 6-week follow-up data for all patients randomized to Misgav Ladach or traditional cesarean section.

Parameter	Misgav Ladach CS (n = 80)	Traditional CS (n = 80)	p
Operating time (minutes), mean [SD]	20.4 [6.1]	30.4 [6.1]	<0.001*
Apgar score at 1 minute,[a] mean [SD]	8.3 [1.7]	8.5 [0.9]	0.58*
Apgar score at 5 minutes,[a] mean [SD]	9.0 [1.9]	9.2 [1.5]	0.70*
Stillbirth/born alive	2/80	1/85	0.48**
Perinatal death/discharged alive	3/79	4/82	0.52**
Presence of febrile morbidity, yes/no	2/78	5/75	0.44**
Use of postoperative antibiotics, yes/no	7/73	10/70	0.44***
Presence of wound infection, yes/no	5/75	16/64	0.01***
Analgesic doses (pethidine), mean [SD]	1.3 [0.6]	1.9 [0.7]	<0.001*
Analgesic doses (ibuprufen), mean [SD]	15.1 [2.0]	16.4 [1.8]	<0.001*
Pain grade (Visual Analogue Scale), mean [SD]	3.0 [1.5]	4.9 [2.0]	<0.01*
Time to first fluid feed (hours), mean [SD]	19.1 [4.5]	20.6 [4.0]	0.01*
Time to first solid feed (hours), mean [SD]	41.2 [9.3]	46.1 [9.0]	<0.01*
Incisional hernia, yes/no	0/48[b]	2/41[c]	0.22**
Presence of hypertrophic scar, yes/no	1/47[b]	21/22[c]	<0.01***

[a]Single pregnancies only.
[b]Among 48 procedures.
[c]Among 43 procedures.
*Mann-Whitney U-test; **Fisher's exact test; ***chi-square test.

three patients in the Misgav Ladach group (one each for wound infection, respiratory tract infection, and urinary tract infection) and in six in the traditional group (two each for wound infection, respiratory tract infection, and persistent unexplained fever).

The number of analgesic (pethidine or ipubrofen) doses required by the patients during the postoperative period were significantly less in the Misgav Ladach group. Even the evaluation of incisional pain grade during the immediate postoperative period showed significantly less pain in the group with the Misgav Ladach procedure. Furthermore, the patients of the Misgav Ladach group began voluntary fluid and solid food intake significantly before those operated on with the traditional procedure.

Discharge was later than 7 days postoperatively for three patients (3.8%) in the Misgav Ladach group and for four (5.0%) in the traditional group. The causes for the late discharge were two renal failures in eclampsia and one urinary infection in the Misgav Ladach CS group and one malaria, one renal failure in eclampsia, and two wound infections in the traditional CS group.

Altogether 48 patients (60.0%) in the Misgav Ladach group and 43 (53.8%) in the traditional procedure group appeared for the 6-week follow-up; the difference between groups was not significant (p = 0.4, chi-square test). Two incisional hernias were found in the patients operated with the traditional procedure and none in the Misgav Ladach group, but the difference was not significant. The presence of a hypertrophic scar was significantly associated with the traditional procedure.

Discussion

At the Misgav Ladach Hospital in Jerusalem, Stark and colleagues, based on Joel-Cohen's time and motion studies in gynecologic surgery, evolved an improved method for CS [1, 3]. This Misgav Ladach procedure, although incorporating the method of opening the abdomen developed by Joel-Cohen for hysterectomy operations, goes well beyond, bringing together ideas from various sources, both surgical and gynecologic. Other distinctive features of the Misgav Ladach CS include single-layer closure of the uterus and nonclosure of the peritoneal layers [1, 10]. These surgical details are not common practice for CSs performed in Kenya and other low income countries, where this operation is still generally done with midline subumbilical laparotomy, double-layer closure of the uterus, and closure of visceral and parietal peritoneal layers. The other details of the Misgav Ladach CS, including exteriorization of the uterus and manual extraction of the placenta, are instead common practice.

Stark and colleagues based the introduction of changes in an already well standardized operation on some important philosophical surgical considerations. First is the idea of surgical minimalism. Only those surgical maneuvers that are shown to be necessary are used; and wherever possible, the alternative is chosen that least disrupts the tissue. Thus suturing the peritoneal layers and the double-layer closure of the uterus is avoided. The second principle is that of operating in harmony with physiologic and anatomic considerations. Using the Joel-Cohen method for opening the abdomen, the level of skin incision and the level of separation of the recti muscles are well away from muscle insertion sites. In this way little force is needed at separation, reducing disruption of blood vessels and nerves, which are vulnerable near the site of muscle fixation [1, 3, 10].

The Joel-Cohen skin incision is a distinctive feature of the Misgav Ladach CS [2]. The choice of abdominal incision for CS must be determined by desire to achieve quick, adequate exposure, which is especially important in emergency situations, and to avoid postoperative complications, such as wound disruption and incisional hernia. Although it has been found that the lag time from incision to delivery is significantly shorter through a low midline abdominal incision than with a Pfannenstiel incision [30], it must be pointed out that Stark demonstrated a significant reduction in operative duration with the Joel-Cohen incision compared with the Pfannenstiel incision [3]. On the other hand, it has been found in general and gynecologic surgery that a transverse laparotomy heals better than a midline vertical incision, reducing the risk of wound dehiscence and incisional hernia [31–36]. In our experience with the limited time of only a 6-week follow-up, we

found 4.7% incidence of incisional hernia in the group of women operated on with the traditional procedure in contrast to none in the Misgav Ladach group. This finding, although not statistically significant, encourages us to use the Misgav Ladach CS to prevent incisional hernia. This consideration is important because wound hernia is a major disability in women with a heavy workload, such as those living in low income countries. Another advantage of transverse incisions, such as the Joel-Cohen incision, versus low midline laparotomy is the fact that the skin components of this incision, following the well established lines of Langer, are not under tension. It is not surprising then, that as is showed by our study the risk of hypertrophic scar formation, a particular hazard in Africa [29] is significantly reduced. Furthermore, it must be pointed out that the Joel-Cohen incision, being higher than the Pfannenstiel incision, is easier to perform, results in less bleeding [3], and allows better operative exposure, as was shown in a comparison between the Pfannenstiel and Maylard laparotomy, the latter making use of the same skin incision as the Joel-Cohen [37]. It can be objected that because the abdominal scar of the Joel-Cohen incision is higher than that of the Pfannenstiel some women do not like it because they wish to hide the scar. This is still not a factor in low income countries; and the fact that the method is becoming popular in Israel, Italy, and Sweden, which are high income countries, makes this unlikely to be a major disadvantage [11].

Regarding closure of the transverse lower uterine segment incision, the need for the second layer of imbricating suture in the traditional two-layer method of repair has been recently questioned by several studies. These studies have reported decreased operating time, with no increased need of additional uterine hemostatic sutures and no increased risk of endometritis or scar rupture during subsequent labor with the use of continuous, locked, single-layer repair when compared with the two-layer repair [38–40]. Closure in a single layer not only saves time, it causes less ischemia and provides better healing with less sacculation. Although some have proposed a single-layer continuous nonlocking repair [41] or a single-layer interrupted suture for closing the uterine wound [42], to avoid ischemia, we believe that a locked suture is not associated with local ischemia, as retraction of the uterus reduces tissue volume and thus releases any tension around the stitch.

Another feature of the Misgav Ladach method is leaving the visceral and parietal peritoneum unstitched, bringing down the omentum to cover the previously repaired uterine wall. Omitting suturing of the peritoneal layers has long been practiced by abdominal surgeons with good results, especially because it has been shown that closing the peritoneum as a separate layer does not play a significant role in laparotomy wound healing [43]. In addition, suturing peritoneal layers seems to increase adhesion formation; and as surgeons we are concerned with limiting adhesions, as they may lead to intestinal obstruction and infertility [44]. Skin and mucosal surfaces, being of ectodermal origin, heal by approximation of wound edges, unlike the peritoneum, which, being of mesodermal origin, heals by mesothelial migration from the underlying tissues to multiple sites of repair [7]. Large peritoneal defects heal nearly as rapidly as small ones [45]. Following surgery, after initial production of an inflammatory exudate containing first a large number of polymorphonuclear neutrophils and later macrophages and a fibrin gel matrix, degradation of the fibrin gel matrix into fibrin split products occurs through activation of plasmin by the tissue plasminogen activator system [46]. Within 3 days the peritoneal defects are covered by new mesothelial cells recruited by cytokines and other macrophage-secreted mediators. After 5 to 8 days the peritorieal surface is completely repaired [6, 45, 47, 48]. Experimental studies have shown that the reduction in peritoneal plasminogen activating activity that occurs after injury, inflammation, and ischemia plays a key role in adhesion formation, [49–51]. Suturing peritoneal surfaces produces ischemic necrosis in adjacent tissue and thus promotes adhesion formation, probably because the peritoneum is damaged and not able to absorb the fibrin gel matrix owing to the reduced fibrinolytic activity [52–55]. Based on these experimental studies, many authors have demonstrated clinically that nonclosure of peritoneum during CS reduces infectious morbidity and postoperative pain, provides less troublesome bowel function, and saves operating time [5, 6, 8, 9]. Studies contemplating a second look, either at laparoscopy or at laparotomy, in CS patients have shown a reduction (in one case significant) in adhesion formation in the group with peritoneal nonclosure [13, 56].

The other technical details in our study were similar for the two procedures, in particular manual extraction of the placenta, uterus exteriorization, and removal of easily accessible blood clots, avoiding the mopping up of spilled amniotic fluid and liquid blood, and the decreased use of towels in the peritoneal cavity. Although manual extraction of the placenta seems in some studies to increase the infectious morbidity rate [57–59] and operative blood loss [57, 60], we followed the advice of Stark [1] regarding this step because we believed that manual removal makes the third stage of the delivery much quicker. Extraabdominal uterine exteriorization was always performed, as advised by Stark [1], because in our experience it makes it easier to suture the uterus, preventing damage to abdominal organs when stitching, facilitates manual contraction of the uterus, and can contribute to diminished blood loss [61]. Our data do not support the view of others [58, 62] who think that uterine exteriorization carries some risk of infectious morbidity. Finally, removal of blood clots without packing the peritoneal cavity with towels has the aim of decreasing the risk of adhesion formation [63] and avoiding reducing the bacteriostatic effect of amniotic fluid [64, 65].

Our study demonstrated that the women who underwent the Misgav Ladach procedure compared with the women who underwent the traditional CS procedure done in low income countries showed some significant differences in outcomes. In particular, there was less operating time, less wound infection, less postoperative pain, and less postoperative paralytic ileus. Furthermore, the Misgav Ladach procedure was not burdened by the presence of intraoperative and early and late postoperative complications. Although these advantages are important anywhere, they are particularly important in low income countries. Being faster than the traditional CS method, the Misgav Ladach procedure helps save theater and staff time and decreases the amount of anesthetic needed. Even the suture materials used for the Misgav Ladach method are less. In addition, causing fewer wound infections, the Misgav Ladach CS reduces the need for antibiotics and dressings. Moreover, the reduction in postoperative pain and paralytic ileus not only lessens the need for postoperative analgesia, it allows earlier ambulation, thereby reducing complications such as thrombosis. It also allows earlier breast-feeding and nursing care of the baby by the mother and earlier alimentation, avoiding the need for postoperative starvation and intravenous fluids. Lastly, it

allows earlier discharge from hospital, freeing beds for others. Taking into account all these considerations, the Misgav Ladach procedure could reduce the financial burden that afflicts many rural hospital in low income countries.

As we have already pointed out, the Misgav Ladach technique is the result of reexamining every step of the traditional CS to evaluate its necessity and efficacy in achieving its purpose. Because some of the conventional steps of the traditional CS appear to be superfluous and sometimes dangerous, the time reduction derived from suturing the uterus in one layer and nonclosure of the peritoneal layers is an added benefit. Certainly a second added benefit due to fewer steps being performed is that the method is easier to learn and easier to use. In our experience, the only difficulty with learning and teaching the Misgav Ladach technique is mastering the Joel-Cohen incision, as the midline laparotomy is a more common and more well known method for opening the abdomen. This is an undoubted advantage for hospitals in rural settings where CS is performed by nonspecialist doctors and even by nonmedical staff.

Conclusions

We are aware that until the Misgav Ladach method is widely accepted there might be some confusion related to introducing a new method. We believe, however, that it should become the standard method for performing CS, especially in low income countries.

Résumé

La césarienne (CS) est l'intervention majeure la plus fréquemment réalisée dans beaucoup de pays à basse économie. Pour évaluer une nouvelle technique de césarienne, appelé le procédé de "Misgav Ladach", dans une étude randomisée à l'hôpital Nazareth Hospital (Kiambu District, Kenya), 160 patientes ont été allouées soit au procédé de "Misgav Ladach" (n = 80) soit à la césarienne traditionnelle CS (n = 80), comme réalisée dans la plus grande majorité des hôpitaux ruraux dans les pays à revenu peu élevé. On a analysé la durée de l'opération, la présence d'infection et la morbidité hyperthermique, le degré de la douleur postopératoire, le début de l'alimentation liquidienne et solide, le développement d'une éventration, et la survenue d'une cicatrice hypertrophique. La durée opératoire pour le procédé de «Misgav Ladach» a été significativement plus courte (20.4 (SD = 6.1) versus 30.4 (SD = 6.1) minutes ($p < 0.001$)). On a noté cinq cas d'infection pariétale (6,2%) dans la technique de Misgav Ladach comparés à 16 cas (20.0%) dans le groupe contrôle ($p = 0.01$). Les patientes dans le groupe Misgav Ladach ont eu besoin de moins de doses d'analgésiques dans la période postopératoire: 1.3 (SD = 0.6) versus 1.9 (SD = 0.7) ampoules de Péthidine ($p < 0.001$) et 15.1 (SD = 2.0) versus 16.4 (SD = 1.8) compresses d'ibuprofène ($p < 0.001$). La douleur au niveau de la cicatrice était significativement moindre dans le groupe «Misgav Ladach» avec un score à l'échelle visuelle analogue de 3,0 (SD = 1.5) versus 4,9 (SD = 2.0), $p < 0.01$. De plus, les patients dans le groupe «Misgav Ladach» ont commencé à boire des liquides (19.1, SD = 4.5, versus 20.6, SD = 4.0 heures, $p = 0.01$) et a mangé des aliments solides (41.2, SD = 9.3, versus 46.1, SD = 9.0 heures, $p < 0.01$) plus tôt que celles du group de contrôle. A six semaines, il y avait plus de femmes qui avaient une cicatrice hypertrophique dans le groupe de césarienne classique (2.1% versus 48.8%, $p < 0.001$). Nous concluons que le procédé de «Misgav Ladach» devrait être la méthode de référence pour césarienne dans les pays à revenue bas, surtout dans les hôpitaux ruraux.

Resumen

La operación de cesárea (CS) es la intervención más frecuente en paises subdesarrollados. Con objeto evaluar una nueva técnica de CS, denominada Misgaw Ladach, se efectuó un estudio randomizado en el Hospital de Nazareth (distrito de Kiambu, Kenya). Se recopilaron 160 pacientes en las que se realizó la técnica de Misgaw Ladach (n = 80) o la CS convencional, como se realiza en la mayoria de los hospitales rurales en los paises en vias de desarrollo (n = 80). Ambos grupos se analizaron para valorar el tiempo operatorio, la infección y la morbilidad febril, el grado de dolor postoperatorio, el momento en que se comenzó la ingesta liquida y sólida, el desarrollo de eventraciones y de cicatrización queloidea. El tiempo operatorio con la técnica de Misgaw Ladach es significativamente más corto: 20.4 (SD = 6.1) vs 30.4 (SD = 6.1) minutos ($p < 0.001$). Con la técnica de Misgaw Ladach se observaron 5 infecciones de la herida operatoria (6.2%) frente a 16 (20%) en el grupo control ($p = 0.01$). El número de dosis analgésicas requeridas por las operadas con la técnica de Misgaw Ladach fue significativamente menor: 1.3 (SD = 0.6) vs 1.9 (SD = 0.7) ampollas de petidina ($p < 0.001$) y 15.1 (SD = 2.0) vs 16.4 (SD = 1.8) apósitos de Ibuprofen ($p < 0.001$). El dolor de la herida operatoria fue significativamente menor con la técnica de Misgaw Ladach: En la escala analógica visual alcanzó un grado de 3.0 (SD = 1.5) vs 4.9 (SD = 2.0), ($p < 0.01$). Además, las pacientes operadas con la técnica de Misgaw Ladach empezaron voluntariamente a beber (19.1, SD = 4.5 vs 20.6 SD = 4.0 horas, $p = 0.01$) y a ingerir alimentos sólidos (41.2 SD = 9.3 vs 46.1 SD = 9.0 horas, $p < 0.01$), mucho antes que las del grupo control. Tras un seguimiento de 6 semanas se observaron cicatrices queloideas en el 2.1% de las intervenciones realizadas con la técnica de Misgaw Ladach frente a un 48.8% de las operadas de cesárea con la técnica tradicional ($p < 0.001$). Concluimos señalando que la técnica de Misgaw Ladach CS debe convertirse en el método estándar para la realización de una cesárea en pueblos económicamente débiles y, especialmente en los hospitales rurales.

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