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Early outcome of myomectomy by laparotomy, minilaparotomy and laparoscopically assisted minilaparotomy. A randomized prospective study

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BACKGROUND: To compare in the first 7 days after surgery the outcome of myomectomy performed by three laparotomic approaches: laparotomy (LT), minilaparotomy (MLT) and laparoscopically assisted minilaparotomy (LA-MLT). METHODS: Fifty-one women with 5–15 cm total myoma diameter were randomized blindly using a computer randomization list, to LT (n = 17), MLT (n = 17) or LA-MLT (n = 17). RESULTS: Mean operation length was similar in the three groups. Mean (± SEM) time of paralytic ileus (55.0 ± 4.5 versus 33.4 ± 3.4 h; $P < 0.01$) and discharge (141.6 ± 5.2 versus 81.5 ± 8.2 h; $P < 0.01$) was longer in LT than LA-MLT or even MLT. In comparison with LA-MLT, LT induced a greater haemoglobin decline (–3.07 ± 0.3 versus –1.8 ± 0.15 mg/dl; $P < 0.025$), and a greater post-operative stress, as documented by increased prolactin (+15.1 ± 3.8 versus +0.16 ± 4.5 ng/ml; $P < 0.03$) and decreased insulin sensitivity (fasting glucose/insulin; –7.5 ± 2.6 versus –0.7 ± 2.1; $P < 0.02$). Seven days after surgery, abdominal pain ($P < 0.05$) was higher after LT (3.0 ± 0.6) than MLT (0.5 ± 0.2) and LA-MLT (0.9 ± 0.4). CONCLUSIONS: In selected cases, myomectomy by LA-MLT offers some advantages versus LT and, to a smaller extent, MLT.

Key words: laparoscopy/laparotomy/minilaparotomy/myomectomy

Introduction

Myomas are benign, hormone-sensitive, fibromuscular tumours of the uterus that are detected in 25–40% of women in their reproductive years (Cramer and Patel, 1990). Myomectomy is advisable for women who wish to preserve their childbearing capabilities and it is needed when myomas are either asymptomatic, but growing rapidly and causing infertility/recurrent abortion, or symptomatic, causing abnormal uterine bleeding or pain (Buttram *et al*., 1981; Vollenhoven *et al*., 1990; Donnez *et al*., 1996).

Beside operative hysteroscopy, which represents a valid approach for submucous myomas, or vaginal myomectomy, four different operative techniques have been described for the surgical approach to myomas: laparotomy (LT), laparoscopy (LA), minilaparotomy (MLT) and laparoscopically assisted minilaparotomy (LA-MLT) (Vollenhoven *et al*., 1990). All four of these techniques can be used depending upon the surgeon's preference, but few studies have specifically compared their clinical outcome.

Ours is a prospective randomized study aimed to compare the outcome in the first 7 days after surgery of myomectomy performed with three different laparotomic techniques: LT, MLT and LA-MLT. In order to have a biochemical evaluation of the surgical stress induced by the three procedures, the increase of stress hormones induced by surgery, i.e. cortisol (Plumpton *et al*., 1969), prolactin (Frantz *et al*., 1972), and the reduction of insulin sensitivity (Brandi *et al*., 1993), was also considered.

Materials and methods

From January 2001 to July 2002, 51 out of 68 women requiring surgical myomectomy at our Institute of Obstetrics and Gynaecology matched the criteria for enrolment. Each woman gave her informed consent to be included into the study, which was previously approved by the local ethics committee and Institutional Review Board. Inclusion criteria were the presence of either symptomatic myoma or myoma associated with infertility. Transvaginal and abdominal ultrasound was used to obtain information on the number, size, localization and relationship with an endometrial strip of the myoma. Inclusion criteria to enter the study were the presence of less than five intramural or sub-serous myomas (without peduncle) with a total diameter between 5 and 15 cm. After enrolment by a physician, each woman was randomized blindly by a nurse to LT (n = 17), MLT (n = 17) or LA-MLT (n = 17), using a computer-generated list of randomization. The same surgeons (A.C. or A.V.) performed all surgical procedures.

LT is performed with a 10–12 cm supra-pubic incision. The s.c. fat and abdominal fascia are opened crosswise and the abdominal muscle is opened longitudinally on the midline. The parietal peritoneum is

Table I. Mean ± SEM age, body mass index, number of myomas, and maximum myoma diameter of women undergoing myomectomy by laparotomy (LT; $n = 17$), minilaparotomy (MLT; $n = 17$) or laparoscopically assisted minilaparotomy (LA-MLT; $n = 17$)

	LT	MLT	LA-MLT
Age (years)	37.7 ± 0.9	39.4 ± 1.6	37.6 ± 1.9
Body mass index (kg/m^2)	24.3 ± 1.5	23.9 ± 0.9	24.7 ± 1.3
Myomas (n)	1.58 ± 0.7	1.87 ± 0.3	1.18 ± 0.4
Max diameter (cm)	5.8 ± 0.4	6.8 ± 0.7	7.1 ± 0.7

Table II. Mean ± SEM surgical parameters following myomectomy by laparotomy (LT; $n = 17$), minilaparotomy (MLT; $n = 17$) and laparoscopically assisted minilaparotomy (LA-MLT; $n = 17$)

	LT	MLT	LA-MLT
Operation time (min)	91.3 ± 7.2	85.9 ± 7.2	92.6 ± 4.4
Incision length (cm)	11.0 ± 0.09	7.0 ± 0.08**	5.9 ± 0.44**§
Max fever (°C)	37.8 ± 0.09	37.8 ± 0.10	37.7 ± 0.09
Duration of fever (h)	53.0 ± 6.5	66.0 ± 10.6	39.7 ± 10.0
Time of paralytic ileus (h)	55.0 ± 4.5	41.8 ± 3.9*	33.4 ± 3.4**§
Time to discharge (h)	141.6 ± 5.2	119.3 ± 9.6**	81.5 ± 8.2**§
Use of antipyretic (%)	11.7	12.5	17.6
Use of analgesic (%)	58.8	62.5	58.8

*$P < 0.05$; **$P < 0.01$ versus LT; §$P < 0.05$ versus MLT, by ANOVA followed by the post-hoc Fisher's test.

visualized and it is opened longitudinally to reach the pelvic cavity. Subsequently, a separator is inserted through the abdominal breach and an intestinal compress is inserted. After examination of the uterus and adnexa, myomectomy is performed. No pharmacological vasoconstriction or mechanical vascular occlusion technique is used before uterine incision. When possible, uterine incisions are performed on the anterior wall or the fundus in an attempt to reduce post-operative adhesions. The uterine defects are closed in a single or double layer with interrupted sutures of Vicryl 1–0 polyglactin 910 (Ethicon SpA, Italy). The serosa is approximated with Vicryl 3–0. During the procedure the uterus is continuously irrigated with a Ringer lactate solution. After the control of haemostasis and repeated washing of the pelvic cavity, Interceed™ (Ethicon Inc.) is placed on the uterine suture to prevent adhesions. Laparotomy is closed in separate layers.

MLT is performed with an ~5 cm incision, 1–2 cm above the pubic symphysis. The abdominal fascia is opened crosswise or longitudinally. A uterine manipulator is used to elevate the uterus toward the suprapubic incision. Trans-peritoneal palpation is used to identify a major myoma, and a corkscrew manipulator is inserted into it blindly, through the peritoneum. The parietal peritoneum is then incised just above the myoma during the traction performed on the corkscrew, and the myoma along with the uterus is forced out of the peritoneum and the minilaparotomic incision. Myomectomy and uterus reconstruction is performed directly outside the peritoneum, as in the LT procedure. To prevent adhesions, Interceed™ is placed on the uterine suture. Then the uterus is replaced in the pelvic cavity, and after an accurate rinsing the abdominal incision is closed in multiple layers.

In the LA-MLT, a pneumoperitoneum is obtained with carbon dioxide insufflation through a Veress needle. A 10 mm port is inserted through the umbilicus to introduce the laparoscope, which is connected to a camera for video monitoring. An accessory 5 mm trocar is inserted into the abdomen to the left of the umbilicus. The video camera is used to identify the myoma and to obtain visual guidance for the insertion of the corkscrew through the peritoneum. The accessory trocar is used to insert operative instruments and the suction irrigator cannula. During formation of the pneumoperitoneum, the minilaparotomic incision is performed, as in the MLT procedure. Thereafter, the surgical times follow those previously described for MLT. After the closure of peritoneum, haemostasis is further controlled under videolaparoscopy, and an accurate rinsing of the pelvic cavity is performed via a suction-irrigator. No peritoneal or incisional instillation of topical analgesics is used in either laparotomy or laparoscopy procedures. For the first 12 h after surgery, each subject receives an i.v. analgesic therapy. Analgesics consist of ketoprofen (45 mg/12 h) and tramadol (150 mg/12 h). Thereafter, analgesics are suspended and administered only on a patient's demand.

The primary outcome of the study was the comparison between the three surgical procedures of the time of paralytic ileus and time of discharge from the hospital. Time of discharge was evaluated both as absolute time and as number of women discharged 3 days after operation. Secondary outcomes were differences in time of operation, maximal fever, duration of fever (body temperature >37°C), post-operative use of analgesics after the first 12 h post-surgery, use of antipyretics, blood loss, post-operative stress and post-operative pain. Evaluation of blood loss was performed by means of the 24 h, 48 h and 7 day haemoglobin modification. Post-operative stress was assessed after 24 h, 48 h and 7 days, by modifications of the stress hormones cortisol (Plumpton *et al*., 1969) and prolactin (Frantz *et al*., 1972), and by the modification of insulin resistance (Brandi *et al*., 1993), roughly evaluated by the fasting glucose/insulin ratio (Caro, 1991). A visual analogue scale (VAS), applicable both to the entire abdomen and specifically to the laparotomic and laparoscopic sutures, was used to evaluate post-operative pain. The VAS consisted of a non-graduated 10 cm line ranging from 'no pain' to 'pain as bad as it could be'. Adequate explanation of the method was given to the patients before surgery.

Statistical analyses

A power calculation revealed that ⩾17 subjects for each group were necessary to detect a difference of ⩾10 h in time of canalization or discharge, with a probability of type I error of 0.05 and type II error of 0.20. Statistical analysis was performed with the statistical package StatView 5.0.1 for Apple Macintosh (SAS Institute Inc., USA, 1998). All analyses were performed blindly except those referring to pain at the laparotomic or laparoscopic sutures. Parametric tests were used after having evaluated the normal distribution of the data to be analysed. Analysis of variance (ANOVA) was used to compare baseline characteristics and net modifications at single time-points observed in the three groups. When significant, Fisher's post-hoc test was used to identify significant comparisons. The modifications in time observed in the three groups were compared by ANOVA for repeated measures. The numbers of subjects who used analgesics or antipyretics or who were discharged at day 3 after operation were compared between the three groups by contingency tables and χ^2-test. For all statistical evaluation, $P < 0.05$ was used to reject the null hypothesis.

Results are expressed as the mean ± SEM.

Results

Mean age, body mass index (BMI), number of myomas and maximum myoma diameter was similar in the three groups (Table I). Supra-pubic incision length was longer in the LT than MLT or LA-MLT procedure ($P < 0.01$; Table II). Operation time, maximal post-operative fever and duration of fever were similar between the three procedures, as was the use

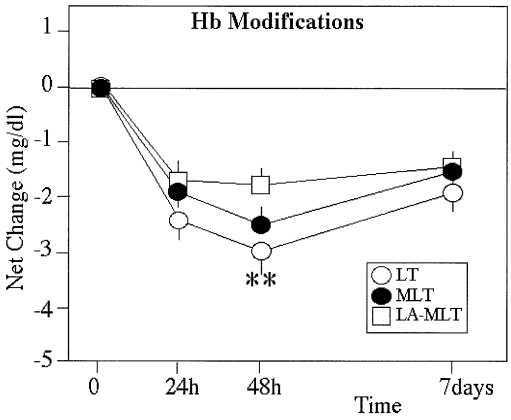

Figure 1. Mean ± SEM net modifications of haemoglobin (Hb) observed after 24 h, 48 h and 7 days in women undergoing surgical myomectomy by laparotomy (LT; $n = 17$), minilaparotomy (MLT; $n = 17$) or laparoscopically assisted minilaparotomy (LA-MLT; $n = 17$). $^{**}P < 0.025$ versus corresponding value of LA-MLT.

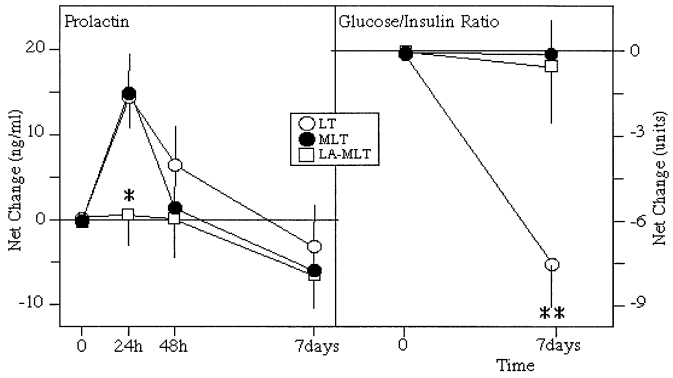

Figure 2. Mean ± SEM net modifications of prolactin (left panel) and glucose/insulin ratio (right panel) observed in women undergoing surgical myomectomy by laparotomy (LT; $n = 17$), minilaparotomy (MLT; $n = 17$) or laparoscopically assisted minilaparotomy (LA-MLT; $n = 17$). $^{*}P < 0.05$; versus corresponding LT and MLT values. $^{**}P < 0.025$ versus corresponding MLT and LA-MLT values.

of analgesic and antipyretics (Table II). Elevation of body temperature >37°C was observed in all patients. Increase in body temperature >38°C was observed in four of 17 subjects (23.5%), in each of the groups. Time of paralytic ileus was significantly lower after LA-MLT than LT ($P < 0.01$; Table II). Time of canalization after MLT was intermediate between the two, but still significantly shorter than after LT ($P < 0.05$; Table II). Time of discharge from the hospital was shorter in the two minilaparotomic techniques than after LT ($P < 0.01$) and also shorter after LA-MLT than MLT ($P < 0.05$; Table II). Accordingly, number of patients discharged at day 3 after operation was higher after LA-MLT than after LT (10/17 versus 0/17; $P < 0.005$). Intermediate values were observed for MLT (3/17).

All procedures were associated with a significant decline ($P < 0.01$) of haemoglobin concentration (Figure 1), but the net haemoglobin decline observed 48 h after LA-MLT (–1.8 ± 0.15 mg/dl) was significantly smaller than that observed after LT (–3.07 ± 0.3 mg/dl) ($P < 0.025$) (Figure 1). Intermediate declines were observed in the MLT group (–2.4 ± 0.4 mg/dl) (Figure 1).

Cortisol levels from pre-operative values of 17.6 ± 1.0 µg/dl declined ($P < 0.04$) after 24 h (–2.0 ± 1.2 µg/dl), 48 h (–1.3 ± 1.3 µg/dl) and 7 days (–3.3 ± 0.8 µg/dl) with no difference between the three groups. Conversely, the increase of prolactin observed 24 h after LT (+15.1 ± 3.8 ng/ml) or MLT (+15.8 ± 4.6 ng/ml) was significantly greater ($P < 0.03$) than that observed following LA-MLT (+0.16 ± 4.5 ng/ml) (Figure 2). Thereafter, levels of prolactin remained higher in the LT group until 7 days after the operation, but this difference was not statistically significant.

Glucose/insulin ratio from baseline value significantly decreased after 7 days in the LT group (–7.5 ± 2.6; $P < 0.01$) but not in the MLT (–0.05 ± 0.7) or LA-MLT group (–0.7 ± 2.1). The decrement of glucose/insulin ratio in the LT group was significantly higher ($P < 0.025$) than that observed in the other two groups (Figure 2).

The VAS score at the supra-pubic incision was similar in the three procedures from operation to the 7th day after surgery

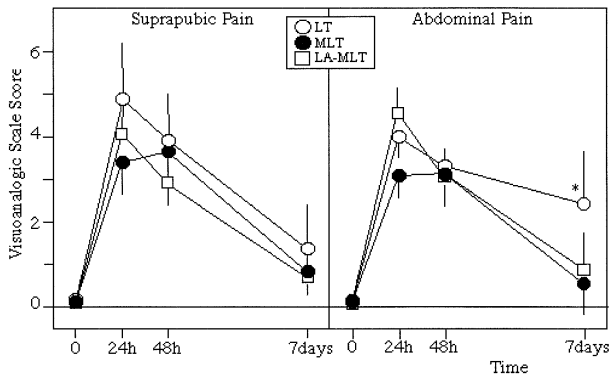

Figure 3. Mean ± SEM score values of the visual analogue scale (VAS) applied to the supra-pubic suture (left panel) or the entire abdomen (right panel) observed in women undergoing surgical myomectomy by laparotomy (LT; $n = 17$), minilaparotomy (MLT; $n = 17$) or laparoscopically assisted minilaparotomy (LA-MLT; $n = 17$). $^{*}P < 0.05$ versus corresponding MLT and LA-MLT values.

(Figure 3). In LA-MLT, VAS score at site of optical and accessory trocars was <0.3 for all the period after surgery. At the 24 h and 48 h evaluation, the VAS score for abdominal pain was similar in all three procedures, but at the 7 day evaluation it was significantly higher ($P < 0.05$) after LT (3.0 ± 0.6) than after MLT (0.5 ± 0.2) or LA-MLT (0.9 ± 0.4) (Figure 3).

Discussion

To our knowledge, there are only two randomized prospective studies comparing the early outcome of myomectomy by LT to that obtained with an alternative surgical approach, i.e. laparoscopy (Mais *et al.*, 1996; Serracchioli *et al.*, 2000). The study of Mais et al., performed in women with a mean number of myomas of 2.4 and a mean maximum myoma size of 4 cm, reported that laparoscopy reduced post-operative pain, time of discharge and time of recovery. Similar results on time of discharge were reported by Serracchioli *et al.* (2000), in

which mean number of myomas was 2.7 and maximal myoma size was ~7 cm. Not all surgeons are comfortable with laparoscopic myomectomy, and criticisms about the accuracy of uterine repair have been made following several reports of suture dehiscence in pregnant uteri (Harris, 1992; Dubuisson *et al*., 1995; Friedmann *et al*., 1996; Pelosi and Pelosi, 1997; Dubuisson *et al*., 2000; Hockstein, 2000; Hasbargen *et al*., 2002). In order to maintain the efficacy of uterine repair and to reduce the clinical impact of myomectomy by LT, two alternative surgical approaches have been proposed: MLT and LA-MLT (Nezhat *et al*., 1994; Bendetti-Panici *et al*., 1996; Goldberg *et al*., 1999; Holub *et al*., 2001; Seidman *et al*., 2001).

In two retrospective non-randomized studies, LA-MLT induced a similar blood loss, but fewer days of hospitalization, fewer days to resume normal activity (Nezhat *et al*., 1994; Goldberg *et al*., 1999) and less post-operative use of analgesics (Goldberg *et al*., 1999). To our knowledge, ours is the first randomized study reporting that MLT and LA-MLT offer advantages in comparison with classic LT. Indeed, despite a similar operation time, MLT and LA-MLT had a reduced time of paralytic ileus and discharge from the hospital. In contrast to time of paralytic ileus, time of discharge offers a composite picture of the post-intervention period, taking into consideration time of canalization, extent and duration of fever, needs of medical treatment, general clinical conditions of the individual and willing patient. Obviously, clinical judgement is not completely objective, but in this study variation was reduced by the same clinical criteria applied to all individuals by the same medical personnel. In all cases the clinical judgement was rather conservative, and it is likely that a shorter length of hospitalization can be achieved for all three procedures. Of the three procedures, LA-MLT showed the shortest time to patient's discharge from the hospital. Interestingly, the mean time to discharge after LA-MLT (81.5 h) was very close to that reported by Serracchioli *et al*. (2000) after laparoscopic myomectomy (75.6 h). The number of patients discharged from the hospital 3 days after LA-MLT was ~60 versus 0% after LT. This rate is slightly lower than that reported by Mais *et al*. (1996) of 90% after laparoscopy versus 10% after LT.

It is noteworthy that our MLT technique differs from that previously described (Nezhat *et al*., 1994; Benedetti-Panici, 1996). A corkscrew placed into a major myoma is used to force the myoma and the uterus through a small incision of the peritoneum, an incision that is performed during myoma traction. The peritoneum is not opened in advance, and no intestinal compress is inserted into the abdomen. Accordingly, this technique is very close to laparoscopy in terms of contamination of the peritoneal cavity and manipulation of the intestine.

Post-operative stress was evaluated by serum modification of stress hormones including cortisol (Plumpton *et al*., 1969) and prolactin (Frantz *et al*., 1972), and by the acquired resistance to insulin (Brandi *et al*., 1993). This allowed us a more objective evaluation of the surgical stress associated with the different procedures. In our hands, single cortisol measurements did not prove to be useful to evaluate post-operative stress. Prolactin was lower in LA-MLT than LT and even MLT, and insulin sensitivity at 7 days was significantly reduced only by LT but not by MLT or LA-MLT. Accordingly, the results indicate an overall lower post-operative surgical stress after the two minilaparotomic approaches, particularly LA-MLT. Data on abdominal pain at 7 days confirm this view.

Among the three procedures, it was LA-MLT that showed the lowest blood loss, the shortest duration of fever, the shortest time of paralytic ileus and discharge from the hospital, and no post-operative increase in the stress hormone prolactin. All these indices, apart from time of discharge, were slightly but not significantly different from those obtained with MLT. It cannot be excluded that statistical significance is achieved by increasing the number of interventions. In addition, LA-MLT allows a clear vision of the pelvic cavity, furnishes a visual guidance to the trans-peritoneal insertion of the corkscrew manipulator into the myoma, and permits adhesiolysis. It may be associated with complications linked to the blind insertion of the Veress needle and the optical trocar (Mayol *et al*., 1997; Schefer *et al*., 2001), but these may be greatly reduced by the use of technical variants such as open laparoscopy (Mayol *et al*., 1997; Hasson *et al*., 2000).

Myomectomy by MLT or LA-MLT is more feasible than by laparoscopy. It allows an accurate uterine repair, as during LT, but in comparison with the latter, it seems to induce a reduced post-operative stress. In particular, LA-MLT furnishes a more accurate cleaning of the pelvic cavity, because after peritoneum closure, homeostasis is further controlled under videolaparoscopy, and repeated washings are performed for complete debris' removal, as is the case during classic laparoscopy. This probably contributes to a further reduction of the post-surgical stress, which allows a prompter recovery and a reduced hospitalization time. Prospective randomized studies are required to confirm the results of this study, and to compare the early and late clinical outcome of myomectomy by MLT or LA-MLT with that performed by laparoscopy.

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