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Open or laparoscopic preperitoneal mesh repair for recurrent inguinal hernia?

A randomized controlled trial

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Abstract
Background: Giant prosthetic reinforcement of the visceral sac (GPRVS), an open preperitoneal mesh repair, is a very effective groin hernia repair. Laparoscopic transabdominal preperitoneal repair (TAPP), based on the same principle, is expected to combine low recurrence rates with minimal postoperation morbidity.
Methods: Seventy-nine patients with 93 recurrent and 15 concomitant primary inguinal hernias were randomized between GPRVS (37 patients) and TAPP (42 patients). Operating time, complications, pain, analgesia use, disability period, and recurrences were recorded.
Results: Mean operating time was 56 min with GPRVS versus 79 min with TAPP ($p < 0.001$). Most complications were minor, except for a pulmonary embolus and an ileus, both after GPRVS. Patients experienced less pain after a laparoscopic repair. Average disability period was 23 days with GPRVS versus 13 days with TAPP ($p = 0.03$) for work, and 29 versus 21 days, respectively ($p = 0.07$) for physical activities. Recurrence rates at a mean follow-up of 34 months were 1 in 52 (1.9%) for GPRVS versus 7 in 56 (12.5%) for TAPP ($p = 0.04$). Hospital costs in U.S. dollars were comparable, with GPRVS at $1,150 and TAPP at $1,179.
Conclusions: Laparoscopic repair of recurrent inguinal hernia has a lower morbidity than GPRVS. However, laparoscopic repair is a difficult operation, and the potential technical failure rate is higher. With regard to recurrence rates, the open preperitoneal prosthetic mesh repair remains the best repair.

Key words: Inguinal hernia — Laparoscopy — Mesh — Randomized trial

The traditional anterior approach in the repair of a recurrent hernia carries a high failure rate, from approximately 5% for the Shouldice technique to more than 30% for other techniques [2]. The use of a large preperitoneal mesh for the repair of recurrent inguinal hernia, as propagated by Stoppa et al. [18] has proved to be very effective [20]. In a series of complex recurrent inguinal hernias, our recurrence rate with this "giant prosthetic reinforcement of the visceral sac" technique (GPRVS) was 1%, and the procedure has become our standard repair for recurrent inguinal hernias [1].

Laparoscopic repair is based on the same principles as preperitoneal mesh repair. It can combine the low recurrence rate of the open technique with a quick postoperation recovery. Several randomized trials have addressed this issue by comparing laparoscopic repair with various anterior repairs in mainly or exclusively primary inguinal hernia patients [3, 11, 13, 19]. Only one trial has compared an open preperitoneal repair with a laparoscopic preperitoneal repair, in a group of patients with mainly primary inguinal hernia [4]. No such trial has been reported only for patients with recurrent inguinal hernia. The aim of this randomized controlled study was to compare morbidity, cost, and recurrence rates of laparoscopic transabdominal preperitoneal mesh repair (TAPP) and open preperitoneal mesh repair (GPRVS) for recurrent inguinal hernia.

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Patients and methods

Study design

An independent nonclinical investigator was assigned to the project by the Board of Directors at the University Hospital of Maastricht. The randomized controlled trial was approved by the institutional ethical committee and by the scientific committee. All patients eligible for general anesthesia (ASA 1-2-3), between 20 and 80 years of age, with a recurrent inguinal hernia were randomly assigned to either GPRVS or TAPP repair. Pregnant women; patients with coagulation disorders, advanced carcinoma, history of lower abdominal or other pelvic surgery (except appendicectomy); patients requiring concomitant surgery; and patients with a recurrence after a preperitoneal repair were excluded from randomization. Patients with giant scrotal recurrent hernias also were excluded because these hernias can be difficult to manage laparoscopically. After submitting written informed consent, patients were randomized by the sealed-envelope technique.

Outcomes and instruments

Postoperation morbidity, convalescence, pain, cost, and recurrence were assessed. Hospital stay was standardized: Patients were admitted the day before surgery and discharged the morning after the operation, whenever possible. Operating time, surgical findings, postoperation complications, and hospital stay after surgery were recorded. Postoperation pain was measured with a visual analogue scale (VAS) from 1 (no pain) to 10 (intolerable pain) and a verbal rating scale (VRS) with four response possibilities: no pain, mild pain, moderate pain, and severe pain. At discharge, patients received a questionnaire to report pain levels as well as amount and type of analgesia use during the first 7 postoperation days. The date of work and physical activity resumption was recorded. Patients were instructed that there were no restrictions regarding return to routine activities, unless this would cause discomfort or pain.

Two abdominal muscle tests were used as an objective measure of physical performance. These exercises were a modification of a test described by Payne et al. [15]. In the first test, the patient crosses the arms on the chest, and performs curled sit-ups. In the second test, the patient pulls up his or her flexed legs. These exercises were performed for 30 s, or until the patient felt uncomfortable. Muscle tests were performed before the operation, and 1 day, 10 days, and 6 weeks after the operation. Postoperation performance was expressed as a percentage of preoperation performance.

Follow-up involved physical examination by the authors 10 days, 6 weeks, and once every year thereafter until 5 years after operation. A recurrent hernia is defined as any symptomatic or asymptomatic defect in the abdominal wall, with herniation of abdominal contents, exacerbated by a Valsalva maneuver.

Anesthesia

Premedication, anesthesia, and postoperation pain medication were standardized. Premedication consisted of paracetamol 1000 mg. All patients underwent general anesthesia with thiopentone sodium 4–5 mg/kg, vecuronium 0.1 mg/kg and fentanyl 1 μg/kg. Maintenance of anesthesia was by N_2O–O_2 mixture. Isoflurane up to 1.2 vol% and intravenous (IV) boli of fentanyl 1 μg/kg were used when required. No opiate antagonists were used at the end of anesthesia. Postoperation analgesia consisted of 1000 mg paracetamol three times daily, when needed.

Surgical techniques

The open repairs were performed by five surgeons, or by surgical residents assisted by one of the surgeons. Laparoscopic repairs were performed by four laparoscopic surgeons with varying experience in laparoscopic hernia repair, or by surgical residents assisted by a laparoscopic surgeon.

The GPRVS is by definition a bilateral reinforcement. A concomitant primary hernia either known before surgery or discovered intraoperatively was therefore automatically repaired. With the laparoscopic repair, all pre- and intraoperatively discovered hernias were repaired, and normal inguinal areas were not reinforced.

A urinary catheter was introduced to maintain an empty bladder during the operation, then removed at the end of the procedure. Prophylactic antibiotics were used only for the GPRVS procedure.

The details of the GPRVS have been described [1]. Access is gained to the preperitoneal and prevesical space through a lower abdominal midline incision. The peritoneal sac is dissected away from the abdominal and pelvic wall, and the hernial sac is reduced. A large polypropylene mesh (26 × 18 cm) (Marlex, C. R. Bard, Billerica, MA) with two vertical slits of approximately 10 cm in the upper border is positioned around the spermatic cords. The vertical slits are closed with a running nonabsorbable suture. The large mesh covers both inguinofemoral areas.

In laparoscopic transabdominal preperitoneal repair (TAPP), a CO_2 pneumoperitoneum is created with a Veress needle. Three cannulas are used for access to the abdominal cavity. The peritoneum is opened at the upper border of the inguinal hernia defect from the medial umbilical ligament to the level of the iliac spine. A direct sac is reduced. Then an indirect sac is reduced and dissected off the vas deferens and testicular vessels. When the indirect sac is very large, it is transected. A 10 × 15-cm polypropylene mesh (Prolene, Ethicon, Somerville, NJ) with rounded edges is positioned over the inguinofemoral area, widely overlapping the edges of the hernial defect. The mesh is not anchored by staples or sutures. The peritoneum is closed with a running absorbable suture. An incidentally discovered contralateral hernia is repaired at the same time.

Costs

Cost analysis was carried out from the hospital perspective. The inguinal hernia treatment consisted of five activities: outpatient clinic before surgery, hospital day, operation, recovery-room stay, and outpatient clinic after surgery. The costs per activity consisted of direct and indirect cost. Direct costs included personnel costs as well as both medical and nonmedical material costs. Indirect costs consisted of the general overhead. Costs of laboratory tests, x-rays, medications, and the like were allocated to the activity for which they were requested or given. Costs of complications (additional outpatient visits, readmissions etc.) were calculated separately. These costs are presented in U.S. dollars.

Statistical analysis

Results were analyzed in terms of intention to treat. The Kolmogorov-Smirnov test was used to test for normality. The unpaired Student *t*-test was performed to determine differences between normally distributed variables. The unpaired Mann-Whitney test was used for differences between ordinal variables and data not distributed normally. Chi-square testing was used to analyze categorical variables, and Fisher's exact test was used when any expected cell value in a 2 × 2 table was less than 5. Statistical significance was indicated by p values less than 0.05.

Results

From November 1993 until March 1996, a total of 129 patients ages 20 to 80 years with unilateral or bilateral recurrent inguinal hernias were treated in the authors' department, 79 of which were randomized. Reasons for noninclusion were ambulatory treatment (3 patients), regional anesthesia (10 patients), previous lower abdominal surgery (4 patients), concomitant surgery (5 patients), giant scrotal recurrence (5 patients), previous preperitoneal repair (3 patients), patient refusal (6 patients), and unknown (6 patients). Eight patients experienced a recurrence while participating in a trial for primary inguinal hernia repair and were not included in a second trial for ethical reasons. Patient characteristics given in Table 1 show that the two groups were comparable.

Table 1. Patient characteristics

	GPRVS	TAPP
Patients	37	42
Female patients	1	1
Working patients	16 (43%)	16 (38%)
Patients performing physical activities	29 (78%)	33 (79%)
Age (SD)	57 (13)	58 (12)
Body Mass Index (SD)	25.1 (2.8)	24.2 (2.9)
Risk factors for recurrence[a]	11 (30%)	10 (24%)
Recurrent hernias	41	52
Primary hernias	11	4

[a] Prostatism, chronic lung disease, constipation, or strenuous physical labor.

Table 2. Complications

	GPRVS	TAPP
Vas deferens injury	0	1
Urinary	1 (retention)	2 (infection)
Chest infection	0	1
Pulmonary embolus	1	0
Ileus/laparotomy	1	0
Wound infection	4[a]	0[a]
Hematoma	5	10
Seroma	7	10
Inguinal hypesthesia	0	0
Painful testicle (transient)	1	2
Testicular swelling (transient)	2	2
Testicular atrophy	1	0
Chronic neuralgia	0	0

[a] $p = 0.04$.

Surgical results and hospital stay

Surgical trainees performed 65% of the GPRVS procedures and 29% of the laparoscopic repairs ($p < 0.001$). One patient assigned to a laparoscopic repair underwent a GPRVS procedure because of laparoscopic equipment supply problems. According to the intention-to-treat principle, the patient was retained for analysis in the laparoscopic group. Operation time was significantly different between groups: 56 (SD, 16) min for GPRVS versus 79 (SD, 32) min for laparoscopic repair ($p < 0.001$). After a GPRVS, 77% of patients were discharged within 24 h, as compared with 92.5% of patients after a laparoscopic repair ($p = 0.02$).

Complications

Complications are listed in Table 2. One patient was readmitted 8 days after a GPRVS with an ileus. At laparotomy, small bowel loops were found to be adherent to the mesh through a peritoneal tear. This was easily corrected, and the patient had an uneventful recovery. One patient was readmitted with a pulmonary embolus and treated with standard anticoagulation therapy. All wound infections were superficial. Treated on an outpatient basis, they healed without further problems. Two patients eventually had scar excision under local anesthesia for cosmetic reasons.

Pain and analgesia use

The mean VAS scores during the first postoperative week were 2.9 (SD, 1.5; range, 0–7) for GPRVS and 2.2 (SD, 1.6; range 0–7) for the laparoscopic repair ($p = 0.005$). Median (first to third quartile) VRS scores were 1 (1–1) for GPRVS and 1 (1–1) for laparoscopic repair ($p = 0.05$). Ten days and 6 weeks after operation, VAS and VRS scores were comparable. The median total analgesia use in the first postoperative week was 3.5 tablets (0–11 tablets) in the GPRVS group, and 1 tablet (range, 0–6 tablets) in the laparoscopic group ($p = 0.06$).

Resumption of activities

The average disability period for work was significantly different: 23 (SD, 12.4; range, 1–41) days for GPRVS and 13 (SD, 8.2; range, 1–30) days for TAPP ($p = 0.03$). Return to physical activities was after 29 (SD, 13.4; range, 1–57) days for GPRVS and 21 (SD, 15.5; range, 1–74) days for TAPP ($p = 0.07$).

Abdominal muscle tests

Preoperation absolute performance was comparable between the two groups for both muscle tests. The results are presented in Fig. 1. Postoperation performance was significantly better in the laparoscopic group at postoperation days 1 and 10. At 6 weeks, the results were comparable between the two groups.

Costs

The costs are presented in Table 3. Total costs resulting from complications are $2,721 for all GPRVS procedures (mean additional cost, $74), and $197 for all TAPP procedures (mean additional cost, $5). When these additional costs are included, the costs of both repairs become virtually identical. Cost of recurrences is not included in the analysis because it is unclear how many procedures eventually will require a repair.

Follow-up and recurrences

The mean follow-up time in March 1998 was 34 months (range, 6–50 months). In the GPRVS group, one patient died of pulmonary disease within the first year after his hernia repair. One patient moved abroad after 1 year, and was lost to follow-up thereafter. All other patients completed the 2-year follow-up by physical examination. In the laparoscopic group, one patient died of a malignancy 6 months after his hernia repair. In the course of his disease, he underwent a laparotomy, on which occasion the hernia repair was found to be intact. One patient had a 2-year follow-up by telephone interview. All other patients completed the 2-year follow-up by physical examination.

The actual recurrence rate after GPRVS was 1 in 52 hernias (1.9%), or 1 in 37 patients (2.7%). One small asymptomatic recurrence was found at physical examination 1 year after operation. The patient had a postoperation wound infection, for which additional outpatient clinic vis-

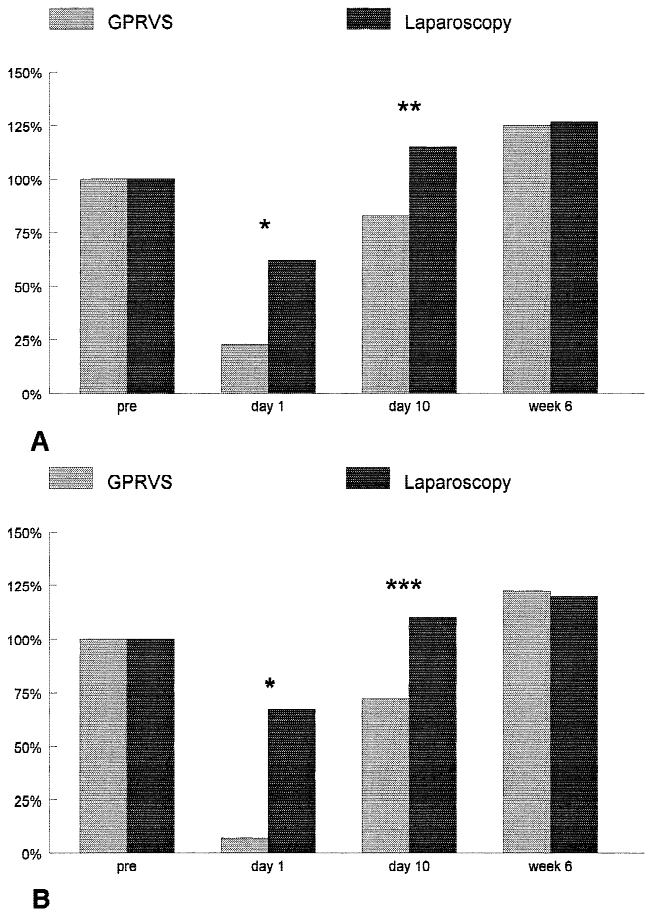

Fig. 1. Abdominal muscle tests. **A** Sit-up test; **B** Knees-up test. Postoperative performance is expressed as a percentage of preoperative performance. *$p < 0.001$; **$p = 0.01$; ***$p = 0.001$; Student's *t*-test.

Table 3. Costs in U.S. dollars

	GPRVS	TAPP
Theater costs	566	716
Other costs[a]	510	458
Costs of complications	74	5
Total costs	1,150	1,179

[a] Outpatient clinic, hospital stay, recovery room.

its were required. The small recurrence may have gone unnoticed because attention was directed at the wound problem. The asymptomatic recurrence was not repaired. There were no cases of severe chronic pain. One patient had a persistent minor groin pain.

The recurrence rate after laparoscopic repair was 7 in 56 hernias (12.5%), or 6 in 42 patients (14.3%). Four of the recurrences, described as "seroma" or "bulging" 6 weeks after operation, were found to be recurrences at the 1-year follow-up. One patient with a recurrence diagnosed after 1 year did not attend the 6-week follow-up visit. Two recurrences were noted by the patients, one after 3 months and the other after 5 months. Four of the seven recurrences were asymptomatic at the time of discovery, two of which later became symptomatic.

So far, four recurrences have been repaired. They were all medial recurrences, and obviously the prosthetic mesh had not been placed medially enough. After the 1-year follow-up, no new recurrences were observed. There were no patients with severe chronic pain. Two patients had a persistent minor groin pain. The difference in recurrence rates, 1.9% for GPRVS and 12.5% for TAPP, is statistically significant ($p = 0.04$).

Discussion

The difference in recurrence rate, 1.9% for GPRVS and 12.5% for TAPP, is clearly in favor of the open preperitoneal mesh repair. The 12.5% recurrence rate after laparoscopic repair of recurrent inguinal hernia is higher than expected. In a randomized trial for both primary and recurrent inguinal hernia, Champault et al. [4] reported recurrence rates of 2% for GPRVS and 6% for the laparoscopic repair. Felix et al. [7] and Sandbichler et al. [17] reported series of laparoscopic repair of recurrent hernias with recurrence rates of 1% and 0.5%, respectively.

Generally, the short-term recurrence rate of laparoscopic inguinal hernia repair is reported to be less than 5%. The strict adherence to physical examination as a follow-up method and the strict definition of recurrence in this study can only partially explain the high recurrence rate. In both the open and laparoscopic repair procedures, the aim is to cover the whole inguinofemoral area by a preperitoneal prosthetic mesh, and recurrences should not occur. When they do occur, recurrences must be regarded as technical failures.

Recurrences after laparoscopic repair most often result from using too small a mesh, or not using staples to fix the mesh [6, 14]. The authors have used a large 10 × 15-cm mesh, which was not stapled. Most recurrences after laparoscopic hernia repair occurred medially, and the technique was adjusted. The mesh is now placed at least until the midline, and occasionally hernia staples are used when an adequate overlap (2 cm) cannot be achieved medially. The totally extraperitoneal technique is now used more often, allowing for better visual control in the medial part of the operating field. Since this policy was adopted, only a few recurrences have been experienced.

This learning curve effect has been observed by several authors [4, 8, 12, 16], and it has been suggested that a laparoscopic surgeon should perform 50 repairs to become experienced. In the current study, the laparoscopic repair was performed or assisted by four laparoscopic surgeons, none of whom had performed 50 repairs at the start of the study. Obviously, the learning curve effect was underestimated. Considering that the open repair was performed most often by residents, and the laparoscopic repair most often by surgeons, the recurrence rates in this study suggest that the open repair is easier to learn than the laparoscopic repair. It has been argued that "poor results of laparoscopic hernioplasty should be blamed on a lack of expertise and not on the laparoscopic approach per se" [6]. It is, however, still a matter of debate whether it is worthwhile going through the effort to gain the necessary expertise [21].

The mean follow-up in this study is 34 months. For conventional repair, it has been estimated that only 25% of recurrences occur in the first postoperation year, whereas

50% will appear after 5 years [10]. For the open preperitoneal mesh repair, the long-term recurrence rate is not substantially different from the short-term recurrence rate [1, 18, 20]. This also is expected for laparoscopic repair because it is based on the same method of inlay mesh repair. In the current series, no new recurrences were observed after 1 year of follow-up. Therefore, it is believed that the long-term results of the study will be essentially the same.

Two complications after GPRVS, a pulmonary embolus and a mechanic ileus requiring a laparotomy, can be considered potentially dangerous, and indicate the invasiveness of the procedure. As expected, there were less wound problems after a laparoscopic repair than after a GPRVS.

Randomized trials have shown that laparoscopic repair causes less postoperation pain and less postoperation disability than anterior inguinal (conventional) hernia repair [3, 11, 13, 19]. Champault et al. [4] compared laparoscopic repair with an open preperitoneal repair (Stoppa repair) and found a significant difference in postoperation pain and return to work in favor of the laparoscopic repair. The findings of the current study confirm this. It is clear that less pain and disability benefit both the individual patient and society. However, when asked, most patients consider the traditional outcome measure of recurrence more important than the speed of recovery [9].

In this study, the hospital cost of both procedures was comparable. The two major complications after GPRVS contributed considerably to the cost of the open procedure. Laparoscopic hernia repair can be performed easily in a day surgery setting, as shown by Evans et al. [5]. After performing 300 laparoscopic repairs, these authors report operating times of 24 min for unilateral and 38 min for bilateral repair. In this setting, laparoscopic repair is substantially less expensive than reported in the current study.

Laparoscopic recurrent inguinal hernia repair causes less postoperation pain and disability than GPRVS. Laparoscopic repair is technically more difficult, and the potential for technical failure is higher. In discussing treatment options with a patient, these issues should be addressed. In the authors' opinion, laparoscopic inguinal hernia repair should be performed only by experienced laparoscopic surgeons who assess their personal recurrence rates. With regard to recurrence rates, the open preperitoneal mesh repair remains the best repair for most patients and surgeons alike.

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