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Original Article

J Shaheed Suhrawardy Med Coll, June 2016, Vol.8, No.1 ISSN 2226-5368

Open versus Laparoscopic Inguinal Hernioplasty - Outcome Correlation

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Abstract

Background: Repair of inguinal hernias in men is a common surgical procedure, but the most effective surgical technique is still in debate. **Methods:** We randomly assigned men with inguinal hernias at Mitford Hospital surgery, ward to either open mesh or laparoscopic mesh repair. The primary aim was to detect recurrence of hernias in both groups at 6 month. Secondary aims were to detect complications and patient compliance. **Results:** of the 70 patients who were randomly assigned to one of the two procedures, 62 underwent operation; 6 month follow-up was completed in 55 (78.6%). Recurrences were only one in the laparoscopic group (3.6%) and 1 in the open group (3.7%). The rate of complications was lower in the laparoscopic-surgery group than in the open-surgery group (17.6% vs. 27%). The laparoscopic- surgery group had less pain initially than the open-surgery group on the day of surgery (difference in mean score on a visual-analogue scale, 10.2 mm; 95 percent confidence interval, 4.8 to 15.6) and at two weeks (6.1 mm; 95 percent confidence interval, 1.7 to 10.5) and returned to normal activities earlier (adjusted hazard ratio for a shorter time to return to normal activities, 1.2; 95% confidence interval, 1.1 to 1.3). Hospital stay was shorter in laparoscopic group (2.6 days vs 3.2 days). Patients' satisfaction with surgery was 95% in the laparoscopic group and 87% in open group. Nenety six laparoscopic and 87% of open surgery patients perceived that they were healthy after surgery. Total treatment cost was more in laparoscopic group. **Conclusions:** The laparoscopic technique is superior to the open technique for mesh repair of primary hernias. [J Shaheed Suhrawardy Med Coll 2016;8(1): 3-7]

Keywords: Laparoscopic Inguinal Hernioplasty.

Introduction

Surgical repair of inguinal hernias is a common procedure in adult men. However, recurrence of hernias has been reported to occur after repair in 15 percent or more cases, and postoperative pain and disability are frequent[1-5]. When traditional surgical methods are used, outcomes after repair of recurrent hernias have been worse than after primary repair[6,7]. After the introduction of tension free surgical repair with the use of prosthetic mesh, recurrence rates were reported to be less than 5 percent, and patients' comfort was reported to be substantially improved over that obtained by the traditional, tension-producing techniques[8,9]. A laparoscopic method of performing a tension-free repair has subsequently been reported to result in low recurrence rates and to be associated with substantially less pain in the immediate postoperative period and earlier return to normal activities than the open-repair technique[10,11]. The laparoscopic technique, however, requires general anesthesia, and it is more often associated with some intra-operative complications than is open repair[11-13], although such complications are infrequent and rare in skilled hands. In our country, laparoscopic facilities are now widely available in medical colleges and some district hospitals also. So, minimal invasive procedures are now well practiced in those centers. Inguinal hernias are now regularly repaired with both open and laparoscopic approach in Sir Salimullah Medical College Mitford Hospital.

We conducted a randomized trial to compare recurrence rates and other outcomes after either of the two standardized tension-free hernioplasty : open repair and laparoscopic repair.

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Conflict of interest: No conflict of interest
Contributions by authors: All authors contributed form protocol to write up of the article

Methodology

Men admitted to general-surgery ward in Sir Salimullah Medical College Mitford Hospital who were 18 years of age or older, had a diagnosis of inguinal hernia, and gave written informed consent were eligible for random assignment to open tension-free repair or laparoscopic tension-free repair. Patients who had systemic disease that is a constant threat to life or those who were unlikely to survive for 24 hours, with or without an operation were excluded, as were those who had contraindications to general anesthesia, bowel obstruction, bowel strangulation, peritonitis, bowel perforation, local or systemic infection, contraindications to pelvic laparoscopy, a history of repair with mesh, or a life expectancy of less than two years. Patients who were participating in another trial were also excluded. Randomization was carried out by a computer-generated, permuted-block sequence and was stratified according to the type of hernia (primary or recurrent), whether the hernia was unilateral or bilateral, and the study site. In patients with bilateral hernias, both sides were repaired simultaneously; one side was chosen randomly to be the "study" hernia to be included in the intention-to-treat analysis.

The open procedure was performed according to the Lichtenstein method.18 Laparoscopic repairs were performed either by a Transabdominal Preperitoneal (TAPP) approach or by a Totally Extraperitoneal (TEP) approach[19-22]. All repairs involved the use of prolene mesh. Recurrent hernias were repaired by the same standardized procedures as were primary hernias. All the patients were given standardized postoperative instructions that did not restrict their activities unless the activities caused pain.

Determination of the Primary Outcome: The primary outcome of the trial was recurrence of a hernia within 6 months after the repair. The patients were followed for 6 months. Postoperatively, each patient was examined at second week, at third month and 6th month. Recurrences were confirmed by examination by an independent surgeon. A patient with bilateral hernias who had a recurrence on the side opposite the side of the study hernia was considered not to have had a recurrence in the intention-to-treat analysis.

Determination of Secondary Outcomes: Secondary outcomes were peroperative(injury to- inferior epigastric artery, testicular artery, internal iliac vessels, gonadal vein, vas difference, ilioinguinal nerve, gut and urinary bladder) and post operative surgical complications (pain, wound infection, hematoma, wound dehiscence, scrotal hematoma and scar hypertrophy) and patient compliance (return to activity, total hospital stay, patient's perceived health, total treatment cost and patient's satisfaction). Complications were assessed intra-operatively and at specified intervals postoperatively. Long-term complications were assessed at the three-month and 6th month. Life-threatening complications were defined before the start of the study and were assessed for 30 days after the procedure. All life-threatening complications were reviewed by an independent end-points committee to determine whether the event was related to the operation.

Patient compliance was assessed at baseline, two weeks, third month and sixth month. Pain was assessed with the use of a visual-analogue scale on the day of the operation and daily until the first postoperative visit (at two weeks)[23].

Organization and Monitoring: Each patient was assessed by the principal investigator or co-principal investigator during the preoperative days and informed written consent for study was taken by them to ensure compliance with study protocols. All patients were prepared for surgery by the whole surgical team and senior anesthetists. Deaths and life-threatening complications were determined to be related or unrelated to the treatment by different senior surgeon and anesthetists.

Statistical Analysis: The study was designed to detect no difference in recurrence rates between the groups with a sample of 70 patients and a power of 80 percent.15 The data and safety monitoring team terminated enrollment two weeks early because they determined that the study had sufficient power to detect a difference in the rate of recurrence within 6 months. The study included 55 patients who underwent surgery, and thus it had more than 88 percent power to distinguish a difference in recurrence rates, allowing a two-sided type I error rate of 5 percent.

In the primary analysis, the rates of recurrence were compared between the two groups according to the intention to treat. The recurrence were compared with the use of O'Brien–Fleming boundaries to account for sequential monitoring of the primary outcome.25 All 95 percent confidence intervals for the 6 month recurrence rates were adjusted for sequential monitoring, as were the 95 percent confidence intervals for the rates or mean values of each secondary outcome. Subgroup analyses of the primary outcome are presented as adjusted odds ratios calculated from logistic-regression analyses after adjustment for stratification factors (primary or recurrent hernia, unilateral or bilateral hernia, and study site). Proportions were compared on the basis of adjusted odds ratios obtained by logistic-regression analysis to control for stratification factors. Differences in outcomes related to pain and functional status were compared by multiple linear-regression analysis, with generalized estimating equations used to control for stratification factors and to account for repeated assessments. Differences in the times to return to normal activity, after adjustment for stratification factors, were assessed by Cox regression analysis. Statistical tests were not adjusted for comparisons related to multiple secondary end points or subgroup analyses. Analyses controlling for stratification factors were pre-specified.

Table-1 shows that, the characteristics of the hernia, coexisting conditions, and ASA classifications were similar in the two groups. Coexisting conditions were determined to be present or absent by the examining physician according to defined criteria on the basis of current medications and problem lists in their charts[15] or on the basis of the patients' own report. American Society of Anesthesiologists (ASA) class I denotes healthy status, class II mild systemic disease, and class III severe systemic disease.

Table-1: Baseline Characteristics of the Patients, According to Treatment Group.

Characteristic	Open Repair (n=27)	Laparoscopic Repair (n=28)
Age (yr)	52.4	53.6
Duration of hernia (%)		
<6 wk	7.4	7.1
6 wk to 1 yr	37.0	35.7
>1 yr	55.5	57.2
Hernia (%)		
Unilateral	81.5	89.3
Bilateral	18.5	10.7
Primary	88.9	82.1
Recurrent	11.1	17.9
Coexisting conditions (%)		
Congestive heart failure	7.4	3.6
Hypertension	11.1	7.1
COPD	7.4	7.1
Chronic cough	11.1	14.3
Prostatism	7.4	10.7
Diabetes	7.4	10.7
Smoking	37.0	42.8
ASA class (%)		
I	74.0	82.1
II	22.2	17.9
III	3.7	0

Table-2: Characteristics of the Repair Procedures, Postoperative Complications, and Recurrences at 6month. (n=55)

Variable	Open Repair (%)	Laparoscopic Repair (%)
Type of anesthesia		
General	26.0	100
Regional	74.0	0
Type of laparoscopic repair		
Totally extraperitoneal	NA	21.4
Transabdominal preperitoneal	NA	78.6
Intraoperative complications	7.4	14.3
Injury to spermatic-cord structure	3.7	0
Injury to vessel	3.7	3.6
Peritoneal defect	0	10.7
Immediate postoperative complications	14.8	0
Urinary retention	7.4	0
Urinary tract infection	3.7	0
Hematoma or seroma	3.7	0
Wound infection	3.7	0
Neuralgia or other pain	3.7	0
Recurrence at 6 months	3.7	3.6

Results:

Between January 2013 and July 2013, 96 eligible patients were screened. Of these patients, 70 (72.9 percent) with inguinal hernias met the entry criteria and were randomly assigned to either open or laparoscopic hernia repair. The 6 month follow-up period ended in January 2014 and was completed in 88.7 percent (55) of the 62 patients who underwent surgery. Laparoscopic repair was done in 30 cases and open repair in 32. Out of that 30, 28 patients (93.3%) completed 6 month follow up, whereas, 27 patients (84.4%) of 32 open surgery patients completed the follow up.

The intention-to-treat analysis showed that at 6 month, recurrences were same in the two groups (1 recurrence among 28 laparoscopic patients [3.6 percent] and 1 recurrence among 27 open patients [3.7 percent]). In additional prespecified analyses, we found a significant interaction between treatment group and the type of hernia (primary or recurrent) (P=0.012) but not between treatment group and whether the hernia was unilateral or bilateral (P=0.29). With respect to the repair of primary hernias, there was no recurrence in either procedure. The same was not true with respect to the repair of recurrent hernias; the number of recurrence was similar: 1 of 28 patients in the laparoscopic group had a recurrence (3.6 percent), as compared with 1 of 27 such patients in the open group (3.7 percent).

Overall, 13 of the 55 patients who underwent a repair procedure (23.64 percent) had at least one complication; there were 4 complications among the 28 patients in the laparoscopic group (14.3 percent) and 6 among the 27 patients in the open group (22.2 percent). Intra-operative complications occurred more in the laparoscopic group (14.3%) than in the open group. Immediate postoperative complications were more in open cases (14.8%). The rate of long-term complications (those assessed at three months and 6th month visit) were similar in the two groups. Operating time was more for laparoscopic group (52 minutes versus 35 minutes in open group).

Patients in the open-repair group had significantly greater levels of pain (at rest, at work or during exercise, and during normal activities) than did those in the laparoscopic group during the two-week postoperative assessment period. On the day of surgery, the difference in the mean score on the visual-analogue scale was greatest (10.2 mm [95 percent confidence interval, 4.8 to 15.6]), but the score decreased to 6.1 mm (95 percent confidence interval, 1.7 to 10.5) by the time of the two-week assessment. The two treatment groups were similar with respect to all pain assessments by the time the three-month visit took place.

The time to the resumption of daily activities was significantly shorter among those undergoing laparoscopic repair (median time, four days) than among those undergoing open repair (five days) (adjusted hazard ratio for a shorter time to return to normal activities, 1.2; 95 percent confidence interval, 1.1 to 1.3). Approximately half the patients were sexually active before the operation; the time to the resumption of sexual activity was similar in the two groups (median time, 14 days in the laparoscopic group and 14 days in the open group). More patients in the laparoscopic group than in the open group was able to perform specific activities (e.g., climbing stairs and

engaging in vigorous activities, such as weight lifting) at two weeks. Hospital stay was shorter in laparoscopic group (2.6 days, 3.2 days in open group). Patients' satisfaction with surgery was 95% in the laparoscopic group and 87% in open group. 96% laparoscopic and 87% of open surgery patients perceived that they were healthy after surgery. Total treatment cost was more in laparoscopic group (5000TK in contrast to 3000TK in open group). At three months of follow-up, however, differences in activity level between the groups were not apparent.

Discussion

This randomized trial compared two tension-free, mesh-based hernia-repair techniques: the Lichtenstein open procedure and the laparoscopic procedure. Overall, same recurrence rates were found in both open and laparoscopic technique. There was significant interaction between the surgical approach and the type of hernia (primary or recurrent). No recurrence was in primary hernias; similar recurrence associated with the both techniques for the repair of recurrent hernias. The presence of bilateral hernias did not alter the rate of recurrence after either procedure.

Intra-operative complications were more frequent in the laparoscopic-repair group (14.3) than in the open-repair group, and immediate postoperative complications were more frequent in open group (14.8 in open group), although rates of long-term complications were similar in the two groups. These results are consistent with others' findings[11,12].

As other studies have reported, patients who underwent a laparoscopic repair returned to their usual activities one day sooner than those who underwent an open repair[11,12]. Differences in activity levels were not apparent three months after the procedure and thereafter. Patients who underwent an open repair experienced significantly higher levels of pain than those who underwent a laparoscopic repair, both on the day of operation and at two weeks, but no significant differences were apparent after two weeks. Though statistically significant, the magnitude of the differences in pain may not be clinically meaningful[26,27]. Results of sequential SF-36 assessments showed no significant differences between the two groups at any time. Because of the large number of secondary end points considered over several periods, some statistically significant findings could have occurred by chance alone.

The results of our randomized trial may be a good indicator of the results that can be expected in the general population when hernia repair is performed by surgeons who are practicing outside of specialized centers.

Limitation

The average age of the men enrolled was high, and their health-related quality of life was below that of the general population[15]. We excluded patients who had previously under weit a hernia repair with the use of mesh, and thus the data cannot be generalized to second repair procedures in these difficult cases.

Conclusion

We conclude that for inguinal hernias, the laparoscopic hernioplasty is superior to the open technique of tension-free repair, both in terms of patient compliance and in terms of safety.

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