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An assessment of pain and return to normal activity

Laparoscopic herniorrhaphy vs open tension-free Lichtenstein repair

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Abstract
Background: Laparoscopic herniorrhaphy is controversial and deserves critical evaluation.
Methods: In a randomized prospective study transabdominal preperitoneal laparoscopic herniorrhaphy ($n = 24$) was compared in patients to the tension-free Lichtenstein repair ($n = 29$) utilizing validated and reliable pain and activity assessment tools. The Sickness Impact Profile (SIP) was used to compare preoperative normal activity to postoperative activity. A Pain-O-Meter (visual analogue scale plus affective and sensory pain descriptors) assessed intensity of pain. The total pain assessment score and SIP were compared across time (postoperative day 1–42). Analgesic medication was used as a covariate.
Results: The total pain score was less for laparoscopic herniorrhaphy but this did not reach statistical significance. Similarly, the SIP showed modest improvement for laparoscopic herniorrhaphy. No differences between groups were noted for morphine equivalents of administered analgesics or length of hospitalization.
Conclusion: Further investigation of laparoscopic herniorrhaphy is warranted.

Key words: Laparoscopic herniorrhaphy — Lichtenstein herniorrhaphy — Sickness impact profile — Pain-O-Meter

Many surgeons agree that laparoscopic herniorrhaphy is appropriate for patients with bilateral and recurrent inguinal hernias, but skepticism remains over the use of this technique for initial unilateral hernias. Important controversies remain and the benefits of importing laparoscopic techniques to inguinal hernia repair are not completely self-evident. For this reason, laparoscopic inguinal herniorrhaphy is still under investigation, and intensive evaluation is required to prove that a decreased morbidity or a reduced recurrence rate exists before its adoption is recommended to the wider surgical community.

In general, nurses and physicians expect less pain than patients say they experience [9]. Exact reporting of patient postoperative pain may also be complicated even further by bias. An accurate and objective postoperative pain assessment tool has been reported by one of the co-investigators [7]. Because this tool has been validated [4, 5, 11] and pain reduction is of prime concern to the patient and physician, it is logical that pain be objectively measured.

The Sickness Impact Profile (SIP) has been utilized since 1977 [2]. It is a 136-item questionnaire that can accurately determine return to normal activity when administered at appropriate intervals. This instrument quantitatively evaluates dysfunction in physical, psychosocial, and independence categories of dysfunction.

We hypothesize that because less tissue division and suturing is required, laparoscopic herniorrhaphy (transabdominal preperitoneal) is less painful and has an associated shorter hospitalization and an earlier return to normal activity than the open tension-free prosthetic Lichtenstein repair.

Methodology

Design

The design for this study was a prospective randomized controlled clinical trial. Patients from the Omaha and Lincoln, Nebraska, Veterans Administration hospitals were randomized prospectively 1 day before surgery to the treatment or control group. The treatment group underwent a laparoscopic herniorrhaphy (transabdominal preperitoneal technique). The control group underwent a traditional tension-free Lichtenstein repair. A registered nurse collected data on all patients during hospitalization. Before discharge, the

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patients were instructed by the nurse on how to complete and return all data forms mailed to their homes. The nurse was available to the patients via telephone if additional help was needed for completion of the forms. Study dates for this project were August 18, 1993, through August 29, 1995.

Study population

Fifty-three male patients, 20 years of age or older, participated in the study. Sixteen direct, 21 indirect, seven combined, nine recurrent, and no femoral hernias were repaired. Twenty-four patients were randomly assigned to the laparoscopic group and 29 patients to the Lichtenstein group. Randomization schedules were developed using the PLAN procedure from the Statistical Analysis Systems (SAS) software. This schedule incorporated a balanced allotment every 20 patients. Only male subjects were used in the study. Criteria for inclusion were: (1) diagnosis of unilateral inguinal hernia on clinical examination, (2) a signed informed consent, and (3) the ability to read English. Exclusion criteria included (1) bilateral inguinal hernias, (2) inability to tolerate a general anesthetic, (3) patients requiring additional major surgery under the same anesthetic, (4) previous preperitoneal pelvic or extensive lower abdominal surgery, (5) drug addiction, and (6) the presence of either an incarcerated or strangulated hernia.

Procedure

Each surgical procedure was performed by a specific, standardized technique. Videotape and a slide presentation for the operating resident surgeon, given by the primary investigator, helped assure conformity to the prescribed operating technique. All operations were conducted under the direct operating room supervision of a fully trained staff surgeon. Laparoscopic operations were supervised only by staff experienced in 25 or more previously performed laparoscopic herniorrhaphies.

Laparoscopic transabdominal preperitoneal herniorrhaphy was performed under general anesthesia. After laparoscopy, a transverse peritoneal incision was made above the hernia. A single 12 × 8–10 cm patch of polypropylene mesh was secured in the preperitoneal space with staples after hernia sac dissection and reduction into the peritoneal cavity. No staples were applied lateral to the external iliac vessels below the iliopubic tract. Staples were otherwise placed at 1-cm intervals around the periphery of the mesh and into Cooper's ligament. The peritoneal closure was accomplished with staples.

The open tension-free prosthetic Lichtenstein repair [1] was performed under general, regional, or local anesthesia with sedation. Direct and indirect sacs were reduced and the spermatic cord was skeletonized. A 6 × 12–16 cm patch of polypropylene mesh was tailored to cover the defect, care being taken to avoid excessive tension. A running 2-0 Prolene (Ethicon, Inc., Sommerville, NJ) suture attached mesh to fascia just anterior to the pubic tubercle and to Poupart's ligament inferiorly. Superiorly, interrupted sutures were used to secure the mesh to the rectus sheath conjoined tendon, and internal oblique muscle. A single nonabsorbable suture was used to close the keyhole defect in the mesh lateral to the cord. The external oblique aponeurosis, subcutaneous fascia, and skin were closed in the usual fashion.

Data collection

Demographic and background variables. The demographic variables were measured on a standardized form and included age, sex, race/ethnicity, educational level, and household income.

Operative time. The time between incision and wound closure was obtained for each operative procedure.

Pain intensity and quality. The Pain-O-Meter (POM) tool was designed by Johansson to assess the intensity of the sensory and affective components of pain, overall pain intensity, as well as the quality of pain. The POM is a hard white plastic tool which is 8 inches long, 2 inches wide, and 1 inch thick. It is lightweight and can easily be held by the patient. A list of 15 sensory and 11 affective pain descriptors are located on the front side of the POM. Patients are asked to select sensory and affective words describing their pain at preselected intervals and to record their pain description on a standard pain assessment form. An intensity value (from a low of 1 to a high of 5) is predetermined for each sensory and affective word located on front of the POM. A 10-cm visual analogue scale (VAS) with a movable marker is located on the back side of the POM (POM-VAS). The POM-VAS represents a continuum ranging from a low of 0 to a high of 10 cm. The subjects' pain score is determined by measuring the distance in centimeters from 0 to the marker's position placed on the scale by the subjects. A total descriptive pain score can be obtained by adding the sensory and affective scores. Pain assessment was performed at least 4 h after an intramuscular or oral analgesic was administered. Measurements of pain and activity were performed in both groups preoperatively and incrementally up to postoperative day 42. The amount of analgesic medications taken by each patient was recorded during the period of the study and converted to morphine equivalents. During the patient's recovery period, supplementary nonsteroidal analgesics were not administered.

Because length of hospitalization has been considered a factor in relation to patient perception of pain, the number of postoperative hospital days was recorded.

Activity. The Sickness Impact Profile (SIP) was used to measure the subject's physical activity, psychosocial activity, and independence. The SIP is comprised of 12 categories. Scores are determined by a preset weight for each item and each score is *inversely proportional* to the degree of activity or independence. (A low SIP score indicates a minimal impact on activity or independence). The SIP score can be evaluated by 12 categories and three domains (physical, psychosocial, and independence) as well as a total SIP score. The questionnaire contains 136 questions and is designed to detect differences over time or between groups. This questionnaire also determines the return to normal activity if administered at appropriate intervals. It is designed to quantitate the patient's perception of performance in each category. A quantitative evaluation of physical dysfunction as well as psychosocial categories of dysfunction can thus be determined with this instrument.

Outcome. Patients were evaluated by a staff surgeon. Included in this evaluation were questions concerning disability, persistent pain, infection, associated conditions such as urinary or sexual dysfunction, and physical examination evidence of hernia recurrence.

Data analysis

Univariate descriptive summary statistics were obtained for all variables in the study at each time point for each patient group. The principal method used for comparing the temporal patterns of responses is the repeated-measures analysis of variance because this method takes into account the correlations between measurements taken across time. We used this method and Student's *t*-test for the analysis of data. Comparison of measurements was carried out over the entire hospitalization and follow-up period.

Medications. The analgesic medications were converted to morphine equivalents and were used as a covariate in the group comparisons.

Distribution. The assumption for the repeated-measures analysis is that the underlying distribution of the data is normal. The Kolmogorov's statistic was used to test for the normality of the distribution.

Results

Demographics

All patients were male. Patient age ranged from 20 to 83 years with a mean of 58 years in the laparoscopic group and

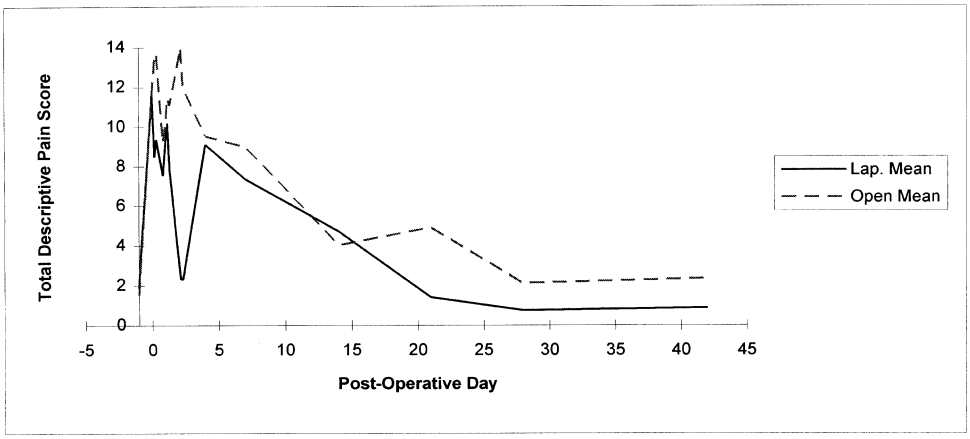

Fig. 1. Graphic analysis of pain as measured over time. The total descriptive pain score is the sum of the affective and sensory descriptor (visual analogue) scores.

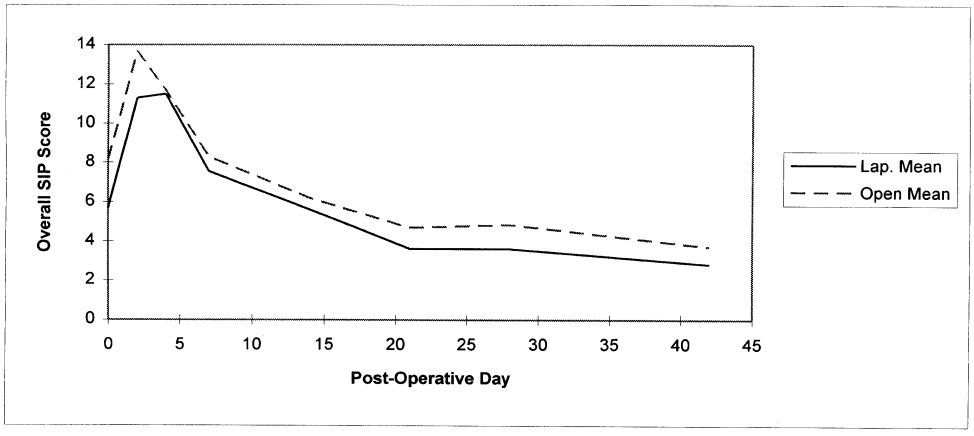

Fig. 2. Graphic analysis of disability (SIP profile) as measured over time.

Table 1. Patient demographics

	Occupation				Race		
	Actively employed	Retired or unemployed	Married	College graduate or higher	Caucasian	Black	Income $30,000 +
Laparoscopic herniorrhaphy patients (n = 24)	13 (57%)	10 (43%)	14 (58%)	4 (17%)	20 (83%)	4 (17%)	2 (9%)
Lichtenstein herniorrhaphy patients (n = 29)	19 (66%)	10 (34%)	14 (48%)	2 (7%)	26 (90%)	3 (10%)	1 (4%)
No response	1		0	1	0		4

a mean of 57 years in the Lichtenstein group. For employment status, race, level of education, income level, and marital status, refer to Table 1.

Operative time

Operative time was 109 min for the laparoscopic herniorrhaphy and 87 min for the open procedure.

Pain assessment

The scores for sensory, affective, and total descriptive pain (Fig. 1) were less but did not reach statistical significance for the laparoscopic herniorrhaphy group during the 1st postoperative week. During hospitalization and after the 1st postoperative week, sensory pain was similar in the two groups. The affective and total descriptive pain score were less for the laparoscopic herniorrhaphy group during the hospitalization also. The pain assessment by the Visual Analog Scale reiterated that, by the middle of the 1st postoperative week, the level of pain experienced by the laparoscopic herniorrhaphy group was less than that by the open group. The average length of hospitalization was 1.7 days for the laparoscopic herniorrhaphy group and 1.8 days for the Lichtenstein herniorrhaphy patients.

Morphine requirements

The averages for total in-house pain medication, converted to mg morphine equivalence, were less for the laparoscopic

herniorrhaphy group (18.5 mg) than for the open group (21.5 mg). This difference, however did not reach statistical significance.

Activity assessment

Measures of physical, psychosocial, and independence activity exhibited a similar temporal pattern (Fig. 2). Although the difference was not statistically significant, the pattern consistently favored the laparoscopic herniorrhaphy group over time.

Outcome

Postoperative follow-up for complications revealed no significant difference between groups. Two patients in each group experienced prolonged groin pain, and one patient in the Lichtenstein group had persistent leg pain. A trocar-site hematoma did require rehospitalization and postoperative discomfort for this patient was increased as a result. Follow-up ranged from 1 to 24 months with a mean of 11 months. Three patients were lost to follow-up. One patient was found to have a 10 × 5 × 5 cm atypical smooth muscle tumor of uncertain malignant potential at laparoscopy. The hernia was repaired laparoscopically and tumor excision was completed laparoscopically as well. Two hernia recurrences occurred after a Lichtenstein repair. In one patient, a direct recurrence adjacent to the pubic tubercle was noted after initial repair of an indirect hernia, and in the second patient, a re-recurrence was found on examination after repair of a recurrent pantaloon hernia.

Discussion

It is essential to rely upon well-defined sampling and statistical methods for the evaluation of any new operation. Unfortunately, accurate assessment of pain and return to normal activity have been problematic in previous studies comparing laparoscopic herniorrhaphy to open herniorrhaphy. The purpose of the SIP profile is to measure a broad base of health-related dysfunction, and for that purpose it serves adequately. In this investigation, assessment tools with test–retest reliability and established validity have been utilized [2].

Postoperative pain is best evaluated over time by repeated measurements correctly oriented to the administration of analgesics. Local anesthesia was given at the time of operation in four of the 53 patients studied (three Lichtenstein, one laparoscopic) and provided no observable effect on the outcome of pain assessment in this study. The limited improvement of pain relief for the laparoscopic group is dissimilar to other comparative studies. Payne, in a prospective randomized investigation comparing the Lichtenstein repair to laparoscopic herniorrhaphy (TAPP), demonstrated a more significant decrease in postoperative pain for laparoscopic herniorrhaphy [10]. Other prospective comparative studies using a variety of open suture approximation repairs demonstrated the same result [3, 8, 12]. Finally, Traverso in a prospective study comparing his own tension-free mesh repair to the TAPP demonstrated less postoperative pain in patients undergoing the open repair [6].

Two hernia recurrences within the Lichtenstein repair were observed. Although interesting, the incidence of recurrence was not of statistical significance. The recurrences may represent surgeon inexperience but faculty supervision was documented for both operations. Suture placement within the pubic periosteum for medial mesh fixation was avoided assiduously as that suture may cause increased postoperative discomfort. Inexperience in placing the suture just above the periosteum was felt to lead to one recurrence. No operation upon the patient with the second hernia recurrence has been done.

Conclusions

This randomized prospective study demonstrates a moderate decrease in pain during the early postoperative period for patients undergoing laparoscopic hernia repair. This, however, did not influence postoperative convalescence as there was no significant difference in postoperative disability between groups. A multicenter comparative study based on valid and reliable assessment measures and in which all commonly used open herniorrhaphy techniques are systematically compared to laparoscopic herniorrhaphy would be of value.

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