Prospective Randomized Comparison of the Shouldice and Lichtenstein Hernia Repair Procedures

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**Objective:** To compare the Lichtenstein, tension-free mesh, and the Shouldice, 4-layer Bassini repair of the inguinal hernia.

**Design:** Prospective randomized clinical trial.

**Setting:** A private suburban hernia center.

**Patients:** Six hundred seventy-two men with inguinal hernias, aged 20 to 90 years, seen at the hernia center between January 1, 1990, and December 31, 1995.

**Interventions:** Slightly modified Shouldice and Lichtenstein repairs were used to repair primary and recurrent inguinal hernias.

**Main Outcome Measures:** Recurrence rates, symptoms (including patient satisfaction), and infections.

**Results:** A total of 717 repairs in 672 patients, including 45 bilateral repairs, have been monitored to date. Recurrence of hernia occurred in 7 Shouldice repairs and 2 mesh repairs. Twelve superficial infections associated with Shouldice and 6 associated with mesh repairs were found.

**Conclusions:** Both types of hernia repair are comparable and effective, but long-term results favor the Lichtenstein technique for reducing recurrences (to a \( P \) value of .10), ease of technical mastery, and application to the outpatient setting by use of a local anesthetic.

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This is the preliminary report of a randomized, prospective comparison of the “Shouldice” 4-layer modified Bassini inguinal hernia repair and the “Lichtenstein” polypropylene tension-free mesh procedure. The null hypothesis for this study was that there is no difference between the 2 repairs in complication rates, recurrence rates, and applicability to the repair of primary and recurrent inguinal hernias in men. Other objectives were to determine whether either technique was easier to apply to the ambulatory outpatient, whether one method was easier to learn and probably teach, and whether the mesh patch is unnecessarily risky, requiring a careful selection criterion.

The Shouldice method was the technique used at the Lansing Hernia Center, Lansing, Mich, for 10 years before the inception of this study. The impressive experience offered by the Shouldice Clinic, Toronto, Ontario, and others in the surgical literature was the motivating factor for this preference. Nevertheless, suggestions from the literature were increasing to adopt a “best practice” approach and reduce unnecessary and expensive variations. These considerations, as well as an increasing number of surgeons in the area switching to the Lichtenstein mesh repair, led to a concern that Peacock was correct in warning surgeons that modern biologically based hernia repair requires the use of a patch. Evidence-based analysis through randomized clinical trials is essential before considering the standardization implicit in practice guidelines.

See Invited Commentary at end of article

Six hundred seventy-two patients were included in the study. Forty-five of the patients underwent bilateral repairs. One side received the Shouldice repair and the other side received the Lichtenstein technique. The method of the first repair was chosen by coin toss randomization. The opposite side received the other repair. Between the single-sided repair and the bilateral repairs, there were a total of 717 repairs. There were 7 early recurrences.
PATIENTS AND METHODS

The Lansing Hernia Center is a solo general surgical practice that specializes in the repair of abdominal hernias of all types. All male patients with inguinal hernias who presented to the Lansing Hernia Center between January 1, 1990, and December 31, 1995, were included in the study. Subjects were between 20 and 90 years of age. All patients were informed of the ongoing study and asked by me to participate in the study. All agreed to do so even when they preferred a particular type of repair. The center being near Toronto was a benefit as most people had heard of the Shouldice Clinic. The Lichtenstein repair was occasionally harder to convince patients about its merits. During the study, 31 patients who had chosen the laparoscopic technique underwent the laparoscopic repair and were excluded from the study. Study subjects were randomized to receive either a modified Shouldice technique or a tension-free repair popularized by Lichtenstein. Randomization was accomplished using the coin toss method. Ninety-nine percent of the follow-up was by the author at 1, 4, and 52 weeks. At the first visit, each person was informed of the repair he was to receive. All patients were examined, underwent surgical repair, and had their recovery monitored by myself. Patients were asked to assign themselves to 1 of 3 categories in an informal work activity survey. The categories were no lifting, some lifting, and heavy lifting. Patients were evaluated 1 week following their operation by an interval history and focused physical examination. They were evaluated again at 1 month and yearly thereafter when possible. Patients were encouraged to return to the center for any problem or concerns by the assurance of lifetime complimentary (without charge) follow-up evaluation and repair of any recurrence that might develop. The follow-up rate was excellent at 1 year but declined at 2 years and beyond. The percentage of patients seen at scheduled follow-up was as follows: 99.9% at 1 week, 99.9% at 1 month, 97.9% at 1 year, 82.4% at 2 years, 67.3% at 3 years, and 64.5% at 4 years. The reputation of the center contributed to patient loyalty according to the patients who returned to the center with recurrences. All study patients were requested to inform me at the Lansing Hernia Center of their decision to submit to surgery by another surgeon or have the surgeon or primary care physician contact the author with evidence of any complications.

OPERATIVE TECHNIQUES

Anesthesia for most of the repair procedures was done under a local field block technique described elsewhere.6 Epidural regional blocks or general anesthetics provided by anesthesiologists were the next most requested anesthesia. Anesthetic choice was based on patient preference and therefore was not randomized. Antibiotics were not used unless the patient expected that they would be given from previous knowledge or experience.

Infections were classified as either superficial or deep. Superficial infections were defined as the presence of swelling and erythema for a portion of the wound length and a minimal amount of purulent material expressed from the wound, eg, a “stitch abscess.” Minimal peri-incisional erythema and folliculitis were not included. A deep infection was present, by definition, if the majority of the wound length was involved or if purulent material could be expressed from the deep suprafascial space requiring formal wound opening and possible removal of the mesh.

The Shouldice procedure was learned from personal observation at the Shouldice Clinic, a book,7 and instructional articles.2 The Lichtenstein procedure was learned from a book,10 instructional videos, and personal communication with Irving L. Lichtenstein, MD. Slight modifications were made in each procedure but the procedures were similar to the described techniques of each clinic. The first Shouldice procedure was popularized by Lichtenstein. Randomization was accomplished using the coin toss method. Ninety-nine percent of the follow-up was by the author at 1, 4, and 52 weeks. No attempt was made to measure the leisure time activity.

The infection rate was too low to be significant, with no deep infections and only 18 superficial infections confirmed. These superficial infections were evenly distributed between the repairs, which was relevant when viewed from the perspective that 3 patients received antibiotics during the study. No wounds were widely opened and no mesh was removed. Nine patients (6 in the Lichtenstein cohort and 3 in the Shouldice cohort) were admitted to the hospital for voiding problems, pain control, and emotional concerns.

The age of the patients was evenly distributed with good match between the 2 arms of the study (Figure). The patients with bilateral repairs were asked which side was the most symptomatic. Discomfort was equally distributed between the 2 repairs.

One patient with a mesh recurrence refused repair for 30 months, at which time a protrusion above the pre-

from the 337 total Shouldice repairs for a 2% incidence, while the mesh repair failed in 2 (0.5%) of 371 procedures. Using the 2-tailed Fisher exact test, P = .10 for early recurrence, statistically rejecting the null hypothesis in favor of the Lichtenstein repair. For early recurrence, at least, the Lichtenstein repair is superior to the Shouldice technique in this study. Four of the recurrences were within 10 months of the date of the repair. Failed repairs from the study were not randomized again; all received the Lichtenstein repair. The average follow-up has been 3 years as of January 1998 (range, 3-8 years). There were slightly more direct hernias that recurred. Five of the 291 direct hernias recurred and 4 of the 426 indirect hernias recurred.

The time from original repair to the diagnosis of recurrence averaged 21.5 months. Five recurrences were in patients receiving a local anesthetic and 3 were in those receiving an epidural block. The numbers seem to parallel the total number of patients in each cohort by percentage.

Because of the small differences in the rate of complications, no conclusions regarding which is the better procedure can be drawn (Table 1).

The informal work activity survey did not correlate with the recurrence rate. Only 3 of the recurrences occurred in the “some lifting” group. It appears that the 2 arms of the study were matched for this work activity evaluation (Table 2).
dice repair done at the beginning of the study in 1990 was technically as close to the last one done at the end of the study in 1995.

In the Lichtenstein modification, no attempt was made to preserve the “false cord,” and the imbrication of the floor of the canal was omitted even in the case of direct hernias. In the Shouldice modification, the repair was done with 000 Prolene (Ethicon) sutures, not stainless steel wire as is the standard at the Shouldice Clinic.

I performed all operations with 1 assistant, usually a certified operating room technician. The procedure consisted of an emphasis on sharp dissection of the fascial layers through an adequate skin incision. The skin was prepared using an iodine-povidone (Betadine) 3-minute scrub and paint unless there was an allergic history to iodine, in which case a septic scrub (Septisol) was substituted. Blood vessels were tied with 000 chromic “catgut” ligatures. Electrocautery was used on 6 hernias that had recurred multiple times. An attempt was made to identify and preserve the ilioinguinal nerve. The iliohypogastric nerve was preserved when identified, although there was no attempt to expose it. The cord was isolated using the standard Penrose drain. Fascial layers were carefully identified, and attached fat was removed when encountered. Preperitoneal fat was separated from the cord structures. The fat was removed with the cremaster muscle in the Shouldice repair and reduced into the inguinal ring with the sack in the case of the Lichtenstein repair. Cord lipomas were handled in a similar manner. Large sacs were transected at the middle of the spermatic cord. There was no attempt to dissect distal sac remnants free from the spermatic cord structures. Peritoneal sacs were ligated in the typical high ligation fashion for the Shouldice technique and inverted without ligation for the Lichtenstein repair. The woven polypropylene patch, Marlex (Bard, Salt Lake City, Utah) and Trilene (Meadox Medical Inc, Oakland, NJ), measured 2.5 × 10 cm. The ends were tucked flat beneath the external oblique muscle above the internal oblique muscle lateral to the internal ring. It covered the transversalis fascia entirely to create an artificial internal inguinal ring of approximately 1 cm. The patch was sewn to the shelving border of the inguinal ligament, the fascia overlying the pubic tubercle, and the surface of the internal abdominal oblique muscle using a running 000 Prolene suture. It was not fashioned or shaped to fit, except when it was notched to encircle the cord and surround the internal ring. The subcutaneous layer, including Scarpa fascia, was approximated using a space-obliterating, running, 3-layer closure of 000 absorbable polyglycolic acid suture (Dexon-Parke Davis, Vicryl-Ethicon). Skin tapers (Steri Strips, 3M, Eagan, Minn) were applied to the skin in an occlusive overlapping manner. The fact that no other external dressing was used allowed the early application of an icebag to the wound. The icebag was usually applied within 10 minutes of the completion of the operation. In an adoption of the Shouldice Clinic technique, the patient and 1 walked arm-in-arm back to the recovery area immediately following the operation.

Following surgery, no limitation of activity was imposed. For many years, such limitations have been known to be unnecessary. The active recovery program of the Shouldice Clinic was described in detail in a 10-minute audiotape that was sent home with all patients. Verbal instructions reduced the number of postoperative telephone calls by alleviating patient concerns about what was normal for the postoperative course of events.

STATISTICAL ANALYSIS

The 2-tailed Fisher exact test was used to test the null hypothesis. The χ² test was not used due to the concerns that the total number of recurrences was low enough that it might make the test invalid. Statistical evaluation was done using SAS software (SAS Institute, Cary, NC).

“Don’t expect a consensus on hernia repair.” These title words lead off the November 1995 issue of the OR Manager. After all these years and thousands of articles, there still is no consensus and no standard way of repairing the inguinal hernia. Should there be? Will the increasing emphasis on outcome studies and cost-effectiveness analysis result in a standard operation in the manner of practice guidelines?

Certainly, the scrutiny being given to the cost and quality debate seems to lead to specific questions of best practice for diagnosis and treatment assumptions. Hernia repair is big business. The number and cost of repairs, in expended resources and work time lost, leave little doubt as to the magnitude. Even now that the procedure has become largely performed in an ambulatory outpatient setting, the numbers are impressive: 700 000 repairs a year and increasing. With so many operations being performed and so many articles on the subject, one might wonder why there is no agreement on which repair gives the best value. While there are
many anecdotal reports expounding on the virtues of an author’s favorite operation, there are relatively few randomized controlled trials comparing the different procedural techniques. There are those who believe that all the current operations work well enough and that the problem is too simple a fix to require in-depth analysis and standardization. If this view is correct, why are we confronted by the embarrassing statistic that 1 in 10 repairs are for recurrent hernias?

Other nations, as well, are finding higher than expected recurrence rates. A little math results in a depressing 70,000 to 80,000 added repairs a year at an estimated cost of $150 million, not counting the cost of the first repair. Who is having all these recurrences? We surgeons are. Who is repairing them? Someone else is—even though we are convinced that since the operation will be offered by surgeons with varying degrees of skill and experience, the comparable patient experience. If an operation is more technically demanding, it is a relative drawback and should be included in the decision-making algorithm when choosing which operation to perform. I hope this study will stimulate large multicenter prospective trials to determine whether the results will be similar in the hands of a number of surgeons and residents, thereby improving the external validity and mitigating the effects of specialization on results. If the findings of this study are supported, the Lichtenstein technique should be the benchmark taught to surgical residents and offered to all male patients as their primary repair.

Statistical analysis was performed by Robert J. Tempelman, PhD, Department of Animal Sciences, Michigan State University, East Lansing. I thank proofreaders Stephen Reis, PhD, Carla Clos, Tom Jarosch, Nancy Edminster, Ruby Graham, and Susan McGillicuddy.

Reprints not available from the author.

REFERENCES

The unique experience of McGillicuddy reflects another advantage of the hernia center concept. By concentrating on hernia repairs as his sole surgical practice, he has been able to collect sufficient patient data for analysis.

We should not be surprised at the low hernia recurrence rate (Shouldice, 2%; Lichtenstein, 0.5%). These results in terms of recurrence reflect the results of reports regularly found in the surgical literature today.3,4

The advantage, as stressed by the author, is the simplicity of the onlay mesh approach. This cannot be denied. The disadvantage relates to the use of prosthetic mesh in all patients. The basic principle of placing a foreign body in every hernia repair without regard to type of hernia, the so-called haberdashery or "one suit fits all" approach, should not be promulgated. As a young surgeon, I was proud to be known as a "McVay man," meaning that I used the Cooper ligament repair for all types of hernias, small or large. In hindsight, I certainly opened the posterior inguinal wall unnecessarily in many patients when a simple closure of the internal ring after high ligation of the hernia sac would have sufficed. The same concern surfaces when we note the suggestion that onlay mesh be used in all patients during primary groin hernia repair. Let us not create a new generation of "haberdashery surgeons," ie, "one suit (repair) fits all."5

As I understand the anterior onlay mesh technique, the mesh rests between the external and internal oblique aponeuroses. One of the several advantages of polypropylene mesh is its ability to create a modest tissue reaction, which has been looked upon as increasing local scar tissue, thus "toughening" the tissues in the repair area. There may be a danger that the propinquity of the ilioinguinal, iliohypogastric, and genitofemoral nerves beneath and adjacent to the inserted mesh will become involved in the above-mentioned inflammatory reaction with subsequent chronic inguinal pain (see author's Table 1). This hypothesis must be explored.

Another concern of onlay mesh relates to the early or late breakdown of the posterior inguinal wall beneath the mesh, which allows omentum or bowel to become trapped between the onlay mesh and that portion of the posterior inguinal wall that remains intact.3 This complication (recurrence) is particularly dangerous because its presence is hidden by the overlying mesh.

The author has reported superb results in the repair of inguinal hernias using onlay prosthetic mesh. He now proposes that this be the primary approach in all patients. In addition, he proposes that surgical residents be taught this operative approach as the primary repair for all male patients. In light of the concerns mentioned above, I cannot support this all-inclusive position for onlay mesh. I will continue to espouse a selective approach wherein the placement of inlay prosthetic mesh always will be a useful consideration, particularly in patients at high risk of subsequent recurrence.

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