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.2,3 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.4 Evidence-based analysis through randomized clinical trials is essential before considering the standardization implicit in practice guidelines.5-7

See Invited Commentary at end of article

RESULTS

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 internal 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. Etiological 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 subfascial 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, and instructional articles. The Lichtenstein procedure was learned from a book, 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 and Lichtenstein repairs were done in 1990, and December 31, 1995, were included in the study.

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). 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-
viable patch was repaired by insertion of a second mesh above the first, with good results to date. The second patient with a mesh recurrence required a single suture to tighten the internal ring to relieve the patient’s symptoms. The mean weight for the patients with 9 recurrent hernias was lower than the average for all patients; the mean weight in the group with recurrences was 70.7 kg and for the whole subject population was 76.0 kg. It is doubtful that weight was a causative factor. Weight has been implicated in recurrences on both sides of the weight spectrum but is yet an unproven risk factor.2 Hematomas were not documented except to state that no wounds were evacuated during the study. Because sliding hernias were repaired in the same manner as nonsliding hernias, no record was kept of the number of sliding hernias. There were no deaths within 1 year of the operation. Hydroceles were evenly divided between the 2 repairs. There were 7 problem hydroceles in the Shouldice cohort and 6 in the Lichtenstein cohort. There were no other factors that approached significance, including length of time the hernia was present and use of a truss. There were 4 femoral hernias repaired during the study period that were not included in the analyses. The study was concluded after 5 years when the number of early recurrences was believed to be 1 sided. Follow-up is ongoing.

“Don’t expect a consensus on hernia repair.” These title words lead off the November 1995 issue of the OR Manager.13 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.14 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.11 If this view is correct, why are we confronted by the embarrassing statistic that 1 in 10 repairs are for recurrent hernias?16 Other nations, as well, are finding higher than expected recurrence rates.17 A little mathematics 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 the ones who are responsibly repairing the patients. Who is having all these recurrences? We surgeons are.

These 2 procedures represent the current point of disension among hernia surgeons in the United States today. Simply stated, the disension is: Does a foreign body (mesh) improve on an adequate anatomic repair without adding to the morbidity? While this preliminary report sets forth only the early recurrences for the procedures, it adds weight to Dr Peacock’s challenge. If long-term follow-up changes the trend of these conclusions, the change will be the subject of another article. The initial assumption that both techniques are applicable to the ambulatory outpatient setting proved to be true. After the 2 techniques were refined by experience, they could be done in approximately the same time and through a similar-sized incision. Of the 2 procedures, the mesh patch repair was easier to learn and perform under a local anesthetic without benefit of relaxation. Coupled with the short-term recurrence advantage, it is not surprising more hernia centers are using prosthetics.18,19 Following the conclusion of the trial, the Lichtenstein repair has been offered exclusively at the Lansing Hernia Center.

We surgeons should not try to select the patients with hernia for mesh repairs who will be “high risk for recurrence” since in this study there were no more problems with the polypropylene mesh than with the sutured repair. Specifically, the infectious risk proved insignificant and allergic manifestations were nonexistent, making polypropylene mesh close to an ideal synthetic material.20 When a repair is simple, relatively inexpensive, and as secure as the Lichtenstein procedure, there is no reason to keep doing procedures the old way. We should not be inventing new techniques that offer no real benefits when those techniques have not been subjected to the scrutiny of objective comparisons.

In a special comment in Hernia,12 Wantz attributes early recurrences to the hernioplasty technique with justification. In anticipation of the concern that early recurrences may be an indication of technical problems and not a result of a fault with the repair, Wantz is convinced that the ease of a procedure is as important as the mechanical advantages offered by the method. I am convinced that since the operation will be offered by surgeons with varying degrees of skill and experience, the more “foolproof” a method the better. The randomization in this report provided that the 2 methods were given 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.

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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.\(^1\,^2\)

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,\(^3\) the so-called haberdashery or “one suit fits all” approach, should not be promulgated.\(^4\)

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 hernia, ie, 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 “haberadashery 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.\(^5\) 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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