

Shouldice Versus Lichtenstein Hernia Repair Techniques: A Prospective Randomized Study

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Abstract

Background: The objectives of this study was to compare the tension-free mesh (Lichtenstein), and the 4-layer tissue repair (Shouldice) techniques of inguinal hernia surgery and to determine to what extent doctors in a general surgical unit were able to reproduce the excellent results reported from specialist hernia centres. **Methods:** Patients with primary unilateral inguinal hernia were over an 18 month period randomized to either the Shouldice group (experiment) or to the Lichtenstein group (control). The operating time, convalescence, hospital stay, postoperative analgesic consumption and complications, were assessed and compared. **Results:** There Lichtenstein group had a shorter operating time but had a higher occurrence of

persistent postoperative pain compared to the Shouldice group. There was no significant difference in convalescence between the two groups and no recurrences have been recorded in either group. **Conclusion:** Despite Shouldice being more challenging to perform compared to Lichtenstein, the postoperative results are comparable. Our experience shows that both procedures can be taught to medical officers who can perform them with relative safety, efficacy and reproducibility to surgeons. Shouldice method being the more cost effective procedure should be encouraged in men with primary unilateral inguinal hernias.

Key Words: Hernia, Lichtenstein, Shouldice, Clinical Trial

Introduction

Inguinal hernia repair is one of the most commonly performed general surgical operations worldwide with a male to female ratio of 12:1 (1-3). In the United States, hernia surgery accounts for nearly 800,000 cases per year (4). During the previous century, both Shouldice and Lichtenstein techniques were popularized, with the former considered by most surgeons as the gold-standard of inguinal hernia repair. However, because of the technological advances, simplicity and acceptable results, the Lichtenstein is currently the most widely practiced procedure. Due to cost implications, some patients may not afford the mesh necessary for the Lichtenstein technique and it is important to know if offering the Shouldice technique is associated with poorer outcomes. This study, carried out in the general surgical unit of the Garissa Provincial General Hospital, aimed to compare the Shouldice to the Lichtenstein technique and to determine to what extent the doctors in the unit were able to reproduce

the excellent results reported from specialist hernia centres.

Methods

A single institution prospective randomized study based at the general surgical unit of the Garissa Provincial General Hospital was conducted over an 18 month period. The hospital ethics committee approved the study. The inclusion criteria was men between 18 and 80 years of age with clinically manifest, unilateral and primary inguinal hernia. Exclusion criteria were irreducibility, femoral hernia, coagulation abnormalities, anticoagulant treatment, and patients for whom anaesthesia was considered unsuitable. Obesity, huge hernias or scrotal hernias did not disqualify from participation. Verbal and written consent was obtained from each patient. Fifty cards were divided into two groups; in one group each card was marked 'Shouldice', whereas in the other 'Lichtenstein'. All cards were placed in similar opaque envelopes. Recruitment of patients

was done by two doctors who did not operate on the patients. After confirming the diagnosis and eligibility, they picked an envelope thereby randomly assigning a repair procedure. The designated repair technique was revealed to the operating doctor just before skin incision by opening the patient's sealed envelope.

In a pretrial training programme the two participating doctors (one general surgeon and one medical officer) were taught to perform both methods in a standard manner. When they were thoroughly familiar with the techniques, the study commenced. Surgery was performed under spinal or general anaesthesia in accordance with the patient's preference or anaesthetist's opinion. Both the Shouldice repair and the Lichtenstein repair were performed as described by European Hernia Society guidelines (5). Prophylactic antibiotics were not used. Postoperatively, there were no restrictions to any activities. Patients were encouraged to ambulate as soon as they were comfortable enough to do so. We routinely prescribed analgesics (diclofenac 50mg tid for three days) to all patients. Sick leave was prescribed routinely for no more than two weeks initially and extended for one week at a time when indicated. Wounds were exposed after 24 hours and thereafter left open.

Variables recorded included age, testicle size on side of operation, type of hernia (direct, indirect, combined and sliding), type of anaesthesia, duration of operation, duration of hospitalisation. The operation time was defined as the time from the skin incision to the placement of the last suture during wound closure. Operations lasting 70 min or more were considered prolonged and indicative of technical difficulty. Postoperative pain was documented at 24 hours postoperatively and if present the patient's analgesia was supplemented with tramadol 100mg bid for 3 days. We collected information on postoperative complications including wound infection, seroma, haematoma and urinary retention. Infections were classified as either superficial or deep. Superficial infections were defined as presence of swelling and erythema for a portion of the wound length and a minimal amount of purulent material expressed from the wound, e.g., a 'suture abscess'. A deep infection was present if 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 if present.

Follow-up evaluation was performed by physical examination and personal interview; done by the two recruiting doctors. This was done at twenty four hours postoperatively, after two weeks, three

months and yearly for two years. Patients were encouraged to return to the hospital, at any time, for any problem or concerns; and their files marked for review by any of the 8 doctors in the general surgical unit. A follow up over the phone interview was performed if a patient could not access the hospital at the designated time of review. At twenty four hours after operation, the patients were asked about persisting pain and their ambulatory status was determined as either ambulant (walking un-aided) or not ambulant (walking aided). At the two week follow up patients were asked about persisting pain, use of supplemental tramadol, usage of analgesics beyond 1 week and number of days taken to return to daily activities (RTDA). At the three month follow up patients with persisting discomfort or incomplete recovery were examined clinically. Recovery was defined as incomplete when discomfort in the operated groin interfered with normal activities. Recurrence was defined as a clinically manifest bulge or a protrusion exacerbated by the valsava maneuver in the groin. Data was recorded and transferred to a prospective database for analysis every six months for two years.

Statistical analysis were performed using Microsoft excel and SPSS (SPSS, Chicago, Illinois, USA). For the analysis of differences between two groups we used a 2-tailed student's t-test where appropriate and the p value of <0.05 was considered significant.

Results

Of the fifty patients randomized, five did not show up for surgery. The two groups were similar in terms of patient age and types of hernia (Table 1). All surgeries were conducted under spinal anaesthesia. There was significant difference in the operation times between the Lichtenstein (median time 40 min) and the Shouldice (median time 60 min) methods (p=0.0001) (Table 2). More technically difficult operations were encountered in the Shouldice group (7 of 22 operations) as compared to the 3 of 23 Lichtenstein operations.

Table 1: Types of hernia and age variation between the two groups

		Shouldice (n=22)	Lichtenstein (n=23)
Types of hernia	Direct	3	5
	Indirect	18	17
	Combined	1	1
	All types	22	23
Age (years)	Median (range) ⁺	63.5 (25-76)	60 (22-80)

⁺values are median (range).

Table 2: Perioperative data for hernia repair

	Shouldice (n=22)	Lichtenstein (n=23)	p value
Operating time (min) ⁺	60 (40-90)	40 (30-80)	0.0001
No. of technically difficult operations (%)	7 (31.8)	2 (8.7)	-
No. of patients ambulant at 24 hours	22	23	-
Hospital stay (hours) [*]	34.4 ± 12.99	33.9 ± 11.81	0.802

*Values are mean (standard deviation). ⁺values are median (range)

Only ten patients underwent a telephone interview due to logistical hindrances in attending a clinic review. There were no major complications related to the operation and no reoperations. One patient complained of urinary retention which prolonged his hospital stay. No other postoperative complication was noted. Majority of the patients were ambulant twenty four hours after the operation and were allowed home at that point (Table 2). There was no significant difference in the number of days taken to return to daily activities (RTDA) between the two

groups (p=0.89) (Table 3). There was no significant difference in postoperative pain between the two groups. One patient had persistent chronic pain after Lichtenstein repair. This was classified as neuralgia on account of its radiation along the inguinal nerve. Persistent discomfort, if any, was considered mild by all patients. There were no recurrences in both groups. There was no correlation between skill level of operating doctor and the duration of the operation or patient outcomes (Table 4).

Table 3: Postoperative data for hernia repair

		Shouldice (n=22)	Lichtenstein (n=23)	p value
Postoperative complications (%)	Urinary retention	0	1 (4.3)	-
Postoperative pain (%)	24 hours	3 (13.6)	4 (17.4)	-
	2 weeks	1 (4.5)	3 (13)	-
	3 months	0	1 (4.3)	-
Convalescence	No. of days taken to RTDA ⁺	4 (3-7)	4 (3-7)	0.86

⁺values are median (range)

Table 4: Perioperative data per skill level of operating doctor

		Shouldice (n=22)		p value	Lichtenstein (n=23)		p value
		Surgeon (n=10)	Medical Officer (n=12)		Surgeon (n=10)	Medical Officer (n=13)	
Operating time (min) ⁺		60 (40-90)	60 (55-75)	0.914	40 (35-45)	40 (30-80)	0.383
No. of technically difficult operations		3	4		0	2	
Postoperative complications	Urinary retention	0	0		0	1	
Postoperative complications	24 hours	1	2		1	3	
	2 weeks	1	0		0	3	

⁺values are median (range)

Discussion

This study has shown that hernia surgery can be conducted with a low rate of complications. Failure of inguinal hernia repair leads to increased patient discomfort, re-operations and may result in a considerable economic burden (6).

Our study showed that the Lichtenstein technique took a shorter time, reflecting the ease of the operation is also reported by Hetzer et al, (7). This is contradicted by Danielsson who reports no significant difference in duration of operation between Lichtenstein and Shouldice methods performed by surgeons in training (8). In our experience despite the Shouldice technique requiring considerable time to learn and taking longer to perform; performing either method carefully results in similar convalescence period and complications. This was relatively similar to what Barth et al found; however all of our patients took a median of 4 days to return to daily activities as compared to 9 days (9). Chronic pain has been associated with the use of mesh; also evidenced in our study as both persistent postoperative pain and chronic pain was found more commonly in the Lichtenstein group (10,11).

We report no recurrences in both procedures. Amato et al, in the Cochrane review of randomized and quasi-randomized clinical trials report a significantly higher recurrence rate with Shouldice technique than mesh techniques (12). In contrast, specialist hernia centers report no significant difference in recurrence rate between the two methods; with the Lichtenstein institute reporting 0.1 per cent compared to less than 1 per cent observed in the Shouldice hospital (13, 14). These reported results have been excellent which might be at least partly because all operations were done by experts (15). We report that excellent results can be achieved in non-specialist centers and attribute our results to the pretrial training programme that ensured that the operating doctors had acceptable proficiency at performing both procedures.

Wilkiemeyer et al found a significant difference in both operation time and recurrence rates between junior surgical residents and senior surgical residents performing open inguinal hernia repair (16). In our study, there was no significant difference in skill level of operating doctor and length of operation. Furthermore, there was no significant difference in complication rates between the patients operated by the different operating doctors. We assert that medical officers can be trained to perform safe inguinal hernia surgery.

In the face of at least equivalent and possibly better repair results with the Shouldice technique, cost of the procedure itself must be examined in this time

of fiscal responsibility (17). It's very economical cost structure makes it one of the commonest methods of hernia repair; in most parts of the developing world and even in Canada, Shouldice repair accounts for 25% of all inguinal hernia repair (18). The extra cost of buying a polypropylene mesh (Prolene, Ethicon, Belgium) is borne by the patient. Indeed, many authors have questioned routine use of the more expensive modalities (19-21).

Conclusion

Despite the Shouldice repair having longer operation times, the postoperative outcomes are comparable to Lichtenstein repair. Both procedures can be taught to medical officers in rural hospitals who can perform them with relative safety, efficacy and reproducibility to surgeons. Being a more cost-effective method, the Shouldice technique should be encouraged in men with primary unilateral inguinal hernia.

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