

Tension-free inguinal hernia repair comparing shouldice repair with mesh plug repair: A prospective randomized controlled clinical trial

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Abstract

Tension-free inguinal hernioplasty is sine-qua-non for a good hernia repair and is aptly fulfilled by both mesh plug repair and a correctly done Shouldice repair. To clarify the effectiveness of Shouldice repair in comparison with mesh plug repair for inguinal hernia. A randomized, bias-free study was conducted on 120 patients with blinding adopted during the computation of results. All 120 patients underwent 120 repairs after being randomized into 2 groups. Sixty repairs were done with plug mesh secured with 2-0 prolene sutures, while the other 60 patients underwent Shouldice repair using 1-0 prolene sutures. Duration of surgery and ergonomics were noted for each case. The operative time was comparable (mean of 38 min for the Shouldice group and 36 min for the mesh group), ($P > 0.5$; insignificant). Postoperative complications were minimal in both series. Both groups recorded no recurrences till date. However, Shouldice scored better than mesh when cost of the mesh and Shouldice sutures were compared, other factors being similar. Mesh repair is definitely the more popular version of the two but in countries where cost factors still play a part and prevent many from seeking early treatment, a well constructed Shouldice is an equally effective and less costly treatment option for inguinal hernias.

Key words: Inguinal hernias, plug mesh repair, shouldice repair

Introduction

Ambulatory surgery for hernia has become the need of the hour. Since the mid 1980s there has been an increase in the use of prosthetic mesh in surgery for hernia. Rutkow[1] had predicted that out of 7,50,00 hernia operations performed in the US in 1998, almost 80% would involve the use of mesh prosthesis. The tissue-based groin herniorrhaphy techniques create tension on the suture line, are difficult repairs to perform, and are associated with greater number of complications. Also, the level of patient discomfort and disability is higher coupled with prolonged convalescence. The failure rate for the repair of primary groin hernia using the patient's own tissues is unacceptably high, approaching 15%, with an even higher percentage for the repair of recurrent hernia. [2]

Usher [3] was the first to report the use of prosthetic polypropylene mesh in the repair of inguinal and incisional

hernia. Lichtenstein^[4] began using a rolled or cylindrical or cigarette mesh plug for treatment of femoral and recurrent inguinal hernia and reported its efficacy in 1974. Gilbert^[5] in the late 1980s improved upon the Lichtenstein device by fashioning a flat piece of mesh into a cone or umbrella. Learning of his success with this technique, Rutkow and Robbins^[6] began using hand-fashioned umbrella plugs in 1989. By the end of 1991 they were using mesh plugs to treat all types of inguinal hernia^[7]. Since 1993 they have started using pre-manufactured umbrella 'Marlex mesh' and found it simpler to use than a hand-fashioned plug. In 2400 mesh plug repairs, they have reported a recurrence rate of less than 1% in primary hernia and 2% for recurrent hernia^[8]. Fisher et al^[9] in their phase II evaluation of the Marlex plug in an unselected cohort of 72 patients of groin hernia in 1997-98, found the results comparable to or even better than those after laparoscopic and Shouldice repair (SR) respectively.

SR is considered the current golden standard for herniorrhaphy with a recurrence rate of 0.2%. However, the results are not always reproducible in non-specialist centers. The tension created in the repair accounts for a prolonged period of postoperative pain and abstinence from normal activities and work for at least 6-8 weeks. The mesh plug repair (MPR) is a tension-free repair adaptable to any groin hernia, including recurrent hernia. It offers excellent patient comfort and satisfaction, a short hospital stay, rapid rehabilitation and lower complication and recurrence rates.

Inguinal hernia repair, which accounts for 10-15% of all surgical procedures^[10], is doomed to failure unless rendered free of tension. Both mesh plug repair and Shouldice repair adopt the finer tricks of the trade, which include adequate dissection, perfect suture material selection and a meticulously performed tension-free repair.^[11]

The two techniques were compared with respect to operative time taken, postoperative complications, recurrence rates and cost-benefit factors.

Patients and Methods

This study was carried out in Al-Kadymia Teaching Hospital, Baghdad, from the period of January 2002 to January 2006. A total of 120 patients presenting with unilateral, nonobstructive & reducible inguinal hernias were randomized into 2 groups of 60 each. 100 of them were primary hernias and 20 cases were recurrent hernias.

All patients who had bilateral inguinal hernias or presented with complications of inguinal hernia, i.e., obstruction, strangulation etc., were excluded from the study. All patients had to have their clinical chemistry parameters like routine blood, blood sugar, serum urea /creatinine, chest X-ray, ECG and vitals checked and

within normal limits to get clearance for surgery.

The repair procedures were explained to all patients and duly signed, informed consent was obtained from them. All patients received a single dose of cefuroxime 1000 mg at the induction of anaesthesia. A skin crease approach following Langer's line was adopted in all cases. The incision was deepened, tackling subcutaneous neuro-vascular structures as usual till the external oblique aponeurosis was reached. The resulting slit was about an inch above the inguinal ligament, which provided a large lower leaf for optimal closure. A gentle sweeping action with the index finger under the aponeurosis helps to open this plane widely for an adequate repair or mesh insertion.

The cremasteric fascia was always incised which helped mobilize the cord structures properly. A direct sac was always pushed back and the fascia transversalis repaired with 2-0 loosely wound continuous prolene sutures in mesh group. An indirect sac on the other hand was opened, ligated and transected at its neck. In the "mesh" group, hand fashioned mesh plug, made from a 7.5x7.5 piece of the mesh, was inserted tapered end first into the internal ring and pushed beneath its crurae. The plug was kept in place by inserting 4-6 interrupted 2/0 prolene sutures through the outer margins of the plug and the crurae. These are not strength sutures but only holding sutures to keep the plug in position, and any crural tissue, even if flimsy suffices.

All indirect and direct mesh plug repairs are further reinforced by a second piece of flat mesh 9 cm x 6 cm. The onlay patch is placed by a sutureless technique on the anterior surface of the posterior wall of the canal from the pubic tubercle to well above and lateral to the internal ring. The lateral portion of the pre-shaped onlay patch was split to allow the passage of the cord. The split was sutured on itself to provide an opening for the cord while functioning as a

pseudo internal ring. The onlay patch is not an integral part of the repair but is intended solely to strengthen the direct space, thus serving as prophylaxis against future direct herniation by creating further tissue growth in the remaining part of the wall. In case of direct hernia the patch shall prevent any future indirect herniation.

In shouldice group, a four-layer tissue reconstruction using two separate sutures. A continuous technique distributes the strength of the repair evenly and should be without tension. A relaxing incision is rarely required. The first two layers represent an overlapped reconstruction. It begins medially, anchoring over the pubic tubercle, leaving a sufficient end to tie the returning suture after the second layer. The infero-lateral flap of transversalis fascia is sutured to the lateral edge of the rectus sheath by reaching underneath the superior-medial flap. The reconstruction then moves laterally to the aponeurosis of the transversus abdominis and the edge of the internal oblique muscle.

The lateral extent of this layer redefines the internal ring and should include the superior stump of the divided lateral flap of cremasteric muscle. This buttresses the internal ring and helps prevent an indirect recurrence. The suturing is then reversed to begin the second layer. The superior flap of transversalis fascia is sutured to the shelving portion of the inguinal ligament then tied at the pubic tubercle. The periosteum should not be included in any bite as this can result in a painful osteitis.

The next stage of reconstruction creates a two-layered imbrication to provide reinforcement. The layer is begun superior and slightly lateral to deep ring, anchoring the suture to the internal oblique fascia. The inferior flap of the external oblique, millimeters above and parallel to the inguinal ligament, is tacked to the edge of the internal oblique and transversus muscles. In addition, only a small bite of the internal oblique is required, no more than

5 mm. excessively large bites will create tension. At the pubic tubercle, the direction is reversed for the fourth layer and taken back to the internal ring and affixed.

The importance of mobilizing the inferior flap of external oblique by previously incising the superficial thigh fascia is realized here. The additional mobility allows the external oblique to be used in the third and fourth layers to cover the medial portion of the repair that is susceptible to recurrence. The inguinal canal is reconstructed by re-approximating the remaining external oblique fascia, returning the cord to its anatomical position. The inferior stump of the medial flap of cremasteric muscle is included in the first suture medially to stabilize the position of the testes to the abdominal wall and prevent drooping.

In both the groups, having checked for haemostasis meticulously and after replacing the safeguarded iliohypogastric nerve and the cord structures, the external oblique aponeurosis was closed with 2-0 continuous prolene sutures. The skin was apposed using 3-0 simple interrupted mersilk sutures. Operative time taken from skin incision to skin closure was recorded in all cases of both groups. Patients of both groups were routinely given oral analgesics, which they were advised to continue for 72 h into the postoperative period. All patients were observed for 4-6 hours and were discharged only when they emptied their bladders and felt comfortable and confident with themselves. Only a few had to be detained overnight.

The emergency communication protocol was explained to all patients and necessary advice given to all on discharge. The first reviews on the patients of both groups were carried out on the 7th postoperative day. Detailed records were kept concerning their pain profile, return to normal activities and early postoperative complications in the form of superficial surgical site infections, wound gape, scrotal

indurations, testicular atrophy, neuralgia, mesh/darn infection requiring withdrawal and recurrence. Stitches were removed on the 7th post-operative day for all save those who experienced early wound complications. Patients were followed up at 1, 3, 6, 9, 12 and 18 months postoperatively and evaluated for any residual complications and recurrences.

Results

All patients in the study were males. Only unilateral cases were taken up for the study. There were 60 patients in each group, details of whom are tabulated in [Table - 1]. The duration of surgery from incision to closure for the 'mesh' series ranged from 30-40 min (mean 36.25 min), while that for the 'shouldice' series ranged from 35-50 mins (mean 38.00 min), The difference in operative time between the two groups was statistically insignificant ($P = 0.596$, i.e., >0.05).

The postoperative courses for both groups were largely uneventful and were followed up meticulously. For ease of presentation, the postoperative course of both series is tabulated in [Table - 2]. It may note that the differences in the postoperative events between the two groups as shown in [Table - 2] were statistically insignificant. Seven patients in the 'mesh' group and 4 patients in the 'shouldice' group suffered some form of minor surgical site infection, but none of the patients need removal of the mesh or packing of the wound. Major complications and recurrences were not recorded till date in any of the 120 patients [Table - 3].

All patients in our series were regularly followed-up 1, 3, 6, 9, 12 and 18 months postoperatively. Follow-up records dealt mainly with any residual complications and recurrences. Some of the patients have been lost in follow-up and excluded from the study. Median follow-up in each group was 38 months (24-58 months).

The suture material cost per patient in the Shouldice group was less expensive in comparison to mesh cost per patient in mesh group. Keeping all other expenditures constant, the cost-effectiveness of the shouldice technique over the mesh is evident.

Discussion:-

In the present study of MPR, a hand-fashioned polypropylene plug was inserted into the hernia defect and was kept in position by multiple interrupted sutures. An onlay patch further reinforced the repair by sutureless technique, placing the patch on the anterior surface of the posterior wall of the inguinal canal. While comparing the results of MPR with those of SR, it was observed that MPR took on an average 30-40 minutes, whereas SR took 35-50 minutes (statistically not significant). Complication rates in both groups were very minimal. In no case was there any need to remove the mesh. The average hospital stay was nearly similar in both groups. Postoperative pain and discomfort, Ambulation and return to work were comparable in both groups. In a short follow-up of (24-58) months no recurrence was observed in either group.

There were no major differences in the postoperative complications recorded between the two groups we studied. Only 12% of our mesh group recorded superficial surgical site infections in comparison with 6% in the shouldice group. Scrotal indurations recorded were 5% for both groups. Koukourou^[12] had recorded no differences in early or late complications. Qazi *et al*^[13] similarly recorded a postoperative infection incidence of 12% with shouldice and 8% with mesh repair. They however noted 6% scrotal hematomas in their shouldice repair group and 2% in their mesh group in contrast to our series, which recorded none. No case of nerve entrapment neuralgia was observed in our study.

There were no recurrences noted till date in any of the two groups under study. Our findings compare well with 0.8% recurrence rates of Moloney in 1958 and Abrahamson in 1997. More recently, Omer Farooq^[14] in 2005 reported 0.6% recurrence rates with shouldice repair. Mills^[15] in 1998 similarly recorded no recurrences with mesh repair.

Koukourou^[12] in 2001 compared the darn repair with mesh and reported no differences in early or late complications and achieved comparable recurrence rates. Operative time recorded in our trial was not only comparable but also better than other series'. Nashimura et al,^[16] while comparing the MPR technique for adult inguinal hernia with conventional sutured repairs, concluded that MPR for adult inguinal hernia is a useful operative procedure with a shorter operating time, less postoperative wound pain and almost the same recurrence rate as seen in conventional repairs. They also proved that there is no significant difference in the postoperative white cell count and the CRP between patients with conventional sutured repairs and MPR.

In Robbin and Rutkow's[8] experience of treating more than 6000 patients of hernia and more than a decade of experience with the mesh plug, it was observed that the use of MPR under ultra short-acting epidural anaesthesia, essentially eliminated postoperative urinary retention. They did not observe any correlation of pain and numbness with the preservation or sacrifice of ilioinguinal and genitofemoral nerves. They recommend several months of conservative treatment for all cases of ilioinguinal and genitofemoral neuralgia following groin hernia surgery. None of their patients required repeat surgery for this condition. They have opined that it is the tension-producing repair, not the rare entrapment of a nerve, which is the cause of pain.

Dieudonne,^[17] in a recent publication on plug repair of groin hernias has published results of 3332 plugs inserted in groin hernias. On a ten-year follow-up there was a 1.4% recurrence rate. They used only plugs and no onlay patches. They observed no significant difference in chronic postoperative pain between prosthetic and Shouldice surgery. The risk of plug shrinkage and migration appears to be exceptional and rather minor considering the thousands of operations performed. In their Shouldice surgery, pain was attributed to the use of steel treads in the repair. In present study prolene sutures was used instead of stainless steel wire. Some surgeons do not routinely open the hernia sac for manual or visual inspection. In all reducible hernias it is best that the unopened sac be placed back into the abdominal cavity, the inverted hernia sac involutes in a few days without any problems. Ligation of the sac at its neck, a routine practice till recently, produces a miniature peritonitis contributing to postoperative discomfort and malaise.

The mesh plug repair does not require expensive and technologically advanced equipment. It is also among the easiest of hernia repairs for the average surgeon to learn and has a minimal learning curve. The technique concurs with the present growing advocacy of surgical minimalism. On the other hand, SR is difficult to perform in obese patients and in those with thin and stretched fascia transversals. It is not an easy technique to learn as confirmed by the practice at the Shouldice Clinic, where 100 operations need to be done by the staff as assistants before embarking on their own.

The cost effective aspect of the shouldice (direct benefits), places it at a more favorable position than mesh because the majority of inguinal hernia patients from the lower socio-economic. [18].

As a conclusion, Mesh repair for inguinal hernia is definitely the more popular version of the two but a well-constructed shouldice is equally effective and on the whole, a much less costly treatment option for inguinal hernias. We expect the young surgeons of our generation to appreciate the intricacies underlying a well-constructed shouldice or a well-placed mesh and tailor their treatment options likewise, making it both patient-friendly and cost effective. A mean 38 month follow-up period may not be adequate. A long-term study is desirable and is in progress to judge the efficacy of both the shouldice and mesh repair techniques in terms of recurrence and cost effectiveness.

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Table (1): Baseline characteristics of patients in the two groups

Clinical details	Mesh group	Shouldice group
Median age (age range)	38(18-70)	40(18-76)
Hernia types:-		
Direct : Indirect	50:10	34:26
Right : Left	49:11	30:30
Manual labourers	55	60
Sedentary worker	5	0

Table(2) Postoperative course of patients in the two groups

Postoperative course	Mesh group	Shouldice group
Discharge on 1 st day:2 nd day	55:5	50:5
Average duration of pain	2 days	2 days
Return to baseline activity	5 days	6 days
Return to heavy manual work	28 days	22 days

Table(3) Postoperative complications in the two groups

Complications	Mesh group	Shouldice group
Superficial wound infection	7(12%)	4(6%)
Deep wound infection	0	0
Retention of urine	3(5%)	6(10%)
Neuralgia	0	0
Scrotal indurations	4(6%)	4(6%)
Testicular atrophy	0	0
Recurrence	0	0