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A PROSPECTIVE RANDOMIZED STUDY OF TENSION-FREE HERNIORRHAPHY (MODIFIED SHOULDICE REPAIR) VERSUS TENSION-FREE HERNIOPLASTY (LICHTENSTEIN REPAIR) IN PRIMARY INGUINAL HERNIA

By

Ossama A. Baza, M.D.; Gamal I. Moussa, M. D.; Sherif A. Mostafa, M.D.; Tamer A. Ibrahim and Nagla L. Dabees, M.D.*

Department of General Surgery and Department of Radiology*, Faculty of Medicine, Tanta University

Objective: *Ideal technique for effective inguinal hernia repair is still controversial.*

Patients and methods: *The presented study was conducted on 80 male patients with uncomplicated unilateral primary inguinal hernia. The patients were randomly selected either for modified Shouldice repair (36 patients) or Liechtenstein repairs (44 patients). Patients were followed postoperatively for 2 years.*

Results: *The mean age of the patients was 34.4 years for Shouldice group and 32.7 for Lichtenstein group. The mean operative time was 74 minutes for modified Shouldice repair and 56 minutes for Lichtenstein repair. No intra-operative complications occurred in patients of both groups. Postoperatively, in the Shouldice group, 18 patients (50%) reported slight pain, 12 (33.3%) reported moderate pain and 6 (17.7%) reported severe pain, while in the Liechtenstein group, 11 patients (25%) reported no pain, 20 patients (45.6%) reported slight pain and 13 (29.4%) reported moderate pain. The patients of Lichtenstein group required postoperative analgesia less than patients of Shouldice group. The mean hospital stay was 4 days for Shouldice group and 2 days for Lichtenstein group. The mean time of return to unrestricted physical activities was 16 days in Shouldice group and 12 days in the Lichtenstein group. Early postoperative complications were, inguinal seroma reported in one patient (2.8%) of the Shouldice group and in 3 patients (6.9%) of the Lichtenstein group and superficial wound infection in 2 patients (5.6%) of Shouldice group and in one patient (2.3%) of Lichtenstein group. During the period of follow-up, pain at the surgical site was reported in 6 patients (16.7%) of Shouldice group and in 12 patients (27.3%) of Lichtenstein group, feeling of a foreign body in the groin was reported in 16 patients (36.4%) of Lichtenstein group. There was no statistically significant difference between pre- and postoperative spermogram and Doppler flow parameters for both groups.*

Conclusion: *Both techniques are largely equivalent with advantage for the mesh repair because of easier performance, shorter operative time and rapid return to full physical activities.*

INTRODUCTION

Hernias occupy a good deal of surgical time and account for about 10-15% of all surgical procedures. The majority of operations (80%) are performed for inguinal hernia [1]. Whereas hernia specialists report recurrence rates of 1-5% for primary inguinal hernias, those from non-specialist centers are in the region of 5-20% with early recurrence developing within the first 2 years after the initial operation [2].

Over a century since Bassini herniorrhaphy in 1884, all repairs, regardless of the modifications, have shared one common disadvantage, suture line tension, which is the main cause of recurrence after inguinal hernia repair due to the approximation of normally unopposed tissues. This tension created leading to ischemic pressure necrosis and suture line or tissue disruption. [3,4]

The Shouldice tissue repair for groin hernias, a tested and proven procedure, continues to provide great patient

satisfaction, but in those patients where the fascia transversalis was found attenuated or scarred and has minimal flexibility, mesh must be employed [5] Postoperative pain and recurrences depend on many factors, but induced intraoperative tension can be excluded. So, the Shouldice repair can therefore continue to be used as a routine technique in uncomplicated primary inguinal hernia repair [6]

Collagen from the rectus sheath of hernia patients was abnormal in ultrastructural features as examined by electron microscope and in its physiochemical properties. [7] If abnormal tissue is included in the repair or if the basic metabolic abnormality continues in the tissue used for reconstruction, recurrence is inevitable. [8] The end result of collagen metabolism disorder process is a deficiency of dense connective tissue that argues strongly for the addition of a suitable synthetic substitute [9].

Tension–free hernioplasty for primary inguinal hernia is a concept that permits hernia repair with a prosthetic screen providing permanent reinforcement without distortion of normal anatomy, without any suture line tension, with an ambulatory same–day environment, prompt return to unrestricted activity and a recurrence rate approaching zero[10]. Although the use of laparoscopic techniques for bilateral or recurrent hernias is now accepted, the application of laparoscopy to unilateral primary inguinal hernias remains controversial. Ongoing studies will address the questions of long-term recurrence and cost-effectiveness of laparoscopic hernia repair [11]. In this study, we are aiming to answer the question is there still a place for endogenous tissue repair?

PATIENTS AND METHODS

This study was conducted on 80 male patients with uncomplicated unilateral primary inguinal hernia admitted to the Department of General Surgery, Gastroenterology unit, Tanta University Hospitals.

All the patients were subjected to, full history taking, thorough clinical examination, routine laboratory investigations, x-ray chest and abdominal ultrasonography.

Testicular function has been evaluated preoperatively with spermogram and testicular perfusion with color Doppler ultrasonography.

Operative Techniques: The patients were randomly selected either for modified Shouldice repair (endogenous tension-free tissue repair) or Lichtenstein repairs (exogenous tension-free tissue repair).

Modified Shouldice Repair:

The fascia transversalis was divided along the line of the inguinal canal starting laterally at the internal ring to the pubic bone.

The first suture line picked up the free edge of lateral flap of fascia transversalis and was carried upwards and medially deep to the medial flap. Medially it was fixed to the lateral edge of the rectus abdominis and more laterally to the undersurface of the internal oblique, transversus abdominis and fascia transversalis using interrupted `O` polypropylene stitch (Fig.1).

The second suture line picked up the free edge of the medial flap, overlapping the first suture line, to be fixed to the deep surface of the shelving edge of inguinal ligament with interrupted stitches (Fig.2).

The third suture line approximated the medical flap to the shelving edge of the inguinal ligament, slightly superficial and parallel to the second line and reinforcing it (Fig.3).

Multiple small vertical release incisions (each was 5 millimeters in length) were made in the anterior rectus sheath to relief the tension on the suture lines (Fig.4).

Liechtenstein repair:

The surgical technique as described by Liechtenstein in 1989 [3], was adopted in patients belonging to this group (Fig.5 and 6).

Postoperative management and follow-up:

For each patient the following data were obtained: operative details, operative time, intra-operative complications, type and amount of postoperative analgesics used, time to ambulate, hospital stay, time to return to routine daily activities, return to unrestricted physical activities and postoperative complications.

Postoperatively, every patient received routinely an ampoule of diclofenac sodium I.M. (Olfen®, mepha, Egypt).

To assess postoperative pain, the patient completed a visual analogue pain score in the first postoperative 24 hours, after explanation by an independent assessor who was unaware of the procedure performed. (mild pain with score from 1-3, moderate from 4-7 and sever pain above 7).

Patients were examined postoperatively in the outpatient clinic at 1,3,6 months, 1 and 2 years. Spermogram and testicular perfusion with color Doppler ultrasonography were done 6 months postoperatively.

Statistical analysis:

The collected data were organized, tabulated and

statistically analyzed using SPSS® software statistical computer package version 10. For quantitative data, the mean and standard deviation were calculated. The difference between two means was statistically analyzed using the student-t test. For qualitative data, statistical analysis was done using Fisher exact test. For qualitative data with multiple parameters, Chi square was used. The 5% level of significance was adopted for interpretation of results of tests of significance.

RESULTS

The present study was conducted on 80 male patients with uncomplicated unilateral primary inguinal hernia. The type of repair was randomly selected either modified Shouldice repair (36 patients) or Lichtenstein repair (44 patients). Four patients, with direct inguinal hernia randomized for Shouldice repair were excluded from this group because of marked attenuation of the fascia transversalis that the underlying extraperitoneal fat was visible, they underwent Lichtenstein repair.

The age of the patients ranged between 18-62 years with a mean age of 34.4 years for Shouldice group and 32.7 for Lichtenstein group. Forty patients were manual workers, 24 sedentary work, 8 students, 4 retired and 4 solders. Thirty-six patients were heavy cigarette smokers, 14 light smokers, 9 water pipe smokers and 21 patients were non-smokers. Fifty-eight patients (72.5%) presented with indirect inguinal hernia, 16 patients (20%) with direct inguinal hernia and 6 patients (7.5%) with pantaloon hernia. There was no statistical significant difference ($p>0.05$) between two groups as regard to the age of the patients, the type of work, the degree of smoking and the type of the hernia.

The operative time: The time for modified Shouldice repair ranged from 60 to 90 minutes (a mean of 74 minutes & SD:+8.6) and that for Lichtenstein repair ranged from 50 to 70 minutes (a mean of 56 minutes & SD:+5). There was a significant difference ($p<0.05$) in the operating time between both groups. No intra-operative complications occurred in all patients included in this study.

Postoperative pain: - Postoperatively, every patient received routinely an ampoule of diclofenac sodium I.M. (Olfen®, mepha, Egypt) and patients were questioned about the degree of postoperative pain they experienced during the first postoperative 24 hours as documented with the visual analogue pain scale. In the Shouldice group, 18 patients (50%) reported mild pain, 12 patients (33.3%) reported moderate pain and 6 patients (16.7%) severe pain. In the Lichtenstein group, 11patients (25%) reported no pain, 20 (45.6%) mild pain and 13 (29.4%) moderate pain, The difference in pain in the postoperative period in both groups was statistically significant ($p<0.05$) . In comparing patients in both groups, as regard the amount of postoperative analgesia required, it was found that the Lichtenstein group patients required statistically significant less pain medications than patients in Shouldice group.

The mean time for patients to ambulate was 10 h. (from 8 to12 & SD+ 2.3) and 9 h. (from 6to11 & SD+ 2.8) for Shouldice and Lichtenstein groups respectively without statistically significant difference ($p>0.05$).

The mean hospital stay: It was 4 days (from 2 to7 days & SD+ 2.3) for Shouldice group and 2 days (from 1to3 days & SD+ 1.2) for Lichtenstein group, the difference was statistically significant ($p<0.05$). This significant difference resulted from the increased number of patients in Shouldice group requiring analgesia, also the duration and type of pain as they discharged only when they have tolerable pain.

Return to usual daily activity required 7 days (from 5 to9 days & SD+ 2.6) and 4 days (from 3 to 6 days & SD+ 2.2) for Shouldice and Lichtenstein groups respectively. Return to unrestricted physical activities required a mean time of 16 days (SD+ 3.5) in Shouldice group (a mean of 17.5 days for the patients with strenuous jobs and a mean of 13.8 days for those with sedentary jobs) and 12 days (SD+ 2.8) in Lichtenstein group (a mean of 14.6 days for the patients with strenuous jobs and 7 to 12 days with a mean of 10.5 days for those with sedentary work), the difference was statistically significant ($p<0.05$).

Early postoperative complications (Table 1): One patient (2.8%) in the Shouldice group and 3 patients (6.9%) in the Lichtenstein group developed seroma. All seromas were managed conservatively except one in Lichtenstein group, which required single sonographically guided aspiration under complete aseptic condition in the outpatient clinic. The seromas developed in patients with large inguino-scrotal hernias. Superficial wound infection was encountered in 2 patients (5.6%) of Shouldice group and in one patient (2.3%) of Lichtenstein group, all were managed by local dressing only. Urine retention occurred in one patient (2.8%) of Shouldice group, which was managed by single catheterization. One patient (2.3%) of Lichtenstein group developed headache as a complication of spinal anesthesia and was treated by simple analgesics for 3 days. Chest infection occurred in one patient (2.8%) of Shouldice group and in 2 patients (4.6%) of Lichtenstein group who were heavy smokers, treated by proper antibiotic and mucolytics. All differences in both groups regarding early postoperative complications was statistically not significant ($p>0.05$).

Late postoperative follow up results: Every patient had 5 visits of follow-up: 1,3,6 months and 1 & 2 years postoperatively. Testicular function has been evaluated

with spermogram and testicular perfusion with color Doppler ultrasonography preoperatively and 6 months after the operation. As regard to spermatic parameters studies (Table 2), the preoperative semen count of available patients (22 patients in Shouldice group & 27 patients in Lichtenstein group) ranged between 26 and 83 million/ml (a mean of 58 million/ml) in Shouldice group and between 29 to 81.5 million/ml (a mean of 61 million/ml) in Lichtenstein group, while the postoperative semen count ranged between 27.4 to 82.2 million/ml (a mean of 58.2 million/ml) in Shouldice group and between 29 to 82.4 million/ml (a mean of 61.7 million/ml) in Lichtenstein group. There was no statistically significant difference between pre and postoperative spermogram in both groups ($p>0.05$). The testicular perfusion with color Doppler ultrasonography found no statistically significant difference between the pre & postoperative flow parameters for both groups (peak systolic volume, end diastolic volume, resistivity index and pulsitility index). Discomfort or pain at the surgical site was reported in 6 patients (16.7%) of Shouldice group and in 12 patients (27.3%) of Lichtenstein group. Feeling of a foreign body in the groin was reported in 16 patients (36.4%) of Lichtenstein group. None of patients developed testicular atrophy, hydrocele or recurrence of the hernia.

Table 1: ***Early and late postoperative complications.***

Postoperative Complications	*Number of patients*			
	Shouldice Group		*Liechtenstein Group*	
	Number	*%*	*Number*	*%*
Seroma	1	2.8	3	6.9
Hematoma	-	0	-	0
Superficial wound infection	2	5.6	1	2.3
Urine retention	1	2.8	-	0
Post-dural puncture headache	-	0	1	2.3
Respiratory tract infection	1	2.8	2	4.6
Discomfort or pain at the surgical site	6	16.7	12	27.3
Feeling of a foreign body in the groin	-	0	16	36.4
Hydrocele	-	0	-	0
Recurrence	-	0	-	0

Table 2: ***The mean pre- & postoperative spermatic parameters in both groups.***

Spermatic parameter	*Shouldice Group*		*Lichtenstein Group*	
	Preoperative	*Postoperative*	*Preoperative*	*Postoperative*
Spermatic count	58 mill./ml	58.2 mill./ml	61mill./ml	61.7 mill./ml
Spermatic motility	74.3%	75.1%	74.8%	75.3%
Abnormal forms	15.3 %	14.8%	15.1%	15.6%

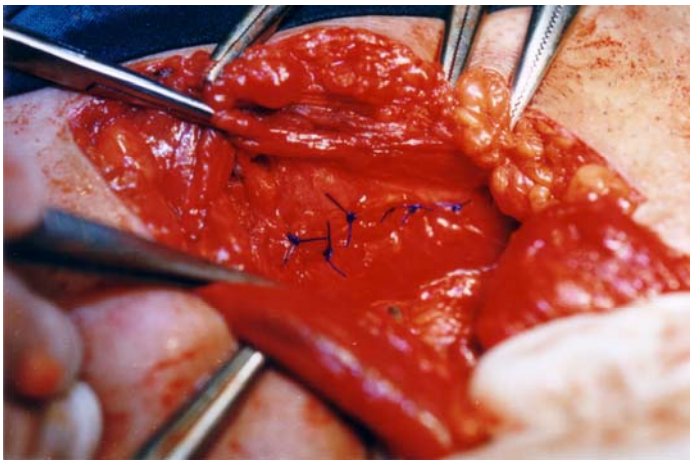

Figure 1*: The first suture line in Shouldice repair*

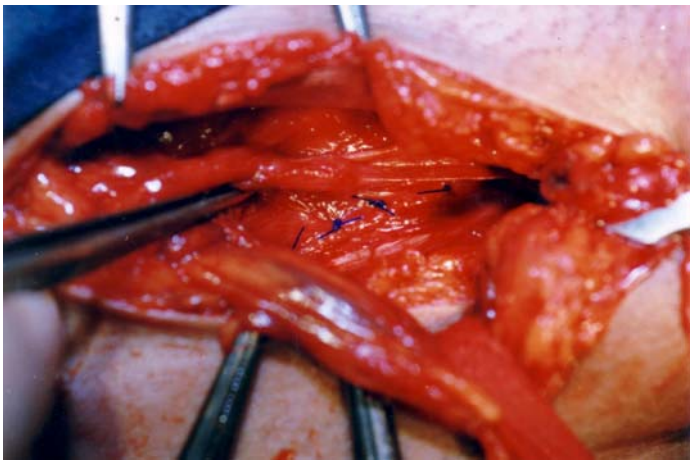

Figure 2*: The second suture line in Shouldice repair.*

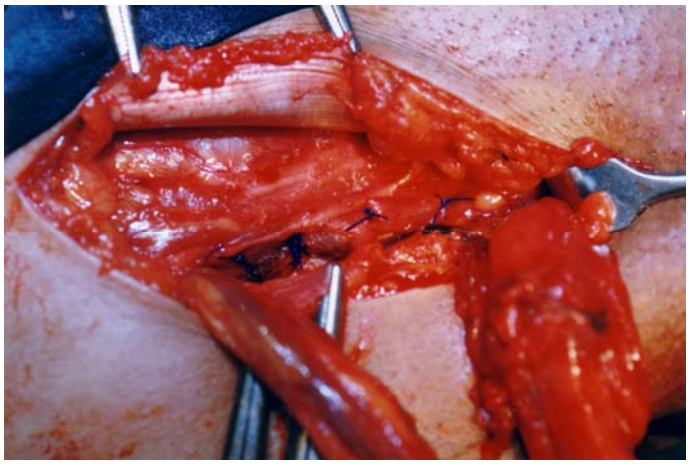

Figure 3*: The third suture line in Shouldice repair.*

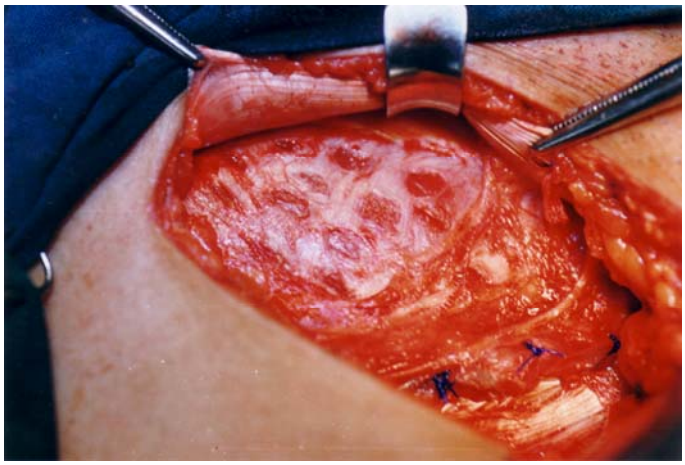

Figure 4*: Multiple small vertical release incisions were done in the rectus sheath.*

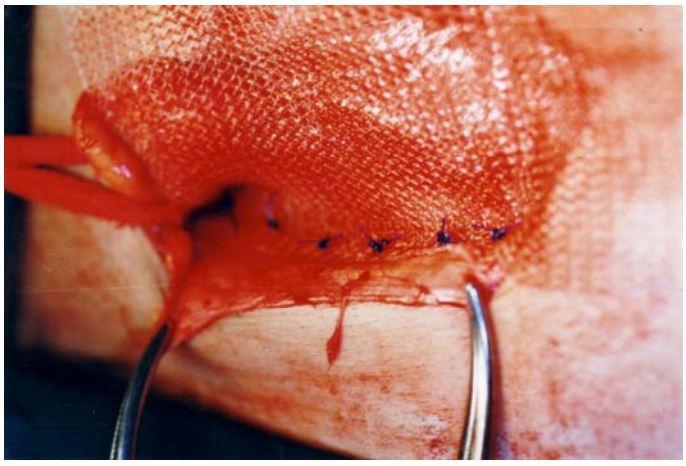

Figure 5*: Fixation of the mesh to the inguinal ligament in Lichtenstein repair.*

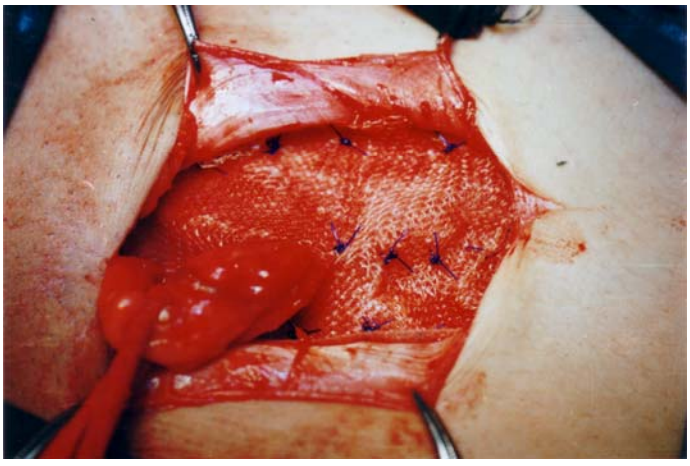

Figure 6*: Complete fixation of the mesh in Lichtenstein repair.*

DISCUSSION

Traditional tissue-based techniques (e.g., Bassini, McVay, and Shouldice) characterized the armamentarium of the inguinal hernia surgery during the 1970s and early 1980s. With the need to reduce the rate of hernia recurrence, as well as postoperative pain and convalescence, the treatment of inguinal hernias underwent a dramatic evolution over the past 15 years. The major advances included the introduction of the concept of tension-free hernia repair, the wide use of prosthetic materials, and the development of laparoscopic hernioplasty [11]. Tension can be relieved easily either by using a relaxing incision [12] or by using a mesh that reinforces the floor of the canal and eliminates tension on the suture line [13]

In our study the mean operative time for modified Shouldice repair was 74 minutes and that for Lichtenstein repair was 56 minutes. The operative time in a study conducted on 105 patients was 95 minutes for the Shouldice repair and 80 minutes for the Lichtenstein repair [14]. In a study conducted by Thapar and his coworkers [15], the main operative time was 81 minutes for the Shouldice herniorrhaphy. On the other hand, the operative time was shorter in another study, this time was 47 minutes for the Shouldice repair and 36 minutes for the Liechtenstein repair [16]. While Bringman and his colleagues [17] reported in their study that the mean operative time for the Liechtenstein repair was 35 minutes.

No intra-operative complications were reported in all of our patients. These results coincided with the results reported by Zieren and his colleagues [16] whom did not face any intra-operative complications during Shouldice and Lichtenstein hernia repair.

In this study, as regard postoperative pain, during the first postoperative day, in the Shouldice group, 18 patients (50%) reported slight pain, 12 (33.3%) reported moderate pain and 6 (16.7%) reported severe pain. In the Lichtenstein group, 11 patients (25%) reported no pain, 20 (45.6%) slight pain and 13 (29.4%) moderate pain. In comparing patients in both groups, as regard the amount of postoperative analgesia required, it was found that the Lichtenstein group patients required statistically significant less pain medications than patients in Shouldice group. Zieren and his coworkers [16] reported that, postoperative pain and analgesic requirements were significantly lower in the Lichtenstein group than in the Shouldice group. Patients of the Lichtenstein group required analgesics for a mean of 3 days, while patients of the Shouldice repair required analgesics for a mean of 10 days. Danielsson and his colleagues [18] reported that, after 2 days the pain was mild in most of the patients of the Shouldice group, while it was very mild in most of the patient of Lichtenstein group and the duration of the use of analgesics was 3 days after mesh repair and 5 days after Shouldice repair. On the other hand, Schmitz and coworkers [19] reported that, there was no significant difference in the pain sensation levels and the amount of analgesic tablets consumed between the two types of repair.

As regards the early postoperative complications, one patient (2.8%) in the Shouldice group and 3 patients (6.9%) in the Lichtenstein group developed seroma. Superficial wound infection was encountered in 2 patients (5.6%) of Shouldice group and in one patient (2.3%) of Lichtenstein group. We did not find a significant difference between the two groups. Zieren and his associates (16) reported, one seroma (1.25%) in the Shouldice and 2 (2.5%) in the Lichtenstein group, 4 hematomas (5%) in the Shouldice and 5 (5.25%) in the Liechtenstein group, 2 wound infections (2.5%) in each group and 2 cases of urine retention (2.5%) in the Shouldice and one (1.25%) in the Lichtenstein group. Schmitz and his coworkers [19] reported that, 6 patients (18.75%) in the mesh group and 4 patients (12.5%) in the Shouldice group developed uncomplicated hematomas, one patient (3.1%) of the Shouldice group developed temporary scrotal swelling. They concluded that, the number of complications in both groups was comparable. McGillicuddy and his coworkers [20] reported, 18 superficial infections (2.7%) evenly distributed between the two repairs with no deep infections.

In our study, the mean hospital stay was 4 days for Shouldice group and 2 days for Lichtenstein group. This significant difference resulted from the increased number of patients in Shouldice group requiring analgesia as they were discharged home only when they had tolerable pain. Zieren and his coworkers[16] reported hospital stay equal to ours for both groups. Hay and his colleagues[21] reported that, the mean postoperative hospital stay was 3 days for the Shouldice repair. On the other hand, Barth and associates [14] reported that, 92% of patients whom underwent Lichtenstein repair were discharged on the day of operation, while Berndsen and his coworkers [22] reported that 78% of their patients operated on with Liechtenstein repair left the hospital on the day of operation.

In the present study, the mean time of return to unrestricted physical activities was 16 days in the patients of Shouldice group (a mean of, 17.5 days for the patients with strenuous jobs and 13.8 days for the patients with sedentary jobs) and 12 days in the patients of the Lichtenstein group (a mean of, 14.6 days for the patients with strenuous jobs and 10.5 days for the patients with sedentary jobs). Barth and his coworkers [14] found that, 50% of the patients of the Shouldice group returned to work by 10 days for sedentary jobs and by 13 days for strenuous jobs and 50% of the patients of the Lichtenstein group returned to work by 8

days for sedentary jobs and by 13 days for strenuous jobs. Bringman and his coworkers[17] reported that, the patients who underwent mesh repair were able to return to work after 7 days for the office workers and 15 days for the manual workers. Danielsson and colleagues [18] reported that, the patients returned to usual activities after a mean of 23.3 days for the Shouldice group and a mean of 18.2 days for the Lichtenstein group.

In our study, there was no statistically significant difference between pre and postoperative spermogram and the testicular perfusion with color Doppler ultrasonography for both groups. Aydede and his coworkers[23] reported that, there was no statistically significant difference between pre- and postoperative spermogram results for both Shouldice and Lichtenstein repair, while Doppler flow parameters showed statistically significant differences between pre-operative and early postoperative values but no statistically difference was found between pre-operative and late postoperative values of both groups.

In this study, during the period of follow-up, discomfort or pain at the surgical site was reported in 6 patients (16.7%) of Shouldice group and in 12 patients (27.3%) of Lichtenstein group. Feeling of a foreign body in the groin was reported in 16 patients (36.4%) of Lichtenstein group. None of patients developed postoperative, hydrocele or recurrence of the hernia. Heikkinen and his coworkers[24] found that, 20% of their patients presented by postoperative discomfort or pain at surgical site and 3.4% hernia recurrence 5 years after Lichtenstein repair. Post and his colleagues[25] reported that, the feeling of a foreign body after Lichtenstein repair with light weight mesh was 17.2% versus 43.8 % with conventional mesh. Junge and coworkers[6] reported that, no recurrence was found 4 years after Shouldice repair. While, Nordin and colleagues [26] reported 7 recurrences (4.7%) after Shouldice repair and one (0.7%) after the mesh repair, chronic groin pain was 4.2% and 5.6% in the Shouldice and Lichtenstein groups respectively. On the other hand, Leibl and his coworkers[27] reported a recurrence rate of 5% for the Shouldice repair and Grant [28] reported a recurrence rate of 1.4% for Liechtenstein and 4.4% for Shouldice repair. The higher incidence of recurrence in these studies than in our study may be due to the long period of follow up for 4 to 8 years.

CONCLUSION:

The multiple release incisions of the rectus sheath used in the modified Shouldice repair reduce the tension on the suture lines and could be used safely to obtain an actual tension-free herniorrhaphy. Both techniques are largely equivalent with a slight advantage falling to the mesh repair because of ease of performance, shorter operative time and rapid return to full physical activities.

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