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A single-blind, randomized controlled study to compare Desarda technique with Lichtenstein technique by evaluating short- and long-term outcomes after 3 years of follow-up in primary inguinal hernias

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Abstract:

BACKGROUND: Lichtenstein tension-free repair is associated with postoperative complications and dysfunctions; hence, there is a need to look for a new hernia repair techniques while retaining its advantages. Desarda technique is a physiologic repair and essentially restores physiology of the inguinal canal. This single-blind, randomized controlled study was conducted to compare Desarda with Lichtenstein technique evaluating short- and long-term outcomes after 3 years of follow-up in primary inguinal hernias.

MATERIALS AND METHODS: One hundred and twenty-three adult male patients with primary inguinal hernia (both direct and indirect) were randomly allocated intraoperatively to Lichtenstein repair, Mesh (M) Group or Desarda repair, nonmesh (NM) Group. Baseline characteristics were recorded before the surgery. Short- and long-term outcomes and patients responses on patient global impression of change (PGIC) and Prolo scale after surgery were recorded.

RESULTS: Sixty-two patients were assigned to NM and 61 to M group. Surgery time was significantly higher for M group ($P < 0.001$). Postsurgical pain was significantly higher ($P < 0.001$) in M than NM group whereas complications were comparable. The total mean duration of follow-up for M was 35.2 months while for NM was 35.7 months. The recurrence rate was not significantly different; however, chronic groin pain was significantly higher in M compared to NM ($P = 0.05$). After surgery, PGIC score was consistently higher in NM group with better functionality in NM group.

CONCLUSIONS: After 3 years of follow-up, Lichtenstein technique and Desarda technique results were similar. After considering the pros and cons of both the methods, a tailor-made approach is required while choosing a procedure for hernia repair.

Keywords:

Desarda technique, Lichtenstein technique, patient global impression of change scale, primary inguinal hernia, Prolo scale

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Introduction

Inguinal hernias comprise about 96% of all groin hernias.^[1] About 27% of men and 3%

of women ranged between 1 and 85 years are at risk of developing an inguinal hernia, and around 20 million hernias are estimated to be repaired every year. It ultimately raises the healthcare cost and resource

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utilization.^[2] Patients with an inguinal hernia are at risk of incarceration, although occurrences of strangulation are rare.^[3] The primary treatment for inguinal hernia is repaired through the surgery. For asymptomatic hernias, in elderly patients who are unfit for the surgery may have expectant management.^[4] Surgery is elective in hernia repair until it becomes symptomatic.

For the treatment of hernias, both the open or laparoscopic surgeries are used. Laparoscopy is generally performed when the hernia is small and easy to access. The method ensures faster recovery and leaves smaller scars.^[5] Open hernia repair is performed using various techniques. The Shouldice operation is popular in patients who cannot bear the cost of mesh. A review performed by Deysine *et al.* suggested that the technique has a 1% recurrence rate when performed by experienced surgeons.^[6] However, the rate of recurrence is lower in mesh repair compared to nonmesh repair.^[7] Currently, the Lichtenstein tension-free mesh repair has become the standard of care.^[1] It is suitable for adult patients and has low complications. It is cost-effective and time-effective.^[8] According to the European Hernia Society Guidelines, the Lichtenstein technique and endoscopic methods are recommended for primary inguinal hernia treatment in adult men.^[9]

However, the technique has some postsurgical complications such as foreign body hypersensitivity, discomfort, abdominal wall stiffness, surgical-site infections, and mesh migration which typically affects the quality of life (QOL) of patients.^[10-13] Intense chronic inflammation may also result in meshoma or plugoma at the site of mesh placement, and it has become a new surgical challenge.^[14] Moreover, previous studies suggested that sexual function may also be affected seriously by the use of prosthetic mesh.^[15]

Due to postoperative complications and dysfunction, there is a need to look for new hernia repair techniques, which reduce the complications while retaining advantages of mesh repair, including reproducibility, low recurrence, ease of performance, and simplicity. In 2001, the Desarda method, a tissue-based mesh free hernia repair was introduced.^[16,17] The objective of this single-blinded, randomized controlled study was to compare Desarda technique with Lichtenstein technique by evaluating QOL, and short- and long-term outcomes after 3 years of follow-up.

Materials and Methods

Patients

Indian patients were recruited in the Department of General Surgery, Kempegowda Institute of Medical

Sciences. This protocol was approved by the Institutional Ethics Committee.

A total of 202 patients were screened in the study of which 79 patients were excluded from the study. A total of 123 adult male patients with primary inguinal hernia (both direct and indirect) were randomly allocated intraoperatively to undergo one of the two repairs: Lichtenstein repair was designated as the M Group (Mesh used), and Desarda repair was designated as the NM Group (No Mesh used). Patients were included in the study based on the presence of a primary, reducible inguinal or inguinoscrotal hernia; unilateral or bilateral. Patients with obstructive uropathy, chronic obstructive pulmonary disease, old and debilitated patients of poor general condition, patients with strangulated hernia, recurrent hernias, American Society of Anaesthesiologists grade >3, and perioperative finding of separated, thin, and/or weak external oblique aponeurosis (EOA) were excluded from the study.

The patients were provided with thorough information on the trial and surgery and signed informed consent form were obtained from each patient. The protocol details were discussed with the study team, and the surgical procedures were practiced. Enrollment of eligible patients began on August 2013 and ended on October 2013. The patients were followed for a minimum of 3 years until October 2016.

Treatment

The diagnosis of primary inguinal hernia was made on the basis of history and clinical examination. Patient baseline characteristics were recorded [Table 1]. The patients

Table 1: Distribution of various characteristics and demography of the patient groups studied

Characteristic	M group (n=61)	NM group (n=62)	P
Age (years)	53.13±11.31	49.97±13.25	0.06 (Student's <i>t</i> -test)
Symptom duration (weeks)	12.5	14.3	0.415 (Fisher exact test)
Inguinal pain at presentation (%)	54.8	53.3	0.906 (Chi-square test)
Type of hernia (%)			
Left direct inguinal hernia	35.5	33.3	0.06 (Fisher exact test)
Left indirect inguinal hernia	0	6.7	
Right direct inguinal hernia	51.6	26.7	
Right indirect inguinal hernia	12.9	33.3	
Presence of comorbid conditions	48.4	33.3	0.232 (Chi-square test)
Body mass index	24.19±2.80	23.82±2.23	0.567 (Student's <i>t</i> -test)

M: Mesh, NM: Nonmesh

were allotted to either of the interventional groups randomly by a computer-generated randomization chart using the closed-sequence method. This was a simple randomization (non-restricted type). Patients were blinded regarding the type of procedure they were undergoing. The evaluation of blinding was done by asking patients to guess the type of procedure they underwent at 48 h and 7 days after the procedure. The guesses made by the patients were recorded and analyzed. The type of procedure, the patient will undergo according to the randomization chart, was conveyed to the surgeon through a telephonic message by the research assistant at the time of surgery.

All patients underwent the surgical procedures under spinal anesthesia. In Lichtenstein hernioplasty, a 3-inch × 6-inch polypropylene mesh (Prolene, Johnson and Johnson) was used for all patients. The mesh was 0.5-mm thick with a burst strength of approximately 14 kg/cm². Polypropylene 2-0 was used to suture the mesh in place. The medial most stitch fixed the mesh 2 cm medial to the pubic tubercle, where the anterior rectus sheath inserts into the pubic bone. Periosteal sutures were not taken. Intermittent prolene sutures were used. The nerve was preserved in all cases. The same surgical team performed all cases; hence, unlikely, individual surgical performance varied in this series. In Desarda repair,^[16,17] an undetached strip of the EOA is sutured to the inguinal ligament below and the muscle arch above, behind the cord, to form a new posterior wall using 1-0 polypropylene interrupted sutures. One dose of Monocef 1 g (Aristo Pharma) was injected in all patients. All surgeries were performed by the same surgical team. The decision to exclude the patients from the study based on EOA morphology during the operation was taken by the team. Two patients were excluded from the study at the time of operation.

Sutures were removed on the 7th postoperative day, and the patients discharged when they felt comfortable and requested for discharge. The wound was inspected 48 h after surgery and every 48 h up to 7 days thereafter. Scrotal support was advised for all patients to avoid bias.

Urinary retention in immediate postoperative period was treated with placement of indwelling catheter removed after 24 h. This was done to prevent confounding bias with pain scale. Patients were followed up at 1 month, 3 months, 6 months, 1 year, 2 years, and 3 years (±1 month) by arranging clinic visits in the departments' examination rooms.

Outcome assessment

The following parameters were measured for both the groups. Operating time was calculated from the time of placement of the first incision to the application of

last skin suture. Time for repair was also calculated separately to avoid bias in cases with complicated hernias. It was calculated as the time from start of actual repair procedure (after complete reduction of hernia sac), i.e., preparation for mesh placement in Lichtenstein technique or placement of the first suture to fix superior flap of EOA to the inguinal ligament to the placement of last skin suture. The patients were followed up for postoperative hematoma, seroma, infection, and scrotal swelling. Patients were followed up for complications chronic groin pain (inguinodynia), A pain rating of >3 on the visual analog scale [VAS] was considered the presence of pain in these patients. Time taken to resume occupation, and recurrence. The VAS scale^[18] was used for pain assessment. In long-term pain assessment, a pain score on VAS scale >3 was considered the presence of chronic groin pain. The patient global impression of change (PGIC) scale^[19] was used to assess patient perception regarding the overall change following surgery. The Prolo scale^[20] was administered to the patients to measure surgical outcomes. Cost-effectiveness of the two procedures was compared.

Statistical analysis

Data were analyzed according to the intention-to-treat principle. Descriptive and inferential statistical analysis was carried out in the present study. Results of continuous variables are presented as mean ± standard deviation, and results of categorical variables are presented as percentage. $P < 0.05$ was considered statistically significant. Student's *t*-test (two-tailed, independent) was used to find the significance of study parameters on a continuous scale between two groups (intergroup analysis) on metric parameters. Leven's test has been performed to assess the homogeneity of variance. Chi-square/Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups.

Results

A total of 202 patients were screened for the study, of which 79 patients were excluded as they have not fulfilled the inclusion criteria. Of these, 62 patients were assigned to NM group and 61 to M group [Figure 1]. No significant difference was present in the baseline characteristics, comorbidities, and hernia characteristics of two groups as evidenced by the two-tailed Exact Fisher and Pearson Chi-square tests of $P > 0.05$ [Table 1].

Patient's blinding guess for the type of procedure, they were undergone, was similar in both the groups [Table 2].

Two patients with more than 50 years of age in the NM group after randomization were found to have splayed and thin EOA. They underwent mesh repair with no

complications; however, their data were not included in the current analysis. Short-term outcomes following surgery were studied in both groups. Surgery time, including both total duration and repair time, was higher in M group compared to NM group. The surgery time was significantly higher for M group ($P < 0.001$). Postsurgical pain measured on VAS scale on day 1, 2, and 3 after the surgery was found significantly higher ($P < 0.001$) in M group than NM group. Though the mean VAS does not appear to be clinically significant, the number of patients complaining for pain was large. For an individual patient experiencing severe pain, this is a significant factor with the maximum VAS in the study for an individual patient going up to 8. The rates of postsurgical complications were comparable in both the groups. The number of seroma patients was higher in the NM group than M group (6 vs. 5, $P = 0.694$). One patient each from both groups experienced swelling at the operation site ($P = 1.000$). Two patients from M group suffered from hematoma and superficial surgical site infection, respectively ($P = 1.000$) [Table 3].

The total mean duration of follow-up for M group was 35.2 months while the NM group was 35.7 months. One patient in the M group had a recurrence after 4 months of repair. On reexploration, the recurrence was at the medial end of the mesh, a typically described site in this technique. No recurrences were found in the NM group patients. Significantly higher number of patients from M group suffered from chronic groin pain compared to the NM group ($P = 0.05$) [Table 4].

Cost data collected for both the groups. It has been found that average cost of NM group (Rs. 12,380 ± 450) was lower than M group (Rs. 14,890 ± 470). The difference of Rs. 2500 between the groups was found.

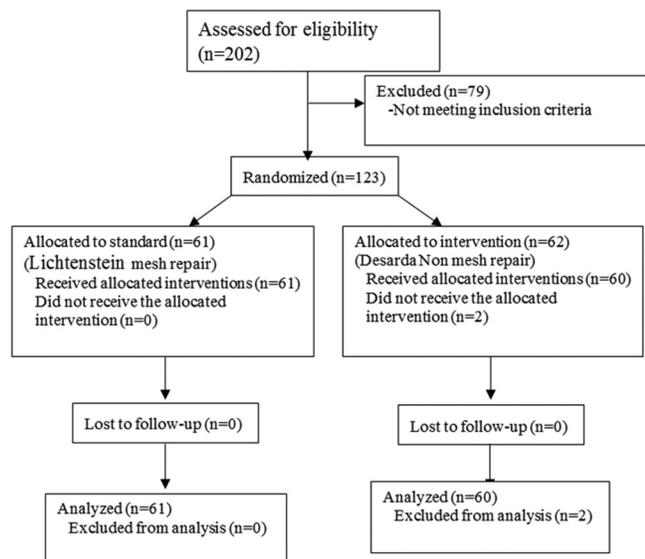


Figure 1: Patient allocation flow diagram

PGIC score was consistently higher in the NM group patients than M group patients. The difference was statistically significant ($P = 0.048$) at and after 2 years of follow-up. It has revealed that patients in the NM group were more satisfied by the repair procedure than M group [Table 5].

On modified Prolo scale, both functional and economic scores at 2 and 3 months of follow-up were more in the NM group than M group. The economic status was similar to both the groups at both 2nd and 3rd months of follow-up. Patients in the M group were functioning suboptimally than patients in the NM group, and the difference was statistically significant (P at 2 months = 0.040 and P at

Table 2: Patient blinding guess in two groups of patients studied using the Chi-square test/Fisher exact test

	Group M (n=61), n (%)	Group NM (n=60), n (%)	P
6 h			
Desarda	36 (58.1)	30 (50)	0.527
Lichtenstein	25 (41.9)	30 (50)	
7 days			
Desarda	32 (51.6)	28 (46.7)	0.699
Lichtenstein	29 (48.4)	32 (53.3)	

M: Mesh, NM: Nonmesh

Table 3: Patient outcomes following the surgery-short term

	Group M	Group NM	P
Surgery time			
Duration of surgery - only repair	56.61±5.23	46.00±4.43	<0.001**
Duration of surgery (total)	74.52±4.72	64.67±4.90	<0.001**
Pain on VAS scale			
Postoperative day 1	5.84±0.45	4.70±0.60	<0.001**
Postoperative day 2	4.65±0.66	3.63±0.61	<0.001**
Postoperative day 3	3.71±0.64	2.90±0.66	<0.001**
Complications			
Seroma	5	6	0.694
Swelling	1	1	1.000
Hematoma	1	0	1.000
Infection	1	0	1.000

**Significant. VAS: Visual analog scale, M: Mesh, NM: Nonmesh

Table 4: Long-term outcomes following surgery

	3 months (%)	6 months (%)	1 year (%)	3 years (%)
Chronic groin pain				
Group M	10 (16.1)	12 (19.4)	12 (19.4)	12 (19.4)
Group NM	0 (0)	2 (3.2)	2 (3.2)	2 (3.2)
P	0.05	0.05	0.05	0.05
Recurrence				
Group M	0	1	1	1
Group NM	0	0	0	0
P	1.000	1.000	1.000	1.000

M: Mesh, NM: Nonmesh

3 months = 0.038) [Table 6]. A subgroup analysis of variables between direct and indirect hernias found no difference in the outcomes after surgery in terms of pain on VAS scale, seroma, recurrence, and long-term pain in both groups except for operative time. Operative time is significantly higher ($P = 0.03$) in indirect hernia, especially for M group [Table 7].

Discussion

The Lichtenstein repair and the Desarda repair were found to be comparable after 3 years of follow-up regarding the recurrence and symptom resolution, except for the postsurgical pain.

The present study is the first to use patient-reported outcome measures to compare QOL following hernia repair surgery using different procedures and found better QOL following Desarda's procedure. The immediate postoperative pain was significantly less in the NM group. There were multiple seromas in the NM group as like in M group in the initial part of the study; however, at a later point, the difference was not statistically significant. This was an unexplained

occurrence which we chose to mention, especially for those who are trying this technique should not be discouraged due to the appearance of a seroma in the immediate postoperative period. At the end of the follow-up visit, both procedures stood equal in most of the postoperative outcomes except for immediate postoperative pain and chronic groin pain. The incidence of groin pain was quite higher (19.4%) in the M group. It might be due to the varying definition and perception of pain between races and ethnic groups; moreover, there are no reliable studies in the Indian population. Localization of pain within the inguinal region was different for every patient. Patients in the NM group suffering from inguinodynia did not have typical neuralgic type of pain. Pain described by the NM patients was mild to moderate requiring occasional analgesics. There was no significant difference found in recurrence rate among both the groups. The recurrence was observed in only one case from M group. It may be due to faulty technique and can happen with any experienced surgeon. The normal rate of recurrence is <1% and can occur up to 1 year after surgery. As it is already a proven point, we did not stress much on it. Prolo scale revealed that the functionality of patients with Lichtenstein's repair was relatively low. This can be attributed to the relatively high rate of groin pain after mesh placement and foreign body sensation as complained by most people, though it was not considered as pain. Furthermore, in this study, there was no difference in the economic scale between the two groups, as these patients were carrying out their work at a suboptimal level of comfort. PGIC scale showed more satisfaction of the patients in NM group in the long term. Despite the randomization, there were more direct hernias in the M group; however, the 2 (3%) direct hernias in the NM group were excluded from the study, which partly explains the difference. However, the statistics would be different if these two patients had either pain or a recurrence changing the entire study results given the limited sample size and power. As randomization does not necessarily guarantee equal numbers, we have quantified our randomization in view

Table 5: Patients Global Impression of Change scale

PGIC scale time	Group M	Group NM	P
1 month	5.4	5.8	0.062
3 months	5.4	6.2	0.056
1 year	5.7	6.2	0.053
2 years	5.8 (58)	6.6 (57)	0.048
3 years	5.9 (55)	6.7 (56)	0.048

PGIC: Patients Global Impression of Change, M: Mesh, NM: Nonmesh

Table 6: Patient responses on the modified Prolo scale

Time of scoring	Scale	Group M	Group NM	P
At 3 months	Economic scale	4.4	4.8	0.067
	Functional scale	3.5	4.7	0.038
At 2 months	Economic scale	4.6 (55)	4.9 (56)	0.066
	Functional scale	3.8 (55)	4.8 (56)	0.040

M: Mesh, NM: Nonmesh

Table 7: Subgroup analysis of variables between direct and indirect hernias

Procedure performed	Type of hernia				P (t-test and Chi-square test were used)
	Direct hernias		Indirect hernias		
	M Group (52)	NM Group (36+2 [excluded])	M Group (8)	NM Group (24)	
Operative time (min)	45.4±2.55	40.8±3.39	67.82±5.82	51.2±3.68	0.03
Pain on VAS scale	5.58±0.32	4.5±0.35	6.1±1.03	4.9±0.52	0.08
Seroma rate (%)	7.6	8.3	12.5	12.5	0.7
Long-term pain (%)					
3 months	13.4	0	37.5	0	>0.05
6 months	17.3	2.7	37.5	4.1	
1 year	17.3	2.7	37.5	4.1	
3 years	17.3	2.7	37.5	4.1	
Recurrence (%)	1.9	0	0	0	

VAS: Visual analog scale, M: Mesh, NM: Nonmesh

of these differences and it was adequate. In the light of these, it is fairly clear that patients undergoing Desarda procedure have better QOL in the long term.

A similar study was conducted by Szopinski *et al.* in 2006. They compared Desarda and Lichtenstein techniques in 203 patients, followed up for 3 years, shown that results from both the techniques were similar except seroma formation. The results are similar to the current study.^[21] A 6-month follow-up study conducted by Mitura and Romańczuk suggested that the Desarda and Lichtenstein techniques are similar in respect of surgery time, postsurgical complications, and pain intensity.^[22] A comparative study conducted by Desarda *et al.* showed that the recurrence rate is significantly higher ($P = 0.003$) in the mesh group. No recurrence was found in patients undergoing Desarda (author's) technique. They also observed that the significantly higher number (13 [6.4%] out of 203 mesh group patients) of patients in the mesh group had chronic groin pain.^[23]

Lichtenstein's method is a gold standard and a quite popular surgery for hernia repair even after the dawn of laparoscopic repair. It is easy to perform and shows reproducible results. However, the method has some potential drawbacks. Though, in the present study, we encountered only chronic groin pain and recurrence, many other investigators also reported postsurgical complications such as pain, infection, migration, perforation, rejection, testicular ischemia, and recurrences after Lichtenstein's repair.^[24-26]

The known drawback of Desarda technique to date is the use of the originally unhealthy tissue for repair. It has been postulated that a hernia occurs due to a decrease in Type I and III collagen ratio due to a defect in matrix metalloproteinase metabolism; hence, any tissue-based repair would not give the cure to a hernia.^[27] In this study, we came across two patients aged above 50 that had splayed and thin EOA that cannot be used for repair. However, Desarda's procedure has no inherent risk of implant infection, orchitis, or infertility as seen with Lichtenstein's procedure. In addition, as the technique does not require prosthetic mesh and other instruments to place it, ultimately reducing the healthcare cost and can be used in rural areas where the cost of a treatment and implant availability is a constraint. Our data also support the cost-effectiveness of the technique.

Investigators worldwide making efforts to optimize the results of inguinal hernia surgery and lower the number of complications. The use of prosthetic mesh in younger patients is controversial as some studies have postulated sexual impairment after mesh implantation.^[28,29] Mesh repairs are to be used with caution as young

patients have 10%–20% risk of chronic groin pain and impaired functioning throughout the life with mesh repair. In contrast, Desarda procedure was better for indirect hernias than mesh repair, although there is no statistical difference in the subgroup analysis. Desarda technique is not suited for large direct hernias with an intraoperative finding of a splayed external oblique, although it is better suited for small direct hernias, indirect hernias, young patients, strangulated hernias, and immunocompromised patients. It gives better QOL compared to mesh repair. Desarda is an ideal repair for young patients with virgin hernias, though recurrence rates are equal to mesh (Lichtenstein) repair in multiple studies. In case of a recurrence with Desarda, mesh repair can be used as a fallback procedure.

Most of the studies conducted earlier^[21,23,30,31] in addition to the current study suggests that Desarda technique despite some technical inadequacies is superior to mesh repair in the short term and is relatively pain- and discomfort-free in the long term. It has to be the natural choice in particular subset of hernias which are unsuitable for mesh placement. It is also advantageous in a clinical setting where mesh availability or monetary restrictions play a role. From our experience, we concluded that it is fairly advantageous for young people to undergo Desarda technique compared to mesh repair, further research is required to find the correct patient segment to whom the technique is most advantageous.

Conclusions

While choosing a procedure, a tailor-made approach must be used. For large direct hernias with collagen defects, Lichtenstein's technique is the procedure of choice. In younger patients with indirect hernia, the use of mesh should be avoided to reduce complications and morbidity, whereas in elderly patient with poor muscle tone and direct hernias, the risk of finding a splayed EOA is higher, and the Lichtenstein's technique is recommended. For patients who do not fit into any of the risk category or in rural areas where treatment cost is a constraint, a mesh-free procedure should be preferred due to the low risk of complications and if in case of failure surgeon has the option of mesh repair. In addition, for patients in whom mesh repair is contraindicated such as strangulated hernia and immune compromised state, Desarda's repair is the procedure of choice.

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Conflicts of interest

There are no conflicts of interest.

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