

Original Article

Desarda Versus Lichtenstein Repair for Primary Inguinal Hernia in Men: Results of A Randomized Control Trial

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Abstract:

Inguinal hernia is a very common surgical problem for which mesh based technique particularly Lichtenstein repair is considered as standard. However, it is not free from some major and bothersome complications. Desarda technique of non-mesh hernia repair invented by the Indian surgeon is claimed as low cost tension free procedure with promising results. The objective of the study is to evaluate the feasibility of Desarda procedure in country like Bangladesh as a treatment of primary inguinal hernia in men by comparing with Lichtenstein repair in terms of various parameters. One hundred and sixty male patients between ages of 18-70 years with uncomplicated primary inguinal hernia were initially randomized to perform the one of the two procedures in every alternate patient. Outcome were measured and analyzed. A total of 100 patients were finally studied with a follow up of 2 years. Operative time and immediate post-operative pain were significantly less in Desarda arm. Cost and foreign body sensation were also in favour of Desarda group. There was no recurrence in either group. Desarda repair is easy to perform and takes less time. It is cost effective with a comparable clinical outcome to standard Lichtenstein repair at least in short term.

Key words: Desarda repair, Lichtenstein repair, Mesh, Recurrence, Chronic pain.

Introduction:

Inguinal hernia is a very common illness and its incidence rises with age and more common in male. Its incidence is 386 for men and 44 for female per 100000 population¹. The estimated lifetime risk for inguinal hernia is 27% for men and 3% for women². The history of hernia is as old as the history of surgery, with the first repair dating back to 1559³. Till today surgery offers the only chance to cure⁴. Considering the

anatomy and pathology of inguinal hernia, emphasis was given on restoring the anatomical integrity of inguinal canal by means of tissue based technique or by covering the defect with synthetic material. Until beginning of this century there were various tissue based surgery techniques bear the name of the surgeon who promoted the method concerned (Marcy, Bassini, Halsted, Mcvay, Shouldice etc.). The concept of tension-free repair of the defect had already emerged at the end of the 19th century but a suitable biomaterial in the form of polypropylene mesh only became available in 1960. In 1884 Lichtenstein described reinforcement of posterior wall of the inguinal canal using a mesh, called as mesh repair. Since 1990, the hernia surgery has been performed endoscopically by means of both transperitoneal (TAPP) and preperitoneal (TEP) approach. Before publication of The European Hernia Society Guideline (EHS) in 2009, there was no consensus about the approach to inguinal hernia in adults. The European Hernia Society (EHS) guideline strongly recommends mesh technique either open or laparoendoscopic method for adult inguinal hernia. Shouldice technique is considered as best non mesh repair for primary inguinal hernia⁵. However, considerations such as postoperative morbidity affecting quality of life, the cost to the health care system, sepsis rate and understanding the physiological

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contribution to the pathological process of hernia are equally important. Considering all things Dr. Mohan P Desarda reported a novel technique of a tissue based hernia repair in the year of 1998 based on concept of providing strong, mobile and physiologically dynamic posterior inguinal wall without using any prosthesis. The technique requires less complicated dissection or suturing, no mesh is needed and easy to learn⁶. The aim of this study is to compare the clinical outcome of the standard mesh based Lichtenstein repair with the Desarda tissue based repair for the treatment of primary inguinal hernia in adults.

Material and Methods:

The randomized prospective comparative study was conducted from October 2013 to October 2016 in the Department of Surgery, Faridpur Medical College Hospital 135 kilometers away from the capital city of Dhaka.

The study was approved by local ethical committee. Informed consent was obtained from all participating patients after explaining the purpose of this study. Many patients declined to enter into the trial.

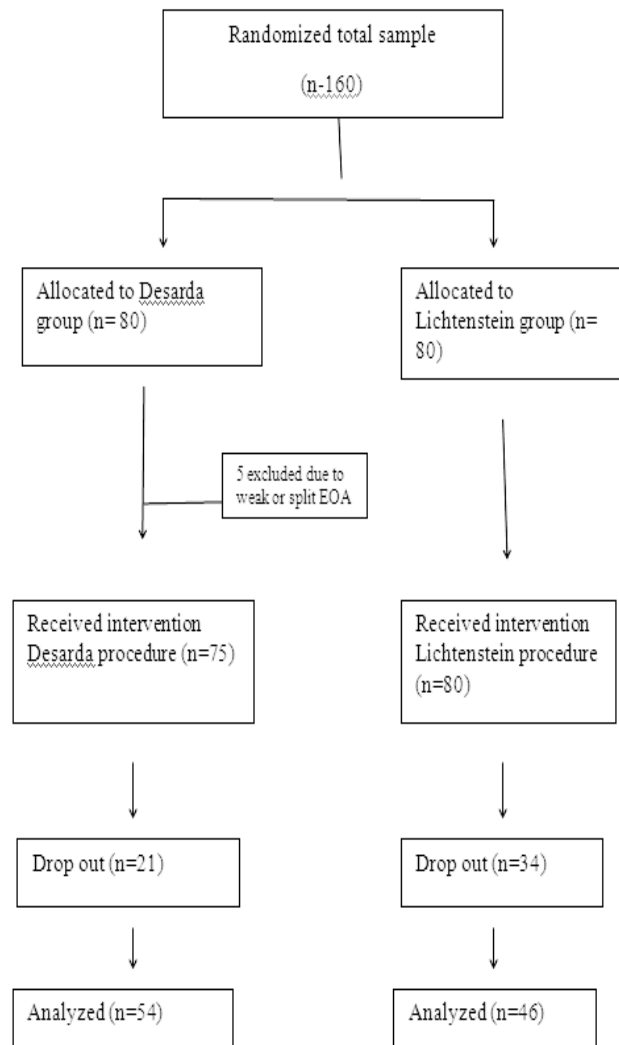
All male patients between 18 to 70 years of age who were diagnosed as primary unilateral uncomplicated inguinal hernia with optimum fitness for surgery were included in this study. Patients with strangulated or obstructed hernia, recurrent hernia, bronchial asthma, split external oblique aponeurosis (EOA) assessed during operation and who were lost from follow up in any point of study were excluded.

A total of 160 patients were randomly allocated to undergo one of the two techniques: Desarda tissue based repair (D) or the standard Lichtenstein mesh repair (L). Every alternate patient received the same technique. Some five patients were excluded from the study per-operatively from D group for weak and /or split EOA. So finally D group consists of 75 patients and L group of 80 patients. All the procedures were done by corresponding author of this article and some residents of same surgical unit who received proper training on performing both techniques.

Surgical technique

All patients of both groups were operated under subarachnoid block with preoperative 1 gram ceftriaxone as prophylactic antibiotics. The Lichtenstein tension free mesh repair was done by standard procedure described in European Hernia Society guideline⁷. A 7.5x15 cm polypropylene (Prolene® Ethicon) was tailored to fit as a tension free repair with good overlap. Fixation was done using non-absorbable 3-0 polypropylene suture. EOA was closed

Flow diagram of the trial



Tissue based technique was performed according to the original description of Mohan P. Desarda⁶. The inventor of the technique had modified his own action later on. In 2008, he started to use continuous absorbable suture (No 1 PDS) instead of interrupted suture with non-absorbable monofilament (1-0 Polyamide)⁸. We did the modified procedure with 1-0 polyglactin 910 (vicryl®) as a suture material of choice as PDS is not very popular in our country.

Patients were allowed to oral feeds 6 hours after surgery. All patients of both groups received Diclofenac sodium suppository eight hourly as an analgesic of choice up to 2nd post operative day (POD) and then on demand. Intensity of pain was measured on Visual Analogue Scale (VAS) daily and checks dress with evaluation of seroma, haematoma or minor SSI was done on 2nd and 3rd POD. Patients were discharged on 3rd POD when they could perform basic activity. Few patients stayed couple of days more for pain, discomfort or wound related events.

Follow up

The trial ended in October 2016. Patients were followed up for next two years upto October 2018. We used phone call for most of the patients as a tool. We have lost a number of participants during follow up. Many of them closed themselves from the trial deliberately. They were followed up at 1 month, 6 month then yearly for next two years. Fifty five patients were lost during follow-up, 21 from D group and 34 from L. Finally at the end of the second year the study comprised of 54 participants in Desarda (D) group and 46 in Lichtenstein (L) group, a total of 100 patients as a sample size.

Outcome measure

Measured primary outcome were recurrence, chronic pain and foreign body sensation. Secondary end points were the severity of post-operative pain, operating time, hospital stay and cost of surgery.

Return to basic activity was defined as the patient's ability to do elementary activities (i.e., dressing, walking, and washing) and returning to all previously performed activities termed as work activity. Chronic post-operative inguinal pain (CPIP) is defined as a level of discomfort rated by the patient as ≥ moderate and impacting daily activity lasting at least 6 months post-operatively.

Statistical analysis

Data were collected by use of interview schedule and from phone calls. Data were entered into a computer and a data file was constructed. Data were analysed by Independent Student 't' test (continuous variable) & Chi-square test (categorical variable). Statistical significance was considered as p< 0.05. Statistical analyses were done by using SPSS 22.0 (Statistical Package for the Social Sciences by SPSS Inc., Chicago, IL, USA, 2017).

Results:

The mean age of the patients in D group is 50.33 years while in L group is 56.17 years.

Table I: Comparison of age distribution between two groups (n=100)

Variable	Desarda(n=54) Mean±SD	Lichtenstein (n=46) Mean±SD
Age	50.33±5.12	56.17±6.34

Data were expressed as mean±SD

The baseline characteristics of hernia are shown in table -II.

Table II: Baseline characteristics of Hernia (n=100)

Feature	Desarda(n=54) No. (%)	Lichtenstein (n=46) No.(%)
Site		
Right	35 (64.81%)	30(65.21%)
Left	19 (35.19%)	16 (34.79%)
Direct	14(25.92%)	11 (23.91%)
Indirect	40 (74.08%)	33 (71.73%)
Pantaloon	00(00%)	2(4.34%)

Figures in the parentheses indicate corresponding percentage.

Both types of hernia (direct and indirect) on either side were seen on each group. Two cases of pantaloon hernia are present in L group (4.34%).

Forty Nine (90.74%) patients of Desarda (D) group were discharged from hospital on 3rd POD whereas 80.43% patients of L group but it is not statistically significant (Table-III).

Table III: Hospital stay at 3rd POD (n=100)

Feature	Desarda(n=54) No. (%)	Lichtenstein (n=46) No. (%)	p value
3 rd POD	49(90.74%)	37(80.43%)	0.138
>3 rd POD	5(9.26%)	9(19.57%)	
Total	54(100.0%)	46(100.0%)	

Figures in the parentheses indicate corresponding percentage;

Chi-squared Test (χ^2) was done to analyze the data

Herniotomy was done in the usual way. Time required for hernioplasty (repair or strengthening of posterior wall) was measured only. There is significant difference in mean operating time found in our study (21.78 min vs 37.48 min in D and L group respectively) (Table - IV).

Table IV: Comparison of mean operating time (minutes) only for repair (n=100)

	Desarda(n=54) Mean±SD	Lichtenstein (n=46) Mean±SD	p value
Operating time (min)	21.78±2.14	37.48±4.52	<0.001*

Unpaired student t-test was performed to compare between two groups, *significant

Post-operative pain was assessed by visual analogue scale (VAS) ranging from 0-10 level. The mean pain score at 1st POD in D group was 2.81 and 4.04 in L group with p value <0.001. In 3rd POD it was 2.25 in D group and 3.13 in L group with p value < 0.001. Both were found significant statistically (Table-V).

Table V: Comparison of post-operative pain by VAS (n=100)

Feature	Desarda(n=54) Mean±SD	Lichtenstein (n=46) Mean±SD	p value
VAS at 1 st POD	2.81±1.21	4.08±1.42	<0.001*
VAS at 3 rd POD	2.25±0.97	3.13±1.02	<0.001*

Unpaired student t-test was performed to compare between two groups, *significant

Forty (74.07%) patients in D group returned to their basic activity within one to two days whereas 69.57% in L group. 3-5 days were required for 25.93% patients in D group and 30.43% in L group for returning to their basic activity. We found no statistically significant difference in two groups (p value-.617). A mean 14.19 days were required to resume their work activity in patients of D group and 16.90 days in patients of L group which was statistically significant (Table-VI).

Table VI: Return to activity (n=100)

Feature	Basic activity		p value	Work activity (Mean days)		p value
	Desarda (n=54) No. (%)	Lichtenstein (n=46) No. (%)		Desarda (n=54) Mean±SD	Lichtenstein (n=46) Mean±SD	
Day 1-2	40(74.07%)	32 (69.57%)	0.617	14.19±3.52	16.90±3.61	0.001*
Day 3-5	14(25.93%)	14 (30.43%)				

Chi-squared Test (χ^2) Unpaired student t-test, *significant

No statistically significant difference observed in early or immediate complications after surgery (Seroma, cord edema, minor SSI etc) in either group. Two (3.70%) patients developed chronic postoperative inguinal pain in D group whereas five (10.86%) patients in L group. Though the difference is wide but it is statistically not significant (P value=0.161).

We have found a significant difference in foreign body (FB) sensation as a late complication. No patients in D group had FB sensation but 8 patients (17.39%) in L group felt the problem (P= 0.001) (Table -VII).

Table VII: Post-operative complications (n=100)

Postoperative complications	Desarda (n=54) No. (%)	Lichtenstein (n=46) No. (%)	p value
Early			
Seroma	3 (5.56%)	4 (8.6%)	0.539
Testicular/cord odema	3 (5.56%)	5 (10.86%)	0.328
Minor SSI	1 (1.85%)	2 (4.35%)	0.465
No complication	47 (87.02%)	35 (76.09)	0.155
Late			
Foreignbody sensation	0 (0%)	8 (17.39%)	0.001*
Chronic pain	2 (3.70%)	5 (10.86%)	0.161
Recurrence	0.0	0.0	-

Figures in the parentheses indicate corresponding percentage;

Chi-squared Test (χ^2) was done to analyze the data, *significant

The cost of surgery was calculated in Bangladeshi currency and assessed by only cost of mesh and suture material used. There was significant difference in the cost between two groups (Table-VIII).

Table VIII: Comparison of cost of surgery (suture and mesh) (n=100)

Feature	Desarda(n=54) Mean±SD	Lichtenstein(n=46) Mean±SD	p value
Cost of surgery (BDT)	600.0±195.00	2700.0±320.0	<0.001*

Unpaired student t-test was performed to compare between two groups, *significant

Forty Seven (87.02%) patients in D group and 76.09% in L group left hospital without any complication (p=0.155). There was no recurrence in 2 years follow up in any group.

Discussion:

Choosing the best or most suitable groin hernia repair technique is a true challenge. The best operative technique should have the following attributes; low risk of complication (pain and recurrence), easy to learn, fast recovery, reproducible results and cost effectiveness. The decision also depends upon many factors like; hernia characteristics, anesthesia type, the surgeon's preference, training, capabilities and logistics. The patient's wishes must be considered. There are cultural differences between surgeons, countries and regions. Emotions may play a role as well⁹. One single standard technique for all hernias does not exist. In most situations a mesh repair is preferred. However, a minority of surgeons hold the opinion that mesh use should be avoided as much as possible⁹. Dr. Mohan P. Desarda in 1998 published a new non-mesh technique of hernia surgery with promising result. Till now randomized trial to evaluate the effectiveness is still scanty.

Considering the above matters present study compares the results and clinical outcome of Desarda (D) and Lichtenstein (L) technique.

Post-operative pain was assessed by Visual Analogue Scale from 0-10. The patients in L group experienced significantly more pain (4.08 vs. 2.80) in 1st POD and in 3rd POD as well. There are some other studies having similar observation^{10,11,12} indicating that Desarda repair as acclaimed by its inventor indeed a tension free tissue repair. Many studies have shown no difference in immediate post-operative pain^{13,14}. As the day passes difference in pain intensity between two arms was reduced indicating that immediate post-operative pain is comparable in two groups.

Maximum patients in either arm were discharged from hospital at 3rd POD when they were able to return to their basic activity like walking, bending and light weight bearing. Nearly similar numbers of patients have returned to their basic activity at day 1-2 after surgery. There are some studies with similar results^{14,15}. But when followed up to observe the required time to resume their work activity D group showed statistical superiority (14.19 vs 16.90 days, p=0.001). There are some RCTs showing results in favor of Desarda group^{16,17}.

Post-operative morbidity was slightly higher in L groups in terms of seroma, cord edema, minor SSI but statistically not significant. Risk of seroma formation varies between 0.5% and 12.2%. Most seromas disappear spontaneously within 6-8 weeks. Results of 13 systematic review show seroma after open mesh versus open non-mesh is 2.04% vs 1.6%; OR 1.52¹⁸. No significant difference observed in most of the randomized trial in mesh vs non-mesh repair as in our study^{12,16,19}. Where there is higher seroma it can be explained by influence of synthetic mesh on surrounding tissue²⁰.

The risk of wound infection following inguinal hernia surgery with or without mesh should be below 5%. The use of mesh in inguinal hernia repair is not associated with a higher risk of wound infection¹⁸. The rate of wound infection in mesh vs non-mesh technique of inguinal hernia surgery is found 3.4% vs 2.8% in a systematic review of 16 trials²¹. Our results (4.35 vs 1.85%, L and D respectively) are consistent with most of the RCTs published so far^{12-15, 20}.

Cord edema may be as a result of extensive dissection of sac from cord or pampiniform plexus. In case of large hernia transection of sac and leaving the distal hernia sac undisturbed recommended¹⁸. It is our routine practice and we have found no significant cord edema in our study.

In our study, level of chronic pain, foreign body sensation and recurrence were considered as primary outcome to be measured. Though International association for The Study of Pain (IASP) defined chronic pain as pain lasting for 3 months or more, we in our study set the duration as 6 months or more which is supported by The Hernia Surge group guideline²². Chronic post-operative inguinal pain (CPIP) is defined as a level of discomfort rated by the patient as \geq moderate and impacting daily activity²². We have found no significant difference in CPIP in our study though early post-operative pain was lower in D group. There are many RCTs those have shown similar results in CPIP^{11,12,15,20} but one study concluded that CPIP was more frequent in L group where they considered persistent pain more than one month instead of 3 or 6 months¹⁴. Chronic groin pain after hernia repair with mesh was reported to range from 28.7% to 43.3%²³. However much less incidence was recorded in our series 3.7% vs 10.86% in D and L group respectively (p=0.161). The influence of different surgical techniques on chronic groin pain after hernia surgery remains unclear. The cause of such pain is still obscure. Overall the incidence of clinically significant CPIP is in the 10%-12% range, decreasing over time. There are many risk factors for post herniorrhaphy inguinal pain unrelated to mesh, type of mesh or fixation technique. Younger age, female gender or preoperative pain level may also determine the degree of CPIP²².

In our study operating time was significantly shorter in D group than that of L group (21.78 vs 37.48, p<0.001). Duration of surgery is a surgeon dependent variable but it reflects the ease of an operation. We calculated operating time as time taken only for repair as because time usually varies in dissection of sac of different types which should not be included to compare the repair procedure. Many RCTs of different parts of the world published similar results^{11,13,15,17,19,24}.

The longer operating time in L group may be attributed to mesh tailoring, lateral placement and fixation of mesh. In Desarda operation continuous suturing is used instead of interrupted used in Lichtenstein repair.

The cost of the surgery should be taken into consideration in country like Bangladesh to compare the surgical procedure. The economic aspects of inguinal hernia operation can be examined from different perspectives. The direct cost of operation, the number of OPD visit and hospital stay and the indirect cost includes restrictions in usual activities, time from absence of work, production loses etc. In our study both direct and indirect cost in terms of operation cost and returns to work activity both are in favour of D group. The Desarda method appears to save the cost (Table VI & VIII).

Use of mesh in hernia surgery has been blamed for more infection¹⁷, mesh migration, mesh foreign body reaction, mesh rejection, mesh degradation, mesh shrinkage and mesh erosion²⁵.

We have 17.39% patients with persistent foreign body sensation in our study. They felt something in their groin during walking, running even sometime during postural changes. This is a recognized complication of mesh hernioplasty as seen in many studies^{10,15}. In a study Neogi P, et al it reaches up to 38.3%. On the other hand there was no such complication in D group as no synthetic material was used. The EHS guideline shows that significantly more men in when standard polypropylene were used could feel the mesh in groin than patients with lightweight mesh (22.6% vs14.7%. p= 0.025)¹⁸. Therefore we can understand that use of mesh even in good quality is not free from such complication.

EHS guideline concludes that operation technique using mesh results in lower recurrence than technique which do not use mesh but we found no recurrence in our study in either group at 2 years follow up. Many studies show similar results^{10,14,15}. However, Desarda, in a clinical trial in small district in India comparing his technique to Lichtenstein repair reported no recurrence in his technique versus 4 recurrences in mesh group²⁶.

Though it is a randomized comparative prospective trial, the sample size of the current study is small; follow up period is short, phone calls used as a follow up tools, and a number of surgeons involved to do the surgeries.

Conclusion:

The European Hernia Society (EHS) recommends mesh technique for inguinal hernia correction in men but in our study we found Desarda technique is quite comparable to Lichtenstein technique, even superior over the mesh based procedure in terms of cost and operative time. Desarda technique eliminates the chance of bothersome foreign body sensation in groin. This is a newer technique in the history of hernia surgery with a promising result at least in a short term.

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