

A Randomized Trial Comparing Lichtenstein Repair and No Mesh Desarda Repair for Inguinal Hernia: A Study of 1382 Patients

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Background: *The objective of this study is to compare the outcomes of Lichtenstein repair and no mesh Desarda repair for inguinal hernia.*

Methods: *This is a prospective randomized trial of 1382 patients having 1461 hernias operated from January 2002 to December 2011. 704 patients were operated using Lichtenstein repair and 678 using Desarda repair. The variables like age, sex, type of hernia, duration of surgery, pain on the first, third and fifth day, hospital stay, complications, re-explorations, morbidity and time to return to normal activities were analyzed. Follow up period was from 1-10 years (median 6.5 years).*

Results: *There were no significant differences regarding age, sex, type of hernia, and pain in both the groups. The operation time was 48 minutes in Desarda group and 39 minutes in the Lichtenstein group that is significant ($p < 0.05$). The recurrence was 0.5 % in Desarda group and 0.4% in Lichtenstein group. There were 8 cases of infection to the polypropylene mesh in the Lichtenstein group, 3 of this required re-exploration. The morbidity was also significantly more in Lichtenstein group (7.5%) as compared to Desarda group (3.4%). The mean time to return to normal routine non-strenuous work in the Desarda group was 8.26 days v 12.58 days in the Lichtenstein group. The mean hospital stay was 29 hrs. in Desarda group while it was 49 hours in the Lichtenstein group in those patients who were hospitalized.*

Conclusions: *Desarda repair scores significantly over the Lichtenstein repair. Morbidity due to complications and re-explorations for sepsis were significantly higher in mesh group. Period of return to normal work was also less in the Desarda group. No mesh Desarda repair is a better choice as compared with the Lichtenstein mesh repair.*

Key words: Lichtenstein, Desarda, Inguinal, Hernia, Repair, Randomized, Trial.

Introduction

The surgeons use different techniques in Cuba for inguinal hernia repair like Bassini or Shouldice and its modifications or different types of mesh repairs. Inguinal hernia mesh repair, although probably providing superior results with regards recurrence rate, is not available in many parts of the world. Hernia treatment has become a health problem in Cuba because of its social, economic and labour implications due to its high incidence in population¹. Until recently, the only parameters to be evaluated were recurrence, complication rates etc. Today, other parameters like cost, post-surgery wellbeing and quality of life have gained importance. The demand of general surgeons is to identify operation that is simple to perform without the need for any foreign body or complicated dissection and also has low complication rates. Avoidance of use of foreign material where ever possible is a basic surgical principle.

The authors read about the Desarda repair which seems be simple in concept, avoids the use of mesh and gives the desired results. This repair is based on the concept of providing a strong and physiologically dynamic posterior wall to the inguinal canal. An undetached strip of the aponeurosis of the external oblique muscle replaces the absent aponeurotic element in the posterior wall and the weakened conjoint muscle receives additional strength from the external oblique muscle to keep it physiologically dynamic².

There are still many controversies to answer. Which is the best technique for repair³? Is hernioplasty better than herniorrhaphy? Which is the best technique for hernioplasty or herniorrhaphy? The objective of this study is to evaluate the Lichtenstein mesh repair and compare it with the “No mesh, physiological repair” described by Desarda. Two techniques have been compared, an open mesh repair with an open non mesh repair in this study.

Patients and Methods

A prospective randomized trial was carried out in 1382 patients having 1461 hernias operated from January 2002 to December 2011. 691 patients were allotted to both the groups, but 13 patients wanted shift from Desarda group to Lichtenstein group in the operating theatre before the surgery. Therefore there were 704 patients having 758 hernias in the Lichtenstein group and 678 patients having 703 hernias in the Desardagroup. All the patients from both sexes older than 16 years with primary inguinal hernias were included. Recurrent hernias and patients operated on emergency basis were excluded. The diagnosis of inguinal hernia and its type was made by clinical examination. Information was given to the patients as regards the anesthetic procedures. The surgeon or the patient chose the type of anaesthesia after discussion with the surgeon before surgery. The Randomization was performed using a consecutively numbered, sealed envelope, which was opened, in theatre and all patients having an even number were operated by the Lichtenstein and uneven numbers by the Desarda technique. The operating surgeon completed a data sheet. The operating surgeon was of consultant level for all the operations. The evaluator was also a surgeon of consultant level. All the patients signed a written informed consent. Approval of the local ethical committee was obtained prior to the onset of the study.

Desarda repair was performed according to the surgical technique described by Dr. Desarda. A strip is separated from the upper leaf of the external oblique aponeurosis (EOA) keeping its insertion and continuity with the muscle intact. This strip is sutured with inguinal ligament below and newly formed upper leaf of EOA above behind the spermatic cord to form the new inguinal floor. Mesh prosthesis repair was undertaken as described in the textbooks. Polypropylene mesh of size 10X15 cms was used. Mesh was trimmed wherever required keeping muscle cover of minimum 2-3 cms. Prophylactic antibiotic was administered in the operating room before surgery (Cefazoline 1g.) in the Lichtenstein group only. Operation time was measured from taking incision on the skin to the closure of the skin incision. A data sheet was completed by the operating surgeon including type of hernia (Nyhus classification)⁽⁴⁾, anaesthesia, technical details and intra-operative complications. All patients were discharged as soon as their post-surgical recovery allowed and all patients were instructed to do daily, routine, non-strenuous work after discharge. A non-steroidal anti-inflammatory (Diclofenac) analgesic was prescribed for a period of 5 days and continued if required. Patients were asked to complete a pain score on the first, third and fifth day after surgery using a linear analogue scale.^(5,6) The consultants followed all the patients at 7 days, 15 days, 1 month, 6 months and then yearly thereafter.

Further data was added at discharge and thereafter during each follow up about post-operative early and late complications. Pus discharge from the wound was treated as wound infection, postoperative testicular swelling as testicular ischemia and reduction in the size of the testes as atrophy. Hematoma or Seroma was diagnosed as per the fluid aspirated from the wound swelling. Appearance of the bulge on cough during clinical examination was treated as recurrence. Period for return to normal light work was measured from the operation date till the patient was able to carry normal duties like office work or other non- strenuous work. The Student T test was used to compare the independent measures and the Mann Whitney-U test for non-parametric data.

The Chi-squared test and Fisher's exact test were used to measure the association between quality variables.

Results

There was no significant difference in relation to sex, age, or type in both the groups (Table 1). Local anesthesia was used in 273 patients in Lichtenstein group and 490 patients in the Desarda group. All those 763 (55.2%) patients were operated on as outpatient basis without hospitalization. In the remainder of 619 patients who were treated as in-patients, the mean hospital stay was 29 hours in Desarda group and 49 hours in the Lichtenstein group ($p < 0.05$). 62 patients from Lichtenstein group required to stay for more than 3 days in the hospital due to local wound complications or for some other reasons compared to only 5 patients from the Desarda group, a significant difference. ($p < 0.05$) (Table 2).

Table 1. Age, Sex, Location and Type of Hernia.

Age, Sex, Type	Lichtenstein Group (n=704)			Desarda Group (n=678)	
Median Age:	57.5			58.3	
	Number	%		Number.	%
Sex					
Male	646	91.7		625	92.2
Female	58	8.3		53	7.8
Location					
Right	330	46.8		330	48.7
Left	320	45.5		323	47.6
Bilateral	54	7.7		25	3.4
Type of Hernia					
I, II	283	40.2		302	44.6
IIIa, IIIb	367	52.1		345	50.8
IV	54	7.7		31	4.6

Tolerance to local anesthesia was good during surgery in 68% and 67% respectively (NS). The mean duration of surgery was 39 minutes for Lichtenstein and 48 minutes for Desarda group ($p < 0.05$). Analysis of pain scores from day one to day 5 showed no significant difference (Table 3). There was no incidence of severe pain in either group. The recurrence rate was 0.5% in the Desarda group, and

0.4% in the Lichtenstein group (NS). Three patients in the Lichtenstein group required re-exploration and mesh removal for the sepsis. This is significantly higher than the Desarda group ($p < 0.05$) (Table 4). Fifty three (7.5%) of the patients developed post-operative complications in the Lichtenstein group compared to 26 (3.4%) patients in the Desarda group ($p < 0.05$) (Table 5). A total of 89% patients returned to work within 7-15 days in the Desarda group with a mean of 8.26 days as against the 59% of patients in the Lichtenstein group with a mean of 12.58 days ($p < 0.05$) (Table 6). There was no case of chronic groin pain lasting longer than 6 months in either of the groups. Follow up was complete in over 97% at 1 year, 92% at 2 years, 89% at 3 years, 83% at 4 years, 80% at 5 years, 80% at 6 years, 76% at 7 years, 73% at 8 years, 72% at 9 years and 70% at 10 years with no significant difference between the two groups. There was no incidence of severe pain or chronic groin pain in both the groups

Table 2. Anaesthesia and Hospital Stay

Anaesthesia and Hospital Stay	Surgical Technique			
	Lichtenstein Group (n=704)		Desarda Group (n=678)	
	Number.	%	Number.	%
Anesthesia				
Local	273	38.7	490	72.3
Spinal	382	54.3	173	25.5
General	49	7.0	15	2.2
Hospitalization				
Outdoor surgery without hospitalization	273	38.7	490	72.3
Short Term Hospitalization (<3 days)	369	52.5	183	27.0
Long Term Hospitalization (>3 days)	62	8.8	5	0.7

Table 3. Duration of Surgery and Pain

Duration Tolerance and Pain	Surgical Technique			
	Lichtenstein Group (n=704)		Desarda Group (n=678)	
Duration of Surgery				
Average	39 minutes		48 minutes	P< 0.01
	No.	%	No.	%
Pain: Mild to Moderate				
First Day	396	56.2	416	61.3
Up to Third Day	214	30.4	195	28.7
Up to Fifth Day	94	13.4	67	10.0

Table. 4. Repeat Surgery for Sepsis or Recurrence

Lichtenstein Group N 704	3 Mesh removal For sepsis	0.4%	3 Recurrence	0.4%
Desarda Group N 678	NIL	NIL	4 Recurrence	0.5%

Table 5. Postoperative Complications (Morbidity)

Morbidity	Lichtenstein Group (Number = 704)		Desarda Group (Number = 678)		Total (Number =1382)	
	No.	%	No.	%	No.	%
Seroma	12	1.7	5	0.7	17	1.2
Wound Infection	9	1.3	6	0.8	15	1.0
Haematoma	7	1.0	4	0.5	11	0.8
Orchitis	6	0.8	2	0.2	8	0.6
Testicular Atrophy	3	0.4	-	-	3	0.2
Sepsis without Re-exploration	5	0.7	-	-	5	0.4
Sepsis Requiring Re-exploration	3	0.4	-	-	3	0.2
Recurrence	3	0.4	4	0.5	7	0.5
Total	53	7.5	26	3.4	79	5.7

Table 6. Return to Normal Work.No Heavy Work

Patients Returned to Normal Work	Surgical Technique			
	Lichtenstein Group n=704		Desarda Group n=678	
	No.	%	No.	%
1 - 7 Days	12	1.8	24	3.5
8 - 15 Days	407	57.6	579	85.3
16 - 30 Days	285	40.6	75	11.2

Discussion

Mesh repair is now widely used in the developed world and is often referred to as the gold standard despite a relative paucity of clinical trials comparing mesh with suture repair. The cost of surgery⁷ and the post-operative morbidity affecting the quality of life are important considerations in the inguinal

hernia surgery. There are no clear scientific evidences to prove that the mesh prosthetic repair is superior to the non-prosthetic repair in this respect⁸. There are advantages and disadvantages associated with all types of open inguinal hernia repairs. Existing non-prosthetic repair (Bassini/Shouldice) is blamed for causing tissue tension and mesh prosthetic repair is blamed for known complications of a foreign body. Desarda sutures an undetached strip of the external oblique aponeurosis between the muscle arch and the inguinal ligament to give a strong and physiologically dynamic posterior wall⁹. This results in a tension free repair without the use of any foreign body. Being simple to perform, it also eliminates the disadvantage of technical difficulty seen with Shouldice repair. It is also important to note that Desarda was the first to advocate performing the inguinal hernia repair on physiological considerations to give complete cure from hernia.

Different studies have tried to give an answer as to which of the existing operation is best for inguinal hernia repair^{10, 11}. The EU Hernia Trialist collaboration¹² made a systematic revision of the randomized prospective studies and the analysis of the results of these different studies. It showed that the duration of surgery was less in hernioplasty in six studies, longer in three and equal in the remaining six. In this study, the operating time in the Desarda group was slightly more than the Mesh group. Post-operative pain after mesh prosthetic repair may be less than after Shouldice repair because of reduced tension^{12, 13}. Results in the present study have shown that there are no significant differences between the two groups for pain on the first to fifth day after surgery. There was no significant difference in analgesic requirements between the two groups.

General overall morbidity was 5.0% in this study, which is similar to the rates described in other studies (7-12%)¹⁴.

However, the morbidity was higher (7.5%) in the Lichtenstein group as compared to the 3.4% Desarda group. There were 8 mesh infections after surgery in the Lichtenstein group. Two cases required partial excision of the mesh and total excision in one case. Desarda technique has lower morbidity as compared to mesh hernioplasty. There was no significant difference in the recurrence rate seen in both the groups (0.4% v 0.5%). The author believes that the four cases of recurrences seen in Desarda group were due to failure of proper lateralization of the cord and insufficient narrowing of the internal ring as advised by Desarda. This was evident at re-exploration in those cases that needed only narrowing of the internal ring with few more stitches. Post-operative stay and the period required to return to normal work after surgery was also significantly in favour of the Desarda group. 62 patients from Lichtenstein group required to stay for more than 3 days in the hospital due to local wound complications or for some other reasons compared to only 5 patients from the Desarda group, a significant difference. It was also significant that the mean period required for the patients to return to work in the Desarda group was 8.26 days while it was 12.58 days in the Lichtenstein group.

The Authors would make a special mention about the marked difference noted in the type of anaesthetic used, 39% v 72% for local, 54% v 25% for spinal and 7% v 2% for general anaesthetic in Lichtenstein v Desarda group. This could be because of the choice given to the surgeon and the patients. The consultant of mesh group might have influenced and preferred spinal or general anaesthetic over local. This could affect the statistics of hospital stay of the patients who required hospitalization.

The external oblique muscle technique satisfies all criteria of modern hernia surgery. It is simple and easy to do. It does not require risky or complicated dissection. There is no tension in the suture line. It does not require any foreign material and it does not use weak muscle or fascia transversalis for repair. It does not use mesh prosthesis so it is more economical and also avoids morbidity associated with foreign bodies like rejection, infection and chronic groin pain. Szopinski et al¹⁵ stated in their randomized controlled trial (RCT) that the "Desarda technique has the potential to enlarge the number of tissue based methods available to treat groin hernias. The most evident indications for use of the Desarda technique include use in young patients, in contaminated surgical fields, in the presence of financial constraints, or if a patient disagrees with the use of mesh." The author has similar

impression after this study. Situma et al¹⁶ compared Desarda technique with the modified Bassini technique in their RCT and concluded that there is no difference in short-term outcome between Desarda and modified Bassini inguinal hernia repair as regards resumption of normal gait and patterns of pain. Manyilira¹⁷ concluded in their RCT that the efficacy of the Desarda technique in respect of the early clinical outcomes of hernia repair is similar to that of Lichtenstein method. However the operator in this study showed that the Desarda repair takes a significantly shorter operative time. The author feels that this study is only for 100 patients and follow up was also for a short period.

Dr. Desarda's new theory about factors that prevent inguinal hernia formation in the normal individuals:

The authors wish to make a special mention about the new concepts postulated by Desarda about the factors that prevent inguinal hernia formation in the normal healthy individuals.

1. He stated that the posterior wall of inguinal canal is not formed by just transversalis fascia but is formed by two layers, transversalis fascia and the aponeurotic extensions from the Transversus Abdominis Aponeurotic arch.
2. Transversalis fascia is thin and delicate and does not give any protection. Protection is given by the aponeurotic extensions from the Transversus Abdominis Aponeurotic arch.
3. Concepts of the obliquity of inguinal canal or shutter mechanism are not perfect⁹.

The author made a search about the inguinal canal anatomy through books or publications made by stalwarts in this field like Nehus, MacVay etc. and agree to the new concepts described by Dr. Desarda in his publication in BMC Surgery in 2003⁹.

Conclusion

This study has shown that Desarda repair for inguinal hernia gives the same or better results when compared with the Lichtenstein Mesh repair. It can be easily done under local anaesthesia without hospitalization. It has rapid recovery and avoidance of specific mesh related complications. It is technically simpler than the other no mesh repairs like Shouldice repair. The author strongly recommends that all the surgeons get acquainted with this technique.

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