

Original article

TITLE: **Randomized controlled trial comparing open prosthesis repair and Desarda's no mesh repair for inguinal hernia (A study of 836 patients)**

Running title: Open mesh repair and no mesh repair for inguinal hernia, a comparative study

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ABSTRACT

The objective of this study is to compare the results of open mesh prosthesis repair and Dr. Desarda's no mesh repair for inguinal hernia.

Methods: This is a prospective study of 836 patients having 868 hernias operated from September 2001 to December 2007. 424 operations were operated using mesh and 412 using the Desarda repair. Data of hospital stay, intra-operative complications, ambulation, pain, cost and postoperative early and late complications were recorded and compared. Follow up period was 6 months to 80 months (mean 4.3 years).

Results: The mean stay in the Desarda repair was 9 hours while it was 24 hours in the mesh group. There were 13 complications in the Desarda repair while there were 32 complications in the mesh group. There was one recurrence seen with the Desarda repair while there were 3 recurrences and 3 explorations for sepsis in the mesh group. At the end of 1 year there were 28 patients who had chronic groin pain in mesh group while there was no incidence of chronic groin pain in the Desarda repair. Mean period of return to work was 8.26 days in Desarda group and 12.58 days in the mesh group. The cost of surgery was significantly in favour of Desarda repair.

Conclusions: The results of the Desarda repair look very promising. This repair has minimal complications. It does not use any foreign body like mesh prosthesis for repairs and therefore it has no known complications as seen with the prosthetic repairs. It scores significantly over the prosthetic repairs in all respects including the cost of surgery. Desarda repair is a better choice as compared with mesh prosthetic repairs.

Key words: Inguinal hernia, open repair, Desarda repair, mesh repair, district hospital

INTRODUCTION

The surgeons use different techniques for inguinal hernia repair like Bassini and its modifications, modified Shouldice or repairs with different mesh prostheses in our country. The standard mesh is not available at many places and it is expensive also.⁽¹⁾ Hernia treatment has become a health problem because of its economical and labour implications due to its high incidence in the population.⁽²⁾ Parameters like cost, post surgery well being and quality of life have gained importance in addition to recurrence, complication rates, etc. The demand of general surgeons is to find a surgery that is simple, without any complicated dissection or the use of foreign body like a mesh and also gives a recurrence rate of less than 1% without any major complications.

The author read about the Dr. Desarda repair⁽¹⁾, which does not use mesh and gives the desired results also. 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 dynamic.

There are still many controversies to answer. Which is the best technique for repair?⁽³⁾ Is hernioplasty better or herniorrhaphy? Which is the best technique for hernioplasty? Does laparoscopic surgery have a better cost-efficiency ratio than open surgery? The objective of this study is to give answer to some of these questions, mainly as regards the evaluation of post-operative complications and the cost for prosthetic and non prosthetic techniques of open inguinal hernia repair.

METHODS

A prospective study was carried out in consecutive 836 patients (424 prosthesis hernioplasty and 412 Desarda's herniorrhaphy) having 868 hernias, operated from September 2001 to December 2007. The randomization was done by sealed envelope method. The design was blind for the patient. The evaluator was a fixed surgeon of consultant level for each group. All patients from both sexes older than 16 years with primary and recurrent inguinal hernias were included. Patients operated on emergency basis were excluded. All the patients signed a written informed consent.

The surgical techniques used were as described by Dr. Desarda and mesh prosthesis repair as described in the text books. Prophylactic antibiotic was administered in the operating room before surgery (Gentamicine 80 mg and Metronidazol 500 mg) in those cases where mesh prosthesis was used. All patients were instructed on discharge to do daily routine non-strenuous work. Non-steroid anti-inflammatory (Diclofanac) analgesic was given in twice a day dose for a period of 5 days and later as demanded. All the patients were followed by the consultants after 8 days, 1 month, 6 months and then yearly. A protocol to collect data was prepared including different variables for age, location, sex, type of hernia (Nyhus classification) ⁽⁴⁾, anesthesia, hospitalization, duration of operation, magnitude of pain on first, third and fifth day after surgery according to a numeric verbal scale ^(5,6), chronic groin pain, complications, recurrence, re-explorations and the cost. The SPSS software was used for all statistical analysis.

RESULTS

There was no significant difference in relation to sex, age, location and type of inguinal hernia in both the groups. (Table No. 1). Local anesthesia was used in 173 patients in prosthesis group and 367 patients in the Desarda group. All those 540 (64.4%) patients were operated on an outdoor basis without hospitalization. The mean hospital stay in Desarda group was 9 hrs while it was 24 hours in the mesh group. (Table No. 2) Tolerance was good during surgery under local anaesthesia in 68% and 67% respectively in both the groups. The mean duration of the surgical procedure from skin to skin was 39 minutes for prosthesis group and 36 minutes for Desarda group ($p>0.05$). Analysis of pain through verbal scale did not show any significant difference (Table no. 3). There was no incidence of severe pain in both the groups. The recurrence rate was 0.2% in Desarda's group, and 0.7% in the prosthesis group. In addition, 3 patients required re-exploration and mesh removal for the sepsis in the prosthesis group. Thus 1.4% of patients in the prosthesis group required surgical intervention for recurrence and sepsis together, which was much higher than the Desarda group (Table No. 4). 32 (7.5%) patients showed complications in the prosthesis group while 13 (3.0%) patients showed complications in the Desarda group which was significant ($p<0.05$) (Table No. 5). 95% patients returned to work within 7-12 days in the Desarda group with a mean of 8.26 days while 91% patients returned to work within 7-20 days with a mean of 12.58 days in the prosthesis group which was significant ($p<0.05$). No patient had discomfort for more than 15 days in the Desarda repair, where as, in the mesh group, 8 patients had moderate pain and 30 patients had mild pain or discomfort at the end of 1 month; 4 patients had moderate pain while 28 patients had mild pain/ discomfort at the end of 6 month and 28 patients continued to have mild pain or discomfort at the end of 1 year.

DISCUSSION

Inguinal hernia is a very common condition for which surgical intervention is required. Newer techniques are developed as the complication rate of older ones become unacceptable. The Lichtenstein technique and its modifications are widely practiced in the world but their complication rates and failures are more in the hands of non-consultant staff. Mesh repair, plug repair, plug and mesh repair or recently introduced PHS have all confused what is best and what to follow in the minds of such surgeons.

The cost of surgery ⁽⁷⁾ 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.^(8,9) There are advantages and disadvantages with both types of traditionally done open inguinal hernia repairs. Existing non prosthetic repair (Shouldice) is blamed for sutures under tension and mesh prosthetic repair is blamed for known complications of a foreign body. Dr. 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 wall. ⁽¹⁰⁾ This makes this repair tension free without use of any foreign body. This eliminates disadvantages seen with Schouldice repair and all types of mesh prosthetic repairs as well.

In this present study of 836 patients, the new method of hernia repair described by Dr. Desarda seems to be superior to the open mesh method on many counts. Both the groups are statistically similar with regards to age, sex, and co morbid conditions. The hospital stay, postoperative pain, complications and the time taken for the patient to return to work are all significantly less in the Desarda repair compared to the mesh repair. Chronic groin pain affects the quality of life of the

patients. Since quality of life is an important consideration after any surgery this new method of hernia repair described by Dr.Desarda seems to score over the mesh repair on this count also.

Different studies have tried to give an answer as to which of the existing operations is the best for inguinal hernia repair. ^(11, 12) The EU Hernia Trialist collaboration ⁽¹³⁾ made a systematic revision of the randomized prospective studies and the analysis of the results of these different studies showed that the duration of surgery was less in hernioplasty in six studies, longer in three of them and there was no specification in other six. There are no significant differences in the duration of surgery between the two techniques in this study also. The post operative pain in mesh prosthetic repair is less than Shouldice repair because it is tension free. ^(13, 14) The results of this study have shown that there are no significant differences between the two techniques in the valuation of pain during the first week after surgery. There are no significant differences between both techniques as far as amount and mode of analgesic requirement is concerned. But, the incidence of chronic groin pain is significantly higher in the mesh prosthesis group. Morbidity in general was 5.0%, which is similar to the rates described in the other studies (7-12%).⁽¹⁵⁾ The complication rate was higher in the prosthetic group (32 cases, 7.5%) as against 13 (3%) in the Desarda group. There were a total of 3 mesh infections after 5-7 month of surgery. All three cases required surgical intervention.

This new technique of inguinal hernia repair is easy to learn and does not require complicated dissection. As the steps in this surgery are fixed there is very less scope for modification by individual surgeon. Hence even in the hand of junior surgeons this technique will prove to be very effective. Moreover, the new technique of hernia repair does not need any costly mesh or laparoscopic instruments. This makes this repair highly cost effective. A cost effective repair that gives excellent results will go a long way in reducing health care cost in those days of cost

ergonomics. Recently, Dr. Desarda has introduced repair of all layers by the absorbable PDS II No.1 (Ethicon) continuous sutures.⁽¹⁶⁾ This saves time and one packet of suture material, reducing the operative cost further. This new method of hernia repair described by Dr Desarda is based on physiological principle. The posterior wall of the canal is made up of the transversalis fascia, which is strengthened medially by the falx inguinalis or edge of rectus and more laterally by the aponeurotic extensions from the transversus abdominis arch that make the posterior wall strong. But these aponeurotic extensions are absent or deficient in 53% of the population.⁽¹⁰⁾ Strong musculo-aponeurotic structures around the inguinal canal still give protection to prevent the herniation in such individuals. This protection is lost if those muscles are also weak. The weak and physiologically a-dynamic posterior wall of inguinal canal in such individuals leads to hernia formation.⁽¹⁾

CONCLUSIONS: We have seen the same satisfactory or even better results with Dr. Desarda herniorrhaphy as compared to the mesh hernioplasty in this prospective randomized controlled study. It saves the cost of surgery and also saves on the working man hours due to less morbidity in the postoperative period. Therefore, we recommend the training of surgeons (specialists-residents) in the Dr. Desarda technique in all the hospitals.

REFERENCES

- 1- Desarda MP. Inguinal herniorrhaphy with an undetached strip of external oblique aponeurosis: a new approach used in 400 patients. *Eur J. Surg.* 2001; 167:01-06.
- 2- Rutkow MI. Epidemiologic, economic and sociologic aspects of hernia surgery in the United States in the 1900s. *Surg. North Am* 1998; 78:941-51.
- 3- Porrero JL, et al. Reparación de la hernia inguinal primaria: Lichtenstein frente a Shouldice. Estudio prospectivo y aleatorizado sobre el dolor y los costos hospitalarios. *Cir Esp.* 2005; 77(2): 5-8.
- 4- Aragon FJ. Nuevas técnicas protésicas para el tratamiento de la hernia inguinal. Ediciones Avila. 2001; p. 22-23.
- 5- Price DD, Bush FM, Long S, Harkins SW. A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. *Pain.* 1994; 56:217-26.
- 6- Porrero JL, Sanchez-Cabezudo C, Lee P. Study of unilateral post-herniorrhaphy analgesia with local anaesthetic and monitored anaesthesia care. *Ambulatory Surg* 1998; 6:211-4.
- 7- Costos hospitalarios. Comunicación personal. Departamento económico. Hospital Enrique Cabrera. Enero. 2005.
- 8- Porrero JL. El cambio de la cirugía de la hernia en la última década. En: Celdran A, De la Pinta JC, editores. *Fundamentos de la hernioplastia sin tensión*. Madrid: Fundación Jiménez Díaz: 1999. P. 9-11.
- 9- Scott N, Go PMNYH, Graham P, McCormack K, Ross SJ, Grant AM. Open Mesh versus non-Mesh for groin hernia repair. *Cochrane Database of Systematic Reviews* 2002, Issue 4. Art. No.: CD002197.

- 10- Desarda MP. Surgical physiology of inguinal hernia repair-a study of 200 cases. *BMC Surgery* 2003; 3:1-9.
- 11- Simons MP, Kifignen J, Van Geldere D, Hoitsma HFW, Obertop H. Role of the Shouldice technique in inguinal hernia repair: a systematic review of controlled trials and meta-analysis. *Br J Surg* 1996; 83:734-8.
- 12- Mc Gillicuddy JE. Prospective randomized comparison of the Shouldice and Lichtenstein hernia repair procedures. *Arch Surg* 1998; 133: 974-8.
- 13- EU Hernia Trialist Collaboration. Mesh compared with non-mesh methods of open groin hernia repair: systematic review of randomized controlled trials. *Br J Surg* 2000; 87: 854-9.
- 14- Kingsnorth AN, Porter Chs, Bennett DH, Walker AJ, Hyland ME, Sodergren S. Lichtenstein patch or prefix plug and patch in inguinal hernia: a prospective double-blind randomized controlled trial of short-term outcome. *Surgery* 2000; 127: 276-83.
- 15- Gilbert AI, Felton IL. Infection on inguinal hernia repair considering biomaterials and antibiotics. *Surg Gynecol* 1993; 117: 126-30.
16. Desarda MP. No-mesh inguinal hernia repair with continuous absorbable sutures: A dream or reality? (a study of 229 patients). *Saudi J Gastroenterol* 2008;14:122-7

LEGENDS

Table no. 1. Age, sex, location and type of hernia

Age sex location	Surgical technique			
	Prosthesis Hernioplasty n=424		Desarda Herniorrhaphy n=412	
Average Age:	57.5		58.3	
////////////////////	No.	%	No.	%
Sex				
Male	395	99.1	384	93.2
Female	29	6.9	28	6.8
Location				
Right	206	48.5	202	49.0
Left	200	47.3	196	47.6
Bilateral	18	4.2	14	3.4
Type of Hernia				
I, II	186	43.8	204	49.5
IIIa, IIIb	196	46.2	186	45.1
IV	42	10.0	22	5.4

Table no. 2. Anesthesia and hospital stay

Anesthesia and hospital stay	Surgical technique			
	Prosthesis Hernioplasty n=424		Desarda Herniorrhaphy n=412	
////////////////////	No.	%	No.	%
Anesthesia				
Local	173	41.0	367	89.0
Spinal	237	56.0	45	11.0
General	14	3.0	-	-
Hospitalization				
Out door surgery without hospitalization	180	42.4	370	90.0
Short Term Hospitalization (1-3 days)	237	56.0	42	10.0
Long Term Hospitalization (more than 3 days)	7	1.6	-	-

Table no. 3. Duration of surgery and pain

Duration of surgery and pain	Surgical technique			
	Prosthesis Hernioplasty N=424		Desarda Herniorrhaphy n=412	
Duration of surgery:				
Average	39 minutes		36 minutes	
////////////////////	No.	%	No.	%
Pain: Mild to moderate				
First Day	227	54.0	248	60.0
Up to Third Day	131	31.0	119	29.0
Up to Fifth Day	66	15.0	45	11.0

There was no incidence of severe pain in both the groups

Table no. 4. Recurrence and re-exploration

Prosthesis Hernioplasty	3 Mesh removal For sepsis	3 Recurrences	1.4%
Desarda Herniorrhaphy	-	1 Recurrence	0.2%

Table no. 5. Morbidity

Morbidity	Surgical technique					
	Prosthesis Hernioplasty n=424		Desarda Herniorrhaphy n=412		TOTAL n=836	
////////////////////	No.	%	No.	%	No.	%
Seroma	8	1.9	2	0.4	10	1.1
Mild infection	6	1.4	4	1.0	10	1.1
Hematoma	4	0.9	2	0.5	6	0.7
Orchitis	4	0.9	1	0.2	5	0.6
Testicular atrophy	2	0.5	-	-	2	0.2
Chronic Suppuration	3	0.7	-	-	3	0.3
Bradycardia	2	0.5	3	0.7	5	0.6
Recurrence	3	0.7	1	0.2	4	0.4
TOTAL	32	7.5	13	3.0	45	5.0