

Desarda Technique Versus Lichtenstein Mesh Repair for the Treatment of Inguinal Hernia A Short-Term Randomized Controlled Trial

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Abstract

Background: Several techniques of tissue and mesh repair for inguinal hernia have been developed over the last decades but still drawbacks are present. Desarda, who has used a new technique since 1990, seeks to get over the challenges faced with the use of the tissue repair and mesh repair techniques. It is based on the concept of providing a strong, mobile and physiologically dynamic posterior inguinal wall. This study is attempt to establish the influence of this new technique on early clinical outcomes of inguinal hernia repair, and if proved to be effective it will be a basis for the promotion of its use in Egypt.

Aim: To compare the short-term outcome of the Desarda's repair with the Lichtenstein technique for the treatment of primary inguinal hernias among adult patients at Assiut University Hospital.

Patients and Methods: The study was a single-center, randomized controlled trial. It was carried out at general surgical outpatient clinic in Assiut University Hospital. Which is the main teaching hospital for Assiut University Faculty of Medicine from March 2013 and February 2015.

Results: Males constituted 100% of the subjects, the majority (61%) had inguinal hernias on the right side. (73%) indirect hernias, direct hernia in Lichtenstein arm (35%) more than in Desarda arm (8%).

Conclusion: The Desarda repair was shown to take a significantly shorter operative time than the Lichtenstein repair and it can safely be employed as one day case surgery and in district hospitals.

Recommendations: Further larger clinical trials are needed for comparing the Lichtenstein and Desarda methods to generalize the results through at regional and district hospitals in Egypt in addition to encourage continuing medical education and to acquire skills to do the desarda method of inguinal hernia repair.

Key Words: *Inguinal hernia – Mesh – Lichtenstein – Desarda.*

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Introduction

WIDESPREAD and easily tolerated, the inguinal hernia is seen as a minor disorder. Because hernia surgery may be performed easily and successfully in both in-and out-patient environments it is too often dismissed as a trivial complaint. On the other hand, in many countries it is considered a specialization. Unless inguinal hernia is treated properly, in fact, it may turn out to be very disabling.

Furthermore, international statistics show that recurrences exceed the 10% mark. This means high social costs. The fact that the solution to the problem is by no means straight forward is reflected in the existence of about 80 techniques, of which over 20 are currently in use.

Prof. Desarda of India has used a newly developed technique since 1990, seeking to get over the challenges faced with the use of the tissue repair and mesh repair techniques. It is based on the concept of providing a strong, mobile and physiologically dynamic posterior inguinal wall. The technique is simple, easy to learn and do. It does not require complicated dissection or suturing. There is no tension on the suture line. It does not require any foreign material and does not use weakened muscles or transversalis fascia for repair. The results are superior to those previously published in the field of hernia surgery [2-3].

The effectiveness of the Desarda technique has not been well investigated. There are no sufficiently large data from randomised comparative studies to consult. There are reports of its excellent results from the ongoing clinical trials in Poland, Cuba, South Korea, Albania and India [2]. The surgical

treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. It has been said that the history of groin hernias is the history of surgery itself [4]. Despite the frequency of this procedure, no surgeon has ideal results, and complications such as postoperative pain, nerve injury, infection, and recurrence continue to challenge surgeons [1], the true incidence of hernias is unknown. Approximately 75% of all hernias occur in the inguinal region. Two thirds of these are indirect, and the remainder are direct inguinal hernias.

Desarda's repair:

Factors that are said to prevent herniation are not restored in the traditional techniques of inguinal hernia repair and yet 70-98% of patients are cured [3]. The problem of our age is to find an operation that is simple, does not require implantation of a foreign body like a mesh, has a recurrence rate of less than 1-2% and does not produce major complications during or after surgery in the hands of non-consultant staff [2]. In Desarda's repair the newly formed posterior wall is kept physiologically dynamic by the additional muscle strength provided by external oblique muscle to the weakened muscles of the muscle arch. This new method of inguinal hernia repair is based on physiological principles [3].

Comparison of Desarda and Lichtenstein repairs, and other comparative studies:

There are no comparative studies involving Desarda's and mesh repairs that have been carried out in Egypt. However reports from other parts of the world indicate the increasing interest in the Desarda' repair method. Clinical trials are being conducted to compare this new method and the mesh repair techniques [2]. Therefore the current study can build the following hypotheses.

H0: (Null hypothesis): The mean pain score (on the 3rd and 7th postoperative day), or the mean postoperative day of return to normal gait is the same in adult patients who undergo the Desarda's repair as in those who undergo the Lichtenstein technique of hernia repair at Assiut University Hospital.

H1 (hypothesis): The mean pain score (on the 3rd and 7th postoperative day), or the mean postoperative day of return to normal gait is different in adult patients who undergo the Desarda's repair from what it is in those who undergo the Lichtenstein technique of hernia repair at Assiut University Hospital.

Based on the previous studies, our current study tries to answer the following research question: Is there a difference in the short-term outcome of the Desarda's repair compared to the Lichtenstein technique for the treatment of primary inguinal hernias among adult patients at Assiut University Hospital?

Aim of work:

To compare the short-term outcome of the Desarda's repair with the Lichtenstein technique for the treatment of primary inguinal hernias among adult patients at Assiut University Hospital.

Patients and Methods

This study is a single-center, randomized controlled trial carried out at the General Surgical Outpatient Clinic in Assiut University Hospital, which is the main teaching hospital of Assiut University Faculty of Medicine from March 2013 and February 2015.

- Target population:

All adult patients with groin hernias who sought treatment at the General Surgery Department (Unit B1), Assiut University Hospital during the study period.

- Study population:

All adult patients who presented to the outpatient clinic with a primary, reducible inguinal or inguinoscrotal hernia.

Inclusion criteria:

- Participants with a primary, uncomplicated inguinal hernia, adult males.
- Signed informed consent.
- Good condition of external oblique aponeurosis (assessed during the operation).

- Exclusion criteria:

Age less than 18 years, impaired mental state, complicated inguinal hernia and recurrent inguinal hernia.

Sampling procedure:

Patients with inguinal hernias seen in the outpatient clinic were interviewed and clinical assessment made by the Principal Investigator (PI). The surgery is run by a general surgical professor who is assisted by an assistant lecturer, senior resident, intern doctors and nursing officers.

Screening for suitability for surgery included history taking, physical examination, requesting for and reviewing the laboratory tests. This was aimed at recording the key research variables and major co-morbidities. Those who did not satisfy the inclusion criteria and had other medical problems were offered the routine care given to all patients in outpatient clinic.

Preparation:

The visual analogue scale for pain assessment was carefully explained to each participant. The participant was then shaved and emptied the urinary bladder where necessary. Then the patient was asked to lie supine on the operating table. Amoxicillin-Clavulanate 1.2g was administered intravenously in the beginning of operation. The participant's abdomen and inguinal areas were prepared using povidone-iodine solution and Isopropyl Alcohol 75% from the subcostal transverse line to the mid-thigh. All patients received Spinal anesthesia.

Herniotomy:

The groin skin crease (transverse) incision measuring between 7.5cm and 10cm was employed in every participant, starting 2cm above and lateral to the pubic tubercle. The External Oblique Aponeurosis (EOA) was incised in the line of its fibres, starting at the superficial ring to about 2cm laterals to the deep inguinal ring. Care was taken not to damage the ilioinguinal and iliohypogastric nerves just beneath the aponeurosis.

The spermatic cord was mobilized by placing a finger around the cord at the level of the pubic tubercle. The fascial layers of the cord were picked up between two artery forceps, and a dissecting scissor was used to split open these layers over the anteromedial aspect of the cord. The sac was then identified and dissected free from the cord structures with a combination of sharp scissor dissection and blunt dissection by gauze stripping, and cleared to the level of the deep ring. The freed cord was drawn away from the field using Ali Pasha ring forceps. The hernia sac was then opened and the visceral contents examined and manually reduced.

Traction using three haemostats applied to the opened margins of the sac bringing the deep inguinal ring and the neck of the hernial sac into view. The sac was then transfixed and ligated with atraumatic Vicryl 2/0 suture. While for the sliding hernia, the cut edges of the peritoneum were repaired by a continuous atraumatic mounted on 2/0

Vicryl suture after reducing the viscus back into the abdominal cavity.

The excess sac was excised about 1cm distal to the ligature, and the cut edges checked for haemostasis before the sac was dropped back behind the internal ring in the transversalis fascia and if the sac was adherent onto or continuous with tunica vaginalis, was left in-situ. The repair was then embarked on.

Ethical consideration:

All official permission letters taken from director of the Surgery Department before start in the data collection. The study purpose and treatment were carefully explained to the patients individually. Then they were consented to participate in the study. They were allowed to ask questions freely to ensure that they had understood.

Results

The baseline demographic characteristics of the study population shows, males constituted 100% of the subjects in this study. The median age of the study subjects at 43 years, the Min.-Max. range 18-82. 28/52 (53%) of the subjects had overweight Body Mass Index (BMI). Whereas 24/52 46% had normal BMI. Manual laborers, mainly farmers constituted the vast majority of study subjects (48%) (Table 1).

Table (1): Baseline demographic characteristics of the study population.

Factor	Summary measure N	Percent
<i>Gender:</i>		
Male	56	100
Female	0	
<i>Age:</i>		
<20	3	5.7
20-29	9	17.3
30-39	9	17.3
40-49	12	23
50-59	10	19
>60	8	15
<i>Occupation:</i>		
Nonphysical	10	19
Light physical	12	23
Heavy physical	25	48
None or retired	5	9.6
Smoker	32	61
<i>BMI:</i>		
Under-weight (<20)	0	
Normal (20-25)	24	46
Overweight (26-30)	28	53
Obese (30-35)	0	
Morbid obese (>35)	0	

More than 59% of the participants presented to Assiut University Hospital with hernias that had lasted for less than 60 months (5 years). The majority (61%) had inguinal hernias on the right side. There was 38/52 (73%) indirect hernias and 2/52 (5%) participants with pantaloona hernia (Table 2).

Table (2): Baseline clinical characteristics of the study population.

Factor	Summary measure N	Percent
Duration of Hernia (months):		
<60	31	60
>60	21	40
Hernia location:		
Right side	32	62
Left side	20	38
Hernia type:		
Indirect	38	73
Direct	12	25
Dual (pantaloona hernia)	2	5

The distribution of both baseline demographic characteristics as well clinical characteristics was similar in the two interventions with no statistically difference in both groups ($p < 0.05$). There were noticeably more participants with direct hernia in Lichtenstein arm 10/28 (35%) than in Desarda arm 2/24 (8%) (Tables 3,4).

Table (3): Comparison of baseline characteristics of study groups and comparison of demographic characteristics.

Factor	Lichtenstein (N=28)	Desarda (N=24)	p-value
Gender:			
Male	28	24	
Female	0	0	
Age:			
<20	3	0	
20-29	4	5	
30-39	5	4	0.565
40-49	5	7	
50-59	5	5	
>60	5	3	
Occupation:			
Nonphysical	6	4	
Light physical	10	8	0.903
Heavy physical	10	9	
None or retired	2	3	
Smoker	15	17	
Non smoker	13	7	0.202
BMI:			
Under-weight (<20)	0	0	
Normal (20-25)	12	10	
Overweight (26-30)	16	14	0.945
Obese (31-35)	0	0	
Very obese (>35)	0	0	

The distribution of baseline demographic characteristics was similar in the two intervention arms and the differences were not statistically significant ($p > 0.05$).

Table (4): Comparison of clinical characteristics.

Factor	Lichtenstein (N=28)	Desarda (N=24)	p-value
Duration of Hernia (months):			
<60	7	14	1.00
>60	11	10	
Hernia location:			
Right side	16	16	0.572
Left side	12	8	
Hernia type:			
Indirect	17	21	
Direct	10	2	0.0646
Dual	1	1	

Regarding the operative time, the Lichtenstein repair took longer to accomplish-a difference of 10 minutes compared to the Desarda repair and the differences was extremely statistically significant ($p = 0.0001$) (Table 5).

Table (5): Comparison of operative time.

Factor	Lichtenstein (Mean \pm SD)	Desarda (Mean \pm SD)	p-value
Operative time (min)	44.21 \pm 4.54	33.541 \pm 2.78	0.0001

The primary outcome of the patients as well the length of hospital stay demonstrated in both Tables (6,7), there was generally no significant statistical difference in mean pain scores at the three time points between the two intervention groups ($p > 0.05$).

The difference of the mean day of return to normal gait between the groups was not statistically significant ($p = 0.0548$).

Table (6): Summary of primary outcomes.

Factor pain score (VAS)	Lichtenstein (Mean \pm SD)	Desarda (Mean \pm SD)	p-value
• First day	3.60 \pm 1.54	3.16 \pm 0.963	0.232
• 3rd day	1.42 \pm 0.959	1.12 \pm 0.946	0.258
• 7th day	0.78 \pm 0.832	0.58 \pm 0.503	0.304
• Days taken to return to normal gait	1.60 \pm 0.916	1.20 \pm 0.414	0.0548

Table (7): Comparison of hospital stay.

Factor	Lichtenstein	Desarda	p-value
• Outdoor surgery without hospitalization	0	0	
• Short term hospitalization (<2 days)	26	23	0.646
• Long term hospitalization (>2 days)	2	1	

Discussion

Inguinal hernia is a common surgical problem in Assiut University Hospitals. The need to find an efficient, safe but simple and affordable method of hernia repair provided the basis for this study. This study was designed to establish the short-term clinical outcomes of hernia repair using the Desarda's technique (a non-mesh tissue-only repair) which is acclaimed to be able to restore the normal physiology of the inguinal canal as compared to the mesh-based repairs. It is also reported to be free of common postoperative complications normally associated with mesh repairs and other tension tissue repairs such as the Lichtenstein and modified Bassini methods respectively.

In this study there was no statistically significant difference between the Desarda and Lichtenstein methods as regard to acute postoperative pain scores; time to resumption of normal gait (ability to move freely, bend, squat, stoop, walk up a few stairs, or carry light weights of about 5kg); and perioperative complications. However, a significant difference as regard to operative time was observed in this study ($p=0.0001$).

Demographic and clinical characteristics:

The median age of the participant of this study at presentation is 43 years (min.-max.: 18-82). The body-mass index was either normal or over weight. Neither obese nor underweight patient participated in the study. Occupation of the participants in this study was mainly 71% physical (light or heavy) due to the nature of work in our community that depend on manual labour.

Right side hernia constituted 62% of the 56 inguinal hernia, indirect hernias constituted 71% at Assiut University Hospitals. We found only 2 (3.5%) pantaloons hernia of the 56 inguinal hernias.

The distribution of the demographic and clinical characteristics in the two intervention arms of this study was similar. This implies that the process of randomization was accurate, and that any influence of these variables on the key outcomes of surgery was similarly distributed in the two study arms.

Assessment of pain:

Pain was scored on a visual analogue scale of 0 to 10. The pain experienced by the participants in the two study arms was similar at the three time points (first day, 3rd day, 7th day). The mean pain score was highest on the first postoperative day (POD) in both arms. The overall trend showed lower scores among the Desarda group, but this was not statistically significant ($p=0.235$). The

highest pain score among mesh arm was 7 and the lowest was 3 while the highest score among Desarda arm was 5 and the lowest 2. In this study the mean pain scores on the first POD were 3.60 ± 1.54 for Lichtenstein and 3.16 ± 0.963 for Desarda and on the 3th POD were 1.42 ± 0.959 for Lichtenstein and 1.12 ± 0.946 by the 7th POD the pain scores decreased dramatically or disappeared totally and the mean pain scores for the mesh arm was 0.78 ± 0.832 while in Desarda arm was 0.58 ± 0.503 . By the 10th POD the pain scores were 0 except in the 3 cases reported in the complication as groin pain which was neurogenic in nature due to nerve entrapment.

The similarity in pain scores in the study arms possibly confirms that the Desarda repair, as acclaimed by its inventor and others, is indeed a tension-free tissue repair. That the participants in this study experienced more pain on the first POD, it is recommended that we can use local analgesia like lidocaine infiltration to control pain on the first day after hernia surgery. The relatively low pain scores on 3th and 7th POD was most likely achieved by the analgesic effect of Diclofenac 75mg given to all participants at regular doses. It is interesting to note that 5 subjects in the Lichtenstein group reported neuropathic type of pain (due to nerve injury or entrapment), only one participant developed similar pain in Desarda group on the 10th POD. This difference was however not statistically significant. All these participants had experienced complete remission of pain by the 14th POD.

In comparison with other studies such as Rodriguez et al., [9], it showed the same result that there is no significant differences regarding pain, but the study that has been conducted by Szopinski et al., [10], showed significant differences in chronic pain that experienced by 4.8 and 2.9% of patients from groups Desarda and Lichtenstein, respectively ($p=0.464$).

Complications:

There was no significant difference between the two study arms with regard to intra-operative and postoperative complications. The commonest complication in this study was scrotal edema [five (17%) in the Lichtenstein repair and three (12.00%) in the Desarda's repair] and groin pain and numbness. There were no wound site hematomata or infection. These complications were successively managed conservatively.

Wound sepsis was not observed in this study. Intravenous injection of (Amoxicillin + Clavulan-

ate) 1.2g was administered to patients at the start of operation in this study. This may, though not exclusively, explain the absence of wound sepsis in this series also attention was paid to the routine infection control.

Severe adverse events:

The absence of adverse events in this study demonstrates that both Desarda and Lichtenstein methods can safely be employed in theatres in resource constrained district hospitals.

The study conducted by Rodriguez et al., [6], showed that 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 study done by Szopinski et al., [7,8], showed two recurrences observed in each group ($p=1.000$) and there was significantly less seroma product; the Desarda group ($p=0.004$).

Conclusions:

This study has shown that the efficacy of the Desarda technique in respect of influencing the short-term outcomes of hernia repair is comparable to those of Lichtenstein method. In the operator's hands, the Desarda repair was shown to take a significantly shorter operative time than the Lichtenstein repair. The Desarda and Lichtenstein methods can safely be employed as one day case surgery and in district hospitals. The null hypothesis of the study was indeed true, and it is therefore accepted.

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الملخص العربي

مقدمة: هناك طرق متعددة ومختلفة لاصلاح الفتق الاربى اما عن طريق استخدام الانسجة الطبيعية او باستخدام الشبكة الجراحية ومع كثرة الطرق المختلفة ما يزال هناك بعض المشكلات. بروفيسور ديساردا الهندي الجنسية قد استخدم طريقة مختلفة لاصلاح الفتق الاربى بالانسجة الطبيعية لتقوية الجدار الخلفى للمنطقة الاربية منذ عام ١٩٩٠. تهدف هذه الطريقة المبتكرة الى تفادى المشكلات الناتجة عن استخدام الانسجة الطبيعية ومقارنة نتائجها باستخدام الشبكة الجراحية التى لا تزال لها بعض العيوب فى اصلاح الفتق عن طريق الشق الجراحى. هذا البحث يهدف الى تقييم هذه الطريقة الجديدة على مرضى الفتق الاربى ومدى جدواها الجراحى على المدى القصير والبعيد لمرضى الفتق الاربى من مصر ايضا.

الهدف من البحث: مقارنة النتائج الجراحية القصيرة المدى من حيث الالم والمضاعفات ما بين استخدام الشبكة الجراحية بطريقة ليختنشتين وبين طريقة ديساردا المبتكرة فى علاج الفتق الاربى للبالغين فى مستشفيات جامعة اسيوط.

خطة البحث: تم اختيار مجموعة المرضى الخاضعين للدراسة من اللذين يعانون من الفتق الاربى من الناحية الواحدة، الا يكون الفتق مصحوب بمضاعفات مثل الاختناق، ان يكون العمر فوق ١٨ عام وان لا يكون الفتق مرتجع.

تم جمع المعلومات اللازمة من المرضى وتصنيف الفتق واختيار الطريقة التى سيتم بها اصلاح الفتق ليختنشتين او ديساردا.

النتائج: اظهرت النتائج عدم وجود فروق ذات اهمية احصائية ما بين الطريقتين من حيث الالم والمضاعفات الناتجة بعد الجراحة وان كان الالم اقل فى طريقة ديساردا من الناحية الاكلينكية وليست الاحصائية. اما من ناحية الوقت المستهلك فى اجراء الجراحة فقد كان اقل باستخدام طريقة ديساردا وكان الفارق فى الوقت له دلالة احصائية ما بين الطريقتين. وقد كانت النتائج العامة النهائية تشير انه لا يوجد فرق جوهري ما بين الطريقتين من حيث الالم والمضاعفات باستثناء الوقت وهو ما يشير الى الاحتياج الى متابعة المرضى على المدى البعيد لمعرفة اذا كان هناك اختلافات اخرى قبل اعتماد طريقة ديساردا كبديل لطريقة ليختنشتين لتجنب مضاعفات استخدام الشبكة الجراحية كجسم غريب قابل للالتهابات واطالة فترة التماثل للشفاء.