

To
The Director,
Research Training and Monitoring Cell,
College of Physicians and Surgeons, Pakistan,
7th Central Street, Phase-II,
Defense Housing Authority,
Karachi -75500.

Dear Sir,

Enclosed here with please find research protocol titled: **Comparison of Desarda and Lichtenstein mesh plasty in inguinal hernia repair** Prepared by **Dr. Liaquat Ali Khan**, TMO General Surgery, **Saidu Teaching Hospital Swat** as a prerequisite for FCPS-II in General Surgery.

Date of submission of research protocol: *****

RTMC Registration Number: SGR-2012-027-6065

Enrolment Number: 102061

FCPS-I Roll Number: F-09-15314

Year and Month of passing FCPS-1: November 2012

Trainee's Signature _____

Name of Supervisor: Dr. Manzoor Ali

Qualification: MBBS, FRCS

Designation: **Professor, Head of Department,**

Department: **General Surgery,**

Training Institute: Govt. Saidu Teaching Hospital Saidu Sharif Swat.

Supervisor's Signature

Official Stamp _____

Yours Sincerely,

Dr. **Liaquat Ali Khan**

T.M.O General Surgery,

Ayub Teaching Hospital, Abbottabad.

Comparison of Desarda and Lichtenstein mesh plasty in inguinal hernia repair

INTRODUCTION

Inguinal hernia is among the most common problems encountered by general surgeons and may have significant complications. Globally, inguinal hernia is the most common type of hernia, comprising of approximately 75% of all abdominal wall hernias.¹

It is more common in men and in the age group above 50 years. Of the inguinal hernias, the most common are the indirect. They are predominantly unilateral and at the right side. The bilateral are rarer (affecting about 12% of patients), the direct and the combined ones being more frequent than the indirect.²

Inguinal hernia repair is one of the most common general surgical operations worldwide accounting for 10 to 15% of all surgical procedures and is the second most common surgical procedure after appendectomy. It has been estimated that worldwide over 20 million repairs of inguinal hernia are carried out each year, the specific operation rates varying between countries from around 100–300 per 100 000 population per year. In the United Kingdom some 100 000 inguinal hernias are repaired each year and approximately 750 000 inguinal hernias are repaired each year in the United States.¹

There were no written surgical guidelines for hernia treatment until 2009, when the European Hernia Society (EHS) published its recommendations based on analysis of the literature and the results of clinical trials. In the EHS guidelines, mesh-based techniques, the Lichtenstein technique in particular and endoscopic methods are recommended for treatment of symptomatic primary inguinal hernia in adult men.³ The Shouldice method has been acknowledged to be acceptable as well. Schumpelick emphasized the effectiveness of the Shouldice technique during his presentation at the 2011 EHS Congress in Ghent.

The synthetic prostheses most often used in the inguinal area can create new clinical problems, such as foreign body sensation in the groin, discomfort, and abdominal wall stiffness, which may affect the everyday functioning of the patient.⁴ Surgical-site infections, often with clinical symptoms delayed for many years, are more frequent after hernia treatment using mesh.⁵ Migration of the mesh from the primary site of implantation in the abdominal cavity is one

of the most dangerous complications. Additionally, sexual function are also reported to be affected after surgical hernia treatment with mesh.⁶

Desarda method, which was presented in 2001 and became a new surgical option for tissue-based groin hernia repair was promising **as the results presented by other authors were also comparable**. A randomized trial **conducted by Szopinski et al** comparing outcomes after hernia repair with Desarda (D) and mesh-based Lichtenstein techniques (L) included 208 male patients. It was observed that chronic pain was experienced by 4.8 and 2.9% of patients from groups D and L, respectively ($p = 0.464$) along with two recurrences in each group. There was significantly less seroma production in the D group ($p = 0.004$).³

The observed complication rates and postoperative dysfunction have influenced many investigators to look for new hernia repair techniques or to modify old ones. This study is aimed to compare the outcome of standard mesh-based Lichtenstein technique with the tissue-based Desarda technique in terms of post-operative pain and recurrence.

OBJECTIVE:

To compare the outcome of standard mesh-based Lichtenstein technique with the tissue-based Desarda technique.

OPERATIONAL DEFINITIONS:

Inguinal Hernia: A common type of hernia in which a loop of the intestine protrudes directly through a weak area of the abdominal wall in the groin region.

Outcome:

Recurrence: The reappearance of signs and symptoms of hernia after surgical procedure.

Return to normal activity: The patient's ability to perform elementary activities [i.e., dressing, walking, bathing (basic activity)]; usual activities at home [i.e., preparing food, cleaning house (home activity)]; and returning to all previously performed activities (work activity).

Chronic Post-operative Pain: It will be considered no pain if zero to ~~mild~~ **severe** pain **if 8-10** ~~achieved~~ **observed** on Visual analogue ~~score~~ **scale** (VAS) within a month.

Visual analogue score is ~~further~~ divided in grades as follows:

Grade 0 = No pain

Grade 1 = Mild pain (Score 1-3)

Grade 2 = moderate pain (Score 4 – 7)

Grade 3 = Severe pain (Score 8-10)

Sheffield scale:

0, no pain; 1, no pain at rest but it appears during movement; 2, temporary pain at rest and moderate during movement; 3, constant pain at rest and severe during movements.

HYPOTHESIS:

The Desarda repair is as effective as the standard Lichtenstein procedure, allowing successful hernia repair without mesh.

MATERIAL AND METHODS:

STUDY DESIGN: Randomized Controlled Trial.
SETTINGS: Surgery Department, **Saidu Teaching Hospital, Swat.**
DURATION: Minimum 6 months after approval of synopsis.
SAMPLE SIZE: Sample size will be ____ (____ in each group), sample size will be calculated using the WHO software for sample size calculation using the formula of hypothesis tests for two populations (one sided test) with the following assumption:

Level of significance = 5%

Anticipated population proportion = 4.8%³
 (Desarda group)

Anticipated population proportion = 2.9%
 (Lichtenstein group)

Statistical power = 80%

SAMPLING TECHNIQUE: Non probability Purposive sampling

SAMPLE SELECTION:

INCLUSION CRITERIA:

- All patients with inguinal hernia.
- All patients with 20-60 years of age.
- Either gender.

EXCLUSIN CRITERIA:

- Patients with other co-morbid condition e.g. diabetes, anemia, and malnourishments. These are confounding factors.
- Patients with an external oblique aponeurosis that is divided, tiny, and/or weak.
- Recurrent or strangulated hernias or mental disorders, those participating in other clinical trials
- Patients with a history of a forced hernia reduction with subsequent hospitalization, a history of infection, or the presence of any scar in the inguinal area.

DATA COLLECTION PROCEDURE:

Approval will be taken from the hospital ethical committee. All patients meeting the inclusion and exclusion criteria admitted in wards will be enrolled in the study. The purpose and benefits of study will be explained to patients and they will be assured that his/her confidentiality will be maintained and informed consent will be obtained.

Demographic characteristics like name, age, sex, address and phone number of all patients will be recorded. Complete history will be taken and complete general physical and systemic examination will be done.

Patients will be divided into two groups by blocked randomization. Group A will undergo hernia repair through Desarda technique & group B will undergo hernia repair through Lichtenstein technique. First patient will be decided after a coin toss & after that alternate patient will be included in either group.

Follow up will be after 7 days and one month on which time recurrence will be recorded and pain will be graded by a different surgeon not aware of the surgical technique used.

All information will be recorded on a pre-designed Performa. Strictly exclusion criteria will be followed to control confounders and bias in the study results.

DATA ANALYSIS:

The data collected from the patients through Performa's will be entered in SPSS latest version. Mean \pm SD will be calculated for continuous variables like age and duration of symptoms and disease. Frequencies and percentages will be calculated for categorical variables like gender, and outcomes like recurrence and pain. Age, gender and duration of disease will be stratified to see the effect modifiers. Chi-square test will be used to compare the outcome of both the techniques while keeping p value of ≤ 0.05 as significant. Post-stratification chi-square test will also be applied to compare the strata. All the results will be presented as tables and graphs.

REFERENCES:

1. Mabula JB, Chalya PL. Surgical management of inguinal hernias at Bugando Medical Centre in northwestern Tanzania: our experiences in a resource-limited setting. *BMC Res Notes*. 2012; 5(1):585.
2. Maciel GS, Simões RL, do Carmo FP, Garcia JW, Paulo DN. Results of the simultaneous bilateral inguinal hernia repair by the Lichtenstein technique. *Rev Col Bras Cir*. 2013; 40(5):370-3.
3. Szopinski J, Dabrowiecki S, Pierscinski S, Jackowski M, Jaworski M, Szuflet Z. Desarda versus Lichtenstein technique for primary inguinal hernia treatment: 3-year results of a randomized clinical trial. *World J Surg*. 2012; 36(5):984-92.
4. Genç V, Ensari C, Ergul Z, Kulacoglu H. A very late-onset deep infection after prosthetic inguinal hernia repair. *Chirurgia (Bucur)*. 2010; 105(4):555-7.
5. Pielaciński K, Szczepanik AB, Misiak A, Wróblewski T. Randomized clinical trial comparing inguinal hernia repair with Lichtenstein technique using non-absorbable or partially absorbable mesh. Preliminary report. *WideochirInne Tech Maloinwazyjne*. 2011; 6(4):190-206.
6. Schouten N, van Dalen T, Smakman N, Clevers GJ, Davids PH, Verleisdonk EJ, *et al*. Impairment of sexual activity before and after endoscopic totally extraperitoneal (TEP) hernia repair. *SurgEndosc*. 2012; 26(1):230-4.

Comparison of Desarda and Lichtenstein mesh plasty in inguinal hernia repair

PROFORMA

Name: ----- Date: -----

Age: ----- Gender: -----

Address:-----

Phone Number: -----

GROUP A B

Duration of Disease _____

OUTCOME :

Recurrence: Yes No

PAIN: According to Visual Analogue Score

Grade 0 = No pain

Grade 1 = Mild pain (Score 1-3)

Grade 2 = moderate pain (Score 4 – 7)

Grade 3 = Severe pain (Score 8-10)

According to Sheffield scale:

0 = no pain

1 = no pain at rest but it appears during movement

2 = temporary pain at rest and moderate during movement

3 = constant pain at rest and severe during movements. Return

Return to normal activity: Yes No