Date 01/09/2020

Title: A Comparative Study on Effects of Defect Closure Versus Non-Closure in Laparoscopic Totally Extraperitoneal Repair of Direct Inguinal Hernia

Running Title: Study on Effects of Defect Closure in Laparoscopic TEP Repair of Direct Inguinal Hernia

AIMS AND OBJECTIVES:

Aim: To Compare the Effects of Defect Closure versus Non-Closure on Outcomes of Laparoscopic TEP Direct Inguinal Hernia Repair**.**

Primary Objectives

- To compare Seroma formation rate in defect closure and non-closure groups.
- To compare the score of pain in VAS on different interval of time in both groups.

Secondary objectives

- To evaluate the operative time and the length of post-operative hospital stays in both groups.
- To evaluate the complication rate: vessel / visceral injury / vas injury/ peritoneal tear.
- Days to resume normal activities and work.

RESEARCH HYPOTHESES

Null Hypothesis: There is no difference between defect closure and non-closure of Laparoscopic TEP direct Inguinal hernia repair.

Alternate Hypothesis: Defect closure is superior to non-closure in laparoscopic direct inguinal hernia repair.

Review of Literature

Materials and Methods:

a) **Type of study design**: A prospective cohort study reported as the CONSORT guideline.

b) **Study Population**: Patients attending the outpatient department of surgery with complain of inguinal hernia

c) **Population/Participants:**

Inclusion criteria

1. Age greater than18 years
2. uncomplicated direct inguinal hernia (≥M3)

Exclusion criteria

1. Defect size ≤M2
2. Complicated hernia (irreducible, obstructed, or recurrent hernia)
3. Patient unfit for general anesthesia
4. Patient not giving consent

d) **Setting**: The study was conducted at B.P. Koirala institute of Health science (BPKIHS), Dharan, an independent health university in Nepal.

e) **Study period**: The study was conducted over a period of 12 months from September 2020 to August 2021.

f) **Ethical clearance:** The study was performed in accordance with the principle of the declaration of Helsinki and after approved by the Institutional Review Committee and Protocol committee.

ENROLLMENT OF PATIENTS

Patients with inguinal hernia presenting to surgery OPD with the inclusion criteria of age greater than 18 years and uncomplicated direct inguinal hernia (≥M3) were enrolled in the study. A total of 88 patients were enrolled in the study using the purposive alternate number sampling

technique. They were divided into 2 groups: 44 patients each in the defect closure and non-closure groups. All patients were explained and familiarized with the visual analog score (VAS) pain chart preoperatively.

At discharge the patient will be given a chart to fill which will have daily visual assessment of pain as well as the following instructions:

- To return to normal activity as soon as possible.
- To record all analgesic intake.
- To return for follow up at 10days, 1 months, 3 months and 6 months
- To return at any time if any complication arises.
- During the follow up, assessment data will be recorded using annexure.

ANNEXURES

Proforma

Particulars of patient Serial no:

Patient ID:

Date:

Name:

Age:

Sex: Male / Female

Address:

Occupation: No / Student / Business / Service/ Others

Religion: Hindu / Buddhist / Muslim / Kirati / Christian

Marital status: Unmarried / Married

Socio-economic status: Low / Medium / High

Phone no:

History

Examination of the patient

1. Direct/ Indirect:
2. Defect Size: if applicable
3. Content: Empty/Omentum/Bowel
4. Cough impulse: Present/Absent
5. Reducibility: Complete/Incomplete

ASA grading:

Operative Procedure and Date:

Operative Time:

Operative Detail:

1. Type of hernia:

2. Contents:
3. Type of Mesh used

Intra Operative Complications:

1. Injury to Visceral organs: Yes/No
2. Injury to vessels: Yes/No
3. Peritoneal tear: Yes/No
4. Injury to vas: Yes/No

Late complications:

1. Seroma formation: Yes/No
2. Incisional hernia/recurrence: Yes/No

FOLLOWUP

Follow up Performa (seroma formation questionnaire to be filled up by 10 days, 30 days, 3 months and 6 months)

Day 10

1. Seroma formation: yes / No
2. Pain: yes/ No
3. Recurrence: yes / No

1 months

1. Seroma formation: yes / No
2. Pain: yes/ No
3. Recurrence yes/ No

3rd month

1. Seroma formation: yes / No
2. Pain: yes / No
3. Recurrence yes / No

6th month

1. Seroma formation: yes / No
2. Pain: yes / No
3. Recurrence yes / No

Date 01/09/2020

Participant Informed Consent Form

Protocol Number: _____

Participant Identification number for the study: _____

Title of the research: "A Comparative Study on Effects of Defect Closure Versus Non-Closure in Laparoscopic Totally Extraperitoneal Repair of Direct Inguinal Hernia".

Name of the candidate: _____, age _____ years, address_____ Telephone: (residence) _____ (mobile)_____ (friend/parents) _____ Email_____,
The content of the information sheet dated_____ that was provided have been read carefully by me/explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.
The nature and purpose of the study and its potential risks/ benefit and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from BPKIHS. I give permission for these individuals to have access to my record.

I hereby give consent to take part in the above study and allow to perform the procedure and any other medical service that may become necessary during the procedure.

I also consent for medical photographs/ video and I have been informed that these photographs/ video will be used without revealing the identity. I understand that these along with the information I provide may be used in my medical record, for purpose of publication in textbook or medical journal and dissertation purpose, or for medical education.

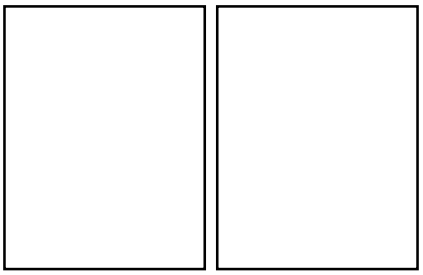
The consent form has been signed by me when I was not under the influence of any drugs.

Patient's signature _____
Researcher/Doctor's signature_____
Witness signature _____
Date _____

If not literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions and to understand the nature of study. I confirm that the individual has given consent freely.

Thumb print of participant



Researcher/Doctor's signature _____

Date: