Date 15/03/2018

Tittle: A Comparative Longitudinal Study Between Bilateral and Unilateral Totally Extra Peritoneal Repair Among Patients with Unilateral Inguinal Hernia at Tertiary Care Hospital in Eastern Nepal

Running Tittle: Bilateral vs Unilateral Totally Extraperitoneal Repair Among Patients With Unilateral Inguinal Hernia

AIMS AND OBJECTIVES:

AIMS

To study the feasibility and desirability of bilateral TEP repair in patients with clinically unilateral hernia

Primary Objective: To study and compare pain and complication rates in unilateral and bilateral total extra peritoneal repair.

Secondary Objective:

- To study the recurrence in both unilateral and bilateral TEP repair
- To study the difference in duration elapsed before return to work and day to day activity.
- To find the incidence of occult hernias in regional population.

Research Hypothesis:

Null Hypothesis-There is no difference betweenthe effects of bilateral TEP repair in patients with clinically unilateral hernia

Alternate hypothesis- There is a difference between the effects of bilateral TEP repair in patients with clinically unilateral hernia

Review of Literature

It has been reported that there is a significantly high chance of contralateral concurrent occult or subsequent inguinal hernia in patients with unilateral inguinal hernia. The objective of this study is to investigate the feasibility of bilateral laparoscopic exploration for all unilateral cases followed by laparoscopic bilateral TEP repair and to compare complications, recurrence rates, postoperative pain, and operative duration with prospectively performed unilateral repairs.

Materials and Methods :

a) **Type of study design**: A hospital based longitudinal comparative study.

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

c) **Population/Participants:**

Inclusion criteria

1. Age group of 16 years and above
2. Clinically diagnosed unilateral inguinal hernias

Exclusion criteria

1. Complicated hernia (obstructed, strangulated)
2. Past history of pelvic radio-therapy
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 March 2018 to March 2019.

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 attending the OPD for inguinal hernia will be counseled about the trial and fully encouraged to understand the difference in the two procedures and an informed consent acquired after which they will be enrolled in the study for a bilateral TEP to be performed on them, and controls should be taken from the patients who denied for bilateral repair for unilateral hernia and undergo unilateral TEP repair.

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 7days, 3 months, 6 months
- To return at any time should any complication arise.
- During the follow up assessment data will be recorded using annexure.

ANNEXURES

PRO FORMA

Patient ID: …….

Serial No.: ……. Date: ……

Name : -…… IP No.: ……....

Age : -……..... Years Phone no.

Address: -……...

Diagnosis: ……

Symptom duration: .....days

Hernia: unilateral / bilateral

BMI:

Education:

Income:

Symptoms:

- pain - yes/no,
- anorexia - yes/no
- nausea/vomiting - yes/no
- fever -yes/no

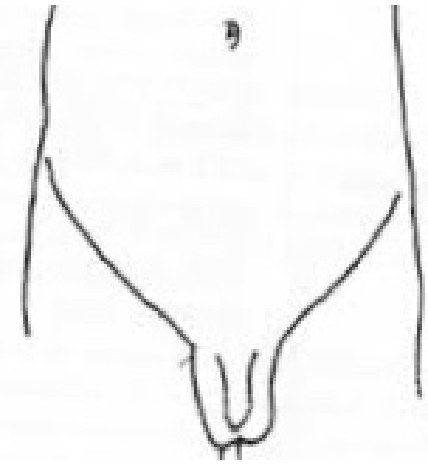
General physical examination:

BP: Pulse: Temperature: Respiratory rate:

Jaundice: Anemia: Lymphadenopathy: Cyanosis:

Clubbing: Edema: Dehydration:

PRE-OPERATIVE WORK UP



VAS Score:

Blood pressure:

BMI:

Height:

Weight

Dimension of Hernia

Reducible

Duration of Hernia

Primary or recurrent

Bilateral or Unilateral

Occupation:

Co-morbidity:

Pain Assessment

Oral analgesic name:

Oral analgesic dose:

Oral analgesic frequency per dose:

Intravenous analgesic name:

Intra venous analgesic dose:

Intra venous analgesic frequency per dose:

VAS score:

Post-Operative Assessment on evening of surgery

General Condition:

Urinary Retention:

Early recurrence:

Bleeding from Port site:

Hematoma Formation:

Pneumoscrotum:

Pain: (6h)-

(12h)-

(24h)-

Intra Operative Assessment

Operation Time

Bleeding(ml)

Peritoneal Breach

Nerve Injury

Vas Deferens Injury

Tearing of Inferior Epigastric Vessels

Major Visceral Injury

Major Vascular Injury

Patient

Tick the appropriate box:

		P	R		
	0	**1**	**2**	**3**	**x**
L					
M					
F					

P = primary hernia
R = recurrent hernia

0 = no hernia detectable
1 = < 1,5 cm (one finger)
2 = < 3 cm (two fingers)
3 = > 3 cm (more than two fingers)
x = not investigated

L = lateral/ indirect hernia
M = medial/ direct hernia
F = Femoral hernia

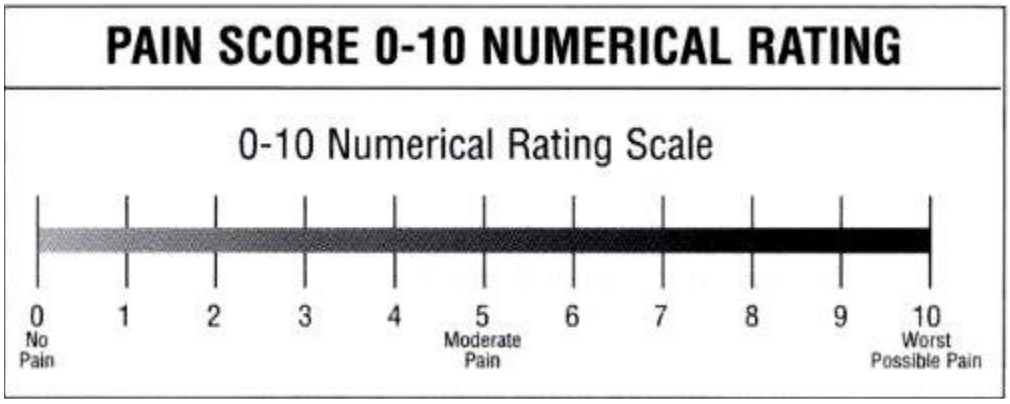
Diagnosis: _____

Operation: _____

Type of mesh used: _____

For future database items

Post-operative pain will be evaluated by pictorial visual analogue scale within next 7days. They will be questioned about the severity of pain by using visual analogue scale. The pain score of 1-2 will be regarded as mild pain, 3-5 moderate pain 6-8: severe pain and 9-10: worst pain. An additional requirement of analgesic after 24 hrs post-operatively will be noted.



DAY 1=

DAY 2=

DAY 3=

DAY4=

DAY5=

DAY6=

DAY7=

FOLLOWUP

Number of Follow up Visits

Recurrence

Any complications:

Which Complication:

VAS score(Visit 1):

VAS score(Visit 2):

VAS score(Visit 3):

Analgesic intake

(Visit 1):

(Visit 2):

(Visit 3):

Recurrence
Seroma
Pneumoscrotum
Hematoma
Neuralgia

Date 15/03/2018

Participant Informed Consent Form

Protocol Number: _____

Participant Identification number for the study: _____

Title of the research:'' A Comparative Longitudinal Study Between Bilateral and Unilateral Totally Extra Peritoneal Repair Among Patients with Unilateral Inguinal Hernia at Tertiary Care Hospital in Eastern Nepal''

Name of the candidate: _____, aged _____ 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 that may become necessary during the procedure.

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: _____

Date:

Witness signature _____

If illiterate

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:

Witness signature _____

Right	Left