Comparison of Extended Totally Extra peritoneal Repair (ETEP) and Subcutaneous OnLay Endoscopic Approach (SCOLA) for the treatment of Para umbilical Hernias (PUH) in terms of intraoperative factors and postoperative complications.

Date of document: 18/12/2025

SYNOPSIS

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Lahore – Pakistan

KING EDWARD MEDICAL UNIVERSITY, LAHORE

Title of Research Project: **Comparison of Extended Totally Extra peritoneal Repair (ETEP) and Subcutaneous OnLay Endoscopic Approach (SCOLA) for the treatment of Para umbilical Hernias (PUH) in terms of intraoperative factors and postoperative complications.**		
Synopsis Submitted For: ☐ **MD / MS / MDS** ☒ **Ph. D** ☐ **M. Phil** ☐ **Research Grant**	**Discipline:** **MS General surgery**	
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Qualification	**Year**	**Institution**

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MBBS	**2020**	**King Edward Medical University Lahore**
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House surgeon – Ophthalmology ward unit II MHL (01-05-2020 to 31-07-2020)

House surgeon – North surgical ward MHL (01-08-2020 to 31-10-2020)

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Name of Parent Institution (if on Deputation):

Name of Academic Supervisor / Principal Investigator: **Prof Dr Ahmed Uzair Qureshi**	**Signature:**	**Date:**
Name of Co Supervisor / Co-Principal Investigator	**Signature:**	**Date:**

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Name of Chairman/ Head of Department **Prof Dr Ahmed Uzair Qureshi**	**Signature:**	**Date:**
Name of Principal/ Dean	**Signature:**	**Date:**
Convener, Institutional Review Board **PROF. DR. SAQIB SAEED**	**Signature:**	**Date:**

Chairman (Advanced Studies & Research Board) ☐ **Approved** ☐ **Not Approved** **Vice Chancellor, KEMU**	**Signature:**	**Date:**

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TITLE:

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INTRODUCTION:

Para umbilical Hernias (PUH) are bulging of a part of intestine, peritoneal fat or omenta through the side of umbilicus. PUH are associated with defective collagen, old age, smoking and high intra abdominal pressure such as coughing, prostatic symptoms, constipation, obesity and pregnancy. Short neck of hernial sac makes PUH more prone to be irreducible, obstructed and strangulated that leads to surgical treatment[1]. In the last decade of previous century treatment of PUH has evolved from traditionally open repair to minimally invasive surgery such as IPOM, PPOM, TAPP, MILOS, ETEP, SCOLA, and TARUP. MIS provides multiple benefits to patient as compared to open surgery like short hospital stay, decrease incidence of surgical site infection (SSI) and wound dehiscence[2].

ETEP (Extended Totally Extra Peritoneal) and SCOLA (Subcutaneous OnLay endoscopic Approach) are novel approaches in hernia repair. ETEP has been compared in multiple studies with IPOM where ETEP is showing promising results regarding postoperative pain and early return to activities. In ETEP Extra peritoneal working space and inexpensive polypropylene mesh placement is associated with decrease incidence of intraperitoneal complications and cost effective respectively. But ETEP has been associated with longer operative time(113minutes), steep learning curve and increased conversation rate to IPOM and open repair(10%)[3-6].

SCOLA repair was introduced to repair the hernias which were associated with divarication of recti. As compared to the open repair SCOLA technique has provided good cosmetic results specially in those patients who were not ideal candidates for abdominoplasty. Dissection in subcutaneous tissue and preaponeurotic placement of mesh makes this technique more prone to SSI(6.3%) and seroma formation(25%)[7,8].

Till now there is no comparative study between SCOLA and ETEP. Most of studies previously done are either case based, descriptive or cohort[1,2,4]. Benefits of each technique need to be evaluated in terms of preoperative factors, intraoperative challenges and post-operative complications. If any one these technique proves better than the other then this study will guide the surgeons in training to focus on that technique.

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OBJECTIVES:

The objective of this study is to compare the outcomes of ETEP verses SCOLA in terms of preoperative factors, intraoperative factors and post operative complications in patients with Para umbilical hernias(PUH).

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OPERATIONAL DEFINITIONS:

Intraoperative factors

Intraoperative factors will include operative time, conversion to any other procedure, hernial contents and divarication of recti.

Operative time

Operative time will include time from the first incision to approximation of skin by skin stapler.

Conversion to any other procedure

If the operating surgeon has to shift the operative technique to IPOM or open hernia repair then this will be considered as conversion to any other procedure.

Hernial contents

Hernial contents will include fat, omentum or bowel.

Divarication of recti

An inter recti distance more than 2cm will be considered as diastasis of recti.

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Postoperative complications

Postoperative complications will include postoperative pain, rescue analgesia, Drain volume, seroma and surgical site infection.

Postoperative pain

Postoperative pain will be assessed by the visual analogue score(0-10) with zero showing no pain and 10 showing maximum pain.

Rescue analgesia

Rescue analgesia will include injection nalbuphine 3mg given for breakthrough pain. VAS score more than 4 will be considered as breakthrough pain. It will be measured as rescue analgesia given or not.

Drain output

Drain output will include amount and type of fluid (blood, serous, serosanginous,). Drains will be removed when drain out will be less than 25ml over 24h. Drain output more than 100ml will be considered as high drain output and less than 100ml will be considered as low output. Drain out put will be measured as high output or low output.

Seroma

Collection of serous fluid at the operative site after hernia repair surgery within 30 days once the drains placed at the site of surgery would been out.

Surgical site infections.

If a Patient presents with hyperemia and pus discharge from wound within 30 days of operation requiring opening of wound or change in antibiotics will be labeled as surgical site infection.

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HYPOTHESIS:

Extended Totally Extra peritoneal Repair (ETEP) is better than the Subcutaneous OnLay Endoscopic Approach (SCOLA) for the treatment of PUH in terms of intraoperative factors and postoperative complications.

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MATERIAL AND METHODS:

STUDY DESIGN:

Randomized controlled trial.

SETTING:

The study will be conducted at the surgical floor in Mayo Hospital Lahore.

DURATION OF STUDY:

6 Months from the date of approval of synopsis

SAMPLE SIZE:

Sample size of 86 patients (43 patients in each group) is estimated by using 5% level of significance, 90% power of the test with expected percentage of seroma in ETEP as 3.3%[3] and in SCOLA as 25%[8].

$$n = \frac{\left\{ z_{1-\alpha} \sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Z1-α = confidence level 95%

Z1-β = power of the test 90%

P1 = population proportion 1= 3.3%

P2 = population proportion 2 = 25%

SAMPLING TECHNIQUE:

Non probability convenient sampling

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SAMPLE SELECTION:

Inclusion Criteria:

- Adults of age group from 18 to 65 years
- Patients of both gender admit with diagnosis of Para umbilical Hernias through outdoor department, documented on clinical examination by consultant general surgeon.

Exclusion Criteria:

- Patients with hernial defect more than 5cm, documented on peroperative findings
- Patients with complicated hernias including irreducible and obstructed varieties, documented on clinical findings.
- Patients who require abdominoplasty, opinion given by operative surgeon.
- Patients with intermediate to high risk of MACE during the surgery, documented on fitness performa filled by cardiology team.
- Patients with previous midline incision or laparotomy, documented on clinical examination.

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DATA COLLECTION PROCEDURE:

All the patients who will fulfill the inclusion criteria will be admitted through OPD after taking their consent to be part of study. Risk to benefit ratio will be explained to them Preoperatively demographics of the patients including age, gender, BMI, hypertension, diabetes will be noted(CRF A). All the patient who fulfill inclusion criteria will be divided into two groups at the time surgery through lottery method. Group A and B will represent ETEP and SCOLA respectively.

All the procedures will be performed by same surgical team.

Intraoperative parameters including hernial content, hernial rent size, divarication of recti, operative time and conversion to any other technique of hernia repair will be noted by operating Surgeon.

Postoperatively all the patients will be kept under observation for vitals derangement or hematoma formation or any primary bleeding complication . All the patients will be kept nil per oral for 6 hours . All the patients will be mobilized after 6 hours . Ringer lactate solution 1 liter will be given once during the period of NPO. Amoxicillin / Clavulanic acid 1.2g intravenous injection will be given three time a day for as many days as patient stay in ward. Injection ketorolac 30mg two times a day will be given for as many days as patient stays in ward. Rescue analgesia will be given as injection nalbuphine 3mg intravenous for breakthrough pain. Abdominal belt will be advised to all the patients postoperatively. 24h drain output will be monitored on the next day. All the patients will be discharged on the next day with oral antibiotics (Amoxicillin/ Clavulanic acid 1g two times a day), oral analgesic (acetaminophen 1g three times a day) for 7 days, abdominal belt and drains.

All the patients will be called back for follow up visit at 3rd day, 7th day, 1st month and at any day with complication for post operative pain, drain output, seroma formation and surgical site infection(CRF B).

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DATA ANALYSIS PRODECURE:

The data will be analyzed by SPSS v26.0. Mean and standard deviation will he used for quantitative data and frequency and ratios will be used for qualitative data. Quantitative variables (Age, BMI, hernial rent size, operative time, VAS score, total rescue analgesia, drain volume) will be assessed by t-test. Qualitative variables(gender, diabetes, hypertension, operative technique, hernial contents, divarication of recti, seroma and SSI) will be compared using chi-square test. P value < 0.05 will be considered as significant.

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OUTCOME & UTILIZATION:

If any of these techniques proves better than the other then it will help the surgeons in training to focus on that technique for proper preoperative patients selection ,lesser number of postoperative complications.

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SCHEDULE/PHASING:

	Month				
	1st	2nd-3th	4th	5th	6th
Review literature					
Data collection					
Data Analysis					
Thesis writing					

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Thesis submission					

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8. Claus C, Cavazzola L, Malcher F. SubCutaneous OnLay endoscopic Approach (SCOLA) for midline ventral hernias associated with diastasis recti. Hernia. 2021;25(4):957-62.

Annexure I

Comparison of Extended Totally Extra peritoneal Repair (ETEP) and Subcutaneous OnLay Endoscopic Approach (SCOLA) for the treatment of Para umbilical Hernias (PUH) in terms of intraoperative factors and postoperative complications.

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CRF (A) **Day**

Biodata

Registration number Name

Age Gender Profession

Inclusion criteria

Patient's age is between 18 year to 65 years and diagnosis of the patient is para umbilical hernia	Yes	No

Exclusion criteria

Hernial defect is more than 5cm	Yes	No
Patient's hernia is of irreducible and obstructed variety	Yes	No
Patient is a candidate of abdominoplasty	Yes	No
Patient with high risk of MACE during surgery	Yes	No
Patient with precious midline incision or laparotomy	Yes	No

Is patient giving consent **YES** **No**

Alloted Group **Group A** **Group B**

Preoperative variable	**Value**
Age	
Gender	
BMI	
Diabetes	
Hypertension	

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CRF (B)

Date **Day** ☐

Registration number Name

Allocated group **Group A** **Group B**

Intraoperative and postoperative variables

Intraoperative Variables	**Value**
Operative technique	
Hernial rent size	
Divarication of recti	
Contents of hernia Operative time	
Conversion to other technique	

Postoperative variables	**Day 0**	**Day 1**	**Day 3**	**Day 7**	**1 month**	**3 month**	**6 month**
VAS score							
Total rescue analgesia							
Total drain volume							
Drain contents							
Seroma							
Surgical site infection							

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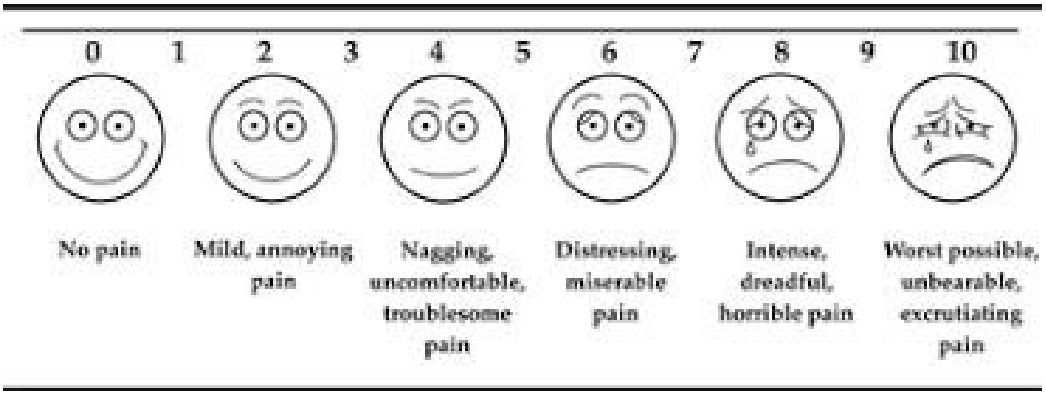

ANNEXURE II

Consent form

Comparison of Extended Totally Extraperitoneal Repair (ETEP) and Subcutaneous Onlay Endoscopic Approach (SCOLA) for the Treatment of Para-umbilical Hernias (PUH) in terms of intraoperative factors, postoperative complications, learning curve, patient satisfaction, and financial burden.

I have been fully informed by my doctor about the complete details and the basic objectives of this research study. I have also been informed about the possible benefits and risks associated with participation in this research study.

I understand that my participation in this research study is entirely voluntary, and that I may withdraw from the study at any time of my own free will without any penalty. In such a situation, my doctor will remain fully responsible for my complete medical treatment.

I understand that my doctor or any person authorized by them may contact me at any time regarding this research study. I am also aware that all information provided by me will be kept confidential and will be used only for the purposes of this research study.

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By signing below, I indicate that I have read and understood the above information and voluntarily agree to participate in this research study.

Participant's Name: _____

Signature/Thumb Impression: _____

Date: _____

Investigator's Name: _____

Signature: