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Study comparing single-incision laparoscopy versus multitrocar laparoscopy totally extraperitoneal inguinal hernia repair (TEP) at 2 years

Submission date
07/08/2017

Recruitment status
No longer recruiting

Registration date
17/08/2017

Overall study status
Completed

Last Edited
13/07/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
An inguinal hernia usually occurs when fatty tissue or a part of the bowel pokes through into the groin at the top of the inner thigh. Multitrocar laparoscopy (MTL) is a popular surgical treatment for inguinal hernia repair. Compared to open techniques, laparoscopic (keyhole surgery) treatment results in less pain, faster recovery, early return to daily activities and better cosmetic results. The next step for inguinal hernia repair is single-incision laparoscopy (SIL), where only a single small incision (cut) is used. SIL totally extraperitoneal repair (SILTEP) has been found to be feasible and safe. Early reports are promising, but the advantages of SILTEP over conventional multitrocar laparoscopic TEP (MTLTEP) have not been clearly defined. The aim of this study is to compare the short and mid-term outcomes of SILTEP and MTLTEP inguinal hernia repair.

Who can participate?
Patients aged over 18 undergoing laparoscopic surgery for inguinal hernia

What does the study involve?
Participants are randomly allocated into two groups to undergo SILTEP or MTLTEP. Complications during surgery and pain after surgery are recorded. All participants are assessed for complications, inguinal hernia recurrence and days needed to return to daily activities at 7 and 30 days after surgery. During follow-up the participants are contacted by phone to assess their surgical and cosmetic satisfaction.

What are the possible benefits and risks of participating?
SILTEP and MTLTEP inguinal hernia repairs are feasible and safe. Both techniques are commonly performed. SILTEP could reduce complications and improve cosmetic results.

Where is the study run from?
Department of Gastrointestinal Surgery, European School of Laparoscopic Surgery, Saint-Pierre University Hospital, Université Libre de Bruxelles (Belgium)

When is the study starting and how long is it expected to run for?
January 2013 to July 2016

Who is funding the study?
Université Libre de Bruxelles (Belgium)

Who is the main contact?
Prof. Giovanni Dapri
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SIL/MTL-TEP:210

Study information

Scientific Title
Prospective randomised study comparing single-incision laparoscopy versus multitrocar laparoscopy totally extraperitoneal inguinal hernia repair (TEP) at 2 years

Study objectives

Single-incision laparoscopy totally extraperitoneal (SILTEP) inguinal hernia repair can reduce the postoperative pain and improve the cosmetic results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval. Both surgical procedures are frequently used in inguinal hernia repair and have been reported as feasible and safe.

Study design
Single-centre randomized prospective interventional clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Unilateral or bilateral inguinal hernia requiring surgical treatment

Interventions
Participants are randomised using computer-generated randomized numbers in sealed envelopes to either:

Single-incision laparoscopy totally extraperitoneal (SILTEP) inguinal hernia repair:
A 1.5 cm umbilical scar is created in the opposite region of the hernia to treat and the anterior rectus fascia is opened. A fascial purse-string suture using Vicryl 1 is placed starting at 9 o'clock position. An 11-mm reusable rigid trocar is introduced behind the rectus muscle into the preperitoneal space. The 0° regular scope is advanced into the 11-mm trocar and the preperitoneal space is insufflated. The space is dissected using the optical system from medial to lateral side. At the time of hernia sac retraction, a reusable monocurved grasping forceps is introduced inside the purse-string suture, at 9 o'clock position and parallel to the 11-mm trocar. The hernia sac is reduced, the peritoneal sheet is retracted and the spermatic elements are skeletonized. A 15 cm x 10 cm polypropylene mesh is introduced through the 11-mm trocar. The mesh is adequately positioned using the monocurved umbilical grasper, placing the lateral corner anteriorly to the peritoneal sheet and the medial corner under the pubic bone.

Multitrocar laparoscopy totally extraperitoneal (MTLTEP) inguinal hernia repair:
The operation start with an infraumbilical vertical incision approximately 1.5-2 cm long and the

rectus fascia on the opposite side of hernia is opened. A space is created slightly off the midline behind the rectus muscle and in front of the posterior rectus sheath. Subsequently, a 11-mm reusable rigid trocar is introduced behind the rectus muscle into the preperitoneal space. The 0° regular scope is advanced into the 11-mm trocar and used for blunt dissection of the areolar tissue in the preperitoneal space using a gentle sweeping motion. Under direct visualization, two other 6-mm trocars are placed. In unilateral hernias, the first 6-mm trocar is placed through the midline between the umbilicus and the pubis, while the second 6-mm trocar through the horizontal umbilical line 3 cm internal to the ipsilateral anterior superior iliac spine. In bilateral hernias, two 6-mm trocars are inserted through the horizontal umbilical line, 2-3 cm internal to anterior superior iliac spines. Two atraumatic grasping forceps are used to isolate and reduce the hernia sac, to retract the peritoneal sheet and to skeletonize and accurately identify all spermatic cord structures. A 15 cm x 10 cm polypropylene mesh is appropriately placed.

All patients were assessed for early postoperative complications at office consultation on 7 and 30 day from surgery. Late postoperative complications (after 30 days), inguinal hernia recurrences and days to return to ADL were recorded too. The mean follow-up was 27 ± 8 months (SILTEP: 28.37 ± 7.29 months; MTLTEP: 26.42 ± 9.04 months). During follow-up the patients were contacted and consulted by phone call questionnaire. The interview was performed on 30/06/2016. Surgical and cosmetic satisfaction were evaluated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mid-term outcomes:
1. Late postoperative complications, measured using the number of umbilical hematoma, inguinal hematoma, inguinal seroma (no case reported), umbilical infection (no case reported), testicular atrophy and chronic pain reported by each patient at follow-up (after 30 days from surgery and during interview)
2. Late inguinal hernia recurrence, measured using the number of inguinal hernia recurrence reported by each patient at follow-up (after 30 days from surgery and during interview)
3. Surgical satisfaction, measured using a numerical rating scale (NRS) at follow-up (during interview)
4. Cosmetic satisfaction, measured using a score questionnaire at follow-up (during interview)

Secondary outcome measures
1. Perioperative outcomes:
1.1. Operative time, calculated using the time from the skin incision until fascia closure at the end of surgical procedure
1.2. Mesh fixation, measured using the number of tack devices used to fix the mesh (if it was necessary) at the end of surgical procedure. (one tack device was used for each mesh fixed)
1.3. Operative complications, measured using the number of peritoneal tear repair, epigastric vessels injury, corona mortis bleeding and conversion to TAPP (transabdominal preperitoneal) repair during surgical procedure
1.4. Postoperative pain, assessed using a visual analogue scale (VAS) at 6, 12, 18 and 24 hours after surgery
1.5. Hospital stay, measured using the number of days of patient’s hospitalization
2. Short-term outcomes:
2.1. Early postoperative complications, measured using the number of umbilical hematoma, inguinal hematoma, inguinal seroma, umbilical infection (abscess), urinary retention and testicular atrophy at office consultation on 7 and 30 days from surgery

2.2. Early inguinal hernia recurrence, measured using the number of inguinal hernia recurrence reported by each patient at office consultation on 7 and 30 days from surgery
2.3. Days to return to activity daily living (ADL), measured using the number of days necessary to return to ADL for each patient evaluated at consultation on 7 and 30 days from surgery or during the interview

Overall study start date
01/01/2013

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years or over)
2. Unilateral or bilateral inguinal hernia
3. Patient's approval

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
210 (SILTEP group: 113; MTLTEP group: 97)

Key exclusion criteria
1. Age <18 years
2. Patient refusal to partecipate in the study
3. Inability to receive general anesthesia
4. Concomitant surgical procedures out of hernia repair

Date of first enrolment
14/01/2013

Date of final enrolment
28/05/2015

Locations

Countries of recruitment
Belgium

Study participating centre
Saint-Pierre University Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05cmp5q80

Funder(s)

Funder type
University/education

Funder Name
Université Libre de Bruxelles

Results and Publications

Publication and dissemination plan
Trial results will be communicated in conference presentations and peer-reviewed journal publications.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Giovanni Dapri (giovanni@dapri.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No