Systematic Review Protocol – Comparative outcome of laparoscopic unilateral vs bilateral total extra-peritoneal (TEP) inguinal hernia repair.

Background

Inguinal hernia repair is one of the most commonly performed surgical procedures worldwide. Repair techniques are increasingly being performed laparoscopically, either by transabdominal preperitoneal (TAPP) or total extra-peritoneal (TEP) approaches. While both laparoscopic techniques report similar outcomes [1,2,3], TEP is often preferred for being minimally invasive, as it does not breach the peritoneal cavity. One advantage shared by both laparoscopic techniques is that they allow for concurrent repair of the contralateral side without the need for further incisions.

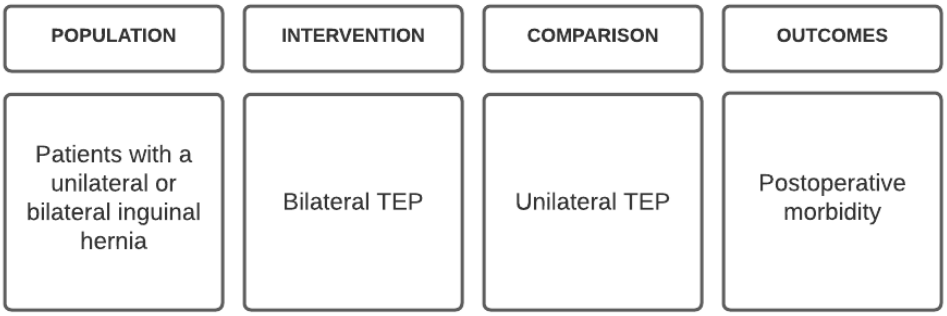
The literature, including large population-based studies [4,5], shows minimal differences between outcomes of bilateral and unilateral TEP operations. Current perceived disadvantages of bilateral TEP are attributed to mildly raised intraoperative and postoperative complications [4,5], and in some cases an elevated risk of urinary bladder injuries [5], higher reoperation rate [5], as well as short-term postoperative pain/discomfort [6]. However, there have been no systematic reviews conducted on the topic, nor has there been an individual journal article sufficiently conclusive to address the comparison of operation outcomes.

This systematic review aims to summarize the existing evidence, and conclusively address whether bilateral TEP operations are associated with increased morbidity compared to TEP repair of unilateral hernias.

Review question:

“Do patients undergoing bilateral TEP inguinal hernia repair have the same outcome as patients following unilateral TEP hernia repair?”

PICO:



Inclusion criteria

Types of participants

This review will include all adult patients (> 16 years) undergoing an elective unilateral or bilateral TEP operation. No exclusion will be made for country, race, or sex. Participants with recurrent inguinal hernia, history of previous lower abdominal surgery, uncorrected coagulopathy, as well as those unfit for general anaesthesia or undergoing emergency hernia procedures will be excluded.

Types of intervention

This review will exclusively focus on the standard 3-port TEP laparoscopic technique for unilateral and bilateral inguinal hernia repair. Variations in TEP technique (eg. needlescopic, single incision, changes in port number/placement etc.) will be excluded. Other laparoscopic techniques (eg. TAPP), or open repairs (eg. Lichtenstein) will not be considered.

Types of outcome measure

The primary outcome of interest is patient morbidity, reported through parameters such as intraoperative and postoperative complications. Secondary outcomes are length of hospital stay, operative time, recurrence, urinary retention, haematoma/bruising, wound infection, and time to return to work.

Types of studies

This review will limit its scope to empirical, quantitative papers (RCTs as well as prospective and retrospective observational studies). Qualitative papers, as well as case reports, and editorials/expert opinion pieces will be excluded. Non-English language papers, and papers with less than 10 participants will be excluded.

Search strategy

1. A preliminary search of the literature has been conducted to identify relevant keywords as well as MeSH and Emtree terms, gathered from article titles/abstracts and listed subject headings which showed promise for answering the question we posed.

2. Terms identified in this way, and the synonyms used by respective databases, will be used in an extensive search of the literature.

3. Further references are to be gathered by cross-checking reference lists manually from articles which meet the abstract screening criteria. A record must be kept of all articles gathered via this method. No attempt will be made at gathering unpublished data.

Relevant search terms identified by Step.1:

Keywords	MeSH terms	Emtree terms
• Unilateral • Bilateral • Unilateral vs bilateral • Contralateral • Sequential • Simultaneous • TEP • Total(ly) extraperitoneal • Inguinal • Hernia repair • Morbidity • Outcomes • Quality of life • QoL • Recurrence • Intraoperative complications • Postoperative complications	• "Hernia, Inguinal"[Mesh] • "Herniorrhaphy"[Mesh] • "Laparoscopy"[Mesh] • "Treatment Outcome"[Mesh] • "Intraoperative Complications"[Mesh] • "Postoperative Complications"[Mesh] • "Pain, Postoperative"[Mesh] • "Recurrence"[Mesh] • "Quality of Life"[Mesh]	• exp hernioplasty/ • exp herniorrhaphy/ • exp inguinal hernia/ • exp laparoscopic surgery/ • exp treatment outcome/ or *patient-reported outcome/ • exp postoperative complication/ • exp peroperative complication/ • exp postoperative pain/ • exp quality of life/

Where applicable, truncated word searches will be used. Database specific field tags will be applied to search either: all available text or title/abstract.

Search terms structured by concept and formatted for search:

Concept 1: Inguinal hernia repair

Inguinal AND hernia AND (repair OR hernioplast* OR herniorrhaphy)

MeSH terms: "Hernia, Inguinal"[Mesh], "Herniorrhaphy"[Mesh]

Emtree terms: exp hernioplasty/, exp herniorrhaphy/, exp inguinal hernia/

Concept 2: TEP

TEP OR “totally extraperitoneal” OR “total extraperitoneal” OR “totally extra-peritoneal” OR “total extra-peritoneal”

MeSH term: "Laparoscopy"[Mesh]

Emtree term: exp laparoscopic surgery/

Concept 3: Unilateral vs bilateral

(Unilateral AND Bilateral) OR contralateral* OR simultaneous* OR sequential*

Concept 4: Outcomes

Outcome* OR morbidity OR “quality of life” OR QoL OR recurrence OR ((postoperative OR intraoperative) AND complication*))

MeSH terms: "Treatment Outcome"[Mesh] OR "Intraoperative Complications"[Mesh] OR "Postoperative Complications"[Mesh] OR "Pain, Postoperative"[Mesh] OR "Recurrence"[Mesh] OR "Quality of Life"[Mesh]

Emtree terms: exp treatment outcome/ or *patient-reported outcome/, exp postoperative complication/, exp peroperative complication/, exp postoperative pain/, exp quality of life/

Databases:

All articles published up until the end of September 2021 and indexed in the following databases will be searched:

- Pubmed/MEDLINE
- EMBASE
- Cochrane Library
- Scopus
- Web of Science

All search strings must be recorded, as well as the date on which the search is conducted. Search results yielded from each search string will be downloaded as separate bibliography files to be opened in the reference manager, Mendeley. At minimum the following parameters must be filled: author names, publication year, journal, DOI, URL link, and abstract.

Tags will be assigned to each journal article in Mendeley during both the abstract and full text screening processes. This is to document inclusion or exclusion of an article based on the aforementioned criteria, as well as reasons for inclusion or exclusion. Screening is to be conducted by one researcher, where any uncertainties in article selection are to be adjudicated through discussion with two third parties.

Title and abstract screening criteria:

Tags will be assigned from the following pool, where appropriate:

"0" - Exclude, outside scope of review.

Must be accompanied by one of the following tags:

"Irrelevant"
"Non-English language"
"Excluded study design"
"Full text unavailable/Abstract-only paper"
"Duplicate"

"1" - Include, evidence of direct comparison between unilateral and bilateral TEP operations.

"2" - Include, comparison between unilateral and bilateral TEP possible (eg. as incidental or secondary interest).

Full text PDFs will be downloaded from journal articles tagged "1" or "2", and subjected to the full text screening criteria:

Full text screening criteria:

Either of the following two tags will be applied to the subgroup of title-and-abstract-screened papers:

“1” - Include in final analysis, only if all of the following criteria are met:

1. Participants > 16 years of age.
2. More than 10 patients included in the study.
3. Primary inguinal hernia.
4. Elective unilateral or bilateral TEP operation.

“0” - Exclude from final analysis, if any of the following is true for participants (who can not be isolated from the dataset).

1. Recurrent unilateral or bilateral hernia.
2. Emergency hernia procedures (obstructed or strangulated).
3. History of previous lower abdominal surgery.
4. Uncorrected coagulopathy.
5. Patients unfit for general anaesthesia.
6. Non-TEP hernia repair.

A holistic representation of the screening process is to be presented in a CONSORT-style flow diagram.

Data collection

Data extraction will include study identifiers and study design; participant, exposure, and outcome information, as well as information about analytical methods. Information missing from publications will be noted.

Study identifiers will be defined as: the authors’ names, study title, publication type, publication date, journal, volume, issue, and page numbers of publication, place of publication, DOI, and time frame of study. Information regarding the design characteristics of each study, how the arms of the study were defined, the characteristics of the exposure and comparison groups, the outcomes of interest (and how they were measured), as well as the results will be extracted from each article. Details regarding the specific methodology of the TEP operations will also be extracted.

The software REVMAN© version 5 will be used in the extraction of data from the selected journal articles, as well as further statistical analysis and data synthesis.

Critical appraisal

The GRADE criteria will be applied to each article included for final analysis. The internal validity of each included study will be assessed and reported on. Specific parameters of interest in the criteria are the risk of bias, consistency, directness, precision, and publication bias.

Data synthesis

Quantitative synthesis will be carried out through meta-analysis.

A judgement of clinical heterogeneity between included papers will be made, as well as the extent to which this heterogeneity may affect the conclusions of the meta-analysis. Statistical heterogeneity of the included studies will be assessed through Cochran's Q test, as well as I^2 index (a I^2 value of < 0.25 will be considered homogenous).

The summary effect size will be estimated in the form of Odds Ratio for dichotomous outcomes underlying morbidity such as seroma occurrence. Mean Difference or Standardized Mean Difference will be used for continuous variables such as operative time and length of hospital stay. The random effects model will be used in this meta-analysis. A forest plot will be constructed to visually inspect how the effect estimates of each individual study are distributed around the null value, as well as the overall effect estimate.

References

[1]
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Gass, M., Rosella, L., Banz, V. et al. Bilateral total extraperitoneal inguinal hernia repair (TEP) has outcomes similar to those for unilateral TEP: population-based analysis of prospective data of 6,505 patients. Surg Endosc 26, 1364–1368 (2012). https://doi.org/10.1007/s00464-011-2040-3
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Malouf, P.A., Descallar, J. & Berney, C.R. Bilateral totally extraperitoneal (TEP) repair of the ultrasound-diagnosed asymptomatic contralateral inguinal hernia. Surg Endosc 32, 955–962 (2018). https://doi.org/10.1007/s00464-017-5771-y
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