INPLASY PROTOCOL

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None declared.

Biologic versus Synthetic Mesh for Ventral Hernia Repair: a protocol for systematic review and meta-analysis

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Review question / Objective: **To compare the clinical outcomes of utilizing biologic mesh versus synthetic mesh during ventral hernia repair (VHR).**
Eligibility criteria: **Inclusion criteria were randomized controlled trials comparing biologic and synthetic mesh in ventral hernia repair. Studies were included if they were focused on adults (over age 18), human subjects, and were published in the English language. Studies were limited to only VHR and needed to compare biologic with synthetic mesh. Repair could be done open, laparoscopically, or robotically. Exclusion criteria included: (1) articles that only included synthetic or biologic mesh (ex. comparing two types of biologic mesh) or (2) procedures for other types of hernias, for example inguinal or hiatal.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 October 2022 and was last updated on 03 October 2022 (registration number INPLASY2022100016).

INTRODUCTION

Review question / Objective: **To compare the clinical outcomes of utilizing biologic mesh versus synthetic mesh during ventral hernia repair (VHR).**

Rationale: **Synthetic mesh is widely utilized in clean ventral hernia repair, however the treatment for contaminated ventral hernia cases remains controversial. Many surgeons utilize biologic mesh in these patients and settings as opposed to synthetic mesh despite a lack of high-quality evidence to support such practices.**

Condition being studied: Ventral hernia repair.

METHODS

Search strategy: A review of the literature was conducted using Cochrane Library, EMBASE, Clinicaltrials.gov and PubMed. The following search term strategy was utilized: Ventral Hernia (medical subject heading or MeSH: hernia, ventral), hernia (MeSH: Abdominal hernia), mesh (MeSH: Surgical mesh), biologic, natural, synthetic, artificial, dermal matrix, recurrence/ recurrent, intestinal wall, repair.

Participant or population: Adults (>18 years old) undergoing ventral hernia repair.

Intervention: Biologic mesh for ventral hernia repair.

Comparator: Synthetic mesh for ventral hernia repair.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Inclusion criteria were randomized controlled trials comparing biologic and synthetic mesh in ventral hernia repair. Studies were included if they were focused on adults (over age 18), human subjects, and were published in the English language. Studies were limited to only VHR and needed to compare biologic with synthetic mesh. Repair could be done open, laparoscopically, or robotically. Exclusion criteria included: (1) articles that only included synthetic or biologic mesh (ex. comparing two types of biologic mesh) or (2) procedures for other types of hernias, for example inguinal or hiatal.

Information sources: Cochrane Library, EMBASE, Clinicaltrials.gov and PubMed were searched. When articles analyzing the same or overlapping patient populations and outcomes were identified, the most recent article was included. References of selected manuscripts and systematic reviews and meta-analyses were reviewed to ensure all potential articles were included in this review.

Main outcome(s): Primary outcome was major complications defined as deep/organ space surgical site infection (SSI), reoperations, hernia recurrences, or deaths.

Additional outcome(s): Secondary outcomes included each of the individual components of the primary outcome, superficial SSI, and quality of life.

Data management: Data was recorded in an Excel spreadsheet. Two authors independently selected the studies and independently extracted the data. The two authors discussed any disagreements and if an agreement was not met, they discussed with the senior author. We performed all analyses using the software, Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020., and StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC.

Quality assessment / Risk of bias analysis: All studies included were appraised using the Critical Appraisal Skills Programme (CASP) evaluation tool. A CASP score was calculated for each of the trials with a maximum score of 22. The studies were divided into categories based on their score: high quality was a score ≥15, moderate was a score of 10-14, while low quality was a score ≤9.

Strategy of data synthesis: When more than one RCT at low risk of bias was available from the studies included in quantitative synthesis, meta-analyses were performed independently for the primary outcome and each secondary outcome. To determine appropriateness of data combination across the studies, clinical heterogeneity in patients, interventions, and outcome measures was evaluated. We assessed statistical heterogeneity of the studies included using I2. During analysis, when I2 value was >50%, it was considered to have significant heterogeneity. Random-effect model was reported in the case of large clinical or statistical heterogeneity results; otherwise, we used a Mantel-Haenszel approach to perform fixed-effect models.

To allow computation, studies with no observed case in one arm, we added a constant continuity adjustment of 0.5 to all cells of a 2x2 table. We expressed pooled effect size of all outcomes as risk ratios with 95% confidence intervals. Funnel plots were performed to assess for potential publication bias. We performed all analyses using the software, Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020., and StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC.

Subgroup analysis: We planned on performing subgroup analysis based on wound class.

Sensitivity analysis: Not applicable.

Language restriction: only randomized clinical trials published in English will be considered for inclusion.

Country(ies) involved: United States of America.

Other relevant information: Ali Siddiqui and Nicole Lyons contributed equally to this work. University of Houston, Houston, Texas, USA is the other affiliated institution.

Keywords: ventral hernia; biologic mesh; synthetic mesh; hernia; hernia recurrence.

Dissemination plans: publication of the manuscript in a medical or surgical journal.

Contributions of each author:

Author 1 - Nicole Lyons - The author wrote the protocol, performed the literature search, acquired the data, analyzed and interpreted the data, drafted the manuscript, critically revised the manuscript.

Author 2 - Ali Siddiqui - The author helped with study conception and design, wrote the protocol, performed the literature search, acquired the data, analyzed and interpreted the data, drafted the manuscript, critically revised the manuscript.

Author 3 - Oluwatunmininu Anwoju - The author helped with study conception and design, analyzed and interpreted the data, critically revised the manuscript.

Author 4 - Brianna Cohen - The author analyzed and interpreted the data, critically revised the manuscript.

Author 5 - Walter Ramsey - The author analyzed and interpreted the data, critically revised the manuscript.

Author 6 - Christopher O'Neil - The author analyzed and interpreted the data, critically revised the manuscript.

Author 7 - Zuhair Ali - The author analyzed and interpreted the data, critically revised the manuscript.

Author 8 - Mike Liang - The author helped with study conception and design, coordinating the review, supervision, analyzed and interpreted the data, drafted the manuscript, critically revised the manuscript.