INPLASY PROTOCOL

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None declared.

Application of TiLOOP bra decreases complication risk of implant-based breast reconstruction: a meta-analysis

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Review question / Objective: **P: breast cancer patients; I: implant-based breast reconstruction with the use of TiLOOP bra; C: implant-based breast reconstruction with the use of non-TiLOOP bra techniques; O: postoperative complications and patient satisfaction in physical well-being.**
Condition being studied: **The postoperative complications could be categorized into two groups: major complications and minor complications. Major complications were defined as those events that could lead to additional surgical intervention and include revisions and reconstructive failure, while minor complications were defined as those that could be treated conservatively without surgical intervention. All these postoperative complications is closely related to the final outcomes of implant-based breast reconstruction and patient satisfaction. In our analysis, we mainly focused on the postoperative complications including infection, seroma, hematoma, unplanned return to operating room (OR), implant loss, and flap/skin/nipple necrosis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 October 2022 and was last updated on 16 October 2022 (registration number INPLASY2022100062).

INTRODUCTION

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METHODS

Participant or population: Breast cancer patients who underwent implant-based breast reconstruction (IBBR) after mastectomy.

Intervention: Implant-based breast reconstruction with the use of TiLOOP bra.

Comparator: Implant-based breast reconstruction with the use of non-TiLOOP bra techniques (i.e. other types of mesh and simple prosthesis).

Study designs to be included: Prospective randomized controlled study and retrospective study (owing to the lack of prospective trials).

Eligibility criteria: All studies demonstrating the impact of TiLOOP bra use on the outcome of implant-based breast reconstruction, single-arm studies animals studies, other cancers, single-arm studies, reviews, letters, case reports, unavailable data or without full-text articles were excluded.

Information sources: We searched PubMed, Cochrane, and Embase for randomized clinical trials or retrospective studies comparing the complications of TiLOOP bra with other techniques. We also searched other unpublished data on clinicaltrials.gov.

Main outcome(s): We want to access both the potential benefits and risks of TiLOOP bra in IBBR comparing with other techniques, including the risk of postoperative complications and patient satisfaction in physical well-being. The postoperative complications included infection, seroma, hematoma, unplanned return to operating room (OR), implant loss, and flap/skin/nipple necrosis.

Quality assessment / Risk of bias analysis: The Methodological Index for Non-Randomized Trials (MINORS) criteria was used to assess the risk of bias.

Strategy of data synthesis: The risk ratios and mean differences were calculated and compared between the TiLOOP bra and the non-TiLOOP bra groups. R-Studio was used to run the meta-analysis via the meta packages (version 6.0-0). The pooled risks for complications were calculated and compared between the TiLOOP bra group and the control group (non-TiLOOP bra). And the mean differences (MD) with 95 % CI were pooled with random-effect meta-analysis.

Subgroup analysis: We conducted subgroup analyses to investigate the possible sources of heterogeneity by using reconstruction stage and reconstruction technique types.

Sensitivity analysis: To assess the stability of our results, sensitivity analysis was conducted by repeating the analyses and omitting one study each time.

Country(ies) involved: China.

Keywords: Breast cancer; Implant-based breast reconstruction; Biological meshes; Synthetic meshes; Postoperative complications; Patient satisfaction.

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