INPLASY PROTOCOL

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Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None declared.

Update evidence for applying subcutaneous negative pressure drains to prevent surgical site infections after gastrointestinal surgery

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Review question / Objective: **The review question is following. P: Patients who received gastrointestinal surgery, I: Placement of subcutaneous drains, C: Simple skin closure without drain, O: incidence of surgical site infections.**
Condition being studied: **Superficial incisional SSIs occur in the skin or subcutaneous tissue after surgery. Risk factors for superficial SSIs are dirty wounds, immune-compromised hosts, smoking, diabetes, and obesity. Various strategies have been tested to prevent superficial SSIs, such as anti-biotics coated absorbable sutures, high-pressure wound lavage, and negative pressure wound therapy including subcutaneous drainage. All these materials and techniques decreased superficial SSIs to some extent, but the exact clinical effect of each approach still needs to be updated.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2023 and was last updated on 31 May 2023 (registration number INPLASY202350115).

INTRODUCTION

Review question / Objective: **The review question is following. P: Patients who received gastrointestinal surgery, I: Placement of subcutaneous drains, C: Simple skin closure without drain, O: incidence of surgical site infections.**

Rationale: **Surgical site infections (SSIs) occur in the area where surgery has been performed. The incidence of SSIs is varied depending on the type of surgery. SSIs cause delayed wound healing, pain, discomfort, and fever, decreasing the quality of life and increasing medical costs. Superficial SSIs are the area around the skin and subcutaneous tissue. Subcutaneous drains were used to attempt to decrease SSIs following subcutaneous fluid collection. However, the clinical effect**

of the subcutaneous drain was not wholly proven.

Condition being studied: Superficial incisional SSIs occur in the skin or subcutaneous tissue after surgery. Risk factors for superficial SSIs are dirty wounds, immune-compromised hosts, smoking, diabetes, and obesity. Various strategies have been tested to prevent superficial SSIs, such as anti-biotics coated absorbable sutures, high-pressure wound lavage, and negative pressure wound therapy including subcutaneous drainage. All these materials and techniques decreased superficial SSIs to some extent, but the exact clinical effect of each approach still needs to be updated.

METHODS

Search strategy: Search dates is from January 1, 2000 to March 31, 2023.
A systematic literature search is performed independently by two and more authors using PubMed, MEDLINE, Cochrane Library, and EMBASE.
Terms for PubMed are follows; ((("surgery"[MeSH Subheading] OR "surgery"[All Fields] OR "surgical procedures, operative"[MeSH Terms] OR ("surgical"[All Fields] AND "procedures"[All Fields] AND "operative"[All Fields]) OR "operative surgical procedures"[All Fields] OR "general surgery"[MeSH Terms] OR ("general"[All Fields] AND "surgery"[All Fields]) OR "general surgery"[All Fields] OR "surgery s"[All Fields] OR "surgerys"[All Fields] OR "surgeries"[All Fields]) AND ("subcutaneous"[All Fields] OR "subcutaneously"[All Fields] OR "subcutanous"[All Fields]) AND ("drain"[All Fields] OR "drain s"[All Fields] OR "drained"[All Fields] OR "draining"[All Fields] OR "drains"[All Fields])) AND ((meta-analysis[Filter] OR randomized controlledtrial[Filter]) AND (2000:2023[pdat])).

Participant or population: Patients must have undergone gastrointestinal surgery. Clinical outcomes after using a subcutaneous drain should compare to standard wound management. The report should be written in English.

Intervention: Placement of a subcutaneous drain after gastrointestinal surgery.

Comparator: Comparator is conventional wound management without subcutaneous drain.

Study designs to be included: The study design should be randomized controlled trials.

Eligibility criteria: No further eligible criteria rather than described above.

Information sources: Electronic database will be PubMed, MEDLINE, Cochrane Library, and EMBASE. All trial should eb registered in any public registration, such as UMIN and ClinicalTrials. Grey literature will be excluded.

Main outcome(s): Incidence of Superficial SSs and mortality.

Additional outcome(s): Incidence of postoperative bleeding, wound dehiscence, fluid collection, pain, length of hospital stay, and medical expenses.

Data management: Study selection; Independent two and more reviewers select records according to inclusion criteria with blinding manner. Disagreements between individual judgements will be resolved by consensus discussion.

Quality assessment / Risk of bias analysis: Authors mentioned above independently assessed the risk of bias for each study using the criteria outlined in the Cochrane handbook for systematic reviews of interventions and the Cochrane effective practice and organization of care (EPOC) guidance. We assessed random sequence generation, allocation concealment, the blinding of participants and personnel, the blinding of outcome assessments, incomplete outcome data, selective reporting, and other sources of bias. We judged each potential source of bias as

high, low, or unclear and justified our judgment. We used the EPOC risk of bias guidance to help reach our judgments. Other authors settled any disagreement between the independent authors.

Strategy of data synthesis: Data will combine using RevMan to obtain a forest plot and funnel plot. Heterogeneity was assessed by use of the I2 index and Cochran Q test. Pooled prevalence and the corresponding 95% confidence interval were carried out by the random effects. P-value of less than 0.05 was deemed statistically significant in all analyses.

Subgroup analysis: Subgroup analyses will be conducted on predetermined factors (gender, smoker, obesity, malnutrition, anastomosis, laparoscopic surgery, and so on).

Sensitivity analysis: Inspection of the funnel plot and Egger's test were adopted to evaluate for publication bias.

Language restriction: English.

Country(ies) involved: Japan (Japan Society for Surgical Infection).

Keywords: subcutaneous drains/ surgical site infections/gastrointestinal surgery.

Dissemination plans: The results will be submitted to the journals, such as JAMA surgery, Ann Surg, and Surgery. It also will adapt the recomendations to the guidelines of Japan Society for Surgical Infection.

Contributions of each author:

Author 1 - Toru Mizuguchi - Toru Mizuguchi coordinate and assume primary responsibility for this review. He collects the literature and performs statistical analysis. And he will read and approve the final manuscript.
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Author 2 - Hiroji Shinkawa - Hiroji Shinkawa helps design the study. He screens literature and revised the statistical methodology. And he will read and approve the final manuscript.
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Author 3 - Keita Kouzu - Keita Kouzu screens literature and resolves conflicts with professional knowledge. And he will read and approve the final manuscript.
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