

INPLASY PROTOCOL

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None.

Clinical efficacy of surgical versus conservative treatment for multiple rib fractures: a meta-analysis of randomized controlled trials

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Review question / Objective: About 10-20% of the adult patients with high-energy trauma have multiple rib fractures (MRFs). MRFs are often associated with flail chest (FC) due to the loss of rib support in the chest wall. FC resulting in paradoxical chest wall movement, leading to life-threatening conditions like acute respiratory distress syndrome (ARDS) and hemodynamics disorders, which associated with significant risk of morbidity and mortality. Surgical stable rib fracture (SSRF) is an important treatment for MRFs. In single center randomized controlled trial (SC-RCT) and other related studies, surgical treatment has been shown to quickly restore chest wall integrity and physiological respiratory mechanics, and reduce the hospital length of stay, ventilation time and complication rate. However, it is quite difficult to design and implement multicenter randomized controlled trial (MC-RCT) on SSRF, which makes it hard to provide convincing evidences for the benefits of SSRF in MRFs. The surgical treatment of MRFs remains controversial in the academic community, no consensus has been reached to define the ultimate indications and timing.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2020 and was last updated on 01 June 2020 (registration number INPLASY202060001).

INTRODUCTION

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chest wall. FC resulting in paradoxical chest wall movement, leading to life-threatening conditions like acute respiratory distress syndrome (ARDS) and hemodynamics disorders, which associated with significant risk of morbidity

and mortality. Surgical stable rib fracture (SSRF) is an important treatment for MRFs. In single center randomized controlled trial (SC-RCT) and other related studies, surgical treatment has been shown to quickly restore chest wall integrity and physiological respiratory mechanics, and reduce the hospital length of stay, ventilation time and complication rate. However, it is quite difficult to design and implement multicenter randomized controlled trial (MC-RCT) on SSRF, which makes it hard to provide convincing evidences for the benefits of SSRF in MRFs. The surgical treatment of MRFs remains controversial in the academic community, no consensus has been reached to define the ultimate indications and timing.

Rationale: This meta-analysis was carried out and reported based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) and AMSTAR (Assessing the methodological quality of systematic reviews) guidelines.

Condition being studied: Up to now, nearly 10 articles on meta-analysis of MRFs have been collected. In only two meta-analyses (one from Brazil conducted in 2015 and another from United Kingdom in 2016), the included studies were all RCTs, however, these RCTs only included a few studies (3 studies in each) involving small sample size of 61 undergoing surgical vs. 62 conservative treatment. In response to recent development in surgical treatment for MRFs and reports on RCTs for MRFs, we included 7 RCTs involving larger sample size (260 patients with surgical and 278 patients with conservative treatment) in systematic evaluation in an effort to provide more convincing evidences for clinical choice between surgical and conservative treatment for MRFs.

METHODS

Search strategy: With the Medical Subject Headings (MeSH) terms “rib fractures”, “flail chest”, “surgical procedures, operative”, “thorascopes”, “conservative treatment”, “randomized controlled trial”

and “clinical trial”, we searched six databases (PubMed, Medline, Embase, Cochrane, Cnki, Wanfang database) for literature (published until Jan 2020) regarding RCTs on operative reduction and internal fixation versus conservative treatment for MRFs.

Participant or population: Each included study was independently assessed by two reviewers (R.L. and S.W.); disagreements were resolved by a consultation with two other reviewers (Y.L. and X.Y.). Two reviewers (R.L. and S.W.) independently assessed the quality of all included studies. Discrepancies were resolved by consensus between two senior reviewers (J.T. and J.F.).

Intervention: The patients in the surgical group received operative reduction and internal fixation for MRFs, while those in the control group received conservative therapy.

Comparator: The clinical outcomes were compared between the surgical group and the conservative group.

Study designs to be included: All studies were RCTs.

Eligibility criteria: Inclusion criteria(DPICO): (Design) all studies were RCTs; (Patient) the subjects were MRFs caused by trauma yet without serious organ-system lesions (AIS-ISS score 9-20 points), pathological fractures, chronic severe underlying diseases; (Intervention) the patients in the surgical group received operative reduction and internal fixation for MRFs, while those in the control group received conservative therapy; (Control) the clinical outcomes were compared between the surgical group and the conservative group; (Outcome) hospital length of stay, ICU length of stay, duration of mechanical ventilation, the incidence of pneumonia, chest wall deformity, tracheostomy, mortality, dyspnea. Exclusion criteria: (i) RCTs with incomplete data or without main outcome indicators; (ii) non-randomized controlled trials; (iii) the studies without clearly-

defined inclusion and exclusion criteria and those studies in which the included objects or intervention measures failed to meet the requirements; (iv) case reports, reviews, commentary articles, abstracts and systematic evaluations; (v) repeated reporting; (vi) literature of low quality; (vii) studies with research purpose or operation type different from those defined in this study.

Information sources: We searched six databases (PubMed, Medline, Embase, Cochrane, Cnki, Wanfang database), the retrieved data included title of the article, the first author, year of publication, source of literature, study site, number of cases, patients' age and gender, specific details of intervention, follow-up time, major outcome measures etc.

Main outcome(s): Hospital length of stay, ICU length of stay, duration of mechanical ventilation, the incidence of pneumonia, chest wall deformity, tracheostomy, mortality, dyspnea.

Quality assessment / Risk of bias analysis: The quality of the literature was evaluated by the modified Jadad rating scale, including the following items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment (with 2 scores for appropriate, 1 score for unclear and 0 for inappropriate for the above three items), and withdrawal and exit (1 for descriptive, 0 for none-descriptive). On a scale of 7, 1-3 scores represent low-quality and 4-7 high-quality research.

Strategy of data synthesis: Review Manager 5.3 statistical software provided by Cochrane was used for meta-analysis. The χ^2 test was used for statistical heterogeneity test (the test level $\alpha = 0.05$), and the heterogeneity was quantitatively evaluated by I²-statistics. For heterogeneity (I² > 50%, P < 0.05), the random effects (RE) model was used, and for homogeneity (I² < 50%, P > 0.05), the fixed effects (FE) model was used. If heterogeneity was noted for the study effect, its causes should be further

explored through subgroup analysis or sensitivity analysis. The continuous variable was expressed as weighted mean difference (WMD) and the binary variable was expressed as relative risk (RR) with 95% confidence interval (95% CI) calculated for both. We considered statistical significance present when the P-value < 0.05.

Subgroup analysis: The included studies were divided into three subgroups by year (before or in 2010 group, 2011-2015 group and 2016-2020 group). Subgroup analysis of hospital length of stay and the subgroup analysis of incidence of pneumonia was carried out.

Sensibility analysis: Sequential exclusion was used to evaluate the sensitivity of the rate of tracheostomy, hospital length of stay, ICU length of stay and duration of mechanical ventilation. The sources of heterogeneity did not found, indicating the stability of the results of the meta-analysis on these outcomes.

Keywords: Rib fractures, Flail chest, Surgery, Randomized controlled trial, Meta-analysis.

Contributions of each author:

Author 1 - Rui Long - Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Software; Writing-Original Draft; Writing-Review & Editing.

Author 2 - Junying Tian - Translate; Validation; Supervision; Writing-Review & Editing.

Author 3 - Shasha Wu - Data curation; Methodology; Software; Validation.

Author 4 - Yang Li - Investigation; Validation; Supervision.

Author 5 - Xiuhua Yang - Investigation; Validation; Supervision.

Author 6 - Jun Fei - Conceptualization; Project administration; Resources; Validation; Supervision; Writing-Review & Editing.