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Quality Improvement Strategies for Preventing Tracheostomy-Related Pressure Injuries in Children: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 May 2026 and was last updated on 26 May 2026.

INTRODUCTION

Review question / Objective To systematically review and, where appropriate, meta-analyse the effectiveness of interventions for preventing tracheostomy-related medical device-related pressure injuries in children.

Using the PICOS framework:
Population: Children aged ≤18 years undergoing or living with tracheostomy.
Intervention: Preventive strategies such as prophylactic dressings, silver-containing foam dressings, Velcro®-type securement devices, modified ties, or bundled nursing protocols.
Comparator: Usual care, no dressing, standard dressings, traditional twill ties, or alternative preventive interventions.
Outcomes: Incidence and severity of tracheostomy-related pressure injuries or peristomal skin breakdown.
Study designs: Randomized controlled trials, quasi-experimental studies, and prospective or retrospective cohort studies.

Objective:
To evaluate and compare the effectiveness of available preventive interventions in reducing the incidence and severity of tracheostomy-related pressure injuries in paediatric patients, and to provide evidence to inform clinical nursing practice and future research.

Condition being studied Tracheostomy-related medical device-related pressure injury is a skin or tissue injury caused by sustained pressure, friction, shear, and moisture associated with a tracheostomy tube, ties, flanges, or dressings. In children, this condition commonly affects the peristomal area, neck, and surrounding skin after tracheostomy.

Children are particularly vulnerable because they have more delicate skin, smaller anatomical structures, limited mobility, and frequent exposure to airway secretions. Pressure injuries may range from mild skin redness or irritation to severe wounds involving deeper tissue. These injuries can cause pain, increase infection risk, prolong hospital

stay, increase healthcare costs, and add to caregiver burden.

This review focuses on tracheostomy-related pressure injuries in paediatric patients and evaluates strategies intended to prevent these complications, including protective dressings, silver-containing foam dressings, modified securement devices, and bundled nursing care protocols.

METHODS

Participant or population Children and adolescents aged 18 years or younger who have undergone tracheostomy or are receiving care with a tracheostomy tube will be included. Participants may be in the immediate postoperative period, during inpatient care, or receiving ongoing tracheostomy management.

Eligible participants include paediatric patients of any sex, underlying diagnosis, indication for tracheostomy, or duration of cannulation. This may include children with airway obstruction, congenital anomalies, neuromuscular disease, chronic lung disease, malignancy, or other conditions requiring tracheostomy.

Studies involving mixed adult and paediatric populations will be included only if data for participants aged 18 years or younger can be extracted separately. Studies exclusively involving adults, animal studies, cadaver studies, or laboratory-based studies will be excluded.

Intervention The review will evaluate interventions intended to prevent tracheostomy-related medical device-related pressure injuries in children.

Eligible interventions may include single or bundled preventive strategies, such as:

Protective or prophylactic dressings, including foam dressings, silicone dressings, hydrocolloid dressings, Mepilex®, and silver-containing foam dressings such as Mepilex® Ag.

Modified tracheostomy securement methods, including Velcro®-type ties, hook-and-loop fasteners, silicone fasteners, adjustable fasteners, or other alternatives to traditional twill ties.

Nursing or quality improvement bundles, such as standardized skin assessment, regular dressing changes, secretion management, multidisciplinary wound prevention protocols, caregiver education, and postoperative tracheostomy care pathways.

Interventions may be delivered in hospital, intensive care, surgical, or home-care settings. Studies evaluating interventions aimed at treating established pressure injuries only, without a preventive component, will be excluded.

Comparator Comparators will include usual care, no intervention, placebo, or alternative preventive interventions.

For dressing-related interventions, comparators may include standard care, no dressing, traditional gauze, standard Mepilex®, hydrocolloid dressings, silicone dressings, or other prophylactic dressings.

For securement-related interventions, comparators may include conventional twill ties, standard tracheostomy ties, or other securement devices.

For bundled care interventions, comparators may include routine postoperative or tracheostomy care before implementation of the bundle, standard nursing care, or another prevention protocol.

Studies without a relevant comparator group will be excluded.

Study designs to be included Randomized controlled trials, quasi-experimental studies, non-randomized controlled trials, controlled before-and-after studies, interrupted time series, and prospective or retrospective cohort studies will be included. Case reports, uncontrolled case series, reviews, conference abstracts, editorials, letters, expert opinions, guidelines, animal studies, and laboratory studies will be excluded.

Eligibility criteria Additional eligibility criteria will include studies published in any language and conducted in any country or healthcare setting. Studies must report original clinical data on preventive interventions for tracheostomy-related pressure injuries in paediatric patients and provide sufficient outcome data for extraction.

Studies will be excluded if they focus only on treatment of established pressure injuries, do not report tracheostomy-related skin or pressure injury outcomes, lack a comparator group, or do not provide extractable paediatric data. Duplicate publications will be excluded, with the most complete or most recent dataset retained. Studies involving adults only, animals, cadavers, or laboratory models will also be excluded.

Information sources Information sources will include electronic searches of PubMed, Embase, Cochrane Library including CENTRAL, Web of

Science Core Collection, CINAHL, CNKI, Wanfang Data, and VIP from database inception to the search date. No language restrictions will be applied.

Additional sources will include manual screening of the reference lists of included studies and relevant reviews. Clinical trial registries, including ClinicalTrials.gov and the Chinese Clinical Trial Registry, will be searched to identify unpublished or ongoing studies. Where necessary, corresponding authors of eligible or potentially eligible studies will be contacted by email to request missing data or clarification.

Main outcome(s) The main outcome will be the incidence of tracheostomy-related medical device-related pressure injury in children, including peristomal skin breakdown or pressure injury associated with the tracheostomy tube, ties, flanges, or dressings.

Where reported, pressure injuries will be classified by severity or stage according to recognized systems such as the NPIAP/EPUAP pressure injury staging system. Outcomes will be assessed during the postoperative or follow-up period reported by each included study, such as within 5–8 days after tracheostomy, 7 days postoperatively, until first tube change, hospital discharge, or the longest available follow-up.

For dichotomous outcomes, effect measures will include risk ratios, odds ratios, or risk differences with 95% confidence intervals or credible intervals, depending on the analysis model. Where appropriate, pooled estimates will be calculated using meta-analysis.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of included studies will be assessed independently by two reviewers. Disagreements will be resolved through discussion or consultation with a third reviewer.
Randomized controlled trials will be assessed using the Cochrane Risk of Bias 2.0 tool, covering bias arising from the randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selection of the reported result.
Non-randomized studies, including cohort studies and quasi-experimental studies, will be assessed using the ROBINS-I tool, covering bias due to confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, outcome measurement, and selective reporting.

Each study will receive an overall risk of bias judgement. The results will be summarized narratively and, where appropriate, presented in tables. Risk of bias assessments will be considered when interpreting the certainty and reliability of the review findings.

Strategy of data synthesis Data will be synthesized narratively and, where sufficient comparable data are available, quantitatively using meta-analysis. Study characteristics, interventions, comparators, outcomes, and risk of bias will first be summarized in tables.

For dichotomous outcomes, such as pressure injury incidence, effect estimates will be expressed as risk ratios, odds ratios, or risk differences with 95% confidence intervals or credible intervals. A random-effects model will be used where clinical or methodological heterogeneity is expected. Statistical heterogeneity will be assessed using the Chi-square test and I^2 statistic.

Where studies compare multiple preventive interventions, Bayesian network meta-analysis may be conducted to estimate relative effects and rank interventions. Model convergence will be assessed using appropriate diagnostics, and inconsistency will be explored where possible. Sparse or zero-event data will be handled using suitable continuity corrections or Bayesian methods.

If meta-analysis is not appropriate because of heterogeneity or insufficient data, findings will be presented as a structured narrative synthesis. Sensitivity or subgroup analyses may be conducted according to study design, intervention type, comparator, outcome definition, or risk of bias where data permit.

Subgroup analysis Subgroup analysis will be conducted where sufficient data are available. Planned subgroup analyses may include:

Type of intervention, such as prophylactic dressings, silver-containing foam dressings, Velcro®-type securement devices, traditional ties, or bundled nursing protocols.
Type of comparator, such as usual care, no dressing, standard foam dressing, standard Mepilex®, or conventional twill ties.
Study design, including randomized controlled trials versus non-randomized or observational studies.
Timing of assessment, such as early postoperative follow-up, first tracheostomy tube change, hospital discharge, or longer follow-up.

Participant characteristics, where reported, such as age group, underlying diagnosis, indication for tracheostomy, or high-risk populations.
Risk of bias or study quality, comparing studies at lower versus higher risk of bias.

Subgroup analyses will be considered exploratory because the number of eligible studies is expected to be limited.

Sensitivity analysis Sensitivity analysis will be performed where sufficient data are available to assess the robustness of the review findings. Planned sensitivity analyses may include excluding studies at high or serious risk of bias, excluding non-randomized or retrospective studies, and analysing randomized controlled trials separately.

Additional sensitivity analyses may examine the influence of zero-event studies, continuity corrections, alternative effect measures such as risk ratio versus odds ratio, and fixed-effect versus random-effects models. Where network meta-analysis is conducted, sensitivity analyses may assess the impact of model assumptions, sparse data, and studies contributing indirect evidence.

If any single study has a disproportionate influence on the pooled estimate, leave-one-out analysis may be performed. The results of sensitivity analyses will be compared with the primary analysis to determine whether conclusions remain consistent.

Country(ies) involved China. The review is being carried out by authors affiliated with the National Center for Children's Health, Beijing Children's Hospital, Capital Medical University, Beijing, China.

Keywords Pediatrics; Tracheostomy; Medical device-related pressure injury; Pressure injury prevention; Mepilex; Velcro tie.

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