

TITLE: Nasal Bridle Devices for the Securement of Nasoenteric Feeding Tubes in Adult Patients: Comparative Clinical Effectiveness, Safety, and Cost-Effectiveness

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CONTEXT AND POLICY ISSUES

Nasogastric tube feeding is frequently used to provide nutrition by the enteral route for hospitalized patients who are unable to take food orally due to their medical conditions. Traditionally, nasoenteric tubes are held in place with adhesive tape. However, this securement technique is associated with a high rate of involuntary dislodgement, estimated between 20% to 40%.^{1,2}

Reinserting dislodged feeding tubes causes lost clinician productivity since it engages qualified hospital staff who could otherwise be serving other health care needs.² Reduced caloric intake and the need for patients to undergo sedation and further confirmatory radiographs to ensure proper positioning of replacement tubes have safety inferences.¹ In addition to the potential safety complications from reinsertion, there are also associated cost implications. Therefore, the reduction in unintended dislodgement of feeding tubes is clinically relevant to improve patient outcomes and reduce costs.

Securement of nasoenteric tubes with nasal bridles is an alternative method intended to minimize inadvertent dislodgement. The correctly positioned bridle enters one nostril, wraps around the nasal septum, and exits the opposite nostril, where both ends are attached to a feeding tube.³ Tethering to the nasal septum is expected to provide a more reliable anchoring of the nasoenteric tube than adhesive tape on the face. However, the comparative effectiveness and safety of nasal bridles relative to adhesive tape techniques are not well established.

The aim of this report is to summarize and compare the current evidence of the clinical effectiveness, safety and cost-effectiveness of nasal bridles and adhesive tapes as nasoenteric tube securement interventions to inform decisions for future research.

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RESEARCH QUESTIONS

1. What is the comparative clinical effectiveness of nasal bridle devices versus adhesive for the securement of nasoenteric feeding tubes?
2. What is the clinical evidence regarding the safety of nasal bridle devices for the securement of nasoenteric feeding tubes?
3. What is the cost-effectiveness of nasal bridle devices for the securement of nasoenteric feeding tubes?

KEY FINDINGS

A meta-analysis by Bechtold et al.⁴ and a systematic review by Brugnolli et al.² found that the dislodgement rate of nasoenteric tubes is significantly lower when secured with nasal bridles than when secured with an adhesive tape technique. The meta-analysis⁴ evaluated one randomized controlled trial (RCT) and four prospective cohort studies (n=544) and reported an odds ratio (OR) with 95% confidence interval (CI) of 0.16 (0.10, 0.27; $P < 0.01$) in favor of nasal bridles, while one RCT and two prospective cohort studies (n=232) in the systematic review² (all of which were also included in the meta-analysis⁴) reported dislodgement rates ranging from 6.5% to 10% for nasal bridles compared to a dislodgement rates ranging from 32.6% to 63.0% for adhesive tapes. Data on caloric intake, safety, and cost were insufficient or inconsistent and could not suggest any advantage of one securement technique (nasal bridles or adhesive tape) over the other.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, CINAHL, The Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011, and November 24, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed, and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

| | |
|----------------------|---|
| Population | Adult patients who require nasoenteric feeding |
| Intervention | Nasal bridle devices (e.g., AMT Bridle Nasal Tube Retention System) |
| Comparator | Q1 to 3: Any adhesive securement method (e.g., tape, precut adhesive) Q2: No comparator required |
| Outcomes | Q1: Clinical effectiveness (e.g., rate of tube dislodgement, time to failure, rate of referral for PEG placement, caloric intake, nutritional status, patient discomfort, patient satisfaction, quality of life) Q2: Safety (e.g., skin complications, sinusitis, epistaxis, external nasal ulceration) Q3: Cost-effectiveness outcomes (e.g., cost per QALY, cost per health outcome) |
| Study Designs | HTA/Systematic Reviews/Meta-Analyses, Randomized Controlled Trials, Non-Randomized Studies, Economic Evaluations |

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published before 2011. Studies included in an already selected systematic review, abstract or narrative review with insufficient information to permit critical appraisal, and case reports were also excluded.

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised using AMSTAR instrument.⁵ Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were narratively described.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 94 citations were identified in the literature search. Following the screening of titles and abstracts, 87 citations were excluded, and seven potentially relevant reports from the electronic search were retrieved for full-text review. Eight potentially relevant publications were retrieved from the grey literature search, and two papers were identified from references of other reports. Of these 17 potentially relevant articles, 15 articles were excluded for various reasons, while two publications^{2,4} met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Further details of the characteristic of the included studies^{2,4} are provided in Table A1, Appendix 2.

Study Design

Bechtold et al.⁴ conducted a meta-analysis of five prospective cohort studies and one randomized controlled trial (RCT), while Brugnolli et al.² performed a systematic review of five studies including two RCTs, two historically controlled prospective cohort studies, and a quality improvement project with a before-and-after prospective cohort design. The publication dates of the included studies ranged from 1999 to 2013 for the study by Bechtold et al.⁴ and 1995 to 2010 for the study by Brugnolli et al.²

Country of Origin

The meta-analysis by Bechtold et al.⁴ and all its primary studies were conducted in the United States of America (USA). The systematic review by Brugnolli et al.² was performed by authors from Italy, with four primary studies from the USA and one from Germany. Three primary studies, all conducted in the USA, were common to both the meta-analysis⁴ and the systematic review.²

Patient Population

The study by Bechtold et al.⁴ included 594 patients with mean ages ranging from 48 to 66 years, while the study by Brugnolli et al.² reported that a total of 335 patients were included in four of its five primary studies. For the remaining primary study, the sample size was reported as not specified. Patient's age was broadly reported as 18 years or older for study by Brugnolli et al.² Most of the patients who participated in the studies were in the intensive care unit (ICU).

Interventions and Comparators

Nasal bridle and adhesive tape techniques to secure nasogastric tubes were the intervention and comparator, respectively, in the studies by both Bechtold et al.⁴ and Brugnolli et al.² In the meta-analysis,⁴ nasogastric tubes sizes ranged from 8 to 16 French (Fr) and in the systematic review,² tube sizes ranged from 8 to ≥ 14 Fr.

Outcomes

The primary outcome in the study by Bechtold et al.⁴ was tube dislodgement and secondary outcomes were skin complications such as erythema and frank ulcerations and sinusitis.⁴ Pooled estimates of the primary and secondary outcomes comparing the effect of nasal bridles with traditional adhesive tape were reported. Heterogeneity was considered significant if the calculated $I^2 > 50\%$ or $P < 0.10$. In the study by Brugnolli et al.,² the primary outcome measures were tube-dwelling time, unplanned nasogastric tube extubation or dislodgement, need for tube replacement, patient discomfort, and complications such as pneumonia, skin or mucosa lesions, and reduced caloric intake. Secondary outcomes included cost, and mortality.² According to the authors, the results were presented in a quantitative narrative synthesis without pooling since meta-analysis was neither feasible nor appropriate due to the heterogeneity of the study designs, populations, types of intervention, and the small number of included studies.²

Summary of Critical Appraisal

Further details of the strengths and limitations of the included studies^{2,4} have been provided in Table A2, Appendix 3.

Both Bechtold et al.⁴ and Brugnolli et al.² performed comprehensive searches covering multiple databases and grey literature for relevant reports. Each study specified inclusion and exclusion criteria and provided a list of included studies with summary of the study characteristics.^{2,4} None of the authors in either the meta-analysis⁴ or systematic review² had any conflict of interest that could potentially influence the conduct and reporting of their studies.

In the studies by both by Bechtold et al.⁴ and Brugnolli et al.,² two reviewers independently screened citations for eligibility, reviewed full-text articles, and extracted data for the analysis. They resolved discrepancies by consensus or through a third party. In the study by Bechtold et al.,⁴ the quality of included primary studies was independently assessed and documented by two reviewers using the Effective Public Health Practice Project (EPHPP) model.⁶ The EPHPP Quality Assessment Tool for Quantitative Studies evaluates the quality of a study as strong, moderate, or weak based on criteria ratings for selection bias, study design, confounders, blinding, data collection methods, withdrawal and dropout descriptions, intervention integrity, and analysis. One RCT was graded high quality while five non-randomized prospective cohort studies were moderate quality. A funnel plots analysis showed no publication bias for any of the outcomes included in the meta-analysis.⁴ Two reviewers in the study by Brugnolli et al.² independently assessed the risk of bias of each primary study using the Cochrane Risk of Bias tool.⁵ The criteria for risk assessment in the Cochrane Risk of Bias tool are selection bias (random sequence generation and allocation concealment), performance bias (blinding), attrition bias (incomplete outcome data), reporting bias (selective reporting) and other bias. The risk of bias was scored as low for one RCT in all quality measures except performance bias (blinding). The nature of the intervention made blinding impractical. All the remaining four primary cohort studies had a high risk of bias in all measures, except selective reporting, in which two of them had a low risk of bias.

Bechtold et al.⁴ assessed heterogeneity between primary studies by calculating the I^2 , and examined the contribution of each towards statistically significant heterogeneity ($I^2 > 50\%$ or $P < 0.10$) through sensitivity analysis. Data for outcomes such as the pain, erosion of the nasal septum, or complications, including epistaxis, and aspiration were limited, making it inappropriate to draw any firm conclusions in these regards.⁴ For example, in the systematic review² only one RCT (also included in the meta-analysis⁴ reported on nasal ulceration, while one prospective cohort study reported one episode of epistaxis.² Further, although the meta-analysis broadly reported a 13% incidence of skin complications, the conditions were described as ranging from erythema to frank ulcerations without any specifics. Although Brugnolli et al.² reported heterogeneity among their included primary studies, they did not report how this was determined.

Except for patients in one primary study from Germany which did not provide information about its setting and patients' characteristics, the patients in the studies by Bechtold et al.⁴ and Brugnolli et al.² were enrolled from ICUs of university hospitals and a private tertiary hospitals. However, patients' characteristics and medical history were inadequately reported. Therefore, the generalizability of the findings of the meta-analysis⁴ and the systematic review² in other settings and patient populations is unknown.

Summary of Findings

Findings from the Bechtold et al. meta-analysis⁴ and Brugnolli et al. systematic review² have been reported below. Further details are provided in Table A3, Appendix 4

What is the comparative clinical effectiveness of nasal bridle devices versus adhesive for the securement of nasoenteric feeding tubes?

Unintentional dislodgement or removal

Three primary studies (n=404) common to both the meta-analysis⁴ and the systematic review² reported statistically significantly lower dislodgements with nasoenteric tubes secured with bridles than that those secured with adhesive tape technique ($P < 0.0001$ in two studies and $P = 0.004$ in one study). The meta-analysis included two additional studies which also reported tube dislodgement data. Thus, the meta-analysis⁴ of five primary studies (n=544) showed that dislodgement was significantly lower when nasoenteric tubes were secured with nasal bridles than when they were secured by tape alone (14% versus 40%, respectively). The pooled odds ratio (OR) 95 % confidence interval (CI) was 0.16 (0.10, 0.27), $P < 0.01$.

Time until failure

Two primary studies of the systematic review² measured the days until failure, comparing bridle versus adhesive tape techniques. One study (n=80) found no significant difference in time until failure between the bridled and tape methods of securing nasoenteric tubes ($P < 0.21$), whereas the other study (n = not specified), demonstrated a significantly longer time until failure with the nasal bridle technique ($P < 0.001$).

Caloric intake

One primary study (common to both the meta-analysis⁴ and systematic review²; n=80) reported that patients for who nasoenteric tubes were secured with nasal bridles received a significantly higher percentage of their caloric goal than patients for who nasoenteric tubes were secured by tape technique ($P = 0.016$).

What is the clinical evidence regarding the safety of nasal bridle devices for the securement of nasoenteric feeding tubes?

Four primary studies, including three which were common to both the meta-analysis⁴ and systematic review,² showed that skin complications occurred significantly more frequently among patients for who nasal bridles were used than in patients for who tubes were secured by tape alone. The meta-analysis found that skin complications occurred in 13% of patients with nasal bridles compared with 3% in patients with adhesive tape, indicating that the use of a nasal bridles increased the risk of skin complications (OR, 4.27; 95% CI: 1.79, 10.23; $P < 0.01$). Skin complications included erythema and frank ulcerations, but data were not provided for specific skin conditions. Heterogeneity across these studies was not statistically significant ($I^2 = 44\%$, $P = 0.15$). Analysis of two primary studies (n=130) found that of 73 patients who had their tubes secure with adhesive tape, 5% developed sinusitis, whereas none of 57 patients with bridle-secured tubes had sinusitis.⁴ The difference was not statistically significant.

The three primary studies of the systematic review² which were also included in the meta-analysis⁴ reported on external nasal ulceration, epistaxis, and sinusitis. However, the results varied between studies. One study (n=62) reported four cases (6.5%) of nasal ulceration per 800 tube-feeding days in the bridle group with no incidence of nasal ulceration in the tape group. All the ulcerations were associated with red rubber catheter bridles and switching to umbilical tape bridles eliminated further ulceration. Another study (n=80) found no difference

between bridled and unbridled patients concerning external nasal ulceration and sinusitis ($P = 0.12$ and $P = 0.49$, respectively). One study ($n=90$) reported one episode (1.1%) of epistaxis, which resolved without specific medical therapy in the bridled group.

What is the clinical evidence regarding the safety of nasal bridle devices for the securement of nasoenteric feeding tubes?

One primary study (common to both the meta-analysis⁴ and systematic review²; $n=62$) estimated that the use of nasal bridles would result in a savings of US\$4,038 over the course of three months compared to the tape technique. The savings were expected to accrue from efficient improvement in caloric intake, reduction in staff time, decreased exposure to repeated radiography, and reduced use of materials associated with repeated reinsertions of inadvertently removed nasoenteric feeding tubes.

Limitations

The literature search for this report found only two studies – a meta-analysis⁴ and a systematic review² which met the inclusion criteria. Between them, there was a total of eight unique primary studies, although only seven studies (one RCT and six prospective cohort studies) compared bridles with adhesive tape while one study compared different adhesive techniques. Of the primary studies that investigated bridles, one did not report the number of patients, and only one had a sample size greater than 100. Further, three primary studies which accounted for 68% of the reported number of patients were common to both the meta-analysis⁴ and the systematic review². Therefore, interpreting common findings from the meta-analysis⁴ and the systematic review² together should be done cautiously to avoid overstating their effect.

Apart from one primary study of the systematic review² which did not report the settings, all the patients included in primary studies of both the meta-analysis⁴ and the systematic review² which evaluated nasal bridle were enrolled from ICUs of university hospitals and a private tertiary hospital in the USA. Therefore, the generalizability of the reported findings in other setting, including Canadian settings, and among different patient populations is unknown.

Patient-reported outcomes such as pain, discomfort, satisfaction, and quality of life were not reported in either the meta-analysis⁴ or the systematic review². Also, data on safety outcomes were limited, with only a few primary studies reporting adverse events, even so, with data that cannot support firm conclusions. One reason given for limited use of nasal bridles in clinical practice is the perceived risk of patient discomfort among clinicians.⁴ Given this, further studies may be needed to explore the safety and patient-reported outcomes of nasal bridle intervention.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

One meta-analysis⁴ and a systematic review² were included in this report. Together both comprised one RCT and six non-randomized primary studies that compared bridles with adhesive tape for the securement of nasogastric tubes. Three of the primary studies were common to both the meta-analysis and systematic review. Both the meta-analysis⁴ and the systematic review² found that the use of nasal bridles to secure nasogastric tubes was associated with statistically significantly lower dislodgements of nasogastric tubes than securement with adhesive tape technique. Caloric intake data were reported by only one primary study common to both the meta-analysis⁴ and systematic review,² which found that patients with nasal bridles received a significantly higher ($P = 0.016$) percentage of their caloric goal than patients adhesive tape securement. There were inconsistent data on time until failure. One primary study found no significant difference between the bridled and tape methods of securing nasogastric tubes ($P < 0.21$), whereas another study showed a significantly longer time until failure with the nasal bridle technique ($P < 0.001$). Data on external nasal ulceration, epistaxis, and sinusitis were also inconsistent. One primary study ($n=62$) estimated that the use of nasal bridles would result in a savings of US\$4,038 over three months compared to the adhesive tape technique due to the efficient improvement in caloric intake, reduction in staff time, decreased exposure to repeated radiography, and reduction in materials used for reinsertions of nasogastric tubes.

Overall, nasal bridles appear to be more efficient than adhesive tapes at securing nasogastric tubes and preventing dislodgement. However, data on caloric intake, safety, and cost-effectiveness were either insufficient or inconsistent. Considering that both the meta-analysis and systematic reviews² included in this report had a small number of primary studies with small sample sizes and that three of these studies were common to both, the available evidence is inconclusive. Therefore, there is a need for more well-designed studies to assess the comparative clinical and cost effectiveness of the nasal bridle and adhesive tape techniques to secure nasogastric tubes.

PREPARED BY:

Canadian Agency for Drugs and Technologies in Health

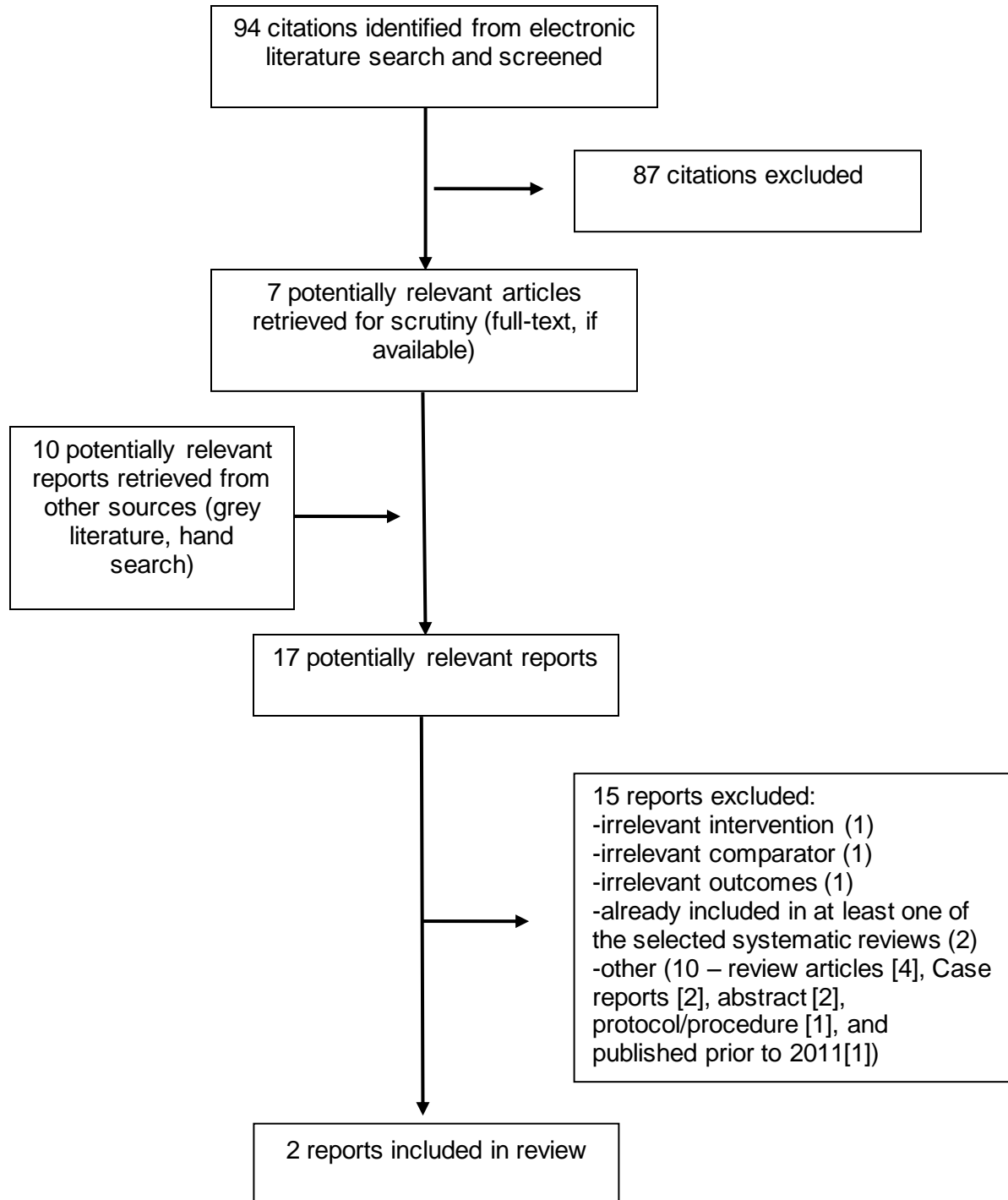
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APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

| First Author, Publication Year, Country | Types and numbers of primary studies included | Population Characteristics | Intervention | Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|--|---|---------------------------|-----------------------------|---|
| Bechtold, 2014 ⁴ | A total of six studies (five prospective cohort studies and one RCT) were included. They were performed at university hospitals and a private tertiary hospital in the USA. | 594 patients with mean age ranging from 48 to 66 years | Nasal bridles | Adhesive tape alone | <u>Primary:</u> Pooled estimates of dislodgement <u>Secondary:</u> Skin complications, and sinusitis |
| Brugnoni, 2014 ² | A total of five studies including two RCTs and three prospective cohort studies. Details about the settings of the studies were not reported. Three primary studies (including one RCT) are common to the study by Bechtold et al. ⁴ , which has been included in this report | Four of the five primary studies reported a total of 335 patients from ICUs. The sample size and the study setting for the fifth study were not reported. | Nasal bridle ^a | Tape technique ^a | <u>Primary</u> Tube-dwelling time, unplanned tube extubation or dislodgement, need for tube replacement, patient's discomfort, and complications such as pneumonia, skin or mucosa lesions, and reduced caloric intake. <u>Secondary</u> Nurse satisfaction, cost, and mortality. |

ICU = intensive care unit; RCT = randomized controlled trial; USA = United State of America

^a One of the five included studies compared three taping methods (butterfly, clear tape, and pink tape) while the remaining four studies compared nasal bridle with tape technique

APPENDIX 3: Critical Appraisal of Included Publications

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using the AMSTAR instrument ⁹

| Strengths | Limitations |
|--|--|
| <p>Bechtold, 2014⁴</p> <ul style="list-style-type: none"> • A comprehensive literature search covering multiple databases, abstracts from major conferences, and a manual search of references of the retrieved articles and reviews for additional relevant articles was performed. Primary study authors were contacted for clarifications if data were incomplete, missing, or required clarification. • Two reviewers independently screened citations, selected studies for inclusion, and extracted data for the analysis. Disagreements were resolved by consensus or through a third party. • The quality of the included primary studies was assessed using the Effective Public Health Practice Project model, which evaluates study quality as strong, moderate, or weak based on criteria ratings for selection bias, study design, confounders, blinding, data collection methods, withdrawal and dropout descriptions, intervention integrity, and analysis. One study was rated to be of strong methodologic quality, while the other five studies had moderate quality. Thus, according to the model of assessment, no poor quality studies were included in this systematic review. • A funnel plot analysis showed no publication bias for any of the outcomes covered in the meta-analysis • Heterogeneity was analyzed by calculating the I^2 measure of inconsistency. I^2 was considered significant if $P < 0.10$ or $> 50\%$ and sensitivity analyses were used to examine sources of heterogeneity. • The authors had no conflict of interest or financial disclosure to make. | <ul style="list-style-type: none"> • The exclusion criteria were not adequately described. Thus it is unknown whether potentially relevant studies were left out. • Four of the five included studies were prospective cohort studies with only one randomized controlled trial, and there were limited data for outcomes such as the pain, erosion of the nasal septum, or complications, including epistaxis, and aspiration. Thus more rigorous studies may be required to confirm the study finding. • Patients were enrolled from university hospitals and a private tertiary hospital. However, patients' characteristics and medical history were inadequately reported. Thus the generalizability of the reported findings is uncertain. |
| <p>Brugnolli, 2014²</p> <ul style="list-style-type: none"> • A comprehensive literature search of multiple electronic databases, websites, reference lists, and existing systematic reviews and papers identified by experts in the field for published and unpublished reports from 1966 to May 2011 in any language. • Inclusion and exclusion criteria were clearly specified • Two reviewers independently screened the titles and abstracts for eligibility, resolving discrepancies by consensus. • Two reviewers independently reviewed full-text articles of all of the selected citations using a standardized form and guide previously pilot tested. Disagreements were resolved by consensus or by consultation with a third reviewer. • Data for each included study were extracted by one reviewer and verified by a second reviewer, with discrepancy resolved by consensus | <ul style="list-style-type: none"> • Data could not be pooled and meta-analyzed due to the heterogeneity of the study designs, populations and types of intervention and the small number of included studies. • In General, the included studies did not have a high methodological quality. One RCT was rated as having a low risk of bias with respect to selection bias, and attrition bias, while these risks of bias were rated as unclear or high in remaining four studies. Four studies had a high risk of performance bias, and the risk was assessed as unclear in the other study. Three studies had a low risk of reporting bias, while this bias was high in two other studies. • Four of the five included studies enrolled patients admitted to the ICU (n=335). The patients' characteristics, setting, and sample size of the remaining study was inadequately reported. Therefore, the |

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using the AMSTAR instrument⁹

| Strengths | Limitations |
|--|--|
| <ul style="list-style-type: none"> • A list of included studies with a summary of study characteristics was provided. • Two review authors independently assessed the risk of bias of each study using the Cochrane Risk of Bias tool and resolved any discrepancy by consensus. • Authors had no conflict of interest or financial disclosure to make. The study was supported by the Centre of Higher Education for Health Sciences of Trento with the collaboration of the University of Verona. | <p>generalizability of the findings of the systematic review in other settings and patient populations is unknown.</p> <ul style="list-style-type: none"> • |

ICU = intensive care unit; RCT = randomized controlled trial

APPENDIX 4: Main Study Findings and Author’s Conclusions

| Table A3: Summary of Findings of Included Studies | |
|---|--|
| Main Study Findings | Author’s Conclusions |
| Bechtold, 2014 ⁴ | |
| <p><u>Unintentional dislodgement or removal</u></p> <ul style="list-style-type: none"> Analysis of one RCT and five non-randomized studies (n=544) showed that dislodgement of the nasoenteric tube was significantly higher nas oenteric tubes were secured by tape alone (40% [138/341]) than when they were secured by nasal bridles (14% [28/203]). OR (95% CI) was 0.16 (0.10, 0.27); $P < 0.01$. Heterogeneity across these studies was not statistically significant ($I^2 = 0\%$, $P = 0.66$). <p><u>Safety</u></p> <ul style="list-style-type: none"> Analysis of one RCT and three non-randomized studies (n=438) showed that skin complications occurred significantly more frequently among patients for whom nasal bridles were used (13% [20/156]) than in patients for whom tape alone was used (3% [9/282]) to secure the tubes. Thus, the use of a nasal bridle was associated with an increased risk of skin complications, with OR (95% CI) of 4.27 (1.79, 10.23); $P < 0.01$. Skin complications ranged from erythema to frank ulcerations. Heterogeneity across these studies was not statistically significant ($I^2 = 44\%$, $P = 0.15$). One RCT and one non-randomized study (n=130) found that sinusitis occurred in 5% (4/73) of patients for whom adhesive tape was used to secure the tube, whereas none of 57 patients for whom the nasal bridle was used reported this complication. The difference was not statistically significant | <ul style="list-style-type: none"> “Nasal bridles appear to be more effective at securing nasoenteric tubes and preventing dislodgement than traditional use of tape alone.”⁴ Page 1 |
| Brugnolli, 2014 ² | |
| <p><u>Unintentional dislodgement or removal</u></p> <ul style="list-style-type: none"> One RCT and two non-randomized studies (n=232) found that tape technique resulted in statistically significantly more dislodgements than the nasal bridle ($P < 0.0001$ in two studies and $P = 0.004$ in one study). <p><u>Time until failure</u></p> <ul style="list-style-type: none"> Two studies measured the days until failure, comparing bridle versus tape technique. One RCT (n=80) did not find any significant difference in the time to failure between the bridled and the tape techniques ($P < 0.21$), whereas one non-randomized study (n=not determined) demonstrated a significantly longer time until failure in bridled patients ($P < 0.001$) | <ul style="list-style-type: none"> “Despite the large number of patients receiving this intervention, there is insufficient evidence to suggest one securing technique or device over another. Data are lacking on the beneficial effects of the various methods or systems. There is little or no statistically significant evidence regarding bridling of nasogastric tubes but more research is needed. There is a need for more well-designed studies conducted in various clinical settings.”² Page 7 |

Table A3: Summary of Findings of Included Studies

| Main Study Findings | Author's Conclusions |
|--|----------------------|
| <p><u>Caloric intake</u></p> <ul style="list-style-type: none"> One RCT (n=80) showed that patients with nasal bridles received a significantly higher percentage of their caloric goal than unbridled patients ($P = 0.016$) <p><u>Safety</u></p> <ul style="list-style-type: none"> One RCT (n=80) found no difference between bridled and unbridled patients with respect to external nasal ulceration and sinusitis ($P = 0.12$ and $P = 0.49$, respectively). One non-randomized study (n=62) reported four cases of nasal ulceration per 800 tube-feeding days in the bridle group with no incidence of nasal ulceration in the tape group. All the ulcerations were associated with red rubber catheter bridles. A switch to umbilical tape bridles eliminated further ulceration. One non-randomized study (n=90) reported one episode of epistaxis, which resolved without specific medical therapy in the bridled group. <p><u>Cost effectiveness</u></p> <ul style="list-style-type: none"> One non-randomized study (62) found that the use of nasal bridles resulted in a savings of US\$4,038 over the course of three months compared to tape technique. The savings are expected to accrue from efficient improvement in caloric intake and reduction in staff time, exposure to repeated radiography and use of materials associated with repeated reinsertions of inadvertently removed nasogastric feeding tubes. | |

CI = Confidence intervals; MD = mean difference; OR = odds ratio

APPENDIX 5: Additional References of Potential Interest*Published before 2011*

1. Beavan J, Conroy SP, Harwood R et al. Does looped nasogastric tube feeding improve nutritional delivery for patients with dysphagia after acute stroke? A randomized controlled trial. *Age Ageing*. 2010;39(5): 624-30.
2. Seder CW, et al. Nasal bridling decreases feeding tube dislodgment and may increase caloric intake in the surgical intensive care unit: a randomized controlled trial. *Crit Care Med*. 2010 Mar;38(3):797-801

Primary study of already included Meta-analysis

3. Parks J, Klaus S, Staggs V, Pena M. Outcomes of nasal bridling to secure enteral tubes in burn patients. *Am J Crit Care*. 2013 Mar;22(2):136-42.

Narrative review with insufficient information to permit critical appraisal

4. Gurram KC. Nasal bridle: married to your tube [Internet]. *Practical Gastroenterology*. (Nutritional Issues in Gastroenterology, Series #91). 2011 Jan [cited 2016 Dec 26]. Available from: <https://med.virginia.edu/ginutrition/wp-content/uploads/sites/199/2014/06/GurramArticle.pdf>

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5. Griffin J. EB75 Focused on Feeding Tube Retention: A Nurse-Driven Trial of a Nasal Bridle System. *Crit Care Nurs*. 2015;35(2): e36-7.

Case reports

6. Jackson RS, Sharma S. Retained nasal tube bridle system insertion stylet presenting as nasal foreign body: a report of two cases. *Am J Otolaryngol*. 2015 Mar;36(2):296-8.