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CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Urinary Catheters as Replacement Feeding Tubes: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Authors: Casey Gray, Aleksandra Grobelna

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Abbreviations

ACI	Agency for Clinical Innovation
AGREE	Appraisal of Guidelines for Research and Evaluation
CADTH	Canadian Agency for Drugs and Technologies in Health
cm	centimeter
CRD	Centre for Reviews and Dissemination
GDG	Guideline Development Group
GENCA	Gastroenterological Nurses College of Australia
NHMRC	National Health and Medical Research Council
NICE	The National Institute for Health and Care Excellence
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Context and Policy Issues

Enteral tube feeding is undertaken to supplement or provide total nutrition when oral feeding is not safe, adequate, or efficient.[1] Enteral tube feeding involves the delivery of a nutritionally complete feed directly into the stomach or small intestine via a tube inserted through a stoma.[2] The National Institute for Health and Care Excellence (NICE) recommends consideration of gastrostomy (feeding directly into the stomach) for people likely to need support with feeding for four or more weeks, and jejunostomy (feeding directly into the small intestine) for patients with upper gastrointestinal dysfunction or an inaccessible upper gastrointestinal tract.[3] Enteral feeding tubes are normally inserted endoscopically, and can also be inserted with radiologic guidance or surgically [2]

Gastrostomy and jejunostomy feeding tubes may require replacement due to deterioration, damage, or dislodgement.[4] Use of Foley catheters as replacement gastrostomy or jejunostomy feeding tubes has been documented in the literature for various reasons (e.g., when conventional replacement feeding tubes are out of stock).[4] However, the comparative clinical-effectiveness –including safety– and cost-effectiveness of using Foley catheters versus approved gastrostomy or jejunostomy tubes is not known.

The objective of the report is to summarize the evidence regarding the clinical effectiveness, cost-effectiveness, and guidelines for the use of urinary catheters versus conventional feeding tubes as replacement feeding tubes in adult inpatients in acute care.

Research Questions

1. What is the comparative clinical effectiveness of urinary catheters versus conventional gastrostomy or jejunostomy replacement feeding tubes in adult inpatients in acute care?
2. What is the cost-effectiveness of urinary catheters for adult inpatients in acute care requiring replacement gastrostomy or jejunostomy feeding tubes?
3. What are the evidence-based guidelines regarding replacement of gastrostomy or jejunostomy feeding tubes in adult inpatients in acute care?

Key Findings

One evidence-based guideline was identified that provides recommendations regarding the use of urinary catheters as replacement gastrostomy tubes. Based on low quality evidence, the guideline includes a cautious recommendation for the use of Foley catheters for temporary replacement of inadvertently displaced gastrostomy tubes for patients with well-established ostomy tracts. No guidelines regarding the use of urinary catheters as replacement jejunostomy tubes, or evidence on the comparative clinical effectiveness or cost-effectiveness of urinary catheters as replacement tubes for gastrostomy or jejunostomy was identified.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, the Cochrane Library, 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, 2014 and April 10, 2019.

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 inpatients in acute care who are fed by gastrostomy or jejunostomy feeding tubes and require a replacement tube
Intervention	Urinary catheters (also called Foley catheters) as replacement gastrostomy or jejunostomy feeding tubes
Comparator	Q1-Q2: Approved replacement gastrostomy or jejunostomy feeding tubes Q3: No comparator
Outcomes	Q1: Clinical effectiveness (i.e., effectiveness for feeding; harms) Q2: Cost-effectiveness Q3: Guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2014. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

Guidelines were assessed with the AGREE II instrument.[5] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 149 citations were identified in the literature search. Following screening of titles and abstracts, 147 citations were excluded and two potentially relevant reports from the electronic search were retrieved for full-text review. Two potentially relevant publications were retrieved from the grey literature search for full text review. Of these potentially relevant articles, two studies were excluded due to lack of a comparator group and one publication was excluded due to use of a non-systematic search methodology. One evidence-based guideline met the inclusion criteria and was included in this report. No relevant systematic reviews, meta-analyses, randomized studies, non-randomized studies, or economic evaluations were identified. Appendix 1 presents the PRISMA[6] flowchart of the study selection.

Summary of Study Characteristics

Details regarding the characteristics of included publications are provided in Appendix 2.

Study Design

One evidence-based guideline[7] was included in this report. The guideline was published in 2019 by the Agency for Clinical Innovation (ACI) and the Gastroenterological Nurses College of Australia (GENCA).[7] The guideline development group was composed of members of ACI and GENCA. A literature review on existing guidelines and relevant papers was commissioned to identify evidence. The study designs and searching methods were not reported. The quality of evidence was graded using the National Health and Medical Research Council (NHMRC) hierarchy. Stakeholder feedback was sought for two drafts of the guideline however it is unclear how agreement on final recommendations was reached. Recommendations were graded according to the NHMRC grades of recommendations (criteria are presented in Appendix 2, Table 3).

Country of Origin

The guideline was published for an Australian audience.[7]

Patient Population

The guideline was intended to offer guidance to health care professionals involved in the care of people with gastrostomy tubes and devices. The relevant recommendations were specific to those with a mature stoma tract who had inadvertently removed their gastrostomy tube or device.[7]

Interventions and Comparators

The intervention of interest in the relevant recommendations was the use of a Foley catheter as a temporary replacement gastrostomy tube or device.[7]

Outcomes

The guideline presented evidence-based recommendations regarding care for people with gastrostomy tubes and devices in general, as well as an appraisal of the quality of evidence upon which the recommendations were based.[7]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Strengths and weaknesses of the evidence-based guideline[7] were assessed using the AGREE II instrument.[5] Strengths include a clearly defined scope, purpose, and target users; inclusion of relevant stakeholders in the guideline development group; a rigorous and transparent process for developing and updating recommendations; and specific and unambiguous recommendations.[7] Key limitations were failure to consider the views and preferences of the target population in the formulation of recommendations, a lack of clarity in the literature search methods, and information about the potential influence of competing interests of guideline development group members or the funding organizations.[7]

Summary of Findings

Clinical-Effectiveness of Urinary Catheters as Replacement Feeding Tubes

No relevant evidence regarding the comparative clinical effectiveness of urinary catheters versus gastrostomy tubes or jejunostomy tubes as replacement feeding tubes were identified.

Cost-Effectiveness of Urinary Catheters as Replacement Feeding Tubes

No relevant evidence regarding the cost-effectiveness of urinary catheters as replacement gastrostomy tubes or jejunostomy tubes was identified.

Guidelines

One guideline provided recommendations on the use of urinary catheters as replacement gastrostomy tubes for enteral feeding based on weak quality evidence.

Two recommendations are provided in the ACI and GENCA guideline regarding the use of Foley urinary catheters as replacement gastrostomy tubes or devices based on a weak body of evidence, and advises caution if recommendations are applied.[7] For inadvertent removal of a gastrostomy tube or device in patients with a mature stoma tract, the guideline development group recommends use of an equal-sized, adequately secured Foley catheter as a temporary replacement if a dedicated device is not available.[7] They further recommend against long-term replacement of feeding tubes or devices with Foley catheters due to the potential risks that may arise based on differences in the design of Foley catheters compared with approved tubes.[7]

The recommendations are not applicable to patients with immature stoma tracts and it remains unclear whether their use would be safe as a temporary or longer-term measure in that population. No recommendations regarding the use of urinary catheters as replacement jejunostomy tubes was identified and therefore the findings are not considered generalizable to patients with a jejunostomy.

Appendix 4 presents a table of the main study findings and authors' conclusions.

Limitations

Beyond the few concerns with methodological quality of the included guideline,[8] there are a few limitations to note with respect to this report. First, no comparative evidence on the clinical- or cost-effectiveness of urinary catheters for enteral feeding was identified. Single group observational studies and case-series studies exist in the literature; however, no eligible studies that included a comparison group of patients using approved replacement tubes were found. Second, no eligible evidence-based guidelines addressed the use of urinary catheters as replacement jejunostomy tubes could be identified. The included ACI and GENCA guideline pertains only to gastrostomy tubes and devices and it is unclear if the recommendations can be generalized to patients requiring replacement jejunostomy tubes or devices.[7] Finally, the included guideline was developed by a group consisting of health professionals and medical specialists in Australia.[7] As such, it is unclear how the evidence would have been interpreted by stakeholders in Canada and the generalizability of recommendations to the Canadian context is uncertain.

Conclusions and Implications for Decision or Policy Making

One evidence-based guideline was included in this report.[7] No evidence was identified on the comparative clinical effectiveness or cost-effectiveness of urinary catheters as replacement gastrostomy tubes or jejunostomy tubes.

The ACI and GENCA guideline includes recommendations regarding the use of Foley catheters as replacement tubes for enteral feeding based on poor quality evidence. More specifically, the guideline development group recommends the use of Foley urinary catheters as temporary replacement gastrostomy tubes or devices for patients with mature stoma tracts who have inadvertently removed their gastrostomy tubes or devices.[7] No recommendations addressed jejunostomy tubes. The evidence base underpinning the guideline was considered to be of poor quality. It is possible that future research using high quality study designs could prompt a change in the direction or strength of the recommendations.

There was also a lack of comparative clinical evidence on the safety and effectiveness of urinary catheters as replacement gastrostomy or jejunostomy tubes identified for this report. Evidence from a single-arm retrospective study using a low quality design provides some insight. For example, in a study of 21 patients who used Foley catheters as temporary replacement gastrostomy tubes over a two year period, 42.6% resulted in complications (i.e., burst catheter balloon, tube blockage, and tube migration into small intestine with intact balloons).[9] The source population also included patients who received approved gastrostomy replacement tubes. Since those data were not analyzed, it is not known if complication rates differed between those who received Foley catheters and those who received approved gastrostomy tubes. Evidence from a case series off 11 patients suggested that the use of a Foley catheter as a gastrostomy tube was associated with an increased risk of pancreatitis (a rare, but serious potential complication of gastrostomy tube dislodgement) as compared with approved gastrostomy tubes.[10] There may be ethical reasons not to randomize patients to receive an unapproved device where there is evidence of potential safety concerns and randomized studies may be inappropriate. However, future comparative research using large samples in databases of existing cases may help to reduce uncertainty.

Similar to the current report, a 2008 CADTH report on Foley catheters for enteral feeding did not identify any comparative evidence on the use of urinary catheters as replacement gastrostomy- or jejunostomy tubes.[11] The report included one evidence-based guideline from the Wound, Ostomy and Continence Nurses Society which, in contrast with the ACI and GENCA guideline,[7] explicitly stated that Foley catheters have a higher rate of complications compared with commercial gastrostomy tubes and are not intended for the purpose of gastrostomy feeding.[11] It is unclear what led the ACI and GENCA guideline development group to cautiously recommend Foley catheters under specific conditions.

No evidence specific to Canada was identified. The included guideline was developed by a group consisting of health professionals and medical specialists in Australia.[7] With no clinical or cost-effectiveness evidence conducted in this country, it is not possible to determine if the evidence would have been interpreted similarly by stakeholders in Canada, and in turn, if the recommendations are generalizable to the Canadian context.

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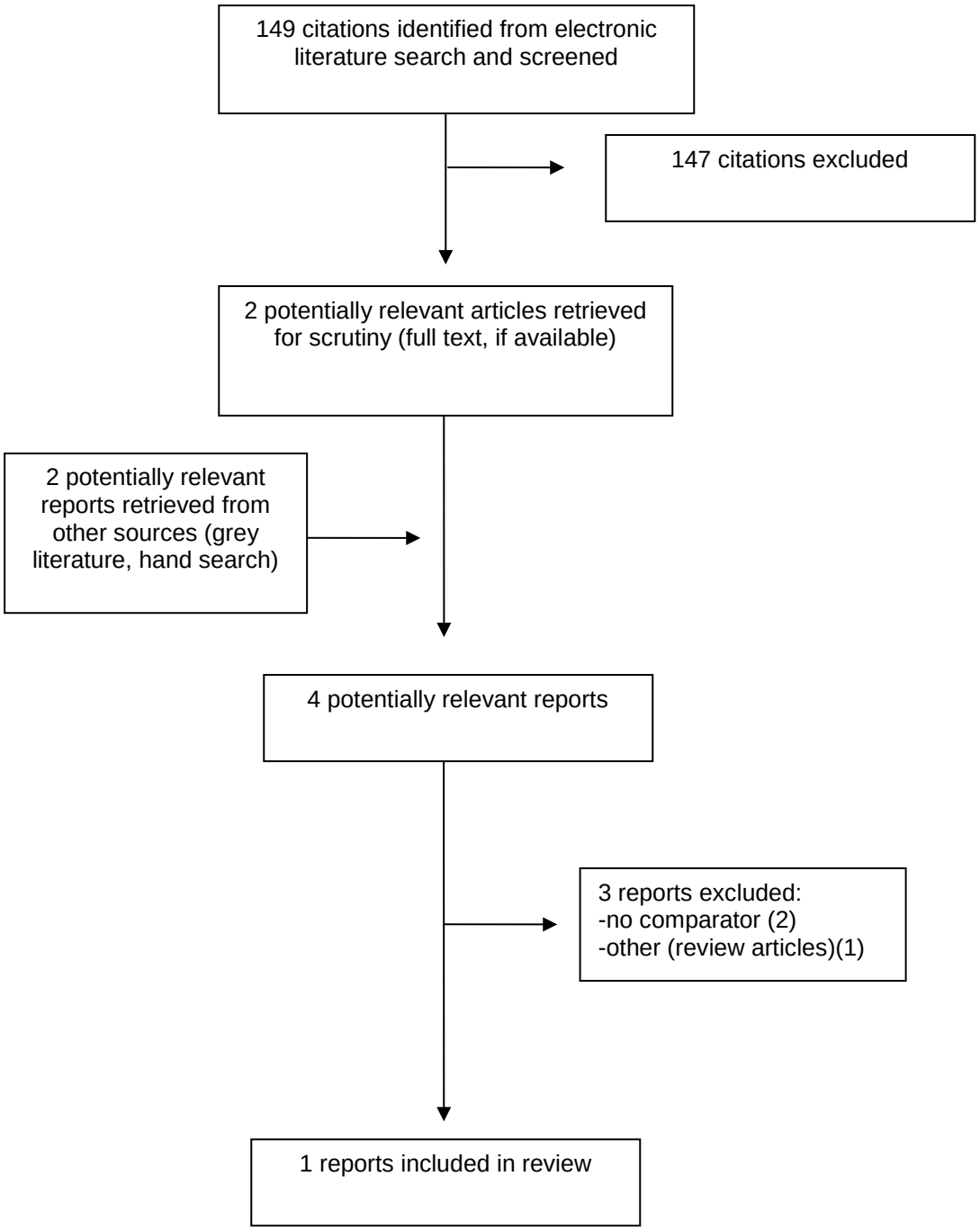
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Guideline

Group and/or First Author, Year, Country	Objective	Guideline Development Group, Intended Users	Recommendations Development and Evaluation Methodology
ACI and GENCA, 2019, Australia	Aim: to provide guidelines for all health care professionals involved in the care of people with gastrostomy tubes and devices; to inform health service planning	GDG composed of members from ACI and GENCA representing nurses, allied health professionals, medical specialists Intended users: health care professionals involved in the care of adults and children with gastrostomy tubes and devices; health care organizations and governments responsible for health service planning	Initial literature review conducted by GDG Evidence check review was commissioned to summarize and critically appraise existing evidence on gastronomy tube and device care. Literature on existing guidelines and relevant papers published between 2003 and 2013 was reviewed. Unclear if systematic searching methods were used. Evidence quality graded using NHMRC hierarchy First and second draft reviewed by external stakeholders in February 2014 and May 2014. Feedback was considered by GDG before agreement on final version (unclear how agreement was reached). Recommendations were graded according to the NHMRC grades of recommendations

ACI = Agency for Clinical Innovation ; GENCA = Gastroenterological Nurses College of Australia; GDG = Guideline Development Group; NHMRC = National Health and Medical Research Council;

Table 3: Grade Recommendations and Level of Evidence for Guidelines

Grade of Recommendations	Strength of Evidence
ACI & GENCA, 2015[7]	
NHMRC levels of evidence and grades for recommendations	
Grade A: One or more level I studies with a low risk of bias or several level II studies with a low risk of bias; all studies consistent; very large clinical impact; population studies is same as guideline target; directly applies to Australian healthcare context	Excellent: Body of evidence can be trusted to guide practice
Grade B: One or two Level II studies with a low risk of bias or SR/several Level III studies with a low risk of bias; most studies consistent and inconsistency can be explained; substantial clinical impact; population studied is similar to the target population; applied so Australian context with few caveats	Good: Body of evidence can be trusted to guide practice in most situations

Grade of Recommendations	Strength of Evidence
Grade C: One or two Level III studies with a low risk of bias or Level I or II studies with a moderate risk of bias; some inconsistency reflects uncertainty; moderate clinical impact; population studied differs from target, but is clinically sensible to apply evidence to target; probably applicable to Australian context	Satisfactory: Body of evidence provides some support for recommendation(s) but care to be taken in its application
Grade D: Level IV studies or Level I to III studies/SRs with a high risk of bias; inconsistent evidence; slight or restricted clinical impact; population studied differs from target population and unclear if sensible to generalizable; not applicable to Australian context	Poor: Body of evidence is weak and recommendation must be applied with caution

SR = systematic review

Appendix 3: Critical Appraisal of Included Publications

Table 4: Strengths and Limitations of Guidelines using AGREE II[5]

Item	Guideline
	ACI & GENCA, 2015[7]
Domain 1: Scope and Purpose	
1. The overall objective(s) of the guideline is (are) specifically described.	X
2. The health question(s) covered by the guideline is (are) specifically described.	X
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	X
Domain 2: Stakeholder Involvement	
4. The guideline development group includes individuals from all relevant professional groups.	X
5. The views and preferences of the target population (patients, public, etc.) have been sought.	--
6. The target users of the guideline are clearly defined.	X
Domain 3: Rigour of Development	
7. Systematic methods were used to search for evidence.	Unclear
8. The criteria for selecting the evidence are clearly described.	--
9. The strengths and limitations of the body of evidence are clearly described.	--
10. The methods for formulating the recommendations are clearly described.	X
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	X
12. There is an explicit link between the recommendations and the supporting evidence.	X
13. The guideline has been externally reviewed by experts prior to its publication.	X
14. A procedure for updating the guideline is provided.	X
Domain 4: Clarity of Presentation	
15. The recommendations are specific and unambiguous.	X
16. The different options for management of the condition or health issue are clearly presented.	X
17. Key recommendations are easily identifiable.	--
Domain 5: Applicability	
18. The guideline describes facilitators and barriers to its application.	X
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	X
20. The potential resource implications of applying the recommendations have been considered.	--
21. The guideline presents monitoring and/or auditing criteria.	X
Domain 6: Editorial Independence	
22. The views of the funding body have not influenced the content of the guideline.	--
23. Competing interests of guideline development group members have been recorded and addressed.	--

ACI = Agency for Clinical Innovation; AGREE = appraisal of guidelines for research and evaluation; GENCA = Gastroenterological Nurses College of Australia

Appendix 4: Main Study Findings and Authors' Conclusions

Table 5: Summary of Recommendations in Included Guidelines

Recommendations	Strength of Evidence and Recommendations
ACI & GENCA, 2015[7]	
For inadvertent removal of a gastrostomy tube or device if the stoma tract is mature:	
"If a dedicated gastrostomy device is not available a Foley catheter can be used for this purpose as a **temporary** measure to protect the tract. (Grade D) -- A Foley catheter of equivalent size that is adequately secured can be used in the interim for medication or feeding but should be **replaced with a dedicated gastrostomy tube or device as soon as possible**." (p.54)	Body of evidence is weak and recommendation must be applied with caution
"Foley catheters are not recommended as a long term replacement feeding tube or device because: -- They do not have an external flange increasing the risk of migration and obstruction and are not designed as a long term gastrostomy device (Grade D) -- A "spigot" or stopper is required to cap off the proximal end when not in use and it may be at risk of being lost or being unavailable -- Standard tube length is 40cm – outlet obstruction becomes a risk if the tube is allowed to migrate in (see the point above) -- Their closed distal end causes the tube to be at risk of obstruction -- There is increased risk of posterior gastric mucosa ulceration due to exposed distal tube past the balloon -- The manufacturer's guidelines are for urinary bladder insertion." (p.54)	Body of evidence is weak and recommendation must be applied with caution

ACI = Agency for Clinical Innovation; cm = centimeter; GENCA = Gastroenterological Nurses College of Australia