



STOMA COVER USE BY FULLY LARYNGECTOMIZED PATIENTS

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PURPOSE OF THE PRESENTATION

- Summarize a health technology assessment done in collaboration by 2 hospital-based HTA units located in Québec and Montréal, Canada
- Project completed in 2018
- Focus on the implications of the findings for the EBM approach and HTA, particularly in respect to methodological quality appraisal

BACKGROUND

- Laryngectomy is the surgical removal of the larynx
 - Portion of the throat housing the vocal cords, allowing a person to produce sound
- Following this procedure, the person breathes through an opening in the neck called a stoma
- The use of stoma covers has been a common clinical practice for laryngectomized patients for many years

Three main types of stoma covers



Laryngofoam and Heat and moisture exchangers (HME)



Cloth, foam and Buchanan bibs

Stoma cover supplies

- In Québec, Canada, laryngectomized patients can obtain stoma covers through a dedicated program called *Service d'aide aux laryngectomisés (SAL)*
- The program's allocation has included cloth and foam covers but the supply of HMEs has been limited

Evaluation questions

- What is the **clinical effectiveness** of stoma covers in the care of totally laryngectomized patients?
- What are the **undesirable effects** associated with the main types of stoma covers being used?
- What are the **organizational aspects** associated with the provision of stoma covers for laryngectomized patients?

Need for a new systematic review

- Guidelines (2) and systematic review (1)
 - Deemed of generally low methodological quality
 - Limited scope with respect to evaluation questions
- Given these limitations, a new systematic review was undertaken

A twofold study

- Systematic review of the relevant literature
- Enquiries
 - Managers and clinical coordinators
 - Clinicians working with laryngectomized persons in ambulatory care

SYSTEMATIC REVIEW – METHODOLOGY, QUALITY APPRAISAL AND MAIN CONCLUSIONS

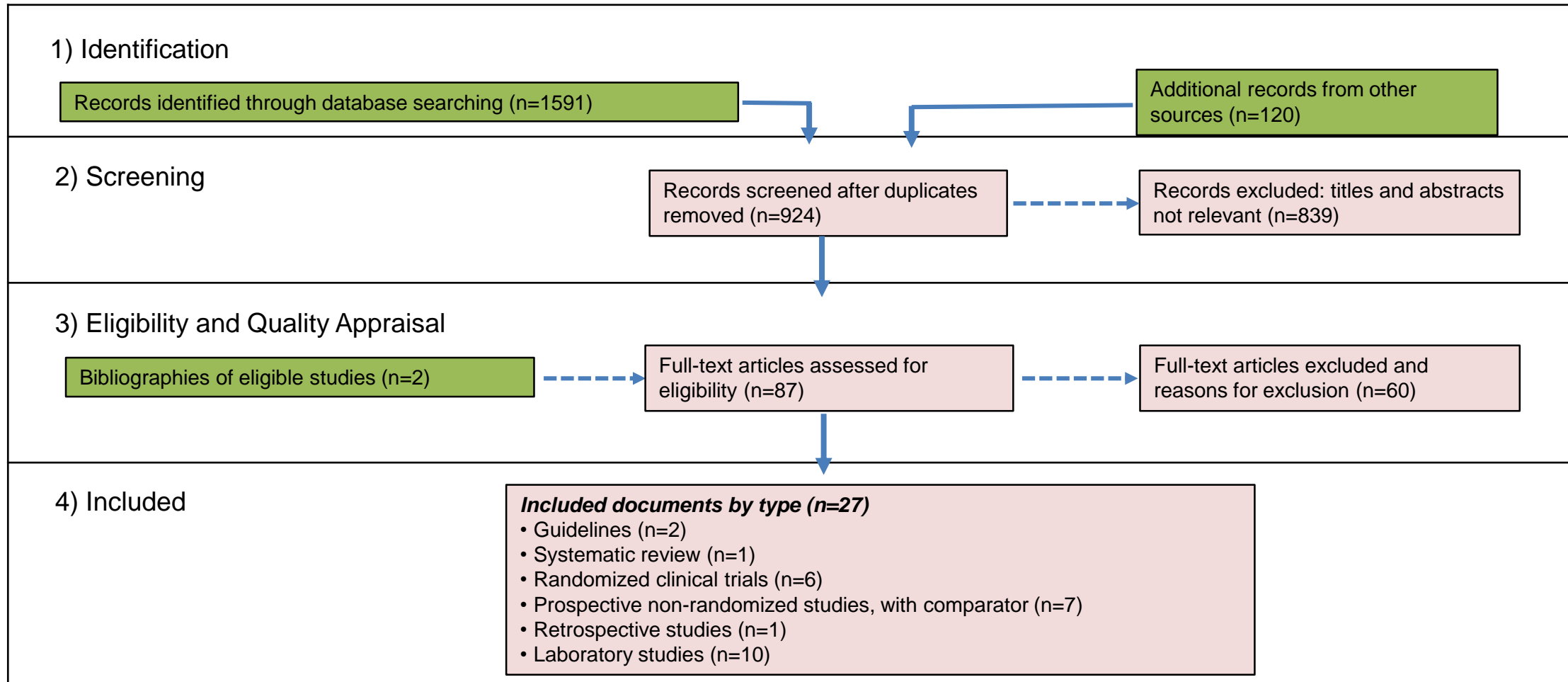
Methodology

- Literature search in 5 databases (PubMed, Embase, CINAHL, MEDLINE, EBM Reviews) (last search 6 Feb. 2018)
- Grey literature search (last search 6 Feb. 2018)
- Systematic review with a narrative approach (Popay et al., 2006)
- Data reported according to PRISMA (Moher et al., 2009)
- Appraisal of methodological quality
- R-AMSTAR, AGREE (Kung et al., 2010, Brouwers et al. 2010)
 - Primary studies: Various methodological quality appraisal tools adapted by *CHU de Québec*

Main dimensions appraised

- Efficacy
 - Endotracheal absolute temperature and humidity
 - Quality of the air filtered
- Effectiveness
 - Protection of the airway
 - Quality of life and social aspects
 - Speech and communication
- Safety
 - Immediate postoperative complications and long-term undesirable effects associated with stoma cover use

Selection flow diagram



Bibliographical search conducted on September 19th, 2017

Main characteristics of selected studies

- Guidelines (2)
 - Nursing guidelines for recently laryngectomized patients
 - Evaluation and care of head and neck cancer patients
- Systematic review (1)
 - Objective: Compare outcomes associated with passive humidification (HME) against active humidification (heated humidifier)
- Primary studies (24)
 - 6 RCTs, 8 observational studies and 10 laboratory studies

Methodological quality appraisal

- Most studies deemed of low quality
- Report measures which clinical significance is unknown (technical performance)
- Reproducibility of the methods used raised concerns
- Methods used were generally inadequately described
- Few compared different types of stoma covers
- Much heterogeneity in the characteristics of included studies (methods used, populations, interventions, comparators, outcomes and settings)

Methodological quality appraisal (con't)

- A likely publication bias favoring HMEs was observed
- 17 of the 24 included studies were sponsored by an HME manufacturer
 - Research financing, studies published by company employees

Main conclusions

- Did not provide conclusive evidence concerning the efficacy, clinical effectiveness and safety of the various types of stoma covers
- Some of the results favor HMEs compared to no protection, cloth or foam covers
- Few undesirable events were reported
- However, low quality of evidence, lack of comparative studies
- Concern with respect to publication bias

FIELD DATA ENQUIRIES' METHODOLOGY AND MAIN RESULTS

Field data

Patient Volume, Stoma Covers supplied

- Number of patients receiving supplies (2016-2017): 2655
 - CHUM: 1544 ($\approx 60\%$)
 - CHU de Québec: 1111 ($\approx 40\%$)
- Foam protectors: 84-89% of the stoma covers being supplied from 2014-2015 to 2016-2017
- Other types of stoma covers supplied: cloth filters and HME

Enquiries methodology

- Semi-directed interviews (Patton et al., 2002)
 - Conducted December-January 2018
- Online survey
 - Close and open-ended questions
 - Descriptive analysis of results (small N)
 - Conducted from 8 December 2017 through 10 January 2018
- Main dimensions appraised
 - Clinical and organisational context in which stoma covers are being used
 - Perceptions of clinicians towards stoma cover use

Semi-directed interviews with key informants

- Key informants (N=5) playing a role into the management of the SAL-PAC program
- Confirm that the industry is quite present in the clinical settings to promote its products
 - HME samples being offered to patients in the immediate post-operative period
 - Creates a pressure on the program: patients deem that HMEs should be provided free of charge by the Québec Health Care System

Survey of clinicians attitudes and preferences towards practice

- **30 respondents**
- **Response rate 77% (30/39)**
- All of the respondents were working in an academic setting
- **Speech therapists: 50% of the sample**
- Ear Nose and Throat surgeons: 27%
- Nurses: 17%
- Respiratory therapists: 7%

Main sources of information being used

- Main sources being used by clinicians were:
 - **Clinical experience (100% totally or partly agreed)**
 - **Academic training (70%)**
 - Scientific presentations (63%) and publications (60%)
 - **Information being provided by sales representatives (60%)**
- Two sources were less often used:
 - Practice guidelines (40%)
 - Clinical algorithms adopted by the setting (37%)

Stoma covers being recommended

- Stoma covers most recommended:
 - Reusable cloth bib (70% totally or partly agreed)
 - Single use HME (63%)
 - Hands-free speaking valve w/ HME (60%)
- Stoma covers less recommended:
 - Foam stoma covers (laryngofoam) (47%)
 - Buchanan bibs (cloth and foam) (23%)

CONCLUSIONS

IMPLICATIONS FOR THE EBM APPROACH AND HTA

Implications for EBM

- Evidence tends to support the practice recommending a stoma cover after a total laryngectomy, making it rational
- However, the quality of the evidence is low:
 - Probably explains why clinicians' decisions are partly based on information provided by commercial representatives
- Fosters the need for fair methodological quality research, independent of industry
 - Need for an objective criteria, adapting the choice of a cover to the patient's condition

Implications for HTA

Industry sponsorship of research

- Industry sponsorship of many of the included studies is preoccupying
 - Studies' conclusions are generally positive and the quality of the evidence is low
 - These observations are similar to those of other studies that appraised the impact of industry sponsorship on research outcome (Criss and Gadepalli, 2017 and Lundh et al., 2017, 2018)

Implications for HTA

Industry sponsorship of research - (con't)

- It has been suggested that industry sponsorship of research may cause a meta-bias
 - Industry sponsorship in itself is not a bias-producing process, but a risk factor for bias (Lundh 2017, Goodman 2011)
- Industry sponsorship of research may present a significant challenge for methodological quality appraisal in HTA
 - Current methodological quality appraisal tools, such as the CC Risk of Bias appraisal, does not allow to determine the risk of bias associated with industry sponsorship of research (Lundh, 2017, 2018)

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