Protocol

Chewing gum and preoperative fasting – A systematic review

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Protocol

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Introduction

In preparation for anesthesia fasting is an important part, and non-adherence to fasting guidelines causes surgery postponements and cancellations¹. Pulmonary aspiration is the leading cause of airway-related death in anesthesia². Fasting guidelines seek to reduce the risk of aspiration³. However, there are divergent opinions whether chewing gum prior to surgery is a clinical relevant risk factor for aspiration. International recommendations are diverse ranging from 2 hour preoperatively³ to gum chewing not being a reason for postponing or cancellation of surgery⁴. Others do not recommend a specific fasting period on gum chewing^{5,6} This is probably due to conflicting results being published as some studies report that chewing gum influences gastric emptying, volume and acidity^{7,8}, while others report no influence at all^{9,10}. Moreover, preoperative gum chewing may even be beneficial as it can increase patient wellbeing¹¹.

The most relevant outcome measure when studying chewing gum in the preoperative period is the risk of aspiration. This outcome is difficult to investigate directly, since the risk of aspiration is small $(3/10.000)^{12}$, and therefore different surrogate-outcome measures are used to give an estimate of the aspiration risk¹³.

There is therefore a need to clarify advantages and disadvantages associated with gum chewing prior to anesthesia and if a safety interval for gum chewing prior to anesthesia can be defined. The questions are most important in elective surgery, but are also relevant factors to assess when preparing for emergency surgery.

Materials and methods

Objective:

The goal of this systematic review is to evaluate possible advantages and disadvantages on the use of preoperative chewing gum during the preoperative fasting period.

We will seek to answer the following questions:

- 1) How long time before surgery is it safe to use chewing gum?
- 2) What effects do chewing gum has on parameters affecting patient safety during anesthesia induction?
- 3) What positive effects do chewing gum in the preoperative period has?

This systematic review will be conducted in accordance with the PRISMA statement¹⁴.

Protocol and registration:

The systematic review protocol will be registered at PROSPERO¹ (Centre for Reviews and Dissemination, University of York.

Eligibility criteria:

Inclusion criteria:

Randomized controlled trials, meta-analysis, observational studies, case series and case reports reporting on chewing gum in the preoperative period will be included.

No restrictions regarding participants' age are applied.

Exclusion criteria:

Animal studies and studies reported in language other than English, French, Danish, Swedish or Norwegian are not included.

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¹ http://www.crd.york.ac.uk/prospero/

Participants:

- Participants will be included irrespective of surgery and age
- Patients scheduled for both elective and emergency surgery will be included
- Participants will be included irrespective of preoperative risk profile for aspiration during surgery (Diabetes, pregnant patients are included)
- Trials of healthy volunteers will be included

Systematic literature search:

The search will be conducted within 6 months of the date the draft is submitted for review. A systematic search of databases: PubMed, EMBASE and Cochrane Library was developed and conducted in corporation between both authors. Articles addressing "guar gum" are removed using the search term NOT, since these are not relevant to this reviews objective.

The search strategy in each databases are as follows:

PubMed:

- 1. exp stomach emptying/ or exp stomach motility/ or ("gastric emptying" or "gastric acidity" or "gastric motility").mp.
- 2. exp pulmonary aspiration/ or exp acid aspiration/ or exp aspiration pneumonia/ or aspiration.mp.
- 3. exp mortality/ or mortality.mp.
- 4. exp diet restriction/ or (fasting or NPO or nil-by-mouth).mp.
- 5. exp chewing gum/ or ("chewing gum" or "bubble gum" or "sugarless gum" or gum).mp.
- 6. ((5 and 4) or (5 and 3) or (5 and 2) or (5 and 1)) not "guar gum".mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
- 7. limit 6 to (human and (danish or english or french or norwegian or swedish))

Cochrane Library:

ID	Search Hits
#1	MeSH descriptor: [Mortality] explode all trees
#2	MeSH descriptor: [Pneumonia, Aspiration] explode all trees
#3	MeSH descriptor: [Respiratory Aspiration of Gastric Contents] explode all trees
#4	MeSH descriptor: [Respiratory Aspiration] explode all trees
#5	MeSH descriptor: [Gastric Emptying] explode all trees

#6	MeSH descriptor: [Fasting] explode all trees
#7	MeSH descriptor: [Chewing Gum] explode all trees
#8	aspiration or #2 or #3 or #4
#9	"gastric emptying" or "gastric motility" or "gastric acidity" or #5
#10	fasting or "nil-by-mouth" or NPO or #6
#11	"chewing gum" or gum or "sugarless gum" or "bubble gum" or #7
#12	(#1 and #11) or (#8 and #11) or (#9 and #11) or (#10 and #11)
#13	#12 not (animals.sh. not (humans.sh. and animals.sh.)) not "guar gum'

Additionally, reference lists of included articles will be searched to find otherwise missed literature.

Study selection:

Two of the authors will independently screen the titles and abstracts found in the literature search and any unclear issues will be conferred with a senior author. Trials that do not match the inclusion criteria will be excluded.

Secondly, the remaining trials will be evaluated in full text for eligibility, and the authors will provide detailed description of the included and excluded articles. All excluded trials are listed, stating the reason for exclusion and any unclear issues will be conferred with a senior author.

Assessment of included studies:

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of rating quality of evidence and grading strength of recommendations in systematic reviews will be used to assess our results and rate the quality of evidence and strength of recommendations for individual outcomes of the review.

We intend to use the Cochrane Risk of Bias Assessment Tool for randomized controlled trials¹⁷ Risk of bias in observational studies will be assessed using GRADE system.¹⁸ The results will be presented in a table with summary of findings.

Outcomes

All data from both healthcare personnel and patients will be included Primary outcome:

- 1. All cause mortality
- 2. The beneficial effect of preoperative gum chewing defined as Patient experienced wellbeing or as defined by author

Secondary outcomes:

- 1. The harmful or adverse effects of preoperative gum chewing defined as Change in volume of gastric content, Change in acidity of gastric content, Change in rate of gastric emptying or as defined by author)
- 2. Aspiration

We will not institute any limitations regarding patient categories or outcome definitions. Surrogate outcomes will be accepted since the real outcomes (mortality and aspiration) are not expected to be found. Accepted surrogate-outcomes of aspiration are volume of gastric content and acidity of gastric content.

Data collection process:

We have developed a data extraction sheet (based on the Cochrane Consumers and Communication Review Group's data extraction template¹⁹). It will be pilot-tested on ten randomly-selected included studies and adjusted accordingly. Data extraction will be performed by two independent authors, and any disagreement resolved by consensus or by senior reviewer.

Planned methods of analysis:

Data extracted will be compared in text and tables. If possible data will be pooled using statistical analysis.

Economy:

No conflicts of interests.

Publication:

The systematic review will be reported in accordance with the PRISMA statement¹⁴ and is expected to be published in a peer reviewed English-language journal. Authorship will occur in accordance with international Committee of Medical Journal Editors' rules (the Vancouver Group). The right to data and know-how that emerges in connection with the trial will belong to the primary investigator and the Department of Anesthesiology, University of Copenhagen, Herlev Hospital.

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