Systematic Review Protocol:

Supraglottic airway devices in obese patients


1 Associate Professor, Department of Anaesthesia and Intensive Medicine, 1st Medical Faculty, Charles University in Prague, General University Hospital, Prague, Czech Republic

2 Assistant Professor, Department of Anaesthesia and Intensive Medicine, 1st Medical Faculty, Charles University in Prague, General University Hospital, Prague, Czech Republic

3 Assistant Professor and Head, Department of Anaesthesia and Intensive Medicine, 2nd Medical Faculty, Charles University in Prague, University Hospital in Motol, Prague, Czech Republic

4 Clinical Director, Department of Anaesthetics, Antrim Area Teaching Hospital, Antrim, United Kingdom/Northern Ireland

5 Senior Librarian, 1st Medical Faculty, Charles University in Prague, Czech Republic

Background:

Supraglottic airway devices have been used for routine airway management and maintenance during anesthesia in patients without increased risks for aspiration of gastric contents since 1990s. Second indication for the use of these devices is difficult airway management, where they can be used for oxygenation and also as conduits for insertion of tracheal tubes in the scenarios of difficult or failed intubation and in the cases of difficult oxygenation with the facemask. With new, improved versions of these devices, some borderline indications for their use, such as laparoscopies or insertion in the obese patients have appeared.

Obesity represents one of the most serious healthcare problems in developed countries [1]. It affects not only adults as its incidence has gradually increased in children as well. The numbers of overweight (BMI 25-29.9 kg.m^2) and obese (BMI >
30 kg.m\(^2\)) individuals increased worldwide between 1980-2013 by 27.5% in adults and by 47.3% in children [2]. In the United States, 60-70% of the adult population is overweight and more than 30% of them obese. Western Europe, including the United Kingdom, has a prevalence of adult obesity over 20% with an increasing trend.

Obesity is associated with an increased incidence of perioperative and anesthetic complications.

Morbidly obese patients have increased risk for aspiration of gastric contents associated with elevated intraabdominal pressure, higher incidence of gastroesophageal reflux and hiatus hernias [3]. Some studies also showed larger residual volume of gastric fluid after a period of fasting which may be associated with enlarged total volume of stomach [4] but more recent trials showed only slightly lower pH of gastric fluid in the obese [5]. Obese patients are more difficult to ventilate due to increased airway resistance and decreased chest and lung compliance [6].

In non-obese population, insertion of supraglottic airway devices is associated with significantly lower complications such as hoarseness, laryngospasm, cough or sore throat [7].

A number of studies have investigated the indications, the efficacy and complications associated with the supraglottic airway devices in obese patients but no official summary and review of the published literature have been performed so far.

**Review questions:**

This systematic review aims to investigate, through the available medical literature, current areas and safety of use of the supraglottic airway devices in overweight and obese patients.

Specific review questions will be:

1. Comparison of the use of different supraglottic airway devices in obese patients
2. Comparison of the use of supraglottic airway devices and tracheal intubation in obese patients
3. Complication rate with the supraglottic airway devices - obese vs. non-obese patients
Inclusion criteria:

**Types of participants:**

The participants studied will be the patients in the perioperative settings (operating room) of both genders, without any age limitations. Body mass index of the patients must lie between 25 and 30 kg/m² (overweight population), and over 30 kg/m² (obese population).

**Types of intervention(s):**

Clinical studies (for types of studies see below) investigating the use of supraglottic airway devices for perioperative airway management in overweight (Body Mass Index 25-30 kg/m²) and obese (Body Mass Index over 30 kg/m²) patients. Both elective uses and emergency insertions (situations of difficult airway management) will be included.

**Types of outcome measure(s):**

Following outcomes will be studied as primary outcomes:

- Total success rate of insertion of these devices (%)
- Complication rate associated with the insertion (%)

Secondary outcomes will include:

- Time of insertion (sec)
- Oropharyngeal seal pressure (cmH₂O)
- The incidence of postoperative sore throat (%)

**Types of studies:**

Following clinical evidence will be included into this systematic review:

- 1. Randomized-controlled trials (RCT)
- 2. Quasi-randomized controlled trials
- 3. Cross-over prospective trials
- 4. Prospective cohort studies
- 5. Retrospective cohort studies
6. Case-control studies

Following articles will be excluded:

- 1. Case reports
- 2. Editorials
- 3. Letters to the editor
- 4. Reviews

**Search strategy:**

The search strategy will strive to access all published and unpublished studies and will be divided into three levels:

1. Identification of keywords using MeSH terms in Medline
2. Keywords and terms identified through this preliminary search will be used for the extensive search of the medical databases.
3. Reference lists and bibliographies of the manuscripts retrieved from the stage (1) and (2) will be searched.

- The initial search terms will be “overweight”, “obesity”, “laryngeal mask”, “supraglottic airway”, (“complications”).
- Articles published since 1983 in English, French, German and Spanish and indexed in the following databases will be searched:

  MEDLINE, PubMed, EMBASE, SCOPUS, CINAHL, Cochrane Register of Controlled Trials (CENTRAL), WebSearch (Google, Google Scholar)

Full texts of the articles identified by this search, and those considered to meet the inclusion criteria, will be obtained for synthesis of data. Decision whether these articles meet the inclusion criteria will be performed based on their title, abstract and subject descriptors.

A search of the grey literature sources will be performed through the Conference Proceedings Citation Index (Web of Science™ Core Collection), Northern Light Life Sciences Conference Abstract website and through the Google.com website with completion of the CADTH Grey Matters checklist. Following Clinical Trial registries will be searched for unpublished/undergoing studies: ClinicalTrials.gov, Australian New Zealand Clinical Trial Registry, EudraCT, International ISRCTN.org, German Clinical Trial Register and Chinese Clinical Trial Register.
Two members of the team will independently select manuscripts against the inclusion criteria. Disagreement between the reviewers in article selection will be sorted out at a meeting of these two persons and the third member of team. When more than 50% agreement, selected articles will be retrieved.

**Critical appraisal:**

The studies identified through the search mechanisms will be grouped according to the study design to:

- Randomized-controlled trials (RCT)
- Non-randomized controlled trials
- Cohort studies (prospective retrospective)

All these studies will be subsequently assessed for a methodological validity and risk of bias by two members of the team. Different risk of bias assessment tools will be used according to the study design:

- For randomized controlled studies - Cochrane Collaboration’s Risk of Bias tool
- For non-randomized trials - EPOC (Effective Practice an Organization of Care Group) guidance
- For observational cohort studies (prospective, retrospective) - Newcastle-Ottawa Scale (NOS)

Each study included in the systematic review will be scored/graded for a level/risk of bias.

**Data collection:**

Special data extraction form containing:

- year of publication
- name of authors
- journal (IF yes/no, PubMed inclusion yes/no, full text available yes/no)
- language (English, Spanish, German, French)
- study design
- number of participants
- clinical context
- details of intervention/details of comparator (if any)
• outcomes (success rate, complication, time of insertion, oropharyngeal seal pressure, postoperative sore throat)
• characteristics of operators

Two reviewers will extract the data.

Data synthesis:

Studies will be put into the groups according to performed comparisons. A synopsis table(s) will be created.

Data will be presented separately for RCTs and for other sources (quasi-RCT, cohort studies).

If the level of heterogenicity is considered low (by three different members of the team), the data will be combined in order to provide meta-analysis.

References