Tracheostomy decannulation protocols in pediatric patients

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Abstract

Abstract Objetives: Currently, there is scarce evidence about protocols and algorithms for making decisions to support the decannulation process of pediatric patients. The aim of the present study is to make a systematic review of decannulation protocols in pediatric patients that are available in the published literature. Methods: Systematic review of relevant published literature until January 2020 based on studies where a decannulation algorithm or protocol was applied to 1 to 18 year-old pediatric patients who suffered tracheostomy. Main outcomes were Successful decannulation and length of hospital stay. Results: Twenty two studies were included in the review. All the studies were descriptive. Reason for tracheostomy was reported in 76% of the studies most being because of upper airway and facial disorders. Decannulation protocols or algorithms were used in all studies with the exception of one. The successful decannulation rate was over 70% in most studies. Vital signs monitoring as well as partial oxygen saturation were the most used variables in most of cases to decide on decannulation. Conclusion: The lack of proven variabilities which can be used during the decannulation process makes it difficult to provide specific recommendations for decannulation protocols. More level II studies are needed in order to evaluate its effectiveness. There is no consensus amongst the authors regarding the use of the test of occlusion on the tracheostomy cannula, but they agree that polysomnography is a complementary method to fibroscopy which may be related to decannulation success prediction.

Aim:

In order to better understand the various practices of tracheostomy decannulation the aim of the present study is to make a systematic review of decannulation protocols in pediatric patients that are available in the published literature.

METHODS DESIGN

Criteria for including studies

A search was performed on PubMed, Lilacs, Central Cochrane and Scielo electronic databases looking for relevant published literature published until January 2020 based on studies where a decannulation algorithm or protocol was applied to 1 to 18 year-old pediatric patients who suffered tracheostomy. The eligibility criteria were applied independently by two evaluators aiming to include the studies on the revision and the bias risk was independently evaluated by two statisticians using the "STROBE" observational studies guide.

Results

Twenty two studies were included in the review for data extraction and analysis. Meta-Analysis could not be performed due to lack of statistical requirements necessary for its development. All the studies were descriptive - 17 retrospective, one prospective and 4 case series. Design was according to the aim of the study in 90% of them. Information related to methods such as the setting study, inclusion criteria and measured variables was fulfilled in almost all of them too. Reason for tracheostomy was reported in 76% of the studies most being because of upper airway and facial disorders. The primary outcome (successful decannulation), was defined in only 4 studies: in two of them success was defined by if the patient persisted decannulated for 6 months, and in the other two studies if the patient remained decannulated for 2 years

or until the end of treatment. The successful decannulation rate was over 70% in most studies (between 70 to 100% per protocol and on the first attempt). Vital signs monitoring as well as partial oxygen saturation were the most used variables in most of cases to decide on decannulation. Polysomnography could be a good predictor of success as well as a parameter that could help determine if the decannulation procedure could be done.

Introduction

Background

Tracheotomy is a surgical procedure that consists of opening of the airway anterior tracheal wall and creating a stoma where a cannula is placed into the trachea to facilitate ventilation. The term tracheotomy refers only to the trachea surgical incision and tracheostomy refers to the creation of a stoma and the stoma itself. The first cases of tracheostomy in children have been documented as being performed at the beginning of the 17^{th} century.(1)

Tracheostomy procedures increased in the mid-19th century with the diphtheria epidemic that affected Europe. In 1833, Trousseau reported that 50 children were saved because of this procedure.(2)

Indications

Both the indications of tracheostomy and characteristics of children with tracheostomy have profoundly changed in the last 50 years reflecting the changes that took place in the managment of children in a delicate condition. Until half of the 20^{th} century and before the introduction of generalized vaccination - haemophilus influenza and corynebacterium diphtheriae - viral infections and acute bacteriophage infections, the diphtheria, and epiglottitis, were the main causes of airway complication leading to the first practices of pediatric tracheostomy. At the end of the 1900's an increase in the use of endotracheal intubation and respiratory support for premature infants had led to a higher rate of premature babies with the need of mechanical ventilation and associated upper airway abnormalities. (3-4)

This is how vaccination programs, better intubation procedures and the development of new technologies in intensive care have diminished emergency tracheotomy and, far from diminishing its incidence, this situation has led to the appearance of other indicators like prolonged mechanical ventilation turning tracheostomy in a programmed, long term elective procedure.(5) Most of the published studies developed in The United States and Europe consider that the most frequent causes of tracheostomy are congenital upper airway abnormalities and prolonged mechanical ventilation.(4-5)

In his review published in 2017, Watters mentioned that in a retrospective study on 917 tracheostomized children aged between 0 and 18 collected from 36 pediatric hospitals, the most frequent underlying conditions were chronic lung disease (56%), worsening of neurological function (48%) and upper airways anomalies(47%).(4) (6)

However, the situation in developing countries is probably quite different, especially in the prevalence of tracheostomy.

There is an overall increase in the prevalence of patients who need prolonged mechanical ventilation (PMV) and also in the number of children who survive with complex medical conditions for whom tracheostomy and domiciliary mechanical ventilation could be part of their treatment.

In 2008 a study that was conducted in Ricardo Gutierrez Children's Hospital in Argentina analysed the prevalence of tracheostomy in children on mechanical ventilation support (MVS), and it was 20% during a 6-month period. It was higher than shown in other published series.(7-11)

Coinciding with previous studies, patients who underwent tracheostomy presented more length of stay and mechanical ventilation (MV) than non-tracheostomized ones. However, the mortality rate was higher in non-tracheostomized patients with more than 14 days of MV. This could probably be because of the prolonged use of mechanical ventilation and the chronicity of this children's situation.(12)

At this moment pediatric tracheostomy mortality rate ranks from 0.5% to 5%.[4]

In 2016, a Transference Program of mechanical ventilation chronic dependant patients or technology dependant patients was tested in the same hospital, ranging from intensive care areas to pediatric rooms. During the study, 247 patients entered the pediatric intensive care unit. Twenty four were tracheostomized. They were ventilation dependants, and clinically stable. There were 9.7% of technology dependant patients in the intensive care unit (ICU), which means the same number of beds required for severe acute patients.[13] It is because of all this that the there is a need to strengthen and implement programs, protocols and action algorithms on these patients that lead to a quick and effective dischargement whenever possible considering each particular case. Long term tracheostomy leads to a higher medical mortality rate and to a negative psychosocial impact. Because of this, decannulation is a priority when a tracheostomy is done.[14]

Up to this date, literature lacks well-established guidelines to determine the steps for decannulation. There is scarce evidence about protocols and algorithms for making decisions to support the decannulation process of the pediatric patients.

The lack of consensus for an optimal decannulation protocol may be, in part, attributed to the low amount of prospective studies centered on decannulation or the lack of studies comparing different decannulation methods.

Regarding the factors that predict success in decannulation, studies have attempted to define clinical predictors of successful decannulation. There is a consensus among authors that prior to decannulation, certain assessments must be done, and clear criteria must be established. Decannulation protocols vary widely in these reports with success rates ranging from 67% to 94%.[4]

In 2015 Knolman & Col in their review about decannulation protocols found that the studies obtained were case series or retrospective studies, with differences in the variables measured between them before decannulation. In spite of discrepancies and heterogeneity, they agreed in the different steps or goals accomplishment. Once a tracheostomy underlying indication gets corrected or solved, the patient can be considered a candidate for an eventual decannulation. A previous endoscopic assessment and progressive capping trials ensure a proper static and dynamic permeability of the airway.[15]

In 2013 Mitchell et Al published a clinical consensus about pediatric and adult tracheostomy manage. Experts agreed in that criteria must be established before a decannulation process. There was consensus in that children who underwent tracheostomy should be weaned off from mechanical support during 2 to 4 months. They should not present bronchoaspiration events and the need of tracheal secretions suction. Flexible laryngoscopy is recommended to confirm both permeability and mobility of at least one vocal cord and the elimination of any suprastomal obstructive granulation before attempting a decannulation. Children up to 2 years old must be tested capping the cannula during the day and releasing it during the night for several weeks. Other options are also mentioned, for example a sleep assessment and an exercise test. These recommendations are based on expert's opinions and serve as solid evidence guidelines even though they are for adult patients. But there is room for further discussions and investigations regarding this topic.[16]

The role of polysomnography (PSG) in the decannulation process has been slowly increasing in acceptance even though its daily use is questionable. This is because of the financial cost it implies, the length of stay, availability of medical supplies and the need for trained physicians and health personnel. Several authors conclude that it is useful as complement of the fibronoschopy in preparing for a decannulation.[17-19]

Despite decannulation being so relevant, there are no studies in which the efficiency of the protocols has been proved.

In order to provide a better understanding on the topic in this area, a systematic review has been performed, to research the scientific evidence that is currently available, which evaluates decannulation protocols on pediatric patients.

Objectives

The objective of this present investigation is to undertake a systematic revision of available literature on decannulation protocols in pediatric patients.

Methods

A systematic review was performed using a standardized methodology searching on electronic databases (PubMed, LiLacs, Central Cochrane and Scielo) with relevant literature published until January 2020. Used keywords were: protocol, consensus, score, clinical guidelines, triage, scale, scoring, algorithm, health indicators, tracheostomy. No language restrictions were imposed. There was also a manual search of the references in the selected articles.

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to perform this review.[20]

Criteria to consider studies :

- Pediatric tracheostomized patients aged 1 to 18 years old
- Studies where a decannulation protocol or algorithm was applied

Outcome measures:

- length of hospital stay
- Successful decannulation
- Mortality
- Complications with tracheostomy or decannulation

The studies were included without considering the state of publication, nor restrictions based on study type, although other studies were eliminated when they did not have any contact information to obtain sufficient data to analyze the results.

Data collection and analysis

Study selection

Once the search was done, two authors, MC and MP, applied separately the eligibility criteria to decide which studies include. Any disagreement between the authors was solved through discussion with a third author, EM, to try to reach an agreement. In case of not getting access to a complete text or abstract, we attempted to get in contact with the main investigator to get a copy of the study. With the results of the search in each base and with the subsequent eligibility criteria application a flow chart was made.

Data extraction and management

Information from the studies was extracted using a data extraction chart (Appendix 1I)

In the case of any relevant information not published in the articles, we have attempt to contact the main author to ask for the missing data.

Risk of bias evaluation in the included studies

The risk of bias in these studies was evaluated using the STROBE guidelines.[21] (Appendix 2)

This guide is made up of 22 items which include questions about the design of information, participants, main variables, data registration, etc. having to answer yes or no to each one. Two statistic reviewers SC and MC evaluated the items in each article and in case of any disagreement, MP revised it and it was resolved by consensus.

Analysis

A meta-analysis was not possible due to the heterogeneity of study and variables. Continuous variables were expressed as media, standard or medium range deviation and interquartile range (IQR) according to the distribution; and categorical variables such as absolute frequency and percentage.

Results

Search results

We identified a total of 1875 records.(1791 in PUBMED, 53 in LILACS and 31 in Scielo). 109 were selected by title and abstract reading including pediatric and adult population, 6 out of the 109 studies were eliminated because of being duplicated in the other bases and 4 because on the basis of being reviews or consensus and were used as theoretical framework and for supporting arguments. 76 out of the 99 resulting articles corresponded with adult population (76.76%) 22 with pediatric population (22.22%) and 1 study about predictors was not aligned with the objective after reading the full text. A total of 22 studies were included for data extraction and analysis. The selection process with the reasons by which studies were excluded is enumerated in the flowchart.(Image 1).

After analyzing the selected studies it was decided to undertake a systematic review of existing studies about decannulation without meta-analysis due to the lack of statistical requirements necessary for its development.

Methodological quality evaluation of included studies

In most of the studies the design was described and agreed with the study's objective (item 4 90% of positive response). Information related to material and methods such as setting, participants inclusion criteria and measured variables was also accomplished in almost all of them (90%, 77% and 60% respectively). 90% correctly described the population and measured variables results and interpreted their findings (Image 2 and Image 3).

Included studies

Characteristics detailed in the included studies are shown in table 1. All the included studies are descriptive (17 retrospective[15][18-20][22-34], 1 prospective[35] and 4 series of cases.[36-39]

The studies were all in a single center. Most of the studies were from the USA (United States of America), [14] [18-19] [23] [26] [28] [30] [32-35] [37] 6 from Europe, [21- 22] [24-25] [31] [38] 2 from India, [29] [36] and 1 from Australia.

The total amount of patients in the studies was 1222, the age range between 0 and 21 years old. The most frequent underlying disease was acquired or congenital airway alteration, and chronic pulmonary disease.[22] [24-27] [29] [31] [33-36] [38-39] Few studies informed the severity of the disease in the included patients.[19] [22] [24-26] [31-33] [39]

None of the studies informed if the tracheostomy was performed by percutane or surgical technique. The indication of tracheostomy was informed on 76% of studies, most of the times by alterations in facial and upper airways.[17] [22-26] [31] [33] [39].

The duration of the mechanical ventilation support (MVS) was only measured in one study (around 19 days).[30] Even though the inclusion criteria were well-detailed in 15 studies[14] [18-19] [22] [24-30] [35-38] the exclusion criteria were only mentioned in 9 [14] [18-19] [29] [31] [33] [36-38]. Decannulation protocols or algorithms were used in all studies with the exception of one.[34]Polysomnography (PSM) took place in half the studies[17-19] [25-28] [31] [33-34] [37] and only when \soutin was necessary in 3.[24] [29] [35]Radiography test was only mentioned in 2 protocols[30] [37] and endoscopy in most of them. In 9 studies[14] [17] [23-24] [27-28] [33] [35] [37] the indication to start the decannulation protocol was that patients were clinically stable and in 5 of them that the cause of tracheotomy was resolved.[22] [28] [30] [33] [35] In 11 studies[17] [23-26] [28-29] [33-34] [37] [39] the decrease of the cannula diameter was the prior step to the its occlusion which was done in 14 studies.[19] [22-24] [26] [28-33] [36] [38-39] Only in three studies the cannula was changed, mostly for smaller cannulas.[22] [36] [38] Only at the beginning of two protocols there was an education plan for parents and intervening professionals.[30] [38] Decannulation criteria were presented in almost all the studies - 19 studies - from which clinical and monitoring parameters such as partial oxygen saturation (spo2) were selected by the majority as measures defining or non-defining decannulation.

PSG was chosen by 8[17-19) (27-28) (31) (33) (37),cough effectivity only in 3 studies[24) (32-33) and endoscopy in 4.[14) (31-33)

Non-invasive ventilation (NIV) was used in 4 studies but after decannulation as a rescue maneuver.[25) (28-29) (34)The main outcome, in this case a successful decannulation, was only defined in 4 studies[18) (27) (35) (38) in two out of which the success was defined by the patient sustaining a stable decannulation for 6 months[27) (35) and in the other 2 studies for 2 years[18) or till the end of the tracing.[38) The post-decannulation observation period varied greatly among studies. The majority from 3 hours to 5 days[14) (17) (19) (23-24) (29) (31) (36) (39) or 3 to 6 months. [25) (27) (35)

Decannulation success ratio was over 70% in most studies - between 70 and 100% by protocol and in the first attempt - . As to PSG various authors concluded that in could be a good success predictor or, no less important, a parameter that could aid in decision making process when undertaking a decannulation.[17-19) (27-28) (33) (37)As to protocols usage it is mentioned in only two studies that it may aid to avoid a failure in decannulation but there are not any conclusions due to the nature of the designs.

Each study description is presented on the chart of included studies (chart 2).

Discussion

The main finding of the current revision is that in the scientific literature there are no studies with high levels of evidence, such as randomized clinical trials, on decannulation protocols in pediatrics. Nor analytic observational studies on cohorts of patients, where decannulation protocols are evaluated in a prospective way. Most studies were retrospective studies and case series, with limited numbers of patients.

The study of Wirtz et al[14) evaluated a decannulation protocol whose key point was to restrict the used resources. This approach makes it unique amongst the rest of the studies. The patients who were included had stable lung function with no breathing obstruction and with no less than 2 months without ventilatory support. The specific protocol consisted in laryngoscopy and bronchoscopy, prior to decannulation, with the aim of testing the respiratory tract. The airways are evaluated through a transnasal approached flexible bronchoscopy and the tracheostomy cannula is taken away in the operating room if the airways are considered to be eligible for decannulation. Unless any complications occur, the patient is discharged the next day. No occlusion or cannula reduction, nor polysomnography are performed. According to this study, the spontaneous ventilation during endoscopy is an important factor, since it allows the testing for obstruction or dynamic collapse. The authors believe this to be a higher ranked test, over daily routine capping, for decannulation processes suggested in other protocols.

The implementation of the reduction of the tracheostomy tube diameter and its occlusion are common in most protocols. However, its use is not universal nor standardized.

One of the arguments supporting this procedure is that it may not lead only to a successful decannulation, but also to a better adjustment to the child to the changing physiology of their breathing tract. The claims against the use of this protocol on a daily basis is that the reduction in the size of the lumen may result in cannula obstruction, due to its small diameter. During the plugging, the airway cross-sectional area is reduced to such a level that those patients who would not tolerate it, would tolerate decannulation.

Regarding polysomnography, in 1996, Tunkel et al,[17)published a study on the utility of polysomnography (PSG) during the assessment when planning decannulation. PSG provides objective data on the dynamic factors influencing the upper airways permeability when the pharyngeal muscle tone is lowered to its top. The authors reached the conclusion that the sleep studies close to the normal ranges of PSG are correlated to a successful decannulation.

The existing literature is composed of retrospective revisions and case series, and there are many discrepancies when it comes to define what a “favorable” PSG is, for determining the tracheostomy tube extraction.[18-19)

Currently, the PSG role has expanded amongst pediatric patients with obstructive apneas and central apneas, neuromuscular disorders as well as respiratory support dependent patients. Gurbani et al,[18) in the Cincin-

nati Children's Hospital Medical Center (CCHMC) studied the breathing and sleeping parameters associated with a successful decannulation, and the agreement between microlaryngoscopy, bronchoscopy(MLB) and polysomnography(PSG).

Microlaryngoscopy is the gold standard for the anatomy evaluation of the airways prior to decannulation. According to this study, certain PSG parameters which include the obstructive index (OI), apnea/hypopnea index (AHI) and hypoventilation, with a favorable MLB, seem to be good predictors for successful decannulation in patients with complex airways. They concluded that the combined use of MLB and PSG rises the predictability of successful decannulation in these children, above any other factor on its own. So, PSG must be considered a crucial part during the evaluation process for decannulation, especially amongst children with important breathing airways problems. Robinson et al,[(19)] also concluded that PSG may be a complementary trial for decannulation preparation. In the study of Lee et al,[(10)] the authors studied the utility of polysomnography with occluded tracheostomy tube, as a complement for endoscopy, for predicting the decannulation outcome.

In a retrospective review of the patients who had been tested with a PSG before the test, 30 children were included. 26 out of those 30 had a successful decannulation and 4 of them failed to finish the procedure. The predictive factors of the decannulation outcome were the index of apnea/hypopnea and desaturation events. They concluded that it is a useful and objective tool to be used as a complement of endoscopy and the evaluation of the functional airways.

Moreover, the anxiety generated by the decannulation process is something that should be also taken into account. The perspective of decannulation may cause significant anxiety on the patient and his family.

Previously, in other studies such as Black et al,[(22)]and Waddell et al,[(23)] panic was mentioned as a cause of failed decannulation. The pediatric decannulation protocol suggested in Great Ormond Street Hospital in United Kingdom (UK) includes the prior evaluation and mandatory psychological preparation.

Finally, given the evidence so far it is not possible to set as the ultimate truth any of the measures or variables which were part of these protocols, although it would be possible to give certain recommendations.

Mitchell[(16),] who was previously mentioned in this article, claimed that no consensus was reached regarding many topics, such as the tube change frequency in a mature tracheostomy, or the size of the cannula for children during nocturnal ventilation.

Considering the limitations of the existing studies it is possible to mention as key points the study design, mostly retrospective, case series and with a limited number of recruited patients.

When this review was finished, a multicentric study was published by Schweiger and col [(41)]evaluating the factors associated to a successful decannulation amongst the pediatric population. The study was placed in 4 high complexity hospital centers in Brazil, in the otorhinolaryngology department. Medical registers of under-18 tracheotomized patients were analyzed in a retrospective approach. The most common cause was post intubation laryngitis.

The outcomes showed that age and post intubation laryngitis were associated with a higher probability of successful decannulation. On the other hand, chronic neurological and breathing comorbidities were linked to lower decannulation chances.

The outcomes of the decannulation predictors are also important since they may help in the planning of the decannulation process. And, more importantly, they may be useful for advising health workers, the patient's family or tutor to have realistic expectations about the outcome.

Conclusion

Amongst the most frequent indications are prolonged mechanical ventilation and, to a lesser extent, upper airways obstruction.

Tracheostomy implies such a morbidity and mortality rate, that makes it necessary to plan decannulation from the very first moments of its performance.

According to international literature, mechanical ventilation independence from 3 to 4 previous months and the lack of secretions are considered criteria to suggest decannulation.

In order to evaluate the anatomy of the airway prior to decannulation, laryngoscopy and fibrobronchoscopy are preferred.

There is no consensus amongst the authors regarding the use of the test of occlusion on the tracheostomy cannula, but they agree that polysomnography is a complementary method to fibroscopy which may be related to decannulation success prediction.

The lack of proven variabilities which can be used during the decannulation process makes it difficult to provide specific recommendations for decannulation protocols. More level II studies are needed in order to evaluate its effectiveness.

On the other hand, something that should be also taken into account in the current context of health care is that an ideal protocol should present an efficient use of resources without compromising the patient's safety, optimizing the cost.[(4)] So, the question is: Which is the most safe and effective way to do the decannulation procedure?

To answer this, the health team professionals must study/test/evaluate the safety and effectiveness of their methods. The risk of acute failures must be minimized since they may/can lead to a catastrophic impact over the patient's mobility. Another aspect which needs to be taken into account is the availability and use of resources, material and human,so the accessible, and proper quality assistance can be guaranteed.

Decannulation is the final goal shared by the patient the family and the health team who assist children with chronic tracheostomy. Most pediatric patients can hope for an effective solution to their underlying airway pathology tolerating decannulation.

The current systematic review will allow the subsequent development and study of a decannulation protocol for pediatric patients, as well as identify the theoretical elements which would have a positive impact on the training of the healthcare workers in charge of the tracheostomized patient assistance.

Furthermore, the implementation of a protocol may lead to a substantial modification in the duration of the hospitalization, as well as represent an opportunity to make a more efficient use of resources.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Acknowledgements/Author contributions

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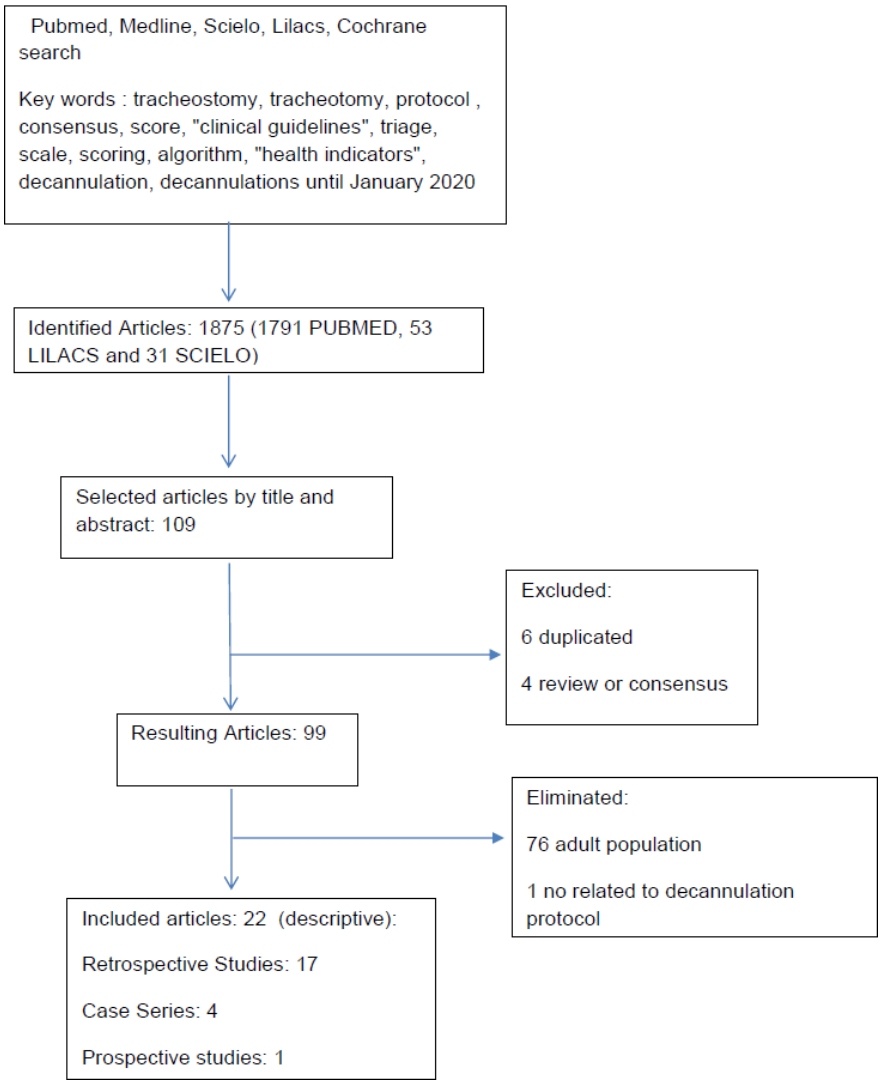
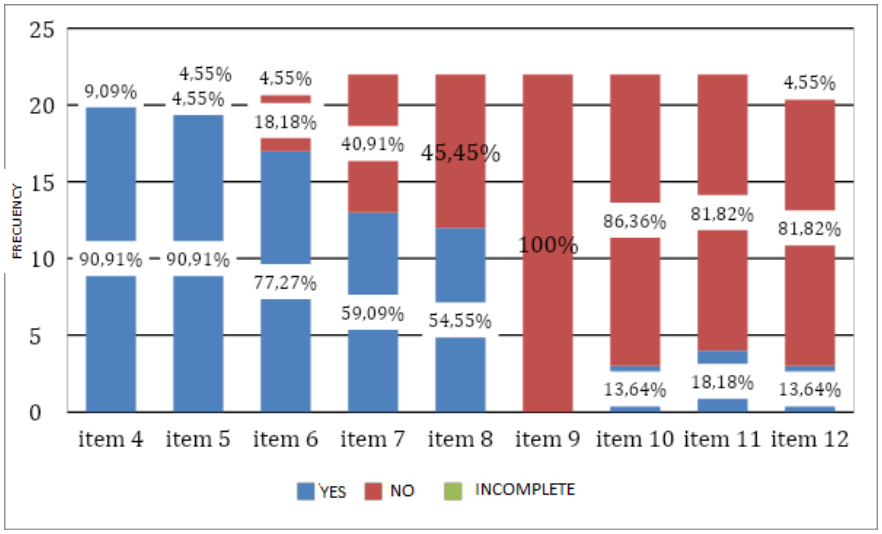
Study selection flow chart





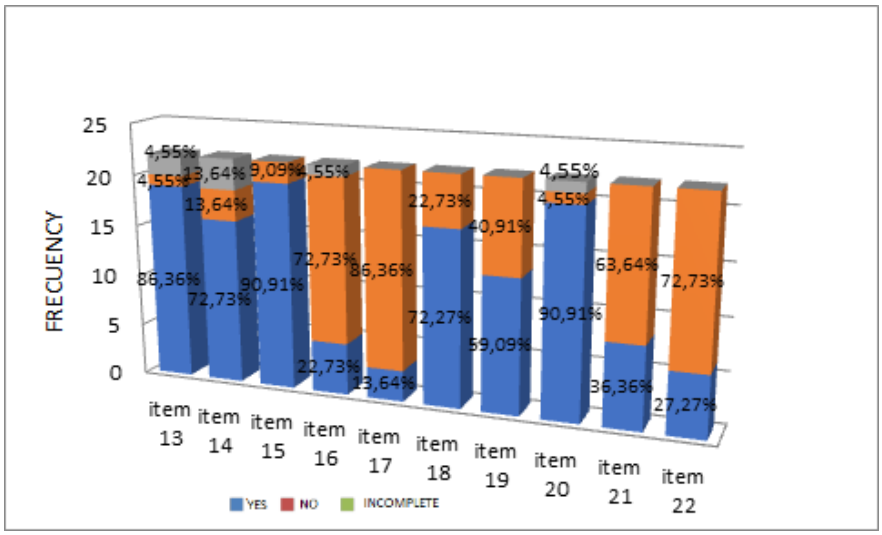


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Table 1. Characteristics of included observational studies.docx available at https://authorea.com/users/356296/articles/479223-tracheostomy-decannulation-protocols-in-pediatric-patients