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Protocolo para decanulação de traqueostomia pediátrica: evidências de validação de conteúdo

Pediatric tracheostomy decannulation protocol: evidence of content validation

Marinisi Sales Aragão Santos[1], *Rhanna Emanuela Fontenele Lima de Carvalho*[2]

ABSTRACT

Purpose: To develop and validate a decannulation protocol for chronically tracheostomized children aged 0–12 years. **Methods:** This methodological study was conducted in four stages: (1) submission of the project to the research ethics committee, (2) systematic review of the literature, (3) preparation of the clinical protocol, and (4) evaluation of the quality of information with specialists. The preparation phase followed the recommendations of the Guide for the Construction of Assistance Protocols. The quality of the protocol was evaluated by eight pediatric specialists using the Appraisal of Guidelines Research and Evaluation (AGREE II). An acceptable suitability of the protocol was considered when there was a 78% or greater agreement among the specialists. **Results:** Based on this systematic review, five recommendations were listed to compose the protocol for decannulating tracheostomy in children represented in a flowchart. The suitability of the protocol varied between 81.94 and 95.83%, with an overall assessment rate of 93.75%. All specialists recommended an appropriate protocol for use in healthcare services. **Conclusion:** The decannulation protocol for chronic children is valid and adequate. Future research with randomized designs is recommended for this population to assess the impact of the use of the protocol and its cost-effectiveness for health services.

Keywords: Tracheostomy; Clinical protocols; Patient safety; Child; Biomedical technology

RESUMO

Objetivo: desenvolver e validar o conteúdo de um protocolo de decanulação para crianças traqueostomizadas crônicas, na faixa etária de 0 a 12 anos. **Métodos:** pesquisa metodológica realizada em quatro etapas: (1) submissão do projeto ao comitê de ética em pesquisa; (2) revisão sistemática da literatura; (3) elaboração do protocolo clínico; (4) avaliação da qualidade das informações com especialistas. A fase de elaboração seguiu as recomendações do Guia para a Construção de Protocolos Assistenciais do Conselho Regional de Enfermagem - COREN – SP. A qualidade do protocolo foi avaliada por oito especialistas em pediatria, por meio do Appraisal of Guidelines Research & Evaluation (AGREE II). Considerou-se a adequabilidade aceitável do protocolo igual ou superior a 78% de concordância entre os especialistas. **Resultados:** a partir da revisão sistemática, foram elencadas cinco recomendações para compor o protocolo de decanulação da traqueostomia em crianças, representado em um fluxograma. A adequabilidade do protocolo variou entre 81,94% e 95,83%, com avaliação global de 93,75%. Todos os especialistas recomendaram o protocolo como adequado para utilização nos serviços de saúde. **Conclusão:** o protocolo de decanulação para crianças traqueostomizadas crônicas foi considerado válido e adequado em seu conteúdo. Recomenda-se a realização de pesquisas futuras com delineamentos randomizados, nessa população, para avaliar o impacto do uso do protocolo e o seu custo-efetividade nos serviços de saúde.

Palavras-chave: Traqueostomia; Protocolos clínicos; Segurança do paciente; Criança; Tecnologia biomédica

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[1]Hospital Infantil Albert Sabin – HIAS – Fortaleza (CE), Brasil.
[2]Mestrado Profissional em Saúde da Criança e do Adolescente, Universidade Estadual do Ceará – UECE – Fortaleza (CE), Brasil.
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Corresponding author: Rhanna Emanuela Fontenele Lima de Carvalho. Email: rhanna.lima@uece.br
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INTRODUCTION

Due to the complexity of patients in the pediatric field, there is commonly a need for the use of life support equipment, such as tracheostomies. The indications for tracheostomy vary according to institutions and population profiles and are often performed on children under 1 year of age[1]. Prolonged mechanical ventilation through intubation and upper airway obstruction are considered the main reasons for recommending this surgical procedure. It is estimated that 0.5% to 2% of children undergoing intubation and mechanical ventilation in intensive care units (ICUs) require tracheostomy[1-3].

Although tracheostomy is a life-saving strategy, it can lead to bronchorrhea, alterations in the swallowing mechanism, increased risk of airway infection, bleeding, difficulty in vocalization, as well as late complications such as granulomas, malacia, stenosis, vascular, and esophageal fistulas. Therefore, to prevent these complications, patient decannulation should be performed as early as possible[4].

Pediatric patients undergoing tracheostomy have specific indications, clinical conditions, and morbidity and mortality risks, which make post-operative care and decannulation planning a challenge for healthcare professionals[5]. This requires a methodical approach to the planning process to ensure the success and safety of the patient[6].

The rates of successful decannulation in the pediatric population range from 38% to 83.5%[7,8], while failure rates range from 9% to 45%[9]. Failure is defined as the need for reinsertion of the tracheostomy tube after its removal, which can occur within the first few days up to several months after the procedure[9].

In order to standardize actions and reduce failures, decannulation protocols have shown to be effective and contribute to successful decannulation rates[10]. Therefore, the development of protocols to guide care practices and routine procedures is essential for organization, management, and quality of services. These instruments guide professionals in making decisions aimed at preventing, recovering, or rehabilitating health, ensure patient care free from harm, and improve communication among healthcare providers[11].

The literature addresses the issue of decannulation protocols for the pediatric population. However, the actions described in these documents are primarily based on individual experiences of experts or healthcare institutions, lacking a described and/or published validation process[2,9,12,13]. Furthermore, the literature highlights the crucial role of multidisciplinary participation in the development of these protocols. This involvement is essential for identifying factors that may compromise the success of decannulation through a careful approach to the pre-procedural stages[5,14].

Based on the information mentioned above, the objective of this study was to develop and validate the content of a decannulation protocol for chronically tracheostomized children receiving care at a tertiary hospital in the state of Ceará, Brazil. Through the utilization of this resource, it is anticipated that the care provided to tracheostomized patients will be enhanced, with a specific focus on safe decannulation, support for clinical practice, and improved interdisciplinary collaboration within the patient care team.

METHODS

This study employed a methodological approach[15] based on the "Guidelines for the Development of Care Protocols" from the Regional Nursing Council of São Paulo (COREN-SP)[11]. The research was conducted in four phases: (1) submission of the project to the research ethics committee; (2) systematic literature review; (3) development of the clinical protocol; and (4) assessment of information quality by experts. The research received ethical approval from the Research Ethics Committee at the Albert Sabin Children's Hospital, under favorable opinion CAAE number: 44996621.7.0000.5042, dated April 7, 2021.

To develop the protocol, a systematic literature review was conducted using the electronic databases MEDLINE/PubMed (via the National Library of Medicine), Cumulated Index to Nursing and Allied Health Literature (CINAHL) with Full Text (EBSCO), and Embase (Elsevier). The research question was formulated using the PICO strategy: P (Population) - tracheostomized children; I (Interest) - tracheostomy decannulation methods; C (Comparison) - no comparison; and O (Outcome) - tracheostomy decannulation. The guiding question was structured as follows: "What are the methods used for tracheostomy decannulation in children?"

The inclusion criteria considered primary studies addressing methods of tracheostomy decannulation in children aged 0 to 12 years, without language or time restrictions. Review studies, editorials, and those that did not provide detailed information about the methods used in the decannulation process were excluded.

A search strategy was employed using keywords and descriptors combined with Boolean operators AND and OR, as follows: 'tracheostomized child' OR children AND procedures OR methods AND 'tracheostomy decannulation' OR decannulation, e 'tracheostomized child' OR children OR infant AND procedures OR 'therapeutic approaches' OR methods AND 'tracheostomy decannulation' OR 'tracheostomy weaning' OR decannulation. The search was conducted from June to July 2021.

The level of evidence, degree of recommendation[16], and risk of bias were assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist[17]. The actions were subsequently presented in charts and a flowchart[11]. Adobe Photoshop 2021 was used for formatting purposes.

The quality assessment was conducted using the Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II), which consists of six domains: (1) scope and purpose; (2) stakeholder involvement; (3) rigor of development; (4) clarity of presentation; (5) applicability; and (6) editorial independence. The sixth domain was not considered as it is not applicable to the study since it did not receive external funding. In addition to providing an overall assessment, AGREE II provide methodological guidance for the development of guidelines and protocols[18].

The tool recommends the participation of four experts in the quality assessment. However, eight pediatric specialists from various regions of Brazil, in the fields of medicine, speech-language pathology, physiotherapy, and nursing, participated in the study. They were selected through snowball sampling[19] and chosen according to pre-established criteria[20].

The specialists were invited to participate in the study through a formal invitation letter. Upon acceptance, they received a questionnaire for characterizing their expertise, the first version of the protocol, the AGREE II instrument (with instructions for quality assessment), and the Informed Consent Form (ICF).

Data analysis was performed by calculating the appropriateness, as proposed by AGREE II[18]. Responses for each item are presented on a Likert scale ranging from 1 to 7 (strongly disagree to strongly agree)[18]. The domain scores are calculated by summing the scores of individual items within each domain, scaling the total as a percentage of the maximum possible score for the domain[18]. Finally, a specialist conducted an overall evaluation of the protocol and determined whether its use was recommended or not[18]. An appropriateness score of 0.78% or higher was considered acceptable[19].

Based on the findings in the consulted literature, the initiation of the decannulation process requires the child to demonstrate resolution or improvement of the initial indication for tracheostomy, clinical stability (absence of infections and significant abnormalities in chest radiography, no ventilatory assistance), adequate oxygen saturation (SpO_2 > 92% in room air), patent airway (absence of anatomical and functional obstructive alterations), and no significant swallowing disorder (absence of aspiration and inefficiency in managing secretions with pharyngeal stasis, evaluated by a speech-language pathologist)[4,6,9,12,21].

Evidence shows that a multidisciplinary approach and the use of protocols lead to reduced morbidity and mortality rates and expedite the time to decannulation[12]. The collaborative efforts of physicians, speech-language pathologists, physiotherapists, nurses, and other professionals enhance the quality and effectiveness of care[14]. In light of this, the protocol represented by the flowchart offers the multidisciplinary team a sequence of actions concerning the decannulation process.

RESULTS

Based on the systematic review, 21 scientific articles published between 1990 and 2021 were identified. The year with the highest number of publications was 2016, with 5 studies, followed by 2017 with 4 studies. Between 2020 and 2021, 7 studies were published. It is important to note that no specific time cutoff was applied to the articles, as the aim was to understand the initial period of publication on the subject. Regarding the country of origin, 19 studies were conducted abroad, while 2 were conducted in Brazil. In terms of the level of evidence and study design, the prevailing level of evidence was 2b, with a retrospective observational approach, and the recommendation grade was B in 15 articles (71.43%). Regarding the risk of bias, 61.9% of the studies were classified as low risk[22]. Based on the studies included in the systematic review, 5 recommendations for proceeding with decannulation in children were identified (Chart 1) and organized in a flowchart (Figure 1).

Chart 1. Recommendations for tracheostomy decannulation in children

Recommendations	References	Scientific evidence
1. Perform endoscopic assessment of airway anatomy and functionality to confirm adequate patency at all levels and exclude or treat complications.	Avelino et al.[2], 2017; Benjamin e Curley[23], 1990; Canning et al. [7], 2020; Kennedy et al. [24], 2021.	Level of Evidence: 2b, 4 and 5 Grade of recommendation: B, C, and D Risk of bias: low to moderate
2. Progressively promote occlusion/packaging of the tracheostomy tube if the airway is patent.	Avelino et al.[2], 2017; Kennedy et al. [24], 2021 Maslan et al.[6], 2017; Mitchell et al.[12], 2013; Pozzi et al.[9], 2017.	Level of Evidence: 2b, 4 and 5 Grade of recommendation: B, C, and D Risk of bias: low, moderate, and high
3. Use pulse oximetry to monitor signs of respiratory distress and desaturation in hospital admissions during the decannulation process.	Canning et al.[7], 2020; Pozzi et al.[9], 2017; Seligman et al.[21], 2019.	Level of Evidence: 2b and 4 Grade of recommendation: B and C Risk of bias: low to moderate
4. Consider polysomnography to assess airway functionality during sleep, depending on the clinical and structural complexity of the patient.	Kennedy et al.[24], 2021; Lee et al.[13], 2016.	Level of Evidence: 2b and 5 Grade of recommendation: B and D Risk of bias: low to moderate
5. Keep the child under hospital observation for 24 hours after decannulation.	Kennedy et al.[24], 2021. Maslan et al.[6], 2017; Prickett and Sobol[28], 2015.	Level of Evidence: 2b Grade of recommendation: B Risk of bias: low to moderate

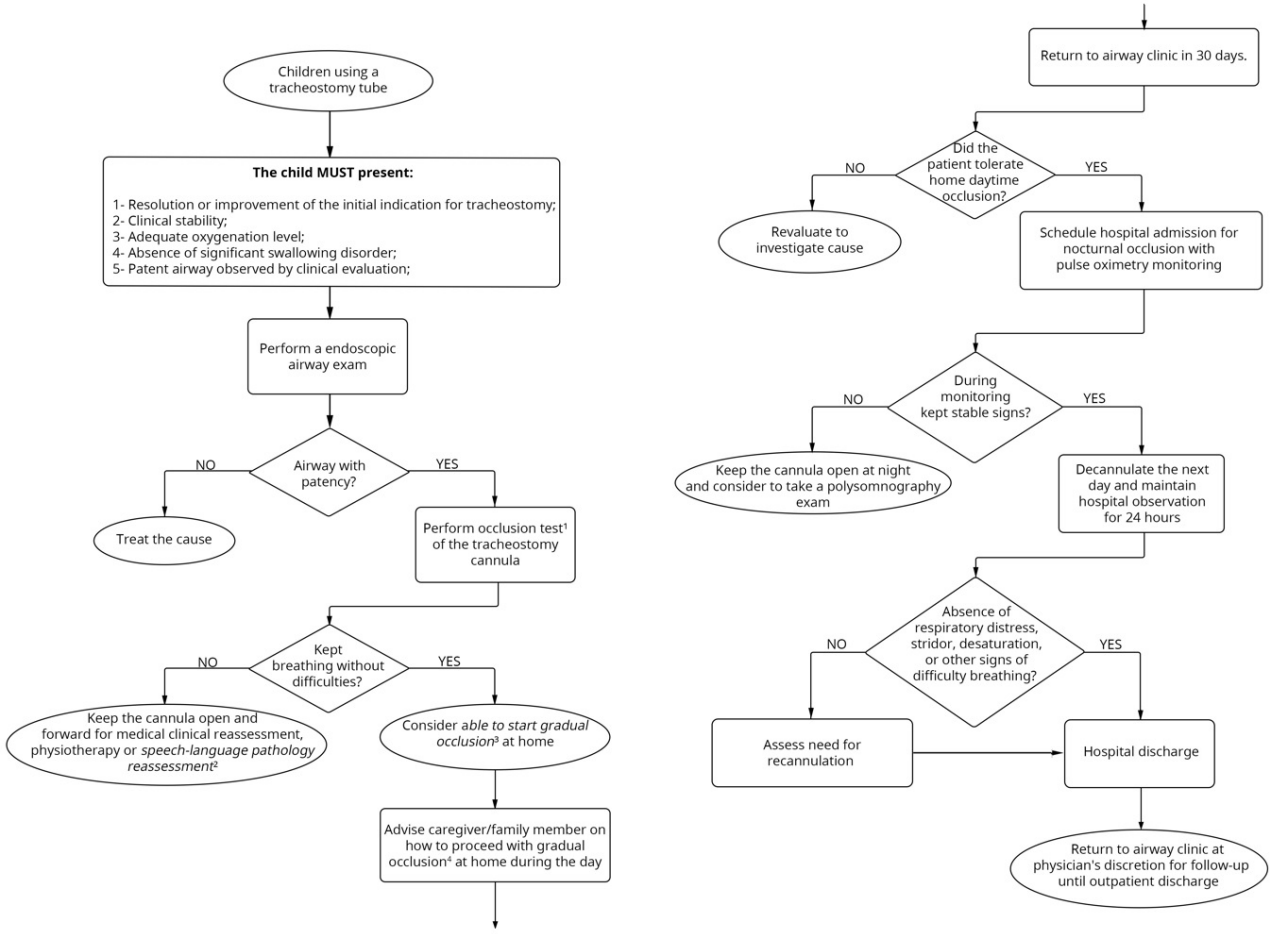

Figure 1. Flowchart for the tracheostomy decannulation process in children

1- Occlusion test: With a gloved finger, promote digital occlusion of the cannula for approximately 5 minutes, observing the child's respiratory behavior associated with pulse oximetry while in an airway follow-up consultation

Who does it: Doctor, speech therapist, or physiotherapist

2- Speech-language pathology reassessment: reassess the presence of dysphagia: salivary stagnation, difficulty in managing secretions, and bronchoaspiration that may make breathing difficult. If necessary, conduct an objective examination of swallowing and reassessing phonation

3- Able to start gradual occlusion: if there are no signs of respiratory distress, such as dyspnea, stridor, desaturation, pallor, cyanosis, presence of continuous intense and persistent cough or other signs of breathing difficulty, and presence of maintenance of vital signs, calm breathing, noise and cough with secretion management while occluded during the occlusion test, consider fit to start home occlusion

4- Gradual occlusion: increase the occlusion time during the day, according to the child's acceptance and respiratory comfort, starting with 5 to 10 minutes and progressing until it remains occluded throughout the day. If a speech and swallowing valve is available, start with the valve and then move on to the syringe/cap plunger, as instructed by the medical professional, speech therapist, or physiotherapist

Note 1: Assessments must be individualized, respecting each child's clinical and maturational process

Note 2: All exams must be medically performed and with the presence of a professional speech therapist in those related to the evaluation of swallowing

Note 3: During the period of hospitalization for observation of nocturnal occlusion and after removal of the cannula, the child must be managed by the nursing team

After its completion, the protocol was assessed for the quality of information by 8 pediatric specialists in the fields of otolaryngology, intensive care medicine, pulmonology, speech-language pathology, physiotherapy, and nursing. The specialists ranged in age from 35 to 63 years, with professional experience ranging from 8 to 37 years. In terms of academic qualifications, 2 held a doctoral degree, 4 were masters, and 2 had specialization/residency qualifications in the relevant area. Seven specialists had teaching experience, with 6 of them having publications and involvement in research groups.

Regarding the AGREE II quality assessment, all domains obtained an agreement above 0.80%, with an overall assessment score of 93.75%. The adequacy of the evaluated domains ranged from 81.94% to 95.83%, with the domain "rigor of development" obtaining the highest score. All specialists recommended the use of the protocol in healthcare services (Chart 2).

Scores below 6 for any item were accompanied by suggestions and questions, including: describing the tracheostomy tube occlusion test, specifying the professional groups involved, providing outpatient follow-up for cases with clinical signs but no need for recannulation, lack of references or research involving families or caregivers of children with tracheostomy, and including adolescents. All suggestions were accepted except for the inclusion of adolescents, as their airway is similar to that of adults and the indications for tracheostomy in adolescents are often different from those for children.

Ultimately, the protocol allows all professionals involved to understand the workflow, enabling them to address potential causes of failure, minimize the risk of recannulation, and facilitate the explanation of the decannulation process to parents or guardians, making them an integral part of the process.

Chart 2. Distribution of scores and suitability of the protocol according to the Appraisal of Guidelines Research & Evaluation domains[18]

Domain 1 - Scope and Purpose	J1	J2	J3	J4	J5	J6	J7	J8	Total
1. The overall objectives of the guideline are clearly described.	7	7	7	6	2	7	7	5	48
2. The health issues covered by the guideline are clearly described.	7	6	7	7	7	7	6	5	52
3. The population (patients, public, etc.) for whom the guideline is intended is clearly described.	7	7	7	7	7	7	7	7	56
Total	21	20	21	20	16	21	20	17	156
Suitability for Domain 1 – 91.66%									
Domain 2 – Stakeholder Engagement	**J1**	**J2**	**J3**	**J4**	**J5**	**J6**	**J7**	**J8**	**Total**
4. The guideline development group includes individuals from all relevant professional groups.	7	7	7	7	2	7	7	2	46
5. The views and preferences of the target population (patients, public, etc.) have been sought.	7	7	7	1	1	7	7	3	40
6. The target users (patients, public, etc.) of the guideline are clearly defined.	7	7	7	7	7	7	7	7	56
Total	21	21	21	15	10	21	21	12	142
Suitability for Domain 2 – 81.94%									
Domain 3 - Rigor of Development	**J1**	**J2**	**J3**	**J4**	**J5**	**J6**	**J7**	**J8**	**Total**
7. Systematic methods were used to search for evidence.	7	7	7	7	7	7	7	6	55
8. The criteria for selecting the evidence are clearly described.	7	7	7	7	7	7	7	5	54
9. The strengths and limitations of the body of evidence are clearly described.	7	7	7	7	7	7	7	5	54
10. The methods for formulating the recommendations are clearly described.	7	7	7	7	7	7	7	5	54
11. The health benefits, side effects, and health risks were considered in formulating the recommendations.	7	7	7	7	7	7	7	5	54
12. There is an explicit relationship between the recommendations and the supporting evidence.	7	7	7	7	7	7	7	6	55
13. The guideline was externally reviewed by experts prior to its publication.	7	7	7	3	7	7	7	7	52
14. A procedure for updating the guideline is provided.	7	7	7	7	6	7	7	6	54
Total	56	56	56	52	55	56	56	45	432
Suitability for Domain 3 – 95.83%									
Domain 4 – Clarity of Presentation	**J1**	**J2**	**J3**	**J4**	**J5**	**J6**	**J7**	**J8**	**Total**
15. The recommendations are specific and unambiguous.	7	7	7	7	5	7	7	5	52
16. The different options for addressing the condition or health issue are clearly presented.	6	7	7	7	5	7	6	6	51
17. Key recommendations are easily identifiable.	7	7	7	7	7	7	7	6	55
Total	20	21	21	21	17	21	20	17	158
Suitability for Domain 4 – 93.05%									
Domain 5 - Applicability	**J1**	**J2**	**J3**	**J4**	**J5**	**J6**	**J7**	**J8**	**Total**
18. The guideline describes the facilitating factors and barriers to its application.	6	7	7	3	6	7	7	6	49
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	7	6	7	7	6	7	7	7	54
20. The potential resource implications of applying the recommendations were considered.	6	7	7	4	7	7	6	6	50
21. The guideline presents monitoring and/or auditing criteria.	6	7	6	6	7	7	7	6	52
Total	25	27	27	20	26	28	27	25	205
Suitability for Domain 5 – 90.10%									
Overall evaluation score: 93.75%									
Technology use recommendation: yes									

Note: J = judges

DISCUSSION

The assessment of airway anatomy and physiology is crucial to achieve a return to physiological breathing. The first recommendation identified in the studies was the endoscopic evaluation of airway anatomy and functionality to confirm patency at all levels, indicating the absence of any obstruction in the airways[2,7,23,24].

As early as the 1990s, researchers emphasized the importance of conducting this assessment before proceeding with decannulation in children[23]. The national recommendations from the Brazilian Academy of Pediatric Otorhinolaryngology and the Brazilian Society of Pediatrics in 2017 also highlight the requirement for an endoscopic evaluation of the airways as a contraindication for decannulation in this population[2]. Besides, a study conducted in New Zealand found that laryngobronchoscopy was performed before decannulation, particularly in cases where the indication for tracheostomy was of a neurological nature[7].

Most participants in a study with experts in the field (92.3%) agreed on the importance of performing endoscopic examination of the airways before proceeding with decannulation[24]. An airway with anatomical and functional integrity is crucial for achieving the liberation from an alternative airway. The endoscopic examination also allows for the assessment of laryngeal functionality and swallowing function[9].

Swallowing problems are common in children with tracheostomy, with a high risk of impairment in the pharyngeal phase and a significant likelihood of laryngotracheal aspiration. The nature and degree of dysphagia influence decannulation readiness. Effective cough reflex, independent management of secretions, absence of salivary or pharyngeal secretion stasis, mild or absent drooling, and efficient swallowing are prerequisites determining the patient's eligibility for tracheostomy removal[4,6,9,21].

The assessment of swallowing during the decannulation process was the most frequently mentioned step in a prior study that emphasized the importance of the speech-language pathologist. The participation of medical professionals and speech-language pathologists was the most mentioned, with 70.8% and 66.6% respectively, and the involvement of physiotherapists and nurses was also deemed relevant[14]. Each specialty operates within its area of expertise, with the medical team responsible for diagnosing and treating airway obstruction pathologies, evaluating the patient's overall clinical condition, and deciding, in collaboration with other professionals, whether decannulation is feasible and the optimal timing to attempt it[14].

The second proposed recommendation was the cuff deflation and tamponade of the tracheostomy tube. When the patient is no longer dependent on ventilation and the cuff is fully deflated, non-invasive assessment of upper airway patency can be performed. Some protocols[2,9,13] employ a combination of reducing the tracheostomy tube size and occlusion. However, due to the narrow airway diameter in children, depending on their age and size, reducing the diameter, and then occluding it may not be possible or may not provide an adequate proportion of the airway to the tracheostomy lumen[24]. Thus, the preference for tamponade alone was a recommendation observed in the analyzed research.

When applying the tamponade method, careful observation of the respiratory pattern is essential and determines whether to proceed with the decannulation process. The presence of respiratory symptoms poses a high risk of decannulation failure. These symptoms may be more prominent in the pediatric population compared to adults due to communication difficulties with children. Therefore, attentive patient observation, monitoring of the respiratory pattern, and effective communication between the healthcare team and the family are crucial[25].

During this phase, occlusion can be achieved using a gloved finger, speaking and swallowing valve, syringe plunger/cap[14], or impermeable adhesive tape[4]. The speaking and swallowing valve is a device that restores subglottic pressure, allowing for improved airflow over the vocal folds, facilitating phonation, and enhancing swallowing ability[2,12].

In a retrospective cohort study[6], patients who tolerated the tamponade test progressed to using a speaking and swallowing valve, followed by complete obstruction of the tracheostomy tube with tracheostomy caps. Success was defined as daytime occlusion for approximately one month while maintaining an appropriate respiratory pattern.

Tamponade tests are typically initiated for a brief period, ranging from five to ten minutes, and gradually increased until achieving full daytime occlusion while maintaining an appropriate respiratory pattern[2,12,14]. It is worth noting that the consulted literature does not provide specific data on the progression time scale for tamponade in the studied population.

According to the American Clinical Consensus on Tracheostomy Care[12], as well as the Brazilian Academy of Pediatric Otorhinolaryngology and the Brazilian Society of Pediatrics[2], the child should undergo a daytime limitation test for several weeks. However, they recommend nighttime occlusion only in a hospital setting with respiratory pattern monitoring.

Among the methods used to monitor respiratory patterns, transcutaneous or pulse oximetry is readily available and accurate. It quantifies SpO_2, detects desaturation events, and episodes of apnea/hypopnea[21], which are considered predictors for successful decannulation in the literature[13]. This method was the third recommended in the protocol.

An observational study[26] used nighttime pulse oximetry to assess the desaturation index for predicting obstructive sleep apnea syndrome (OSAS), which is common in children with tracheostomy. The study found a strong correlation between the desaturation index and the apnea-hypopnea index (AHI), indicating it as a good predictor of OSAS in children.

The etiology of OSAS is multifactorial, involving anatomical and functional factors such as severe nasal obstruction, craniofacial malformations, lymphoid tissue hypertrophy, and neuromuscular diseases[27], conditions commonly present in children with tracheostomy.

Another recommendation identified in the analyzed studies was the performance of polysomnography, which provides quantitative data on the physiology of the upper airways during sleep[13,27]. However, its high cost, specialized techniques, and limited availability hinder its widespread use. Therefore, this recommendation is included in the protocol but should be considered based on the patient's clinical and structural complexity and the presence of signs of respiratory discomfort during nighttime occlusion monitoring using pulse oximetry[21,24].

For the members of the International Pediatric Otolaryngology Group, polysomnography should be performed primarily in patients with comorbidities that increase the likelihood of central sleep apnea and/or obstructive sleep apnea in the absence of tracheostomy[24]. Upper airway patency is maintained by the tonus of the pharynx, which undergoes significant muscular relaxation during sleep, particularly during the rapid eye movement (REM) phase, potentially resulting in impaired airflow passage at multiple levels of the airway[13].

Finally, the fifth recommendation concerns the observation time for inpatients after decannulation: the literature shows a variation between 24 and 48 hours[6,24,28].

According to the International Pediatric Otolaryngology Group, 53.85% of experts in the field reported that the average length of hospital stay after decannulation is 24 to 48 hours; 30.8% reported three to five days and 11.5% reported 0 to 23 hours[24].

A study conducted to determine the appropriate interval for observation of inpatients after decannulation concluded that the risk of failure after tube removal occurs within the first 12 hours. Therefore, up to 24 hours of hospital observation is sufficient in asymptomatic patients[28]. Researchers[6] also suggest that this observation may occur outside of an ICU setting and that this 24-hour period is not a standard for all patients.

Regarding the methodological quality assessment of the clinical protocol, professionals from various specialties with expertise and experience in the subject participated in the study. The diversity and quality of knowledge provided a comprehensive evaluation with suggestions that contributed to improving the protocol's quality. The adequacy percentage in all domains exceeded the recommended thresholds in the literature[29].

Domain 3, rigor of development, obtained the highest percentage in the quality assessment. A study examining the impact of AGREE II items on overall evaluations, overall quality, and recommendation for use revealed that the rigor of development domain is considered the most robust indicator of quality. A high score in this domain indicates minimal bias and guideline development based on evidence[30].

The evaluated domains in this study demonstrated adequacy percentages ranging from 81.94% to 95.83%, exceeding those reported in the literature. For instance, a clinical protocol for diabetes mellitus exhibited low quality, with domain percentages ranging from 27% to 66.7%[30]. Conversely, another protocol focused on cervical cancer prevention achieved results between 76.3% and 87.5%, meeting the criteria for good quality by surpassing the required minimum score of 75%[29].

Lastly, a limitation of this study is the quality of the studies encompassed in the protocol, which were restricted to case series, retrospective reviews, and expert opinions. It is worth noting that the validation process of the protocol originated from this study, underscoring the significance of future research employing randomized designs in this population to ensure the clinical safety of its implementation.

CONCLUSION

The study demonstrated the content validity of the decannulation protocol for children with chronic tracheostomy, with a final adequacy percentage of 93.75%. It emphasizes the importance of a gradual, progressive, and controlled process for tracheostomy decannulation, involving a multidisciplinary team to ensure safety. Further research is recommended to evaluate the impact of implementing the protocol on the care of children aged 0 to 12 years with chronic tracheostomy, as well as its cost-effectiveness in healthcare services.

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