

Clinical Pathway, Laryngeal Edema, Dysphagia, Stridor.

Establishing A Clinical Pathway For Adult Intubated Patients To Prevent Post-Extubation Complications.

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Abstract

Background: An endotracheal tube (ETT) is one of the essential artificial airways that is used for respiratory support for critically ill patients. However, the presence of ETT is associated with various fatal complications which diagnosed mainly in post- extubation time. Those complications include laryngeal edema, laryngospasm, and post-extubation dysphagia (PED) which delay the complete recovery of critically ill patient. The Clinical pathway (CP) is one of the excellent strategies that help the critical care staff to manage and control these complications. **Design:** A methodological research design was used to conduct this study. **Setting:** The study was conducted at Damanhur Chest Hospital in Damanhur city, Egypt. **Subject:** A purposive sample of 30 experts in the field of the study was involved for CP content validity. **Tools:** two tools were used. Tool I: "Intubated Patients' Needs Assessment". Tool II "Integrated Care Pathway Appraisal Tool". **Results:** There was a high consensus among the appraisers on the established CP items and all appraisers agreed that the established CP was valid. **Conclusion:** The established CP for adult intubated patients was recommended for use in future practice to prevent post-extubation complications. **Recommendations:** Critical care nurses should implement the CP for adult intubated patients to prevent the post-extubation complications.

Keywords: clinical pathway, Laryngeal edema, dysphagia, stridor.

Received 27 August 2024; Accepted 11 September 2024; Published March 2025

Introduction

An endotracheal tube (ETT) is one of the essential artificial airways used for intubating critically ill patients. It allows for mechanical ventilation (MV), protection of the airway in patients who are high risk for

aspiration, and supporting breathing in certain illnesses. However, many complications associated with ETT either occurs immediately following intubation or during the consequent days of intensive care unit (ICU) admission. An endotracheal tube impedes the cough reflex, compromises

mucociliary clearance, injures the tracheal epithelial surface, and develops tracheal edema (Lewis et al., 2019; Diggikar, et al., 2022).

The combination of the previous factors puts the intubated patient at great risk for developing ETT-related complications during and post-extubation period. Therefore, tracheal extubation in ICUs is not only an important milestone for patient recovery but also a procedure that carries a considerable risk of complications. An endotracheal tube is associated with significant complications that are time-dependent with a longer duration of intubation resulting in higher complications rates. The complications include laryngeal edema, laryngospasm, and post-extubation dysphagia (PED). Additionally, it results in secondary complications such as obstructive pulmonary edema, and re-intubation which are associated with an overall increase in the duration of MV, increased mortality, and a greater need for tracheostomy (Sheikh, et al., 2016; El Gharib, et al., 2019).

Post-extubation laryngeal edema is a common cause of airway obstruction after extubation in critically ill patients which occurs in approximately 55% of patients in post-extubation time (Lewis et al., 2019). Additionally, PED affects about 45-65% of patients in post-extubation period (Bucyana, 2019).

The high complication rates that occur during extubation and post-extubation time are a matter of specific concern, but the question is how to reduce these complications without increasing the intensive care services. Clinical pathway (CP) is an excellent example of strategies that help the critical care staff to manage and control complications. Clinical pathways are multidisciplinary plans of best clinical practice for specified groups of patients with a particular diagnosis that aid in the coordination and delivery of high-quality care (Sheikh, et al., 2016; El Gharib, et al., 2019).

The post-extubation period is unique as it requires close assessment and observation by the multidisciplinary team,

especially the critical care nurses (CCNs). Because they are in an ideal position to establish a therapeutic relationship with patients, which can help in early detection of any change in patient's condition.

There are several studies developed protocols, guidelines, or nursing interventions to manage post-extubation complications (Schoenberg & Wilson 2018), but up to our knowledge, only one CP study was conducted by Megan, (2017) at the University of Maryland, Baltimore. The study incorporated only one of the post-extubation complications which was post-extubation stridor. Moreover, there is no national study about CPs correlated to post-extubation complications. So, the current methodological research was conducted to establish a clinical pathway for adult intubated patients to prevent many post-extubation complications.

Aim of the study

This study aims to establish a clinical pathway for adult intubated patients to prevent post- extubation complications.

Research questions

- Which components should be included in the establishment of a clinical pathway for adult intubated patients to prevent post- extubation complications?
- What are the appraisers' opinions of the established clinical pathway for adult intubated patients?

Materials and methods

Materials

Design: A methodological research design was used to construct a CP for adult intubated patients to prevent post extubation complications. The researchers utilized the Delphi technique as part of our methodological design to get expert opinions on the established CP.

Setting: The study was conducted at Damanhur Chest Hospital, which involved two main ICUs (unit I and II). The total

beds numbers in both units is 35 beds. The unit 1 consisted of 8 rooms. Each room involved two beds, while unit II consisted of 9 rooms with a bed capacity of 19 beds. These ICUs received patients who had a variety of medical or trauma disorders. They received patients with multiple body system alterations.

Subjects: A purposive sample of 30 experts in the field of the study was involved for CP content validity. The experts included academic experts (lecturers and professors) as well as clinical experts (intensivists, head nurses, and bedside nurses) with at least 5 years of critical care experience. Statistical consultation and the work of Eubank et al. (2016) both indicated that five to ten experts were sufficient for content validation, but they ended up choosing fourteen experts to take part in the consensus development process.

Tools: two tools had been used for getting the essential data for the study:

Tool 1: Intubated Patients' Needs Assessment. This tool was utilized to gather relevant information for identifying the specific needs of the intubated patients.

Tool II: Integrated Care Pathway Appraisal Tool (ICPAT). This tool was adopted from Whittle et al. (2004) with a reliability of 0.96 to evaluate the established CP by the experts. It consisted of 32 key items organized into four domains. **Domain 1** was concerned with the structure of CP, **Domain 2** was concerned with CP documentation, **Domain 3** was concerned with the establishment process of a CP, and **Domain 4** was concerned with the implementation of the CP. Each ICPAT item was rated on a 4 point scale (1- not relevant to 4- very relevant) as follows: **Score of 1:** was given when the item was not relevant, **Score of 2:** was given when the item was relevant but in need of major revision, **Score of 3:** was given when the item was relevant but in need of minor revision and **Score of 4:** was given when the item was very relevant. Quality of the CP and recommendation for

future application were assessed. This contained a series of opinions; yes recommend, yes recommend with modifications and not recommended.

Methods

Approval from the Research Ethics Committee, Faculty of Nursing Alexandria University was obtained. An official letter was obtained from the Faculty of Nursing and was sent to hospital administrative authorities to conduct the study with explanation of the aim of the study. An official approval to carry out the study was obtained from the hospital administrative authorities to collect the necessary data.

This methodological study was conducted in three phases to establish the CP as follows:

Phase One: " Observation and Needs Assessment Phase". This phase aimed at identifying the basic needs of the intubated patients and recorded in Tool 1.

Phase Two: "Establishing Clinical Pathway Phase". This phase was accomplished as follows:

a. Establishment of a Multidisciplinary CP team: the researcher and four academic specialists in critical care nursing and medicine were convened to assess and review the established CP.

b. Literature Review: the researcher reviewed a set of highly-regarded researches and evidence based practices for post extubation support and CPs such as; International Journal of CPs, BMC Medical Research Methodology, American Thoracic Society and American College of Chest Physicians guidelines. The key words which were utilized were: CP, intubated patients, PLE, PED, and ETT complications.

c. Formulation of CP Draft: The CP team met several times and the CP was redrafted before the final agreed format was

ready for piloting on the study setting. The clinical pathway was written in two versions. A short version involved CP algorithm for ease of use in clinical practice, while a comprehensive version was done included the following details: The CP framework included 5 phases; (1) the 1st 24hrs from admission, (2) the subsequent days, (3) pre-extubation, (4) immediately post-extubation and (5) two days following extubation.

Phase three: Appraisal of the established CP: the CP was evaluated by 30 academic and clinical experts using tool II to measure its content validity and applicability by using the Delphi method (Schmalz, et al., 2021 and Hassan, et al., 2021). The Delphi method consisted of two rounds.

Round 1: The Integrated Clinical Pathway Appraisal Tool (tool II) containing the list of statements was circulated online to all 30 members. The item was considered acceptable for the final CP document if 27 (90%) experts agreed on a statement. Ninety percent was chosen as an appropriate cut-off based on work by Hassan et al. (2021), who suggested that at least 90% of experts must agree on an item in order to achieve content validity.

Round 2: The statements that did not meet consensus from round one were reviewed and modified until agreement was reached to retain, or modify the statement from the final CP. At the end, minor modifications were made to the CP in response to the expert's feedback.

Ethical Considerations:

Informed consent was obtained from experts after explaining the aim of the study and participation in the study was on a voluntary basis. Anonymity, privacy of experts and confidentiality of the collected data was maintained during the study. Additionally, ethical approval from ethical committee was given

Statistical Analysis

Using the Statistical Package for Social Studies (SPSS) Version 20.0, the acquired data were processed, tabulated, and statistically evaluated. Numbers and percentages were used to describe qualitative data. The mean standard deviation was used to describe quantitative data. Finally, data analysis and interpretation were carried out. P-values of 0.05 or below were taken to be significant.

Results

Table (1) illustrates the experts' distribution based on their characteristics. As observed in Table 1, the mean age of the experts was 40.53 ± 8.12 and nearly two-thirds were female. Their educational attainment was 16.7% bachelors, 50 %doctorates, 16.7 %post-doctorate, 13.3% technical and 3.3% masters. The expert panel consisted of, 33.3% intensivists, 10 % professors of critical care nursing, 6.7 % professors of critical care medicine, 16.7% lecturers of critical care nursing, 23.3% bedside nurses and 10% head nurses. The mean years of experience were 14 ± 9.62 years.

Table (2) presents results of appraisers' evaluation of the established CP based on domains' scores of the Integrated Care Pathway Appraisal Tool. As shown in table 2a, the CP's content domain was concerned with its specific structure. 100% of appraisers reported that this domain was very precise in describing the structure of the established CP, and the items involved were very relevant. In the second round of appraisals, 100% of appraisers agreed that the current CP provided the most accurate and comprehensive description of the relevant patients, exclusion criteria, and documentation standards in the documentation domain. They also found all items in this domain were very relevant.

As described in table 2b, the development process domain explains the

systematic planning and creation of the existing CP. 100 % of appraisers confirmed that all objects within this domain were relevant. In table 2c, all appraisers agreed that the implementation process domain was very specific in describing the items of the CP implementation which were very relevant. Additionally, all appraisers agreed that the established CP recommended for use in future practice.

Table (3) describes Variability of appraisers' opinions between the first and second round of the Integrated Care Pathway Appraisal Tool. As described in table 3, the coefficient of variation for all four domains of the established CP was ≤ 0.3 . This meant that there was no significant difference in the appraisers' opinions in the first and second rounds of CP appraisal, which indicated that there was a high consensus among the appraisers on the established CP items.

Table (1): Experts' distribution based on their characteristics

Experts' Characteristics	Experts (N=30)
Age (Mean ± SD)	40.53± 8.12
Gender n (%)	
Male	11(36.7)
Female	19(63.3)
Educational attainment n (%)	
Technical	4(13.3)
Bachelor	5(16.7)
Master	1(3.3)
Doctorate	15(50)
Post-doctorate	5(16.7)
Job title n (%)	
Intensivists	10 (33.3)
CCN Professors	3(10)
CCM professors	2(6.7)
CCN Lecturer	5(16.7)
Bedside nurse	7(23.3)
Head nurse	3(10)
Years of experience (Mean ± SD)	14±9.62

Abbreviations: CCN: Critical Care Nursing CCM: Critical Care Medicine
SD: Standard Deviation.

Table (2a): Appraisers' evaluation of the established clinical pathway based on domains' scores of the Integrated Care Pathway Appraisal tool

Integrated Care Pathway Appraisal Tool Domains' scores	First round (N=30)				Second round(N=30)			
	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.
I. Content / Structure of ICP								
o Have identified start and finish points	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Reflect a patient's journey (i.e. moving along a continuum of days/weeks/months/stages/objectives/programs)	0 (0%)	0 (0%)	1 (3.3%)	29 (96.7%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Reflect 24-hour continuous care/treatment (where appropriate)	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Form the record of care for an individual patient	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Allow documentation to be individualized to meet the patient's needs	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Outline the anticipated process of care/treatment	0 (0%)	0 (0%)	1 (3.3%)	29 (96.7%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
II. ICP Documentation								
o Identify the relevant patients in the title of the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Indicate the circumstances when a patient should come off or should not be put on (exclusion criteria)	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Meet local/national minimum standards for documentation (e.g. institution standards if exist)	0 (0%)	0 (0%)	4 (13.3%)	26 (86.7%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Include a reminder that says professional judgment must be applied while taking into account the patient's wishes & needs (i.e., the CP is not a tramline and can be varied)	0 (0%)	0 (0%)	3 (10%)	27 (90%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Reference the evidence on which the content is based	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Include the date of development of the document on the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Include space for the identification of the individual patient on each page	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)

Table (2b): Appraisers' evaluation of the established clinical pathway based on domains' scores of the Integrated Care Pathway Appraisal Tool .

Integrated Care Pathway Appraisal Tool Domains' scores	First round (N=30)				Second round(N=30)			
	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.
III. Development Process								
○ Record decisions made concerning the content of the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Record description/list staff involved in the development of the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Conduct a literature search to gather the evidence base for the clinical content of the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Record the rationale for including and excluding pieces of evidence/guidelines	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Pilot test the CP and audit the CP documentation after the pilot	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Consider clinical risk as part of the content of the CP	0 (0%)	0 (0%)	2 (6.7%)	28 (93.3%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Consider training, education, and competency of staff as part of the content of the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Involve patient and/or their family members in the CP (by using focus groups/questionnaires/complaints/patient diaries, etc.)	0 (0%)	0 (0%)	1 (3.3%)	29 (96.7%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
○ Take into account patients' and family members' multicultural needs	0 (0%)	3 (10%)	27 (90%)	0 (0%)	0 (0%)	0 (0%)	2 (6.7%)	28 (93.3%)

Table (2c): Appraisers' evaluation of the established clinical pathway based on domains' scores of the Integrated Care Pathway Appraisal Tool.

Integrated Care Pathway Appraisal Tool Domains' scores	First round(N=30)				Second round(N=30)			
	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.	Not relevant	Relevant but in need of major revision	Relevant but in need of minor revision	Very relevant.
IV. Implementation Process								
o Establish an on-going training program for the staff	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Identify resources (individuals/time) to undertake the training on how to use the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Establish a system to feedback the variations of the CP to the staff and patients/family members	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Agree on the location where the CP documentation will be stored once finished	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Assess the risks involved in an CP establishment before commencement	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Name an individual responsible for maintaining the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Provide training to staff when a change to the CP content is made	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Provide regular training for new staff that will be using the CP	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Set a review date of one year or less	0 (0%)	0 (0%)	0 (0%)	30 (100%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)
o Get endorsement for the CP establishment from the Trust Board/Clinical Governance Committee	0 (0%)	4 (13.3%)	26 (86.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	30 (100%)

Table (3): Variability of appraisers' opinions between the first and second round of the Integrated Care Pathway Appraisal Tool

Integrated Care Pathway Appraisal Tool Domains	First round			Second round		
	Mean	SD	CV	Mean	SD	CV
Content / Structure of ICP	2.99	0.060	0.02	3	0	0
ICP Documentation	2.97	0.061	0.02	3	0	0
Development Process	2.87	0.061	0.02	2.99	0.025	0.008
Implementation Process	2.88	0.067	0.02	2.98	0.050	0.02

Abbreviations:

CV: coefficient of variability ≤ 0.3

SD: Standard deviation

Discussion

The majority of critically ill patients admitted to the ICUs require endotracheal tube intubation, which is frequently a crucial and life-saving procedure. However, the presence of ETT is associated with a variety of serious complications for critically ill patients, including post-extubation laryngeal damage, post-extubation dysphagia, laryngospasm, and others that are frequently diagnosed in the post-extubation period. These post-extubation complications increase the incidence of re-intubation (Smischney et al., 2018). So, it is necessary for critical care staff to increase their awareness about the risks associated with extubation and post-extubation time and how to develop evidence-based strategies such as CPs to prevent and inhibit these complications (Abd-Elrhman, 2023; McIntyre et al., 2020).

The discussion will focus on the appraisal of the established CP. Regarding the *first domain* (content and structure of CP) of the ICPAT, the results of the current study revealed that the structure of the established CP was very relevant based on the expert evaluation. The finding could be attributed to the fact that the established CP met the essential characteristics of CP that distinguished it from protocols and practical guidelines, such as having a start and finish

time that extended from admission to discharge, reflecting the patient's journey, and outlining the care process. Furthermore, the CP form was utilized to provide a framework for the treatment process and to restructure the health-care process in the form of CPs. The findings was in the same line with Fitri, & Sundari, (2018) and Cui, et al., (2014) who informed that the first step of CP appraisal is whether it highlight the vital features of CP or not.

As regards the *second domain* of the ICPAT, CP documentation, the findings of the current study revealed that experts agreed that the characteristics of the established CP documentation were very relevant. The findings may be justified by the established CP adhering to the universal characteristics of CP documentation. The present CP considered the patients' needs, set the targeted patients' inclusion and exclusion criteria, and provided space for patient identification. The findings were consistent with Fitri and Sundari (2018), who reported that the documentation of CP can specifically record the services needed by the patients. As well, the CP should include the page number on each page, the date, the abbreviation described in the document, and space to write the name of the patient.

Concerning the *third domain* of the ICPAT, the CP's development process, the

current study's findings revealed that the characteristics of the current CP's development process were very relevant. The findings might be attributed to the fact that the current CP identified staff involved in its development, and a literature search was done to acquire evidence for the CP's clinical content using several data sources. As well, the current CP was piloted and took into consideration the clinical risk. Additionally, training, education, and competency of staff were essential parts of the CP development.

The finding was congruent with Chawla et al. (2016), who emphasized on the importance of the CPs development process because CPs are tools that are used to evaluate services or therapies that have been given, and to improve these services, it must involve a process of change in daily practice. Additionally, the CP creates a map of the patient's journey from various perspectives. The map allows the multidisciplinary team to assess the problem and the procedures that will be applied. As a result, the author stated that during this phase, the possible risks that can occur due to the use of CP must be assessed before usage, and a training program for staff was created, as well as the provision of resources to carry out CP training.

Regarding the *fourth domain* of the ICPAT (the CP implementation process), the current study found that the current CP's implementation features were very relevant. The findings may be explained by the fact that the CP establishment was approved and the resources required to practice the established CP were accessible. Furthermore, an ongoing training program for staff was established, and feedback on CP variations was assessed. Furthermore, new staff received ongoing training, and the CP was reviewed on a regular basis.

The findings were consistent with Fitri & Sundari (2018) and Abrahams et al. (2017), who reported that the implementation of CP was very important because a developed

pathway is based on high risk, improvement of outcomes, patient satisfaction, safety, and cost. The author highlighted that the success of CP implementation depended on the clinical service providers, managers, and relevant staff to ensure goals were achieved. Additionally, they clarified that to improve the quality of CP implementation, they focused on teamwork, the need for training of the staff involved, a full-time facilitator needed to supervise the implementation of CP, and that it is best to conduct regular reviews by the CP team.

Conclusion

Based on the current study's findings, it can be concluded that the established CP for adult intubated patients was recommended for use in future practice to prevent post-extubation complications

Recommendations

Responding to the study's findings, the following recommendations have been proposed:

- Use the CPs in clinical practice to improve critically ill patients' outcomes.
- Include the CP in the undergraduate curriculum.
- Incorporate the CP in the patients' sheets for daily adherence.

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