Effect of Implementing Tracheostomy Care Guidelines on Patients' Clinical Outcomes at the Intensive Care Units

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Abstract

Background: Tracheostomy care practices vary widely among healthcare providers, leading to inconsistent patient outcomes; differ widely among healthcare providers and institutions, potentially resulting in inconsistent care. Therefore, standardized tracheostomy care guidelines have been established. **The study aimed** to evaluate the effect of implementing tracheostomy care guidelines on patients' clinical outcomes at the Intensive Care Units. **Method:** A quasi-experimental pretest-posttest research design was performed with a purposive sample of 80 patients with tracheostomy recruited from three Intensive Care Units affiliated with Tanta University Hospitals in Egypt. Data were collected using four tools: **Tool I:** Tracheostomy Patients Assessment Sheet**. Tool II:** Glasgow Coma Scale. **Tool III:** Tracheostomy Patients Clinical Outcomes. **Tool IV:** Tracheostomy Adverse Events. **Results:** The results revealed that statistically significant improvements were observed regarding mechanical ventilator and physiological parameters, and reduced tracheostomy adverse events among the study group ($P<0.5$). Notably, 15% of the study group achieved a high prediction of successful decannulation two weeks post-insertion compared to no one in the control group. **Conclusion:** Implementing tracheostomy care guidelines markedly improves clinical outcomes by enhancing physiological stability, increasing decannulation success, and reducing adverse events. **Recommendations:** Ongoing training program for critical care nurses about tracheostomy care guidelines for updating their knowledge and practice in the ICU. Monitoring of tracheostomy cuff pressure should be integrated into routine care for critically ill patients to improve patient's clinical outcomes and prevent adverse events.

Keywords: Clinical Outcomes, Tracheostomy Care Guidelines.

Introduction:

Tracheostomy is one of the surgical interventions conducted at intensive care units (ICUs) **(Smith et al., 2020).** This procedure is typically indicated for patients requiring long-term mechanical ventilation (MV) and those facing difficulties during the weaning process. It is also recommended for upper airway obstructions caused by laryngeal edema from inhalation injuries, anaphylaxis, trauma, or infections **(Simonds, 2023).**

According to **Wise, Sparks, Spray, Nolder& Willis, (2023)** tracheostomy is a safe intervention for critically ill patients requiring prolonged ventilation who need extended ventilation, with the goal of reducing the duration of mechanical ventilation, facilitate weaning from the ventilator, decrease the need for sedation, and enhance patient comfort. Conversely, **Lubianca, Castagno, and Schuster et al. (2022)** emphasize that several complications can arise during the procedure, immediately afterward, or even long-term. These complications include bleeding, pneumothorax, tracheoesophageal fistula, mucus plugging leading to tube blockage, accidental tube displacement, and infections at the stoma site.

Miu et al. (2024) assert that tracheostomy care requires evidence-based guidelines. Key aspects include ensuring a patent airway, maintaining proper cuff pressure, performing suctioning, humidifying inspired oxygen, practicing oral hygiene, providing adequate nutrition, and maintaining a comprehensive care plan. Additionally, effective communication with the healthcare team regarding any changes to the care plan is essential, along with preparing emergency equipment and adhering to a transport safety checklist.

Significance of the study:

Adverse events related to tracheostomies remain a significant global concern, accounting for approximately half of all airway-related fatalities and cases of hypoxic brain injury in critical care settings**.** The incidence of tracheostomies among patients requiring MV has increased from 16.7 to 34.3 per 100,000 adults **(Abril et al., 2021).** In the United States, more than 110,000 tracheostomy procedures are performed annually **(Kim et al., 2023).** A statistical report from Tanta University Hospitals indicated that in 2021, there were 345 patients on MV in both settings **(Annual statistics of Tanta Emergency Intensive Care Units).**

Therefore, nurses must be equipped with the appropriate evidence-based practice approach to meet tracheostomy patients' needs safely and competently.

The aim of this study was to evaluate the effect of implementing tracheostomy care guidelines on patients' clinical outcomes at the intensive care units.

Research hypothesis:
The critically ill patient who received tracheostomy care guidelines is expected to have an improvement in their clinical outcomes in Intensive Care Units.

Clinical outcomes: Means improving physiological parameters such as; enhancing prediction of successful decannulation, decreasing incidence of adverse events, and maintaining tracheostomy cuff pressure

Subjects and method:

Design: A quasi-experimental pretest-posttest research design was performed in this study.

Settings: This study was conducted at both the Traumatology and Emergency Medicine and Surgical Anesthesia Intensive Care Unit at Tanta University Hospitals.

Subjects: A Purposive sample of 80 adult patients with tracheostomy from the previously mentioned settings who met the inclusion criteria were assigned using the Epi Info program. Based on the total population, there were 145 admissions per year across both settings. The sample size was calculated as the following: Z= confidence level 95%, d= Error proportion (0.05), P= population (60%)

The subjects were divided into two groups:

Control group: Consisted of 40 adult patients who received routine tracheostomy care. which include; assessment of stomal secretion, ensuring well inflated cuff without measurement with a manometer, suctioning, and stomal care for patients with tracheostomy

Study group: Consisted of 40 adult patients who received tracheostomy care-based guidelines from the primary researcher.

Tools of data collection: Four tools were utilized in this study

Tool (I): Tracheostomy Patients Assessment Sheet; it was developed by the researcher following a review of relevant literature to evaluate tracheostomy patients. The assessment consisted of three components, detailed as follows: -

Part (1): Demographic characteristics; concerned with data related to patients' code, age, sex, and job.

Part (2): Clinical data for tracheostomy patients; this part was used to assess clinical and medical data of patients with tracheostomy such as; admission diagnosis, present medical history and past history, the size of the tracheostomy tube and suction catheter size **(Kim et al., 2023).**

Part (3): Mechanical ventilator assessment data; This section was used to assess parameters of mechanical ventilation such as the mode of a mechanical ventilator, a fraction of inspired oxygen (FIO2), respiratory rate (RR), tidal volume (Vt), peak inspiratory pressure (PIP), pressure limit and positive end-expiratory pressure (PEEP) **(Grasselli et al., 2021).**

Tool II: Glasgow Coma Scale (GCS); developed by **Graham Teasdale and Bryan Jennett in 1974** and later adopted by **Cook in 2021**, this tool evaluates a patient's level of consciousness. It includes three domains: eye-opening is scored from 1 to 4, verbal response from 1 to 5, and motor response from 1 to 6.

These scores are added together to provide a total score between 3 and 15 and classified according to Minor GCS ≥ 13, Moderate GCS 9 – 12 and Severe, with GCS ≤ 8

Tool III: Tracheostomy Patients Clinical Outcomes; It was developed by the researchers following a review of pertinent literature **(Ghiani et al., 2022; Battaglini et al., 2023; Poral, Kovammal, Nalamate, Kurien, & Thomas, 2024)** to assess clinical outcomes of tracheostomy patients. It was divided into three parts as the following;

Part (1): Physiological parameters; It included; temperature, heart rate, respiratory rate, mean arterial blood pressure, and oxygen saturation (spo2). The scoring system of this part was noted as mean & standard deviation.

Part (2): Tracheostomy cuff pressure flow sheet; ensuring that cuff pressure was in the recommended ranges from 20-30 cm H_2O. The scoring system was reported as mean ± standard deviation.

Part (3): Prediction of early successful decannulation indicators; involved assessment of the following; consciousness (≥ 5 or <5), hemodynamic stability (no active infection and hemodynamic stability), adequate swallowing, decreased tracheal suctions frequency (≤ 2 or > 2 suction every 8 hours), oxygenation>90%, no comorbidities, absent of sedation, voluntary coughing and ability to tolerate tube capping > 24hours. All items were observed and scored using a dichotomous scale as present was scored (1) and absent was scored (0)

All items were calculated and classified as the following;

< 5 indicated a low successful rate for decannulation. 5-7 indicated a moderate successful rate for decannulation. 8- 9 indicated a highly successful rate for decannulation

Tool IV: Tracheostomy Adverse Events: This tool was developed by the researcher after examining relevant literature **(Narwani, Dacey, & Lerner,, 2024; Twose , Cottam, Jones, Lowes, & Nunn, 2024)** to assess adverse events of tracheostomy and consisted of the following; bleeding, stoma site infection, tracheostomy tube dislodgement, tracheostomy tube occlusion as, respiratory related events.

Scoring system

Present sign was scored (1) and absent sign was scored (0)

Method

The study was accomplished through the following steps:

1-**Administrative process:** Official permission to conduct the study was obtained by the Dean of the Faculty of Nursing to the Director of Anesthesia,

Traumatology and Emergency Medicine and the Surgical Intensive Care Units, Tanta University Hospitals the study and collect data from selected setting.

2-Ethical consideration:

-Approval of Scientific Research Ethics Committee of the Faculty of Nursing was obtained with code number (127/10/22) and the Scientific Research Ethics Committee of the Faculty of Medicine with code number (36109/11/22).

-Patients were assured of privacy and confidentiality regarding data collection. A code number was used instead of names.

-The study was not causing any harm to the patient

3-Validity of tools: content validity of all tools of the study was tested for clarity and applicability by (7) experts in the field of specialty such as Critical Care and Emergency Nursing, Anesthesia and Biostatistics and modifications were done.

4-Reliability of the tool: The reliability of the developed tools was assessed using Cronbach's alpha, which yielded scores of 0.82 for Tool I, 0.85 for Tool II, and 0.95 for Tools III and IV. The overall Cronbach's alpha for the entire study sheet was 0.88.

5-A pilot study:

It was performed on eight adult patients with tracheostomy before the actual study the tools were tested for clarity and applicability, as well as to identify any obstacles the researcher might face during data collection. As a result, the researcher made the necessary modifications prior to the study. Data from the pilot study were excluded from the current research.

6-Field work:

-Data collection for this study was conducted within the period from the end of October 2023 to the end of October 2024.

-The researcher started with a control group of patients first to prevent data contamination.

The present study was conducted through four phases: Assessment, planning, implementation and evaluation.

1. Assessment phase: -

- The researcher assesses patients in both control and study group with tracheostomy immediately after insertion who fulfilled inclusion criteria to obtain baseline data about demographic characteristics as code, age, sex and job using **tool I (part 1)**
- The researcher also, assess clinical data for tracheostomy patients and mechanical ventilator parameters **tool I (part 2&3)**
- Assess level of consciousness using tool II Glasgow Coma Scale (GCS).
- Assess tracheostomy patients' clinical outcomes (physiological parameters, assess tracheostomy cuff pressure, prediction of early successful decannulation) through;
- **Tool III part (1,2, 3).**
- Assess adverse events of tracheostomy and include using a tool (IV).

2. Planning phase: -

- A tracheostomy care guideline for patients in ICU was developed based on the assessment of study subjects and existing guidelines found based on the relevant literature **(Twose et al., 2024)** regarding the effect of implementing tracheostomy care guidelines on patients' clinical outcomes at the Intensive Care Units.

Expected Clinical Outcomes: -

- Improve physiological parameters
- Maintain tracheostomy cuff pressure
- Enhance prediction of successful decannulation
- Decrease the incidence of adverse events

3. Implementation phase: -

At the beginning of this phase, the researcher prepared the patients and equipment, then divided patients into two groups

Control group: Routine care was implemented by nurses as; assessment of stomal secretion, ensuring well-inflated cuff without measurement with manometer, suctioning and stomal care.

Study group: A tracheostomy care guideline was implemented for patients undergoing tracheostomy within 24 hours after insertion by the researcher daily for two weeks during morning and afternoon shifts, while the night shifts, nurses in the critical care unit implemented the guidelines after receiving training from the researcher. The content of tracheostomy care guidelines was applied according to patients' assessment.

A tracheostomy care guideline for mechanically ventilated patients included the following: -

- Maintaining tracheostomy tube stabilization through ensure it is stabilized in a central position, avoiding any angling or contact between the tube and the tracheal mucosa.
- Maintain proper cuff management in which; at 20-30cm H_2O.
- Maintain tracheostomy humidification (active humidification was used for adult patients in the ventilator circuit, temperature modified to 37°c to ensure 100% relative humidity)
- Tracheostomy suctioning; conducted when clinically warranted for the patient, rather than as a routine procedure. Using an open technique, and employ a non-touch method.
- Care for the stoma by minimizing shear and friction forces, and apply barrier wipes around the stoma site for patients with moist skin or excessive secretions.
- Ensure oral hygiene is maintained twice daily, with regular rinsing or moistening of the mouth at intervals.

4. Evaluation phase: -

Evaluation of both groups was done three times immediately, one week, and two weeks after insertion of the tracheostomy tube by using tool I Part (3). Also, tool II, tool III, and tool IV.

A comparison was performed between two groups to determine effect of implementing tracheostomy

care guidelines on patients' clinical outcomes at the Intensive Care Units.

Results:

Table (1) represents socio-demographic characteristics in both studied groups. It was noted that over half (55%) of the control group and more than one-third (37.5%) of the study group were aged between 50 and 60 years, with a mean ± standard deviation (45.60±12.912 and 43.15±10.807) respectively. Also, more than half (52.5%, 57.5%) of them were male respectively.

Figure (1) illustrates patients' clinical characteristics of the studied groups. It was noticed that a higher proportion (40%, 45%) of critically ill patients in the control and study groups were diagnosed with traumatic brain injury, while the lower (10%, 7.5%) of control and study groups were diagnosed with cervical injury and respiratory failure, respectively.

Figure (2) shows modes of mechanical ventilators among the studied groups. The findings of this result highlighted that, immediately after tube insertion the majority (70%, 75%) of the control and study group were on VC SIMV mode respectively. On the other hand, it was noticed that there was a considerable percentage of patients' prognoses to CPAP/PSV 17.5%, 57.5% of the control and study group, respectively post a week after insertion and only 2.5% of the control group compared to a considerable percentage (20%) of the study group were weaned post two weeks after tube insertion.

Table (2) shows the distribution of mechanical ventilator parameters for the studied groups throughout the study. It was observed that there was a significant difference regarding PEEP post-a week and two weeks after tube insertion. In addition, respiratory rate and peak inspiratory pressure post two weeks after insertion among two groups where ($p<0.005$).

Table (3) reveals mean scores of the studied groups regarding level of consciousness using Glasgow Coma scale (GCS) throughout period of study. This table reveals that the mean ± SD of Glasgow coma scale (GCS) in control group was 4.10±1.215 while, 4.80±0.911 in the study group immediately after tube insertion where there was an increase in the mean ± SD to (4.80±1.224 and 5.65±1.122) among control and study group post a week after insertion respectively.Then followed by an increase to (5.20±1.814 and 6.08±1.474) post two weeks after insertion in both groups respectively. In addition**,** a statistically significant difference was observed between control and study group throughout the period of study ($P<0.05$).

Table (4) presents mean scores of physiological parameters and tracheostomy cuff pressure among the studied groups. Concerning physiological parameters, there was a significant decrease in respiratory rate in control and study groups where p

(0.008 and 0.031) respectively throughout the period of study, with a statistically significant difference among both groups post a week from insertion (p=0.028). Regarding mean arterial blood pressure, there was a high statistically significant difference among the two groups two weeks after tracheostomy tube insertion (p=0.000).

Concerning oxygen saturation, A high statistically significant difference among the two groups post-a week and after two weeks from insertion were observed with (p<0.005).

Regarding tracheostomy cuff pressure, there was a high statistically significant difference between both groups post-a week and two weeks after tube insertion (p=0.000).

Table (5) reveals the percentage distribution of prediction of early successful decannulation of the studied groups. This table showed that a considerable percentage of 15% of the study group showed a high prediction of successful decannulation rate post two weeks of insertion where (P= 0.000) compared with no one in the control group. **Additionally,** there were highly statistically significant differences regarding the prediction of successful decannulation post-a week and two weeks after tube insertion among two groups where P= 0.000.

Table (6) shows the percent distribution of bleeding and local signs of stoma site infection among the studied groups. It was noticed that there was a statistically significant increase about local signs of infection among control group regarding all items of local signs of stoma site infection except bleeding beside the tracheal cannula where (p<0.005) and no statistically significant difference was observed regarding bleeding or local signs of infection in the study group (P>0.5)

Table (7); shows a relation between the mode of mechanical ventilator of the studied groups and their early successful decannulation score. It was noted that the higher mean scores for prediction of early successful decannulation at two weeks after tube insertion were (6.00±0.00 and 6.63±1.302) for patients weaned from mechanical ventilation in both control and study groups, respectively. In contrast, lower mean scores for successful decannulation were recorded for patients on PC(SIMV) mode immediately after tube insertion, with scores of (3.67±0.778 and 3.00±1.414) for control and study groups, respectively. Additionally, there was a statistically significant relation between the CPAP/PSV mode and early successful decannulation a week post-insertion, with a P value of 0.029.

Table (8); illustrates the correlation between the prediction of early successful decannulation scores of the studied groups and their physiological parameters. Regarding the control group, it was observed that there was a positive significant

correlation between the prediction of early successful decannulation and (heart rate, mean arterial blood pressure, and oxygen saturation) immediately after tube insertion where (P< 0.05). While, a positive statistically significant correlation was found in relation to (mean arterial blood pressure and oxygen saturation) post a week where (P< 0.05). In addition a highly statistically significant positive correlation with oxygen saturation post two weeks after tube insertion where (P=0.000). There was a significant positive correlation between early successful decannulation and (oxygen saturation and mean arterial blood pressure) immediately and two weeks after tube insertion among study group respectively where (P< 0.05). While, there was a significant positive correlation with (heart rate, mean arterial blood pressure, and oxygen saturation) and a statistically negative correlation with respiratory rate post a week after tube insertion where (P< 0.05). In relation to tracheostomy cuff pressure, it was noticed that a statistically negative correlation with early successful decannulation post a week after tube insertion in the control group where (P< 0.05).

Table (1): Socio-demographic characteristics of both studied groups.

Characteristics	The studied patients (n=80)				χ^2 P
	Control group (n=40)		Study group (n=40)		
	N	%	N	%	
Age (in years)					4.619 0.202
- (21-<30)	5	12.5	3	7.5	
- (30-<40)	8	20.0	11	27.5	
- (40-<50)	5	12.5	11	27.5	
- (50-60)	22	55.0	15	37.5	
Range **Mean ± SD**	**(21-60) 45.60±12.912**		**(21-60) 43.15±10.807**		t=0.847 P=0.360
Gender					FE 0.822
- Male	21	52.5	23	57.5	
- Female	19	47.5	17	42.5	

FE: Fisher' exact test, **X2:** Chi-Square test, **p-value** ≤ 0.05 (significant)

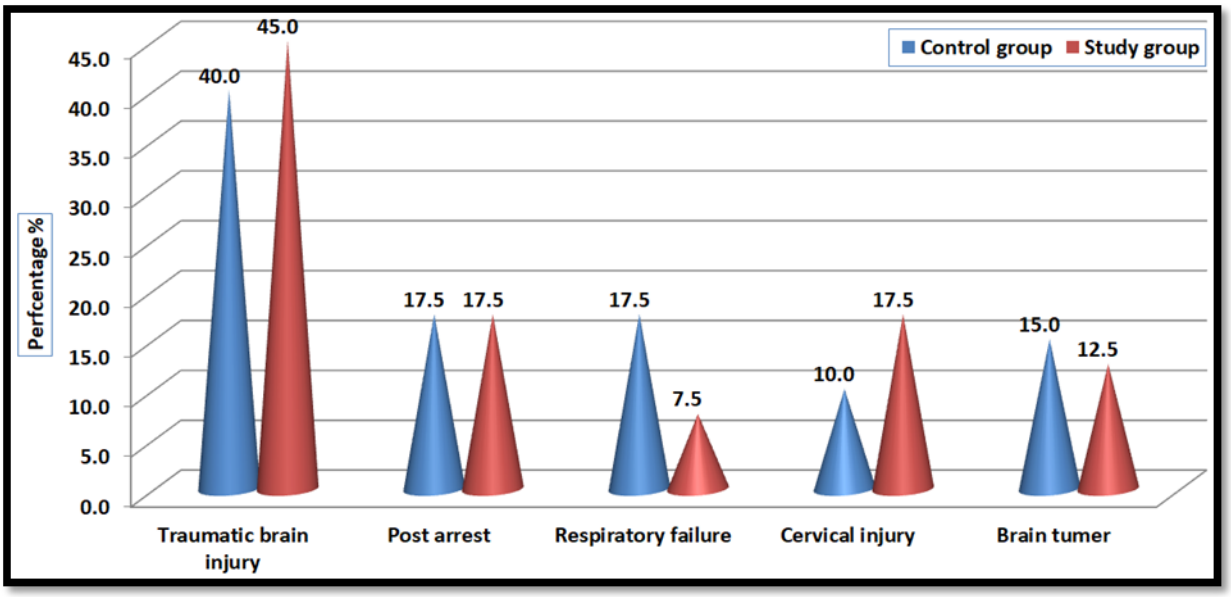

Figure (1): patients' clinical characteristics of the studied groups

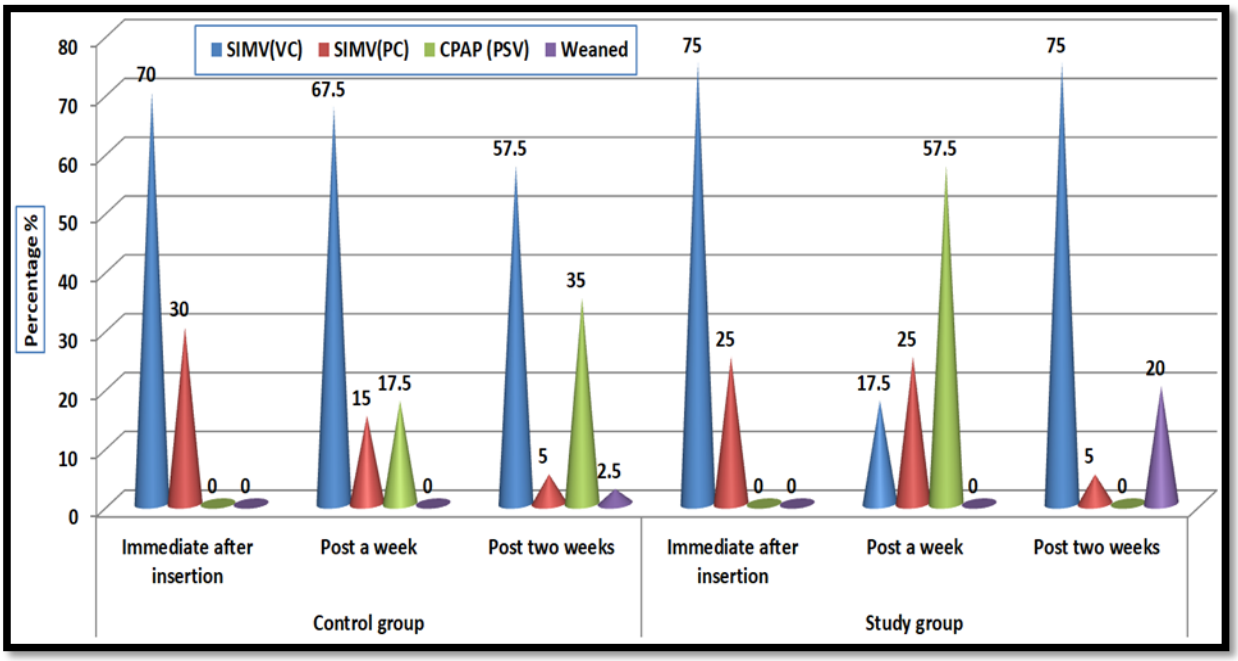

Figure (2): |Modes of mechanical ventilator among the studied groups

Table (2): Distribution of mechanical ventilator parameters for the studied groups throughout period of study

Parameters	The studied patients (n=80) Range Mean ± SD							
	Control group (n=40)			F P	Study group (n=40)			F P
	Immediate after insertion	Post a week	Post two weeks		Immediate after insertion	Post a week	Post two weeks	
1. Fraction of inspired oxygen (%)	(35-70) 47.88±8.979	(30-70) 39.63±9.700	(0-60) 33.25±10.595	**22.484 0.000***	(30-70) 46.88±9.653	(30-60) 38.75±8.530	(0-50) 28.38±15.623	**25.164 0.000***
Control group Vs Study group t , P	0.480, 0.633	0.304, 0.762	1.311, 0.194					
2. Respiratory rate	(12-20) 14.90±1.780	(0-22) 12.55±5.818	(0-24) 9.63±7.594	**8.851 0.000***	(12-22) 14.78±1.901	(90-18) 10.80±6.418	(0-16) 7.18±7.324	**17.615 0.000***
Control group Vs Study group t , P	1.706, 0.092	1.423 , 0.159	**2.033 , 0.046***					
3. Tidal volume	(0-500) 412.50±100.734	(0-500) 336.00±185.649	(0-500) 255.50±223.618	**7.817 0.001***	(0-500) 373.25±16.310	(0-500) 262.00±17.600	(0-500) 166.25±17.912	**10.685 0.000***
Control group Vs Study group t , P	0.428 , 0.670	1.278 , 0.205	1.636 , 0.106					
4. Peak inspiratory pressure	(20-45) 30.38±4.855	(25-45) 33.00±4.501	(0-45) 29.80±8.262	**3.115 0.048***	(20-35) 28.40±3.768	(20-35) 28.65±4.583	(0-35) 22.10±12.017	**9.204 0.000***
Control group Vs Study group t , P	1.803 , 0.075	1.952 , 0.055	**4.283 , 0.000***					
5. Pressure limit	(40-60) 49.38±5.904	(40-60) 51.75±5.133	(0-60) 50.38±10.089	1.047 0.354	(30-60) 47.50±5.883	(30-60) 49.13±6.783	(0-60) 37.63±4.122	**8.824 0.000***
Control group Vs Study group t , P	1.633 , 0.106	1.469 , 0.146	1.808 , 0.074					
6. Positive end expiratory pressure	(5-10) 6.05±1.131	(5-10) 6.13±1.090	(0-10) 6.35±1.610	0.578 0.563	(5-10) 6.58±1.583	(5-10) 6.68±1.591	(0-10) 5.40±2.799	**4.685 0.011***
Control group Vs Study group t , P	1.861 , 0.067	**3.445 , 0.001***	**3.339 , 0.001***					

* Significant at level P<0.05

Table (3): Distribution of the studied groups regarding level of consciousness using Glasgow Coma scale (GCS) throughout period of study

Feature	The studied patients (n=80)													
	Control group (n=40)						χ^2 P	Study group (n=40)						χ^2 P
	Immediate after insertion		Post a week		Post two weeks			Immediate after insertion		Post a week		Post two weeks		
	N	%	N	%	N	%		N	%	N	%	N	%	
• **Eye opening**														
• None	16	40.0	8	20.0	12	30.0		9	22.5	5	12.5	7	17.5	
• To pain	22	55.0	27	67.5	12	30.0	**31.377**	20	50.0	16	40.0	8	20.0	**13.870**
• To speech	0	0.0	5	12.5	13	32.5	**0.000***	8	20.0	16	40.0	17	42.5	**0.031***
• Spontaneous	2	5.0	0	0.0	3	7.5		3	7.5	3	7.5	8	20.0	
• **Motor response**														
• None	4	10.0	4	10.0	4	10.0		2	5.0	0	0.0	0	0.0	
• Abnormal extension	20	50.0	4	10.0	3	7.5	**34.143**	12	30.0	5	12.5	2	5.0	**30.681**
• Abnormal flexion	12	30.0	25	62.5	24	60.0	**0.000***	23	57.5	22	55.0	25	62.5	**0.000***
• Withdrawal from pain	4	10.0	7	17.5	5	12.5		3	7.5	13	32.5	8	20.0	
• Localized pain	0	0.0	0	0.0	4	10.0		0	0.0	0	0.0	5	12.5	
• **Total GCS level**														
• Severe	34	85.0	30	75.0	24	60.0		32	80.0	19	47.5	11	27.5	
• Moderate	6	15.0	10	25.0	13	32.5	**11.005**	8	20.0	21	52.5	26	65.0	**28.107**
• Mild	0	0.0	0	0.0	3	7.5	**0.027***	0	0.0	0	0.0	3	7.5	**0.000***
Range	**(2-7)**		**(2-7)**		**(2-9)**		**F=5.936**	**(3-7)**		**(3-8)**		**(3-9)**		**F=11.862**
Mean ± SD	**4.10±1.215**		**4.80±1.224**		**5.20±1.814**		**P=0.004***	**4.80±0.911**		**5.65±1.122**		**6.08±1.474**		**P=0.000***
Control Vs Study														
t	**2.914**		**3.238**		**2.367**									
P	**0.005***		**0.002***		**0.020***									

(2-5) Severe (6-8) Moderate (9-10) Mild

* Significant at level P<0.05

Table (4): Mean scores of physiological parameters and tracheostomy cuff pressure among the studied groups.

Physiological parameters	The studied patients (n=80) Range Mean ± SD							
	Control group (n=40)			F P	Study group (n=40)			F P
	Immediate after insertion	Post a week	Post two weeks		Pre	Post a weeks	Post two weeks	
1. Heart rate (b/m)	(50-150) 84.55±28.943	(50-120) 80.30±21.825	(50-130) 80.53±21.002	0.391 0.677	(55-140) 85.25±22.685	(55-120) 81.23±17.041	(50-110) 82.65±16.296	0.467 0.628
Control group Vs Study group t , P	0.120 , 0.904	0.428 , 0.670	1.051 , 0.297					
2. Respiratory rate (c/m)	(14-27) 17.30±3.818	(14-24) 18.08±3.331	(12-25) 15.70±3.057	**5.027 0.008***	(14-26) 17.65±3.498	(14-27) 17.40±2.836	(14-20) 16.05±2.160	**3.565 0.031***
Control group Vs Study group t , P	0.808 , 0.422	**2.245 , 0.028***	0.211 , 0.833					
3. Mean arterial blood pressure (mm hg)	(45-110) 69.60±15.884	(50-115) 72.55±18.136	(50-120) 73.68±18.902	0.566 0.569	(50-120) 73.43±16.662	(50-124) 77.80±17.212	(50-115) 80.20±16.212	1.692 0.189
Control group Vs Study group t , P	0.976 , 0.332	1.328 , 0.188	**3.867 , 0.000***					
4. Temperature (^{0}c)	(36.5-38.0) 37.26±0.408	(36.7-38.5) 37.65±0.503	(36.4-38.5) 37.51±0.586	**6.137 0.003***	(36.5-38) 37.19±0.395	(36.2-38.2) 37.25±0.424	(36.4-37.8) 37.15±0.370	0.614 0.543
Control group Vs Study group t , P	1.201 , 0.115	0.506 , 0.615	0.591 , 0.556					
5. Oxygen saturation (SpO_2) %	(88-99) 92.53±3.336	(85-96) 89.33±3.269	(84-98) 90.10±4.199	**8.478 0.000***	(86-99) 90.90±3.136	(85-98) 92.33±3.116	(90-99) 92.73±2.298	**4.447 0.014***
Control group Vs Study group t , P	1.657 , 0.102	**3.286 , 0.002***	**3.468 , 0.001***					
6. Tracheostomy cuff pressure (20-30cm H_2O)	(20-35) 28.75±3.349	(25-90) 51.88±20.213	(20-100) 47.75±19.512	**22.805 0.000***	(20-45) 28.88±4.598	(20-30) 27.25±3.572	(20-30) 27.88±3.376	1.780 0.173
Control group Vs Study group t , P	0.139 , 0.890	**7.587 , 0.000***	**6.348 , 0.000***					

* Significant at level P<0.05

Table (5): Percentage distribution of prediction of early successful decannulation of the studied groups.

Early successful decannulation level	The studied patients (n=80)													
	Control group (n=40)						χ^2 P	Study group (n=40)						χ^2 P
	Immediate after insertion		Post a week		Post two weeks			Immediate after insertion		Post a week		Post two weeks		
	N	%	N	%	N	%		N	%	N	%	N	%	
Low successful rate	32	80.0	35	87.5	30	75.0	2.111 0.348	34	85.0	14	35.0	9	22.5	**46.953 0.000***
Moderate successful rate	8	20.0	5	12.5	10	25.0		6	15.0	26	65.0	25	62.5	
Highly successful rate	0	0.0	0	0.0	0	0.0		0	0.0	0	0.0	6	15.0	
Range Mean ± SD	**(1-6) 3.40±1.236**		**(1-6) 2.85±1.292**		**(1-7) 3.23±1.441**		F=1.797 P=0.170	**(0-5) 3.00±1.396**		**(1-7) 4.75±1.532**		**(2-9) 5.70±1.772**		**F=30.283 P=0.000***
Control Vs Study group t P	1.357 0.179		**5.9970 0.000***		**6.8550 0.000***									

<5 Low successful rate (5-7) Moderate successful rate (8-9) highly successful rate * Significant at level P<0.05

Table (6): Percent distribution of bleeding and local signs of stoma site infection among the studied groups.

Local signs	The studied patients (n=80)													
	Control group (n=40)						χ^2 P	Study group (n=40)						χ^2 P
	Immediate after insertion		Post a week		Post two weeks			Immediate after insertion		Post a week		Post two weeks		
	N	%	N	%	N	%		N	%	N	%	N	%	
Bleeding beside tracheal cannula														
	1	2.5	3	7.5	3	7.5	0.499	3	7.5	1	2.5	0	0.0	0.110
Local signs of stoma site infection														
Fever	3	7.5	13	32.5	10	25.0	**0.001***	2	5.0	1	2.5	0	0.0	0.191
Swelling	3	7.5	19	47.5	19	47.5	**0.000***	2	5.0	4	10.0	2	5.0	0.602
Redness around the stoma	8	20.0	19	47.5	19	47.5	**0.011***	3	7.5	3	7.5	2	5.0	0.869
Bad oder	0	0.0	0	0.0	6	15.0	**0.001***	0	0.0	0	0.0	1	2.5	0.331
Presence of an ulcer around the stoma	0	0.0	0	0.0	3	7.5	**0.034***	0	0.0	0	0.0	0	0.0	-

Table (7): Relation between mode of mechanical ventilator of the studied groups and their early successful decannulation score

Mode of mechanical ventilator	The studied patients (n=80) Early successful decannulation score Mean ± SD					
	Control group (n=40)			Study group (n=40)		
	Immediate after insertion	Post a week	Post two weeks	Immediate after insertion	Post a week	Post two weeks
- VC (SIMV)	3.29±1.384	3.26±1.289	3.04±1.261	3.00±1.414	**5.57±1.134**	5.40±1.850
- PC (SIMV)	**3.67±0.778**	3.50±1.049	4.00±0.00	**3.00±1.414**	4.70±1.829	6.50±0.707
- CPAP /PSV	-	**3.86±1.215**	3.21±1.672	-	4.52±1.473	-
- Weaned	-	-	**6.00±0.00**	-	-	**6.63±1.302**
F , P	0.793 , 0.379	**3.887 , 0.029***	1.626 , 0.200	0.00 , 1.00	1.286 , 0.288	1.795 , 0.180

* Significant at level P<0.05

Table (8): Correlation between early successful decannulation score of the studied groups and their physiological parameters

Physiological parameters	The studied patients (n=80) Early successful decannulation score											
	Control group (n=40)						Study group (n=40)					
	Immediate after insertion		Post a week		Post two weeks		Immediate after insertion		Post a week		Post two weeks	
	r	P	r	P	r	P	r	P	r	P	r	P
1. Heart rate (b/m)	**0.346**	**0.029***	0.239	0.138	0.255	0.112	0.306	0.055	**0.375**	**0.017***	0.281	0.079
2. Respiratory rate (c/m)	0.072	0.660	0.122	0.454	0.103	0.527	-0.110	0.498	**-0.336**	**0.034***	-0.257	0.109
3. Mean arterial blood pressure (mm hg)	**0.418**	**0.007****	**0.355**	**0.025***	0.289	0.071	0.284	0.075	**0.363**	**0.021***	**0.321**	**0.044***
4. Temperature (^{0}c)	0.035	0.832	-0.036	0.825	0.083	0.611	-0.056	0.732	0.089	0.586	0.018	0.910
5. Oxygen saturation (SpO_2) %	**0.626**	**0.000****	**0.413**	**0.008****	**0.606**	**0.000****	**0.527**	**0.000****	**0.431**	**0.005****	0.288	0.072
6. Tracheostomy cuff pressure	-0.093	0.569	0.045	0.781	**-0.410**	**0.009****	0.280	0.081	0.152	0.348	0.019	0.906

r: Pearson'correlation coefficient * Significant at level P<0.05

Discussion:

Safe practices in tracheostomy care increase patients' comfort, decrease the incidence of laryngeal injury, reduce the need for sedation, facilitate weaning from the mechanical ventilator, shorten the length of stay, and decrease the mortality rate.

Part I: Clinical data of studied patients of both groups. The findings

of the study showed that nearly half of both groups were diagnosed with traumatic brain injury. This is because the percentage of men is greater than women in this study, this may be attributed to the fact that severe injuries**.** This finding matched with **(Papaioannou et al.,2024)** who reported that more than half of the total patient number suffered from central nervous system causes, and more than half of them were subjected to tracheostomy.

Part II: Assessment of ventilator mode and parameters of both studied groups. Concerning the mode of the mechanical ventilator, the findings of this result highlighted that the majority of the control and study group were on VC (SIMV) mode immediately after tube insertion.

In addition; a considerable percentage of the study group were weaned post two weeks after tube insertion. This can be justified by after intubation, patients often require immediate respiratory support to ensure adequate oxygenation and ventilation. Volume Control (VC) in Synchronized Intermittent Mandatory Ventilation (SIMV) mode is commonly used to provide consistent tidal volumes and help stabilize respiratory parameters. As a result, SIMV is utilized to facilitate a gradual transition from controlled ventilation to spontaneous breathing.

This finding is along the same line with **Ismail, El-Soussi, Othman, & Hassan, (2022),** who found that most of the studied patients were on SIMV mode.

Part III: Assessment of patient's level of consciousness, physiological parameters, and tracheostomy cuff pressure. In the current study, a statistically significant difference was observed between the control and study groups throughout the study period concerning the Glasgow Coma Scale, this can be justified by near half of both groups were suffering from severe illness as; traumatic brain injury. In harmony with these findings **Alhashemi et al., (2022)** who found that there was a highly statistically significant difference between two groups in relation to Glascow coma scale.

For physiological parameters, this study reveals that there was a statistically significant difference between the control and study groups concerning respiratory rate, mean arterial blood pressure, and oxygen saturation (spo2). This may be related to the support of mechanical ventilator to respiratory function. This finding is in agreement with **Taha, Nashaat, & Mohamed, (2024)** who was noted that there was a significant difference between the intervention

and control groups regarding physiological parameters, including respiratory rate, SpO2, and mean arterial pressure. **On observation of tracheostomy cuff pressure,** there was a highly significant difference between the two groups post-a week and two weeks after tube insertion. This may be associated with the adjustment of tracheostomy cuff pressure using a manometer by the researchers in the study group. While, the nurses in the control group used incorrect volumes. This finding is congruent with **(Dokoohaki, Ebrahimzadeh, & Sharifi, 2024)** who illustrated that there was a highly statistically significant difference between both control and case groups regarding tracheostomy cuff pressure.

Part IV: Effect of tracheostomy care guidelines on early successful decannulation and adverse events.

The current results indicated a highly statistically significant difference only within the study group throughout the study, as well as a highly statistically significant difference between the control and study groups one week and two weeks after tube insertion regarding successful decannulation. Therefore, it is possible to predict early successful decannulation early in the clinical course, while the likelihood of tracheostomy decannulation significantly decreases as the number of comorbidities increases.

The current findings are consistent with **Mannini et al., (2021)** who showed that decannulation probability was successfully predicted with a notable improvement in the estimated weaning time.

Concerning adverse events, the present study found that there was no statistically significant difference among the control or study group throughout the study about bleeding. This can be justified by tracheostomy procedures are safe and have low complication rates. These results are similar to **Alsunaid, Holden, Kohli, Diaz, & O'Meara, (2021)** who revealed that a small amount of bleeding may occur following the initial procedure and after changing the tracheostomy tube; however, this bleeding is typically minimal, self-limiting, and can be managed with topical agents.

Regarding local signs of infection, the current study highlighted that there was a statistically significant increase about local signs of infection including fever, swelling, redness around the stoma, bad odor and presence of ulcer around the stoma in control group post a week and two weeks after insertion. These results were matched with **Ye et al., (2020)** who showed that the rate of pulmonary infection for the routine care group increased more than the comprehensive nursing care group.

Part V: Correlation and relations, tracheostomy cuff pressure, adverse events and early successful decannulation of both studied groups.

Regarding the relation between the mode of the mechanical ventilator of the studied groups and their early successful decannulation score throughout periods of implementation. It was noted that the

higher mean scores for early successful decannulation at two weeks after tube insertion were for patients weaned from mechanical ventilation. Additionally, there was a statistically significant relation between the CPAP/PSV mode and early successful decannulation a week post-insertion. as patients on CPAP/PSV more independent and take spontaneous breathing with only pressure support from mechanical ventilator.

Similarly, Ghiani et al. (2022) reported that using non-invasive ventilation as a weaning strategy led to successful decannulation in 43% of long-term ventilator-dependent patients who had previously experienced weaning failure.**Concerning the correlation between the early successful decannulation score of the studied groups and their mechanical ventilator parameters.** This study demonstrates a statistically significant negative correlation between early successful decannulation and mechanical ventilator parameters fraction of inspired oxygen, respiratory rate, tidal volume, peak inspiratory pressure, pressure limit, and positive end-expiratory. justified by improving ventilator parameters, the patient has adequate lung function and is less dependent on mechanical ventilator. This finding is in agreement with **(Tornari et al., 2021)** who found that a higher FiO2 during tracheostomy, along with increased pressure and peak flow, correlates with a longer delay in decannulation for patients with COVID-19.

Conclusions:

The present study revealed that implementing tracheostomy care guidelines markedly improves clinical outcomes by enhancing physiological stability, increasing decannulation success, and reducing adverse events.

Recommendations:

1. Monitoring of tracheostomy cuff pressure should be integrated into routine care for critically ill patients to improve patient's clinical outcomes and prevent adverse events.
2. Ongoing training program for critical care nurses about tracheostomy care guidelines for updating their knowledge and practice in the ICU.

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