# Effect of Post Tracheostomy Tube Care Bundle on Critically Ill Patient's Outcomes

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## *Abstract*

***Background:*** *Tracheostomy administration and implantation are becoming more common in intensive care units. Because of this, it's essential that nurses have the information and training required to provide tracheostomy patients with safe and effective care. It's critical to increase nurses' knowledge of potential challenges tracheostomy patients might have and to give nurses guidance on how to best care for and help these patients. It outlines the kind of care that should be provided to tracheostomy patients who are critically ill, including endotracheal suctioning and humidification techniques.* ***Objective:*** *to determine the outcomes of implementing post tracheostomy tube care bundle in critically ill patients* ***Setting:*** *This study was carried out in the General ICUs namely, Casualty unit (unit I), General ICU (unit II, III) at the Alexandria Main University Hospital, Egypt.* ***Subjects:*** *A convenience sample of 70 newly admitted adult patients will be included in this study. patients who had stoma site infection were excluded from the study. The sample was equally assigned into two equal groups: group I, the control group (35 patients) and group II, the intervention group (35 patients)* ***Tool:*** *Two tools were used. Tool one: "Critically ill patients assessment sheet". Tool two: "patient's outcomes assessment sheet".* ***Results:*** *There was a statistically significant difference was observed between the intervention and control groups regarding physiological parameters as (respiratory rate, $Spo_2$ ,$Sao_2$ , mean arterial pressure ,temperature and heart rate),signs of respiratory tract infection ,signs of respiratory distress and need for suctioning* ***Conclusion:*** *Implementation of tracheostomy tube care bundle interventions significantly decreased development of respiratory tract infection, signs of respiratory distress and maintained physiological parameters of critically ill patients within the normal ranges.* ***Recommendations:*** *Critical care nurses should assess for signs of respiratory distress and respiratory tract infection.*

**Keywords:** Tracheostomy tube care bundles, patient outcome, critically ill patients

## Introduction

A blocked airway causes a diminished or nonexistent gas exchange in and out of the alveoli, which is known as an airway obstruction. Any point may be blocked, and it may be physical (such as a tumor) or functional (such as having less muscle tone). After a thorough assessment and provision of an alternative route for oxygenation and ventilation, or restoration of the patency of the already-existing natural airway, can an effective treatment for airway obstruction be implemented. In order to reduce the morbidity and mortality associated with critical illness, airway blockage is one of the most difficult issues facing medical professionals in the intensive care unit (Cabrini et al., 2019; Hosokawa et al., 2015).

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) (2014) found that a tracheostomy was present

in 24% of patients who experienced difficulties while being treated in a critical care unit. Tracheostomy tube care should be carried out to keep it in working order and prevent complications. There are three different categories of tracheostomy tube complications: immediate, delayed, and late. Immediate side effects include bleeding, essential displacement, pneumothorax, tube blockage, surgical emphysema, and upper airway loss. Delayed side effects, which appear 7 days after insertion, include tube blockage, either a partial or total displacement, respiratory tract infection, infection at the stoma's location, tracheal ulcers, trachea-esophageal fistula, bleeding, and tube occlusion (Avilés-Jurado et al., 2021).

The tracheostomy care bundle is a multidisciplinary approach that includes a series of procedures to preserve the patient's airway's acceptable patency, increase decannulation rates, and enhance swallowing ability. The bundle consists of a plan for locating and monitoring every patient right after tracheostomy, creating a standardized method for postoperative care, and coordinating all important providers to help every patient reach their maximum clinical potential. It improves patient safety, shortened decannulation time, lower mortality, shorter lengths of stay, focus on knowledge and skills and improve quality of care as maintained physiological parameters of patients, decreased signs of respiratory tract infections, signs of respiratory distress and need for suctioning) (Dawson, 2014; Theses & Rothhaar, 2021).

### *Aims of the Study*

This study aims to determine the effect of implementing tracheostomy tube care bundle on outcomes of critically ill patients.

***Operational definitions in this study include outcomes of critically ill patients such as:***

***Patient related outcomes:*** this includes physiological parameters such as respiratory rate, oxygen saturation (Spo2, Sao2), heart rate, temperature, mean arterial pressure, signs of respiratory tract infections and need for suctioning.

### Research hypotheses

1-Critically ill patients who are subjected to tracheostomy tube care bundle interventions exhibit normal physiological parameters as; respiratory rate, temperature, oxygen saturation ($Sao_2$), heart rate, mean arterial pressure than those who are not.

2-Critically ill patients who are subjected to tracheostomy tube care bundle interventions exhibit less signs of respiratory tract infections.

## Materials and Method

### *Materials*

***Design:*** A quasi experimental research design was used to conduct this study.

***Setting:*** This study was carried out in the General ICUs at Alexandria Main University Hospital Namely, Casualty unit (unit I), General ICU (unit II, III). The general ICUs: unit I, unit II and unit III, IV, V beds capacity is 12, 9,16,8, and 12 beds respectively. General ICU at Smouha university hospital, the bed capacity is 9 beds. Elmouasat General ICU hospital, the bed capacity is 9 beds. general ICUs

***Subjects:*** A convenience sample of 70 critically ill adult patients with tracheostomy tube were included in this study (35 for each group), patients with signs of stoma site infection and hemodynamically unstable were excluded from this study. The study sample size was calculated by power analysis using (Epi-Info 7 program), population size=75 for 3 months, confidence level=95%, margin of error=5%, prevalence of the problem=50%, minimum sample size =65, and final sample size=70.

**Tools:** Two tools were utilized for data collection in this study.

**Tool one: Critically ill patients assessment**
This tool is developed by the researcher

after reviewing the related literature (Morris et al., 2017; Trouillet et al., 2018) to assess critically ill patients with tracheostomy tubes. This tool was consisted of two parts:

**Part I: demographic and clinical data**

It is including demographic data such as patient's age, sex, and clinical data such as admission diagnosis, APACHE II score, length of ICU stay, and comorbidities

**Part II: tracheostomy tube related data**

It is used to assess tracheostomy tube-related data as risk of tube dislodgment including loose ties, patient agitation, ventilator alarms, passage of suction catheter.

**Tool two: patient's outcomes assessment**

It was developed by the researcher after reviewing the related literature (Rubin et al., 2020; Morris et al., 2013; NHS Trust Tracheostomy Guidelines, 2017) to assess the outcomes of critically ill patients with a tracheostomy tube.

Patients related outcomes: it include physiological parameters such as respiratory rate, oxygen saturation (Spo2, Sao2), heart rate, temperature, mean arterial pressure, signs of respiratory distress and signs of respiratory tract infections.

## Method

Approval from the Research Ethics Committee, Faculty of Nursing, Alexandria University was obtained. Permission to conduct the study was obtained from the administrative authorities of the previously mentioned settings after an explanation of the aim of the study. Informed written consent was obtained from patients or relatives in case of unconscious patients, including the aim of the study, potential benefits, risks, discomforts from participation, and the right to refuse to participate in the study. Patients' privacy, anonymity, and confidentiality of the collected data was maintained during the implementation of the study The study tools were developed by the researcher after reviewing the related literature (Avilés-Jurado et al., 2021; Herritt et al., 2018; Swain et al., 2020) The study tools were tested for content validity by five experts in the field of the study. Reliability of the tools one and two were done using chronbach alpha test, its result was 0.8 which is acceptable. A pilot study was carried out on 10% (8 patients) with tracheostomy to assess the clarity and applicability of the tool.

Data were collected by the researcher over a period of seven consecutive months (from January to July 2022)

Critically ill adult patients attached to tracheostomy tube were assigned into two equal groups: the intervention, and control group (35 patients in each) according to the absence of the previously mentioned exclusion criteria.)

Data were collected as follows:

**Phase I: Assessment phase**

**For both groups:**

-The demographic data such as patient's age and sex were obtained and recorded using part I of tool I.

- The clinical data such as admission diagnosis, APACHE II score and comorbidities were assessed and documented using part I of tool I.

-The length of ICU stay was calculated during the study time.

- The tube-related data including sizes and types of tracheostomy tube were assessed and documented using part I of tool I.

-The tracheostomy tube was assessed for the risk of dislodgment and recorded using part II of tool I.

- Patients were assessed for signs of tube dislodgment were also assessed at the baseline and daily for 7 consecutive days using part II of tool I.

**Implementation phase**

TRACHECOMS care bundle was implemented daily by the researcher for 7 consecutive days as follows:

-**Tube care** was performed as follows: Tube tie was inspected every 8 hours and changed using gauze ties as per hospital policy.

-Cuff pressure was measured by the researcher every 8 hours (per shift) using cuff pressure manometer and recorded using part II of tool II.

-**Resuscitation** measures were implemented through placing bedhead signs by the researcher in patient's chart to guide the unit staff.

-**Airway patency** was maintained through tracheal suctioning which was performed according to patient's needs following aseptic technique.

-**Care of stoma** was performed through inspecting the stoma site daily for signs of infection. The stoma site was disinfected daily using distilled (sterile) water in circular motion.

-**Humidification** of the airway was maintained through ensuring that the patient was receiving humidified oxygen either through the wall oxygen or ventilator humidifier.

-**Emergency equipment** was placed at patients' bedside to use it in emergency situations and ensured their presence every shift by the researcher.

-**Communication** with conscious patients was maintained daily using communication board.

-**Mouth care** was performed by the researcher every shift including suctioning oral secretion. Brushing teeth with chlorhexidine was performed twice /day and oral gel.

-**Swallowing** ability of conscious patients attached to tracheostomy tube was assessed daily using small amount of water to drink to check if patient able to swallow or cough due to impaired swallowing. Patients were assessed to ensure that they received the prescribed nutrition.

-For the control group: patients were subjected to the routine care provided by the staff member of the unit such as tube care, suctioning, care of stoma and humidification

**Outcome assessment**

**For both groups:**

**patient's related outcomes were assessed as follows:**

- Physiological parameters such as respiratory rate, oxygen saturation ($Spo_2$, $Sao_2$), heart rate, temperature, mean arterial pressure were assessed and recorded using part III of tool II
- Signs of respiratory distress including intercostal retractions, use of accessory muscles
-Signs of respiratory tract infections (fever, increase in wbc count, positive sputum culture for microorganism, increase need for suctioning-ray changes were assessed every shift and recorded at the baseline and daily for 7 consecutive days using part II of tool III.

**Statistical Analysis**

Data were fed to the computer and analyzed using IBM SPSS software package version 25.0. (Armonk, NY: IBM Corp) Qualitative data were described using the number and percent. Quantitative data were described using mean and standard deviation. The significance of the obtained results was judged at the 5% level.

**Ethical Considerations:**

-Written informed consent was obtained from patients after explaining the aim of the study, the right to refuse to participate in the study was emphasized to subjects, Patients' privacy was maintained during the implementation of the study. Confidentiality of the collected data was maintained during the implementation of the study. The patient has the right to withdraw from the study at any time.

**Results**

**Part I: Patients' demographic and clinical data**

Table I represents the distribution of the studied groups according to demographic and clinical data It was noted from this table that the mean age was 61.80 ± 10.88 for the intervention group compared to 63.97 ± 11.57 for the control group. In relation to **sex**, this table shows that 37.1% of patients in the intervention group were males compared to 34.3% of patients in the control group. There was no statistical significance difference between the two groups regarding age and sex where p=0.421 and p=0.803. **Regarding admission diagnosis,** it was noted that 28.6% of patients in the intervention group diagnosed with respiratory disorder compared to 22.9 % of patients in the control group, 25.7% of patients in the intervention group diagnosed with cardiovascular disorder compared to 51.4% of patients in the control groups. As regard **APACHE II score**, this table shows that the mean APACHE II score was 20.34 ± 3.65 for the intervention group compared to 21.03 ± 3.49 for the control group. In relation to **comorbidities**, this table shows that 40% of patients in the study group had cardiovascular disorders compared to 31.4% for the control group. In relation to **length of ICU stay**, this table shows that the mean length of ICU stay was 20.60 ± 10.65 days for the study group compared to 20.23 ± 6.94 for the control group with no statistical difference between the two groups (p=0.863).

**Table II represents the comparison between the studied groups according to patients related outcomes over seven consecutive days.**

Regarding physiological parameters, it was noted that the mean respiratory rate: in the 1st day (baseline) was 18.69 ± 3.42 for the study group compared to 18.96 ± 1.77 in the control group with no statistical significance differences between the two groups p=0.678 there was statistical significance differences between two groups from 4th day to 7th day p=0.002, p=0.041, p=0.005, p=0.008.

As regard $SPO_2$, it was noted that the mean $SPO_2$ in the 1st day (baseline) was 97.99 ± 0.74 for the study group compared to 94.90 ± 13.51 in the control group with no statistical significance differences between the two groups p=0.185. there was statistical significance differences between two groups from 4th day to 7th day (p=0.044, p=0.024, p=0.020, p=0.012), (p=0.037, p=0.025, p=0.016, p=0.010).

Regarding heart rate, it was noted that the mean heart rate, mean arterial pressure **(**MAP) there was statistically differences between two groups from 4th day to 7th day p=0.027, p=0.005, p=0.012, p=0.001. p=0.015, p=0.004, p=0.001, p<0.001.

Regarding temperature, it was noted that the mean temperature, on the 1st day (baseline) was 36.97 ± 0.24 for the study group compared to 38.67 ± 10.41 in the control group with no statistical significance differences between the two groups p=0.338. There were not statistically differences between two groups from 1st day to 7th day p=0.958, p=0.330, p=1.000, p=0.225.

**Table III indicates comparison between the two studied groups according to patients related outcomes.**

As regard the increase in WBCs count, increase in need for suctioning, it was noted that there was statistically significance differences between the two groups from 3rd day to 7th day( p=0.008, p=0.004, p=0.004, p=0.004, p=0.004. p=0.007, p=0.001, p=0.001, p=0.001, p=0.001.)

As regard positive sputum culture for microorganism, it was noted that there was statistically significant differences between the two groups from 4th day to 7th day p=0.029, p=0.012, p=0.012, p=0.012.

As regard x-ray changes, it was noted that, there was statistically significance differences in 6th day and 7th day p=0.039, p=0.039.

**Discussion**

The TRACHECOMS "care bundle" was developed with the goal of creating a clear, easy tool that could be used to enhance patient safety and quality of care, reduce time to decannulation, and lower mortality. High-quality, secure tracheostomy tube care is provided by TRACHECOMS, and this care encompasses resuscitation, airway, stoma, humidification, environment, communication, mouth care, swallowing, and nutrition (Dawson, 2014; Theses & Rothhaar, 2021)

In relation to physiological parameters, the result of this study showed that there was a significant difference from 4th day between the study and control groups regarding heart rate, respiratory rate, $Spo_2$, $Sao_2$ and mean arterial pressure. This may be explained by implementation of tracheostomy tube care bundle by the researcher which maintained the patient's airway patency, therefore. Vital parameters were within normal.

These results are congruent with the Divo (2017) who conducted tracheostomy care bundle and found that the vital parameters were within normal as implementation of intervention tracheostomy tube care bundle.

In relation to signs of respiratory tract infection, the result of this study showed that there was significant difference between intervention and control groups regarding increase in WBC count (white blood cells), positive sputum culture for microorganism, increase need for suctioning and x-ray changes .This may be explained by using aseptic technique during suctioning by using sterile gloves, suctioning as needed, assessment of secretions related to its color, amount , consistency and implementation of hydration through using humidifier .

These results are in congruent with the results of freeman (2021) who conducted study about tracheostomized patients have lower rates of tube colonization and found that implementation of tracheostomy tube care bundle decrease rate of tube colonization for the intervention group.

Tracheostomy tube care bundle showed effective role for critically ill patients which include tube care, resuscitation, airway, care of the stoma, humidification, environment, communication, mouth care, swallowing and nutrition. TRACHECOMS bundle is an illustration of a bundle used to care for a tracheostomy tube, with each part intended to maintain the tube's functionality and avoid related issues. The purpose of this "care bundle" was to develop a straightforward, easy to use tool that could be used by all hospital departments to improve patient safety, quality of care, maintain stable physiological parameters, decrease complications as stoma site infection and bleeding, decrease complications related to tracheostomy tube, decrease need for suctioning.

## *Conclusion*

Based on the results of this study, it can be concluded that the Implementation of tracheostomy tube care bundle interventions significantly maintained stable physiological parameters as respiratory rate, oxygen saturation and heart rate.

## *Recommendations*

Based on the findings of the current study, it can be recommended that:

- Critical care nurses should implement care to patients attached to tracheostomy tube following bundled approach.
- Undergraduate critical care nursing courses should handle the concept of tracheostomy tube care bundle focusing on its positive outcomes.
- Nurse-led tracheostomy tube care protocols should be developed to detect tracheostomy tube and manage critically ill patients in ICUs

**Table (I): Distribution of the studied groups according to demographic and clinical data**

| Demographic and clinical data | Study (n = 35) | | Control (n = 35) | | Test of Sig. | p value |
|---|---|---|---|---|---|---|
| | No. | % | No. | % | | |
| **Sex** | | | | | | |
| Male | 13 | 37.1 | 12 | 34.3 | $\chi^2$= 0.062 | 0.803 |
| Female | 22 | 62.9 | 23 | 65.7 | | |
| **Age** | | | | | | |
| Min. – Max. | 22.0 – 81.0 | | 27.0 – 82.0 | | t= 0.809 | 0.421 |
| Mean ± SD. | 61.80 ± 10.88 | | 63.97 ± 11.57 | | | |
| **Admission diagnosis** | | | | | | |
| Cardiovascular disorder | 9 | 25.7 | 18 | 51.4 | $\chi^2$= 8.434* | $^{MC}$p= 0.037* |
| Respiratory disorder | 10 | 28.6 | 8 | 22.9 | | |
| Renal disorder | 3 | 8.6 | 5 | 14.3 | | |
| Integumentary disorder | 0 | 0.0 | 0 | 0.0 | | |
| Nervous system disorder | 0 | 0.0 | 0 | 0.0 | | |
| Others | 13 | 37.1 | 4 | 11.4 | | |
| **APACHE II score** | | | | | | |
| Min. – Max. | 13.0 – 28.0 | | 15.0 – 32.0 | | t= 0.804 | 0.424 |
| Mean ± SD. | 20.34 ± 3.65 | | 21.03 ± 3.49 | | | |
| **Comorbidities** | | | | | | |
| None | 8 | 22.9 | 6 | 17.1 | $\chi^2$= 5.770 | $^{MC}$p= 0.600 |
| Cardiovascular disorder | 14 | 40.0 | 11 | 31.4 | | |
| Respiratory disorder | 1 | 2.9 | 5 | 14.3 | | |
| Renal disorder | 3 | 8.6 | 5 | 14.3 | | |
| Integumentary disorder | 1 | 2.9 | 0 | 0.0 | | |
| Nervous system disorder | 1 | 2.9 | 0 | 0.0 | | |
| Others | 3 | 8.6 | 3 | 8.6 | | |
| Cardio+renal+respiratory | 4 | 11.4 | 5 | 14.3 | | |
| **Length of ICU stay** | | | | | | |
| Min.-Max. | 10.0- 60.0 | | 5.0-33.0 | | t=0.173 | 0.863 |
| Mean ±SD | 20.60±10.65 | | 20.23±6.94 | | | |

SD**: Standard deviation** $x^2$**: Chi square test** t**: Student t-test**

**p: p value for comparing between the studied groups**

***: Statistically significant at p ≤ 0.05** MC**:MonteCarloCorrelation**

**Table (II): Distribution of the studied groups according to tracheostomy tube related data over seven consecutive days**

| | Tracheostomy tube related data | | 1st day | | 2nd day | | 3rd day | | 4th day | | 5th day | | 6th day | | 7th day | | Q | p0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | | |
| Risk of tube dislodgement | Loose ties | **Study (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 19 | 54.3 | 19 | 54.3 | 25 | 71.4 | 31 | 88.6 | 31 | 88.6 | 31 | 88.6 | 31 | 88.6 | 78.638* | <0.001* |
| | | Yes | 16 | 45.7 | 16 | 45.7 | 10 | 28.6 | 4 | 11.4 | 4 | 11.4 | 4 | 11.4 | 4 | 11.4 | | |
| | | **Control (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 18 | 51.4 | 20 | 57.1 | 20 | 57.1 | 25 | 71.4 | 25 | 71.4 | 26 | 74.3 | 26 | 74.3 | 66.468* | <0.001* |
| | | Yes | 17 | 48.6 | 15 | 42.9 | 15 | 42.9 | 10 | 28.6 | 10 | 28.6 | 9 | 25.7 | 9 | 25.7 | | |
| | | **$\chi^2$(p)** | **0.057 (0.811)** | | **0.058 (0.810)** | | **1.556 (0.212)** | | **3.214 (0.073)** | | **3.214 (0.073)** | | **2.362 (0.124)** | | **2.362 (0.124)** | | | |
| | Excessive patient s movement | **Study (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 20 | 57.1 | 20 | 57.1 | 26 | 74.3 | 32 | 91.4 | 33 | 94.3 | 34 | 97.1 | 34 | 97.1 | 66.468* | <0.001* |
| | | Yes | 15 | 42.9 | 15 | 42.9 | 9 | 25.7 | 3 | 8.6 | 2 | 5.7 | 1 | 2.9 | 1 | 2.9 | | |
| | | **Control (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 18 | 51.4 | 18 | 51.4 | 25 | 71.4 | 31 | 88.6 | 34 | 97.1 | 35 | 100.0 | 35 | 100.0 | 78.638* | <0.001* |
| | | Yes | 17 | 48.6 | 17 | 48.6 | 10 | 28.6 | 4 | 11.4 | 1 | 2.9 | 0 | 0.0 | 0 | 0.0 | | |
| | | **$\chi^2$(p)** | **0.230 (0.631)** | | **0.230 (0.631)** | | **0.072 (0.788)** | | **0.159 ($^{FE}$p=1.000)** | | **0.348 ($^{FE}$p=1.000)** | | **1.014 ($^{FE}$p=1.000)** | | **1.014 ($^{FE}$p=1.000)** | | | |
| Indicators of tube dislodgment | Ventilator alarms | **Study (n = 35)** | **(n = 32)** | | **(n = 32)** | | **(n = 32)** | | **(n = 32)** | | **(n = 31)** | | **(n = 31)** | | **(n = 31)** | | | |
| | | No | 17 | 53.1 | 17 | 53.1 | 19 | 59.4 | 23 | 71.9 | 27 | 84.4 | 31 | 88.6 | 31 | 88.6 | 66.0* | <0.001* |
| | | Yes | 15 | 46.9 | 15 | 46.9 | 13 | 40.6 | 9 | 28.1 | 5 | 15.6 | 1 | 0.0 | 1 | 0.0 | | |
| | | **Control** | **(n = 35)** | | **(n = 35)** | | **(n = 35)** | | **(n = 35)** | | **(n = 35)** | | **(n = 35)** | | **(n = 35)** | | | |
| | | No | 16 | 45.7 | 16 | 45.7 | 20 | 57.1 | 31 | 88.6 | 34 | 97.1 | 35 | 100.0 | 35 | 100.0 | 93.138* | <0.001* |
| | | Yes | 19 | 54.3 | 19 | 54.3 | 15 | 42.9 | 4 | 11.4 | 1 | 2.9 | 0 | 0.0 | 0 | 0.0 | | |
| | | **$\chi^2$(p)** | **0.367 (0.544)** | | **0.367 (0.544)** | | **0.034 (0.853)** | | **2.980 (0.084)** | | **3.342 ($^{FE}$p=0.096)** | | – | | – | | | |
| | Resistance with passage of suction catheter | **Study (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 27 | 77.1 | 27 | 77.1 | 30 | 85.7 | 33 | 94.3 | 33 | 94.3 | 35 | 100.0 | 35 | 100.0 | 35.023* | <0.001* |
| | | Yes | 8 | 22.9 | 8 | 22.9 | 5 | 14.3 | 2 | 5.7 | 2 | 5.7 | 0 | 0.0 | 0 | 0.0 | | |
| | | **Control (n = 35)** | | | | | | | | | | | | | | | | |
| | | No | 21 | 60.0 | 22 | 62.9 | 26 | 74.3 | 31 | 88.6 | 34 | 97.1 | 35 | 100.0 | 35 | 100.0 | 61.579* | <0.001* |
| | | Yes | 14 | 40.0 | 13 | 37.1 | 9 | 25.7 | 4 | 11.4 | 1 | 2.9 | 0 | 0.0 | 0 | 0.0 | | |
| | | **$\chi^2$(p)** | **2.386 (0.122)** | | **1.701 (0.192)** | | **1.429 (0.232)** | | **0.729 ($^{FE}$p= 0.673)** | | **0.348 ($^{FE}$p= 1.000)** | | – | | – | | | |

$\chi^2$: **Chi square test** MC: **Monte Carlo** FE: **Fisher Exact** **Fr**: **Friedman test** **Q**: **Cochran's test**

$p_0$: p value for comparing between the studied periods in each group p: p value for comparing between the studied groups*: Statistically significant at $p \leq 0.05$.

**Table (III): Comparison between the two studied groups according to physiological parameters over seven consecutive days**

| Physiological parameters | | | 1st day | 2nd day | 3rd day | 4th day | 5th day | 6th day | 7th day | F | p0 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Physiological parameters | Respiratory rate | Study (n = 35) Mean ± SD. | 18.69 ± 3.42 | 18.54 ± 2.86 | 18.45 ± 1.64 | 18.04 ± 0.91 | 17.86 ± 2.58 | 17.85 ± 1.17 | 18.09 ± 0.77 | 1.044 | 0.359 |
| | | Control (n = 35) Mean ± SD. | 18.96 ± 1.77 | 19.15 ± 1.36 | 18.85 ± 1.74 | 18.86 ± 1.20 | 18.84 ± 1.07 | 18.64 ± 1.12 | 18.69 ± 1.05 | 1.115 | 0.343 |
| | | t(p) | **0.417 (0.678)** | **1.141 (0.258)** | **0.982 (0.330)** | **3.210* (0.002*)** | **2.080* (0.041*)** | **2.873* (0.005*)** | **2.723* (0.008*)** | | |
| | $SpO_2$ | Study (n = 35) Mean ± SD. | 97.99 ± 0.74 | 97.94 ± 0.86 | 97.81 ± 0.90 | 97.95 ± 0.84 | 98.12 ± 0.75 | 97.92 ± 0.82 | 98.05 ± 0.87 | 0.896 | 0.476 |
| | | Control (n = 35) Mean ± SD. | 94.90 ± 13.51 | 97.38 ± 2.03 | 97.47 ± 2.11 | 97.49 ± 1.01 | 97.71 ± 0.72 | 97.53 ± 0.53 | 97.20 ± 1.72 | 1.251 | 0.276 |
| | | t(p) | **1.354 (0.185)** | **1.502 (0.140)** | **0.860 (0.394)** | **2.057* (0.044*)** | **2.309* (0.024*)** | **2.384* (0.020*)** | **2.607* (0.012*)** | | |
| | $SaO_2$ | Study (n = 35) Mean ± SD. | 98.27 ± 0.93 | 98.32 ± 0.73 | 97.89 ± 1.54 | 98.09 ± 2.41 | 98.21 ± 2.71 | 98.34 ± 0.90 | 98.52 ± 0.95 | 0.799 | 0.429 |
| | | Control (n = 35) Mean ± SD. | 97.76 ± 2.28 | 97.71 ± 2.38 | 97.88 ± 2.34 | 96.74 ± 2.88 | 97.14 ± 0.59 | 97.85 ± 0.78 | 97.99 ± 0.70 | 2.514 | 0.088 |
| | | t(p) | **1.225 (0.227)** | **1.435 (0.159)** | **0.012 (0.990)** | **2.134* (0.037*)** | **2.287* (0.025*)** | **2.470* (0.016*)** | **2.650* (0.010*)** | | |
| | Heart rate | Study (n = 35) Mean ± SD. | 89.36 ± 5.46 | 90.0 ± 6.64 | 89.93 ± 5.78 | 88.03 ± 6.03 | 87.55 ± 5.23 | 87.43 ± 7.06 | 88.30 ± 4.10 | 1.405 | 0.245 |
| | | Control (n = 35) Mean ± SD. | 89.69 ± 10.72 | 89.38 ± 10.32 | 89.66 ± 8.72 | 91.96 ± 8.33 | 91.53 ± 6.30 | 91.51 ± 6.08 | 92.33 ± 5.75 | 1.614 | 0.186 |
| | | t(p) | **0.164 (0.870)** | **0.299 (0.766)** | **0.157 (0.876)** | **2.260* (0.027*)** | **2.880* (0.005*)** | **2.592* (0.012*)** | **3.370* (0.001*)** | | |
| | Temperature | Study (n = 35) Mean ± SD. | 36.97 ± 0.24 | 37.10 ± 0.26 | 37.06 ± 0.22 | 37.10 ± 0.22 | 37.13 ± 0.19 | 37.08 ± 0.10 | 37.06 ± 0.10 | 2.983* | 0.025* |
| | | Control (n = 35) Mean ± SD. | 38.67 ± 10.41 | 36.99 ± 0.23 | 37.05 ± 0.21 | 37.10 ± 0.24 | 37.10 ± 0.07 | 37.08 ± 0.09 | 37.04 ± 0.07 | 0.856 | 0.362 |
| | | t(p) | **0.964 (0.338)** | **1.988 (0.051)** | **0.112 (0.911)** | **0.052 (0.958)** | **0.986 (0.330)** | **0.000 (1.000)** | **1.226 (0.225)** | | |
| | Mean arterial pressure | Study (n = 35) Mean ± SD. | 93.24 ± 5.14 | 91.05 ± 6.41 | 92.57 ± 5.84 | 92.48 ± 5.91 | 92.76 ± 6.08 | 93.62 ± 5.26 | 92.10 ± 6.27 | 0.733 | 0.624 |
| | | Control (n = 35) Mean ± SD. | 94.10 ± 4.65 | 91.05 ± 5.59 | 92.67 ± 6.04 | 96.38 ± 7.11 | 97.14 ± 6.37 | 98.38 ± 6.69 | 97.52 ± 5.38 | 7.975* | <0.001* |
| | | t(p) | **0.731 (0.467)** | **0.00 (1.000)** | **0.067(0.947)** | **2.499*(0.015*)** | **2.944*(0.004*)** | **3.311*(0.001*)** | **3.887*(<0.001*)** | | |

**SD: Standard deviation** **t: Student t-test**

**F: F test (ANOVA) with repeated measures** p: p value for comparing between the studied groups *: Statistically significant at $p \leq 0.05$ $p_0$: p value for comparing between the studied periods in **each gr**

**Table (IV): Comparison between the two studied groups according to signs of respiratory tract infections.**

| Patients related outcomes | | | 1st day | | 2nd day | | 3rd day | | 4th day | | 5th day | | 6th day | | 7th day | | Q | p0 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % | | |
| Signs of respiratory tract infections | Fever | Study (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 30 | 85.7 | 30 | 85.7 | 32 | 91.4 | 32 | 91.4 | 33 | 94.3 | 33 | 94.3 | 33 | 94.3 | 6.333 | 0.387 |
| | | Yes | 5 | 14.3 | 5 | 14.3 | 3 | 8.6 | 3 | 8.6 | 2 | 5.7 | 2 | 5.7 | 2 | 5.7 | | |
| | | Control (n =35) | | | | | | | | | | | | | | | | |
| | | No | 26 | 74.3 | 26 | 74.3 | 28 | 80.0 | 28 | 80.0 | 30 | 85.7 | 30 | 85.7 | 33 | 94.3 | 14.830* | 0.022* |
| | | Yes | 9 | 25.7 | 9 | 25.7 | 7 | 20.0 | 7 | 20.0 | 5 | 14.3 | 5 | 14.3 | 2 | 5.7 | | |
| | | $\chi^2$(p) | 1.429 (0.232) | | 1.429 (0.232) | | 1.867 (0.172) | | 1.867 (0.172) | | 1.429 ($^{FE}$p= 0.428) | | 1.429 ($^{FE}$p= 0.428) | | 0.000 ($^{FE}$p= 1.000) | | | |
| | Increase in WBC count | Study (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 21 | 60.0 | 21 | 60.0 | 24 | 68.6 | 24 | 68.6 | 25 | 71.4 | 25 | 71.4 | 25 | 71.4 | 19.714* | 0.003* |
| | | Yes | 14 | 40.0 | 14 | 40.0 | 11 | 31.4 | 11 | 31.4 | 10 | 28.6 | 10 | 28.6 | 10 | 28.6 | | |
| | | Control (n =35) | | | | | | | | | | | | | | | | |
| | | No | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 12 | 34.3 | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 0.305 | 0.999 |
| | | $\chi^2$(p) | 3.660 (0.056) | | 3.660 (0.056) | | 6.937* (0.008*) | | 8.235* (0.004*) | | 8.289* (0.004*) | | 8.289* (0.004*) | | 8.289* (0.004*) | | | |
| | Positive sputum culture for microorganism | Study (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 13 | 37.1 | 0.000 | 1.000 |
| | | Yes | 22 | 62.9 | 22 | 62.9 | 22 | 62.9 | 22 | 62.9 | 22 | 62.9 | 22 | 62.9 | 22 | 62.9 | | |
| | | Control (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 8 | 22.9 | 8 | 22.9 | 6 | 17.1 | 5 | 14.3 | 4 | 11.4 | 4 | 11.4 | 4 | 11.4 | 16.560* | 0.011* |
| | | Yes | 27 | 77.1 | 27 | 77.1 | 29 | 82.9 | 30 | 85.7 | 31 | 88.6 | 31 | 88.6 | 31 | 88.6 | | |
| | | $\chi^2$(p) | 1.701 (0.192) | | 1.701 (0.192) | | 3.540 (0.060) | | 4.786* (0.029*) | | 6.293* (0.012*) | | 6.293* (0.012*) | | 6.293* (0.012*) | | | |
| | Increase need for suctioning | Study (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 21 | 60.0 | 21 | 60.0 | 27 | 77.1 | 30 | 85.7 | 29 | 82.9 | 31 | 88.6 | 31 | 88.6 | 35.057* | <0.001* |
| | | Yes | 14 | 40.0 | 14 | 40.0 | 8 | 22.9 | 5 | 14.3 | 6 | 17.1 | 4 | 11.4 | 4 | 11.4 | | |
| | | Control (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 16 | 45.7 | 16 | 45.7 | 16 | 45.7 | 17 | 48.6 | 16 | 45.7 | 16 | 45.7 | 16 | 45.7 | 1.500 | 0.959 |
| | | Yes | 19 | 54.3 | 19 | 54.3 | 19 | 54.3 | 18 | 51.4 | 19 | 54.3 | 19 | 54.3 | 19 | 54.3 | | |
| | | $\chi^2$(p) | 1.433 (0.231) | | 1.433 (0.231) | | 7.295* (0.007*) | | 10.944* (0.001*) | | 10.516* (0.001*) | | 14.570* (0.001*) | | 14.570* (0.001*) | | | |
| | X-ray changes | Study (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 25 | 71.4 | 25 | 71.4 | 24 | 68.6 | 25 | 71.4 | 26 | 74.3 | 28 | 80.0 | 28 | 80.0 | 16.421* | 0.012* |
| | | Yes | 10 | 28.6 | 10 | 28.6 | 11 | 31.4 | 10 | 28.6 | 9 | 25.7 | 7 | 20.0 | 7 | 20.0 | | |
| | | Control (n = 35) | | | | | | | | | | | | | | | | |
| | | No | 20 | 57.1 | 20 | 57.1 | 20 | 57.1 | 20 | 57.1 | 20 | 57.1 | 20 | 57.1 | 20 | 57.1 | 0.000 | 1.000 |
| | | Yes | 15 | 42.9 | 15 | 42.9 | 15 | 42.9 | 15 | 42.9 | 15 | 42.9 | 15 | 42.9 | 15 | 42.9 | | |
| | | $\chi^2$(p) | 1.556(0.212) | | 1.556(0.212) | | 0.979(0.322) | | 1.556(0.212) | | 2.283(0.131) | | 4.242*(0.039*) | | 4.242*(0.039*) | | | |

p: p value for comparing between the studied groups $\chi^2$: **Chi square test FE: Fisher Exact Q: Cochran's test** $p_0$: p value for comparing between the studied periods

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