# ENDOTRACHEAL CUFF PRESSURE MONITORING AND REGULATION; CONTINUOUS VS INTERMITTENT METHOD: A PROSPECTIVE RANDOMIZED TRIAL

**DR MOHAMMAD BASYIR BIN KASIM**

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**DR. MOHAMMAD BASYIR BIN KASIM**

**DISSERTATION SUBMITTED IN FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF ANAESTHESIOLOGY**

**FACULTY OF MEDICINE**
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**ORIGINAL LITERARY WORK DECLARATION**

Name of Candidate: Mohammad Basyir bin Kasim

Registration/Matric No: MGE 150042

Name of Degree: Master of Anaesthesiology

Title of Dissertation ("this Work"): Endotracheal cuff pressure monitoring; continuous vs intermittent method: A Prospective Randomized Trial

Field of Study: Anesthesiology, Medicine

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## ABSTRACT

***Objectives:*** Evaluating the efficacy of TRACOE smart cuff manager which provides continuous regulation as an alternative to conventional intermittent endotracheal cuff pressure manometer usage in monitoring and maintaining desired pressure of 20 to 30 cm H20 in intubated ICU patients. Comparing the rate of complication in the form of ventilator associated pneumonia, length of ICU stay and mortality.

***Methods:*** This is a prospective randomized controlled trial (RCT), single-blinded (patient) involving adult patients intubated in intensive care unit of University of Malaya Medical Centre (UMMC), Kuala Lumpur. A total of 93 patients with minimum age of 18 years old were recruited. Patients were randomized into two groups – TRACOE and conventional method. Several parameters were evaluated – average endotracheal cuff pressure, total number and percentage of pressure outside the desired endotracheal cuff pressure. Complications which include ventilator associated pneumonia, length of ICU stay and rate of mortality were recorded.

***Results:*** TRACOE usage has better efficacy to conventional method in monitoring and maintaining endotracheal cuff pressure, however, it was not statistically significant. There is no difference in the rate of VAP or length of stay in both groups.

***Conclusion:*** The TRACOE smart cuff manager is as effective as the usage of conventional method in maintaining endotracheal cuff pressure and preventing the development of VAP.



***Key words:*** TRACOE, VAP ( ventilator associated pneumonia )

## ABSTRAK

***Objektif:*** Menilai keberkesanan "TRACOE smart cuff manager" yang berupaya mengawal selia tekanan belon tiub pernafasan iaitu dalam julat 20 ke 30 cmH20 sebagai alternatif kepada teknik konvensional pemantauan tekanan yang dilakukan secara berkala bagi pesakit yang dirawat di wad rawatan rapi Pusat Perubatan Universiti Malaya. Perbandingan dibuat bagi melihat keberkesanan teknik-teknik tersebut dalam mengelakkan jangkitan kuman paru-paru yang berkaitan alat bantuan pernafasan ( VAP ), jangka masa rawatan ICU dan kadar kematian.

***Kaedah:*** Ini merupakan kajian rawak terkawal yang melibatkan pesakit-pesakit dewasa yang memerlukan bantuan pernafasan melalui tiub trakea yang dimasukkan ke wad rawatan rapi Pusat Perubatan Universiti Malaya, Kuala Lumpur. Sejumlah 93 orang pesakit dengan umur minima 18 tahun direkrut. Pesakit pesakit dibahagi secara rawak kepada 2 kumpulan iaitu kumpulan yang mengunakan "TRACOE smart cuff manager" dan satu kumpulan lain yang mengunakan teknik konvensional. Parameter-parameter mengenai purata tekanan belon tiub, bilangan dan peratusan tekanan di luar tekanan yg disasarkan. Seterusnya komplikasi utama iaitu jangkitan kuman paru-paru, bilangan hari kemasukan pesakit ke wad rawatan rapi dan kadar kematian direkodkan.

***Keputusan:*** Penggunaan "TRACOE smart cuff manager" menawarkan alternatif yang lebih efisyen dan baik berbanding teknik konvensional dengan merekodkan tiada seorang pesakit pun yang dirawat sebagai "VAP". Walau bagaimanapun, data menunjukkan ianya tidak signikan secara pengiraan statistik pada bilangan pesakit yang dirawat sebagai VAP, jumlah hari rawatan di unit rawatan rapi dan kadar kematian.

***Kesimpulan:*** Penggunaan "TRACOE smart cuff manager" adalah sebanding dengan teknik konvesional bagi pesakit yang memerlukan tiub bantuan pernafasan.



***Kata kunci:*** "TRACOE", VAP (ventilator associate pneumonia).

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I would also wish to express my gratitude to patients and their families who participated in this study. Not to forget my colleagues and all the supporting staff for all the help and support in conducting this trial.

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## TABLE OF CONTENTS

## LIST OF DIAGRAMS

## LIST OF TABLES

## LIST OF SYMBOLS AND ABBREVIATIONS

| | | |
|---|---|---|
| ASA | : | American Society of Anesthesiologists |
| VAP | : | Ventilator associated pneumonia |
| ETT | : | Endotracheal tube |
| RCT | : | Randomized controlled trial |
| SD | : | Standard deviation |
| ICU | : | Intensive care unit |
| SAPP II | : | Simplified Acute Physiology Score II |
| SOFA | : | Sequential Organ Failure Assessment |
| UMMC | : | University Malaya Medical Centre |

## LIST OF APPENDICES

# 1. INTRODUCTION

Most critically ill patients in intensive care units who need mechanical ventilation support require endotracheal intubation. This involves the insertion of an endotracheal tube with a cuff into the airway to facilitate the passage of gas into the lungs. The purpose of the cuffed tubes is to form a seal against the tracheal wall to prevent air leak around the tube, as well as to protect against aspiration of secretions and gastric contents. However, the cuff also exerts a pressure on the tracheal wall that may be dangerous if not inflated correctly and monitored properly.

Cuff pressure of below 20cm H2O (underinflation) is a risk factor for micro aspiration of contaminated oropharyngeal secretions and gastric contents which is a major pathogenetic factor of VAP (Blot, Poelaert, & Kollef, 2014; Saad, Farid,Emmanuelle, Florent, & Malika, 2011). Several guidelines have suggested to maintain an optimal endotracheal tube cuff pressure as a measure to prevent VAP. Sufficient cuff pressure is also essential in ensuring adequate ventilation of the patient. On the other hand, tracheal-tube cuff pressure should not exceed 30 cm H2O to avoid vascular compromise of the trachea, which could result in tracheomalacia and even tracheal necrosis (Lewis, Schiobohm, & Thomas, 1978; S. Nseir et al., 2009).

### *1.1 Background*

Management of the artificial airway is an important part of care rendered by nurses and respiratory therapists. One aspect of airway management is maintenance of an adequate pressure in the ETT cuff. The cuff is inflated to seal the airway to deliver mechanical ventilation. A cuff pressure between 20 to 30 cm $H_2O$ is recommended to provide an adequate seal and reduce the risk of complications.

No guidelines are currently available regarding the use of a continuous or intermittent monitoring of cuff pressure. Some studies advocate the use of a continuous system while others have found no benefit. The aim of this study is to compare the effectiveness of a continuous cuff pressure monitoring system in the Malaysian population in maintaining cuff pressure and preventing VAP.

There are several types of continuous ETT cuff regulator available in the market. We used TRACOE smart cuff manager for this study. TRACOE medical GmbH is founded by Dr. Wolgang Köhler and Hildegard Waldeck. Continuous innovations lead to the introduction of TRACOE smart Cuff Manager in August 2013.

The TRACOE smart Cuff Manager monitors and regulates the internal pressure of High-Volume Low-Pressure cuffs of tracheostomy tubes as well as endotracheal tubes.

**S**afety through innovation

**M**anagement of the optimal cuff pressure

**A**voidance of pressure deviations and pressure peaks

**R**isk reduction of silent aspiration

**T**ime and cost effective

The pressure is maintained between 20  to 30 cmH2O. Visual verification of the cuff pressure is indicated by the inflation level of the blue buffer balloon of the TRACOE smart, which should be inflated between 2/3 and 3/4. Additional checks of the cuff pressure may be performed with a cuff pressure manometer. If the cuff pressure is too low, the TRACOE smart Cuff Manager refills the cuff quickly to its appropriate pressure. Short high pressure peaks e. g. due to coughing will be tolerated by the integrated damping function which inhibits that air escapes instantly from the cuff. The solid shell of the TRACOE smart protects the highly elastic blue balloon from unwanted compression.

TRACOE smart is a latex- and DEHP-free, single patient product with a usage time of 29 days after opening. The subglottic secretion suction with the aim to reduce the VAP rate of patients with an expected ventilation period was classified as category IA of the recommendations. The recommendation specifies that the cuff pressure level should be set between 20 to 30 cmH2O and checked at regular intervals (recommendation category IB). When these two actions are taken in combination, they can help to reduce the incidence of pneumonia.

### *1.2 Hypothesis*

The TRACOE smart cuff manager may be safely used as an alternative method to monitor and maintain ETT cuff pressure in intubated patient in ICU. This study aims to show that the TRACOE smart cuff manager is comparable to the conventional intermittent endotracheal tube pressure monitoring, with regards to maintaining desired ETT cuff pressure hence the prevention against VAP.

## 2. LITERATURE REVIEW

To date, there are no studies published yet in comparing the performance of TRACOE smart cuff manager to the current intermittent ETT cuff pressure monitoring practice. There were, however, several observational studies and randomized controlled trials comparing other type of continuous ETT cuff regulator to the conventional method.

Current practice is to check the tube cuff pressure intermittently (usually every 6-8 hours) using a hand held manometer. However, the compliance to the practice is still questionable; another study looking at this problem is done at the time of this study. Even with good compliance in monitoring ETT cuff pressure regularly, wide variations in cuff pressure can still occur in between measurements. A prospective observational cohort study was done in 2009 (SNseir et al., 2009) where a continuous recording of cuff and airway pressure was performed for 8 hours after a manual cuff pressure adjustment was done at 25cm H20 in 101 patients. Only 18% of study patients spent 100% of recording time with normal (20-30 cmH2O) cuff pressure. 54% of study patients developed cuff underinflation, 73% developed cuff overinflation, and 44% developed both. The percentage of time spent with underinflation significantly increased during the recording period.

Body positioning also affects cuff pressure. A study (Lizy et al., 2014) to assess the effect of changes in body position on cuff pressure in adult patients. Twelve orally intubated and sedated patients received neuromuscular blockers and were positioned in a neutral starting position with cuff pressure at 25 cm H2O. Then, 16 changes in position were performed and the cuff pressure was recorded during an end-expiratory ventilatory

hold. A significant deviation in cuff pressure occurred with all 16 changes ($P < .05$). No pressures were less than the lower limit (20 cm H2O). Pressures were greater than the upper limit (30 cm H2O) in 40.6% of the measurements. In each position, the upper target limit was exceeded at least once. Within-patient variability was substantial ($P=.02$). They concluded that simple changes in patients' positioning can result in potentially harmful cuff pressure.

With regard to intermittent ETT cuff pressure monitoring, the routine of measuring cuff pressure using manometer is not without complication. An experimental study in (Asai et al., 2014) investigated the effects of measuring devices and endotracheal tubes on change in cuff pressure. They concluded that procedures to connect cuff inflators to inflation valves resulted in the loss of cuff pressure by 6.6 cmH2O on average which means that the act of measuring the cuff pressure itself could lead to under inflation of the cuff. Hence by implementing the usage of continuous monitoring device perhaps can reduce this complication.

Saar Nseir at el in November 2015 (Saad Nseir et al., 2015) integrated data from 3 prospective controlled trials (two randomized and one quasi-randomized), which evaluated the impact of continuous control of cuff pressure on the incidence of VAP. Three different devices were used to continuously control pressure. They concluded that continuous control of pressure might be beneficial in reducing the risk for VAP. However, no significant impact of continuous control of cuff pressure was found on duration of mechanical ventilation, ICU length of stay, or mortality.

In 2004, a prospective, randomized open trial (Kunitz et al., 2004) which incorporated the use of an automatic pressure monitoring and regulating device (Tracoe) during a nitrous oxide anaesthesia. It was proven that the automatic device reliably maintained the pressure at the chosen constant level within +/-2 cmH2O. In the control group increases in cuff pressure to 40 cmH2O were common.

However, when Nseir et al conducted a prospective, randomized, controlled, crossover study in December 2015 using a PressureEasy® continuous cuff control device which was compared with a routine case using a manometer, the PressureEasy® did not demonstrate a better control of P cuff between 20 and 30 cmH2O, compared with routine care using a manometer (S Nseir et al., 2015). In fact, the device use resulted in significantly higher time spent with over inflation of tracheal cuff, which might increase the risk for tracheal ischemic lesions.

Study by Brimacombe et al (1999) indicated that, compared with the neutral head-neck position, mucosal pressure exerted on the tracheal wall by the ET tube increased by 22mmHg on the anterior aspect of the ET tube in the flexed position (p= 0.003) and by 11mmHg in the extended position (p= 0.002). The pressure increased by 5 mmHg at the anterior tip and lateral aspect of the cuff in the rotated position. Although evidence from human studies is lacking, cuff overinflation for greater than 15 minutes appears to be an important determinant of tracheal capillary hypoperfusion in animal models ( Nordin et al 1977).

When thirty-five critically ill adult patients were enrolled by M E Memela; Gopalan et al (2014). The mean study time was 11.1 h. The mean Pcuff was 25.6 (standard

deviation 7.1) cmH2O for the intermittent group and 26.6 (8.7) cmH2O for the continuous group. The intermittent pressure measurements were in the low-pressure range (<20 cmH2O) 12% of the time compared with 83% in the target pressure range (20 - 30 cmH2O) and 5% in the high-pressure range (>30 cmH2O). For continuous pressures, 13% of the time was spent in the low-pressure range, 64% in the target pressure range, and 23% in the high-pressure range. For the entire study, 588 events causing Pcuff alterations were recorded.

Tracheal and laryngeal morbidity occur frequently after tracheal intubation, with an incidence ranging from 15 to 94% (Loeser et al 1976, Loeser et al 1978a,b, Jensen et al 1982, Mandoe et al 1992, Suzuki et al 1999, Bennet et al 2000). The most frequently reported symptoms following tracheal intubation are sore throat and hoarseness with an incidence between15% and 80% (Winkel & Knudsen 1971,Loeser et al 1976, Loeser et al 1978a,b,Jensen et al 1982, Harding & McVey 1987,Stout et al 1987, Stride 1990, Herlevsen etal 1992, Christensen et al 1994, Joshi et al1997, Bennet et al 2000). Historically, thesesymptoms were often considered to beminor unavoidable complications of generalanaesthesia (Riding 1975). The influence oflimiting ET tube cuff pressure on theincidence of sore throat is unclear. Sorethroat and hoarseness are associated withdifferent types of endotracheal tubesregardless of ET tube cuff pressure (Jensenet al 1982, Stenqvist & Nilsson 1982,Combes et al 2001). Intubation can causesore throat with an incidence of 40% whenuncuffed ET tubes are used (Loeser et al1980). The incidence of dysphagia following intubation ranges between 15 and 94%(Mandoe et al 1992, Suzuki et al 1999) and does not appear to be associated with excessive ET tube cuff pressures (Combeset al 2001, Braz et al 2004)

## 3. PRODUCT OVERVIEW – TRACOE SMART CUFF MANAGER

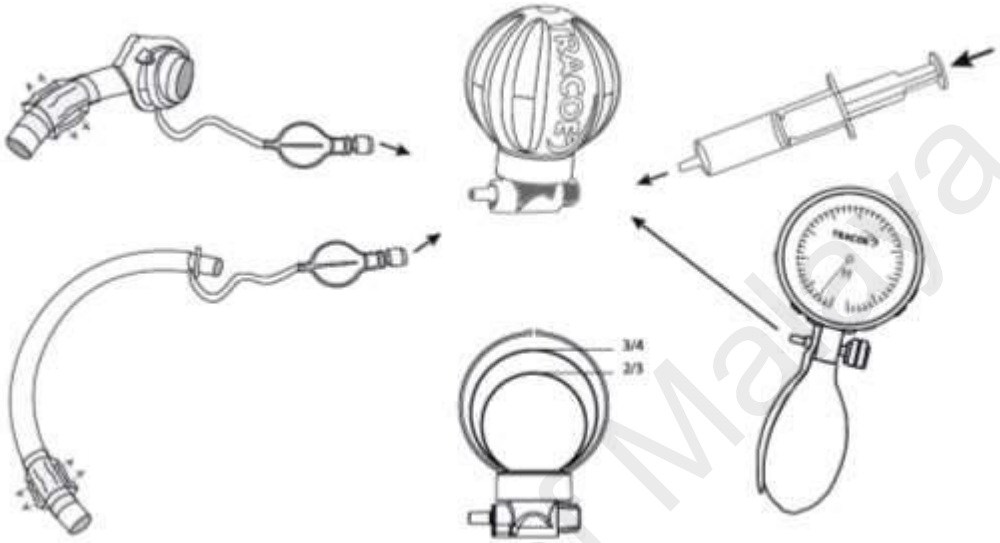


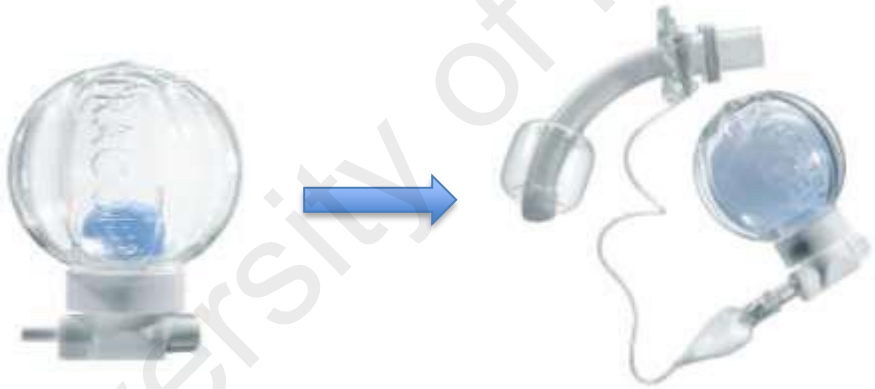

**Fig 3.1 TRACOE Smart Cuff Manager**

The TRACOE smart cuff manager performs continuous cuff pressure regulation between 20-30cmH2O, hence reducing cuff pressure variations and pressure peaks. This minimizes the risk of complications relating to microaspiration and tracheal mucosal injury. It is a single patient use product with a usage time of maximum 29 days and is latex free and DEHP free.

### 3.1 Application of the TRACOE smart

1. Connect the Luer connector (male) of the TRACOE smart cuff manager firmly to the cuff-filling valve of the endotracheal tube.

2. Attach a large-volume syringe to the Luer connector (female) of the TRACOE smart to inflate the blue balloon to 2/3 up to ¾ of the volume of the outer shell (approximately 60ml air). The solid shell of the TRACOE smart protects the highly elastic blue balloon from unwanted compression.



3. If the cuff pressure is too low, the TRACOE smart refills the cuff quickly to its recommended pressure.

4. Short high-pressure peaks (e.g. coughing) will be tolerated by the integrated buffer function which inhibits the air from escaping instantly from the cuff. This maintains the self-sealing-effect of the cuff.

5. Permanent excessive cuff pressure (e.g. new positioning of the patient) will be levelled.

6. Prior to deflation (during extubation), the TRACOE smart needs to be disconnected by gently turning and pulling the TRACOE smart off the tubes valve in one motion. The cuff of the endotracheal tube remains inflated and can now be deflated as usual via the pilot balloon using a syringe.

# 4. METHODOLOGY

This is a prospective randomized controlled trial (RCT), single-blinded (patient) involving adult patients admitted to ICU, University of Malaya Medical Centre (UMMC), Kuala Lumpur.

Inclusion criteria:

1) Intubated patients who are expected to remain intubated for at least 48 hours
2) Adult with minimum age of 18 years old

Exclusion criteria:

1) Patient with restrictive lung disease
2) Suspected aspiration prior to intubation
3) Patient with upper airway pathology
4) Patient who are ventilated in the general ward or who have been ventilated in the general ward for more than 24 hours prior to ICU admission.

## 4.1 Study population

The target population included all patients who were admitted to the ICU during the study period who required mechanical ventilation for more than 48 hours and fit the criteria.

**4.2 Steps**

1. All patients underwent comprehensive review by the trainee anaesthetist (researcher or co-researcher) on the day of recruitment.
2. If all criteria were fulfilled, subjects are then randomized into two groups for the RCT. Group 1: TRACOE smart cuff manager, Group 2: conventional intermittent monitoring using manometer.
3. Trainee Anesthetist randomly chose one envelope from a box (with equal numbers of envelopes for each group) which contained a piece of paper written TRACOE or Manometer.
4. Patient information sheet was given to the next of kin and written consent was taken.
5. Patients who are randomized to TRACOE will be connected to the TRACOE Smart Cuff Manager and the balloon will be inflated with air until it is 2/3 to ¾ (usually 60ml) the volume of the outer shell.
6. A cuff pressure reading will be taken from both group of patients and will be recorded up to 29 days or until the patient was extubated ( which ever came first ). All readings were then charted in the provided patient folders.
7. If the cuff pressure is lower than optimal, it will be inflated and the amount inflated to achieve the intended cuff pressure is recorded. If the cuff pressure is too high, then air is to be removed from the cuff.
8. Follow up was done to determine patients diagnosed with VAP. diagnosis was then made by the infectious disease team of UMMC whom acted as an independent party.
9. Collected data were keyed in and analyzed statistically with SPSS® software version 20 (IBM).

### 4.3 Ethical Consideration

This study has been approved by the Medical Ethics Committee UMMC. Permission was taken from patient's next of kin once they were recruited in the study. Details regarding the study were provided in a patient information sheet. Those whom next of kin were not agreeable, were excluded from the study, but treatment was continued as per usual.

### 4.4 Sample Size

Sample size was calculated using open source software. To achieve 95% chance of detecting a significant difference in the efficacy of the TRACOE smart cuff manager as opposed to conventional management will require a minimum of 68 patients.

As for this study, total of 93 patients were recruited between 15.07.16 and 30.04.19. Patients were excluded if they were extubated or expired within 48 hours of enrolment into the study.

### 4.5 Statistical analysis

Data was analysed using SPSS (statistical analysing software) version 20. All cuff pressure readings recorded was entered. Subsequently, average pressure of the ETT cuff for the duration of the study was calculated and compared between the two groups of patients.

Other parameter that was recorded and analysed was SAPS Score, SOFA score, number of event and pressure outside targeted pressure (20-30 cmH2O), numbers of patients diagnosed with VAP, Length of ICU stay and mortality.

Descriptive statistics was used to check for outliers, normality and to a histogram. Result were tested with independent t-test, pearson chi-square or fisher's exact test for normally distributed data and Mann Whitney and Kruskal-Wallis for non parametric data.

## 5. RESULTS

A total number of 93 samples were collected over a period of July 2016 until April 2019 and the data were analysed in this analysis.

### 5.1 Socio-demographic Data

Mean age of the recruited patients were 51.9 ± 18.6. The youngest patients recruited in the TRACOE and conventional intermittent arms were respectively, 18 and 22 years old, while the oldest patients were respectively, 80 and 83 years old. There were no significant differences (p value > 0.05) in the demographic characteristics between the two groups in terms of age, gender, race, SOFA and SAPS score on the of recruitment. Hence no bias found when method selection decided in terms of age, gender, races, SOFA score and SAPS II score.

| Variables | Method | | Whole group | p-value |
|---|---|---|---|---|
| | Tracoe (n=47) | Intermittent (n=46) | | |
| Age, Mean ± SD | 51.0 ± 18.9 | 52.9 ± 18.5 | 51.9 ± 18.6 | 0.627 |
| Gender, n (%) | | | | |
| Male | 8 (40.0) | 12 (60.0) | 53 (57) | 0.523 |
| Female | 21 (53.8) | 18 (46.2) | 40 (43) | |
| Races, n (%) | | | | |
| 1. Malay | 14 (15.1) | 14 (15.1) | 28 (30.1) | |
| 2. Chinese | 15 (16.1) | 18 (19.4) | 33 (35.5) | 0.939 |
| 3. Indian | 13 (14) | 11 (11.8) | 24 (25.8) | |
| 4. Others | 5 (5.4) | 3(3.2) | 8 (8.6) | |

| | | | | |
|---|---|---|---|---|
| SOFA score, Mean ± SD | 10.6 ± 4.2 | 11.1 ± 4.1 | 10.8 ± 4.1 | 0.519 |
| SAPS II score, Mean ± SD | 51.7 ± 18.5 | 50.5 ± 18.5 | 51.1 ± 18.4 | 0.758 |

*Table 1*

In both groups, mean SOFA score for both groups were comparable where mean SOFA score for TRACOE group were 10.6 ± 4.2 and 11.1 ± 4.1 for conventional group hence p = 0.52. Same goes to SAPS II score for both group of patients recruited, the mean SAPS II score for TRACOE group were 51.7 ± 18.5 and 50.5 ± 18.5 for conventional group hence p = 0.76. Safely said no bias were seen when recruitment of patient was made and during analyzing for any of the group that might affect the outcome studied.

**5.2 Average pressure, percentage and event not within the desirable pressure**

Average cuff pressure was recorded for each patient. No statistically difference between both groups was found. While average pressure seen for both groups were within desired pressure (20-30cmH2O).

The average cuff pressure for TRACOE was 26.9 ± 1.3 cmH20, as compared to the conventional group, 25.4 ± 2.5 cmH2O. Levene's test for normality showed that equality of variance cannot be assumed. Therefore, non-parametric test (Mann-Whitney) was used to analyze the data for average pressure mean between the group. The mean rank for TRACOE 56.44 while mean rank for conventional method was 36.36. Based on Mann-

Whitey U test, p value is < 0.05 thus there is significant difference between TRACOE and conventional method when average pressure is measured.

| Variable | Method | | Whole group | p value |
|---|---|---|---|---|
| | TRACOE (n=47) | Conventional (n=46) | | |
| Average cuff pressure | 26.9 ± 1.3 | 25.4 ± 2.5 | 26.2 ± 2.1 | 0.08 |
| Percentage pressure not within desired value (20-30 cmH20) | 0.21 ± 0.8 | 1.93 ± 3 | 1.06 ± 2.3 | > 0.05 |

*Mann Whitney/ Kruskal-Wallis
*Table 2*

There were significant differences in the percentage pressure not within the desired value (20-30 cmH20) between the two groups (> 0.05) based on Mann-Whitney and Kruskal-Wallis done test as Levene's test for normality showed that equality of variance cannot be assumed. TRACOE showed a result of mean 0.21 ± 0.8 percent when compared to conventional method that showed a mean of 1.93 ± 3 percent. The mean rank percentage for TRACOE group was 34.05 while the mean rank percentage for conventional method was 60.23.

When number of events of the occurrence of at least one reading pressure not within the desired value was studied, there was a significant event in the conventional group. There were only 4 (8.5%) patients in the TRACOE group whom had the event of pressures not within the desired value while there were 30 (65.2%) patients in the conventional method group. When Pearson Chi-Square test was done result showed a p value of <0.001.

**tracvsmano * presencOUT Crosstabulation**

| | | | presencOUT | | |
|---|---|---|---|---|---|
| | | | none | presence | Total |
| tracvsmano | TRACOE | Count | 43 | 4 | 47 |
| | | % within tracvsmano | 91.5% | 8.5% | 100.0% |
| | conventional manometer | Count | 16 | 30 | 46 |
| | | % within tracvsmano | 34.8% | 65.2% | 100.0% |
| Total | | Count | 59 | 34 | 93 |
| | | % within tracvsmano | 63.4% | 36.6% | 100.0% |

*Table 3*

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 32.231[a] | 1 | .000 | | |
| Continuity Correction[b] | 29.833 | 1 | .000 | | |
| Likelihood Ratio | 35.321 | 1 | .000 | | |
| Fisher's Exact Test | | | | .000 | .000 |
| Linear-by-Linear Association | 31.885 | 1 | .000 | | |
| N of Valid Cases | 93 | | | | |

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 16.82.

b. Computed only for a 2x2 table

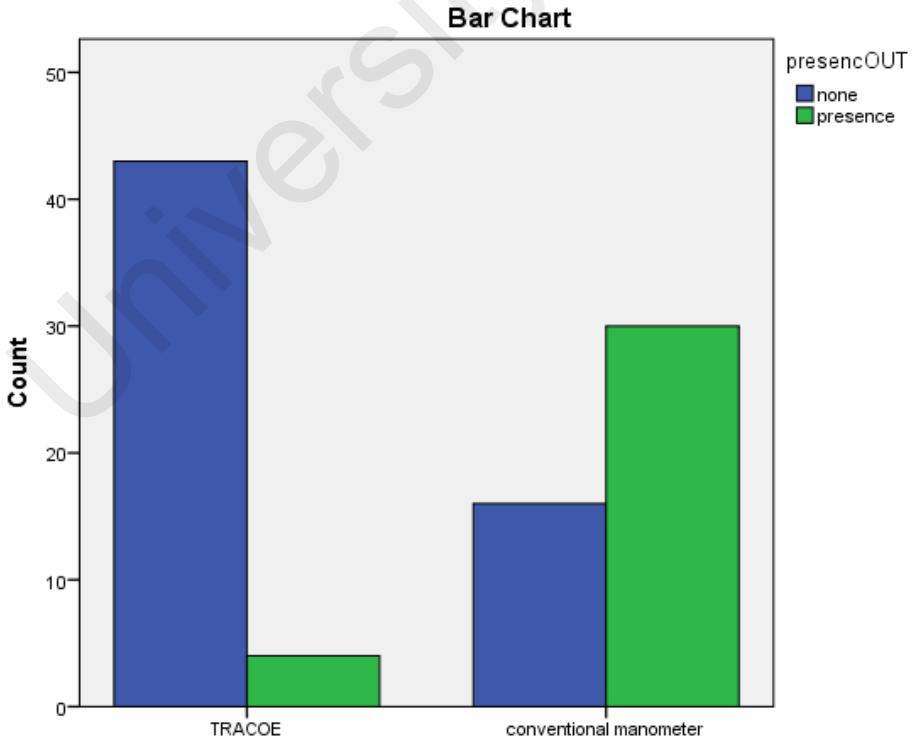



***Diagram 1***

### 5.3 Ventilator associated pneumonia from method studied

Conventional intermittent monitoring using manometer recorded 4 patients diagnosed with VAP while no VAP was diagnosed in TRACOE group. This is however not statistically significant with p = 0.056 as per Fisher's exact test. Only if there were additional one more case recorded it will be calculated as significant (p= 0.026).

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 4.271[a] | 1 | .039 | | |
| Continuity Correction[b] | 2.419 | 1 | .120 | | |
| Likelihood Ratio | 5.815 | 1 | .016 | | |
| Fisher's Exact Test | | | | .056 | .056 |
| Linear-by-Linear Association | 4.225 | 1 | .040 | | |
| N of Valid Cases | 93 | | | | |

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.98.

b. Computed only for a 2x2 table

*Table 4*

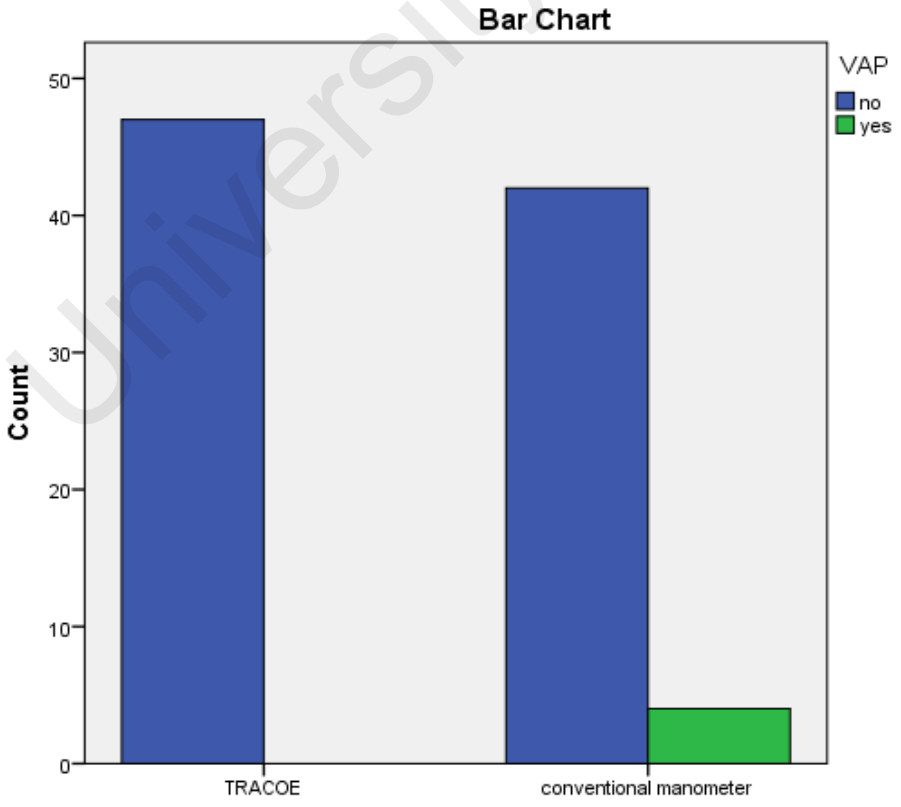



***Diagram 2***

## 5.4 Rate of mortality from method studied

There was significant mortality in conventional group where 23 patients died (67.6% total mortality) while 11 patients died (32.4% total mortality) in the TRACOE group with Pearson Chi-Square test 0.008 ($p<0.05$)

| | | | tracvsmano | | |
|---|---|---|---|---|---|
| | | | TRACOE | conventional manometer | Total |
| mortality | died | Count | 11 | 23 | 34 |
| | | % within mortality | 32.4% | 67.6% | 100.0% |
| | alive | Count | 36 | 23 | 59 |
| | | % within mortality | 61.0% | 39.0% | 100.0% |
| Total | | Count | 47 | 46 | 93 |
| | | % within mortality | 50.5% | 49.5% | 100.0% |

*Table 5*

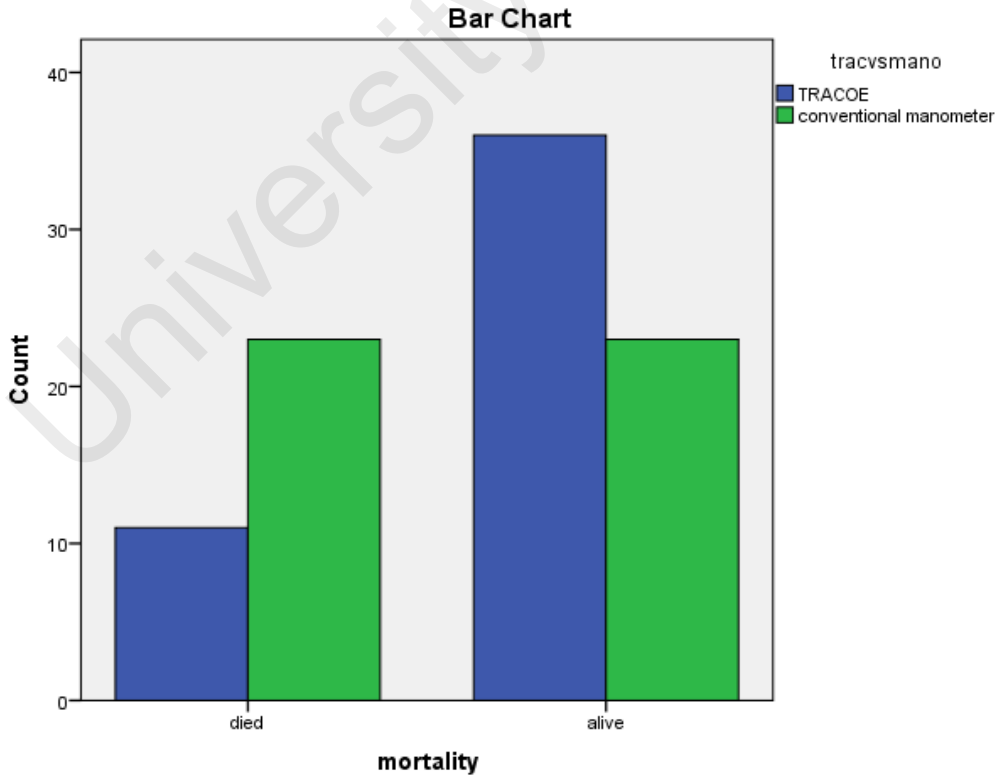



***Diagram 3***

### 5.5 Difference in length of ICU stay from method studied

The average length of ICU stay for patients in the TRACOE group was 9.06 ± 8.84 days, as compared to the conventional group, 10.78 ± 10.1 days. Levene's test for normality showed that equality of variance can be assumed. Therefore, independent T-test was used to analyze the data for average length of ICU stay between the group. Based on the T- test there wass no difference in average length of ICU stay between both groups, p value showed 0.385 ( $p>0.05$). This could be due to the fact that there was a wide standard deviation seen in both groups.

| Variable | Method | | Whole group | p value |
|---|---|---|---|---|
| | TRACOE (n=47) | Conventional (n=46) | | |
| Length of ICU stay (day) | 9.06 ± 8.84 | 10.78 ± 10.1 | 9.91± 9.5 | 0.385 |

*Table 6*

### 5.6 Event of Sore throat from method studied

Sore throat was initially studied as to represent whether the event of tracheal stenosis had occurred. However, the study was dropped as there was a lot of missing data because a significant number of patients had died ($p<0.05$), hence sore throat was unable to be assessed and studied.

## 6. DISCUSSION

More than two thirds of patients admitted to ICU University Malaya Medical Centre required intubation using an ETT. Cuffed ETT is used to seal the residual space in the airway to overcome leakage. ETT cuff pressure is to be maintained between 20 to 30 cmH20 to avoid other complications. Over inflation could lead to tracheal mucosal injury and underinflation may lead to micro aspiration, which is one of the causes of VAP. This study was conducted to assess the efficacy of a continuous regulatory mechanism in comparison with intermittent monitoring.

Ventilator-associated pneumonia (VAP) is a nosocomial airway infection of the lung parenchyma that develops more than 48–72 hours after a patient is intubated and mechanical ventilation is initiated.

VAP is the leading cause of death among critically ill patients, with its associated mortality rate exceeding that of other nosocomial infections such as central line catheter infection, sepsis and respiratory infections. VAP has been identified as a major safety issue among critically ill patients receiving mechanical ventilation. The main contributing factor of VAP is micro aspiration of oropharyngeal organisms from around the endotracheal tube's cuff into the distal bronchi, which is followed by proliferation of bacteria and its invasion of lung parenchyma.

The use of a system for continuous control of endotracheal tube cuff pressure reduced the incidence of ventilator-associated pneumonia (VAP) in one randomized controlled trial (RCT) with 112 patients but not in another RCT with 142 patients. In

several guidelines on the prevention of VAP, the use of a system for continuous or intermittent control of endotracheal cuff pressure was not reviewed.

This study compared the performance of TRACOE smart cuff manager to conventional intermittent cuff pressure regulation using a manometer. The socio-demographic features, namely the age, gender, SAPS II score and SOFA score, were similar between the two groups.

For the final analysis, 47 samples (50.5%) in the TRACOE group were compared with 46 samples (49.5%) in the conventional group. The primary outcome analyzed in this study is to compare the effectiveness of such method to prevent VAP, length of ICU stay and mortality. None of the patients in TRACOE group were diagnosed with VAP while 4 patients from the conventional group were diagnosed with VAP. However, this finding was not statistically significant most probably due to the small number of samples. An addition of one patient diagnosed with VAP would have shown a statistically significant ($p < 0.05$) result as the usage of TRACOE has a more superior advantage. Diagnosis of VAP was made by independent third party which was infectious department, UMMC. This was to avoid bias when diagnosing VAP. No consensus in making diagnosis of VAP Then event of VAP would be higher should other tool and list of criteria had been used, hence will differ the result.

The act of measuring the cuff pressure to the handheld manometer in itself could lead to the loss of cuff pressure as demonstrated by Shota Asai et al (2014). Traditionally, cuff pressure monitoring is performed every 4-6 hours to ensure that it is at the optimal level (20-30cmH2O).

In this study, number and percentage not within the desired pressure were recorded and analyzed. 36.6 percent out of total sample study had at least one event of pressure recorded not within the desired value. The occurrence of the event was statistically significant P value < 0.0001. Out of this result, 65.2 percent of the events occurred when conventional intermittent monitoring method was used. Result shown was statistically significant ($p < 0.0001$) when Pearson chi-square test done.

In addition, patients admitted to ICU who are critically ill may be subjected to multiple interventions/procedures/scans and may be on continuous renal replacement therapy and on multiple inotropic/vasopressor infusions. The dedicated nurse may unintentionally neglect checking the cuff pressure as there are other aspects of his/her care that are more critical at that point of time. This was demonstrated by a qualitative survey conducted by Jordan et al in 2012 in which more than half of the respondents (52%) performed cuff pressure measurements every 6 - 12 hours, while more frequent monitoring (every 2 – 4 hours) was performed by 32%. Fifteen per cent only assessed cuff pressure when a leak occurred, while 1% never performed monitoring. The TRACOE obviates the need for cuff pressure monitoring hence is more time efficient and allows the nursing staff to concentrate on other aspects of patient care. In UMMC, compliance with ETT cuff monitoring and regulation was poor. The conformation study on this issue is concurrently done with this study but with additional samples. That study is expected to be completed soon. This is another reason why continuous automated devices like the TRACOE provide an advantage over conventional intermittent monitoring method.

Besides that, handheld manometers are typically shared between patients which could lead to cross infection. With the use of TRACOE, there would be no need to use a handheld manometer hence limiting the potential for cross infection. The TRACOE also allows for visual signs of cuff leak as the balloon would be deflated in case of leak.

These days, medical health economics is a branch of economics concerned with issues related to efficiency, effectiveness, value and behavior in the production and consumption of health and healthcare, as ICU admissions require intensive one nurse to one patient care with limited space resources. This could be a major consideration and decision of implementing new techniques and additional devices to be purchased. In this study, length of ICU admission was recorded and analyzed. There was no difference in days of ICU stay with the average length of ICU stay for the TRACOE group of 9.06 ± 8.84 days, as compared to the conventional group, 10.78 ± 10.1 days. One of the factors that may contribute to the result was due to higher rate of mortality in conventional group where 23 patients died (67.6% total mortality) as compared to the TRACOE group where 11 patients (33.4% total mortality), p value = 0.008 died. Hence this will result in shorter days of ICU admission.

Sore throat was initially taken into one of the outcomes being studied as to represent risk of tracheal ischemia. This however was unable to be assessed as there was significant ($p < 0.001$) rate of mortality.

## 7. LIMITATIONS

This study is a single center study with a relatively small number of patients hence power to the study would be better if greater number of samples could be gathered. ETT cuff pressure is supposedly to be monitored every 6 hours however the compliance of cuff pressure monitoring was observed to be poor, which leaves a long period of time when the cuff pressure is not monitored and during which cuff pressure could vary significantly. Another study looking at this problem is concurrently ongoing and the result is expected to favor the usage of automated continuous monitoring devices like TRACOE smart cuff pressure regulator. Furthermore, continuous monitoring systems would be more accurate and safe pressures given to the ventilated patient. This is proved by the fact that all patients diagnosed with VAP came from the conventional method group.

## 8. CONCLUSION

TRACOE smart cuff manager may be a suitable and better alternative to the conventional intermittent ETT cuff pressure monitoring using manometer in all intubated patients. While no statistically difference in term of VAP rate in both group studied, there were significant reduction in rate of mortality in TRACO group . the occurrence of pressures not within the desired value was significantly reduce with TRACOE usage.

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