A STUDY OF CONTINUOUS MONITORING OF ENDOTRACHEAL TUBE CUFF PRESSURE USING AN ELECTRONIC DEVICE IN CRITICAL CARE SETTING

BY

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LIST OF ABBREVIATIONS

ASA	**American Society of Anaesthesiologist**
ARDS	**Adult Respiratory Distress Syndrome**
BMI	**Body Mass Index**
cm H_2O	**centimeter of water**
CP	**Cuff Pressure**
CTWP	**Cuff to Tracheal Wall Pressure**
ETT	**Endotracheal Tube**
ICU	**Intensive Care Unit**
ml	**Milliliter**
mm Hg	**Milliliter of Mercury**
PVC	**Polyvinyl-chloride**
SD	**Standard of Deviation**
SIRIM	**Standard Institute for Research of Malaysia**
SPSS ®	**Statistical Package for the Social Science**
VAP	**Ventilator-associated Pneumonia**

ABSTRAK

Kajian Mengenai Pemerhatian Berterusan Tekanan *Belon/'Kuf'* Tiub Endotrakeal Melalui Alat Elektronik Dalam Unit Rawatan Kritikal

Pengenalan : Pemerhatian tekanan belon/'kuf' tiub endotrakeal secara rutinnya tidak dipraktiskan secara berkala dalam kebanyakan unit rawatan kritikal. Tujuan kajian ini adalah untuk menentukan ketepatan atau hubungan antara pengukuran elektronik tekanan belon/'kuf' tiub endotrakeal dengan pemerhatian berterusan (membandingkan dengan manometer aneroid sebagai kawalan) dan kegunaannya dalam merendahkan komplikasi berkaitan penggunaan tiub endotrakeal dengan belon/'kuf' dalam unit rawatan intensif.

Metodologi: Seramai 56 pesakit telah dipilih melibatkan pesakit di unit rawatan rapi yang diintubasi dengan menggunakan tiub endotrakeal dengan belon/'kuf'. Kajian awal telah juga dibuat untuk menentukan keselamatan dan kestabilan alat pemerhatain elektronik ini. Ketepatan bacaan pada belon/'kuf' tiub endotrakeal telah dibandingkan dengan manometer aneroid manual dan variasi bacaannya telah juga diselidik selain daripada komplikasi berkaitan penggunaan tiub endotrakeal dengan belon/'kuf' ini. Komplikasi yang dikaji adalah prevalen pneumonia jangkitan mesin pernafasan, 'stridor' selepas ekstubasi, sakit tekak dan tiub endotrakeal yang tercabut.

Keputusan: Kami telah dapati bahawa terdapat korelasi yang signifikan antara manometer aneroid dengan alat pengukuran elektronik dengan nilai $p < 0.001$ (min 44.16 lwn 44.22 mm Hg). Prevalen pneumonia jangkitan mesin pernafasan, sakit tekak dan tiub endotrakeal yang tercabut adalah 1.8%, 3.6% dan 3.6% masing-masing. Tiada pesakit yang mengalami 'stridor' selepas ekstubasi.

Kesimpulan: Alat pengukuran elektronik untuk tekanan belon/'kuf' tiub endotrakeal adalah setara dengan manometer aneroid dan boleh menurunkan komplikasi berkaitan penggunaan tiub endotrakeal dengan belon/'kuf'.

ABSTRACT

A Study of Continuous Monitoring of Endotracheal Tube Cuff Pressure Using An Electronic Device In Critical Care Setting

Background: The endotracheal tube (ETT) cuff pressure measurement is not a routine practice in many critical care units. The main purpose of this study is to determine the accuracy or relationship of electronic measurement of ETT cuff pressure by continuous method (using aneroid manometer method as the control) and the usefulness of the continuous method toward reducing endotracheal tube-related complications in intensive care settings.

Methods: A total of 56 patients were recruited involving ICU patient intubated with ETT with cuff. A preliminary study was also conducted to determine the safety and stability of this electronic device. The precision of reading of ETT cuff pressure were compared with manual aneroid manometer and the variability of cuff pressure changes were also assessed apart from ETT cuff related complications. The complications that we looked for were the prevalence of ventilator-associated pneumonia (VAP), post-extubation stridor, sore-throat and endotracheal-tube (ETT) dislodgement.

Results: We found that there was a significant correlation between the readings by aneroid manometer with that of electronic measurement device, with *p value* of < 0.001 (mean 44.16 vs 44.22 mm Hg). The prevalence of VAP, sore-throat and endotracheal tube dislodgement were 1.8%, 3.6% and 3.6% respectively. No patient was noticed to have post-extubation stridor.

Conclusion: The readings recorded by the electronic device for ETT cuff measurement was comparable with aneroid manometer and its use could potentially reduce ETT cuff-related complications.

Key words: Endotracheal tube, cuff pressure, aneroid manometer, measurement, monitoring.

1. INTRODUCTION

Patients are being artificially ventilated in the Intensive Care Units (ICUs), for durations ranging from a few hours to weeks. There are many reasons why these patients are being ventilated; including that they may be in severe sepsis, or experiencing slow weaning from artificial ventilation following invasive operations such as cardiac or reconstructive surgeries. Most of the adult patients use endotracheal tubes (ETTs) with cuffs for ventilation. A critical function of the endotracheal tube cuff is to seal the airway, thus preventing aspiration of pharyngeal contents into the trachea and to ensure that there are no leaks passing through the cuff during positive pressure ventilation.

Under-inflating the cuff may result in the loss of some or all of the ventilator-delivered volume, rendering the positive-pressure mechanical ventilation ineffective. On the other hand, even with slight over-inflation, the cuff may exert too much pressure against the trachea, impeding the mucosal blood flow, and eventually predisposes the mucosa to ischaemic complications. Although these complications related to the usage of ETT cuff are well-known, the cuff pressure is not routinely and/or frequently monitored.

ETT cuffs, although conceptually simple, must be inflated carefully until they just fill the trachea, in order for them to function safely. The inflation of the cuff is usually assessed by manual

palpation of the pilot balloon. Determining precisely the cuff pressure and to ensure that it is within the safe range of cuff pressures by using manual palpation are not easy as the method is subjective and thus rather unreliable. Previous studies have demonstrated this unreliability using manual palpation method, existed particularly when detecting high cuff pressures. A more accurate measurement of the pressure cuff pressure could be done by using a small hand-held aneroid manometer.

The practice of using a bedside mercury manometer (modified with oxygen tubing and a stopcock) to fill the ETT cuffs and measure the cuff pressure (CP) though practical and economical, was abandoned after it was found to be flawed. Several medical equipment manufacturers sell devices designed for inflating ETT cuffs and, presumably, for checking CP. Though most inflators obviate additional tubing and stopcocks, they all rely on aneroid manometers; since all manometers contain at least some compressible volume, it is reasonable to wonder how much compressible volume is contained in today's commonly-used cuff inflator and how much that compressible volume affects the CP measurement. Overall there is still a lot of improvement that need to be done for minimizing complications related to the ETT cuff pressure. In the Department of Anaesthesiology and Critical Care, Hospital Kuala Terengganu, a novel method to measure CP was developed. Our staff members have utilized the available pressure monitoring slots of the ICUs' monitor, and through a system of catheters and connectors to inter-phase with the ETT 's pressure cuff to enable a continuous ETT cuff pressure measurement.

The monitoring device that we innovated uses the monitor which is normally available in the ICU, and the components used (tubes and connectors) are reusable. Thus the device is very cost-effective in the long term, and provides a valuable solution to problems related to cuff-pressure in the critical care settings or even in any cases with intubation using ETT with cuffs.

This study aims to test the practicality of the device in measuring ETT cuff pressure continuously through an assemble of electronic device, and the importance of using such monitoring in a critical care setting. Hopefully the study would provides favourable results to suggest that continuous monitoring of cuff pressure of ETT in intubated patients is a part of ICU routine that helps to improve patient's overall outcome.

2. OBJECTIVES

2.1 Aim

To determine the accuracy of electronic measurement of endotracheal cuff pressure by continuous method (using the conventional method as control) and the usefulness of the continuous method towards reducing endotracheal tube-related complications in intensive care settings.

2.2 Objectives

A: General

To study the accuracy of continuous electronic measurement of endotracheal cuff pressure and its relation and usefulness to reduce endotracheal tube-related complications in critical care settings.

B: Specific

a) To determine the accuracy of cuff pressure measured by continuous electronic measurement

b) To determine the variations of cuff pressure in the subjects studied and the factors responsible for the changes

c) To determine the prevalence of endotracheal tube-related complications in the study subjects in term of:

i) prevalence of ventilator-acquired pneumonia (VAP)

ii) prevalence of post-extubation stridor

iii) prevalence of sore-throat

iv) prevalence of endotracheal tube (ETT) dislodgement

2.3 Study Hypothesis

The use of continuous electronic monitoring of endotracheal cuff pressure is an accurate method, is useful in detecting variations in cuff pressure, and has a lesser risk of endotracheal tube-related complications to the patient.

2.4 Research Design

Prospective cross-sectional study.

3. LITERATURE REVIEW

3.1.1 Introduction

History of endotracheal intubation has begun as early as in 1840s when anaesthesia providers began to secure the airway by placing tubes orally into the larynx. This is done to protect the airway from aspiration of gastric contents when they carried out anaesthetic procedures on patients especially during emergencies. This early rigid tube was placed in the larynx and then was packed around it with gauzes to prevent the aspiration of blood and other particles especially from the stomach.

Since then, anaesthesia has undergone a lot of evolution including the techniques used, and wide selection of available drugs that suited the patient's general status. This development enables the anaesthetist to anaesthetize high-risk patients safely and produce favourable outcome. These development also comprises the tube that secure the airway as it been the most important tool for initiation of anaesthesia in any patient. Even though nowadays we have many adjuncts to secure the airway but the endotracheal tube (ETT) is still been the golden tool of securing the airway.

As there are a large number of patients who have been artificially intubated and ventilated in operation theatres and in intensive care units (ICU) ranging from a few minutes duration up to weeks, the care of ETT must also be the priority in making sure that the patient will be safe throughout the ventilation period. Most of the ETTs used are the ones with cuffs which are routinely inflated with air especially in adult patients. The critical function of this cuff is to prevent leak from positive ventilation pressure given and at the same time to prevent from aspiration of gastric contents or secretion including blood from upper airway into the lungs.

3.1.2 **History and Development of Endotracheal Tube**

As mentioned above, the development of ETT had begun as early as 1840s. Then, in 1869, Friedrich Trendelenburg had came up with a device to deliver anaesthetics to the lungs through the trachea by using a soft tube which can be maintained in place by inflating a balloon surrounding the tube. The balloon was found to be superior to the gauze in preventing aspiration. William Macewen in 1880 had promoted and developed a technique of intubation by intubating the trachea via the oral route, thus eliminating the need for tracheotomy in many head and neck procedures. Meanwhile in 1893, Victor Eisenmenger had constructed an apparatus which consisted of a wide-bore semi-rigid endotracheal tube with an inflatable cuff based on previous idea by Friedrich Trendelenburg (Duncum,1947).

The combined work of Joseph Dyer and George Fell then led into the development of an artificial respiration apparatus which changed the world of surgeries especially with thoracic surgery. Surgeons quickly responded into this innovation and gave them chances to perform thoracic surgery with more options and with fewer complications. Prior to that, only few thoracic procedures were performed due to proneness to develop pneumothorax which led to poor outcomes. These advantages of endotracheal anaesthesia and the fact that positive pressure so closely approximates physiological respiration supported its use which endures until the present day (Keyes,1978).

3.1.3 **Endotracheal Tube Cuff and Its Inflation Techniques**

The presence of cuff in ETT is not accidental. The function is so critical even though in smaller-sized patients like in pediatric age-groups usually the option still with uncuffed ETT but with cuff ETT, anaesthesiologists can facilitate their ventilation without worrying about the implied possibility of the ventilation may be ineffective due to leaks. At the same time, it is very reliable to prevent spillage of gastric contents or any secretion from the nasopharynx into the lungs.

Previously, before the introduction of low-pressure, high-volume cuffs after 1970s, people were using high-pressure, low-volume cuffs which were known to lead to more serious endotracheal tube cuff complications. These high-pressure, low-volume cuffs as the name imply, require high pressure to inflate but utilized small air volume to fill the cuffs. So, they tended to inflate in a

non-circular fashion because the thickness of the cuff wall is usually non-uniform as they were made from stiff rubber. This causes the ETT to be displaced away from the center of the trachea. Sometimes the tip of the tube also may come into contact with the trachea which can cause serious damage to the trachea during tidal ventilation. Furthermore, as the trachea is not circular, the ETT need to reshape its cuff to make proper seal within the trachea. This results the cuff-to-wall pressure in trachea to rise more than 100 mm Hg even though it is inflated to minimal occlusive pressure. The dangerous part is the development of trachea ischaemia that can lead to necrosis, which one estimated to occur in 5% to 20% of patients who used this kind of ETT (Guyton,1997).

In an effort to reduce this cuff-induced trachea ischaemia, in late 1960s, an improved cuff design was introduced. This low-pressure, high-volume cuffs were designed to have a large resting diameter but with a thin wall. With the diameter of this cuff being larger than the trachea, inflation of the high volume ultra-thin cuff conformed passively to trachea contours, resulting in large areas of contact but required a lower cuff-to-tracheal wall pressure to achieve a good seal. In addition, when compared with older design cuffs, additional inflation of the cuffs beyond that required to create sufficient seal, will only cause smaller increase in tracheal wall pressure. This high-volume, low-pressure cuff markedly reduced the incidence of trachea-sequelae complications related to endotracheal tube cuff pressure (O Donnell,1995).

Since the introduction of the high-volume, low-pressure endotracheal cuff, the incidence and severity of endotracheal tube cuff induced complications has been reduced (Crawley &Cross, 1975). However, still with over-inflation of any type of cuff can markedly increase intra-cuff pressure. Inflation of the endotracheal cuff with 2 to 3 additional milliliters of air beyond that required for adequate seal can result in an intracuff pressure to be greater than 30 mm Hg. A number of techniques have been developed to minimize the risk of over-inflation of the endotracheal tube cuff. The most commonly utilized techniques include:

1. Inflation with a predetermined volume of air

2. Pilot balloon palpation by anesthesia provider

3. Utilization of a minimal leak technique

4. Utilization minimal occlusive volume technique

5. Direct intracuff pressure measurement

1. Inflation with a predetermined volume of air

Providers who use a predetermined volume technique for inflating the endotracheal tube cuff, inject the cuff with a predetermined volume of air, such as 10 cubic centimeters. The problem with this is that the anesthesia provider could not determine the exact amount of pressure that a predetermined volume of air would exert on the trachea, it could be too low a pressure that would increase the risks of aspiration, or too high a pressure that would induce tracheal damage.

2. Pilot balloon palpation by anesthesia provider

The palpation technique entails injecting air into the cuff until the pilot balloon becomes firm to fingertip palpation. A study in 1990 had demonstrated that estimation of cuff pressure by finger palpation, regardless of the provider experience, had low accuracy in estimating the cuff pressure(Fernandez *et al.*, 1990).

3. Utilization of a minimal leak technique

With the minimal leak technique, anesthesia providers inject air into the cuff until a seal is achieved. Following this, a small volume of air is removed until a small leak is noted at peak inspiration of the patient's breathing. A disadvantage of this technique is that the cuff tends to move inside the trachea and could cause tracheal damage. Also, there is an increased risk of aspiration due to the cuff movement inside the trachea(O Donnell, 1995).

4. Utilization minimal occlusive volume technique

The minimal occlusive volume technique, a variation of the minimal leak technique, is when the cuff is inflated until a seal is obtained at peak inspiration, then a small volume of air is removed until a leak is heard at the point the cuff is inflated with the least amount of air to eliminate the leak. Although this technique reduces the movement of the endotracheal tube and thus provides a lower risk of aspiration, one study had demonstrated that it is associated with up to a 38% incidence of aspiration (Benhard *et al.*, 1979).