

Air Versus Distilled Water Cuff Inflation using Cuffill (Digital Cuff) in Adult Patients Undergoing General Anaesthesia

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ABSTRACT

Introduction: An essential part of anaesthesia is endotracheal intubation. The Endotracheal Tube (ETT) cuff pressure must not be higher than the predicted 22-30 mmHg tracheal perfusion pressure. If the ETT's cuff is inflated with air while under nitrous oxide+oxygen anaesthesia, the cuff pressure may increase dangerously and result in ischaemia of the tracheal mucosa. Hence, distilled water as an alternative agent to air for inflation of cuffs of ETTs was used in the present study.

Aim: To determine whether inflating the ETT cuff with distilled water, instead of air changes the pressure over time. To evaluate changes in cuff pressure over time, and to assess the knowledge about endotracheal cuff pressure monitoring with cuffill.

Materials and Methods: The randomised clinical study was conducted from February 2022 to April 2022. The study included 50 patients undergoing elective surgery under general anaesthesia who were randomly divided into two groups. In Group-A, distilled water was used and in Group-B, air was used

to inflate the cuffs of ETTs. General anaesthesia was given with nitrous oxide, oxygen and relaxant technique. The intra-cuff pressures of ETT cuffs were recorded by AG cuffill. Increase of pressures with time were recorded and analysed.

Results: Mean ET cuff pressure by cuffill with air (Group-B) was 26 ± 2.43 mmH₂O after 0 minutes of intubation. After 15 minutes of intubation mean ET cuff pressure was 31.80 ± 3.39 mmH₂O. Mean ET cuff pressure by cuffill with distilled water (Group-A) was 25.56 ± 2.02 mmHg after 0 minutes of intubation. After 15 minutes of intubation, mean ET cuff pressure was 28.5 ± 2.26 cmH₂O. There was a pressure difference observed between the groups with a mean difference of 3.217, t-value of 4.743 and a p-value of 0.001.

Conclusion: For the purpose of inflating the cuffs of ETTs when the patient is under general anaesthesia with the use of nitrous oxide, oxygen, and relaxant method, distilled water may be considered a more desirable agent than air.

Keywords: Cuffill, Positive pressure ventilation, Stenosis, Trachea

INTRODUCTION

An essential part of anaesthesia is endotracheal intubation [1]. By forming a seal between the patient's trachea and the cuff, the ETT cuff has two primary purposes: to reduce air leakage during Positive Pressure Ventilation (PPV) and to prevent aspiration of gastric contents [2]. Since its commercial introduction in the 20th century, ETT cuffs have undergone several changes, going from first-generation, low-volume, high-pressure cuffs made of inflexible material (reusable rubber) to high-volume, low-pressure cuffs made of softer, more pliable, and disposable material [2]. The cuffs on modern ETTs are made of Polyvinyl Chloride (PVC) (50-80 micron), which is non-toxic, smooth, transparent, and reasonably priced. They are also very compliant, high-volume, low-pressure cuffs. Additionally possessing thermoplastic qualities, these ETTs adapt to the patient's anatomy at body temperature [3].

When the cuff folds, serving as micro-channels, are developed in the surplus material of the cuff, aspiration can become more common [1]. High-volume, low-pressure cuffs can adapt quickly to the varied geometries of the trachea [3].

In order to prevent complications from impeding tracheal mucosal blood flow, the pressure applied to the tracheal mucosa by the ETT cuff should be as low as feasible while still being high enough to create a reliable seal when administering PPV. The ETT cuff pressure must not be higher than the predicted 22-30 mmHg tracheal perfusion pressure [4,5]. When the ETT cuff pressure is higher than the capillary blood pressure supplying the trachea, tracheal damage with pathological alterations starts, and ischaemia with inflammation follows [6].

This can cause mucosal necrosis, ulceration, granulation, and the development of scar tissue, which can result in stenosis if it is not treated [7]. When completely inflated, high-volume, low-pressure

cuffs can expand to a diameter that is between 1.5 and 2 times larger than the normal adult human trachea. As a result of the substantial mucosal contact area, they might be connected to a sore throat [8,9]. When under general anaesthesia with endotracheal intubation, sore throats and coughs are frequent complaints.

A variety of ETT cuff inflating procedures are frequently used. These include palpation of the pilot balloon as a reference for the amount of air required to inflate the cuff, Minimal Leak Technique (MLT), Minimal Occlusive Volume (MOV), and inflating the cuff with a Predefined Volume of Air (PVA) [3].

The aim of this study was to determine whether inflating the ETT cuff with distilled water, instead of air changes the pressure. The secondary objective was to evaluate changes in cuff pressure over time and to assess the knowledge about endotracheal cuff pressure monitoring with Cuffill.

MATERIALS AND METHODS

The randomised clinical study was conducted in Sri Devaraj Urs Academy of Higher Education and Research, Kolar, Karnataka, India. The study commenced on 1st February 2022 and continued till 30th April 2022. The institutional ethics committee had approved the study (DMC/KLR/IEC/636/2021-2022).

Inclusion criteria: The study included patients (males and females) between 18 to 80 years of age who underwent elective surgery (Ear Nose Throat {ENT}, Obstetrics and Gynecology {OBG}, neurosurgery, orthopaedic surgery, oncology surgery) under general anaesthesia, American society of anaesthesiologists physical status 1/2.

Exclusion criteria: Exclusion criteria was patient undergoing any kind of emergency surgery.

Sample size was calculated based on a study by Ahamed M et al., considering ETT cuff pressure [1]. Using the formula: $n=2(z_{\alpha/2}+z_{1-\beta})^2 \sigma^2/d^2$. Where, $Z_{1-\alpha/2}$ =Value of Z at 99% level of confidence (2.6), σ =pooled standard deviation (6.8), d =5% assumed margin of error [5]. A total of 75 patients were enrolled after meeting exclusion criteria. Seventy patients were ultimately included in the analysis. A total 31 patients were included in the Group-A and 39 patients in the Group-B by purposive sampling.

Before the anaesthesia was administered, the patients were examined comprehensively and their medical history was recorded. Patients' weights and other vitals were recorded. Complete haemogram, serum electrolytes, renal function test, Bleeding Time (BT) and Clotting Time (CT), electrocardiogram, chest X-ray were all pre-op tests that were requested.

One day prior to surgery, all patients were evaluated, investigation findings were reviewed, the anaesthetic process was explained, and informed consent was obtained. Patients were given pills of 0.5 mg alprazolam and 150 mg ranitidine the night before surgery, morning dose was repeated, patients were to fast for 8 hours.

Following informed consent, 70 patients posted for elective surgeries under general anaesthesia were divided into two groups: 31 patients in Group-A (Distilled water) and 39 patients in Group-B (air). There were 37 male patients and 33 female patients.

Venous access was secured with 18G Inferior Vena Cava (IVC) and fluids were initiated. After the patient was moved to Operation Theatre (OT), monitoring of their basal Heart Rate (HR), Non Invasive Blood Pressure (NIBP), and Oxygen Saturation (SPO₂) began. Patients were premedicated with Inj. Glycopyrrolate 0.005 mg/kg prior to the induction of anaesthesia. Preoxygenation was carried out with 100% oxygen for three minutes, then propofol injection at 2 mg/kg was used to produce unconsciousness until verbal commands were lost. After the loading dose was given, the required monitoring parameters were again recorded. Tracheal intubation with an appropriate-sized oral ETT was performed after giving succinylcholine 2 mg/kg muscle relaxant and bilateral equal air entry was confirmed by five point auscultation, tube was fixed with plasters. High-volume, low-pressure cuff Portex ETTs (disposable) were used. Every patient in the distilled water group had their ETT held vertically with the cuff facing down, inflated with distilled water, and then sucked out using a syringe. Repeatedly using a syringe filled with distilled water, the cuff was inflated until all of the original air pockets were gone.

distilled water group, extubation occurred after the cuff was drained dry using a syringe. We assumed that the intra-cuff pressure did not rise during the operation because only the initial amount of water came out and no more air could be sucked from the cuff.

STATISTICAL ANALYSIS

The data collected were entered into Microsoft excel sheet (Redmond, USA) and results were analysed. All the quantitative measures was presented as (Mean±SD), Confidence interval, qualitative measures like gender, ASA Physical status etc., by proportions and CI. Independent sample t-test for comparing the mean pressures between the groups:

Normality of the data has been checked using Shapiro-wilk test, and the data is normally disturbed ($p < 0.05$). An unpaired t-test has been employed to determine the ETT cut-off pressure between the two groups.

RESULTS

Most of the patients belonged to 20 to 50 year age group [Table/Fig-1]. Most patients were males ($n=37$) and rest were females ($n=33$). There were no significant differences between two groups with respect to age, gender, ASA status and Body Mass Index (BMI).

Mean cuff pressure in air and distilled water inflated cuffs are shown in [Table/Fig-2]. Mean cuff pressure in Group-B exceeded those in Group-A throughout the study with significant rise in 15 minutes ($p < 0.05$). The pressure at the baseline measurement in the Group-A ranged from 26 ± 2.43 , and in the Group-B, it was 25.56 ± 2.023 .

ETT tube size of 7.5 mm Internal Diameter (ID) showed higher pressure at 15 minutes ($33 \text{ cmH}_2\text{O}$), followed by size 7,8 and 8.5 [Table/Fig-3].

	Group-A	Group-B	p-value
Age (year)	38±10	37±9	0.104
Sex (F/M)	14/17	23/16	0.250
ASA (I/II)	22/9	28/11	0.841
BMI (kg/m ²)	23.53±2.90	23.34±2.48	0.77

[Table/Fig-1]: Patient demographic data.

Values indicate mean±SD and numerical values. Independent sample t-test was used for comparison.

BMI: Body mass index; ASA: American society of Anaesthesiologists; Group-A: Distilled water; Group-B: Air

Pressure (cmH ₂ O)	Group-A: ETT cuff distended with distilled water by Cuffill (n=31)	Group-B: ETT cuff distended with distilled water by Cuffill (n=39)	Mean Difference	t value	df	p-value
Pressure Baseline (0 min)	26±2.43	25.56±2.023	0.436	0.818	68	0.416
Pressure at 15 min	31.81±3.39	29.59±2.26	3.217	4.743	68	0.001*

[Table/Fig-2]: Comparison of Baseline pressure at 0 minutes and pressure at 15 minutes onset in both groups.

Values are mean and SD; p-value by independent sample t-test; p-value of 0.001 which shows statistical significance; p-value<0.05 is considered to be statistically not significant

A 60% N₂O in oxygen, isoflurane, and injectable Vecuronium (0.1 mg per kg) are used to maintain anaesthesia. Patients were mechanically ventilated to maintain end-tidal CO₂ (ETCO₂) between 20 to 30 mmHg. After inducing general anaesthesia and performing endotracheal intubation on the 31 patients in the distilled water group, the cuffs were inflated with 5-8 mL of distilled water until the pilot balloon was full. In each case, the quantity of distilled water injected into the cuff was recorded. Endotracheal intubation was performed on the 39 patients in the air group, and then the cuffs were inflated using a syringe and a Cuffill inflator. The beginning cuff pressure was measured and recorded. Glycopyrrolate 0.02 mg/kg+neostigmine 0.08 mg/kg was able to antagonise the effects of non depolarizing skeletal muscle relaxants. Oral suction was performed once the patient regained full consciousness and had a normal set of defence mechanisms. Patients in the air group had their cuffs deflated using a syringe after the final intra-cuff pressure was measured using AG cuffill. Extubation was completed once all of the air had been sucked out of the cuff. For the patients in the

ETT Tube Size mm ID	Pressure (cmH ₂ O) Baseline (0 min)	Pressure (cmH ₂ O) 15 min	p-value (0 min and 15 mins)
7 (30)	26±2.4	30±3	0.116 & 0.426
7.5 (3)	28±2	33±3	
8 (33)	25.4±1.9	30±3	
8.5 (4)	23.7±1.25	27±2	

[Table/Fig-3]: Comparison of different ETT tube size pressure at 0 and 15 minutes.

ID: Internal diameter

DISCUSSION

Although routine ETT cuff pressure measurement has been advocated as a way to reduce tracheal damage, it is not frequently used. Regular, periodic cuff pressure checks and deflation as needed take time, are distracting, and can cause periods of both over-and under-inflation.

Several strategies have been suggested to stop the increase in ETT cuff pressure caused by N₂O anaesthesia [10]. To prevent

excessive cuff pressures during surgery, devices such re-diffusion systems, pressure release valves, and foam-filled cuffs have been suggested. It has been demonstrated that a number of gas barrier tubes can effectively stop rises in ETT cuff pressures, but they are pricey. Another way to maintain low intracuff pressures is to fill the ETT cuff with N₂O/oxygen mixes or a sample of the inspired gas combination [11].

The cuff may become underinflated or overinflated depending on the N₂O concentration being utilised, and cuff leaks may result. The normal saline-filled cuffs have also stopped the cuff pressure from rising [12]. To our knowledge, there has not been any study that evaluated the efficacy of ETT cuffs filled with water.

To avoid difficulties, the normal ETT cuff pressure should be kept between 20 to 30 cmH₂O [12,13]. This study was carried out to determine the variations in the ETT cuff pressure in two distinct media, distilled water and air. The pressure change in water media was less compared to air media.

A study Beşir A et al., found that cuff pressures were significantly higher in Group-A (air) than in Group S (saline) [12]. In another study Ahmad N et al., found that water-filled ETT cuffs exerted noticeably less pressure than air-filled cuffs over the whole hour of monitoring [14]. At one hour, the increase in mean ETT cuff pressure following air inflation (25.53±8.89) was three times greater than after water distension (7.70±3.63). It was observed that the increase in tracheal cuff pressure occurs primarily during the first hour of anaesthesia. Because the blood/water coefficient of N₂O is not exactly 1.0, the slight increase in cuff pressure was anticipated.

The anaesthetist should take steps to prevent harmful increases in cuff pressure during N₂O anaesthesia in the absence of routine ETT cuff measurement or monitoring. Many other tools and methods have been suggested, but many of them are neither useful nor cost-effective. A feasible, affordable, and non-polluting alternative technique is to utilise sterile, distilled water. In contrast to saline, which is only provided as a 500 mL pack, distilled water is readily available in an operating room in compact 10 mL ampoules or plastic containers. As a result of the substantially reduced rise in cuff pressure during nitrous oxide anaesthesia, water distension of an ETT cuff is a suitable substitute for air inflation [10].

Limitation(s)

Use of nitrous oxide during surgery increases cuff pressure, it might increase postoperative sore throat incidence [15]. The sample size could have been more and studies with distilled water is comparatively less for references.

CONCLUSION(S)

In this investigation, researchers examined the pressure exerted by ETT cuffs filled with air and distilled water while the subjects were under general nitrous oxide anaesthesia. The Cuffill gadget was used to measure cuff pressures. The research found that ETT cuffs loaded with air increased in pressure over time more than those supplied with distilled water. Our findings suggest that using distilled water rather than air to inflate the ET tube is the best course of action.

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Dec 08, 2022
- Manual Googling: Jan 30, 2023
- iThenticate Software: Feb 09, 2023 (10%)

ETYMOLOGY: Author Origin

Date of Submission: **Dec 02, 2022**
Date of Peer Review: **Jan 12, 2023**
Date of Acceptance: **Feb 11, 2023**
Date of Publishing: **Apr 01, 2023**