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**ENDOTRACHEAL TUBE (ETT) CUFF PRESSURE
ASSESSMENT – FEEL VERSUS MEASUREMENT**

Richard Branson, Thomas Blakeman

University of Cincinnati

Dario Rodriquez

711 HPW/RHBA

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711TH HUMAN PERFORMANCE WING,
AIRMAN SYSTEMS DIRECTORATE,
WRIGHT-PATTERSON AIR FORCE BASE, OH 45433
AIR FORCE MATERIEL COMMAND
UNITED STATE AIR FORCE**

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JAMES B. LEHMAN
Research Program Manager
Product Development Branch
Airman Biosciences Division

THERESA A. BEDFORD, Maj, USAF, NC, FNP-BC
Nurse Scientist, En Route Care
Product Development Branch
Airman Biosciences Division

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14. ABSTRACT Background: Mechanical ventilation is a life-saving intervention. The insertion of an ETT is necessary to perform this modality. Accurately managing ETT cuff pressure exerted is paramount to preventing tissue damage/long-term complications. Method: This study evaluated ETT cuff pressures as a consequence of management without use of cuff manometry. US Army Special Operations Aviation Regiment (SOAR) medics were instructed to perform intubation in a simulated airway model. After intubation subjects were instructed to fill ETT cuff with air to what they considered to be acceptable without the use of a cuff manometer. Cuff pressure were measured with a manometer. This procedure was completed three times. Pressure measurements were recorded and compared between subjects and to the accepted range of 20-30 centimeter (cm) water (H₂O). Results: Pressure range was 1 – 203 cm H₂O with 97% being outside the accepted range and 92% were greater than 30 cm H₂O. Conclusions: The results were not within acceptable ranges. The consistently high pressures measured in the cuffs may cause tracheal injuries. A simple and accurate method to measure cuff pressures by these caregivers in austere environments is needed to prevent tracheal injuries due to excess ETT cuff pressure in intubated casualties.						
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DISCLAIMER:

The following final technical report provides results of a study that evaluated Endotracheal Tube (ETT) cuff pressure management without the use of cuff manometry. The funded study title “ETT Cuff Pressure Assessment – Feel Versus Measurement”. The study was approved by the University of Cincinnati Institutional Review Board, the Air Force Research Laboratory, Human Research Protection Office. The final report will include information covering the Background, Methods, Results, and Conclusion.

Disclaimer 1: This material is based on research sponsored by 711th Human Performance Wing (HPW) under agreement number FA86550-15-2-6605; Task Order number: FA8650-17-2-6G21. The U.S. Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon. **Disclaimer 2:** The views and conclusion herein are those of the authors and should not be interpreted as necessarily represent the official policies or endorsement, either expressed or implied, of 711 HPW, the Department of Defense (DoD), US Air Force, US Army, or the U.S. Government.

1.0 BACKGROUND:

Mechanical ventilation of the wounded warrior is a life-saving intervention credited with contributing to a survival rate of greater than 99 percent (%) in critical care transport. The institution of an ETT as a consequence of this modality, however, is not without its own risk. Safely and accurately managing the ETT cuff pressure exerted on the tracheal mucosa is paramount to mitigating untoward tissue damage and avoiding long-term complications. As a protective measure, standard practice recommends maintaining cuff pressures between 20-30 centimeter of water (cmH₂O). Studies indicate that pressures below 20 cmH₂O have been associated with the development of ventilator-associated pneumonia, while pressures in excess of 30 cmH₂O may contribute to tracheal malacia/stenosis. An additional consideration is the absence of cuff manometry as a consequence of logistical constraints, such as is the case in the Special Operations environment. In this setting, medics manage cuff volume by tactile sensation alone, giving rise to the potential for inappropriate pressures exerted on the tracheal wall/mucosa.

2.0 METHODS:

We evaluated ETT cuff pressures as a consequence of management without the use of cuff manometry. US Army 160th Special Operations Aviation Regiment (SOAR) with at least 1 year of experience were recruited to participate in this project. After informed consent was obtained, medics were instructed to perform endotracheal intubation in a simulated airway model (Respi-Sim, Ingmar Medical, Pittsburg, PA). After performing the intubation and filling the ETT cuff with the desired volume of air via a 10 milliliter (mL) syringe, cuff pressure measurements were performed with a digital pressure manometer. The intubation and pressure measurement procedures were performed in triplicate with each medic and the results were compared to the standard accepted range, 20-30 cmH₂O. Data was stored on a computer for future analysis. One hundred subjects were proposed to participate in the study, but travel restrictions implemented by the DoD and University of Cincinnati due to the Coronavirus Disease 2019 (COVID-19) pandemic limited the number of participants to 32, which were the number of subjects achieved pre-pandemic.

Statistical analysis: Due to the wide range in ETT cuff pressures, minimum, maximum, median, and interquartile range (IQR) were calculated as well as the number of pressure measurements that were less than (<) 20 cmH₂O, 20-30 cmH₂O, and greater than (>) 30 cm H₂O. There were 96 total pressure measurements. A secondary analysis was performed as previously detailed grouping medics by years of experience: 1-5 years, 6-10 years, and > 10 years. Additionally, a one-way analysis of variance (ANOVA) was performed to determine differences between the three groups. The significance level was set at 0.05.

3.0 RESULTS

Table 1 shows the years of experience and ETT cuff pressures obtained by each medic. The minimum and maximum pressures were 1 cmH₂O and 203 cmH₂O respectively. Ninety-seven percent of the cuff pressures were outside the acceptable range of 20-30 cmH₂O and 92% were higher than 30 cmH₂O. The median pressure was 84 cmH₂O and the IQR was 59.5 cmH₂O.

Figure 1 shows the disbursement of all the ETT cuff pressures into the three pressure ranges.

Comparison of ETT cuff pressures grouped by medics' years of experience showed that the IQR of the 1-5 year and 6-10-year groups were 50 and 52.5 cmH₂O respectively, but the >10-year group's IQR was 93 cmH₂O. One-way ANOVA analysis showed no statistically significant differences between groups probability value (P) equals (=) 0.15) despite the large difference in median and IQR between the >10-year experience group and the other two groups. This is likely due to the large variance in pressures within the groups. Figure 2 whisker plots show the minimum, maximum, median, and IQR cuff pressures within the groups.

Table 1. Subjects years of experience and measured ETT cuff pressures

Subject #	Experience (yrs)	ETT Cuff pressures (cm H ₂ O)		
1	7	156	85	78
2	7	202	179	153
3	4	89	94	97
4	12	150	160	152
5	9	51	38	80
6	11	187	203	196
7	8	167	186	144
8	7	62	65	48
9	8	99	82	69
10	4	64	58	43
11	6	44	17	31
12	7	102	111	93
13	4	138	177	119
14	1	108	36	55
15	1	76	73	54
16	8	41	35	32
17	7	87	128	91
18	15	82	100	8
19	12	107	127	111
20	11	9	20	27
21	14	1	2	1
22	11	111	152	183
23	2	75	99	76
24	9	92	72	52
25	13	36	87	96
26	1	78	66	48
27	1	105	108	108
28	8	79	80	66
29	1	35	8	21
30	2	82	52	78
31	16	143	138	163
32	5	107	127	83

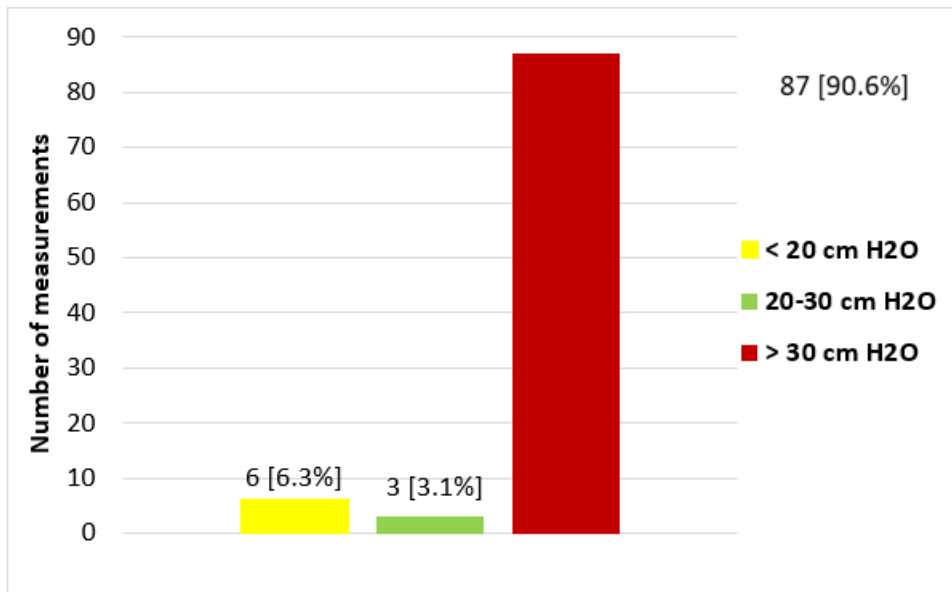


Figure 1. Measured ETT cuff pressure disbursement

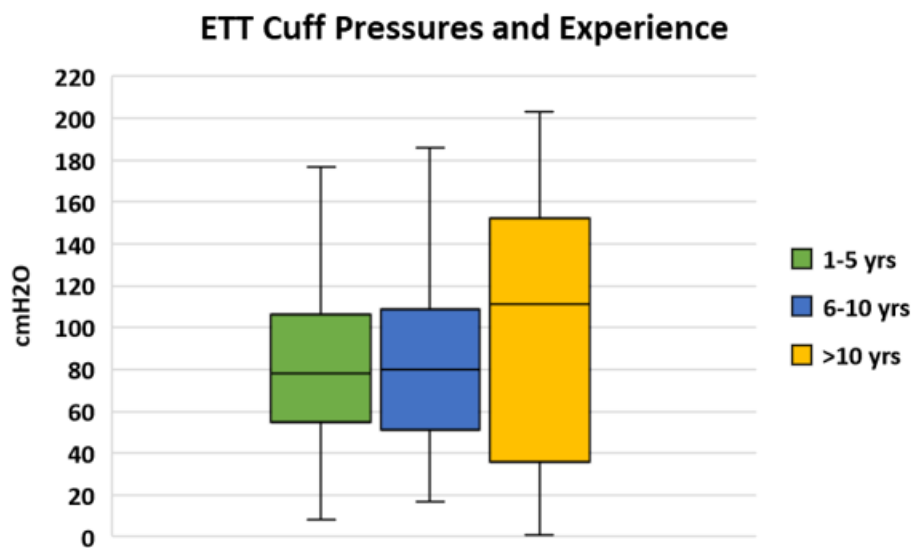


Figure 2. ETT cuff pressures grouped by subjects' years of experience showing minimum, maximum, median, and IQR.

4.0 CONCLUSION

SOAR medics are often required to initiate mechanical ventilation in far forward settings. Their current practice is absent the standard practice of managing the ETT cuff utilizing a cuff manometer. Medics presently inflate the cuff manually and adjust the desired pressure by squeezing the pilot balloon. Previous literature has also elucidated the consequences of aeromedical transport on ETT cuff pressures¹⁻¹⁰, to which recommendations have been made to assist in eliminating potential negative impacts, with the assertion that manometry is available for appropriate initial settings.

Our study showed that despite years of training, SOAR medics were unable to determine if the correct amount of air/pressure was present in the ETT cuff 97% of the time by palpating the pilot balloon. Our findings correlate with the results of previous studies¹¹⁻¹⁸. These studies showed that estimating ETT cuff pressure by manipulating the pilot balloon resulted in pressures outside the accepted range 40-98% of the time. The authors' recommendation was to measure ETT cuff pressure via manometry to ensure accuracy and mitigate patient harm.

Possible solutions

Understanding the performance characteristics of the ETT cuff is crucial to the appropriate management of the controlled airway during mechanical ventilation. Each military medical contingency requires the capability to safely and effectively move critically ill/injured patients through the various echelons of care. The current method used in this community is the "feel" method due to expediency and simplicity. It also negates having to carry additional equipment, although the recommendations in the literature overwhelmingly favor ETT cuff pressure measurement via manometry as the preferred method. In light of the need to minimize equipment that must be carried in an austere environment, there may be some viable alternatives.

Figure 3A shows the gold standard cuff pressure manometer (Cufflator, Posey Products LLC, Neenah, WI). In the absence of this manometer, figure 3B may be the best alternative. This device is a Food and Drug Administration (FDA)-cleared, 10 mL syringe with an integrated digital pressure manometer (AG Cuffill, Hospitech Respiration Ltd, Kfar Saba, Israel). To fill the ETT cuff, the syringe plunger is pulled back to the 10 mL marking and the syringe is connected to the pilot balloon. The plunger is then pushed in, injecting air into the ETT cuff until the pressure manometer reads the desired 20-30 cmH₂O pressure. At this point the syringe is removed without injecting additional air. The reported device accuracy is plus or minus ($\pm$) 2 cmH₂O and is reusable for 100 measurements. This device occupies little space and can easily be carried in the caregiver's pocket.

In absence of the previously detailed devices, a 5 mL syringe (figure 3C) may be the next best alternative. Usual practice is to use a 10 mL syringe to fill the ETT cuff with air. During the hectic environment often surrounding an intubation and especially in an austere setting, the tendency may be to insert a full 10 mL into the ETT cuff which will always lead to ETT cuff over inflation. Sengupta et al¹⁴ showed that only 4.4 ± 1.8 mL of air was required to inflate the cuffs on size 7.0 – 8.5 millimeter (mm) ETT to achieve the desired 20-30 cmH₂O pressure. Even if the tendency is to inject a full syringe of air into the ETT cuff, using a 5 mL syringe may help to mitigate the associated high cuff pressures.

The results of this study demonstrate the variability in ETT cuff pressures set by palpating the pilot balloon and agrees with prior studies that direct pressure measurement is the most reliable and safer despite trade-offs related to convenience. In the absence of a standard ETT cuff pressure manometer, we have provided what appear to be reasonable alternatives.



Figure 3. ETT cuff pressure monitor and alternatives

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LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

%	percent
±	plus or minus
=	equals
<	Less Than
>	Greater Than
cmH ₂ O	centimeter of water
AFRL	Air Force Research Laboratory
ANOVA	analysis of variance
CM	Centimeter
COVID-19	Coronavirus Disease 2019
DoD	Department of Defense
ETT	Endotracheal Tube
FDA	Food and Drug Administration
H ₂ O	Water
HPW	711th Human Performance Wing
IQR	interquartile range
mm	millimeter(s)
mL	milliliter
P	probability value
SOAR	US Army Special Operations Aviation Regiment