Pediatric Anesthesia

Pediatric Anesthesia ISSN 1155-5645

ORIGINAL ARTICLE

An *in vitro* and *in vivo* validation of a novel monitor for intracuff pressure in cuffed endotracheal tubes

Archana S. Ramesh[1], Senthil G. Krishna[1,2], William T. Denman[3] & Joseph D. Tobias[1,2,4]

1 Department of Anesthesiology & Pain Medicine, Nationwide Children's Hospital, Columbus, OH, USA
2 Department of Anesthesiology & Pain Medicine, The Ohio State University, Columbus, OH, USA
3 Department of Anesthesiology, The Massachusetts General Hospital, Boston, MA, USA
4 Department of Pediatrics, Nationwide Children's Hospital, The Ohio State University, Columbus, OH, USA

Keywords
intracuff pressure; cuffed endotracheal tube; pediatric anesthesia

Correspondence
Joseph D. Tobias, Department of Anesthesiology & Pain Medicine, Nationwide Children's Hospital, 700 Children's Drive, Columbus, OH 43205, USA
Email: Joseph.Tobias@Nationwidechildrens.org

Section Editor: Brian Anderson

Accepted 30 June 2014

doi:10.1111/pan.12498

Summary

Background: The clinical practice of pediatric anesthesiology has changed with increasing use of cuffed endotracheal tubes (cETTs) in infants and children. To limit the risk of tracheal mucosal damage, regular monitoring of intracuff pressure (CP) is necessary. This study evaluates the efficacy and accuracy of a novel syringe device that provides a digital readout of the CP.
Methods: The study was conducted in two phases. In phase 1, an *in vitro* study, cETTs of sizes 4.0, 5.0, and 6.0 mm ID were placed into polyvinylchloride tubing of appropriate sizes. The cuffs were then inflated, and the CP was measured simultaneously using the syringe device and a manometer. In phase 2, an *in vivo* study on 200 pediatric patients, the syringe device and the manometer were simultaneously attached to the pilot balloon to measure the CP following endotracheal intubation. Statistical analysis included linear regression analysis and Bland–Altman comparison.
Results: Linear regression analysis of the *in vitro* study demonstrated an R^2 value of 0.9989. Bias and precision were -1.92 ± 0.62 with 95% level of agreement (LOA) ranging from -3.13 to -0.72. For the *in vivo* study, the linear regression analysis demonstrated an R^2 value of 0.9943. The bias and precision were -0.53 ± 0.68 with 95% LOA ranging from -1.86 to 0.81.
Conclusion: The study has demonstrated clinically acceptable correlation between the CPs obtained from the standard manometer and the syringe device both *in vitro* and *in vivo*. This device is a simple, reliable, portable, and affordable method to monitor CP.

Introduction

The clinical practice of pediatric anesthesiology has changed with an increase in the use of cuffed endotracheal tubes (ETTs) even in infants and children (1,2). Although there have been significant improvements in the technology and design of these cuffed ETTs in the recent years making them safer to use in the pediatric population, there remains a concern regarding the effects of excessive cuff pressure on the tracheal mucosa (3–6). Despite this, there may be little attention paid to the inflation of the cuff following endotracheal intubation and the measurement of the intracuff pressure (7). Part of this may be due to the fact that manometers are not readily available in every location where endotracheal intubation occurs. The current study prospectively evaluates the efficacy of a simple and portable novel syringe device (AnapnoGuardCuffill, Hospitech Repsiration; Kiryat Matalone, Petach-Tikva, Israel) that provides a digital readout of the intracuff pressure (Figure 1).

Methods

This study was reviewed and approved by the Institutional Review Board of Nationwide Children's Hospital,

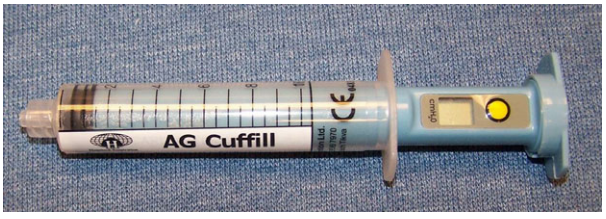

Figure 1 Photograph of the syringe device used in the current study. It provides a digital readout of the intracuff pressure.

Columbus, Ohio on 10/25/2013 (IRB13-00741), and the need for informed consent was waived. There was no change in the clinical practice dictated for these patients. The study was conducted in two phases. Phase one was an *in vitro* study where cuffed ETTs of sizes 4.0, 5.0 and 6.0 mm ID were placed into progressively larger pieces of polyvinylchloride tubing. The cuffs were then inflated to various intracuff pressures. The intracuff pressure was measured simultaneously using the syringe device and a standard manometer (Posey Cufflator Endotracheal Tube Inflator and Manometer™; JT Posey Company, Arcadia, CA, USA). A total of 100 simultaneous pressure readings were obtained from each of the three sizes of the ETTs. Phase two of the study was an *in vivo* study where the syringe device and the manometer were simultaneously attached to the pilot balloon to measure the intracuff pressure following endotracheal intubation in a cohort of pediatric patients presenting for general anesthesia during surgical interventions. Additional data collected included the patient's demographic data (age, weight, and gender), and the size of the ETT. Statistical analysis included a comparison of the intracuff pressures measured by the syringe device and the manometer using a linear regression analysis as well as a Bland–Altman analysis. The latter was used to determine the bias, precision, and level of agreement (LOA).

Results

For the *in vitro* part of the study, there were 100 simultaneous readings from each of the three sizes of the ETT. The linear regression analysis demonstrated an R^2 value of 0.9989, and the Bland–Altman revealed a bias and precision of -1.92 ± 0.62 cmH_2O with 95% cmH_2O LOA ranging from -3.13 to -0.72 cmH_2O (Table 1; Figures 2 and 3). No difference in the accuracy of the device was noted across the results for 4.0, 5.0, and 6.0 mm ID ETTs (Table 1). The *in vivo* study was conducted on 200 pediatric patients ranging in age from 0.3 to 18 years (5.2 ± 4.3 years) and in weight from 5.18 to 119.5 kg (26.2 ± 21.6 kg). There were 134 boys and 66 girls. The size of the ETTs used ranged from 3.0 to 7.0 mm ID. The linear regression analysis demonstrated an R^2 value of 0.9943 (Figure 4). The Bland–Altman revealed a bias and precision of -0.53 ± 0.68 cmH_2O with 95% cmH_2O LOA ranging from -1.86 to 0.81 cmH_2O (Figure 5). No difference in the accuracy of the device was noted based on the age of the patient or the size of the ETT used *in vivo* (Tables 2 and 3).

Discussion

The current study prospectively demonstrates that the syringe device in question can be used to provide a clinically acceptable measurement of the intracuff pressure following endotracheal intubation using a cuffed ETT. This device provides a digital readout of the exact intracuff pressure, has an automatic shutdown, and is FDA and CE approved. The device is built into a 10-ml syringe to allow for it to be used to inflate the cuff as well as simultaneously measure the intracuff pressure. Although it is disposable and ideal for single patient use, it can provide up to 100 readings. This was noted in our study as the entire study was performed with fewer than five devices. Although Bland–Altman analysis demonstrated occasional values outside the 95% LOA, overall the reliability and accuracy were acceptable for clinical care. When compared to the standard manometer, this syringe device is significantly less expensive ($8 vs $300) and can therefore be used in various locations away from the operating room including interhospital patient transport or by emergency medical personnel such as paramedics who provide care outside of the hospital setting. In hospitals with numerous operating rooms and multiple locations of intubation, it may not be practically feasible or cost-effective to have a manometer at

Table 1 Bland–Altman analysis and linear regression analysis for *in vitro* data

Parameter	4.0 mm ID cETT	5.0 mm ID cETT	6.0 mm ID cETT	Total (300 data points)
R^2 value	0.9993	0.9991	0.9986	0.9989
Bias ± precision (cmH_2O)	−1.83 ± 0.59	−1.88 ± 0.59	−2.06 ± 0.65	−1.92 ± 0.62
Level of agreement (cmH_2O)	−2.98 to −0.68	−3.04 to −0.72	−3.33 to −0.79	−3.13 to −0.72

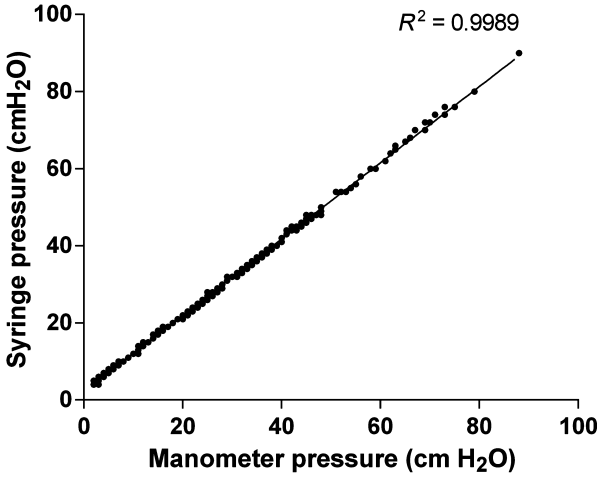

Figure 2 Linear regression analysis for *in vitro* comparison of intracuff measurements obtained from the manometer and the syringe device in phase one of the study.

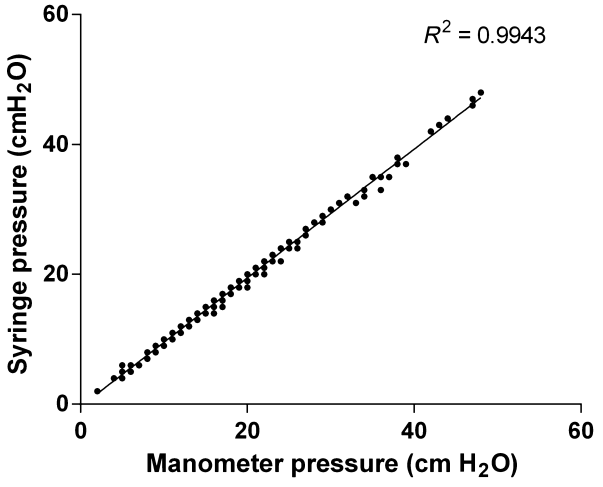

Figure 4 Linear regression analysis for *in vivo* comparison of intracuff measurements obtained from the manometer and the syringe device in phase two of the study.

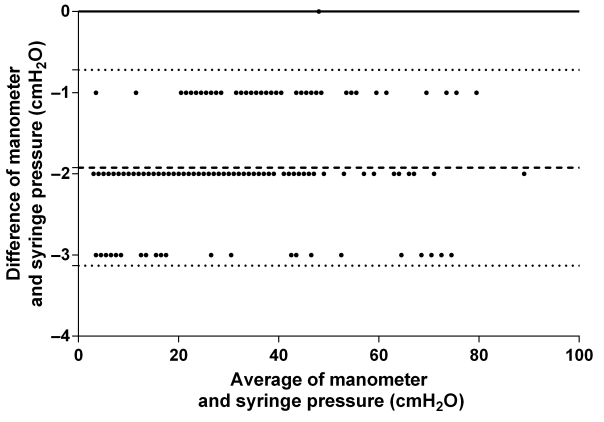

Figure 3 Bland–Altman analysis for *in vitro* comparison of intracuff measurements obtained from the manometer and the syringe device in phase one of the study. The bias (dashed line) and precision (dotted line) are noted on the graph.

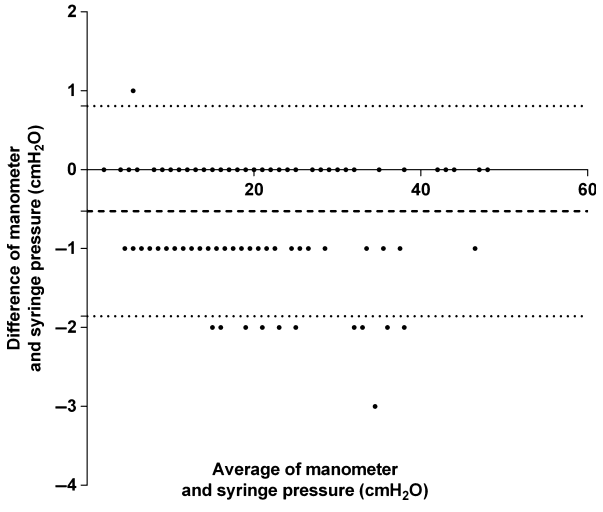

Figure 5 Bland–Altman analysis for *in vivo* comparison of intracuff measurements obtained from the manometer and the syringe device in phase two of the study. The bias (dashed lined) and precision (dotted) line are noted on the graph.

every site. Also, with repeated use in a busy operating room environment, these manometers may become damaged or lost. The current device may provide an alternative option in such scenarios.

Despite the shift in the practice with the routine use of cuffed ETTs in many pediatric operating rooms, we find that there has been limited attention focused on the optimal means of inflating the cuff and on methods to ensure that the intracuff pressure is within an acceptable range. The current device seems to fill that gap in clinical practice and allows an instantaneous and accurate measurement of the intracuff pressure. Despite the improvements in the technology of the cuff, excessive inflation with a high intracuff pressure may still lead to damage of the tracheal mucosa with a potential to cause postoperative respiratory compromise (8). This mandates measurement of the intracuff pressure following initial placement and periodically throughout the time that the cETT is left in place.

Although various clinical techniques have been claimed as acceptable and safe means of inflating the cuff to ensure that the intracuff pressure is within the clinically desired range, some direct measurement of the intracuff pressure is now being suggested as our clinical practice has changed (9). Although this can be

Table 2 Bland–Altman analysis and linear regression analysis for *in vivo* data

Parameter	3.0–3.5 mm ID cETT (31 patients)	4.0–4.5 mm ID cETT (91 patients)	5.0–5.5 mm ID cETT (37 patients)	6.0–6.5 mm ID cETT (26 patients)	7.0–7.5 mm ID cETT (15 patients)	Total *in vivo* data (200 patients)
R^2 value	0.9935	0.9940	0.9937	0.9916	0.9960	0.9943
Bias ± precision (cmH_2O)	−0.65 ± 0.49	−0.49 ± 0.69	−0.49 ± 0.73	−0.65 ± 0.80	−0.33 ± 0.62	−0.53 ± 0.68
Level of agreement (cmH_2O)	−1.60 to 0.31	−1.85 to 0.86	−1.92 to 0.95	−2.22 to 0.91	−1.54 to 0.88	−1.86 to 0.81

Table 3 Bland–Altman analysis and linear regression analysis based on age

Parameter	≤8 years (160 patients)	>8 years (40 patients)
R^2 value	0.9941	0.9927
Bias ± precision (cmH_2O)	−0.51 ± 0.65	−0.60 ± 0.78
Level of agreement (cmH_2O)	−1.79 to 0.78	−2.13 to 0.92

accomplished by having a manometer in every location in which endotracheal intubation occurs, the cost of these devices may be prohibitive. To allow the measurement of intracuff pressure without a costly and somewhat large and cumbersome device, recent devices have entered the clinical market including the syringe device evaluated in the current study. In addition to its accuracy that has been demonstrated in the current study, its advantages include its low cost and size thereby allowing its easy transport to various locations including its use outside of the hospital setting. However, a drawback with this device is that continuous cuff pressure monitoring is not feasible. Also when compared to electronic or pneumatic cuff pressure regulators, this syringe does not regulate the cuff pressure within the desired range automatically.

In summary, this study has demonstrated a clinically acceptable correlation between the intracuff pressure readings obtained from the standard manometer and the syringe cuff pressure measurement device both *in vitro* and *in vivo*. The syringe device is simple, reliable, portable, and affordable method to obtain instantaneous intracuff pressure measurements.

Acknowledgments

This research was carried out without funding.

Conflict of interest

Dr. Denman has received payment for technical and clinical advisory services to Hospitech Respiration, Kiryat Matalone, Petach-Tikva, Israel. Dr. Denman owns equity ownership in Hospitech Respiration.

References

1 Eschertzhuber S, Salgo B, Schmitz A *et al*. Cuffed endotracheal tubes in children reduce sevoflurane and medical gas consumption and related costs. *Acta Anaesthesiol Scand* 2010; **54**: 855–858.

2 Khine HH, Corddry DH, Kettrick RG *et al*. Comparison of cuffed and uncuffed endotracheal tubes in young children during general anesthesia. *Anesthesiology* 1997; **86**: 627–633.

3 Weiss M, Dullenkopf A, Fischer JE *et al*. Prospective randomized controlled multi-centre trial of cuffed or uncuffed endotracheal tubes in small children. European Paediatric Endotracheal Intubation Study Group. *Br J Anaesth* 2009; **103**: 867–873.

4 Weiss M, Dullenkopf A. Cuffed tracheal tubes in children: past, present and future. *Expert Rev Med Devices* 2007; **4**: 73–82.

5 Nordin U. The trachea and cuff induced tracheal injury. An experimental study on causative factors and prevention. *Acta Otolaryngol* 1976; **345**(Suppl): 1–71.

6 Seegobin RD, Hasselt GL. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large cuff volumes. *Br Med J* 1984; **288**: 965–968.

7 Tobias JD, Schwartz L, Rice J *et al*. Cuffed endotracheal tubes in infants and children: should we routinely measure the cuff pressure? *Int J Pediatr Otorhinolaryngol* 2012; **76**: 61–63.

8 Sathyamoorthy MK, Lerman J, Lakshminrusimha S *et al*. Inspiratory stridor after tracheal intubation with a Microcuff® tracheal tube in three young infants. *Anesthesiology* 2013; **118**: 748–750.

9 Tobias JD, Gopalakrishnan S, Rice J *et al*. Cuffed endotracheal tubes in infants and children: a technique to ensure an acceptable intracuff pressure. *ICU Dir* 2013; **4**: 62–64.