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Original Article

An in vitro and in vivo validation of a novel color-coded syringe device for measuring the intracuff pressure in cuffed endotracheal tubes

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Abstract: Background: The clinical practice of pediatric anesthesiology has changed with a transition to the use of cuffed endotracheal tubes (ETTs) in infants and children. The monitoring of intracuff pressure has been suggested as one means to limit the potential for damage to the tracheal mucosa. The current study evaluates the accuracy of a novel, color-coded syringe device which provides three zones (green, clear, and red) to estimate the intracuff pressure. Method: The study was conducted in two phases. Phase 1 was an in vitro study where cuffed ETTs of sizes 4.0 mm, 5.0 mm and 6.0 mm ID were placed into polyvinylchloride tubing of appropriate sizes. A manometer and the syringe device were simultaneously attached to measure the intracuff pressure at the middle of the 3 different zones on the device (red, clear, and green). Phase 2 was an *in vivo* study where the syringe device and the manometer were simultaneously attached to the pilot balloon to measure the intracuff pressure and the corresponding zone on the color-coded syringe following endotracheal intubation. Statistical analysis included a descriptive reporting of the mean ± SD, median, range, and 95% confidence intervals (CI) of the actual intracuff pressure readings at the three zones of the syringe device during both its in vitro and in vivo use. Results: For phase 1 of the study, the 95% CI for the green, clear, and red zones were 21.5-21.8, 29.2-29.5, and 46.5-47.4 cmH_2O respectively. This correlated well with the manufacturer reported values of 20-30, 30-40, and 40-60 cmH_2O for the 3 zones (green, clear, and red respectively). Phase 2 of the study included 200 patients ranging in age from 0.1 to 21.8 years (6.7 ± 5.1 years) and in weight from 4.0 to 129.1 kilograms (29.4 ± 23.3 kgs). The size of the ETTs ranged from 3.0 to 7.0 mm ID. The intracuff pressure measured by the manometer ranged from 4 to 65 cmH_2O (27.6 ± 9.7 cmH_2O). The 95% CI for the green, clear, and red zones were 20.5-21.7, 27.7-29.1, and 41.2-46.5 cmH_2O respectively. There was no significant differences noted when comparing different patient ages or sizes of ETT. Conclusion: The current study demonstrates a clinically acceptable correlation between the zones on this novel, color-coded syringe device and the actual measurement of the intracuff pressure obtained by a manometer for both in vitro and in vivo use. This device is a simple, reliable, portable and affordable method to monitor intracuff pressure.

Keywords: Intracuff pressure, cuffed endotracheal tube, pediatric anesthesia

Introduction

The clinical practice of pediatric anesthesiology continues to change with an increase in the use of cuffed endotracheal tubes (ETTs) even in infants and children [1, 2]. Although there have been improvements in the design of these ETTs which have made them safer for use in the pediatric population, there remains a concern regarding the potential adverse effects on the tracheal mucosa if the intracuff pressure is excessive [3-6]. Despite these issues, it has not become standard practice in the many countries including the United States to routinely measure the intracuff following endotracheal intubation [7]. Part of this may be due to the fact that in most institutions there are not manometers kept in every location where endotracheal intubation occurs. The current study prospectively evaluates the efficacy of a novel device (Tru-Cuff, AES Inc, Black Diamond, WA) which has a color-coded pressure indicator built into a syringe that allows the provider to inflate the cuff of the ETT to an appropriate pressure levels (**Figure 1**).

Figure 1. Photograph of the color-coded syringe device used in the current study. According to the manufacturer, the green zone correlates to an intracuff pressure of 20-30 cmH_2O, the clear zone to 30-40 cmH_2O, and the red zone to 40-60 cmH_2O.

Methods

This study was reviewed by the Institutional Review Board of Nationwide Children's Hospital (Columbus, Ohio) and the need for informed consent was waived. There was no change dictated in clinical practice for these patients. The color-coded syringe device used in the study has 3 zones on the barrel of the syringe (green, clear, and red). According to the manufacturer's description of the device, the green zone correlates to an intracuff pressure of 20-30 cmH_2O, the clear zone to 30-40 cmH_2O, and the red zone to 40-60 cmH_2O.

The study was conducted in two phases. Phase one was an in vitro study where cuffed ETTs of various sizes (4.0 mm, 5.0 mm and 6.0 mm) were placed into progressively larger pieces of polyvinylchloride tubing. The cuffs were then inflated gradually until the indicator was located in the center of the 3 zones (green, clear, and red). At that point, the intracuff pressure was measured simultaneously using a standard manometer (Posey Cufflator Endotracheal Tube Inflator and Manometer™, JT Posey Company, Arcadia, CA). A total of 100 pressure readings were obtained at each of 3 indicator positions for each of the 3 sizes of cuffed 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 after endotracheal intubation and inflation of the cuff using standard clinical practice. At that time, the intracuff pressure from the manometer and the zone on the syringe device were recorded. Additional data collected included the patient's demographic data (age, weight, and gender), and the size of the ETT. Data are presented as descriptive results with the mean ± SD, median, and range. The accuracy of the color-coded syringe device was determined by comparing the syringe indicator's location (green, clear or red) and the intracuff pressures measured by the manometer using 95% confidence intervals (CI).

Results

For phase 1 of the study, there were 100 readings from each of the 3 points of the three sizes of the cuffed ETTs resulting in 300 readings for each of the zones (**Table 1**). At the center of the green and red zone, all of the intracuff pressures were within the manufacturer reported values. The 95% CI for the center of the green and red zones were 21.5-21.8 cmH_2O and 46.5-47.4 cmH_2O respectively. At the center of clear zone, the 95% CI was 29.2-29.5 cmH_2O. Although 53% (158 of 300) of the values were outside the manufacturer reported value, they were all ≤ 3 cmH_2O less than the expected value (30 cmH_2O ranging from 27-29 cmH_2O.

For phase 2 of the study, the cohort included 200 patients ranging in age from 0.1 to 21.8 years (6.7 ± 5.1 years) and in weight from 4.0 to 129.1 kilograms (29.4 ± 23.3 kgs). There were 113 boys and 87 girls. The intracuff pressure ranged from 4 to 65 cmH_2O (27.6 ± 9.7 cmH_2O) with an intracuff pressure ≥ 30 cmH_2O in 57 of 200 patients (28.5%). The size of the ETTs ranged from 3.0 to 7.0 mm ID. There were 8 readings that were below the green zone, all of which were less than 20 cmH_2O when measured by the manometer (range: 4-16 cmH_2O). The 95% CI for the green, clear, and red zones were similar to those noted in the in vitro aspect of the study (20.5-21.7, 27.7-29.1, and 41.2-46.5 cmH_2O respectively). For the green zone measurements (n=80), 21 of 80 of the values (26%) from the manometer were less than 20 cmH_2O. Of these 21 values, 19 were ≤ 3 cmH_2O of the predicted lower limit value of 20 cmH_2O. None of the actual manometer readings for values in the green zone were ≥ 30 cmH_2O. For the values in the clear zone (n=76), 46 of 76 (60%) were < 30 cmH_2O, 27 of these 46 were ≤ 3 cmH_2O of the predicted value (27-29 cmH_2O). None of the 76 actual readings from the manometer were > 40 cmH_2O. For the values in the red zone (n=36), 13 of 36 (36%) were < 40

Table 1. Descriptive statistics for the syringe device with various sized ETTs*

Zone on syringe	4.0 mm ID cETT	5.0 mm ID cETT	6.0 mm ID cETT	All 3 ETTs
Green (20-30 cmH_2O)	21.5 ± 0.8	21.9 ± 0.9	21.5 ± 0.7	21.6 ± 0.8
	22 [20-24]	22 [21-24]	22 [20-23]	22 [20-24]
	21.3-21.7	21.3-22.5	21.3-21.7	21.5-21.8
Clear (30-40 cmH_2O)	29.5 ± 1.1	29.3 ± 1.3	29.3 ± 1.1	29.3 ± 1.1
	30 [27-34]	29 [27-32]	29 [27-31]	29 [27-34]
	29.2-29.7	29.0-29.6	29.0-29.5	29.2-29.5
Red (40-60 cmH_2O)	48.4 ± 3.2	45.7 ± 3.1	46.6 ± 1.8	46.9 ± 3.0
	48 [42-58]	45 [40-53]	46 [44-52]	46 [40-58]
	47.6-49.2	44.9-46.5	46.1-47.1	46.5-47.4

*A total of 100 readings were taken from each zone for each size of the cuffed ETTs to give a total of 900 data points for phase one of the study. The data in the table are listed as the mean ± SD, median [range], and 95% confidence interval. cETT = cuffed endotracheal tube.

cmH_2O. Of these 13, 6 were ≤ 3 cmH_2O of the predicted lower limit value of 40 cmH_2O. 1 of 36 (3%).

Discussion

The current study prospectively demonstrates that this novel color-coded syringe device can be used to provide a clinically acceptable measurement of the intracuff pressure following endotracheal intubation using a cuffed ETT. The potential importance of such measurements is demonstrated by the fact that using standard clinical practice to inflate the cuff resulted in an intracuff pressure ≥ 30 cmH_2O in 57 of the 200 patients (28.5%) in the current study. The device used in the current study provides an estimate of the intracuff pressure using a color-coded system. The green zone represents the usually recommended intracuff pressure of 20-30 cmH_2O. There is an intermediate zone of 30-40 cmH_2O represented by a transitional clear zone (between the green and red zones) as well as a red zone indicative of excessive pressure (40-60 cmH_2O). In the in vitro phase of the current study, the mean, median and 95% CI of the intracuff pressures were within these ranges demonstrating the accuracy of the device. Although some of the actual readings from the manometer for the in vivo aspect of the study were below what would have been predicted based on the zone from the syringe, the majority of these were within 3 cmH_2O of the values predicted by the syringe device.

Although the device is disposable and ideal for single patient use, we used a single device multiple times without any change in its accuracy. The current study was performed with approximately 50 of these devices. Current acquisition costs are approximately $2 per device ($97.50 for a box of 50 devices). Its cost and portability would lend it to being used not only in the operating room, but also in various other locations where endotracheal intubation may occur both in and outside the hospital setting.

With the recent shift to the routine use of cuffed ETTs in many pediatric operating rooms, it has become apparent that it is necessary to avoid over-inflation of the cuff which may result in damage to the tracheal mucosa. Failure to monitor the intracuff pressure and adjust it accordingly may result in postoperative complications including airway edema, stridor, and respiratory insufficiency [7]. To date, there have been limited options to allow such measurements in operating rooms across the United States [8, 9]. The current device seems to fill that gap in technology and allows an instantaneous and accurate measurement of the intracuff pressure. While the design of the ETT may be important, control of the intracuff pressure is recommended. This mandates measurement of the intracuff pressure following initial placement and perhaps throughout the time that the ETT is left in place.

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Disclosure of conflict of interest

None.

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