Correlation and variation of cuff inflating volumes and pressures in different adult models of laryngeal mask airway: a prospective randomized trial

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Abstract

Background : Hyperinflation of laryngeal mask cuffs may carry the risk of airway complications. The manufacturer recommends inflating cuff until the intracuff pressure reaches 60 cmH 2 O, or inflate with the volume of air to not exceed the maximum recommended volume. We prospectively assessed the correlation of cuff inflating volumes and pressures, and the appropriated the cuff inflating volumes to generate an intracuff pressure of 60 cmH 2 O in the adult laryngeal masks from different manufacturers. Methods : Two groups of eighty patients requiring laryngeal mask size 3 and 4 during general anesthesia were randomized into 4 subgroups for each size of the laryngeal mask: Soft Seal ® (Portex ®), AuraOnce TM (Ambu ®), LMA-Classic TM (Teleflex ®) and LMA-ProSeal TM (Teleflex ®). After insertion, the cuff was inflated with 5-ml increments of air up to the maximum recommended volume. After each 5-ml intracuff pressure was measured, the volume of air that generated the intracuff pressure of 60 cmH 2 O was recorded . Results : Mean(SD) volume of air required to achieve the intracuff pressure of 60 cmH 2 O in Soft Seal ® , AuraOnce TM , LMA-Classic TM , LMA-ProSeal TM laryngeal mask size 3 were 11.80(1.88), 9.20(1.88), 8.95(1.50) and 13.50(2.48) ml, respectively, and these volumes in laryngeal mask size 4 were 14.45(4.12), 12.55(1.85), 11.30(1.95) and 18.20(3.47) ml, respectively. The maximum recommended volume resulted in high intracuff pressures (>60 cmH 2 O) in all laryngeal mask types and sizes studied.   Conclusion : Pressure-volume curves of adult laryngeal masks are all in sigmoidal shape. Cuff designs and materials can effect pressure and volume correlation. Approximately half of the maximum recommended volume is required to achieve the intracuff pressure of 60 cmH 2 O except LMA-ProSeal TM which required two-thirds of the maximum recommended volume. Trial registration: Thai Clinical Trials Registry, TCTR20150602001, May 28, 2015

Background

The laryngeal mask hyperinflation related complications range from sore throat to more serious complications such as paralysis of the vocal cord, arytenoid cartilages dislocation, recurrent laryngeal nerve injury and hypoglossal nerve injury [1-6]. The manufacturers recommend inflating the laryngeal mask cuff until the intracuff pressure reaches 60 cmH_2O or to inflate with the volume of air not exceeding the maximum recommended volume (size 3, 20 ml; size 4, 30 ml) if a manometer is not available [7-11]. It is common practice to inflate the laryngeal mask cuff without using a manometer.

The studies of pressure–volume relationship in pediatric laryngeal masks show that approximately half the recommended maximum volume produced a laryngeal mask cuff pressure above the recommended pressure of 60 cmH_2O [12-14]. The previous study of size 4 LMA-ProSeal[TM] showed that inflation with a filling volume of 15-20 ml was the proper position and was optimal for ventilation without leakage [15]. Furthermore, inflation of size 4 LMA-ProSeal[TM] with the maximum recommended volume (30 ml) does not improve the seal pressure and may actually increase the risk of gastric insufflation [15]. However, they are only one adult model and pediatric laryngeal masks studies. There are few studies of cuff inflating volumes and pressures in different adult models of laryngeal mask.

The aims of this study were to assess the correlation of cuff inflating volumes and pressures, and to evaluate the cuff inflating volumes that generate an intracuff pressure of 60 cmH$_2$O in adult laryngeal mask (size 3 and 4) from different manufacturers which are made with varying cuff designs and materials.

Methods

This was a prospective randomized trial. The study was approved by the Ethics Committee of Faculty of Medicine Ramathibodi Hospital, Mahidol University (10-57-33). Written informed consent was obtained from each patient on the day before the operation. We studied 160 Thai patients who were scheduled for all types of surgery under general anesthesia with the laryngeal mask. The patients were older than 18 years of age, weighed 30-70 kg, ASA physical status I-III, and were NPO for 6 hours before the operation. Patients with any pathology of the neck, upper respiratory or upper alimentary tract, risk of aspiration, body mass index (BMI) > 30 kg. m^{-2} and predictors of difficult airway such as restricted mouth opening (< 3 cm of interincisor distance) were excluded. The patients were divided into 2 groups by actual body weight (30-50 kg for laryngeal mask size 3, 50-70 kg for laryngeal mask size 4) and then the patients in each group were randomized by computer into 4 subgroups of laryngeal mask type [Soft Seal® laryngeal mask (Portex® Smiths Medical International Ltd, Hythe Kent, UK); AuraOnce^{TM} laryngeal mask (Ambu® Inc Glen Burnie, MD, USA); LMA-Classic^{TM} (Teleflex® The Laryngeal Mask Company Ltd, Victoria, Seychelles); LMA-ProSeal^{TM} (Teleflex® The Laryngeal Mask Company Ltd, Victoria, Seychelles)] as Fig. 1 and sealed in opaque envelopes.

After standard monitoring such as electrocardiography, noninvasive blood pressure device and pulse oximeter were applied, general anesthesia was conducted with propofol 2.5 mg.kg^{-1} and fentanyl 1 mcg.kg^{-1} intravenously then the randomized laryngeal mask was inserted after the patient was full relaxation. The position of the inflated laryngeal mask was checked by assuring there was no air leakage and there was good chest movement when positive pressure ventilation was performed at an airway pressure of around 20 cmH$_2$O. After the laryngeal mask was fixed with adhesive tape and the vital signs were stable, the ventilation was stopped. The laryngeal mask cuff was fully deflated and connected with a closed system manometer which was composed of a three-way stopcock, 50 ml syringe and manometer (Cuff Inflator Pressure Gauge; VBM, Medizintechnik GmbH, Germany), as shown in Fig. 2. The laryngeal mask cuff was inflated with 5-ml increments of air up to the maximum recommended volume or until the intracuff pressure of 120 cmH$_2$O. After each 5-ml of intracuff pressure was measured and the inflating volume that generated intracuff pressure of 60 cmH$_2$O was recorded, in the end, all intracuff pressures were adjusted to 60 cmH$_2$O.

Statistical analysis

We performed a pilot study on 10 patients each with laryngeal mask size 3 and 4 (total of 20 patients) to find the mean of cuff inflation volume required to achieve the appropriate intracuff pressure of 60

cmH$_2$O. The standard deviation (SD) of cuff inflation volume in laryngeal mask size 3 and 4 was 2.2 ml and 2.26 ml, respectively. We defined the allowable error of volume to be 1 ml, with a 95 percent confidence interval and we worked under the assumption that all laryngeal mask has similar accuracy. The pilot study revealed that sample sizes for laryngeal mask size 3 and 4 are 19 and 20 samples respectively. Therefore sample sizes of each type of laryngeal mask included 39 samples, and the total samples sizes of the 4 types of laryngeal mask consisted of 156 samples. We included 160 patients to compensate for any possible dropouts.

Data were analyzed using SPSS software package version 18.0 (SPSS, Chicago, IL, USA). Mean and standard deviation (SD) were calculated for continuous variables such as age, weight, and height. Frequency and percentages were calculated for categorical variables such as sex and ASA physical status. Median, maximum-minimum values or interquartile range were calculated for discrete variables. The data were reported by different types and sizes of laryngeal mask. The relationship between cuff inflation volume and intracuff pressure in the laryngeal mask were fitted by linear regression line. Qualitative data were analyzed using Chi-square test, Fisher exact test and Monte Carlo test. Quantitative data were analyzed using Kruskal-Wallis H test. A p-value of less than 0.05 was indicated to be statistically significant.

Results

There were no failed insertion, dislodgement of laryngeal mask, airway obstruction or pulmonary aspiration during anesthesia; therefore, all patients enrolled in the study were included in the analysis. Patient characteristics and laryngeal mask size and type are shown in Table 1.

The volume of air generated the intracuff pressure in Soft Seal®, AuraOnce^{TM}, LMA-Classic^{TM}, LMA-ProSeal^{TM} laryngeal mask size 3 and 4 are shown in Table 2.

The laryngeal mask intracuff pressure-volume relationships are depicted in Table 2, Fig. 3 and Fig. 4. The pressure-volume graphs for each laryngeal mask size and type (Fig. 3,4) demonstrate the maximum pressure limits (60 cmH$_2$O) being exceeded well below the recommended maximum inflation volume; approximately half of the maximum inflation volume for each laryngeal mask resulted in pressures around 60 cmH$_2$O, except LMA-ProSeal^{TM} which required two-thirds of the maximum recommended volume.

Discussion

Pressure-volume curves of the four types of adult laryngeal mask are similar sigmoidal (S-shape) curves but they have different levels of pressure and volume correlations which may be caused by their cuff designs and materials. These result agree with the previous studies of pediatric laryngeal masks [12-13].

This study assessed pressure and volume correlation of adult laryngeal masks in the volume range as recommended by the manufacturer. Inflating the laryngeal mask from a fully deflated state to only approximately half to two-thirds of the recommended maximum volume caused the laryngeal mask cuff pressure to rise above the recommended pressure of 60 cmH$_2$O. This is in line with previous studies showing hyperinflation of the laryngeal mask cuff when applying the maximum recommended volume [10-15].

This study shows LMA-ProSeal^{TM} requires approximately two-thirds of the recommended maximum volume to achieve an intracuff pressure of 60 cmH$_2$O, but the other types require approximately half of the recommended maximum volume to achieve this pressure. So the type of laryngeal mask affects pressure and volume correlation due to cuff sizes, designs and materials.

In clinical practice, the intracuff pressure is not routine monitoring. Our results show that small volume of air which was inflated laryngeal mask cuff, it can easily generate high intracuff pressure.

Although the manufacturers suggest that the inflation volumes should not be above the maximum recommended volumes and an intracuff pressure of 60 cm H$_2$O can be achieved by the lower volumes [6-10], a lot of practitioners miss this concept. So, the manufacturer's recommendations should be emphasized that the manometer should be used to monitor the intracuff pressure to prevent excessive intracuff pressure and its complications.

In this study, we found some limitations. First, there were not an equal number of males and females. Female patients were more common. The results may be different in other groups studied.

Second, we used clinical signs for confirmation of laryngeal mask position based on there being no leakage during ventilation at an airway pressure of 20 cmH$_2$O and have good chest movement. It may be better if the fibreoptic assessment were used to confirm the position [15]. Nevertheless, our method is more common and it can be applied to the clinical practice.

Third, we did not study the minimum cuff inflation volume of laryngeal mask that achieves adequate ventilation. Further studies about this volume and intracuff pressure may be useful for cuff inflation technique.

Finally, this study measured the intracuff pressure but this pressure may not be transmitted pressure to adjacent mucosa in the pharynx and larynx. Further studies using microchip sensors attached to laryngeal mask surfaces for measuring transmitted pharyngeal mucosal pressure may be beneficial [16].

Conclusion

Pressure-volume curves of adult laryngeal masks are all in sigmoidal shape. Cuff designs and materials can effect pressure and volume correlation. Approximately half of the maximum recommended volume is required to achieve an intracuff pressure of 60 cmH2O except Proseal LMA which required two-thirds of

the maximum recommended volume. However, the manometer should be used to guide inflation in adult LMA if the inflation volume is higher than that mentioned above or use LMA with cuff pressure pilot valve which enables user to monitor the intracuff pressure.

Abbreviations

ASA: American Society of Anesthesiologists; NPO: nil per os; LMA: Laryngeal mask airway

Declarations

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

All authors were responsible for the conception and design of the study. NR, JW and SJ were responsible for collection of data. RK analyzed and interpreted data. NR and SJ drafted the manuscript and approved the final version. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, Chairperson Prof. Pratak O-Prasertsawat, EC number 10-57-33 on October 22, 2014. Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Disclosure

The preliminary results of this study were presented at the following congresses: Asian and Oceanic Society of Regional Anesthesia and Pain Medicine (AOSRA-PM) Congress combined with Annual Meeting of the Royal College of Anesthesiologists of Thailand 2015 Jan 22-24, Bangkok, Thailand and World Airway Management Meeting (WAMM) 2015 Nov 12-14, Dublin, Ireland.

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Tables

Table 1 Characteristics of patients receiving the four types of laryngeal mask.

Laryngeal mask		Soft Seal® (n=20)	AuraOnce™ (n=20)	LMA-Classic™ (n=20)	LMA-ProSeal™ (n=20)	p value
Size 3	Age (years)	44.2 (16.08)	41.15 (15.90)	47.25 (20.30)	52.65 (17.31)	0.203
	Male/Female, n	1/19	1/19	0/20	0/20	>0.999
	Body weight (kg)	47.4 (3.39)	47.6 (2.85)	47.65 (3.27)	49.55 (4.37)	0.703
	Height (cm)	155.3 (3.16)	155.8 (5.38)	154.4 (4.89)	154.4 (5.43)	0.741
	BMI ($kg.m^{-2}$)	19.67 (1.58)	19.65 (1.54)	20.03 (1.7)	20.82 (1.96)	0.112
	ASA physical status, n (%)					0.188
	1	11 (55%)	11 (55%)	7 (35%)	8 (40%)	
	2	8 (40%)	8 (40%)	10 (50%)	5 (25%)	
	3	1 (5%)	1 (5%)	3 (15%)	7 (35%)	
Size 4	Age (years)	50.10 (11.85)	52.4 (14.16)	55.75 (13.85)	52.1 (15.98)	0.645
	Male/Female, n	1/19	1/19	2/18	6/14	0.078
	Body weight (kg)	62.7 (6.17)	59.2 (5.85)	62.6 (7.17)	59.05 (5.51)	0.093
	Height (cm)	157.4 (5.83)	155.5 (5.72)	159.75 (5.37)	160.45 (5.84)	0.029*
	BMI ($kg.m^{-2}$)	25.34 (2.59)	24.51 (2.4)	24.54 (2.72)	23.03 (2.84)	0.054
	ASA physical status, n (%)					0.409
	1	8 (40%)	4 (20%)	9 (45%)	5 (25%)	
	2	9 (45%)	13 (65%)	8 (40%)	10 (50%)	
	3	3 (15%)	3 (15%)	3 (15%)	5 (25%)	

Data are presented as mean (SD) unless stated otherwise.

Table 2 Cuff volume and pressure at different values.

Laryngeal mask			Soft Seal® (n=20)	AuraOnce™ (n=20)	LMA-Classic™ (n=20)	LMA-ProSeal™ (n=20)
Size 3	Cuff pressure at (cmH$_2$O)	5 ml	24.90 (4.78)	27.85 (10.54)	33.10 (10.81)	17.75 (7.42)
		10 ml	50.40 (9.94)	72.20 (22.40)	72.80 (13.05)	43.15 (10.21)
		15 ml	89.55 (16.81)	109.0 (14.58)	113.60 (12.36)	76.65 (18.51)
		20 ml	115.85 (90.90)	120.0 (0.00)	120.0 (0.00)	107.40 (15.81)
	Cuff volume at (ml)	60 cmH$_2$O	11.80 (1.88)	9.20 (1.88)	8.95 (1.50)	13.50 (2.48)
Size 4	Cuff pressure at (cmH$_2$O)	5 ml	22.55 (9.13)	23.20 (7.10)	24.15 (5.79)	14.55 (4.30)
		10 ml	43.80 (13.63)	46.20 (10.97)	53.95 (9.64)	29.70 (8.78)
		15 ml	68.15 (20.89)	84.65 (17.35)	88.15 (18.49)	49.10 (11.77)
		20 ml	96.60 (25.01)	116.21 (10.20)	113.0 (13.04)	76.45 (20.42)
		25 ml	106.71 (19.73)	120.0 (0.00)	120.0 (0.00)	104.25 (16.99)
		30 ml	-	-	-	114.82 (5.23)
	Cuff pressure at (ml)	60 cmH$_2$O	14.45 (4.12)	12.55 (1.85)	11.30 (1.95)	18.20 (3.47)

Data are presented as mean (SD).

Figures
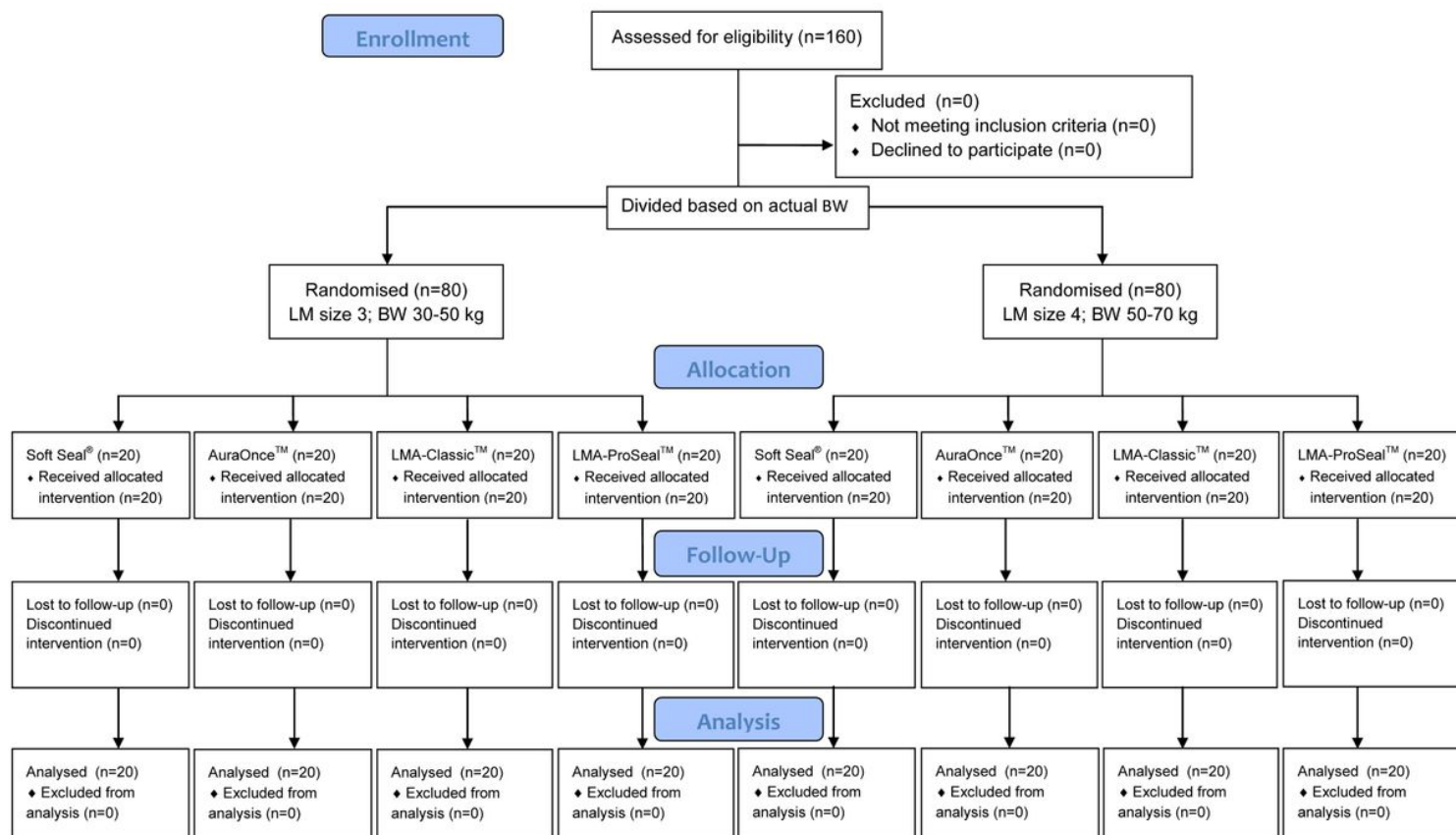
Figure 1

CONSORT Flow Diagram; LM = laryngeal mask.
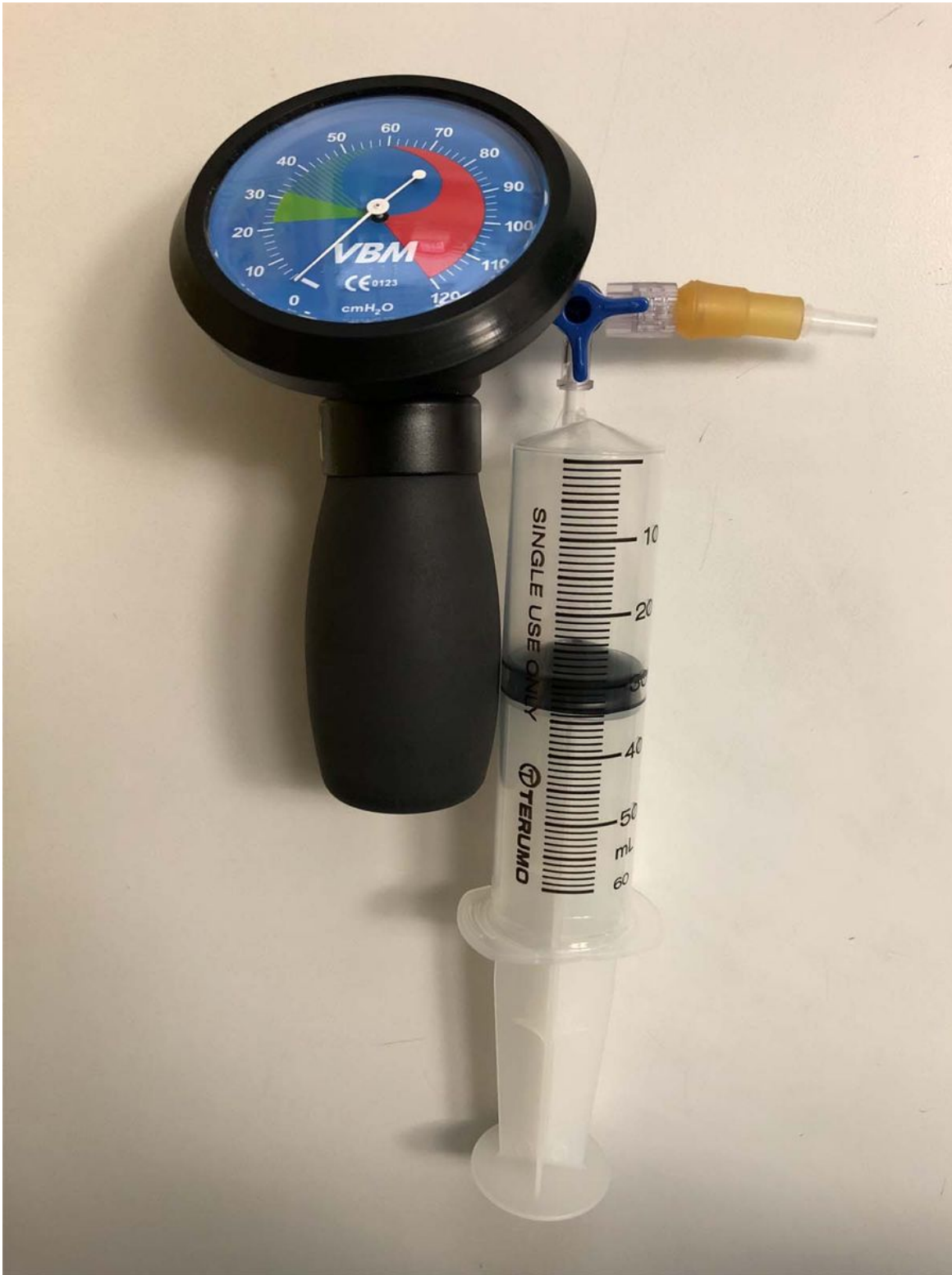
Figure 2

Closed system manometer.
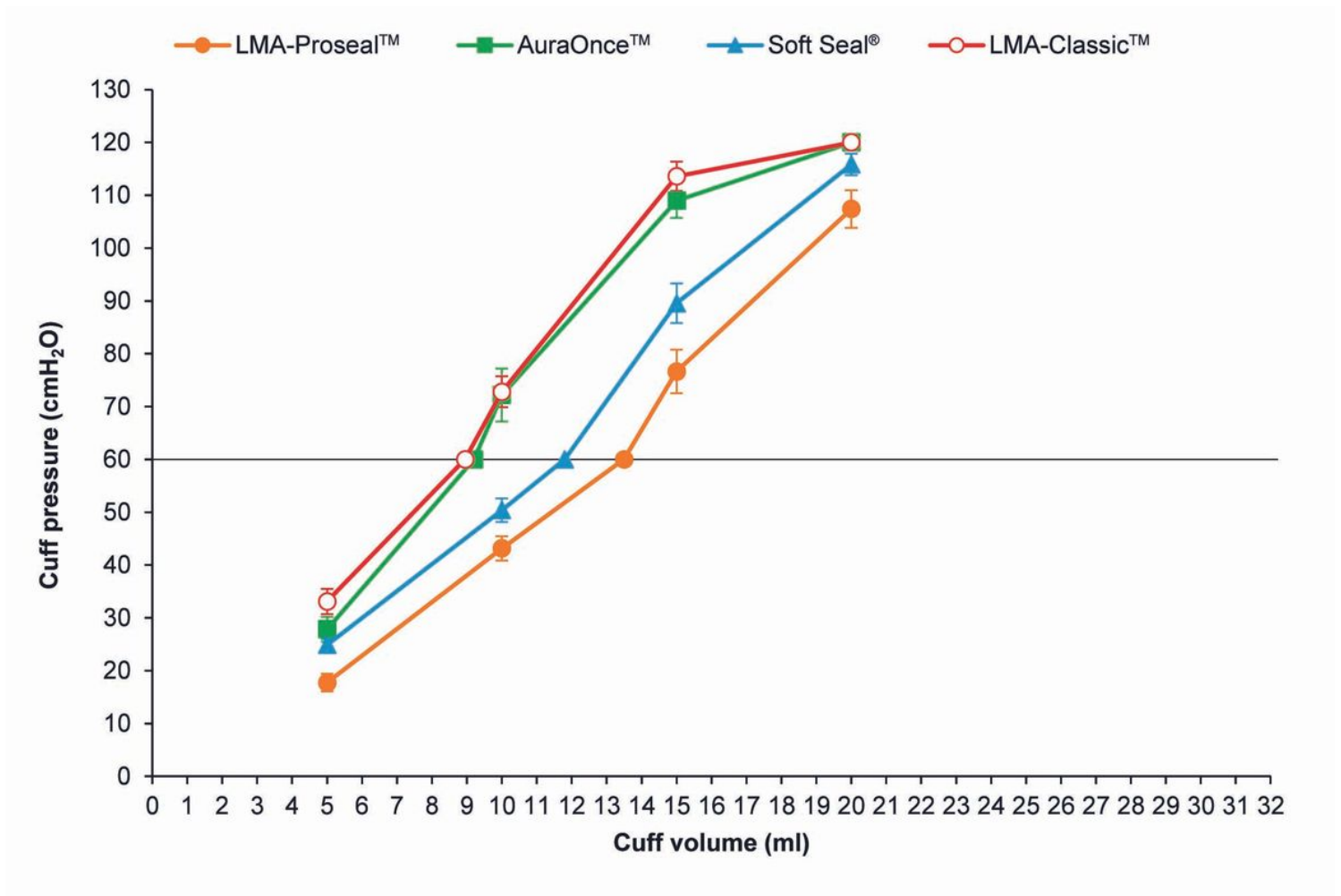
Figure 3

Pressure-volume curves for the four types of laryngeal mask size 3.
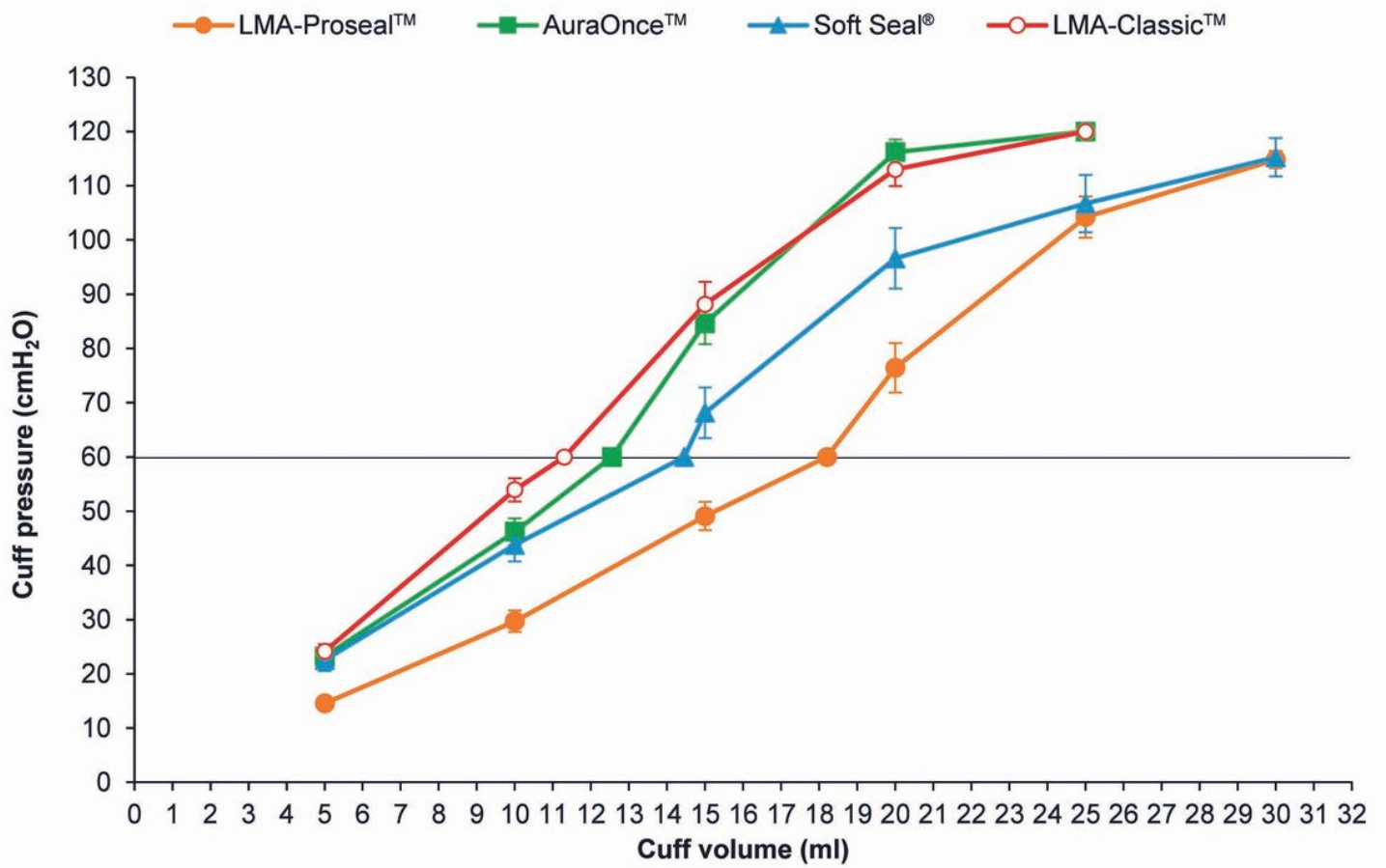
Figure 4

Pressure-volume curves for the four types of laryngeal mask size 4.