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Intraoperative cuff pressure measurements of supraglottic airway devices in the operating theatre : a prospective audit

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Abstract : *Introduction :* Supraglottic airway devices (SADs) are used for airway management for an estimated half of surgical patients worldwide in preference to endotracheal tubes. Intracuff pressure ($P_{INTRACUFF}$) measurement of SADs, is a monitoring parameter that may be overlooked in daily anesthetic practice. Correct intracuff pressures, with a recommended range of 40 to 60 cmH_2O, are important from a clinical perspective to ensure adequate ventilation and to avoid complications due to cuff hypoinflation or hyperinflation. $P_{INTRACUFF}$ may be measured with a dedicated measuring device or by widely used estimation techniques such as manual palpation of the cuff, listening to the disappearance of an audible air leak or injection of a standard volume of air into the cuff via the pilot balloon. These estimation methods do not allow quantification of the $P_{INTRACUFF}$ value to ensure an exact value at the recommended level.

Methods : A prospective single-centre audit of $P_{INTRACUFF}$ of 191 elective and emergency surgery patients with an SAD was performed measuring $P_{INTRACUFF}$ values with a calibrated handheld cuff manometer following induction of anesthesia.

Results : At the commencement of surgery, only 38.2% of the patients had a $P_{INTRACUFF}$ within the recommended range, with measurements exceeding the upper limit of 60 cmH_2O for 62 patients (32.5%). While 29.3% showed values of underinflation, patients who had a size 4 SAD were 3 times more likely to have a $P_{INTRACUFF}$ less than the lower limit of 40 cmH_2O, compared to patients with a size 5 SAD (P=0.012). Patients who had a silicone SAD were 2.8 times more likely to have an inadequate $P_{INTRACUFF,}$ compared to Polyvinyl Chloride SADs.

Conclusions : Our results confirm the need for accurate measurement of SAD $P_{INTRACUFF}$ using a cuff manometer to provide exact intracuff pressure measurements instead of subjective methods.

Key words : Supraglottic airway devices ; extraglottic airway devices ; laryngeal mask airway ; airway management ; monitoring-cuff pressure.

Introduction

Supraglottic airway devices (SADs) have provided effective airway management for millions of patients since their introduction 30 years ago (1). Morbidity has been associated with cuff overinflation (2) and underinflation (3, 4). Optimal occlusive intracuff pressure ($P_{INTRACUFF)}$ should read between 40 and 60 cmH_2O for SADs (5-16). Although a cuff manometer can accurately measure $P_{INTRACUFF}$, none of the national anesthesia associations around the world (ASA, AAGBI, DGAI, ANZCA) have produced guidelines that include mandatory intraoperative cuff pressure monitoring using a cuff manometer as routine practice (17). Manual palpation of the cuff, listening to the disappearance of an audible air leak or injection of a standard volume of air into the cuff via a pilot balloon are

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common practices, which do not guarantee optimal $P_{INTRACUFF}$.

$P_{INTRACUFF}$ has been demonstrated to increase over time, as a result of increased temperature and permeability of inhalational gases including nitrous oxide (18). This phenomenon is more pronounced in silicone SADs as compared to polyvinyl chloride (PVC) SADs (19). Movement and changes to head positioning may also influence the $P_{INTRACUFF}$ (20-22). Thus, accurate $P_{INTRACUFF}$ measurement should not only be performed immediately post-insertion of the SAD, but also throughout the duration of maintenance anesthesia as $P_{INTRACUFF}$ may increase with time. Manufacturers of SADs provide information regarding the maximum cuff inflation volume (30-60 mL) and/or pressure required, either on the SAD device itself, on the sterile package or on the pilot balloon. $P_{INTRACUFF}$ volume differs substantially among SADs, depending on the device, brand, the patient's anatomy and the depth of anesthesia.

The aim of this study was to measure the $P_{INTRACUFF}$ after insertion of a range of SADs using various estimation techniques among surgical patients and to compare these values with recommended evidence-based standard monitoring devices.

Methods

Approval for exemption from full ethical review by the Human Research Ethics Committee (The Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia ; HREC/14/QRBW/186 ; Chairperson : Dr C. Brophy) was obtained prior to inclusion of patients. This study was a single-centre prospective audit of 191 patients undergoing elective or emergency surgery during general anesthesia without the use of nitrous oxide and with a SAD for airway management at a quaternary referral hospital. The cuffed SAD was inflated using subjective methods at the discretion of the anesthesia team. $P_{INTRACUFF}$ values were measured with a calibrated handheld Portex® manometer (Smith Medical, Hythe, UK) by the same research nurse, not aware of the used cuff inflation technique, for all patients following induction of anesthesia. A disposable three-way valve was attached to the cuff pressure manometer to prevent cuff deflation upon measurement. $P_{INTRACUFF}$ values were documented, together with height, weight, body mass index (BMI), age, sex, duration and urgency of surgery, mask type, and method of cuff inflation. In the case of the $P_{INTRACUFF}$ value being outside of the recommended standard range, the anesthesiologist was informed and the $P_{INTRACUFF}$ was adjusted at the anesthesiologist's discretion. The cuffed SADs tested in this study were devices that are normally used in clinical practice within the institution, at the discretion of the attending anesthesiologist and included the LMA-Classic®, LMA-Flexible®, LMA-Supreme®, LMA-ProSeal® and LMA-Protector® (Telefex™ Medical, Athlone, Ireland). Non-cuffed SADs were excluded from this study.

The choice of agents during induction and maintenance of anesthesia was left to the discretion of the anesthesiologist, although no nitrous oxide was administered in this study.

Patient demographic and clinical characteristics were summarized using mean (± SD) and proportion statistics. $P_{INTRACUFF}$ values were categorised into three patient groups : <40 cmH_2O, 40-60 cmH_2O and >60 cmH_2O.

Statistical Analysis

To achieve 80% power with 5% level of significance, a minimum of 186 patients were required to reject the null hypothesis that the observed mean $P_{INTRACUFF}$ of 54.6 cmH_2O (SD 26.4 cmH_2O) (based on a pilot study) in SADs was not different from the recommended mean $P_{INTRACUFF}$. We included 191 patients in this study.

Patient demographic and clinical characteristics were compared between the three patient groups using Chi-square and Kruskal-Wallis test statistics applied for categorical and continuous data as appropriate. Adjusted odds ratios (95% CI) of the $P_{INTRACUFF}$ were calculated for SAD size and type using multinomial logistic regression where $P_{INTRACUFF}$ was categorised into three groups. Selection of the SAD size and type for the multivariable analysis was based on statistical significance with a p-value <0.05 observed in the univariate analysis. Data were entered into Microsoft Excel and all the analyses were performed using SPSS (IBM Corp. released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY : IBM Corp.).

Results

SAD $P_{INTRACUFF}$ was measured for 191 patients and the demographic and clinical profiles of patients were tabulated (see Table 1). There was only one patient who had been categorised as an ASA (American Society of Anesthesiologists physical status) category of 4 and 67, 83 and 40 patients were categorised as ASA 1, 2 and 3 respectively. All patients had a SAD in situ, with the patient's head positioned in the neutral position.

Table 1

Patient characteristics and supraglottic airway device (SAD) size and type for different SAD $P_{INTRACUFF}$ groups

		SAD $P_{INTRACUFF}$ n = 191			
	$P_{INTRACUFF}$ Mean	**<40 cmH_2O (n=56) (29.3%)**	**40-60 cmH_2O (n=73) (38.2%)**	**>60 cmH_2O (n=62) (32.5%)**	**p-value**
Age (years), mean±SD	45.5±17.5	43.3±17.0	44.8±17.5	48.3±17.7	0.270
Gender, n (%)					
Male		27 (25.0)	44 (40.7)	37 (34.3)	0.326
Female		29 (34.9)	29 (34.9)	25 (30.1)	
BMI (kg/m²), mean±SD	27.0±6.1	26.3±5.5	27.2±5.4	27.3±7.3	0.615
Urgency of Surgery, n (%)					
Elective		54 (30.0)	70 (38.9)	56 (31.1)	0.288
Emergency		2 (18.2)	3 (27.3)	6 (54.5)	
Duration of Surgery, n (%)					
≤1 hour		35 (34.0)	37 (35.9)	31 (30.1)	0.309
1+ hours		21 (23.9)	36 (40.9)	31 (35.2)	
SAD Size, n (%)					
3		3 (27.3)	5 (45.5)	3 (27.3)	0.028
4		42 (38.2)	36 (32.7)	32 (29.1)	
5		11 (15.7)	32 (45.7)	27 (38.6)	
SAD Cuff Type, n (%)					
Silicone		27 (33.3)	36 (44.4)	18 (22.2)	0.039
PVC		29 (26.4)	37 (33.6)	44 (40.0)	
Cuff Inflation Evaluation Method[a], n (%)					
Both Tactile & Auditory		0	3 (42.9)	4 (57.1)	0.462
Only Auditory		44 (30.3)	58 (40.0)	43 (29.7)	
Only Tactile		4 (22.2)	6 (33.3)	8 (44.4)	
Others		7 (35.0)	6 (30.0)	7 (35.0)	

[a] Method of cuff pressure estimation has one missing value

Eighty-one patients received a silicone SAD and 110 patients received a PVC SAD. One hundred and ten (57.6%) patients received an LMA-Supreme® whilst 45 (23.6%) had an LMA-Classic®, 29 (15.2%) had an LMA-Protector® and 7 (3.7%) had an LMA-ProSeal®.

Following induction of anesthesia with a cuffed SAD, the median $P_{INTRACUFF,}$ as measured by an independent research nurse, was 50.0 cmH_2O (IQR 36.0-70.0), whilst the mean $P_{INTRACUFF}$ was 55.6 cmH_2O (± SD 28.2). Seventy-three patients (38.2%) had an $P_{INTRACUFF}$ within the recommended standard range (40-60 cmH_20), 56 patients (29.3%) showed cuff values indicating underpressure (< 40 cmH_20), while overpressure (>60 cmH_20) was noticed in 62 patients (32.5%). Forty-five (40%) patients with an LMA-Supreme® had a $P_{INTRACUFF}$ exceeding 60 cmH_2O, whilst 40% with an LMA-Classic® had a $P_{INTRACUFF}$ less than 40 cmH_2O.

Eleven patients received a size 3 SAD (5.8%), 110 received a size 4 (57.6%) and 70 received a size 5 SAD (36.6%). Based on calculated adjusted odd ratios (95%CI), p-values of $P_{INTRACUFF}$ for (<40, 40-60, & >60 cmH_2O) by SAD size and type, patients who had a size 4 SAD had an odds ratio of 3.0 (95% CI : 1.3, 6.9) for having a $P_{INTRACUFF}$ less than 40 cmH_2O compared to patients who had a size 5 SAD (p-value 0.012). SAD size and type did not significantly influence the $P_{INTRACUFF}$ when the latter remained within the recommended standard range.

There was a significant association between SAD type and $P_{INTRACUFF}$ (p=0.039). Lower $P_{INTRACUFF}$ values (< 40 cmH_20) were 2.8 times (95% CI : 1.2, 6.8) more likely seen in silicone SADs (LMA-Classic®, LMA-Protector® or LMA-ProSeal®) compared to PVC SADs, i.e. LMA-Supreme® (p-value 0.02). Furthermore, there was no difference between silicone and PVC SADs with a $P_{INTRACUFF}$ exceeding 60 cmH_2O.

To evaluate the adequacy of manual SAD cuff inflation after induction, the anesthesia team only used the auditory method among 76.3% of patients, the tactile method in 9.5% of patients, both tactile and auditory methods in 3.7% of patients, while the injection of a fixed volume of air was used in 10.5% of patients. None used a manometer to measure the $P_{INTRACUFF}$ at induction, as they were not routinely available in the operating room.

Discussion

This study shows that, after induction of general anesthesia with a cuffed SAD, only 38.2% of patients had an $P_{INTRACUFF}$ within the recommended

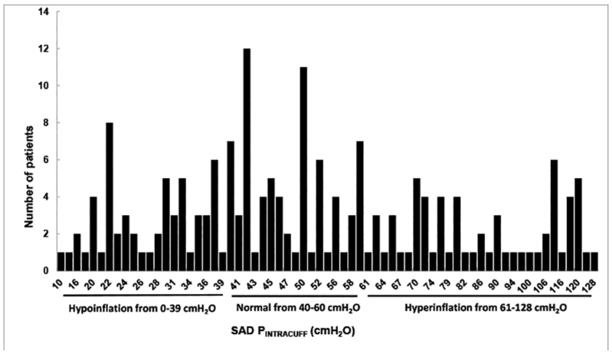

Fig. 1. — Incidence and level of P$_{INTRACUFF}$ in the tested supraglottic airway devices.

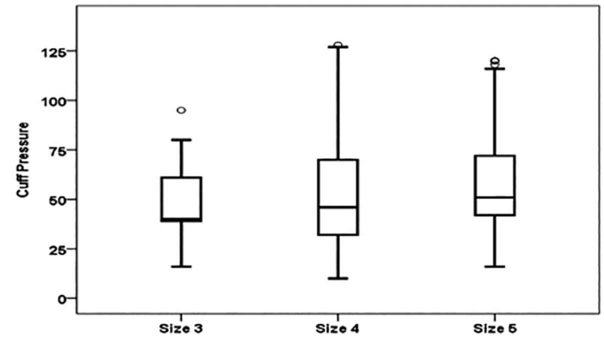

Fig. 3. — Supraglottic airway device P$_{INTRACUFF}$ for different cuff sizes.

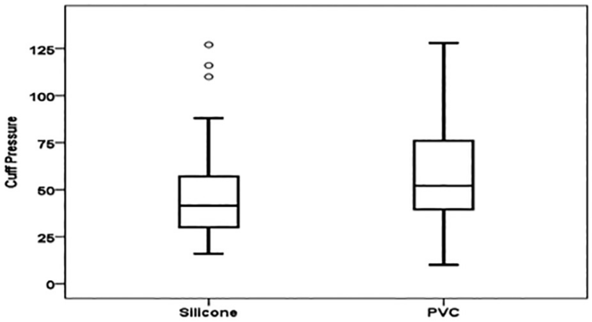

Fig. 2. — Supraglottic airway device P$_{INTRACUFF}$ for different types of cuff material.

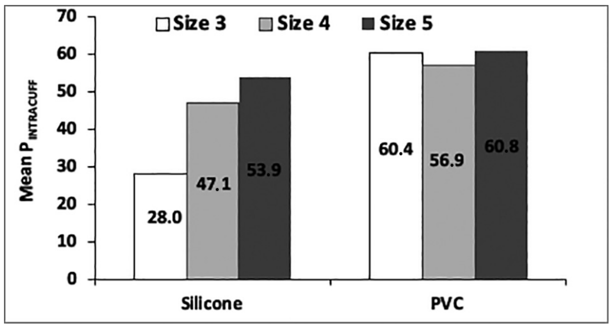

Fig. 4. — Mean supraglottic airway device (SAD) P$_{INTRACUFF}$ for different sizes of silicone versus PVC SADs.

standard range (40-60 cmH$_2$0), while 29.3% of the cuffs were hypoinflated and 32.5% exceeded the recommended maximum 60 cmH$_2$0. This clearly demonstrates the failure of manual estimation methods of SAD cuffs within the recommended cuff pressures and indicates the need for standard measurement with cuff manometers.

Pharyngolaryngeal adverse events following anesthesia, although mild and short-lived in most cases, can potentially cause significant distress and trauma to patients and compromise the overall anesthetic experience for a patient. There are no clinical guidelines in anesthesia that currently specify the routine use of manometry to measure SAD P$_{INTRACUFF}$ intraoperatively, neither in Australia, nor in other scientific societies. Therefore, we urge national anesthesia associations to consider mandatory monitoring of intracuff pressure of supraglottic airway devices during anesthesia to protect our patients from harm due to cuff under- and overpressure.

In contrast to previous studies, lower P$_{INTRACUFF}$ values (< 40 cmH$_2$0) were 2.8 times (95% CI : 1.2, 6.8) more likely seen in silicone SADs (LMA-Classic® or LMA-ProSeal®) compared to PVC SADs, i.e. LMA-Supreme® (p-value 0.02). Many studies showed a substantial increase in cuff pressure when nitrous oxide was used. We omitted the use of nitrous oxide in this study, which may explain the results in our study.

The relationship between mucosal pressure and SAD P$_{INTRACUFF}$ is complex, as the pharynx is a highly distensible structure, which is normally subject to large transient pressure changes and distortion under many physiological conditions. In the studies by Seet *et al.* and Burgard *et al.*, the incidence of composite pharyngolaryngeal complications was 70% lower with SAD P$_{INTRACUFF}$ below 44 mmHg (9, 23). This is equivalent to 60 cmH$_2$O and it is the critical perfusion pressure of the pharyngeal mucosa. Although manufacturer guidelines for SADs have a specified maximum recommended inflation volume, the use of this maximum volume has been shown to be associated with a high risk of hyperinflation and an increased leakage around the SAD cuff (24-26).

Reports of cranial nerve injuries (27-34), recurrent laryngeal nerve injuries (35-38), and lingual nerve paralysis (39-42) suggest that these complications are secondary to pressure neuropraxia from SADs. Furthermore, a case of pharyngolaryngeal rupture, pneumomediastinum and widespread subcutaneous emphysema extending from the cervical region to the anterior abdominal wall has been reported in the literature where there was no difficulty experienced with insertion (43). Although serious complications are rare, the incidence of a postoperative sore throat remains significant at up to 50% (6, 44, 45) and dysphagia or dysphonia (45) may result. The incidence of pulmonary aspiration of gastric contents with an SAD is estimated to be 0.02% (46) which is similar to tracheal intubation in elective patients (46, 47). This incidence can be affected by the choice of SAD size, insertion technique, incorrect positioning of the SAD and more importantly, an inappropriate $P_{INTRACUFF}$ (6). Previous studies suggest that there is little difference in the incidence of a postoperative sore throat between first and second generation SADs, with the exception of the i-gel® with a reported lower incidence, possibly due to the absence of an inflatable cuff (48).

As no continuous cuff pressure measurements were performed during maintenance of anesthesia, no confirmation of a difference in increase in cuff pressure can be provided when using silicone vs PVC cuffed SADs. However, because nitrous oxide was not administered during anesthesia, literature confirms that the increase in cuff pressure during the maintenance phase is less likely going to increase substantially.

A particular limitation of this study is that the intracuff pressure was measured only once following induction of anesthesia, so that fluctuations in pressure by changes in head positioning and changes in the depth of anesthesia, as well as the warming up of gases within the cuff during the maintenance of anesthesia, resulting in an increased $P_{INTRACUFF}$ are not taken into account. It is reasonable to assume that the pressure reported is not representative of the whole period of anesthesia. No adverse events relating to airway trauma were reported in the post-operative period, since the $P_{INTRACUFF}$ was adjusted accordingly when measured to be outside the recommended standard range after induction of anesthesia.

Furthermore, data such as the ventilation mode, volume of air used if this technique was utilised, exact duration of surgery and the presence of blood on the SAD were not recorded, as the aim of this study was to define the range of $P_{INTRACUFF}$ values seen in a setting without the use of routine objective monitoring. Methods of SAD insertion and whether the SAD was fully deflated, partially inflated or completely inflated prior to insertion were not standardised and left to the discretion of the attending anesthesiologist. This could have had more impact on the incidence of adverse events rather than the $P_{INTRACUFF}$ value itself.

Further study is required to include the impact of positive pressure ventilation, as well as measuring cuff pressures at different time points during surgery to accommodate changes in patient position, the depth of anesthesia and the temperature of anesthetic gases over time. This would provide a more complete view of the role of SAD cuff pressures and their contribution to provision of safe anesthetic practice.

Conclusions

$P_{INTRACUFF}$ should be routinely measured using a cuff manometer, to maintain the recommended evidence-based standard with a clear potential of improving patient safety and reducing the risk of adverse events of pressure injury to the airway and sore throat. Our study shows the lack of reliability for the use of subjective estimation methods for achieving the required adequate and safe range of intracuff pressures for SADs.

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