# Laryngeal Mask Airway Cuff Pressure Manometry to Reduce Postoperative Sore Throat

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**Abstract**

**Problem**: Anesthesia providers in the selected organization found that postoperative sore throat was a common patient complaint after the use of a laryngeal mask airway during general anesthesia and estimated its incidence to be approximately 40%.

**Purpose**: The purpose of this evidence-based quality improvement project was to implement manometer use by anesthesia providers on patients undergoing general anesthesia with a laryngeal mask airway and evaluate its effectiveness in reducing the incidence of postoperative sore throat.

**Methods**: Anesthesia providers were educated to manometer use as well as the impact of cuff overinflation on the incidence of postoperative sore throat. Manometers were placed in both anesthesia workrooms for ease of access. Anesthesia providers using a laryngeal mask airway for general anesthesia were encouraged to obtain a manometer to measure and limit cuff pressures to 60 $cmH_2O$ after insertion. Following cuff pressure measurements, providers documented values on the data collection tool and exchanged it with the recovery room nurse during post-anesthesia handoff. Recovery room nurses followed up with patients about the presence of postoperative sore throat prior to discharge, recorded “yes” or “no” on the data collection tool, and placed it in the anesthesia box on the main desk for collection.

**Results**: Amongst the cuff pressures that were measured with a manometer, 100% of cuff pressures were adjusted to the recommended range of < 60 $cmH_2O$, as evidenced by documentation on the data collection tool. Among the data collected, the average percentage of patients who denied postoperative sore throat after manometer use was 80.6%.

**Conclusions**: When a manometer was used to measure and limit laryngeal mask airway cuff pressures to 60 $cmH_2O$ or less, a large percentage of patients denied postoperative sore throat upon hospital discharge. This suggests that the use of a manometer intraoperatively helped reduce the incidence of postoperative sore throat.

## Introduction

The laryngeal mask airway (LMA) is a supraglottic airway device that allows the anesthesia provider to maintain adequate ventilation in patients requiring general anesthesia. Typically, the LMA has an inflatable cuff, which creates a seal when inflated, allowing the LMA to seat and adequate ventilation to occur. However, the pressure exerted on the pharyngeal mucosa by an overinflated cuff can cause decreased pharyngeal mucosal perfusion, leading to postoperative sore throat (POST) (Wong et al., 2013). LMA cuff overinflation may result in additional complications such as hoarseness, dysphagia, dysphonia, and in rare instances, recurrent laryngeal nerve palsy (Bick et al., 2014; Xu, Lian, & Li, 2016). Per manufacturer recommendation, a manometer should be used to limit LMA cuff pressures below 60 $cmH_2O$ (Teleflex, 2016). Although there are manufacturer recommendations in addition to a large body of evidence that supports the routine use of manometry to prevent LMA cuff overinflation, it is still not routine practice. Some studies reported LMA cuffs being overinflated approximately 70% of the time (Bick et al., 2014). This is significant considering approximately 40% to 50% of patients report POST after an LMA is used during general anesthesia (Bick et al., 2014; Seet et al., 2010; Waruingi et al., 2019). Currently, there is no policy at this organization requiring the quantitative measurement of LMA cuff pressures. Anesthesia providers at this organization do not currently measure intraoperative LMA cuff pressures. However, providers in the selected organization agreed that POST is a common complaint after the use of an LMA during general anesthesia and estimate the POST incidence to be approximately 40% of patients. The purpose of this evidence-based quality improvement project was to implement intraoperative LMA cuff manometry by anesthesia providers at a small acute care community hospital and evaluate its effectiveness in reducing the incidence of postoperative sore throat.

## Evidence Review

This evidence review provides a synthesis of the evidence supporting manometer use by the anesthesia provider to decrease the incidence of POST. The review includes studies that support intraoperative manometer use when an LMA is used for general anesthesia, to measure and prevent cuff overinflation, and subsequently decrease the incidence of POST. The quality of the evidence was evaluated using Melnyk and Fineout-Overholt's (2014) level of evidence rating system and Newhouse's (2007) quality of evidence rating system (Tables 1 & 2). The studies included in the evidence review seen in Table 1 were all Level II studies and randomized controlled trials. In addition, all studies were double-blinded except the study conducted by Waruingi et al. (2019), which was a prospective single-blinded study. The quality of the studies, seen in Table 2, were rated as either A or B quality ratings. All studies had similar inclusion and exclusion criteria and all studies assessed the quantitative measurement of LMA cuff pressures and its effect on reducing the incidence of POST. Two major themes identified amongst the evidence review were (1) the use of a quantitative tool to measure and adjust LMA cuff pressures to the recommended range of 60 $cmH_2O$ in an attempt to reduce the incidence of POST and (2) examination of the effect of reducing cuff pressures even further than the established recommendation to evaluate any further effectiveness on reducing POST.

The first theme examined the use of a quantitative tool to measure and adjust LMA cuff pressures to the recommended limit of 60 $cmH_2O$ in an attempt to reduce the incidence of POST. The quantitative measurement of LMA cuff pressures was established by all four studies reviewed as being superior to qualitative assessments. Wong et al. (2014) used a special cuff pilot valve that indicated whether or not the cuff was inflated within optimal ranges below 60 $cmH_2O$, while the other three studies used a manometer to quantitatively measure cuff pressures.

Across all studies, the incidence of POST was found to be significantly less in groups that had their cuff pressures limited to 60 $cmH_2O$ with a quantitative device, whether that be with a manometer or a specialized cuff pilot valve. Quantitative measurements gave providers the benefit of having exact cuff pressure measurements to prevent cuff overinflation above recommended range. Seet et al. (2010) found the incidence of POST to be 13.4% in the group that had a manometer used compared to a 45.6% incidence of POST when no manometer was used to adjust cuff pressures.

The second theme identified examined the effect of a further reduction of cuff pressures. The study conducted by Kang et al. (2014) examined reducing cuff pressures to 25 $cmH_2O$ instead of 60 $cmH_2O$ to assess POST. They found a significantly lower incidence of POST in the lower pressure group (6.1%) than the higher pressure group (24.5%). The study conducted by Waruingi et al. (2019) examined reducing cuff pressures to 30 to 32 $cmH_2O$ as compared to 60 $cmH_2O$ to evaluate its effect on reducing POST. They found that POST was significantly lower in the lower pressure group (25%) than the 60 cmH2O group (65%). Both studies utilized a manometer to measure and adjust cuff pressures to prevent overinflation, with the goal of reducing the incidence of POST.

## Theoretical Framework

Lewin's Change Theory is a middle range theory that explained the process necessary to implement the quantitative measurement of LMA cuff pressures by anesthesia providers at this small community hospital. Lewin's Change Theory is comprised of three stages: the unfreeze stage, the change stage, and the refreeze stage (Hussain et al., 2018). The unfreeze stage consisted of acknowledging that POST was a tangible problem for patients, education of anesthesia providers on the evidence that exists on how providers can alleviate this problem, acknowledging the need for change, and acknowledging any doubts and concerns

(Wojciechowski et al., 2016). The first step in any change process is acknowledgement that a problem exists. After anesthesia providers acknowledged that POST existed and was amenable to improvement, the education phase began. In this phase, providers were educated on how they, as individuals and as a team, could improve patient outcomes. Lewin's second stage, the change stage, is the action phase, which establishes the new standard of practice (Wojciechowski et al., 2016). It consisted of implementation of manometer use to prevent overinflation of LMA cuffs and addressed barriers to implementation. This phase took into account feedback from change champions to determine perceived barriers and areas of weakness. This allowed for adjustments and improvements to the implementation process that aimed for sustainability of the practice change. The refreezing stage, Lewin's third and final stage, consists of support and sustenance, as well as celebrating implementation successes (Wojciechowski et al., 2016). This stage examined the possible methods that could be used to sustain the intraoperative measurement of LMA cuff pressures amongst the entire anesthesia department. One sustainability effort agreed on by the anesthesia department was to incorporate an automatic pop-up prompt within the electronic charting system that required LMA cuff pressure documentation whenever an LMA was placed as an airway device.

## Methods

This practice change took place at a non-profit community hospital in Maryland. All adult patients over the age of 18 years undergoing general anesthesia with an LMA qualified for intraoperative manometer use. Exclusion criteria included pregnancy, body mass index (BMI) greater than 40 $kg/m^2$, a recent upper respiratory tract infection (URI), severe gastroesophageal reflex disease (GERD), symptomatic hiatal hernia, an American Society of Anesthesiologist (ASA) class of 4-6, and a positive COVID status.

This practice change was carried out by the anesthesia team, consisting of eight CRNAs and six anesthesiologists. Anesthesia providers were educated to the significance of POST, current recommendations for LMA cuff pressures, and how to use a manometer (Appendix A). Manometers were stocked in both anesthesia workrooms for ease of access per site recommendation. For each eligible patient, providers were encouraged to use a manometer to check a post-insertion cuff pressure on patients who had an LMA placed for general anesthesia and document the cuff pressure on the data collection tool (Figure 1) located in the manometer box. Once the patient was transported to the post-anesthesia care unit (PACU), the anesthesia provider informed the PACU nurse during handoff that the patient had their cuff pressures measured in the operating room (OR) and reminded PACU nurses to evaluate the patient for the presence of POST prior to discharge. This was done to evaluate the effectiveness of the intervention against the outcome measure of POST reduction.

The data collection tool was transferred with the patient from the OR to the PACU for documentation of the patient's response to POST absence or presence by the PACU nurse (Figure 2), and the tool was placed in the anesthesia box on the PACU desk for collection by the student nurse anesthetist (SRNA) and anesthesia office manager. At the conclusion of this quality improvement project, the collected data was analyzed, and the findings were presented back to project participants and stakeholders.

Structure measures included (1) education of anesthesia providers regarding how to attain optimal LMA cuff pressures to reduce the incidence of POST, (2) education of PACU nurses regarding the impact of LMA cuff overinflation on the incidence of POST, (3) location in the electronic health record (EHR) to document LMA cuff pressures, and (4) availability of manometers on site. Process measures included (1) the use manometers by anesthesia providers

to maintain LMA cuff pressures below 60 $cmH_2O$, (2) documentation of LMA cuff pressure measurements in the EHR, and (3) assessment of POST by PACU nurses in the postoperative phase of care. The outcome measure tracked during implementation was the incidence of POST reported by patients after undergoing general anesthesia with an LMA.

To protect the privacy of project participants, the data collection tool did not collect any patient identifiers. The only information used to match the patient's cuff pressure to their reporting of POST was the intraoperative cuff pressure documented on the collection tool. Education was provided at multiple points during the implementation period to reinforce learning and encourage more providers to participate in implementation. In addition, monthly updates with positive preliminary results was provided to the anesthesia team to encourage manometer use amongst providers. To analyze the data collected and the results of implementation, two run charts were created. The first run chart (Figure 3) examined the percentage of patients who denied POST after intraoperative manometer use. The second run chart (Figure 4) examined anesthesia provider compliance with recommended cuff pressures when a manometer was used.

## Results

The collected data were analyzed and displayed in a run chart format to assess trends over the course of the implementation period. Data trends assessed included presence or absence of POST over time amongst those who had their LMA cuff pressures measured with a manometer intraoperatively as well as the trend of LMA cuff pressures that were maintained below the recommended limit of 60 $cmH_2O$. Thirty one data points were collected and analyzed over the course of implementation. The occurrences of POST for September, October, and November were found to be 14.3%, 20% and 28.6% respectively, with an overall POST occurrence of 19.4%. This translated to 80.6% of patients denying the presence of POST after

manometer use. On an individual and collective basis, the numbers collected during implementation were lower than the POST incidence of 40-50% cited in the literature review. The number of LMA cuff pressures maintained below the recommended limit of 60 $cmH_2O$ remained 100% through the duration of implementation, suggesting that the education provided regarding recommended LMA cuff pressures was applied to clinical practice in the OR. With the original structure of the implementation plan, anesthesia provider compliance with manometer use was going to be collected and analyzed. However, due to the requirement that the data collection method be adjusted per site recommendation, provider compliance unable to be tracked. Lack of access to the electronic health record was a contributing factor, as well as the inability of the SRNA to conduct random observations during the clinical day.

A major barrier identified during implementation was the limited availability of manometer, as there were only two manometers at the site. After gathering input from multiple providers, it was found that participation in manometer use would have likely increased a great deal if one manometer was stocked in each OR. This would have eliminated providers having to remember to take the manometer from the anesthesia workroom before starting their case or remembering to call the anesthesia tech to bring the manometer to the room. Implementing mandatory EHR documentation was discussed as well to increase provider participation. However, it would only make sense to implement mandatory cuff pressure documentation if there was a manometer available in each OR for providers to use.

The use of a LMA with a COVID positive patient was unable to be assessed during implementation. Because it was preferred to prevent aerosolization of the virus, an LMA was never used with a COVID positive patient, due to the possibility of the LMA not creating a perfect airway seal and allowing aerosolization of the virus around and above the LMA. Even

though the surgical procedure and patient criteria may have been appropriate for the use of an LMA during general anesthesia, if the patient was COVID positive, the patient would be intubated with an endotracheal tube to decrease possible aerosolization of the virus for all members in the OR.

## Discussion

Across the literature, the average POST rate ranged from 40% to 50% after a LMA was used during general anesthesia (Bick et al., 2014; Seet et al., 2010; Waruingi et al., 2019). Implementation of manometer use at this organization resulted in a decrease in POST from an estimated 40% to an average of 19.4%, suggesting that the implementation of manometer use contributed to the decrease in POST rates. This reduction in POST was consistent with studies conducted by Seet et al. (2010) and Waruingi et al. (2019), which resulted in a POST incidence of 13.4% and 25% respectively in the cuff pressure limiting groups, compared to the control groups with POST incidences of 45.6% and 65% respectively.

In addition, when a manometer was used to measure and limit LMA cuff pressures, 100% of documented cuff pressures were maintained below 60 $cmH_2O$. The 100% provider compliance with recommended LMA cuff pressures suggests that provider education was successful in having providers adhere to optimal cuff pressure recommendations. In turn, providers who were educated to recommended LMA cuff pressures were able to use manometers appropriately to decrease the incidence of POST.

Variables that may have affected the incidence of POST during the implementation period include use of lidocaine gel for LMA insertion, administration of dexamethasone, and multiple insertion attempts. On multiple instances, the presence of POST was related to multiple

insertion attempts, as noted by the anesthesia provider on the data collection tool. These factors were not controlled for and were not used as inclusion or exclusion criteria for data collection.

## Conclusion

The implementation of manometer usage to limit LMA cuff pressures at this organization resulted in a decrease POST occurrence. As such, it would be beneficial to both patients and the organization to continue manometer use to prevent adverse patient outcomes such as POST. One major benefit to using a manometer to prevent POST is increased patient satisfaction, which leads to increased hospital patient satisfaction scores, a positive relationship with the patient, and future business with the patient and/or friends and family members. In addition, patients are less likely to require additional pain medication if POST can be avoided.

In collecting feedback regarding the quality improvement project, anesthesia providers acknowledged the role of manometer use in decreasing the incidence of POST and the ease of manometer use to limit LMA cuff pressures. In regards to sustainability, feedback from providers suggested that obtaining an appropriate number of manometers to stock the ORs would allow for increased manometer use. It was clear from the data collection that education regarding the manometer's role in decreasing POST was successful. Therefore, if education was retained, and the convenience of having one manometer stocked in each room was a possibility, there would be more providers using the manometer to limit LMA cuff pressures to their recommended range. In addition to making manometers more readily available, mandatory charting of cuff pressures would also increase sustainability of manometer use. As there is already a place in the EHR for documentation of LMA cuff pressures, the anesthesia team would simply work with IT to build in a prompt to remind providers to chart measured cuff pressures.

This would also allow for a quality improvement team to track the effectiveness of manometer use on reducing POST over a longer period of time.

If this quality improvement project can be sustained, there is the potential for future quality improvement projects at this organization using the manometer. For example, in the same way that a manometer can be used to prevent LMA cuff overinflation and reduce POST, it can also be used to prevent endotracheal cuff overinflation, which is also cited in the literature as a method to reduce POST as well.

**References**

Bick, E., Bailes, I., Patel, A., & Brain, A.I.J. (2014). Fewer sore throats and a better seal: why routine manometry for laryngeal mask airways must become the standard of care. *Anaesthesia*, *69*, p.1200-1313. https://doi.org/10.1111/anae.12902

Kang, J.E., Oh, C.S., Choi, J.W., Son, I.S., & Kim, S.H. (2014). Postoperative pharyngolaryngeal adverse events with laryngeal mask airway LMA Supreme) in laparoscopic surgical procedures with cuff pressure limiting 25 cmH2O: prospective, blind, and randomised study. *The Scientific World Journal*, 2014, p.1-7. doi: 10.1155/2014/709801

Melnyk, B.M. & Fineout-Overholt, E.E. (2015). Evidence-based practice in nursing and healthcare: a guide to best practice (3rd ed.). Wolters-Kluwer Health.

Newhouse, R.P. 2007. John Hopkins Nursing evidence-based practice model and guidelines. John Hopkins University.

Seet, E., Yousaf, F., Gupta, S., Subramanyam, R., Wong, D.T., & Chung, F. (2010). Use of manometry for laryngeal mask airway reduces postoperative pharyngolaryngeal adverse events. *Anesthesiology*, 112, p.652-657. DOI: 10.1097/ALN.0b013e3181cf4346

Teleflex. (2016). *LMA Cuff Pressure Monitoring*. Teleflex. https://www.teleflex.com/usa/en/product-areas/anesthesia/airway-management/lma-airways/product-literature/AM_SUP_Anesthesia-Cuff-Pressure-Monitoring-Review_AI_MC-001944.pdf

Waruingi, D., Mung'ayi, V., Gisore, E., & Wanyonyi, S. (2019). A randomised controlled trial of the effect of laryngeal mask airway manometry on postoperative sore throat in

spontaneously breathing adult patients presenting for surgery at a university teaching hospital. *African Health Sciences 19(1),* 1705-1715. doi: 10.4314/ahs.v19i1.47.

Wojciechowski, E., Pearsall, T., Murphy, P., & French, E. (2016). A case review: integrating Lewin's theory with lean's system approach for change. *The Online Journal of Issues in Nursing*, *21*(2). doi**:**10.3912/OJIN.Vol21No02Man04

Wong, D.T., Tam, A.D., Mehta, V., Raveendran, R., Riad, W., & Chung, F.F. New supraglottic airway with built-in pressure indicator decreases postoperative pharyngolaryngeal symptoms: a randomized controlled trial. (2013). *Canadian Journal of Anesthesia*, 60, p.1197-1203. DOI 10.1007/s12630-013-004-2

Xu, R., Lian, Y., & Li, W.X. (2016). Airway complications during and after general anesthesia: a comparison, systematic review and meta-analysis of using flexible laryngeal mask airways and endotracheal tubes. *PLoS ONE*, *11*(7), p.1-19. doi:10.1371/journal.pone.0158137

**Table 1**

*Evidence Review Table*

| Citation: Seet, E., Yousaf, F., Gupta, S., Subramanyam, R., Wong, D.T., & Chung, F. (2010). Use of manometry for laryngeal mask airway reduces postoperative pharyngolaryngeal adverse events. *Anesthesiology*, 112, p.652-657. | | | | | Level II |
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| Purpose/ Hypothesis | Design | Sample | Intervention | Outcomes | Results |
| The purpose of this study was to "compare the incidence of pharyngolaryngeal complications in ambulatory surgical patients managed with manometers to limit intracuff pressure (<60 cm H2O or <44 mmHg) with patients under routine care of LMA insertion without the use of manometry." | Double-blinded randomized control trial | Simple random sampling (The study used computer generated numbers for group placement and numbers were placed in sealed envelopes that were opened just prior to the administration of general anesthesia)<br><br># Eligible: 203<br># Accepted: 200<br># Control:103<br># Intervention: 97<br><br>Inclusion criteria: Adults, aged 18-80 years old, with an ASA I-III, receiving general anesthesia with an LMA for short duration elective ambulatory surgeries (ex. orthopedic, urology, ophthalmology, general surgery, plastic surgery)<br><br>Exclusion criteria: Recent history of upper respiratory tract infection or contraindications to the use of LMA, such BMI | Control: Routine Care.<br><br>Intervention: Pressure-limiting group.<br><br>Intervention fidelity: After induction of general anesthesia, insertion of the LMA, and once the patient had begun spontaneously breathing again, a research assistant measured LMA intracuff pressures using a manometer that was calibrated by the engineering department. If the procedure lasted more than one hour, the research assistant would recheck intracuff pressures again and make the necessary adjustments depending on group allocation.<br><br>In the intervention group, the research assistant would adjust intracuff pressures to between 40-44 mmHg if the initial intracuff pressure was more than 44 mmHg.<br><br>In the control group, the research assistant simply noted the | DV: The primary outcome was the incidence of pharyngeal adverse events, defined as any combination of sore throat, dysphonia, and dysphagia, measured at 1, 2, and 24 hours postoperatively.<br><br>Measurement tool (reliability), time, procedure: Research assistant interviewed patients and conducted a VAS 2hrs post-operatively.<br><br>Sore throat was defined as "constant pain or discomfort in the throat independent of swallowing". Dysphonia was defined as "difficulty speaking or pain on speaking". Dysphagia was | Statistical Procedures(s) and Results: A Chi-square test was used to analyze nominal data. Mann-Whitney U test was used to analyze non-parametric data. Student *t* test was used to analyze continuous data.<br><br>The overall incidence of pharyngolaryngeal complications was significantly lower in the pressure-limiting group compared to the routine care group (13.4 vs 45.6%, $p <$ 0.001).<br><br>The occurrence of sore throat at 2hrs and 24 hrs postoperatively was significantly lower in the pressure-limiting group than the routine care group (2.1% *vs.* 8.7%, $p =$ |

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| | | >40kg/m2, symptomatic hiatal hernia, or severe GERD<br><br>Power analysis:<br>A total sample size of 200 patients was required, based on a power of 90% and an alpha error of 0.05, for the use of the manometer to reduce the incidence of pharyngolaryngeal complication to 21% from 41%.<br><br>Group Homogeneity:<br>No difference between the routine care and pressure limiting group. | intracuff pressure and no further action was taken.<br><br>The attending anesthesiologist was blinded to group assignment and to the intracuff pressure. The research assistant was also blinded to group allocation and interviewed patients using a predetermined questionnaire. | defined as "difficulty or pain provoked by swallowing". | 0.038 and 3.1% *vs.* 13.6%, $p = 0.008$).<br><br>The occurrence of dysphonia was significantly lower in the pressure-limiting group than the routine care group at 1 hr postoperatively (5.2% *vs.* 15.5%, $p = 0.017$).<br><br>Dysphagia was significantly reduced at 1 hr, 2 hrs, and 24 hrs postoperatively in the pressure-limiting group (1% *vs.* 12.6%, $p = 0.001$; 0% *vs.* 12.6%, $p = 0.001$, and 2.1% *vs.* 8.7%, $p = 0.038$, respectively) |
| Citation: Kang, J.E., Oh, C.S., Choi, J.W., Son, I.S., & Kim, S.H. (2014). Postoperative pharyngolaryngeal adverse events with laryngeal mask airway LMA Supreme) in laparoscopic surgical procedures with cuff pressure limiting 25 cmH2O: prospective, blind, and randomised study. *The Scientific World Journal*, p.1-7. doi: 10.1155/2014/709801 | | | | | Level II |
| Purpose/ Hypothesis | Design | Sample | Intervention | Outcomes | Results |
| The purpose of this study was to "compare the postoperative pharyngolaryngeal adverse events between the LMA cuff pressure limiting 25 cmH2O (L group) and at 60 cmH2O (H group)."<br><br>The study hypothesized that "the LMA cuff pressure limiting 25 | Prospective, double-blinded, randomized trial | Sampling Technique:<br>Simple random sampling<br><br># Eligible: 101<br># Accepted: 98<br># Control: 49<br># Intervention: 49<br><br>Inclusion criteria: Adults >18yo undergoing laparoscopic surgery | Control: Group H (limiting LMA cuff pressure to <60 cmH2O per manufacturer recommendation)<br><br>Intervention: Group L (limiting LMA cuff pressure to 25 cmH2O)<br><br>Intervention fidelity:<br>After induction of anesthesia and LMA insertion based on weight | DV: The primary outcome variable was the incidence of postoperative sore throat on POD #2.<br><br>Measurement tool (reliability), time, procedure:<br>Sore throat was defined as "constant pain of discomfort in the throat | Statistical Procedures(s) and Results: An unpaired chi-square test was performed. A p value of <0.05 was considered to be statistically significant.<br><br>Postoperative sore throat was significantly lower in |

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| cmH2O could reduce the postoperative pharyngolaryngeal adverse events, compared with the 60 cmH2O maximum cuff pressure recommended by the manufacturer" | | Exclusion criteria: Neurological or psychiatric disorders, vocal cord paralysis, recent history of respiratory infection within 1 month, allergy to egg or soybean oil<br><br>Power analysis: A sample size of 49 was calculated with an alpha value of 0.05 and a power of 0.9. The minimum detected difference of 75% in incidence of sore throat between groups was considered to have clinical significance.<br><br>Group Homogeneity: Demographic data between the two groups were similar. | per manufacturer recommendation, a 50-mL syringe was used to inflate the LMA cuff with air, and the cuff pressure was adjusted with a manometer. The L group had its cuff pressures limited to 25 cmH2O and cuff pressures were checked and adjusted again after insufflation with CO2. | independent of swallowing." The incidence of postoperative sore throat was collected and recorded at discharge from the PACU on POD#1 and at 24 hours after PACU discharge on POD#2. This data was collected by blinded trained observers who did not participate in any patient care. | the L group (6.1%) than in the H group (24.5%) on POD #2 ($p$=0.012). In addition, postoperative dysphagia was lower in the L group (0.0%) than in the H group (8.2%) on POD#1 and POD#2 ($p$=0.041). |
| Citation: Wong, D.T., Tam, A.D., Mehta, V., Raveendran, R., Riad, W., & Chung, F.F. (2013). New supraglottic airway with built-in pressure indicator decreases postoperative pharyngolaryngeal symptoms: a randomized controlled trial. *Canadian Journal of Anesthesia*, 60, p.1197-1203. DOI 10.1007/s12630-013-004-2 | | | | | Level II |
| Purpose/ Hypothesis | Design | Sample | Intervention | Outcomes | Results |
| The study hypothesized that "using the CPV (cuff pilot valve) with an intracuff pressure-guided strategy would reduce the incidence of postoperative sore throats, dysphonia, and/or dysphagia when compared with using | Randomized, controlled trial | Sampling Technique: Simple random sampling.<br><br># Eligible: 199<br># Accepted: 170<br># Control: 85<br># Intervention: 85<br><br>Inclusion criteria: Adults aged 18-65 years old and ASA I-III undergoing | Control: LMA Classic<br><br>Intervention: CPV (cuff pilot valve) LMA<br><br>Intervention fidelity: After the induction of anesthesia, the CPV LMA was placed and the cuff was inflated by the anesthesiologist with | DV: "The primary outcome was composite pharyngolaryngeal symptoms, defined as sore throat, dysphonia, and/or dysphagia at one, two, and/or 24 hr postoperatively." | Statistical Procedures(s) and Results:<br><br>A Chi-square analysis was used to analyze incidence of pharyngolaryngeal symptoms and a $p <$ .05 was considered to |

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| the LMA with standard practice." | | general anesthesia for the following procedures: knee arthroscopy, plastic, gynecological, or general surgical procedures lasting no more than two-hours.<br><br>Exclusion criteria: Patients with a BMI > 40kg/m2, mouth opening < 2.5cm, symptomatic hiatal hernia, esophageal reflux disease, recent history of upper respiratory tract infection, pre-existing sore throat, dysphonia, or dysphagia. More than two attempts at LMA/CPV placement was also excluded from the study.<br><br>Power analysis: In order to achieve an alpha error of 0.05 and a power of 80%, a sample size of 152 was required.<br><br>Group Homogeneity: Demographic data (age, sex, BMI, perioperative variables) was similar between the two groups. | instruction from a research assistant, until the cuff pressure indicator was within the green zone (indicating 30-44 mmHg). The research assistant would then continue to measure intracuff pressures using an external manometer at 5 and 20 minus after induction of anesthesia. The anesthesiologist was blinded to intracuff pressure measurements and was instructed not to modify or measure cuff pressures during surgery | Sore throat was defined as "constant pain or discomfort in the throat independent of swallowing".<br><br>Measurement tool (reliability), time, procedure:<br>A research assistant asked patients at 1, 2, and 24 hours postoperatively about the presence of sore throat, dysphonia, and/or dysphagia. Yes/No data was collected. | have statistical significance.<br><br>The CPV group (26%) showed significantly less incidence of pharyngolaryngeal symptoms than the LMA group (49%) ($P$=0.002). The CPV group was associated with an absolute risk reduction of 24%.<br><br>The incidence of postoperative sore throat was significantly less in the CPV group at 1 hour (26% vs. 47%; $P < 0.05$), 2 hours (13% vs. 45%; $P < 0.05$), and 24 hours (5% vs. 17%; $P < 0.05$) as compared with the LMA classic group. |
| Citation: Waruingi, D., Mung'ayi, V., Gisore, E., & Wanyonyi, S. (2019). A randomised controlled trial of the effect of laryngeal mask airway manometry on postoperative sore throat in spontaneously breathing adult patients presenting for surgery at a university teaching hospital. *African Health Sciences 19(1), p.*1705-1715. | | | | | Level II |
| Purpose/ Hypothesis | Design | Sample | Intervention | Outcomes | Results |

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| The study hypothesized that "there is no difference in occurrence of postoperative sore throat (POST) in patients who have LMA cuff pressure adjustment and in those whom no LMA cuff pressure adjustment is done." | Prospective single-blinded randomized control trial | Sampling Technique: Simple randomization<br><br># Eligible: 80<br># Accepted: 80<br># Control: 40<br># Intervention: 40<br><br>Inclusion criteria: All elective surgical patients with an ASA I to II, aged 18 to 65 years old receiving general anesthesia with the use of an LMA between July 2015 and December 2015 were included. This included patients undergoing gynecological and obstetric surgery at less than 20 weeks gestation and general surgery including breast, urological, and orthopedic surgeries lasting roughly one hour in duration and in which the patient could breathe spontaneously<br><br>Exclusion criteria: Patients with history of current upper respiratory tract infection, failed LMA insertion after two attempts, severe GERD, symptomatic hiatal hernia, BMI > 40 kg/m2, and patients undergoing ENT or ear, nose, throat procedures. | Control: No adjustment to LMA cuff pressure<br><br>Intervention: LMA cuff pressure adjusted to between 30 to 32 cmH2O.<br><br>Intervention fidelity: After induction of general anesthesia and placement of LMA based on weight per manufacturer recommendation, the LMA cuff was inflated at the discretion of the anesthesiologist. Once the patient was spontaneously breathing, the principle investigator measured the LMA cuff pressure using a manometer that was calibrated by the engineering department. In the intervention group, the cuff pressure was deflated to maintain a pressure of 30 to 32 cm H2O and recorded every five minutes until surgery was complete. The anesthesiologist was blinded to LMA cuff pressure readings and any adjustments that were made. | DV: Occurrence of postoperative sore throat<br><br>Measurement tool (reliability), time, procedure: If postoperative sore throat was present (yes/no), it's severity was collected with the use of a structured questionnaire which used a Numerical Rating Scale (NRS).<br><br>A research assistant (separate from the principle investigator) interviewed patients at 2, 6, and 12 hours postoperatively. | Statistical Procedures(s) and Results: A Pearson Chi Square test was completed. A p-value of <.05 was considered statistically significant.<br><br>The adjustment of LMA cuff pressures to 30 to 32 cmH2O resulted in a significant reduction in the overall occurrence of postoperative sore throat in the intervention group compared to the control group (25% vs. 65%; p<.001). The reduction in POST was seen consistently at 2, 6, and 12 hours postoperatively.<br><br>The study also demonstrated that the median pain score of POST at 2, 6, and 12 hours postoperatively was significantly higher in the control group (p<.001). |

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| | | Power analysis: In order to be sufficient in estimating the difference in occurrence of POST in patients with a 95% confidence at a power of 80% and an alpha = 5%, the study required a minimum sample size of 80 participants.<br><br>Group Homogeneity: Demographic data was similar between the two groups. | | | |

## Table 2

*Synthesis Table*

| **Evidence Based Practice Question (PICO):** Does intracuff pressure monitoring and limitation to < 60 cmH2O (44 mmHg) reduce the incidence of postoperative pharyngolaryngeal complications in patients undergoing general anesthesia with a laryngeal mask airway (LMA)? | | | |
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| **Level of Evidence** | **# of Studies** | **Summary of Findings** | **Overall Quality** |
| II | 4 | Seet et al. (2010) found that limiting LMA intracuff pressure to 40 to 44 mmHg resulted in significantly less pharyngolaryngeal complications (sore throat, dysphonia, and dysphagia) as compared to routine monitoring. | A; Adequate power. Double-blind randomized controlled trial. Addressed possible threats to internal validity (ex. Differences in anesthesiologist experience, number of LMA attempts, use of oral airway, duration of surgery). Patients were blinded to control or intervention group. Anesthesiologist was blinded to group assignment and to intracuff pressure. A research assistant measured intracuff pressures and a separate research assistant who was blinded to group allocation interviewed patients postoperatively to assess for postoperative pharyngolaryngeal complications. The study included a large number of participants (N=200), a variety of surgical patients (ex. General, orthopedic, plastic, urology, opthalmology), a wide age range, and ASA status I-III, which increased generalizability. The results were consistent with other similar studies and concluded with a recommendation to routinely measure LMA intracuff pressure as part of best practice to reduce the incidence of pharyngolaryngeal complications. |
| | | Kang et al. (2014) found that the incidence of postoperative sore throat on POD#2 was significantly less when LMA intracuff pressures were limited to 25 cm H2O as compared to limiting intracuff pressures to less than 60 cm H2O, as recommended by the manufacturer. They also found that the incidence of postoperative dysphagia on POD #1 and POD #2 was significantly less when intracuff pressures were limited to 25 cm H2O. | B; Adequately powered. Prospective double-blind randomized study. Good sample size (N=98). While demographic characteristics were similar between groups, sample population was limited to laparoscopic procedures, which reduces generalizability. Anesthetic technique was standardized and attending anesthesiologist was blinded to the study. Data regarding postoperative sore throat was collected by trained personnel who were blinded to group allocation and patient care, which reduced bias. The results were consistent with other similar studies and concluded with limiting LMA intracuff pressure to reduce the incidence of pharyngolaryngeal complications. |
| | | Wong et al. (2013) found that the use of a cuff pilot valve (CPV) with an intracuff pressure-guided strategy significantly reduced the incidence of pharyngolaryngeal complications. Specifically, the incidence of postoperative | B; Adequate power. Double-blind randomized controlled trial. Anesthesiologist experience with supraglottic airways was included as a criterion for participation in the study, so that provider experience was not a cofounder. Also limited the population of surgery to less than two hour duration, as length of surgery itself can contribute to the incidence of postoperative complications. Sample population |

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| | | sore throat was significantly less in the cuff pilot valve group at 1, 2, and 24 hours postoperatively as compared to the LMA classic group. | included a variety or surgeons and sample patients ranged from 18-65 years old and ASA I-III, lending to generalizability. The sample size was adequate (N=175). Both supraglottic airways were similar in material and shape, which reduced the confounding variable of different LMA brands. A standardized anesthetic technique was used. Patients were randomized into one of two groups. The anesthesiologists were blinded to intracuff pressure monitoring and were instructed not to modify or measure intracuff pressures intraoperatively. The research assistant who collected postoperative data was also blinded group allocation. The results were consistent with other similar studies and concluded that limiting LMA intracuff pressures would reduce the incidence of postoperative pharyngolaryngeal symptoms. |
| | | Waruingi et al. (2019) found that reducing LMA cuff pressures to 30 to 32 cmH2O resulted in a significant reduction in the overall occurrence of postoperative sore throat (POST). The reduction in POST was seen consistently at 2, 6, and 12 hours postoperatively. The study also demonstrated that the median pain score of POST at 2, 6, and 12 hours postoperatively was significantly higher when LMA cuff pressures were not limited to 30 to 32 cmH2O. | B; Adequately powered. Prospective single-blinded randomized controlled trial. Sample size was appropriate (N=80) but could have been larger. It included ASA I-II patients between 18-65 years, whereas most other studies included ASA III patients as well. However, the sample population was taken from a large variety of short duration elective surgeries, which helped support generalizability. Anesthesiologist experience with supraglottic airways was included as a criterion for participation in the study, so that provider experience was not a confounder. The anesthesiologist was blinded to to group allocation and to intracuff pressure, monitored and adjusted by the principle investigator. A separate research assistant who was blinded to group allocation conducted postoperative sore throat data from participants. The study referenced multiple other studies and concluded that there was benefit in using manometry to limit intracuff pressure to less than the manufacturer's recommendation in order to reduce the incidence of postoperative sore throat. |

**Figure 1**

*Random Observations Tool*

| **Random Observations Tool for Data Collection** | | | | | |
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| **Surgery Date** | **OR #** | **Airway device: ETT or LMA?** | **Documented cuff pressure (cm $H_2O$)** | **Reason cuff pressure was not within recommended range** ***(ex. manometer could not be located, patient was hemodynamically unstable, etc)*** | **Follow up intervention (ex. reminders)** |
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**Figure 2**

*POST Outcome Tool*

| **POST Outcome Tool (for PACU RNs)** | | | | |
|---|---|---|---|---|
| **Surgery Date** | **OR #** | **ETT or LMA** | **Documented intra-op cuff pressure (cm $H_2O$)** | **Did the patient complain of a sore throat? YES or NO** |
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**Figure 3**

*Absence of POST*

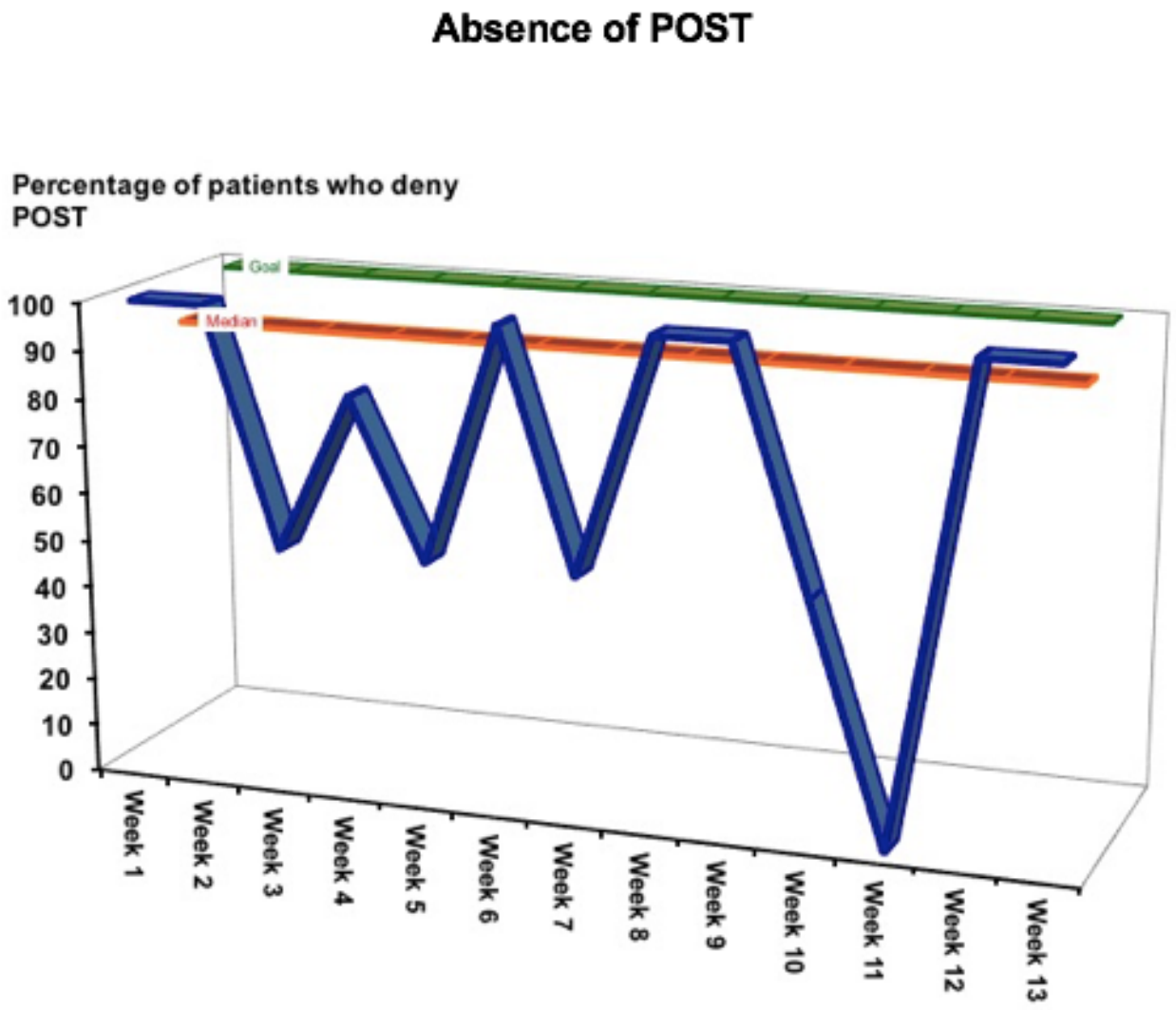
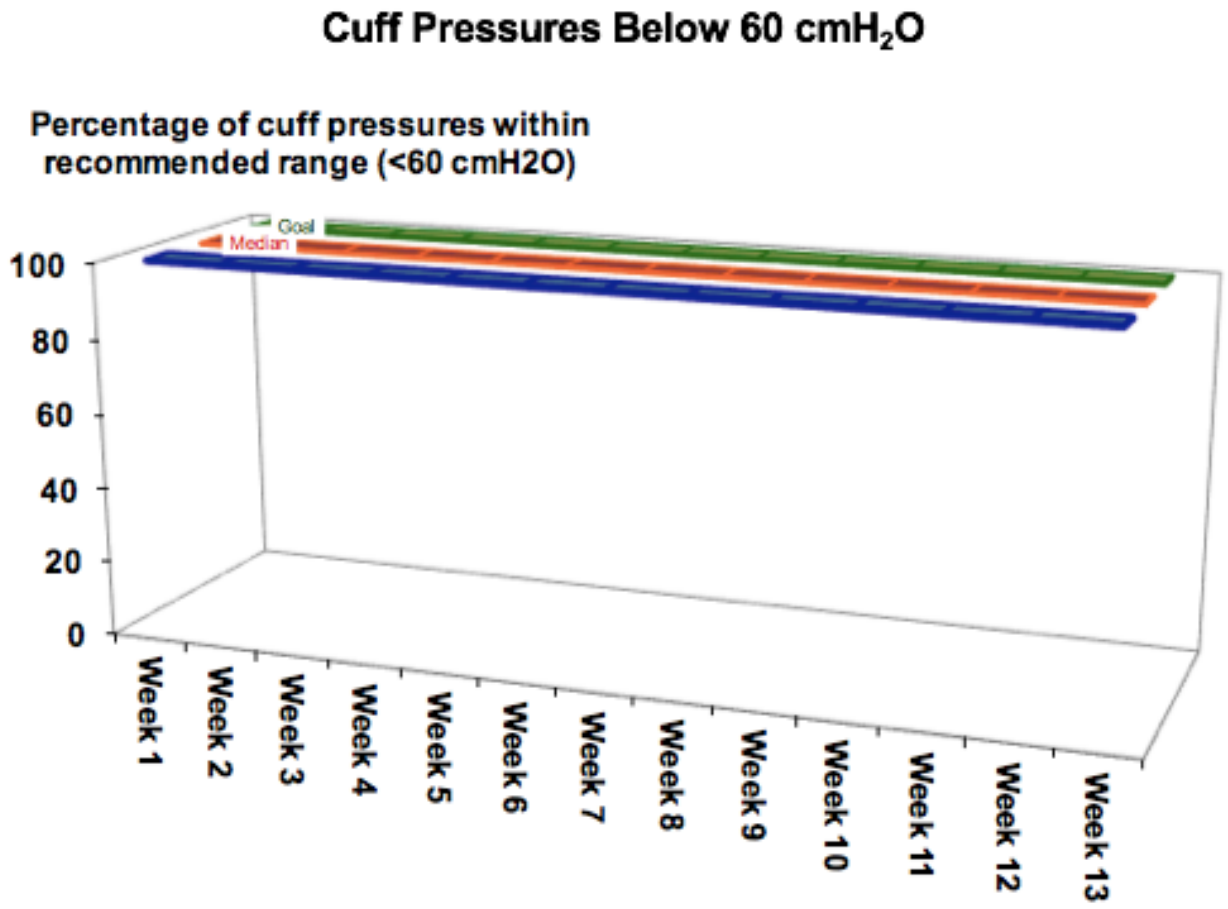


**Figure 4**

*Cuff Pressures Below 60 $cmH_2O$*



# Appendix A

## POSEY CUFFLATOR INSTRUCTIONS FOR USE

NOTE: The Posey Cufflator is designed only for use with air-filled cuffs. Use with saline-filled cuffs will cause damage to the unit and void the product warranty.

1.) Before use, the control inflator needs to be checked as follows:
   a. Close connecting piece with the finger (Fig.1).
   b. Inflate to 120 cm H2O with inflation bulb; value must be constant for 2-3 seconds. If the pressure drops, the device needs repair by the Posey Company.
   c. Inspect the unit and check for cuff leaks prior to use. Prior to intubation or extubation, withdraw all the air from the cuff with a syringe and close the inflation line.


Fig. 1

2.) To properly seal:
   a. Connect the patient to the ventilator.
   b. Connect the Posey Cufflator to the cuff inflation line and inflate the cuff to a pressure within the range of 60-90 cm H2O.
   c. Immediately release air by pressing the red release button (Fig. 2) until the lowest safe pressure level is reached.
   d. Intra-cuff pressure should be maintained at a minimum of 20-25 cm H2O for ETTs and **< 60cmH2O for LMAs**


Fig. 2

Posey
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Posey Company (2015). Posey cufflator application instructions. Retrieved from https://www.vitalitymedical.com/pdf/instructions-posey8199.pdf

- POST can be as high as 44% in patients undergoing general anesthesia with an endotracheal tube (Lui et al., 2010).
- 34 to 42% incidence of POST after the use of LMAs (Wong et al., 2013).
- POST can decrease patient satisfaction, prolong stays in the post anesthesia care unit (PACU) and affect the quality of recovery from surgery (Ganason et al., 2019).
- According to Puthenveettil et al (2018), the recommended cuff pressure for an endotracheal tube should be between 20 to 30 cm H2O and <60 cm H2O for LMAs.


**Quick Step Guide:**

1) Always check manometer prior to use
   a) Close connection piece with finger
   b) Inflate to 120 cm H2O to ensure pressure holds for 2-3 seconds
   c) If the manometer doesn't hold pressure, do not use it.
2) After placing the patient on the ventilator, connect Posey Cufflator to the cuff inflation line and inflate the cuff to 60-90 cm H2O.
3) Immediately release air by pressing the red release button until lowest safe pressure level is reached.
4) **LMA < 60 cm H2O** and **ETT 20-25 cm H2O**

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