CONTENTS

COVER NOTE
Muscle Relaxants—Decamethonium
   C. Ball, R. N. Westhorpe
   709

EDITORIAL
Ultrasound in Regional Anaesthesia—Removing the Blindfold?
   K. Cronin
   717

ORIGINAL PAPERS
A Randomized Trial of Ultrasound-guided Brachial Plexus Anaesthesia in Upper Limb Surgery
   719

Precise Control of End-tidal Carbon Dioxide Levels Using Sequential Rebreathing Circuits
   726

Comparison of Forced-air Warming and Radiant Heating during Transurethral Prostatic Resection under Spinal Anaesthesia
   J. J. Torrie, P. Yip, E. Robinson
   733

Comparison of the Re-usable LMA Classic™ and Two Single-use Laryngeal Masks (LMA Unique™ and SoftScal™) in Airway Management by Novice Personnel
   739

The Effect of Supplemental Oxygen on Postoperative Nausea and Vomiting in Children Undergoing Dental Work
   A. B. P. Donaldson
   744

AUDIT
Long-term Survival of Surgically Treated Hip Fracture in an Australian Regional Hospital
   K. McLeod, M. P. Brodie, P. P. Fahey, R. A. Gray
   749

EQUIPMENT
Evaluation of the SLIPA™ (Streamlined Liner of the Pharynx Airway), a Single Use Supraglottic Airway Device, in 60 Anaesthetized Patients Undergoing Minor Surgical Procedures
   C. Hein, J. Plummer, H. Owens
   756

Anaesthesia and Intensive Care, Vol. 33, No. 6, December 2005
SURVEYS

The Influence of the Current Medicolegal Climate on New South Wales Anaesthetic Practice
L. A. Beckmann

Debriefing After Critical Incidents for Anaesthetic Trainees
H. Tan

Anaesthetic Knowledge of the QT Interval in a Teaching Hospital
S. D. Marshall, P. S. Myles

Fibreoptic Intubation Skills Among Anaesthetists in New Zealand
A. J. Dawson, C. Marsland, P. Baker, B. J. Anderson

Provision for Major Obstetric Haemorrhage: an Australian and New Zealand Survey and Review
S. J. Fowler

POINT OF VIEW

The Theoretical Basis for Using Apnoeic Oxygenation Via the Non-ventilated Lung During One-lung Ventilation to Delay the Onset of Arterial Hypoxaemia
J. Pfitzner, L. Pfitzner

CASE REPORTS

Arterial Oxygen Desaturation During One-lung Ventilation in a Patient with Segmental Pulmonary Infarction
J. Pfitzner, D. G. Lance, M. J. Peacock

Arterial Oxygen Desaturation During only one of two Similar Thorascopic Procedures on the Same Patient
J. Pfitzner, J. A. Fowler, M. Kishore, A. S. Michael, D. G. Lance

Severe Uncontrolled Pain in Buttock in a Patient on Naltrexone: A Diagnostic Challenge
J. M. Graham, B. Evans

Bilateral Brachial Plexopathy Following Laparoscopic Bariatric Surgery
K. E. J. Brunette, D. O. Hutchinson, H. Ismail

Anaphylaxis to Cisatracurium Following Negative Skin Testing
B. A. Fraser, J. A. Smart

CORRESPONDENCE

Effect of hyaluronidase and bicarbonate on local anaesthetic pH. A. Walpole, J. A. Symons

Serotonin syndrome and the anaesthetist A. Warminster

Serotonin syndrome and the anaesthetist—Reply D. Jones, D. A. Story
Management of serotonin syndrome R. Mahajan, R. Gupta, A. Sharma

Nasal insertion of tube to aid in Glidescope use N. Fairweather

Successful guided insertion of a ProSeal LMA in a patient with limited mouth-opening after failed insertion of a flexible LMA J. Brimacombe, C. Keller

Off-label use of drugs remains a concern for anaesthetists caring for children C. Sims

A novel method to facilitate nasogastric tube placement A. Agarwal, D. Gupta

BOOK REVIEWS

Critical Care: The Requisites in Anaesthesiology R. Lee

On-line Electronic Help for Anaesthesiologists—CD Rom J. Russell

Critical Care Focus—II: Trauma M. Parr

The Year in Anaesthesia and Critical Care—Volume 1 I. R. Jenkins


Lippincott’s Interactive Critical Care Library on CD-ROM M. Heaney

Clinical Cases in Anesthesia—3rd Edition N. Martin

Top Tips in Anaesthesia K. Cronin

ANNUAL BEST PAPER AWARD

ACKNOWLEDGEMENTS

INDEX, Volume 33, 2005

FUTURE MEETINGS

INSTRUCTIONS FOR AUTHORS

INDEX TO ADVERTISERS

Anaesthesia and Intensive Care, Vol. 33, No. 6, December 2005
Equipment

Evaluation of the SLIPA™ (Streamlined Liner of the Pharynx Airway), a Single Use Supraglottic Airway Device, in 60 Anaesthetized Patients Undergoing Minor Surgical Procedures

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SUMMARY

The Streamlined Liner of the Pharyngeal Airway, SLIPA™ (Hudson RCI) is a new disposable supraglottic airway device that has no inflatable cuff and has features designed to reduce aspiration risk. This study aimed to assess the insertion success and effectiveness of the SLIPA™ in 60 patients who presented for elective surgery. Ethics committee approval was obtained. Patients were excluded if they were less than 18 years, had not provided written consent or were at risk of pulmonary aspiration. The first 20 SLIPA™ were inserted by the principal investigator (Group A) followed by another 40 inserted by medical officers and anaesthetists of varying experience (Group B). Twenty-one males and 39 females were recruited into the study. Median time to ventilation was 20.4 seconds in Group A (range 12.9-109) and 24.8 seconds in Group B (range 8.2-82.5). Overall success rate was 100% in Group A and 92.5% in Group B. The lowest recorded SpO₂ was 91% in Group B. The incidence of blood and sore throat score >3 (0-10 scale) was 23% and 7% respectively (Groups A and B). Group B reported that use of the device was very easy in 16%, easy in 76%, difficult in 5%, and very difficult in 3%. The SLIPA™ proved to be a reliable airway providing adequate ventilation in both spontaneous breathing and assisted respiration. Most users found the SLIPA™ to be easy or very easy to use.

Key Words: AIRWAY, PHARYNGEAL; disposable supraglottic, SLIPA™

There is a need in anaesthesia for a reliable supraglottic airway device as an alternative to endotracheal intubation. The Laryngeal Mask Airway—Classic™ (LMA-C™) (The Laryngeal Mask Co. Ltd.) was the first to be used in elective procedures and has since been recognised as a valuable rescue airway tool in emergency airway management. It is a relatively expensive device designed for multiple uses and as such requires time-consuming maintenance procedures such as cleaning and autoclaving. Even so, cross-infection remains a risk. Recently, several disposable masks similar to the LMA-C™ have been released; LMA-UniQue™ (LMA Co Ltd), Soft-Seal® Laryngeal Mask (Portex), Laryngeal Airway Device (Marshall Products Ltd.), Laryngoseal™ (Mallinckrodt, Nellcor), Ambu® Laryngeal Mask (Ambu, U.S.A.). All these masks have a cuff that requires inflation to produce an effective seal in the hypopharynx and none offers protection from regurgitation. The LMA ProSeal™, a modified version of the LMA-C™, has an integral drainage tube to facilitate venting (in the case of gastric insufflation) and suction of gastric fluid but to date, is not available in disposable form. The SLIPA™ (Streamlined Liner of the Pharyngeal Airway) (Hudson RCI, Temecula, CA U.S.A.) is so named because it resembles a slipper, with

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Presented in part at the American Society of Anaesthesiologists (ASA) annual meeting Las Vegas, U.S.A., October 2004 and the Australian College of Ambulance Professionals (ACAP) annual meeting, Alice Springs, Australia, September 2004.

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Accepted for publication on July 27, 2005.
prominences such as the heel and toe (Figure 1). Made from soft blow-moulded plastic (ethylenevinylacetate copolymer), the SLIPA™ is inexpensive, disposable and has been designed to conform to the hypopharynx eliminating the need for an inflatable cuff (Figure 2).

**Figure 1:** The SLIPA™ prototype used in this trial. The size of the device is embossed on the breathing tube (not seen here) and the connector is color-coded.

The SLIPA™ is currently available in six adult sizes: 47 mm, 49 mm, 51 mm, 53 mm, 55 mm and 57 mm. Sizing is by estimating the size of the patient's thyroid cartilage (cornu to cornu), and matching that measurement to the widest transverse diameter of SLIPA™ (Figures 3a and 3b). The SLIPA™ has a hollow “sump-like” section with a capacity of up to 50 ml (in the size 53) which the inventor suggested may offer some protection from regurgitation.

The aim of this study was to provide an independent assessment of the SLIPA™, with particular emphasis on ease of insertion and effectiveness as an airway with spontaneous or assisted ventilations in anaesthetized patients.

**METHODS**

Ethics committee approval was received for a trial of the SLIPA™ in patients undergoing elective surgical procedures under general anaesthesia at Flinders Medical Centre, Noarlunga Health Services and the Queen Elizabeth Hospital, Adelaide, South Australia. Male and female patients who would normally be managed by the LMA-C™ and who had provided written consent were included. Patients were excluded if they were under the age of 18 years, suffered from insulin dependent diabetes mellitus (Type I), morbid obesity, gastro-oesophageal reflux, or if they were pregnant or considered to be at risk of pulmonary aspiration.

At the time of this study, the SLIPA™ was not
commercially available and very little had been published regarding its use\textsuperscript{a}. An insertion technique was developed by the principal investigator (CH), utilizing manikins in the training laboratory at the Clinical Skills and Simulation Unit, School of Medicine, Flinders University. Insertion technique was based on an insertion video produced by the inventor of the device, Dr Donald Miller, and by the manufacturer's recommendations. To insert the device, the mouth was opened and the toe of the SLIPA\textsuperscript{™} was put into the mouth and advanced towards the posterior pharyngeal arch. At this stage, a "jaw thrust" was applied by an assistant and the SLIPA\textsuperscript{™} was advanced caudally in a slight sweeping motion with the head of the manikin extended (sniffling position) until the device slipped into the correct position. Many airway part-task trainers were studied\textsuperscript{a} and the Adult Airway Management Trainer (Laerdal) was found to be most suitable for training with a size 47 SLIPA\textsuperscript{™}.

Once proficient in using the SLIPA\textsuperscript{™} on manikins, the principal investigator used the SLIPA\textsuperscript{™} on 20 consenting patients (Group A). A further 40 consenting patients were enrolled into the study with the SLIPA\textsuperscript{™} being inserted by five Resident Medical Officers (RMOs), eight anaesthetic registrars and fourteen anaesthetic consultants (Group B). Prior to inserting the device, the medical officers and anaesthetists were shown the inventor's video and the insertion technique used by the principal investigator. They then had an opportunity to practise using the SLIPA\textsuperscript{™} in the manikin until competent. A jaw thrust was performed by an assistant for each patient to facilitate the SLIPA\textsuperscript{™} sliding behind the base of the tongue. The appropriate size of SLIPA\textsuperscript{™} for each patient was chosen by the principal investigator.

Primary outcomes measured were: time to ventilation (time taken from removal of face mask to first chest inflation), lowest recorded pulse oximeter reading (SpO\textsubscript{2}), and overall success rate (Groups A and B combined). Only two insertion attempts were permitted for each patient.

The anaesthetic technique used was pre-oxygenation and an intravenous premedication (midazolam and/or fentanyl) followed by propofol. Anaesthesia was maintained by an inhalation agent (sevoflurane or isoflurane) in oxygen and either air (most) or nitrous oxide. Patients were appropriately monitored throughout their surgical procedure. Clinical effectiveness of the airway and thus adequate ventilation was defined as observation of chest wall movement with manual ventilation or movement of the reservoir bag with spontaneous breathing, listen-

ing for excessive gas from the mouth and SpO\textsubscript{2} remaining above 92%. Failure to insert the airway or maintain adequate ventilation was managed by an appropriate alternative such as the LMA or facemask. Muscle relaxants were not used.

The medical officers and anaesthetists who inserted the SLIPA\textsuperscript{™} (Group B) were asked at the completion of each case to relate whether they found it "very easy", "easy", "difficult", or "very difficult" to insert and additional comments were encouraged. We also sought additional data in relation to pharyngeal morbidity by assessing whether any blood was found on the device at removal, and if patients had any evidence of a sore throat. Postoperatively patients were asked by the principal investigator to score throat pain on an eleven-point scale (0-10).

**STATISTICAL ANALYSIS**

To ascertain whether there was evidence of a trend to shorter insertion times with increasing experience in the first 20 patients in which the device was inserted (by the principal investigator), we examined the association between time to ventilation and patient sequence using Spearman's correlation coefficient (r).

**RESULTS**

Twenty-one male and 39 female were recruited into the study. Patient demographics are given in Table 1. Overall, the SLIPA\textsuperscript{™} was used successfully (first or second insertion attempts) in 95% of patients and no device required premature removal. Median time to ventilation was 20.4 seconds in Group A (range 12.9-109) and 24.8 seconds in Group B (range 8.2-82.5).

<table>
<thead>
<tr>
<th>Patient demographics (range)</th>
<th>Mean</th>
<th>SD</th>
<th>(range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50 yr</td>
<td>16</td>
<td>(22-81)</td>
</tr>
<tr>
<td>Weight</td>
<td>73 kg</td>
<td>15</td>
<td>(40-112)</td>
</tr>
<tr>
<td>Height</td>
<td>166 cm</td>
<td>9</td>
<td>(150-182)</td>
</tr>
</tbody>
</table>

In the principal investigator group (Group A), there were no failures (Table 2). Of the three failures in Group B, one was attributed to inadequate depth of anaesthesia, one to the smallest device available to us (size 47 mm) being too large for a very small woman (150 cm tall and weighing 40 kg), and one was thought to be due to incorrect size selection. In the latter case, both attempts were made using the same size SLIPA\textsuperscript{™} (Table 2). Failures were managed without further complications by facemask and Guedel airway, size 3 and size 5 LMA-Classic respectively.

*Anaesthesia and Intensive Care, Vol. 33, No. 6, December 2005*
EVALUATION OF THE SLIPA™

TABLE 2

Results: Group A=Principal Investigator, Group B=Medical Officers and Anaesthetists of varying experience.

<table>
<thead>
<tr>
<th></th>
<th>1st Attempt</th>
<th>2nd Attempt</th>
<th>Failure</th>
<th>Lowest SpO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>85%</td>
<td>15%</td>
<td>0%</td>
<td>93%</td>
</tr>
<tr>
<td>Group B</td>
<td>90%</td>
<td>2.5%</td>
<td>7.5%</td>
<td>91%</td>
</tr>
</tbody>
</table>

The lowest SpO₂ recorded was 91%, which was thought to be due to obesity (177 cm tall and weighing 100 kg, BMI 31.9) and head-down position. Time to ventilation in both groups was less than 60 seconds in 53 of the 57 successful insertions.

There was no evidence of a trend to shorter insertion times with increasing experience in the 20 consecutive SLIPA™ inserted by the principal investigator (Group A) (r₃=-0.15, 2-tailed P=0.52). Long times to insertion for patients 7, 11 and 17 (109, 105 and 63 seconds) indicated second attempt insertion times.

Of the five Resident Medical Officers (RMOS), eight anaesthetic registrars and fourteen anaesthetic consultants in Group B, 76% found the SLIPA™ “easy to use”. Negative comments noted in this group were: insertion was made difficult due to limited mouth-opening (three comments) or narrow angled upper front teeth (two comments), the device required a jaw lift to maintain adequate tidal volume (one) and a smell of isoflurane was detected in the room (one comment).

Blood was seen on 14 out of 60 devices (23%) at the time of removal. Four of the 60 patients (7%) reported a sore throat of greater than three on the eleven-point scale (assessed 22 to 197 minutes postoperatively). The overall incidence of any sore throat (score >0) was 23% with the majority described as mild.

DISCUSSION

The high success rate shown here suggests that the SLIPA™ is very easy to learn to use. Furthermore, the fact that no learning curve could be demonstrated here suggests that either the instruction video and manikin practice were sufficient to become proficient in the device use, or patient conditions were extremely easy. Others have found manikin-only training adequate for LMA™ placement [14]. A device that is easy to use and requires little practice to maintain proficiency would lend itself to the failed intubation scenario or emergency setting and to those with limited airway management experience or exposure. All those in this study were inexperienced users of the SLIPA™ (in fact most had not seen the device prior to instruction) and some were inexperienced users of supraglottic devices as a whole (the five RMOS).

The overall success rate of the SLIPA™ in this study was comparable to those reported with the LMA-C™ by experienced and non-experienced users: 88% 11, 94% 15, 97% 16, 97.5% 17, 98% 18-20, 99.8% 21, and 100% 22-27. Similarly, studies of two disposable laryngeal masks (Soft Seal LM™ 95% 16, 96% 28, 100% 27; LMA Unique™ 98% 20, 100% 25) show high insertion rates which would be expected given that they are very similar to the well known LMA-C™. The SLIPA™ is a new supraglottic airway device that does not resemble previous devices and it is reasonable to suggest that success rates and clinical uses may be improved upon in the future.

This study demonstrated the time to establish an effective airway, by measuring from the moment the facemask was removed from the patient’s face to successful device insertion and establishment of the first adequate chest inflation. The shorter insertion time shown here (8.3s) reflected prior preparation of equipment and co-operation of assistants but it is a device that does not require inflation of a cuff and this could contribute to shorter insertion times.

Availability of SLIPA™ devices were limited for this trial and insertion times of greater than 60s in this study reflected opening the packet, checking the device for faults, and lubricating the device prior to the second insertion attempt with another size.

In clinical practice, another size device could be readily prepared and if needed, may decrease second insertion times.

The principal investigator performed the size selection of the device for the 60 patients in this trial and this may have impacted on the outcome. However we wanted to assess ease of use and insertion times and we did not want incorrect measurement to impact on this. Not surprisingly, a non-inflatable device would need to be closely matched to each patient to ensure correct fit. The method of size selection may need refining though only five of the 60 patients here required second insertions. Similarly, a previous study [1] reported only 3/60 sizing errors, a promising fact considering very little is known about this device.

Based on our experience, the following could be investigated as an alternative method of size selection: teenagers and small women—size 47, adult women—size 49 or 51, adult men—size 53 or 55, large men size 57. The LMA™ has been available for over two decades and only recently has much attention been given to selection of size 21, 24, 29, 30.

In this study, we asked the anaesthetists (in Group B) to remove the SLIPA™ in theatre rather than leave it in situ until return of laryngeal reflexes. In the hospitals where this study took place, the LMA™ is usually left in place until the patient is waking. We have since allowed 12 patients to regain consciousness.
with the SLIPA™ in situ and had no problems. Additionally, we asked an assistant to perform a jaw thrust to facilitate a traumatic insertion of the SLIPA™, suggesting that its insertion is a two-person task. However if an assistant is not available, a jaw lift can be performed by the inserter by placing the thumb in the corner of the patient’s mouth and lifting the mandible to create space behind the tongue.

We were interested to see if the semi-rigid toe of the SLIPA™ would lead to high levels of oropharyngeal trauma as evidenced by sore throat. The patients were informed at the time of consent that it was likely that they could have a sore throat, and this was assessed 22 to 197 minutes postoperatively by the principal investigator. Direct and indirect questioning can bias findings, but the incidence of sore throat reported here is similar to those reported with the LMA-C™.

The patients included in this study were not representative of the general population because of the exclusion criteria including extremes of age, diabetes, morbid obesity and pregnancy. The SLIPA™ has a hollow “sump-like” section which may offer some protection or reduction of aspiration risk, although this has only been shown in a model pharynx and was not studied by us. However if the SLIPA is not routinely “suctioned” prior to removal, collected matter may be tipped into the pharynx when it is tilted caudally during removal.

In conclusion, the SLIPA™ proved to be simple to use and created a reliable airway that provided adequate ventilation in the population studied. It is relatively easy to use without an inflatable cuff, but more research would be needed to identify what level of anaesthesia (or coma in emergency patients) is needed to tolerate the device. Further clinical trials can, and should be undertaken because the design features of the SLIPA™ may prove useful in those areas where the LMA™ has been successful such as anaesthesia, failed intubation and in the out-of-hospital setting.

ACKNOWLEDGEMENTS

The help of staff at the Queen Elizabeth Hospital, Noarlunga Health Services and Flinders Medical Centre and South Australian Ambulance Service for assistance throughout the trial is acknowledged. Hudson RCI, Temecula, California (now Teleflex Medical), supplied SLIPA™ devices and Dr Donald Miller (the inventor of the SLIPA™), provided guidance on insertion technique prior to the commencement of the trial. Flinders University Medical Sciences Department provided access to the cadaver.

No author has a potential conflict of interest that relates to the present report. The principal investigator was supported in part by Hudson RCI, to attend the American Society of Anesthesiologists Annual Meeting in Las Vegas, U.S.A., October 2004 to report the results of this study.

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Anaesthesia and Intensive Care, Vol. 33, No. 6, December 2005
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