Ambu
Ideas that work for life

Clinical Evidence Compendium

Published studies, case reports and correspondence

July 2020

Ambu® AuraGain™

2nd Generation disposable laryngeal mask

Taking patient safety and airway managment efficiency to a new level

Contents

Abbreviations:

RCT	Randomised clinical trial
SAD/SGA	Supraglottic airway device
OLP	Oropharyngeal leak pressure
FB	Fibreoptic view
TT	Tracheal tube
AM	Airway manoeuvres
mL	Millilitre
ET/ETT	Endotracheal tube
LMA	Laryngeal mask airway
OSP	Oropharyngeal seal pressure
ASA	The American Society of Anaesthesiologists
ISP	Initial seal pressure
IQR	Interquartile range
PIP	Peak inspiratory pressure
BMI	Body mass index
MRI	Magnetic resonance imaging
FOB	Fibreoptic bronchoscopy

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Preface

Welcome to the first edition of the Ambu® AuraGain™ Clinical Evidence Compendium. This compendium is a collation of all the studies, including clinical trials, simulation studies, case series, reports, conference abstracts and correspondence, relating to this innovative airway management device, up to July 2020.

Since the launch in 2014, Ambu® AuraGain™ has been the subject of numerous peer-reviewed publications. The objective of this Evidence Compendium is to provide a brief summary of all known published data on AuraGain™, in an efficient and easy-to-understand manner. While each study summary is true to the original publication, the original copies can be made available upon request for a comprehensive overview. Should you wish to discuss any publication in this compendium in more detail, do not hesitate to drop an inquiry to: UKCA-Marketing@ambu.com.

In an effort to include all known data irrespective of the outcome, a systematic literature search on AuraGain™ has been conducted to generate the Evidence Compendium, giving the reader every opportunity to obtain a balanced overview of the clinical data that exists for AuraGain™. The study titles are taken from the publications as they appear in their original form, allowing the reader to make a perfectly accurate internet search should they wish to find out more.

We sincerely hope that this evidence compendium provides you with an understanding of the overall clinical landscape regarding AuraGain™ and facilitates your day to day evidence-based practice.

While every effort has been made to provide accurate information, we apologise in advance for any errors or omissions and will be pleased to make any corrections brought to our notice in any following editions.

"Ideas that work for life"

More than a tagline,
"Ideas that work for life" is everything we do

Ambu® AuraGain™

2nd Generation Disposable Laryngeal Mask

The AuraGain is Ambu's 2nd generation laryngeal mask, satisfying 3 fundamental airway management needs by integrating gastric access and intubation capability in an anatomically curved single-use device that facilitates the rapid establishment of a safe airway.

Rapid placement

The original anatomical curve is pre-formed to follow the anatomy of the human airway, and the soft rounded curve of the AuraGain ensures rapid placement and guarantees long-term performance.

High seal pressure

The thin and soft cuff of the AuraGain is designed to deliver high seal pressures - documented up to 40 cmH_2O.*

Gastric control

The integrated gastric access channel is designed with a low friction inner surface to facilitate easy placement of a gastric tube.

Introduce a gastric tube through the device and into the stomach of the patient to enable active and passive management of gastric content, and prevent gastric insufflation.

Integrated intubation capability

The AuraGain provides the added safety feature of intubation capability. This means that in case of an unexpected difficult airway, or a "Cannot Intubate – Cannot mask Ventilate" (CI-CV) situation, where the end-game is to intubate the patient, AuraGain can be used as a conduit for direct endotracheal intubation assisted by a flexible scope (such as the Ambu® aScope 4).

All-round versatility

Rapid placement, high seal pressure, gastric access, and intubation capability make the AuraGain the obvious and safe choice for every procedure where a laryngeal mask is indicated.

Updated max gastric tube recommendation

Ambu® has updated the max gastric tube recommendation printed on the device from 14 Fr to 16 Fr. The version with 14 Fr written on the device is fully compatible with gastric tubes up to 16 Fr.

Key Features

- Integrated gastric access channel for managing gastric content (Up to 16 French)
- The original anatomical curve, flexible cuve, ensuring rapid placement
- Intubating capability using standard ET-tubes
- Integrated bite absorption area prevents airway occlusion
- Navigation marks for guiding flexible scope
- Thin and soft cuff is designed to deliver high seal pressures - documented up to 40 cmH_2O*
- Can be used with an aintree catheter method
- Patented stabilizer pad to help ensure mask placement stability during patient transport
- Patented dead-space reduction feature in pediatric sizes
- LMA is documented with maximm ETT and Gastric Tube capacity
- Pilot balloon identifies mask size and provides tactile indication of degree of inflation
- MR safe
- Phthalate-free material
- Available in 8 sizes

* data on file.

Guidelines & Consensus Documents

Recommendations for the use of the 2nd generation supraglottic airway devices

Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults[1]

"Second-generation SADs have advantages and are recommended; the ideal attributes of a SAD for airway rescue are reliable first-time placement, high seal pressure, separation of gastrointestinal and respiratory tracts, and compatibility with fibre-optically guided tracheal intubation."

"Second-generation SADs offer greater protection against aspiration than first-generation devices and are recommended should intubation fail during a rapid sequence induction."

"Plan B" emphasis maintaining oxygenation with an SAD:

- All anaesthetists should be trained to use and have immediate access to second-generation SADs;
- The use of an Aintree Intubation Catheter over a fibreoptic scope allows guided intubation through an SAD where direct fibre-optically guided intubation is not possible.

4th National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society (NAP4)[2]

"The combination of improved sealing and the presence of a drain tube improves efficacy and creates functional separation of the gastrointestinal tract from the respiratory tract (like an artificial larynx) ... several recent publications have suggested that the use of SADs with effective drain tube should become a 'standard of care'. All hospitals should have second generation SAD available for both routine use and rescue airway management."

"If tracheal intubation is not considered to be indicated but there is some (small) increased concern about regurgitation risk a second generation SAD is a more logical choice, than a first generation one."

"Obstetric anaesthethist should be familar and skilled with SADs for rescuing the airway; particularly those designed to protect from aspiration and to facilitate ventilation and or intubation."

Consensus guidelines for managing the airway in patients with COVID-19[3]

"Single vs. reusable equipment: "Where practical, single-use equipment should be used."

"... when difficulty is encountered... A second-generation supraglottic airway device (SGA) for airway rescue (e.g. i-gel, Ambu AuraGain, LMA ProSeal, LMA Protector)."

"Airway management during cardiac arrest: "An SGA with a high seal pressure should be used in preference to one with a low seal. This will usually be a second-generation SGA where available."

Use of suproglottic airways during the COVID-19 pandemic[4]

"Use of a second-generation SGA is likely to improve airway seal."

"The drain port of a second-generation SGA may provide a potential route for secretion dispersal..."

COVID-19 Airway management principles[5]

"... a second-generation supraglottic airway device (SAD) for airway rescue, also to improve seal."

Staying Ahead of the Curve: Modified Approach to Emergency Caesarean Section Under General Anaesthesia in COVID-19 Pandemic[6]

"If not successful, ... 2nd generation supraglottic device should be inserted."

AuraGain vs. i-gel

Fibreoptic intubation of severely obese patients through supraglottic airway: a prospective, randomised trial of the Ambu® AuraGain™ laryngeal mask vs the i-gel™ airway

Moser, B. et al. (2019). Acta Anaesthesiol Scand. 36(10), pp. 721–727.

Key Points

AuraGain: 54 vs. i-gel 55 — Intubation time (seconds av.)

AuraGain: 77% vs. i-gel 64% — Gastric tube insertion (easy)

AuraGain: 32.8 ± 5.5 vs. i-gel 32.1 ± 5.9 — Oropharyngeal leak pressure

Study Overview

An RCT to compare AuraGain™ & i-gel for:

- **Time to SAD insertion (seconds)**
- **Trans-device ET intubation time (seconds)**
- **Oropharyngeal leak pressure (OLP)**
- **Ease of gastric tube insertion**
- **Gastric content volume (mL)**
- **First-attempt success rate for SAD & gastric tube**
- **Number of tracheal intubation attempts**

Methods

The study comprised of: 44 patients (BMI, 35 kg/m²), mean age 59, undergoing elective surgery with ASA physical status of I-III

AuraGain: 22 patients; size 4 women (n=12), size 5 men (n=10)

i-gel: 22 patients; size 4 women (n=15), size 5 men (n=7)

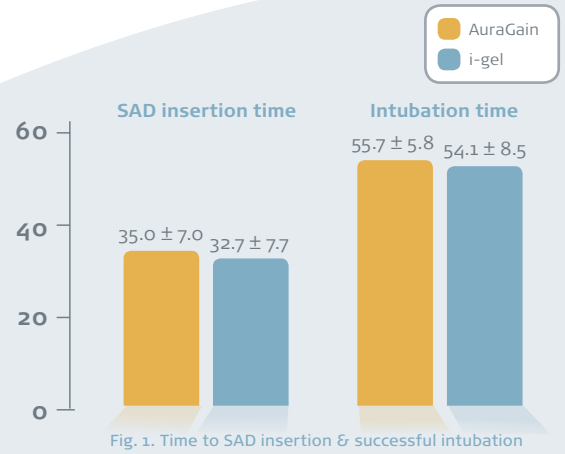

Fig. 1. Time to SAD insertion & successful intubation

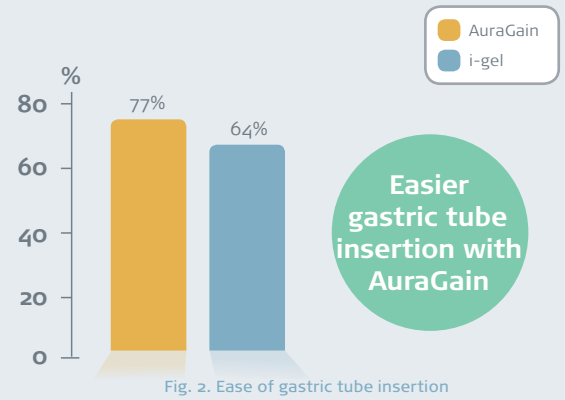

Fig. 2. Ease of gastric tube insertion

Key Findings

1. Time to SAD insertion and trans-device ET intubation were comparable between AuraGain and i-gel groups (Figure 1).
2. The OLP (cmH_2O) measured immediately after insertion was comparable between AuraGain (32.8 ± 5.5) & i-gel (32.1 ± 5.9).
3. Easier gastric tube insertion with AuraGain group (Figure 2):
   Easy = AuraGain 77% vs. i-gel 64%
   Little resistance = AuraGain 18% vs. i-gel 32%
   Significant resistance = AuraGain 5% vs. i-gel 5%
4. Gastric content volume was 8.4 ± 19.0 for AuraGain vs. 7.0 ± 10.2 for i-gel.
5. The first-attempt SAD insertion rate was 95% for AuraGain vs. 100% for i-gel; first-attempt gastric tube insertion rate was 100% for both groups.
6. First-attempt tracheal intubation rate was 91% and second attempt success rate was 9% for both groups.

Conclusion

Intubation time, OLP, gastric content volume, first-attempt SAD & gastric tube insertion rates and first-attempt tracheal intubation success rate were comparable between groups. It was easier to insert a gastric tube with AuraGain group. It was believed that AuraGain could be a good alternative in the airway management in obese patients.

Reference: Moser, B. *et al.* (2019) 'FiberopBc intubaBon of severely obese paBents through supragloHc airway: A prospecBve, randomized trial of the Ambu® AuraGain™ laryngeal mask vs the i-gel™ airway', *Acta Anaesthesiologica Scandinavica*. Blackwell Munksgaard, 63(2), pp. 187–194. doi: 10.1111/aas.13242.

AuraGain vs. i-gel

Evaluation of i-gel®, Ambu® AuraGain™ at low and high cuff-pressure for postoperative airway complications

Deepak, P. G. et al. (2020). Trends Anaesth Crit Care. 30: e32.

Study Overview

An RCT to compared AuraGain vs i-gel for:

- **Oropharyngeal leak pressure (OLP)**
- **Postoperative complications: immediate & postoperative day 1 & 2**

Methods

The study comprised of: 200 patients (age <60 years) undergoing elective laparoscopic surgery with ASA status I-II

AuraGain: 25 cmH_2O cuff pressure (AL) (n=67)

AuraGain: 60 cmH_2O cuff pressure (AH) (n=67)

i-gel (IG): (n=66)

Key Findings

1. OLP before and after pneumoperitoneum were similar in the three groups (IG- 24.22 ± 7.87 and 28.31 ± 8.52, AL-24.40 ± 5.84 and 26.94 ± 5.93, AH-25.02 ± 5.02 and 28.91 ± 5.6).
2. The overall incidence of postoperative sore throat among 3 groups was not significantly different (IG-5.7%, AL-14.9% and AH-17.9%; p=0.135) but dysphagia was seen only with AuraGain at high pressure in 4 patients (5.97%). No other upper airway complication was noted in the study.
3. There is no significant difference between the AuraGain at low cuff pressure and i-gel with respect to upper airway complications when the mean duration of surgery is under 75 minutes.

AuraGain™ Evidence Compendium

AuraGain vs. i-gel

Ambu® AuraGain™ and I-gel™ as barriers to dye placed in the oropharynx - a preliminary study

Sherif, M. J. et al. (2020). Trends Anaesth Crit Care. 30: e17–e18.

Study Overview

An RCT to evaluate AuraGain vs i-gel for:

- **Aspiration prevention**
- **Oropharyngeal leak pressure (OLP)**

Methods

The study comprised of 60 adults (age 18-65 years) with ASA status I-II

AuraGain: 30 adults

i-gel: 30 adults

A standardized general anaesthetic technique was used. 20mL of 0.002% methylene blue in isotonic saline was instilled into the oropharynx by oral and nasal routes (10ml each) with SAD bowl and laryngeal inlet under fiberscopic view. Incidence of dye leak into the bowl of SAD was rechecked fiberscopically.

Key Findings

1. There was no incident of either dye leak into the SAD bowl or dye stain in the gastric aspirate in any patient in both the groups.
2. Both i-gel (31.40 ± 4.99 cmH_2O) and AuraGain (31.33 ± 5.26 cmH_2O) achieved similar OLP (p=0.960).
3. When placed properly and tested for correct placement and performance, both AuraGain and i-gel are equally effective in protecting the upper airway.
4. This makes these devices potentially useful as primary airway rescue devices in patients with obtunded upper airway reflexes and blood and/or secretions in the oropharynx from oral or nasal routes.

References:

Deepak, P. G. *et al.* (2020) 'Evaluation of I-Gel, Ambu-AuraGain at low and high cuff-pressure for postoperative airway complications', *Trends in Anaesthesia and Critical Care*, 30, p. e32. doi: 10.1016/j.tacc.2019.12.082.

Sherif, M. J. *et al.* (2020) 'Ambu® AuraGain™ and I-gel™ as barriers to dye placed in the oropharynx- a preliminary study', *Trends in Anaesthesia and Critical Care*. Elsevier BV, 30, pp. e17–e18. doi: 10.1016/j.tacc.2019.12.046.

AuraGain vs. i-gel & Air-Q

The distance between the glottis and the cuff of a tracheal tube placed through three supraglottic airway devices (SAD) in children, a randomized controlled trial

Lee, J. H. et al. (2019). Eur J Anaesthesiol. 36: 721–727

Key Points

AuraGain: 29.0 ± 7.2 vs. i-gel: 27.9 ± 7.6 — Oropharyngeal leak pressure

AuraGain: 3 [3 to 4] vs. i-gel: 2 [2 to 2] — Fibreoptic view

AuraGain = less vocal cord damage — Safety margin

Study Overview

An RCT to compare AuraGain™, i-gel & Air-Q for:

- **Oropharyngeal leak pressure (OLP)**
- **Safety margin (SM)** = distance from SAD ventilation outlet to proximal cuff of trcheal tube (TT) - distance from ventilation outlet to vocal cord
- **Fibreoptic view* (FB)**

Methods

The study comprised of: 88 children <7 years old, undergoing elective surgery with ASA physical status of I-III

AuraGain: 29 patients; size 1.5 (n=9), size 2 (n=10), size 2.5 (n=10)

Air-Q: 29 patients; size 1 (n=9), size 1.5 (n=10), size 2 (n=10)

i-gel: 30 patients; size 1.5 (n=10), size 2 (n=10), size 2.5 (n=10)

Key Findings

1. The OLP (cmH_2O) measured immediately after insertion & 10 minutes post insertion were comparable between AuraGain & i-gel; Air-Q demonstrated significantly lower OLP (Figure 1).
2. Safety margin was widest with Air-Q followed by AuraGain, while the i-gel had the narrowest safety margin with all size of TT.

	AuraGain	Air-Q	i-gel
SM with the largest TT (cm)	4.4 ± 0.7	7.9 ± 1.1	1.9 ± 1.1
SM with one size smaller TT (cm)	3.1 ± 0.8	5.8 ± 1.4	0.7 ± 1.4
SM with two size smaller TT (cm)	1.2 ± 0.6	4.4 ± 1.3	-0.7 ± 1.5

3. Compared to the AuraGain & Air-Q groups, the fibreoptic view score was worse in i-gel group [IQR] (Figure 2).

*scored using Okuda score (4: <1/3 view covered with epiglottis, 3: 1/3–2/3 view covered with epiglottis, 2: >2/3 view covered with epiglottis, 1: completely covered with epiglottis but having an adequate function)

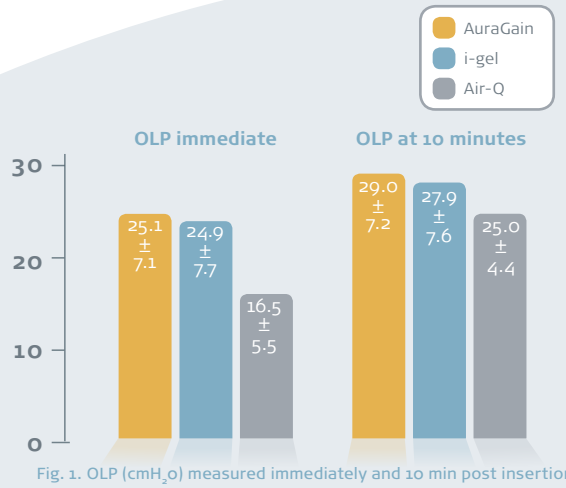

Fig. 1. OLP (cmH_2O) measured immediately and 10 min post insertion

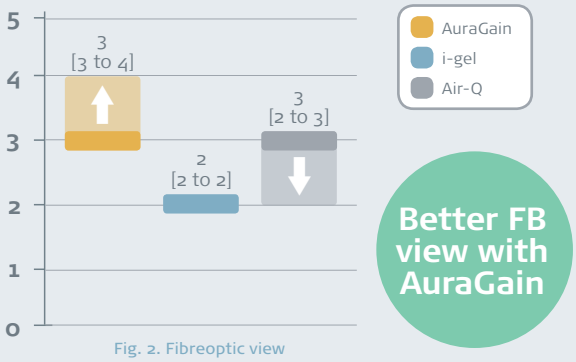

Fig. 2. Fibreoptic view

Conclusion

The OLP was the highest with AuraGain and cuffed TT can be safely located below vocal cords when AuraGain & Air-Q are used as intubation conduit. However, the possibility of vocal cord damage is higher when using the i-gel. Considering the shortest safety margin and the lowest fibreoptic view score, clinicians should be careful in using the i-gel as an intubating conduit in children.

Reference: Lee, J. H. *et al.* (2019) 'The distance between the glottis and the cuff of a tracheal tube placed through three supraglottic airway devices in children: A randomised controlled trial', *European Journal of Anaesthesiology*. Lippincott Williams and Wilkins, 36(10), pp. 721–727. doi: 10.1097/EJA.0000000000001070.

AuraGain vs. LMA ProSeal

Comparison of Ambu® AuraGain™ and LMA® ProSeal in children under controlled ventilation

Joshi, R. et al. (2018). Indian J Anaesth. 62: 455–460.

Key Points

AuraGain: 12 vs. ProSeal 20 — SAD insertion time (median)

AuraGain: 98% vs. ProSeal 83% — Gastric tube insertion (easy)

AuraGain: 23.3 ± 4.6 vs. ProSeal 20.6 ± 4.8 — Oropharyngeal seal pressure

Study Overview

An RCT to compare AuraGain™ & LMA ProSeal for:

- **Median time to device insertion (seconds)**
- **Oropharyngeal seal pressure (OSP)**
- **First-attempt success rate**
- **Fibreoptic view* (FB)**
- **Ease of SAD & gastric tube insertion**

Methods

The study comprised of: 94 children (age 6 months-12 years) undergoing elective surgery with ASA physical status of I-II

AuraGain: 47 patients; size 1.5 (n=13), size 2 (n=31), size 2.5 (n=3)

LMA ProSeal: 47 patients; size 1.5 (n=10), size 2 (n=30), size 2.5 (n=7)

Key Findings

1. AuraGain demonstrated significantly shorter device insertion time (Figure 1).
2. AuraGain demonstrated significantly higher OSP (Figure 2).
3. First-attempt SAD insertion success rate was 95.7% for both groups.
4. Fibreoptic view of the larynx was also comparable between groups:

Fibreoptic view score (%)	1	2	3	4
AuraGain	0	40	49	11
LMA ProSeal	2	32	60	6

5. The ease of SGA & gastric tube insertion were reported
   - **Ease of SGA insertion:**
     No resistance = AuraGain 72% vs. LMA ProSeal 80%
     Mild resistance = AuraGain 23% vs. LMA ProSeal 17%
     Moderate resistance = AuraGain 4% vs. LMA ProSeal 2%
   - **Ease of gastric tube insertion:**
     Easy = AuraGain 98% vs. LMA ProSeal 83%
     Difficult = AuraGain 2% vs. LMA ProSeal 17%

*Brimacombe score: 1-vocal cords not seen, 2-vocal cords plus anterior epiglottis seen, 3-vocal cords plus posterior epiglottis seen, and 4-only vocal cords visible.

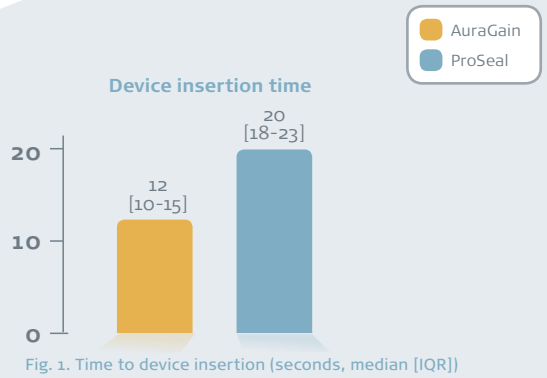

Fig. 1. Time to device insertion (seconds, median [IQR])

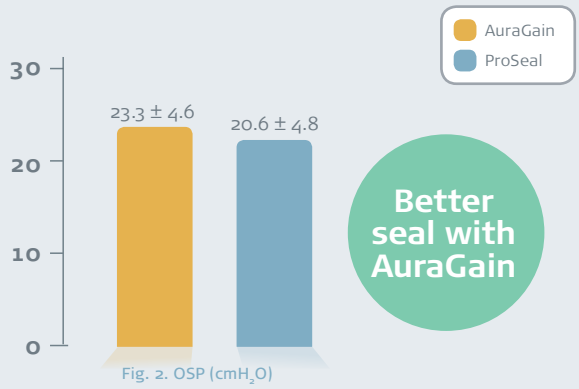

Fig. 2. OSP (cmH_2O)

Conclusion

SAD insertion success rate, ease of insertion and fibreoptic view were comparable between groups. Ambu AuraGain™ provided a significantly better OSP, a shorter insertion time, and an easier gastric tube insertion compared to LMA ProSeal® and can be considered as an option to LMA ProSeal® in children for controlled ventilation.

Reference: Joshi, R. *et al.* (2018) 'Comparision of Ambu® AuraGain™ and LMA® ProSeal in children under controlled ventilation', *Indian Journal of Anaesthesia*. Indian Society of Anaesthetists, 62(6), pp. 455–460. doi: 10.4103/ija.IJA_86_18.

AuraGain vs. LMA Fastrach

A randomised controlled trial comparing fibreoptic-guided tracheal intubation through two supraglottic devices: Ambu® AuraGain™ laryngeal mask and LMA® Fastrach™

Preece, G. et al. (2018). Anaesth Intensive Care. 46: 474–479.

Key Points

AuraGain: 37 vs. Fastrach 44 — SAD insertion time (median)

AuraGain: 69 vs. Fastrach 90 — Intubation time (median)

AuraGain: 100% vs. Fastrach 84% — ETT Success rate

Study Overview

An RCT to compare AuraGain™ & LMA Fastrach for:

- **Median time to device insertion (seconds)**
- **Median time to ETT intubation (seconds)**
- **SAD insertion success rate**
- **ETT insertion success rate**
- **Ease of ETT insertion**
- **Fibreoptic view* (FB)**
- **Postoperative complications**

Methods

The study comprised of: 116 patients (age 54-56) undergoing elective surgery with ASA physical status of I-III

AuraGain: 59 patients; size 3 (n=15), size 4 (n=35), size 5 (n=9)

LMA Fastrach: 57 patients; size 3 (n=5), size 4 (n=36), size 5 (n=16)

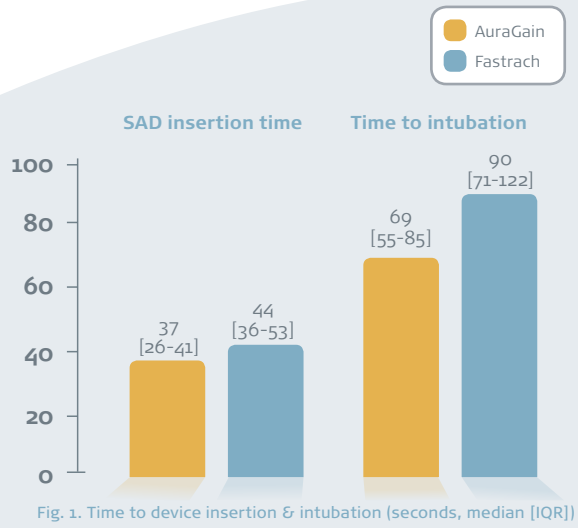

Fig. 1. Time to device insertion & intubation (seconds, median [IQR])

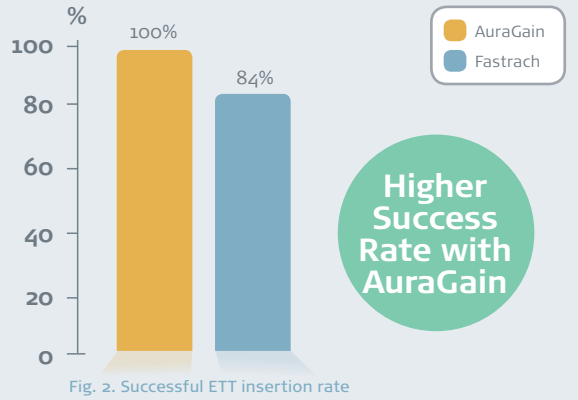

Fig. 2. Successful ETT insertion rate

Key Findings

1. AuraGain demonstrated significantly shorter device insertion time & intubation time compared to LMA Fastrach (Figure 1).
2. SAD insertion success rate was slightly higher in AuraGain (100%) vs. LMA Fastrach (95%) group.
3. AuraGain provided higher ETT insertion success rate vs. LMA Fastrach (Figure 2).
4. It was easier to insert ETT through AuraGain (9/10) than LMA Fastrach (7/10).
5. The fibreoptic view (laryngeal alignment) was superior in the AuraGain group compared to the LMA Fastrach group.

Fibreoptic view score (%)	1	2	3	4
AuraGain	4	32	15	49
LMA F	20	15	28	37

6. Postoperative dysphonia & dysphagia were higher in LMA Fastrach (28% & 9%) vs. AuraGain (20% & 4%).

* Brimacombe and Berry scoring system: 1-vocal cords not visible, 2-vocal cords plus anterior epiglottis visible, 3-vocal cords plus posterior epiglottis visible, and 4-only vocal cords visible.

Conclusion

Ambu AuraGain was found to be superior to the Fastrach LMA as it provided better laryngeal alignment and quicker insertion time. AuraGain also allowed quicker and easier ETT intubation when used as a conduit. The SAD & ETT insertion success rates were also in favour of AuraGain. The postoperative complication rate was comparable between devices.

Reference: Preece, G. *et al.* (2018) 'A randomised controlled trial comparing fibreoptic-guided tracheal intubation through two supraglottic devices: Ambu® AuraGain™ laryngeal mask and LMA® Fastrach™', *Anaesthesia and intensive care*. NLM (Medline), 46(5), pp. 474–479. doi: 10.1177/0310057x1804600508.

AuraGain vs. LMA protector

A prospective, randomised trial of the Ambu® AuraGain™ laryngeal mask versus the LMA® protector airway in paralysed, anesthetised adult men

Moser, B. et al. (2018). Minerva Anestesiol. 84: 684–692.

Key Points

AuraGain: 16 vs. Protector 19 — Intubation time (seconds av.)

AuraGain: 98% vs. Protector 74% — Success rate

AuraGain: 100% vs. Protector 68% — Gastric tube insertion (1st attempt)

Study Overview

An RCT to compare AuraGain™ & LMA protector for:

- **Time to device insertion (seconds)**
- **Time to successful intubation (seconds)**
- **Oropharyngeal leak pressure (OLP)**
- **First-attempt success rate for SAD & gastric tube**
- **Gastric content volume (mL)**
- **Ease of advancing tracheal tube**

Methods

The study comprised of: 93 male patients (age 45-48) undergoing elective surgery with ASA physical status of I-II

AuraGain: 46 patients; size 5

LMA Protector: 47 patients; size 5

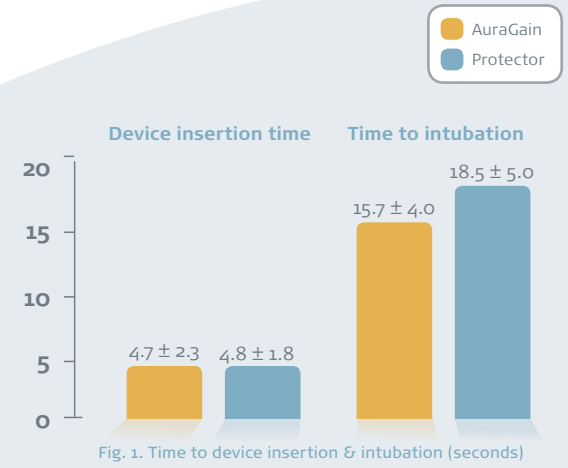

Fig. 1. Time to device insertion & intubation (seconds)

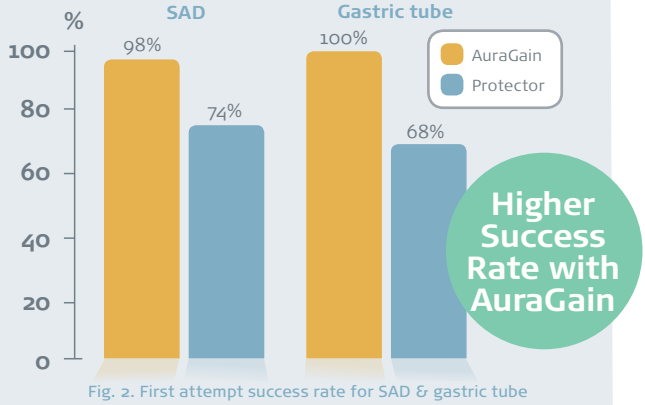

Fig. 2. First attempt success rate for SAD & gastric tube

Key Findings

1. AuraGain demonstrated shorter intubation time, while device insertion time was comparable between devices (Figure 1).
2. AuraGain demonstrated slightly higher OLP (30.1 ± 6.0, cmH_2O) vs. LMA protector (28.2 ± 6.7, cmH_2O).
3. AuraGain demonstrated significantly higher first-attempt SAD & gastric tube insertion success rates compared to LMA protector (Figure 2).
4. Gastric content volume was 5.7 ± 5.2 for AuraGain vs. 8.3 ± 7.8 for LMA protector.
5. Ease of advancing tracheal tube was also reported:

   Easy passage = AuraGain 87% vs. LMA 47%
   Little resistance= AuraGain 11% vs. LMA 26%
   Significant resistance= LMA 28%

Conclusion

Insertion success of laryngeal mask, gastric tube insertion, ease of advancing the tracheal tube and trans-device intubation time were in favour of AuraGain. OLP, SAD insertion time & gastric content volume were similar for both devices. Handling of the device as measured as first-time successful placement was significantly in favour of the AuraGain.

Reference: Moser, B. *et al.* (2018) 'A prospective, randomized trial of the Ambu AuraGainTM laryngeal mask versus the LMA® protector airway in paralyzed, anesthetized adult men', *Minerva anestesiologica*. NLM (Medline), 84(6), pp. 684–692. doi: 10.23736/S0375-9393.17.12254-6.

AuraGain vs. LMA Supreme

Comparison of oropharyngeal leak pressure between the Ambu® AuraGain™ and the LMA® Supreme™ supraglottic airways: a randomised-controlled trial

Wong, D. T. et al. (2018). Can J Anesth. 65: 797–805.

Key Points

AuraGain: 26.4 ± 2.8 vs. Supreme 21.6 ± 3.4
Oropharyngeal leak pressure

AuraGain: 13 vs. Supreme 11
SAD insertion time (av.)

AuraGain = great patient satisfaction
Satisfaction

Study Overview

An RCT to compare AuraGain & LMA Supreme for:

- **Oropharyngeal leak pressure (OLP)**
- **Time to device insertion (seconds)**
- **First-attempt success rate**
- **Ease of SAD insertion**
- **Patient & anaesthesiologist satisfaction**

Methods

The study comprised of: 165 patients (mean age 50 years) undergoing day surgery with ASA physical status of I-III

AuraGain: 81 patients; size 3 (n=10), size 4 (n=38), size 5= (n=33)

LMA Supreme: 84 patients; size 3 (n=2), size 4 (n=31), size 5 (n=51)

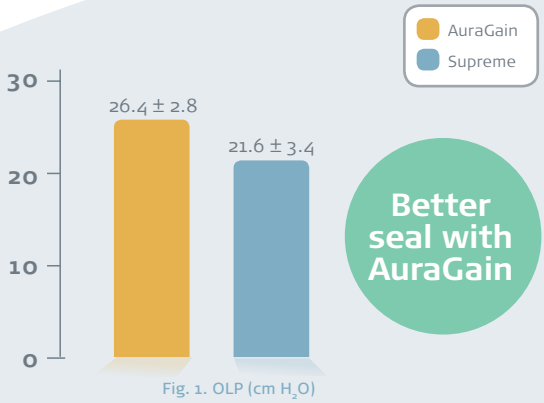

Fig. 1. OLP (cm H_2O)

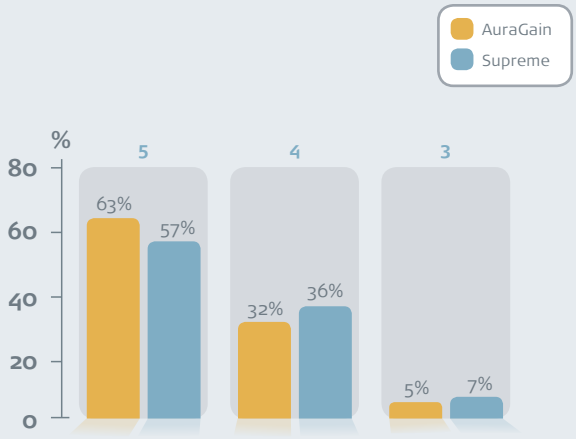

Fig. 2. Patient satisfaction
(0 = very dissatisfied, 5 = extremely satisfied)

Key Findings

1. AuraGain demonstrated significantly higher OLP (Figure 1).
2. Time to successful SAD insertion was comparable between AuraGain (13 ± 4) and LMA Supreme (11 ± 3) group.
3. First-attempt success rate was 77% for AuraGain vs. 94% for LMA Supreme; both devices achieved 100% success rate overall.
4. The ease of SGA insertion was reported to be easy or fair in 86% of the cases in AuraGain vs. 100% in the LMA Supreme group. In 14% of the cases, there was difficulty in inserting AuraGain.
5. Overall patient satisfaction (2h post surgery) was comparable between AuraGain (95% either satisfied or extremely satisfied) vs. LMA Supreme (93%); Overall anaesthesiologists satisfaction was also comparable (AuraGain 93% either high or moderate vs. LMA Supreme 98%) (Figure 2).

Conclusion

AuraGain provided better OLP. A higher OLP may allow for SGAs to be utilized in a wider range of patients and procedures. Device insertion time was comparable between groups. The first attempt success rate & ease of SGA insertion were in favour of LMA Supreme. Overall patient & anaesthesiologists satisfaction were comparable between groups.

Reference: Wong, D. T. *et al.* (2018) 'Comparison of oropharyngeal leak pressure between the Ambu® AuraGain™ and the LMA® Supreme™ supraglottic airways: a randomized-controlled trial', *Canadian Journal of Anesthesia*. Springer New York LLC, 65(7), pp. 797–805. doi: 10.1007/s12630-018-1120-4.

AuraGain vs. LMA Supreme

Ambu® AuraGain™ versus LMA Supreme™ Second Seal™ : a randomised controlled trial comparing oropharyngeal leak pressure and gastric drain functionality in spontaneously breathing patients

Shariffuddin, I. I. et al. (2017). Anaesth Intensive Care. 45: 244–250.

Key Points

AuraGain: 24.1 ± 7.4 vs. LMA SSS 23.6 ± 6.2 — Oropharyngeal leak pressure

AuraGain: 76% vs. LMA SSS 61% — Gastric tube insertion (easy)

AuraGain = Less AM — Additional Manoeuvres (AM)

Study Overview

An RCT to compare AuraGain™ & LMA Supreme Second Seal (LMA SSS) for:

- **Oropharyngeal leak pressure (OLP)**
- **Time to device insertion (seconds)**
- **First-attempt success rate**
- **Ease of SAD insertion & additional manoeuvres (AM)**
- **Gastric tube insertion rate & ease of insertion**

Methods

The study comprised of: 100 patients (age 44-48 years) undergoing elective surgery with ASA physical status of I-III

AuraGain: 50 patients; size 3 (n=26), size 4 (n=24)

LMA SSS: 50 patients; size 3 (n=22), size 4 (n=28)

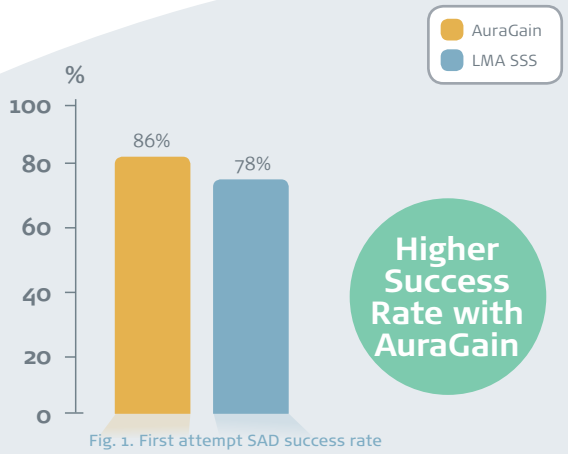

Fig. 1. First attempt SAD success rate

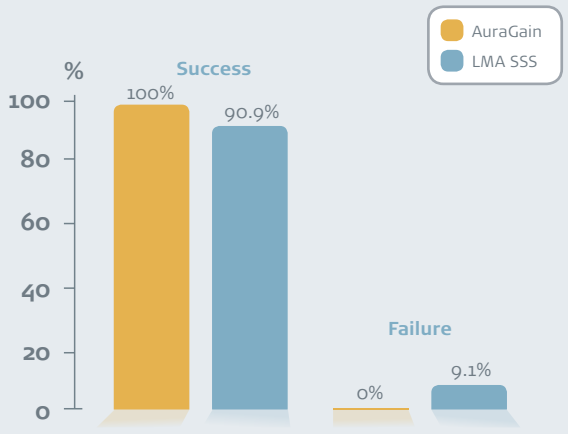

Fig. 2. Gastric tube insertion success rate

Key Findings

1. OLP (cmH_2O) was comparable between AuraGain (24.1 ± 7.4) & LMA SSS (23.6 ± 6.2) groups.
2. Time to successful SAD insertion was longer in AuraGain (33.4 ± 10.9) than LMA SSS (27.3 ± 11.4) group.
3. First-attempt success rate was 86% for AuraGain vs. 78% for LMA SSS; both devices achieved 100% success rate overall (Figure 1).
4. It was easier to insert LMA SSS, however, AuraGain required significantly less additional manoeuvres (28%) compared to LMA SSS (36%).
5. Gastric tube insertion success rate was in favour of AuraGain (Figure 2). The ease of gastric tube insertion was reported as:

   Easy = AuraGain 75.5% vs. LMA SSS 61.4%
   Acceptable = AuraGain 16.35 vs. LMA SSS 22.7%
   Difficult = AuraGain 8.2% vs. LMA SSS 15.9%

Conclusion

The OLP was comparable between groups. AuraGain took longer to insert, however, required significantly less AM. The first attempt success rate, gastric tube insertion success rate & easy of gastric tube insertion were in favour of AuraGain. In conclusion, this study has demonstrated satisfactory performance of the new AuraGain in spontaneously breathing anaesthetised adults.

Reference: Shariffuddin, I. I. *et al.* (2017) 'Ambu® AuraGain™ versus LMA Supreme™ Second Seal™: A randomised controlled trial comparing oropharyngeal leak pressures and gastric drain functionality in spontaneously breathing patients', *Anaesthesia and Intensive Care*. Australian Society of Anaesthetists, 45(2), pp. 244–250. doi: 10.1177/0310057x1704500215.

AuraGain vs. LMA Supreme

A randomised comparison of the Ambu® AuraGain™ versus the LMA Supreme in patients undergoing gynaecologic laparoscopic surgery

Lopez, A. M. et al. (2016). J Clin Monit Comput. 31(6) : 1255–1262.

Key Points

AuraGain: 34 ± 5 vs. Supreme 29 ± 5 — Seal pressure

AuraGain: 100% vs. Supreme 96.5% — Success rate

AuraGain: 13.2 vs. Supreme 11.5 — SAD insertion time (seconds av.)

Study Overview

An RCT to compare AuraGain & LMA Supreme new cuff for:

- **Initial seal pressure (ISP) & airway pressure**
- **Time to device insertion (seconds)**
- **First-attempt success rate**
- **Additional manoeuvres**
- **Fibreoptic view* (FB)**

Methods

The study comprised of: 60 females (age 39-42 years) undergoing laparoscopic surgery

AuraGain: 31 patients; SAD size 4; gastric tube (16G)

LMA Supreme: 29 patients; SAD size 4; gastric tube (16G)

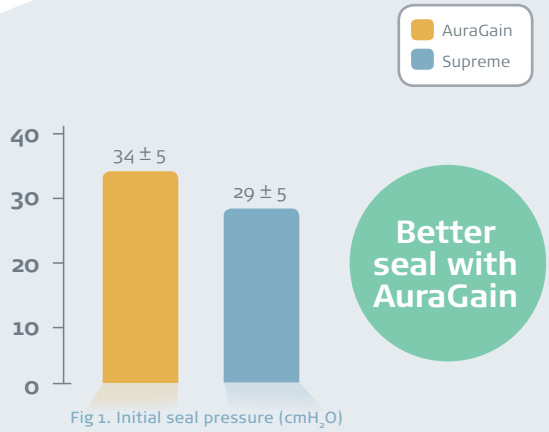

Fig 1. Initial seal pressure (cmH_2O)

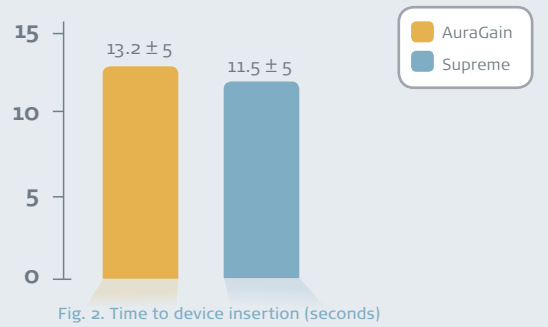

Fig. 2. Time to device insertion (seconds)

Key Findings

1. AuraGain demonstrated significantly higher ISP (Figure 1) & initial airway pressure AuraGain 34 (+/-5) vs. LMA Supreme 29 (+/-5).
2. Time to successful SAD insertion was comparable between groups (Figure 2).
3. First-attempt success rate was 100% for AuraGain vs. 96.5% for LMA Supreme; both devices achieved 100% success rate overall.
4. Both devices required similar amount of additional manoeuvres.
5. The fibreoptic view (laryngeal alignment) was superior in the AuraGain group compared to the LMA Supreme group:

FB score (numbers)	1	2	3
AuraGain	10	21	0
LMA Supreme	9	17	3

*Fibreoptic view: 1 = complete vocal cord, 2 = epiglottis seen inside the tube, 3 = obstructed view.

Conclusion

AuraGain provided better ISP, initial airway pressure, overall success rate & fibreoptic view compared to LMA Supreme new cuff. The time to device insertion and additional airway manoeuvres were comparable between groups. Overall, AuraGain consistently provided higher seal pressures and a clear glottic view, offering the possibility to guide direct tracheal intubation if required.

Reference: Lopez, A. M. *et al.* (2016) 'A randomized comparison of the Ambu AuraGain versus the LMA supreme in patients undergoing gynaecologic laparoscopic surgery', *Journal of Clinical Monitoring and Computing*. Springer Netherlands, 31(6), pp. 1255–1262. doi: 10.1007/s10877-016-9963-0.

AuraGain vs. LMA Supreme

A randomised comparison of the Ambu® AuraGain™ and the LMA® Supreme in infants and children

Jagannathan, N. et al. (2016). Anaesthesia. 71(2) : 205–212.

Key Points

AuraGain: 13 vs. LMA S 13 — SAD insertion time (seconds av.)

AuraGain: 22 [18-26] vs. LMA S 20 [16-26] — Oropharyngeal leak pressure

AuraGain 100% vs. LMA S 86% — Airway quality (clear)

Study Overview

An RCT to compare AuraGain & LMA Supreme for:

- **Oropharyngeal leak pressure (OLP)**
- **Median time to device insertion (seconds)**
- **First-attempt success rate**
- **Ease of SAD & gastric tube insertion**
- **Airway quality & additional manoeuvres (AM)**

Methods

The study comprised of: 100 children (Median age 21 month) undergoing elective surgery with ASA physical status of I-III

AuraGain: 50 patients; size 1.5, 5–10 kg; size 2, 10–20 kg

LMA Supreme: 50 patients; size 1.5, 5–10 kg; size 2, 10–20 kg

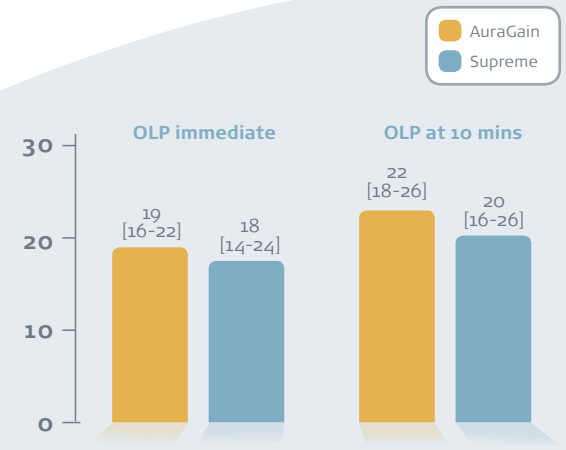

Fig. 1. OLP (cm H_2O) measured immediately and 10 mins post-insertion (median, IQR)

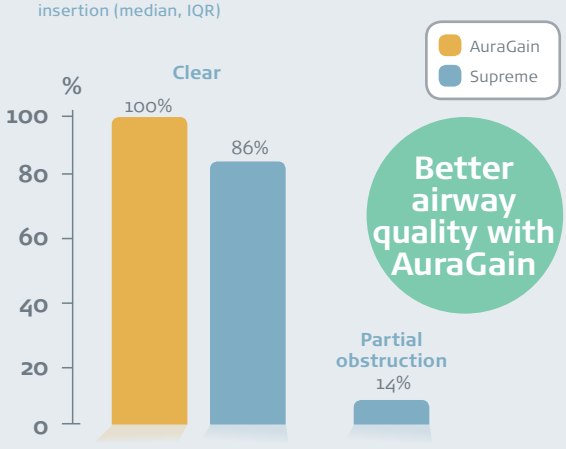

Fig. 2. Airway quality during the maintenance of anaesthesia

Key Findings

1. The OLP (cmH_2O) measured immediately after insertion & 10 minutes post-insertion were comparable between groups (Figure 1).
2. Time to successful SAD insertion was comparable between AuraGain (13 [12-15]) & LMA Supreme (13 [12-14]) group.
3. First-attempt success rate was 96% for AuraGain vs. 100% for LMA Supreme; both devices achieved 100% success rate overall.
4. It was slightly easier to insert LMA Supreme, however, AuraGain did not require additional manoeuvres, whereas LMA Supreme did (14%).
5. The ease of gastric tube insertion was comparable between groups.
6. The airway quality during the maintenance of anaesthesia was better in the AuraGain group (100% clear) vs. LMA supreme (86% clear & 14% partial obstruction) (Figure 2).

Conclusion

The OLP, device insertion time, ease of gastric tube insertion & success rate were comparable between groups. It was slightly easier to insert LMA Supreme, however, it required additional adjustment. The airway quality was better in the AuraGain group.

Reference: Jagannathan, N. *et al.* (2016) 'A randomised comparison of the Ambu® AuraGain™ and the LMA® supreme in infants and children', *Anaesthesia*. Blackwell Publishing Ltd, 71(2), pp. 205–212. doi: 10.1111/anae.13330.

AuraGain vs. Guedel tube

Flexible bronchoscopic intubation through the Ambu® AuraGain™ laryngeal mask versus a slit Guedel tube: a non-inferiority randomised-controlled trial

Moser, B. et al. (2017). Can J Anesth. 64(11): 1119–1128.

Key Points

AuraGain: 21 vs. G. Tube 24 — Intubation time (seconds av.)

AuraGain: 96% vs. G. tube 95% — Intubation success rate

AuraGain = good FB view — Fibreoptic view

Study Overview

An RCT to compare AuraGain & Guedel tube for:

- **Intubation time (seconds)**
- **Intubation success rate**
- **Ease of tracheal tube insertion**
- **Fibreoptic view* (FB)**

Methods

The study comprised of: 88 patients (age 60-65 years) undergoing orthopaedic surgery with ASA status of I-II

AuraGain: 45 patients;

Guedel tube: 43 patients;

ETT size: 7mm

Key Findings

1. All patients were successfully intubated. The time needed for intubation was comparable (Figure 1).
2. Intubation success rate was also comparable between groups (Figure 2).
3. It was easier to insert tracheal tube through AuraGain with 80% having no resistance vs. 70% in Guedel tube group.
4. The fibreoptic view (laryngeal alignment) was superior in the AuraGain group compared to the Guedel tube group:

Fibreoptic view score (%)	1	2	3	4
AuraGain	0	22	53	27
Guedel tube	0	33	58	9

*Fibreoptic view: 4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis visible; 2 = vocal cords plus anterior epiglottis visible; 1 = vocal cords not seen.

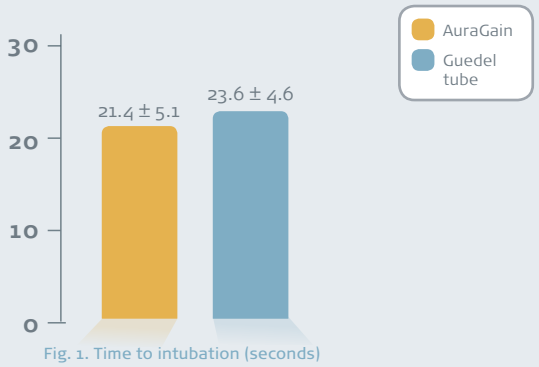

Fig. 1. Time to intubation (seconds)

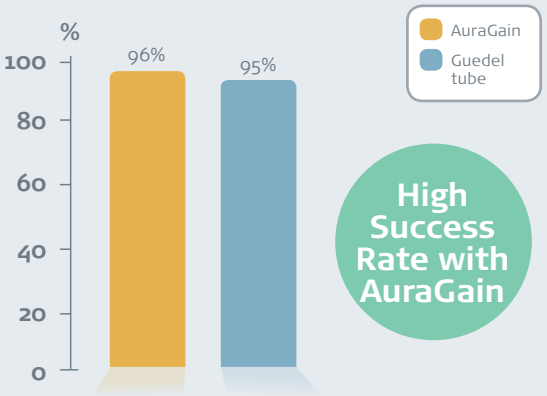

Fig. 2. First attempt intubation success rate

High Success Rate with AuraGain

Conclusion

The AuraGain demonstrated comparable intubation time, success rate and ventilation characteristics with Guedel tube. It aligned well with the glottis in a majority of patients as indicated by the fibreoptic view and the ease of ETT insertion. Bronchoscopic intubation with the AuraGain laryngeal mask can be performed at least as fast as regular bronchoscopic intubation.

Reference: Moser, B. *et al.* (2017) 'Flexible bronchoscopic intubation through the AuraGain™ laryngeal mask versus a slit Guedel tube: a non-inferiority randomized-controlled trial', *Canadian Journal of Anesthesia*. Springer New York LLC, 64(11), pp. 1119–1128. doi: 10.1007/s12630-017-0936-7.

AuraGain

Flexion decreases the ventilation quality of the Ambu® AuraGain™ laryngeal mask in paralysed children: a prospective randomised crossover study

Lee, J. H. et al. (2018). Acta Anaesthesiol Scand. 62: 1080–1085.

Study Overview

A crossover RCT to evaluate AuraGain with assigned neck positions for:

- **Oropharyngeal leak pressure (OLP)**
- **Fibreoptic view**

Methods

The study comprised of 39 children (average age: 2.9 years) undergoing elective surgery with ASA status of I-II

AuraGain was inserted in all cases at different neck positions in a crossover manner, including neutral head an nect position, and then for the flexed, extended and rotated head and neck positions in a random order.

AuraGain size: size 1.5 (n=13), size 2 (n=15), size 2.5 (n=11)

Key Findings

1. The mean OLPs were 26.2 ± 6.7, 33.9 ± 7.2, 23.6 ± 5.8 and 22.2 ± 7.1 cmH_2O in neutral, flexion, extension and right rotation positions, respectively. Compared to the neutral position, the OLPs were significantly different in the flexion, extension and right rotation positions ($p<0.001$; $p=0.014$; $p=0.002$).
2. There was a significant deterioration of fibreoptic view in flexion ($p=0.025$), while a significant improvement in extension ($p=0.008$) and right rotation positions ($p< 0.001$) compared to the neutral position.
3. Clinically, the flexed head and neck position can be used when a better oropharyngeal seal is needed. However, the neutral, extended and rotated neck position can be used in paediatric patients for more effective ventilation with the AuraGain.

AuraGain

The use of an EBUS TBNA Friendly larynx mask

Krasnik, M. (2017). *IASLC 18th World Conference on Lung Cancer.* J THORAC ONCOL. p. S2374.

Study Overview

A case series to evaluate AuraGain during endobronchial ultrasound guided trans-bronchial needle aspiration (EBUS-TBNA) for:

- **First-attempt success rate**
- **Ease of maneuvering an EBUS scope via the AuraGain**
- **Fibreoptic assessment**
- **Intracuff & Peak pressure**

Methods

The study comprised of 20 patients with ASA status of II-III undergoing EBUS-TBNA

AuraGain size 3, 4 or 5 were used

Key Findings

1. First attempt insertion success rate was 95% with an overall success rate of 100%.
2. 90% recorded passing an EBUS scope as being with little resistance, moderate resistance was felt in 2 cases, and no records of high resistance was experienced.
3. Fibreoptic assessment of the alignment of AuraGain and the trachea was recorded as 100% satisfactory to accommodate the performance of the EBUS procedure with needle aspiration of lymphoid nodes of down 3.mm.
4. Average intracuff pressure to obtain seal was 55.55 cmH_2O, and ventilation was performed without a leak at up to pPeak of 35 cmH_2O which was the maximum pressure permitted.
5. The AuraGain was effectively utilized for airway management and with a high degree of success as a conduit for EBUS-TBNA.

AuraGain

Tracheal intubation through Ambu® AuraGain™ laryngeal mask during routine clinical practice

Castro, S. M. et al. (2018). Trends Anaesth Crit Care. 23: 24–25.

Study Overview

An observational study to evaluate AuraGain for:

- **Time to intubation (seconds)**
- **First-attempt success rate**
- **Directed & guided intubation**

Methods

The study comprised of: 31 patients undergoing elective surgery.

After anaesthetic induction, the AuraGain laryngeal mask was placed. AuraGain was used as an intubation conduit.

Key Findings

1. All patients were intubated at the first attempt (100%) in a mean total time of 19.61 ± 14.01 seconds (range 8-75).
2. In 19 cases, it was necessary to correct the position of the laryngeal tube. There were no problems during the removal of the device.
3. 61.35% was directed intubation, and 38.7% was guided intubation.
3. It can be assured that the AuraGain laryngeal mask is a safe, easy and fast insertion device, useful for achieving effective ventilation as well as allowing immediate intubation with the support of a flexible video endoscope.

AuraGain

Fiberoptic intubation through laryngeal mask in a patient who had formally refused an awake intubation

Ivars, C. et al. (2017). Trends Anaesth Crit Care. 12: 33–34.

Study Overview

A case study to evaluate AuraGain during a fibreoptic intubation.

Methods

Case: a patient with all the factors predicting a difficult airway (Mallampati classification III, limited mouth opening, head extension less than 80º) and a long term diabetes, scheduled for a shoulder arthroscopy.

After checking a proper oxygenation and ventilation, fibreoptic intubation through the AuraGain was carried out.

Key Findings

1. The technique was done without any complication in less than 1 minute and with no hemodynamic incident or desaturation.
2. The laryngeal mask is a secure way to manage difficult airways and a rescue technique in difficult ventilation cases.
3. The limited mouth opening and the poor head extension, probably because of diabetes, made that video laryngoscopes were not an option. The fiberoptic intubation is the right choice in cases of mouth opening limitation.
4. Fibreoptic intubation through AuraGain allowed us to practice quick and secure intubation without any difficulty.

References:

Castro, S. M. *et al.* (2018) 'Tracheal intubation through Ambu AuraGain laryngeal mask during routine clinical practice', *Trends in Anaesthesia and Critical Care*. Elsevier BV, 23, pp. 24–25. doi: 10.1016/j.tacc.2018.09.042.

Ivars, C. *et al.* (2017) 'Fiberoptic intubation through laringeal mask in a patient who had formally refused an awake intubation', *Trends in Anaesthesia and Critical Care*. Elsevier BV, 12, pp. 33–34. doi: 10.1016/j.tacc.2017.01.038.

AuraGain

Different difficult airway approaches in a 2,5kg neonate: Ambu® AuraGain™, fiberoptic intubation with Airtraq®/through Ambu® AuraGain™

Hervías, M. et al. (2020). Trends Anaesth Crit Care. 30: e167–e168.

Study Overview

A case study to evaluate AuraGain during a difficult airway management.

Methods

Case: a 2,5 kg new-born with bilateral lip-palate cleft, micrognathia, myelomeningocele and Chiari malformation with difficult airway

- AuraGain was used for MRI on day 7.
- A fibreoptic intubation through the AuraGain was used for the ventriculoperitoneal shunt insertion on day 9.

Key Findings

1. On day 7, spontaneous breathing was maintained.
2. On day 9, when correct ventilation was checked, a FOB inside the ET was used for intubation through the LMA. As the extraction of the LMA could be difficult and lead to possible accidental extubation, the LMA was left with the ET during the procedure and used for safer extubation.
3. No desaturations nor haemodynamic events occurred.
4. LMA & LMA with fibreoptic intubation are good techniques for airway management of the neonate with DA.

References:

Kaminska, H., Gawel, W. B. and Wieczorek, W. (2018) 'Which option for ventilation is optimal for resuscitation performed by nurses? Pilot data', *American Journal of Emergency Medicine*, 36(9), pp. 1710–1711. doi: 10.1016/j.ajem.2018.01.072.

Hervías, M. *et al.* (2020) 'Different diffcult airway approaches in a 2,5kg neonate: Ambu® Auragain™, fiberoptic intubation with Airtraq®/through Ambu® Auragain™', *Trends in Anaesthesia and Critical Care*. Elsevier BV, 30, pp. e167–e168. doi: 10.1016/j.tacc.2019.12.411.

AuraGain

Awake supraglottic airway guided flexible bronchoscopic intubation in patients with anticipated difficult airways: a case series and narrative review

Lim, W. Y. and Wong, P. (2019). Korean J Anesthesiol. 72: pp. 548–557.

Study Overview

AuraGain was evaluated in awake Supraglottic Airway Guided Flexible Bronchoscopic Intubation (SAGFBI).

Methods

Ten difficult airway cases were evaluated. Patient age ranged between 42-76 years

SAD size: size 3 for women & size 4 for men

Tracheal tube size: size 3 = 6.5 mm & size 4 = 7.5 mm

Key Findings

1. The technique was successful and well tolerated by all patients, and associated complications were rare.
2. It also offered the advantages of performing an 'awake test insertion' of the SAD, 'awake look' at the periglottic region and 'awake test ventilation'.
3. In certain patients, awake SAGFBI offers advantages over conventional awake FBI or awake video laryngoscopy. More research is required to evaluate its success and failure rates and identify associated complications.

References:

Evrin, T., Iskrzycki, L. and Gawlowski, P. (2018) *The usage of Ambu® AuraGain™ laryngeal mask airway by the lifeguards, Correspondence*. American Journal of Emergency Medicine. doi: 10.1016/j.ajem.2018.04.052.

Lim, W. Y. and Wong, P. (2019) 'Awake supraglottic airway guided difficult airways: a case series and in patients with anticipated flexible bronchoscopic intubation narrative review', *Korean Journal of Anesthesiology*, 72(6), pp. 548–557. Available at: https://pubmed.ncbi.nlm.nih.gov/31475506/.

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