Evaluation Of Ambu AuraGain Supraglottic Airway Device In 80 Patients

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Introduction

The 4th National Audit Project and subsequent publications have encouraged the use of second generation supraglottic airway devices (SADs) over first generation devices^{1,2}. Despite several devices (e.g. the i-gel, LMA Pro-Seal and LMA Supreme) reaching the market, there is a limited amount of data available on their effectiveness. Ambu (Ballerup, Denmark) have recently relaunched the AuraGain. This CE marked second generation device claims to allow the passage of a nasogastric tube, deliver high seal pressures and facilitate tracheal intubation. Published data on its use are limited³, therefore we report initial evaluation of the AuraGain in routine anaesthetic practice to assess how it functions as a supraglottic airway.

Methods

As this was a clinical evaluation of a CE marked device used for its proper purpose, South East Scotland Regional Ethics Service deemed that formal review was not required. Caldicott Guardian approval was sought and the Theatre Quality Improvement team consulted. Size 3 and 4 AuraGains were available initially, size 5s became available at the end of the evaluation period. A mixed group of consultant anaesthetists used the AuraGain in adult patients as they would any supraglottic airway in their normal clinical practice. There were no specific exclusion criteria. Data recorded included BMI, sex, number of insertion attempts, oropharyngeal leak pressure (OLP) immediately after insertion (manometric stability method⁴, gas flow 5 litres min⁻¹) and evidence of trauma (blood visible on mask removal). As the evaluation aimed to assess how the device functioned simply as a SAD, tracheal intubation or insertion of nasogastric tubes via the devices were not attempted unless clinically indicated.

Results

Twenty six anaesthetists trialled 80 devices, with clinicians reporting they would use the device again in 90% of insertions. Table 1 shows our results to date. Reported observations included the need for good mouth opening due to the size of the device and some difficulty inserting the device although no device took more than 3 insertion attempts. The failure rate was 3.75% (95%) CI 0.78 – 10.57%) - the first failure was due to a poor fit, the second due to high airway pressures being required and the third was due to a smaller size being required but not being available.

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Oropharyngeal leak pressures reported were generally high, with median values of at least 25 cmH₂0 seen across all sizes (see box and whisker plot).



Figure 1. Size 4 Ambu AuraGain Supraglottic Airway Device

Size	Number inserted	% male	Mean BMI (SD)	Mean leak pressure (cmH ₂ 0) (SD)	Cumulative % success on 1 st , 2 nd & 3 rd insertion	Number abandoned (%)	% trauma
3	26	3.85	26.21 (4.97)	23.9 (7.39)	88.46/92.31/100	1 (3.85)	11.54
4	48	27.6 6	28.86 (5.1)	28.17 (6.21)	78.26/100/100	1 (2.08)	2.08
5	6	66.6 7	27.47 (4.77)	30.2 (3.2)	66.67/83.33/100	1 (16.67)	0.00
All	80	22.5 0	27.93 (5.11)	27.03 (6.71)	80.77/96.15/100	3 (3.75)	5.00

Table 1. Data collected based on the first 80 SAD insertions

	35	_
	30	_
	25	_
Leak Pressure	20	_
(0111120)	15	_
	10	_
	5	_
	0	

40

Chart 1. Box and whisker plots to demonstrate the range of leak pressures reported

This preliminary evaluation demonstrates OLPs comparable to other second generation devices⁵, however we have not yet trialed enough devices to determine a clinically useful failure rate. Similarly we did not attempt endotracheal or nasogastric tube insertion. We have demonstrated that the device has a high OLP and that it merits further investigation to fully establish its potential as a second generation device. The increased perceived difficulty inserting the devices needs to be considered, but the relatively high success rate at inserting the devices without any provided training is reassuring.

results.



Size of AuraGain

Conclusions

References

1. Cook TM, Woodall NM, Frerk CM (Editors). Report and Findings. London; 2011 2. Cook TM, Kelly FE. Br J Anaesth 2015 [cited 2015 Jun 7];aev156 – Available from: http://bja.oxfordjournals.org 3. Lopez A, Sala-Blanch X, Valero R, Prats A. Open J Anesthesiol 2014;4:332–9 4. Keller C, Brimacombe JR, Keller K, Morris R. Br J Anaesth 1999; 82: 286–7 5. Mukadder S, Zekine B, Erdogan KG, et al. ScientificWorldJournal 2015: 63

Ambu (Ballerup Denmark), provided all the AuraGains used but have had no input into the evaluation, design or

- 80 Ambu AuraGain new second generation supraglottic airway devices (sizes 3-5) were trialled in routine practice.
- Mean leak pressure of 27cmH₂0 with 100% insertion success within 3 attempts. Popular
 - with large number of anaesthetists.
- There was a failure rate of 3.75% [Cl 0.08-10.6%], 5% incidence of trauma.
- Effective as a supraglottic airway with an OLP similar to other second generation devices.
- Further evaluation required to determine actual failure rate and function as an intubation

conduit.

Summary