

# A clinical evaluation of the Ambu AuraGain in children

The Ambu AuraGain is a new second-generation supraglottic airway with an incorporated gastric drainage channel and the capability of working as a conduit for tracheal intubation. This pilot study presents the generated data of the product performance as a ventilatory device representing size 1½ & 2.

The objective was to assess the clinical performance of the AuraGain for airway maintenance under mechanical ventilation in children. Assessment of the AuraGain as a conduit for direct optical intubation was not performed.

The study included 30 children, ASA I-II, 5 months to 4 years of age, undergoing various procedures; requiring a size 1½ or 2 supraglottic airway. The assessment included insertion success rate, oropharyngeal Leak pressure (OLP), success of gastric tube insertion, and postoperative complications. First attempt insertion success rate was 96.7%, with an overall insertion success rate of 100%. The mean

oropharyngeal leak pressure for all patients was 22.8 (16-38) cmH<sub>2</sub>O. Gastric tube placement was possible in 100% of patients. Fiberoptically assessment revealed 80% full laryngeal view with no evidence of full epiglottic down folding. Immediate Post-OP complications were noted in 3 patients: cough at emergence (n=2) and laryngospasm at extubation (n = 1).

In conclusion, the size 1½ and 2 Ambu AuraGain, was inserted with a high degree of success on the first attempt. The AuraGain was effectively utilized for airway management for a variety of procedures in children undergoing mechanical ventilation with minimal complications. The oropharyngeal leak pressure demonstrated in this study, along with access for gastric decompression; suggest that the Ambu AuraGain is an effective device for positive pressure ventilation in children.

Insertion		Mean OLP
Overall Success rate (≤ 3 att)	30 (100%)	22.8 (16-38) cmH <sub>2</sub> O
1st attempt success rate	29 (96.7%)	

Gastric tube placement:	Size 1½ (N=16) 8 French GT	Size 2 (N=14) 10 French GT
Overall Success rate (≤ 2 attempts)	16 (100%)	14 (100%)
1st attempt insertion success rate	16 (100%)	13 (93%)

Laryngeal view	
Larynx & epiglottis post. Surface seen	16 (53.3%)
Larynx only seen	8 (26.7%)
Visual obstruction of epiglottis to larynx: ≤ 50%	4 (13.3%)
Visual obstruction of epiglottis to larynx: ≥ 50%	2 (6.7%)
Epiglottis down-folded and larynx cannot be seen directly	0

	Immediate Post-OP complications	45 min Post-OP Complications or before discharge
None	27 (90%)	28 (93.3%)
Laryngospasm	1 (3.3%)	0
Persistent Cough	2 (6.7%)	2 (6.7%)
Desaturation ≤ 90%	0	0
Dysphonia	0	0
Sore throat	0	0

