Combined International Multi-Center Phase I and II Study on Safety and Performance of the AMBU A/S Laryngeal Mask

Presentation Time: Monday, 9:15 a.m. - 10:45 a.m.

AUTHORS: **C. A. Hagberg**[1], F. S. Jensen[2], H. Genzwurker[3], R. Krivosic-Horber[4], B. U. Schmitz[1], H. Menu[4];

AFFILIATION:[1]University of Texas Medical School at Houston, Houston, TX, [2]Amtssygehuset i Gentofte, Hellerup, Denmark, [3]University Horpital of Mannheim, Mannheim, Germany, [4]Hopital Roger Salengro, Lille Cedex, France.

Presentation Number: S-211

Introduction: Since the introduction of the LMA, supraglottic airway devices have become an established tool in airway management.[1,2] The Ambu laryngeal mask airway is a new disposable supraglottic airway device similar in design to the LMA-Classic. This multi-center trial was designed to evaluate the performance and safety of the Ambu laryngeal mask in elective surgical patients during positive pressure ventilation.

Methods: Following approval by the local Ethics Committees and written informed consent, 118 (29-30 at each center) patients presenting for elective surgery under total intravenous anesthesia were included. Patients were ASA I/II, Mallampati I/II, aged 18-65 years with a BMI <30 kg/m^2. Propofol was used for induction (2.5mg/kg) and maintenance (12mg/kg/hr propofol) of anesthesia along with a choice of narcotic agent. Patients were ventilated with intermittent positive pressure ventilation, a respiratory rate of 12/min, an inspiratory/expiratory ratio of 1:2, a fresh gas flow of 3L/min in order to maintain CO_2 <45mmHg and SpO_2 ≥95%. Data was collected on size of device, number of insertion attempts, cuff inflation, and oropharyngeal leak pressures. The position of the Ambu laryngeal mask was confirmed with fiberoptic endoscopy and the view recorded. Perioperative and postoperative complications were noted. Patients were examined for sore throat, dysphonia, and dysphagia 1hr and 24hrs postoperatively.

Results: Demographically, patients were 42.8±13.97yrs of age (60.2% female, 39.8% male), 171.2±8.30cm in height, with a BMI of 24.5±3.11kg/m^2 and Mallampati grade I/II (62.9%/37.1%) Patients received a size 3 (0.8%), 4 (51.7%), or 5 (47.5%) Ambu laryngeal mask, according to manufacturer's recommendations. A cuff pressure of 60cm H_2O was accomplished with a volume of 24.3±5.41mL of air. Duration of surgery was 67.0mins (25-250mins). All patients were successfully intubated on the first or second attempt (92.4% and 7.6%, respectively) with an insertion time of 44.9±37.91sec. Oropharyngeal leak pressures were 24.1±5.44cm H_2O. The vocal cords could be visualized by fiberoptic endoscopy in 91.5 % patients and adequate ventilation was achieved in all patients. Complications included blood on the device (8.5%), bucking during removal (0.8%), and minor trauma to the tongue (0.8%), or lips (0.8%). Postoperative complaints 1hr after surgery were sore throat (mild-5.1%, moderate-1.7%), dysphonia (mild-0.8%), dysphagia (mild-2.5%, moderate-1.7%). For complaints 24 hrs after surgery only mild sore throat (2.2%) and mild dysphonia (1.1%) remained.

Discussion: In anesthetized, non-paralyzed patients, the Ambu laryngeal mask is easy and quick to insert. It forms a safe and efficient seal during positive pressure ventilation. Further studies are warranted.

References:

1. Anesth Analg 1996;82:129-33.
2. Anesthesiology 1996;84:686-99.