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Original Contribution

A comparison of the effectiveness of the streamlined liner of pharyngeal airway in paralyzed and nonparalyzed patients undergoing gynecological surgery: a randomized trial☆,☆☆,★

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Abstract

Study Objective: To compare the effectiveness of streamlined liner of pharyngeal airway (SLIPA) in paralyzed and nonparalyzed, anesthetized patients undergoing gynecological surgery.

Design: Prospective randomized double-blind clinical trial.

Setting: Intraoperative.

Patients: A total of 80 female patients with American Society of Anesthesiologists class I or II and who were undergoing gynecological surgery.

Interventions: The patients were randomly allocated to either the nonparalyzed group (group NR, n = 40) or the paralyzed group (group R, n = 40).

Measurements: Oropharyngeal leakage pressure was the primary outcome. Insertion time; number of insertion attempts; success rate at first insertion; involuntary movement; peak inspiratory pressure (PIP); leakage fraction; hemodynamic changes; complications, such as blood tinging, regurgitation, and sore throat; and recovery time were also evaluated for secondary outcomes.

Main Results: Oropharyngeal leakage pressure, which is primary outcome, was no difference among the groups. Insertion time, number of insertion attempts, success rate at first insertion, involuntary movement, leakage fraction, hemodynamic changes, and complications were not statistically different among the groups. The PIP in group NR was significantly increased compared to that of group R ($P = .002$). Recovery time was significantly longer in group R than in group NR ($P < .001$).

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Conclusions: SLIPA had good performance in both paralyzed and nonparalyzed patients. There was no difference in SLIPA performance or complications irrespective of muscle relaxant use, except decrease in PIP and prolong recovery time in paralyzed patients.

1. Introduction

The supraglottic airway device (SAD) is a device that keeps the upper airway patent for ventilation and oxygenation. The SAD is located above the level of the vocal cord and does not need to be passed through the vocal cord. The SAD is less invasive, less stimulating for the respiratory tract during insertion, and more easily placed than endotracheal tube. Thus, the use of SAD has gradually increased, and a variety of SADs have been developed and applied in clinical settings. The streamlined liner of the pharynx airway (SLIPA; SLIPA Medical Ltd, Douglas, Isle of Man, UK; Fig. 1) is a second-generation, disposable SAD made of plastic material. Its hollow chamber is designed in the shape of a boot, resembling the anatomy of the hypopharynx. One advantage of the SLIPA is a lower risk of aspiration due to the large capacity (50 mL) of the chamber, even with the occurrence of regurgitation [1]. In addition, SLIPA has a low incidence of complications related to the cuff and requires less insertion time because it does not require cuff inflation mechanism [1].

The material consistency of SLIPA is harder than that of other SADs, but its stiffness is reduced as it is warmed by body temperature. So, the use of a muscle relaxant might have a greater impact on the insertion and fixation of SLIPA than other SADs. There have been comparative studies evaluating the use of muscle relaxants on the insertion and maintenance of SADs [2–5]. However, there has not yet been a comparative study on SLIPA evaluating the effects of muscle relaxant, although the literature on SLIPA includes studies involving muscle relaxant [6–9] and other studies that did not use muscle relaxant [1,2,10–12]. Because the efficacy and complications for using muscle relaxant on SLIPA are not known yet, it may be clinically valuable to find the basis for minimizing complications by unnecessarily paralyzing the patients or not paralyzing the patients in whom relaxant should be used.

Therefore, we conducted this study to compare the effects of muscle relaxants on the insertion and maintenance of SLIPA.

Fig. 1 The SLIPA (SLIPA Medical Ltd).

2. Materials and methods

2.1. Patients

The study was approved by the Institutional Review Board of Chung-Ang University Hospital (C2014070 [1266]) and was registered in CRIS (KCT0001167). Written informed consent was obtained from all participants, and the study was carried out based on the principles of the Declaration of Helsinki 2000.

All female patients with an American Society of Anesthesiologists physical status 1 to 2 who were between the ages of 20 and 60 years at our institution between June 2014 and July 2015 were assessed for study eligibility. To minimize the effects of the type, procedure, and duration of surgery, only elective nonlaparoscopic gynecological surgeries completed within 2 hours by single team of surgeons were included.

Patients with history of cardiovascular or respiratory disease, obesity (body mass index ≥ 35 kg/m^2), known cervical spine disease, mouth opening less than 2.5 cm, or active upper respiratory tract symptom or at risk for aspiration (eg, nonfasted or history of gastroesophageal reflux disease) were excluded. This decision was made by an investigator who was not otherwise involved in the intervention or data collection of the study.

2.2. Study design and randomization

The study was conducted in a randomized, double-blind manner. All participants were randomly assigned to 2 groups (group R, n = 40; group NR, n = 40) based on a random table generated using PASS 11 (NCSS, Kaysville, UT) by a statistician who did not participate in any other step of the study. The group assignments were enclosed in an envelope which was labeled with the case number. According to the group assignments, 2 types of syringes were prepared.