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# Usage of a semi-rigid intubation endoscope is not superior to a video laryngoscope. A prospective, randomised, controlled trial comparing the SensaScope vs. the McGrath Series 5 in surgical patients



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#### ABSTRACT

Introduction: Numerous guidelines and techniques have been developed to manage difficult airways and to prevent problems in airway management. To achieve an optimal view of the glottis, various video laryngoscopes and video stylets have been developed and introduced in clinical anaesthesia. The aim of this study was to compare the time to place the tracheal tube (TT) with the McGrath<sup>TM</sup> Series 5 (McG; Medtronic Dublin, Ireland) and the semi-rigid intubation endoscope SensaScope<sup>TM</sup> (Sc; Acutronic Medical Systems AG, Hirzel, Switzerland) in elective surgery patients.

*Methods*: With the approval of the local ethics committee, patients were recruited for this prospective, randomised clinical study. Exclusion criteria were age <18 years, emergency surgery and the presence of defined predictors for an expected difficult airway. Time to place the TT was the primary endpoint. Secondary endpoints were time to glottis view, time to first ventilation and the first-pass intubation success rate. Data are shown as medians and interquartile ranges [IQRs].

Results: In this study, we compared the McG and the Sc in 76 patients (McG n=38; Sc n=38). Time to place was shorter when using the McG, 14 s [12-22 s], than when using the Sc, 22 s [16-32 s] (p=.003). Time to glottis view was likewise shorter with the McG, 3 s [2-4 s], than with the Sc, 10 s [7-23 s] (p<.001). Time to first ventilation was longer with the Sc, 32.6 s [26-41 s], than with the McG, 25 s [26-25 s] (25 s) [25 s] (25 s) [25 s] (25 c). Tracheal intubation was more successful with the McG, with success in 25 s 25 s 25 s (25 s) [25 c) compared to 25 s (25 s) patients with the Sc on the first attempt (25 s).

Conclusion: The tracheal intubation was significantly shorter using the video laryngoscope McG. The reasons for these results could be the presence of a large tissue mass at the level of the tongue base that interferes with the exposure of the glottis and the insertion of the TT using the Sc such that getting into the glottic aperture is aggravated.

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### 1. Background

Patient safety has improved through the development of airway management devices and techniques in the last recent years [1-4]. Recognition of the limitations of direct laryngoscopy has led to the

development of intubating devices that do not require a aligning of the oral, pharyngeal and laryngeal axes.

We studied two such non-traditional laryngoscopy techniques: The McGrath Series  $5^{\text{\tiny TM}}$  (McG; Medtronic<sup>®</sup>, Dublin, Ireland) is one of the first fully transportable video laryngoscopes with a hyperangulated blade (Fig. 1). Several studies and case reports have highlighted the benefit of the video laryngoscope in the visualisation of the glottis and found it to be superior in normal and difficult intubation situations [5–14]. With a high-resolution video camera placed within a hyper-angulated, single-use blade of adjustable length, a tube guide or malleable stylet is necessary to follow the high curvature of the blade with an TT [14,15].

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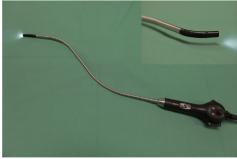


Fig. 1. Depiction of the Non-traditional laryngoscope techniques in the study.

The use of rigid scopes is well established in internal medicine and ear-nose-throat surgery [16,17], and various types have been developed for airway management in anaesthesia and intensive care medicine [18]. In anaesthesia, rigid fibre-optic scopes such as the SensaScope<sup>TM</sup> (Sc; Acutronic Medical Systems AG, Hirzel, Switzerland) and the Bonfils™ (Karl Storz GmbH & Co. KG. Tuttlingen, Germany) may be used as alternatives to flexible fibre-optic and video-based laryngoscopic techniques for both predicted and unpredicted difficult intubation [19-25]. They are fast to set up, portable and more durable than flexible scopes [22]. Their use may be associated with a higher success rate than Macintosh laryngoscopes in difficult airway scenarios [23,25], and, compared with flexible scopes, rigid scopes may reduce intubation time [24,25]. Additionally, complication rates are similar to those of flexible scopes [24,25] and the Macintosh laryngoscope [23]. The benefits are described as portability, fast practical application and high success rate compared with flexible fibre-optic scopes [24,25]. The Sc was introduced to the European market in 2006 and it is a hybrid, guidable semi-rigid video stylet with a steerable tip at the end of the device. A singular feature is the S-shaped curve of the rigid part of the stylet (Fig. 1).

Studies in which video laryngoscopes have been compared with a semi-rigid intubation endoscope in clinical practice are currently missing. We therefore performed a randomised controlled trial to compare the McG and the Sc under clinical circumstances in elective surgery patients with an expected normal airway. Because each device for airway management has unique characteristics and advantages for different situations, it's reasonable to evaluate each also in patients with a normal airway. Semi-rigid intubation endoscopes enable better manoeuvrability, a superior view of the glottis and a shorter intubation time compared with a rigid video stylet [20]. However, intubation using a video laryngoscope might be easier to learn than the fibre-optic technique [9,10], but success rates vary considerably, and there are a high proportion of patients in whom the glottic opening can be visualised but the TT cannot be inserted into the trachea [26–28].

The aim of this study was to evaluate whether the use of the SensaScope improves the time to place compared with the McGrath Series 5 video laryngoscope in surgical patients with an expected normal airway undergoing general anaesthesia. The McG was used for this trial because of the angulated blade and high success rate. Several studies describe a better glottic view was obtained with the videolaryngoscopy, but disadvantages like difficulty in passing the tracheal tube lead to increase the time to place the tracheal tube. We hypothesised that using the Sc would shorten the time to place. Because of the video stylet design with a steerable tip, the Sc is advanced into the glottic aperture, and the loaded tracheal tube is inserted into the trachea after identifying the vocal cords. Because of these advantages (optimised view and a directly guided insertion), we would expected a consequently shorter tracheal

intubation time than that of the McG.

#### 2. Methods

#### 2.1. Research ethics approval

The ethics committee of the Medical Association of the State of Rhineland Palatine (Germany) approved this trial (Registration Nr.: 837.330.14 (9569)). This study is registered with ClinicalTrial.gov register number NCT02348736. Written informed consent was obtained from all patients at least one day before randomisation. Patients were randomised to a treatment group using the GraphPad QuickCalcs Web site: <a href="http://www.graphpad.com/quickcalcs/randmenu">http://www.graphpad.com/quickcalcs/randmenu</a> (accessed January 2015). After sample size calculation, a prospective, randomised, controlled trial in patients undergoing general anaesthesia at a tertiary university hospital (Anaesthesia Division of the Department of Ear-nose-throat Surgery) was designed to examine the hypothesis that a semi-rigid fibre-optic with a steerable tip is superior in terms shorter time to place the TT and higher first-pass intubation success rate.

## 2.2. Patient selection

Patients undergoing elective, routine anaesthesia were asked to participate in this trial. Exclusion criteria were age under 18 years, a history of gastro-oesophageal reflux or potential risk of regurgitation of gastric contents, pregnancy, ASA classification IV and patients with an anticipated difficult airway. A difficult airway was defined as the presence of a Mallampati class IV,  $BMI \ge 40 \text{ kg/m}^2$ , retrognathia, restricted neck movements, or more than two of the following criteria: Mallampati class III, mouth opening less than 35 mm, or a thyromental distance of less than 65 mm [18].

#### 2.3. Setting and intervention

Before induction of general anaesthesia, an McG with a camera stick was positioned at the shortest position (approximately the same length as the size-3 Macintosh blade) for average patients. A standard TT (Mallinckrodt Medical, Athlone, Ireland) size 7.0 mm internal diameter (ID) was used for female patients, and 7.5 mm ID was used for male patients. For intubation in the McG group, a malleable stylet was inserted in the TT in a hockey-stick shape (distal end of TT angulated of  $90^{\circ}$ ). When applying the Sc, the TT was mounted on the 15 mm connector at the proximal part of the shaft before insertion into the patient's mouth. After 3 min of preoxygenation with a facemask, anaesthesia was induced with sufentanil (0.2–0.5  $\mu g\,kg^{-1}$ ) and propofol (2–3 mg  $kg^{-1}$ ). Mivacurium (0.2 mg  $kg^{-1}$ ) or atracurium (0.5 mg  $kg^{-1}$ ) was used for neuromuscular blockade. The individual choice of neuromuscular blocking agent depends on the temporal duration of the surgery,

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