

**NCT02991820**

**IRB16-00549**

**6/24/16**

**Title:** Comparison of Miller and Macintosh laryngoscopes, CMAC and Glidescope videolaryngoscopes in inexperienced users: a pediatric manikin study.

**Investigators:** Joseph D. Tobias, MD

**Describe the background and rationale for this project:**

The commonly used method for endotracheal intubation in children is direct laryngoscopy using a Miller or Macintosh blade. Videolaryngoscopy is a widely accepted pediatric airway management. Videolaryngoscopes (VL) provide an indirect view of glottis without the need to align the oral, pharyngeal, and glottis structures. Some types of VLs provide also direct view of glottis with indirect view. Videolaryngoscopes can be used as a teaching tool for learners as they can visualize all the anatomical structures of larynx at the same time with the performer. VLs may facilitate the learning of endotracheal intubation in inexperienced users in the pediatric population. There are limited data on the use of videolaryngoscopes by anesthesia providers and medical personnel who are inexperienced in the use of videolaryngoscopes.

**How will your study be funded:** No funding is required for this study.

**Provide a potential start date and end date for your study to be included in the IRB application:** start date of 6/27/2016 – end date of 7/30/2016 (1 month period).

**List any sub-Investigators you want to participate as back-up/support on the study -** Julie Rice, Heather Dellinger, SAM Barry

**Describe the significance of the proposed research:** To compare the CMAC and Glidescope videolaryngoscopes (VL) to traditional direct laryngoscopy (DL) using either a Miller or Macintosh laryngoscope by studying the performance of users. This will involve the use of an intubating pediatric manikin to

assess various aspects of endotracheal intubation by experienced and inexperienced users. The inexperienced users in intubation of children will use VLs on a pediatric manikin. We will evaluate the success rates of inexperienced and experienced users and compare their results. These results will help us to see if inexperienced users are successful with VLs. Also we will assess whether VLs are a good teaching tool and if they can be preferred as a first line tool for pediatric intubation.

**State the primary and secondary objectives of the study:** The goal of the study is to test whether time to intubation is shorter with VL as compared to DL. We hypothesize that this difference will be greatest for users with the least experience in DL. Secondary aims include comparing success rates and user-rated ease of intubation between VL and DL.

**If this research is hypothesis driven, succinctly state the hypothesis:** Performers who are inexperienced about direct laryngoscopy and VL will achieve higher overall success rates using videolaryngoscopes than using a direct laryngoscope.

**Outline the major steps and methodologies in the clinical protocol.** Direct laryngoscopy using a Miller and Macintosh laryngoscope as well as indirect laryngoscopy using a CMAC and Glidescope VL devices will be used. Each participant will perform endotracheal intubation on the mannequin using both types of laryngoscope blades and both types of indirect laryngoscopes (total of 4 intubation attempts each). In a given subgroup, a two-tailed paired t-test on a sample of 10 subjects would have 80% power to detect a 15s difference in time to intubation between videolaryngoscopy and direct laryngoscopy at a 95% confidence level, assuming mean time to intubation of  $45 \pm 15$  seconds with videolaryngoscopy and low within-subject correlation ( $r=0.5$ ) between times to intubation with the different methods in the study. Therefore, the study will recruit 10-20 personnel from each of the following 4 groups:

1. Faculty pediatric anesthesiologists
2. CRNAs
3. Trainees (SRNAs, residents, and fellows, and medical students)
4. APNs from the PICU/CTICU. Nurses at NCH

Time to endotracheal intubation, the number of intubation attempts, and the rate of successful endotracheal intubation on first attempt and success of endotracheal intubation within 120 seconds will be recorded. The subjective (rating 1 to 10) for ease of device use and laryngoscopic view judged by the percentage of glottic opening score (POGO) will be recorded. Comparison of these values between experienced and inexperienced users will be performed as well as comparison of CMAC, Glidescope, Miller blade, and Macintosh blade.

**Identify the variables to be measured and how they will be statistically evaluated:**

Time to endotracheal intubation, the number of intubation attempts, and the rate of successful endotracheal intubation on first attempt and success of endotracheal intubation within 120 seconds will be recorded. The subjective (rating 1 to 10) for ease of device use and laryngoscopic view judged by the percentage of glottic opening score (POGO) will be recorded. Comparison of these values between experienced and inexperienced users will be performed as well as comparison of CMAC, Glidescope, Miller blade, and Macintosh blade. Pairwise comparisons among laryngoscopy methods will be performed using paired t-tests for continuous data and McNemar tests for categorical data. Repeated measures ANOVA will be used to assess the moderating effect of user experience on the difference in time to intubation between VL and DL.

**References**

1. Lye ST, Liaw CM, Seet E, Koh KF. Comparison of results from novice and trained personnel using the Macintosh laryngoscope, Pentax AWS®, C-MAC™ and Bonfils intubation fibrescope: a manikin study. Singapore Med J 2013;54:64-8.
2. Sharma DJ, Weightman WM, Travis A. Comparison of the Pentax Airway Scope and McGrath Videolaryngoscope with the Macintosh laryngoscope in tracheal intubation by anaesthetists unfamiliar with videolaryngoscopes: a manikin study. Anaesth Intensive Care 2010;38:39-42.

3. Ray DC, Billington C, Kearns PK, Kirkbride R, Mackintosh K, Reeve CS, et al. A comparison of McGrath and Macintosh laryngoscopes in novice users: a manikin study. *Anaesthesia* 2009;64:1207-10.