

A Prospective Clinical Study of Tom-Stylet, Its Safety, Efficacy for Intubation, Accuracy in Measuring, Guiding ETT Position

Authors: Thomas D. Lei, MD, Department of Pulmonary and Critical Care Medicine, Regional Medical Center of San Jose, CA, USA. Bin Yi, MD PhD, Kaizhi Lu, MD, PhD, Department of Anesthesiology, South West Hospital, Third Military Medical University, Chongqing, China.

Background/Introduction: Intubation is a common procedure to secure a patient's airway and to initiate mechanical ventilation. Proper placement of the endotracheal tube (ETT) is essential to mitigate any potential complications associated with intubation and to achieve adequate ventilation. Post intubation CXR to confirm ETT position, a current common practice, incurs significant cost and radiation exposure to both patients and staffs. A real-time and alternative means to facilitate ETT placement and test ETT tip position is urgently needed. The targeted positioning the ETT tip is between 2 cm and 5 cm from the carina. Tom-Stylet, a novel dual function stylet, was prospectively evaluated in current study. This study was set out to validate the clinical efficacy and safety of Tom-Stylet, i.e. its ability to facilitate oral intubation, to confirm and guide the endotracheal tube (ETT) position and its safety impact on endobronchial mucosa.

Methods: A prospective, single center observation study was conducted blindly on 26 adult patients. Any adult patients requiring general anesthesia for elective surgical procedures (general surgery, ENT, neurosurgery, OB-GYN and urology procedures) meet the inclusion criteria, the only exclusion was patients scheduled for thoracic surgery. 14 females, 12 males were included: mean age 49.4 (17-72); mean height 5'4" (4'11"-5'7"); mean weight 129.4 lb (88.2-220.46). All study subjects were intubated orally by their attending anesthesiologists using Tom-Stylet. The ETT were initially positioned based on physicians' experience and auscultation. Bronchoscopy was performed by investigator physicians only to exam and photograph the baseline endobronchial mucosa on each subject. Tom-Stylet was again inserted, its balloon deployed to measure the ETT position, and the ETT was adjusted accordingly. Post bronchoscopy was performed on each subject to confirm ETT position, to evaluate Tom-Stylet balloon safety on the mucosa and to photograph for records.

Results: Of the 26 subjects, all were successfully intubated orally using Tom-Stylet. 7 cases (27%) were placed in satisfactory position (2- 5cm above the carina) solely based on anesthesiologists' experience, auscultation. 19 cases (73%) required adjustment by using Tom-Stylet guidance. One ETT was required to be pulled back 1 cm; in 18 cases, ETT were pushed down average 2.4 cm (0.5 cm-4 cm). No bronchoscopic injury on trachea mucosa was observed on all study subjects.

Conclusions: Tom-Stylet is a novel and effective stylet for oral intubation. Not only does it facilitate intubation, it also provides real-time ETT position and guides ETT positioning at

point of care. Application of Tom-Stylet can reduce radiation exposure to patients and staff while cutting down care cost.

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