Prospective Study Protocol Sample

Airway Management Skills of Undergraduate Osteopathic Medical Students

INTRODUCTION

Undergraduate Medical Students are trained in, and must master a variety of skills before graduating [1]. Despite the fact that graduating physicians entering internship are expected to be first responders to inpatient resuscitation [2], and that all physicians, regardless of specialty, should learn to recognize life-threatening situations and initiate resuscitation [3], the training of medical students in potentially life-saving skills is not uniform [4,5]. Even before graduation, during their clinical clerkships medical students may be required to participate in resuscitation attempts. The American College of Emergency Physicians "…believes that the public expects all medical students to be able to provide basic emergency care" [3]. To adequately meet this expectation, all medical students should be taught the basics of emergency medical care, preferably prior to entering the clinical years [3].

Rapid and effective airway control, oxygenation, and ventilation are some of the primary goals of Emergency Cardiac Care [6, 7], All health-care providers, including medical students should be familiar with the use of devices for the support of oxygenation and ventilation [8-10].

Devices and methods for the support of oxygenation and ventilation during resuscitation range from basic devices and methods such as ventilation through a bag-valve-mask (BVM) to more advanced devices such as the endotracheal tube (ETT), laryngeal mask airway (LMA) or the esophageal-tracheal combitube airway (ETC).

Bag-valve-mask (BVM) ventilation or ventilation through an advanced airway device are both acceptable means of providing ventilation during resuscitation [6]. Adequate ventilation with a BVM is critically important during the initial stages of resuscitation and when placement of an advanced airway device is delayed or unsuccessful [6]. All healthcare providers including medical students should be competent in the use of the BVM; effective BVM ventilation requires adequate training and frequent practice [6, 8-10]. Because there are times when ventilation with a bag-mask device is inadequate, physicians should also be trained and experienced in the insertion of an advanced airway device [6].

The endotracheal tube, still considered by many to be the "gold standard" in managing the airway during resuscitation [6], provides a patent airway, enables delivery of positive pressure ventilation, can prevent aspiration, allows for suctioning of the tracheobronchial tree, and provides an alternative route for the administration of certain resuscitation medications [6, 11]. An increasing amount of evidence now exists that there are significant risks in the use of endotracheal intubation [6, 12-13, 15-19]. Endotracheal intubation attempts by unskilled providers can produce serious and life-threatening complications, such as airway trauma, prolonged interruption of chest compressions and ventilations, hypoxemia from prolonged intubation attempts or failure to recognize tube misplacement or displacement and hypocapnea from excessive and overzealous hyperventilation [6, 12]. Providers who must perform endotracheal intubation require adequate initial training as well as frequent experience or frequent retraining [6].

The American Heart Association suggests it may be beneficial for providers to train in one primary method of advanced airway management and gain experience and expertise in that method [6].

Despite the fact that endotracheal intubation skills can be difficult to learn [1, 13], can require long practice before achieving mastery [14], and can be associated with high complication rates in the hands of unskilled or inexperienced providers [6, 15-18], securing an airway using an endotracheal tube (ETT) remains the conventional training in the curriculum for airway management in most medical schools [2,4]. Recent availability of other advanced airway devices that are easier to master and show improved retention of skill [2], have brought into question this conventional training.

Medical students usually gain exposure to and training in basic and advanced airway management skills during, or immediately preceding, their transition to clinical training [5]. Medical students generally participate in a standardized Advanced Cardiac Life Support (ACLS) Class or receive training as part of a formalized skills course [5]. A review of the available literature reveals a paucity of studies examining success and retention rates following formal airway management training [1, 2]; the reported success and retention rates show great variability (33% - 80%) [13]. A 2004 survey of American medical schools reported the percentage of graduating medical students proficient in adult endotracheal intubation as 36%. The pediatric intubation proficiency was reported as 10% [4]. A review of the available literature failed to find any research studying the development of confidence through practice following airway management training.

There is a high risk of misidentification of tube placement, displacement or obstruction [6, 13, 18-19] following endotracheal intubation. No single confirmation device or technique, including clinical signs [6, 19], the presence of water vapor in the tube, [6, 20] or secondary confirmation devices ($EtCO_2$ or EIDD) is completely reliable [22-35], so a combination of assessment techniques and devices should be relied upon to assess for correct placement of a ETT on every patient. Even after the ETT is visualized passing through the vocal cords and correct tube position is verified by clinical assessment methods, providers should use additional confirmation devices such as an end-tidal CO_2 ($EtCO_2$) or an esophageal intubation detection device (EIDD) [6].

Although the sensitivity and specificity of individual assessment methods has been studied [6, 16, 22-34], we could find no studies examining confirmation of tube placement as a dynamic skill aggregate or how confidence in assessment of tube placement varies between individual assessment methods.

The purpose of this study is to advance scientific knowledge of how medical students learn, apply and become confident in airway management skills and specifically, how they assess for correct placement of an endotracheal tube and how that confidence varies between different confirmation devices and methods.

METHODOLOGY

Study Design: This is a three-part prospective observational study composed of a series of surveys, cognitive, psychomotor and affective domain assessments of competence and confidence measured immediately preceding, during and immediately following basic and advanced airway management training during Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS) courses as part of a third-

year medical school curriculum. Follow-up measurement of demographic data and knowledge and skill retention will occur at one- and two-year intervals.

Sample: This study will be conducted on a convenience sample of approximately 100 third-year medical students. All subjects are current third-year medical students at the Ohio University College of Osteopathic Medicine undergoing Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS) courses during the transitional Summer quarter immediately preceding their clinical training years. All current students regardless of past exposure to the skills studied will be included. There are no exclusion criteria.

Recruitment & Consent Process: Subjects will be recruited in person and informed consent information given immediately prior to the beginning of BCLS and/or ACLS Classes. After explanation of the study goals, students that choose to participate will receive a short orientation to the study prior to obtaining consent.

Coercion: Participants will be assured during recruitment and the informed consent process that neither participation nor non-participation in the study will have any effect on their status or privileges as OU-COM students or their successful completion of the BCLS and/or ACLS courses.

Deception: No form of deception will be used in this study.

Risks or discomforts: There is little-to-no risk associated with participation in this study. All airway management skills will be practiced and evaluated on mannequins. No human subjects will be harmed. The study final evaluation session will take place prior to and on a different date than the course final evaluation to minimize the possibility of the study negatively affecting subject performance in the course(s).

Benefits: There is no direct benefit to individual study participants, although increased supervised practice of skills and increased interaction with instructors might improve the subjects' skill level. The information this study provides may lead to proposals to improve the education of future physicians, and it is intended to advance our knowledge of how medical students learn, apply and become confident in life-saving airway management skills.

Compensation: Subjects will not be compensated in any way.

Costs: Costs incurred are approximated at $3300. $2000 for SimMan® advanced patient simulator rental, $1100 for EasyCap II® $EtCO_2$ devices and $200 for CO_2 tanks and miscellaneous supplies.

Data handling and storage: The data collection and storage process will protect both confidentiality and privacy. No records will have any personally-identifiable information; only de-identified or non-identifiably data will be used in this study. All resulting data will be stored in electronic format; files will be stored on a password-protected computer stored in a limited-access, locked facility. Only the investigators and study personnel will have access to raw data. Any publications or presentations will utilize aggregate (summarized) data only, not individual data. Although training mannequins will record the subjects during the supervised practice sessions and during the final evaluation, the

recordings will be immediately destroyed following the practice sessions after instructor-supervised debriefing and critique.

Specific Methods: This study has three parts.

Part I: Working Hypothesis: *Basic and advanced airway management training during Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS) courses as part of a third-year medical school curriculum has no short-term on the cognitive and psychomotor skills of the participants nor on their confidence to provide those skills.*

In the first part, following recruitment, explanation of the study goals and methods and the informed consent process, subjects that choose to participate in the study will be given a pre-training survey questionnaire assessing their previous level of exposure to and/or training in basic and advanced airway management skills. Baseline cognitive competence will be assessed through a standardized written evaluation (pre-test) and confidence levels will be assessed through the use of a self-efficacy scale evaluation.

Following baseline assessment, all course students regardless of participation in the study will receive the same training in basic and advanced airway management through lecture, demonstration and supervised practice on mannequins. Instruction and supervised practice will continue for three weeks (3 sessions) with additional, supervised and unsupervised practice opportunities being made available to all students regardless of participation in the study.

During the standard supervised practice sessions, the subjects psychomotor competence will be assessed using an objective performance sheet and confidence will be re-assessed at each session via the self-efficacy scale. Additionally, the cumulative number of practice attempts will be tabulated.

On the day of the final study evaluation, post-training cognitive competence will be assessed using the same standardized written evaluation (post-test), the subjects' psychomotor competence will be assessed using an objective performance sheet and confidence levels will be assessed through the use of the self-efficacy scale evaluation.

Using descriptive and inferential statistics, we will attempt to determine if standardized airway management training accomplishes its stated goals by assessing the psychomotor, cognitive and affective competence data gathered. The development and progression of confidence will be assessed using the concept of self-efficacy and correlated to the amount of practice the subjects engaged.

Part II: Working Hypothesis: *There is no variability on sequencing, accuracy or confidence between the different methods and devices commonly used to confirm endotracheal tube placement, following advanced airway management training during Advanced Cardiac Life Support (ACLS) courses as part of a third-year medical school curriculum.*

In the second part, following recruitment, explanation of the study goals and methods and the informed consent process, subjects that choose to participate in the study will be given a pre-training survey questionnaire assessing their previous level of exposure to and/or training in basic and advanced airway management skills.

Following the baseline survey, all course students regardless of participation in the study will receive the same training in basic and advanced airway management through lecture, demonstration and supervised practice on mannequins. Instruction and supervised practice will continue for three weeks (3 sessions) with additional, supervised and unsupervised practice opportunities being made available to all students regardless of participation in the study.

During the standard supervised practice sessions and on the day of the final study evaluation, the subjects' use of different methods and devices to assess for correct endotracheal tube placement will be sampled. The sequence, accuracy and confidence level of each method and device will be assessed. The frequency of Type-I (false positive) and Type-II (false negative) errors in confirmation will also be tabulated.

Using descriptive and inferential statistics, we will attempt to determine which confirmation devices and methods the subjects were most or least likely to use, in which order they were likely to use them and how confidence varied with the method used. The frequency of Type-I (false positive) and Type-II (false negative) errors in confirmation will then be correlated to the device and method data.

Part III: Working Hypothesis: *Basic and advanced airway management training during Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS) courses as part of a third-year medical school curriculum has no long-term effect on the cognitive and psychomotor skills of the participants nor on their confidence to provide those skills.*

In the third part, follow up will be attempted at one- and two- year intervals in order to assess further training received, retention of cognitive and psychomotor skills, subject application of those skills during their clinical training and progression of confidence/self-efficacy.

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