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Running Title: Neck Simulator Validation

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Abstract

Objectives/Hypothesis: To assess the construct validity of a high-fidelity neck model with simulated lymphadenopathy.

Study design: Prospective experimental validation study.

Methods: Six first year medical students with prior training (novice learners) and six otolaryngology-head and neck surgery (OtoHNS) residents (experts) performed the head and neck lymph node examination on a novel tissue-mimicking construct model of the neck region. Two otolaryngologists, blinded to training type, evaluated the videotaped performances, using two assessment tools specifically designed for the head and neck lymph node examination: a global rating scale (GRS), and a task-based checklist (TBC).

Results: The OtoHNS residents scored significantly higher than the medical students on the GRS ($p=0.008$). There was also a trend towards better scores for the residents on the TBC ($p=0.085$).

Conclusion: This is the first reported study of a high-fidelity lymphadenopathy model with task-specific assessment tools. The neck model demonstrated construct validity, by easily distinguishing between experts and novices on the basis of procedural competence. Using the global rating scale and task-based checklist, this model can be used to provide formative feedback, and to assess technical skills acquisition in trainees.

Level of Evidence: 2b

Introduction

The identification of abnormal masses in the head and neck is an important core competency of all graduating medical students.[1] Palpation of the neck by primary care physicians is the first line of assessment for lymph nodes of the neck, with variably reported sensitivities of 64-76% and specificities of 71-98% in detecting lymphadenopathy.[2-4] A thorough physical examination of lymph node size, location and consistency can assist in effectively detecting head and neck disease. Although imaging modalities such as ultrasound, CT and MRI provide higher anatomic resolution for assessment of neck masses, its scarcity in rural centres, and the focus on cost and resource management, mandate the need for developing clinical palpation skills to detect head and neck disease. Therefore, palpation is often the earliest indicator of infection or neoplasia.[5] Simulation- based medical education is increasingly in undergraduate and post-graduate medical curricula. This paradigm shift stems from recent reductions in physician teaching time and the decreased availability of patients as educational resources.[6] A wide variety of simulators, ranging in quality from low to high-fidelity, have been created and adapted for use in otolaryngology-head and neck surgery (OtoHNS). Numerous studies in certain fields have found simulation-based medical education superior to traditional clinical medication, for "achieving specific clinical skill acquisition goals, and in improving actual patient outcomes".[7] Simulators allow students and faculty to develop or refresh their skills in a non-threatening educational environment, to receive faculty/electronic feedback, and to overcome the inherent challenges in accessing certain traditional learning modalities, all whilst protecting patient

safety.[7] The ability to program simulators to reflect selected findings, conditions or situations broadens the base for experiential learning.

The use of simulators in undergraduate medical education is less well-documented. Enhancement of teaching knowledge and skills related to OtoHNS is absolutely essential for all graduating medical students, especially seeing that up to 25% of all presenting problems to primary care physicians are related to OtoHNS.[1] To date, there have been no studies on the incorporation of a neck lymphadenopathy simulator in undergraduate curricula, for teaching the head and neck lymphadenopathy examination. Medical students currently learn neck palpation by practising on healthy standardized patients (SPs). SPs often have no pathology, and the medical institution's administration must invest both time and finances towards scheduling SPs in advance for teaching. A simulator must first undergo rigorous testing to establish validity, before it can be incorporated into the curricula. Construct validity is defined as the ability of a measurement tool to measure the concept being studied. To demonstrate construct validity, the model must be able to differentiate between experts and novices.[8] Using the high-fidelity neck model as described in Xu et al. 2012, the purpose of this single-center study was to assess its construct validity, integral to establishing its suitability as a learning tool for the head and neck lymph node examination, before its assimilation into undergraduate medical education.[9]

Materials and Methods

Ethical considerations

This study was approved by the ethics board of Western University.

Participants

All participants were invited to participate on a voluntary basis, from the first-year undergraduate medical class of the Schulich School of Medicine & Dentistry, and the residency program at the department of OtoHNS at Western University. A study information sheet and consent form were completed prior to participation in the study. In total, the study recruited six first year medical students with prior training in the head and neck lymphadenopathy examination (novice learners), and six OtoHNS residents (experts). In addition, two otolaryngologists were invited to take part in the study as raters, blinded to the training type.

Settings/Materials

A neck model was developed by Xu et al., 2012, with the intention of teaching first year medical students basic neck palpation and lymphadenopathy assessment skills.[9] The model was built using 3D reconstruction technology, based on 1 mm cadaveric CT images obtained from the Visible Human Project.[10] Using polyvinyl alcohol cryogel (PVA-C), stereolithography and fused deposition modeling (3D printing technologies), the model was created to contain anatomically precise components such as a larynx, the sternocleidomastoid muscles, the vertebral muscles, the spinal cord, and pathological lymph nodes.[9] PVA-C is a non-toxic and biocompatible synthetic polymer with tissue-mimicking properties. The freeze-thaw cycle (FTC) solidifies liquid PVA-C. By altering the initial concentration of PVA-C and the number of FTCs, it is possible to create soft synthetic tissues of varying material stiffness (Table 1). [11-13]

The neck model used for this study contained a 3 cm diameter lymph node in the left anterior cervical chain (Figure 1).

Outcome Measures

Simulators are often paired with robust, validated assessment tools for evaluating trainees as they perform the simulated task. Global rating scales (GRS) and task-based checklists (TBC) have been extensively used together for assessing trainees in various surgical and non-surgical specialities, including otolaryngology. Our search of the literature did not identify any validated assessment tools specifically designed for evaluating a student whilst performing a head and neck lymph node examination. Hence, the GRS and TBC were modified for the lymph node examination (Appendix A). The GRS evaluates general skill domains and overall procedural performance, whereas the TBC tests for individual steps required to correctly perform a procedure. The GRS scored students on a 5-point Likert scale, while the TBC used a Yes/No dichotomy. Faculty could select "not applicable (N/A)" for steps of the procedure that did not apply to the scenario, or that the student did not perform. To establish face and content validity, the assessment tools were refined with a group of expert academic otolaryngologists, using the Delphi technique, a "systematic interactive forecasting method, using a panel of independent experts to find consensus among differing views".[14]

Study Design

The study participants 'performances were video-taped and scored using the GRS and TBC by the two otolaryngologists. The assessors were blinded to the level of training of the learners.

Analysis

Statistical analysis was performed using SPSS version 17.0 for Windows software. Average checklist scores, and GRS scores were compared between groups. The main analyses compared improvements in these measurements between groups, where improvement is a positive post-pre difference. The Mann-Whitney U test (Wilcoxon rank sum test) was used to test for differences between groups. $P<0.025$ was considered statistically significant, following a Bonferonni-corrected alpha threshold.

Results

A total of 24 evaluations were completed for both the novices, and the experts [PGY-1 (n=1); PGY-3 (n=1); PGY-4 (n=3); PGY-5 (n=1)].

The experts scored significantly higher than the novices on the GRS ($p=0.008$) (Figure 2). For all global elements (communication with the patient, time and motion, direction of tension, knowledge of specific procedure, sequence of procedure, and overall performance), the experts outperformed the novices. There was also a trend towards better scores for the experts on the TBC ($p=0.085$).

Discussion

Simulation-based medical education can be adapted to fit the needs of a broad spectrum of trainees, from medical students acquiring new technical skills, to experienced faculty refreshing or remediating their knowledge. Using current technological advances, simulators have quickly grown more intricate in nature, with some high-fidelity models containing life-sized realistic anatomy. Whilst improving patient safety, simulators eliminate the need for scheduling and financially reimbursing SPs.[7]

This study supports the construct validity of a novel neck tissue-mimicking construct, by objectively distinguishing between users of varying experience. Consistent with our hypothesis, the OtoHNS residents (experts) scored significantly higher on the GRS than the medical students (novices). The results also demonstrated a trend towards higher scores for residents on the TBC. We were underpowered to see a difference between groups with the TBC. A sample size of 24 (12 in each group of participants) would have been required to see a meaningful difference, based on a power of 0.80, and α-value of 0.025.

In otolaryngology, a wide variety of simulators are available or under development. However, there is a distinct lack of unified validation concepts and a very limited number of studies that address model characteristics and validation. In a systematic review of simulators in otolaryngology by Javia & Deutsch, only half of all simulators have been validated, most of these investigating only face or content validity.[7] Although the importance of face and content validity are not to be understated, they are subjective measures on the similarity between simulator and reality, and the appropriateness of the simulator as a teaching modality, respectively. Construct validity on the other hand, is an objective measure of the simulator's ability to differentiate between levels of expertise. Establishing the construct validity of a simulator is crucial before its integration as an effective training and assessment tool. In that regard, this study was successful for advancing the model into its next stage of investigation- a comparison between traditional and simulation-based medical education.

This is the first reported study of a high-fidelity lymphadenopathy simulator with task-specific assessment tools. Its unique quality lies in its ability to adjoin simulation- based training with undergraduate medical education. For instance, Javia & Deutsch conducted a systematic

review of published articles that described simulators that could be used in otolaryngology for education, skill acquisition and/or skill improvement.[7] In this review, only eight simulators were identified for procedures in the neck. All eight simulators were developed to enable training in cricothyroidotomy, for surgical residents. Through this study, we have found the neck simulation model to be an excellent substitute for SPs. It offers trainees the opportunity for repetitive use to refine skills, is easily accessible, and harbors no additional long-term costs in its maintenance.

One of the limitations of the study is its small sample size, limiting its ability to elicit differences between experts and novices on the TBC. As a follow-up study, it will be pertinent to increase the sample size, and demonstrate significant results for both assessment tools. In future studies, it may also be possible to distinguish participants with intermediate skill level (i.e. clerks). A simulator capable of differentiating between years of training, can be used to identify the trainee requiring additional support or even remediation.

Conclusion

The tissue mimicking construct has been shown to demonstrate strong construct validity. Objective metrics for assessment of palpation of the neck, including the Global Rating Scale and Task-based Checklist, can differentiate between levels of ability in palpating neck lymphadenopathy. To our knowledge, this is the first study that addresses simulation-based training and assessment of lymphadenopathy in novice learners. This tool may require further refinement, but it shows the potential for its next phase of incorporation within an undergraduate medical education curriculum.

Tables

Table 1. Polyvinyl Alcohol-Cryogel concentrations and simulated tissue composition.

Structure	PVA Concentration	Freeze-Thaw Cycles
Lymph Nodes	10% w/w	6
Muscle	10% w/w	2
Fat	5% w/w	6
Airway	Non-PVA (3D printed)	
Spine	Non-PVA (3D printed)	

Appendix A

Assessment tools

Task-based checklist (TBC)

Task-based checklist (TBC)

	Yes	No
1) Inspection:		
Notes bumps/lumps, masses, scars		
Notes asymmetry, swelling, discoloration, bruising/trauma		
2) Palpate lymph nodes		
Use pads of index and middle fingers		
Note size		
Note shape		
Note delimitation (discrete vs matted together; #)		
Note mobility		
Note consistency		
Note tenderness		

Appendix A Continued

Global Rating Scale

Communication with the patient					
	2	3	4	5	N/A
Unable to communicate essential points of care and concern		Able to communicate the majority of essential points of care and concern		Able to communicate the essential points of care and concern	
Time and Motion					
1	2	3	4	5	N/A
Many unnecessary moves		Efficient time/motion but some unnecessary moves		Clear economy of movement and maximum efficiency	
Direction of Tension					
1	2	3	4	5	N/A
Rarely uses correct angle of tension		Occasionally has tension at incorrect angle		Always has tension at correct angle	
Knowledge of specific procedure (lymph node chains)					
1	2	3	4	5	N/A
Deficient knowledge and needed instruction at most steps		Knew all important steps of operation		Demonstrated familiarity with all aspects of operation	
Sequence of procedure					
1	2	3	4	5	N/A
Frequently stopped and unsure of next move		Some forward planning with reasonable progression		Obviously planned course of operation with effortless flow	
Overall Performance					
1	2	3	4	5	N/A
Poor		Performs majority of physical exam acceptably		Outstanding	

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Figure Legends

Figure 1. Neck Construct with simulated pathology.

Figure 2. Significant differences in Mean Global Rating Scale scores between medical students and residents for Raters One and Two. *, x= significance (p=0.008).

Figures

Figure 1.

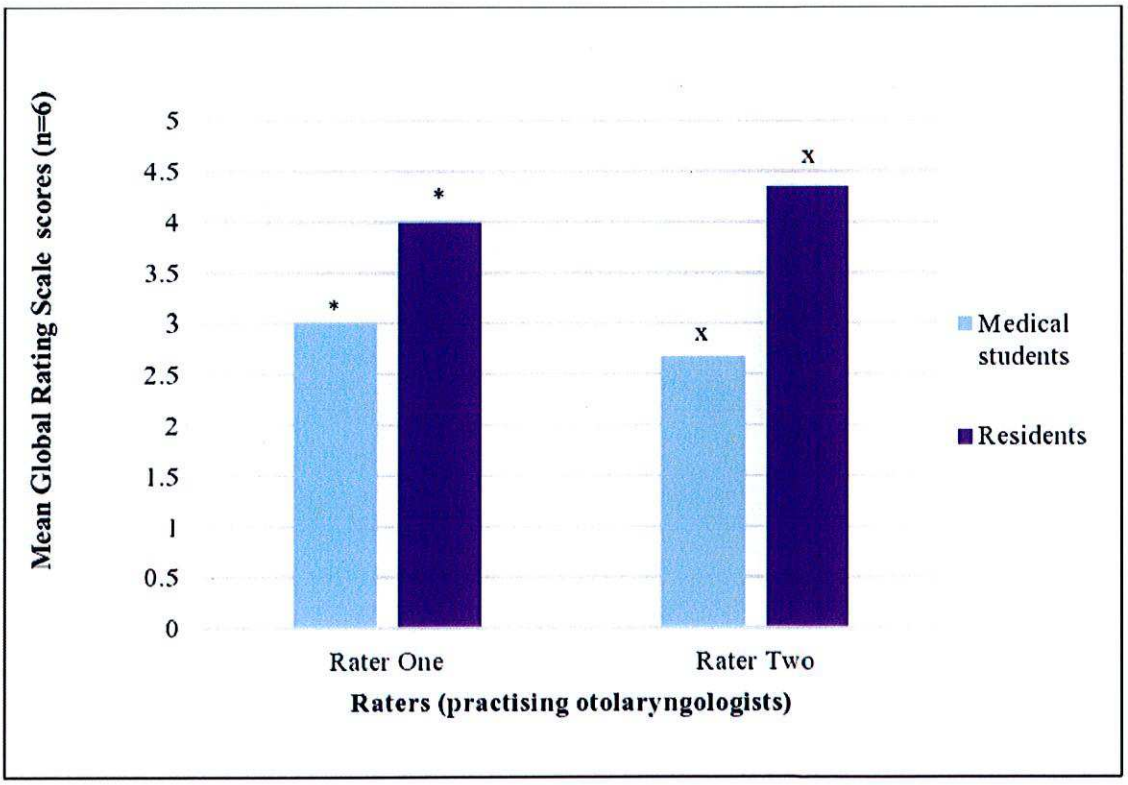

Figure 2.