Degrees of Reality

Airway Anatomy of High-fidelity Human Patient Simulators and Airway Trainers

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ABSTRACT

Background: Human patient simulators and airway training manikins are widely used to train airway management skills to medical professionals. Furthermore, these patient simulators are employed as standardized "patients" to evaluate airway devices. However, little is known about how realistic these patient simulators and airway-training manikins really are. This trial aimed to evaluate the upper airway anatomy of four high-fidelity patient simulators and two airway trainers in comparison with actual patients by means of radiographic measurements. The volume of the pharyngeal airspace was the primary outcome parameter.

Methods: Computed tomography scans of 20 adult trauma patients without head or neck injuries were compared with computed tomography scans of four high-fidelity patient simulators and two airway trainers. By using 14 predefined distances, two cross-sectional areas and three volume parameters of the upper airway, the manikins' similarity to a human patient was assessed.

What We Already Know about This Topic

- Manikins are used for education, training, and research of human airway management, but the fidelity of these airways is typically low

What This Article Tells Us That Is New

- Computed tomography scans of the upper airways revealed that the airway dimensions of the manikins significantly differed from those of humans
- Training, education, and research using the manikins should be reconsidered

Results: The pharyngeal airspace of all manikins differed significantly from the patients' pharyngeal airspace. The HPS Human Patient Simulator (METI®, Sarasota, FL) was the most realistic high-fidelity patient simulator (6/19 [32%] of all parameters were within the 95% CI of human airway measurements).

Conclusion: The airway anatomy of four high-fidelity patient simulators and two airway trainers does not reflect the upper airway anatomy of actual patients. This finding may impact airway training and confound comparative airway device studies.

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AIRWAY management is a key skill in anesthesiology and emergency medical practice. Because failure to manage an airway is associated with a high risk of morbidity and mortality, many anesthesia researchers have focused their educational and research efforts on airway management techniques and devices.[1,2] After the introduction of human patient simulators in the early 1960s, airway management training could be performed, even in high-risk airway situations, without putting actual patients at risk.[3–7] These human patient simulators are now widely used not only for training purposes but also as an innovative way to answer scientific questions in airway management research.[8,9] The ability to simulate either a difficult or normal airway has generated a better understanding of different airway maneuvers and has helped with the assessment of new airway de-

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vices.[10–12] However, while having a realistic device is important for medical simulators used for training, it is even more important for the interpretation of airway research. This is because data gained from manikin-based studies are often transferred into clinical practice.[13] There is still a lack of data proving that manikins used in training and research are realistic examples of actual human airways. For this reason, the validity and extensive use of human patient simulators for airway research have been questioned in the past.[8,14] Some authors have even recommended that manikin-based airway research should stop, favoring real patient trials.[8] Furthermore, it is not clear whether airway skills learned on manikins can be successfully translated into clinical practice.[15–17]

To the best of our knowledge, there is only one study, by Hesselfeldt *et al.*, that compared the subjective similarities of one high-fidelity human patient simulator (SimMan®; Laerdal Medical®, Stavanger, Norway) with actual patients.[18] Another study, by our research group, evaluated the anatomy of a pediatric high-fidelity simulator (SimBaby®; Laerdal Medical®).[19] There is a complete lack of data regarding how realistic, or unrealistic, popular human patient simulators are.

To assess how anatomically realistic the simulators are, the aim of the present study was to compare the upper airway anatomic features of four high-fidelity adult patient simulators and two low-fidelity airway trainers with actual patients by means of radiographic measurements. As the pharyngeal airspace is of major importance for airway management, this measure was defined as the primary outcome parameter.[19,20,21] We hypothesized that the airway anatomy, especially the pharyngeal airspace, of simulators and manikins would be significantly different from human anatomy.

Materials and Methods

After approval from the Institutional Review Board at the Medical University of Vienna, Austria, upper airway computed tomography imaging (CT) data from adults aged 18–45 yr, undergoing radiographic imaging because of trauma, were retrospectively screened for inclusion and exclusion criteria. Only patients treated in the institution's trauma room were enrolled. According to the Institutional Review Board, informed consent was not required.

All patients included in the trial underwent CT scans of the head, cervical spine, chest, and abdomen. Therefore, the upper airway, from the nasal cavity down to the subglottic area, was part of the imaging procedure. Only data obtained with one single CT scanner, using a routine trauma protocol (120 kV, 320 mAs, CTDIvol 71.17, DLP 2605, TI 1.0, cSL 0.6), were evaluated. It is the standard of care in our department for the patient's head to be positioned in a neutral position using special padding.

All patients with diagnosed or obvious craniofacial or cervical dysmorphias; trauma of the face, head, or neck; and patients with upper airway abnormalities were excluded. Furthermore, patients meeting any of the following criteria were not included in the trial: patients with an airway device,

such as a supraglottic airway or an endotracheal tube, patients with a neck collar or their head not kept in a neutral position, or patients with a Glasgow Coma Scale of less than 8.

In the group of patient simulators and airway trainers, high- and low-fidelity manikins were used. Low-fidelity describes simulators that facilitate the training of an isolated skill; high-fidelity simulators, in contrast, allow for full immersion into a real scenario and the ability to provide feedback.[22,23] Furthermore, the airways of the high-fidelity manikins used in this trial could be manipulated to simulate a difficult airway scenario. The high-fidelity human patient simulators, SimMan (SimMan®; Laerdal Medical®), SimMan 3G (SimMan 3G®; Laerdal Medical®), HPS (HPS Human Patient Simulator®; METI®; Sarasota, FL), and HAL (HAL S3000® Mobile Team Trainer; Gaumard®, Miami, FL), and the low-fidelity airway trainers, Laerdal manikin (Laerdal Airway Management Trainer; Laerdal Medical®) and Ambu manikin (Ambu M MegaCode Trainer W®; Ambu A/S®, Ballerup, Denmark), were placed on a standard CT table, with the head kept in a neutral position, using the same special padding used for the trauma population described above. If possible, the manikins' airways were set to an uncomplicated, default airway. The same scan protocol described in the third paragraph of this section for trauma patients was used for all manikins.

Anatomic structures of the upper airway were defined by using the methods described by Schwab *et al.*[24] The retroglossal and hypopharyngeal sections were combined in the term "pharyngeal airspace." The oral airspace is bound by the upper and lower teeth, the hard and soft palate, the tongue, and an imaginary line between the uvula and the posterior border of the tongue. Volume calculations were performed after manually selecting the areas of interest within each sagittal plane of the predefined space. Most distances and areas were measured in the midsagittal plane. Only the widest diameter of the tongue was assessed in a coronal plane. Radiographic evaluation was performed using OSIRIX (OSIRIX Dicom Viewer 3.9.2; Pixmeo Sarl, Bernex, Switzerland). All values except largest coronal diameter of the tongue are displayed in figure 1.

Statistical Analysis

As the pharyngeal space is of particular importance for the fit of any supraglottic airway device, this particular measurement was chosen as the primary outcome parameter. A manikin measurement outside the 95% CI of patient measurements, based on the Student t test, was considered to be clinically significant. A 95% CI for the manikins' measurements was not calculated because each model was CT-scanned only once. However, because new manikins were used and production deviations are negligible, an extremely narrow 95% CI can be assumed. Data are presented as the mean $\pm$ SD, with the corresponding 95% CIs, unless otherwise specified. R 2.8.1 for Macs (R Foundation for Statistical Computing, Vienna, Austria) was used for the statistical analysis.[25]
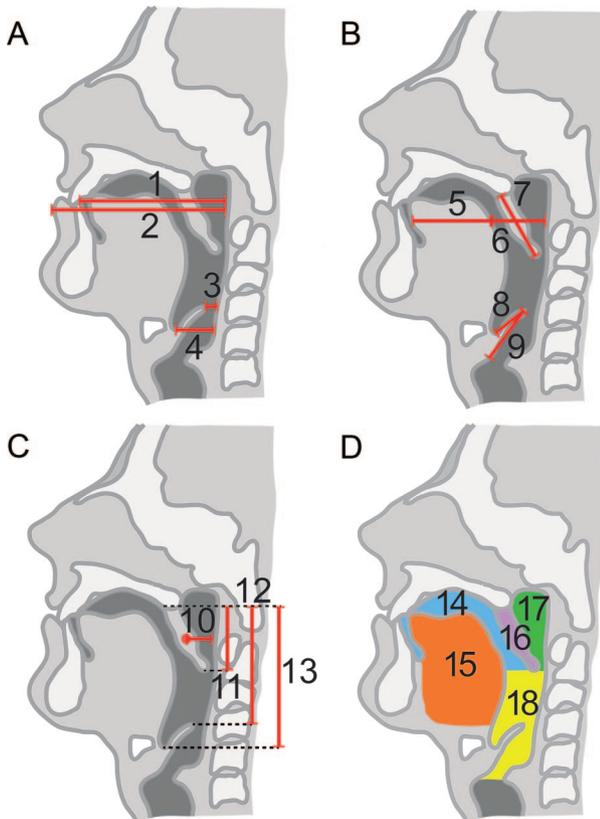
Fig. 1. Airway measures. (*A*) 1 marks the horizontal distance lower alveolar process to posterior pharyngeal wall, 2 marks the horizontal distance outermost portion of lower lip to posterior pharyngeal wall, 3 marks the horizontal distance tip of the epiglottis to posterior pharyngeal wall, 4 marks the horizontal distance vallecula to posterior pharyngeal wall. (*B*) 5 marks the largest horizontal diameter of the tongue, 6 marks the horizontal distance edge of the tongue to posterior pharyngeal wall at level of the largest horizontal diameter of the tongue, 7 marks the curved length of the soft palate, 8 marks the distance vallecula to tip of the epiglottis, 9 marks the distance posterior base of the epiglottis to tip of the epiglottis. (*C*) 10 marks the horizontal distance center of the soft palate to posterior pharyngeal wall, 11 marks the height of the soft palate, 12 marks the vertical distance base of the soft palate to tip of the epiglottis, 13 marks the vertical distance base of the soft palate to vallecula. (*D*) 14 marks the volume of the oral airspace, 15 marks the cross-sectional area of the tongue, 16 marks the cross-sectional area of the soft palate and uvula, 17 marks the volume of the retropalatal airspace, 18 marks the volume of the pharyngeal airspace.

Results

During the screening period, 312 patients who had undergone a trauma CT scan as specified (November 2007–November 2009) were identified. Out of these patients, 20 met all of the inclusion criteria as described in the third paragraph of Materials and Methods, whereas 292 patients had to be excluded because of neck collars, head or cervical trauma, inappropriate image quality, or previously placed airway devices. On average, the patients included in the study were 28 (SD 7) years old, weighed 69 (SD 16) kg, were 170 (SD 8)

cm tall, had a Body Mass Index of 24 (SD 5) kg $\cdot$ m^{-2}, and had a Glasgow Coma Scale score of 15 (range 14 to 15).

The pharyngeal airspace measurements in high- and low-fidelity patient simulators differed significantly from the results obtained from actual patients. Whereas the pharyngeal airspace in patients was 13.5 ± 7.7 cm^3 (95% CI, 9.9–17.1 cm^3), the measurements were much larger in the manikins (SimMan 68.5 cm^3, SimMan 3G 35.4 cm^3, HPS 30.6 cm^3, HAL 40.1 cm^3, Laerdal Manikin 65.9 cm^3). In the Ambu manikin, the pharyngeal airspace could not be assessed because of the lack of anatomic details. An overview regarding the anatomic accuracy of each manikin is shown in table 1. A visual comparison of all manikins is presented in figure 2.

Furthermore, the oral airspace, the horizontal diameter of the tongue, and the distance from the tip of the epiglottis to the posterior pharyngeal wall were different in all manikins when compared with the actual patients. The results of all measurements are presented in table 2.

Discussion

This study demonstrates that there are major differences in pharyngeal airspace and other airway measurements in adult high-fidelity human patient simulators and low-fidelity airway trainers compared with an actual patient's anatomy. The HPS was the most anatomically accurate simulator. The Ambu manikin, however, lacked several anatomic details, rendering comparison measurements impossible for this simulator.

This is, to the best of our knowledge, the first trial to evaluate the airway anatomy of adult simulation manikins with objective, radiographic measurements. Hesselfeldt *et al.* tried to evaluate how realistic the airway was in SimMan manikins while performing bag-mask ventilation, laryngeal mask placement, and tracheal intubation by using a subjective 100 mm visual analog scale.[18] Even though anesthesia professionals rated this manikin as highly realistic in most aspects, there were several differences between man and manikin. In particular, aspects of facemask ventilation and some steps of tracheal intubation were barely acceptable or even unrealistic. Interestingly, the subjective ratings of the study by Hesselfeldt *et al.* are, to some extent, in conflict with our objective, anatomical measurements. Whereas the pharyngeal airspace and the retropalatal airspace are radiographically much wider in nearly all manikins, Hesselfeldt reported that the oropharyngeal airway was appropriate. Kanaya and Chou discussed the value of the pharyngeal airspace and its importance in airway management.[20,21,26] They found that a small pharyngeal airspace is related to difficulties in securing the airway. Therefore, a wide pharyngeal airspace, as found in all manikins in this trial, could lead to an inappropriately easy airway to manage and thereby would bias the results of simulation-based research.

Similar differences between a pediatric patient's anatomy and the anatomy of a high-fidelity pediatric patient simulator

Table 1. Overview about Anatomic Accuracy; Number of Measures within 95% CI of Human Patients (Relative Number)

	SimMan	SimMan 3G	HPS	HAL	Ambu Manikin	Laerdal Manikin
Tongue & Overall Distances (6 measurements)	0 (0%)	2 (33%)	3 (50%)	0 (0%)	0 (0%)*	0 (0%)
Palate & Epiglottis (10 measurements)	4 (40%)	2 (20%)	3 (30%)	1 (10%)	1 (10%)*	1 (10%)
Volumes (3 measurements)	0 (0%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)*	0 (0%)
All Data (19 measurements)	4 (21%)	5 (26%)	6 (32%)	1 (5%)	1 (5%)*	1 (5%)

High-fidelity patient simulators are SimMan, SimMan 3G, HPS, and HAL.

* Because of a lack of anatomic accuracy, not all measurements could be evaluated.

Ambu Manikin = Ambu M MegaCode Trainer W®, Ambu A/S®, Ballerup, Denmark; HAL = HAL S3000® Mobile Team Trainer, Gaumard®, Miami, FL; HPS = HPS Human Patient Simulator®, METI®, Sarasota, FL; Laerdal Manikin = Laerdal Airway Management Trainer®, Laerdal Medical®, Stavanger, Norway; SimMan = SimMan®, Laerdal Medical®, Stavanger, Norway; SimMan 3G = SimMan 3G®, Laerdal Medical®, Stavanger, Norway.

were demonstrated in a previous study evaluating the pediatric simulator SimBaby (SimBaby®, Laerdal Medical®).[19] Such anatomic abnormalities in the manikins could be perceived as unrealistic by more experienced trainees during airway training and may prevent adequate scenario immer-

Fig. 2. Visual comparison of radiographic images (midsagital plane) of patient simulators and airway trainers. Ambu Manikin = Ambu M MegaCode Trainer W®, Ambu A/S®, Ballerup, Denmark; HAL = HAL S3000® Mobile Team Trainer, Gaumard®, Miami, FL; HPS = HPS Human Patient Simulator®, METI®, Sarasota, FL; Laerdal Manikin = Laerdal Airway Management Trainer®, Laerdal Medical®, Stavanger, Norway; SimMan = SimMan®, Laerdal Medical®, Stavanger, Norway; SimMan 3G = SimMan 3G®, Laerdal Medical®, Stavanger, Norway.

sion during high-fidelity simulation. A failure-to-intubate rate of 13%, reported in the Hesselfeldt trial, may be a result of unrealistic anatomy. In inexperienced personnel, an unrealistic airway may lead them to acquire inappropriate airway management techniques.

In a series of manikin trials, Cook et al. found indications that various airway devices perform and techniques are performed differently depending upon the manikin.[27–30] In line with these findings, the same group of authors evaluated the effect of different airway trainers on the duration and difficulty of fiberoptic intubation. They found major differences between the manikins.[31] In all of the studies, experienced anesthesia providers performed differently when using the various manikins. Given this finding and the results of our present study, we believe the assumption that simulator-acquired skills can transfer to a clinical setting should be seriously reconsidered.

Additional evidence emphasizes the problem with applying airway-laboratory studies to real-life clinical situations. Studies have compared the success rate and time of fiberoptic intubation, intubation with a Glidescope (Verathon Inc., Bothell, WA), and a commonly used Macintosh laryngoscope blade, in manikins and actual human patients.[16,32–34] Even though the Glidescope was superior to the Macintosh blade in human patients, these results could not be reproduced in a manikin-based trial. Furthermore, there was no correlation between the time to complete the tasks in humans and in the simulators.

Recently, a critical editorial by Rai and Popat addressed this issue and called for a stop to the common practice of airway research using patient simulators and airway trainers instead of actual patients.[8] Because of the limitations of simulation-based trials, the authors encouraged an "evolution" of airway research from the simulator to the actual patient. These considerations are strongly supported by our findings. We found a major difference between human patients and manikins, which questions the appro-
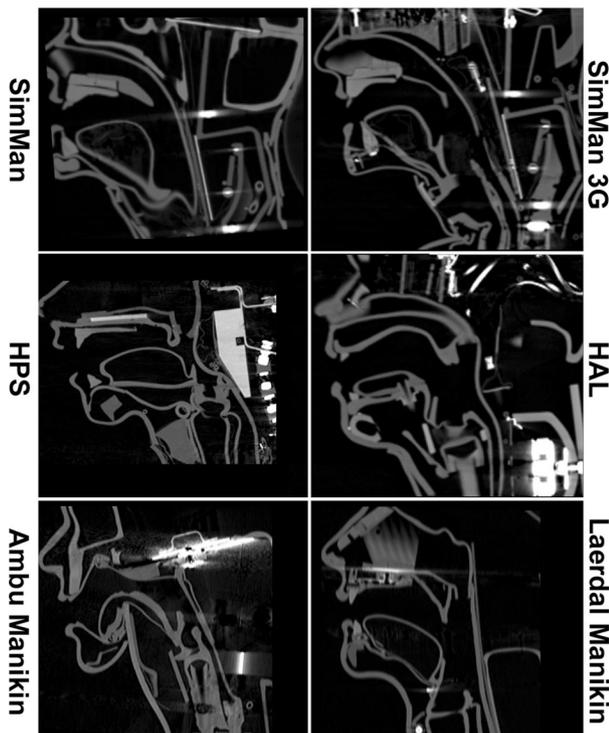
Table 2. Airway Dimensions of 20 Patients Compared with Four High-fidelity Patient Simulators and Two Airway Training Manikins

	Patients		SimMan	SimMan 3G	HPS	HAL	Ambu Manikin	Laerdal Manikin
	Mean (SD)	95% CI						
Tongue								
Cross-sectional area (cm^2)	25.6 (3.7)	23.8–27.5	16.9*	15.0*	24.1	21.5*	N/A	17.5*
Horizontal diameter (cm)	6.3 (0.7)	5.9–6.6	4.6*	4.7*	6.7*	5.3*	5.0*	5.3*
Coronar diameter (cm)	4.4 (0.5)	4.2–4.7	3.8*	4.5	3.3*	4.1*	3.8*	3.9*
Edge–Pharynx (cm)	1.6 (0.7)	1.2–1.9	2.8*	3.4*	1.2	3.9*	2.4*	3.0*
Palate								
Cross-sectional area (cm^2)	2.7 (1.0)	2.3–3.2	4.0*	1.2*	3.2	5.1*	N/A	5.1*
Curved length (cm)	3.7 (0.6)	3.4–4.0	3.5	4.1*	4.3*	3.2*	N/A	4.8*
Height (cm)	2.7 (0.7)	2.4–3.1	2.3*	2.3*	3.1	2.7	N/A	3.8*
Center–Pharynx (cm)	1.5 (0.2)	1.4–1.6	1.5	1.3*	1.8*	2.3*	N/A	2.6*
Palate–Epiglottis (cm)	4.4 (0.9)	4.0–4.9	5.1*	4.3	3.5*	5.1*	N/A	6.7*
Palate–Vallecula (cm)	5.7 (1.0)	5.3–6.2	5.9	5.2*	4.4*	6.8*	N/A	8.3*
Epiglottis								
Anterior length (cm)	1.6 (0.4)	1.4–1.7	1.4	0.9*	0.9*	1.8*	1.8*	1.6
Posterior length (cm)	2.8 (0.7)	2.5–3.2	3.9*	2.9	1.7*	2.4*	2.6	2.4*
Tip–Pharynx (cm)	0.9 (0.4)	0.7–1.1	1.5*	2.5*	0.3*	3.2*	2.0*	2.6*
Vallecula–Pharynx (cm)	1.7 (0.6)	1.4–2.0	2.9*	3.6*	1.4	4.9*	1.2*	3.3*
Overall Distances								
Teeth–Pharynx (cm)	8.1 (0.6)	7.9–8.4	8.7*	8.4	8.4	9.4*	8.8*	9.2*
Lip–Pharynx (cm)	9.5 (0.6)	9.2–9.8	10.2*	10.0*	11.1*	10.9*	10.2*	10.2*
Volumes								
Oral Airspace (cm^3)	4.3 (5.3)	1.9–6.8	54.0*	63.7*	44.9*	85.2*	N/A	74.0*
Retropalatal Airspace (cm^3)	5.1 (2.0)	4.2–6.1	10.6*	5.7	6.3*	15.9*	N/A	16.9*
Pharyngeal Airspace (cm^3)	13.5 (7.7)	9.9–17.1	68.5*	35.4*	30.6*	40.1*	N/A	65.9*

High-fidelity patient simulators are SimMan, SimMan 3G, HPS, and HAL.

* Values above or below 95% CI (level of clinical relevance).

Ambu Manikin = Ambu M MegaCode Trainer W®, Ambu A/S®, Ballerup, Denmark; HAL = HAL S3000® Mobile Team Trainer, Gaumard®, Miami, FL; HPS = HPS Human Patient Simulator®, METI®, Sarasota, FL; Laerdal Manikin = Laerdal Airway Management Trainer®, Laerdal Medical®, Stavanger, Norway; N/A = not applicable; SimMan = SimMan®, Laerdal Medical®, Stavanger, Norway; SimMan 3G = SimMan 3G®, Laerdal Medical®, Stavanger, Norway.

priateness of simulation-based research translating into the care of real patients.

Our study has a few limitations. As distances, areas, and volumes were the target of our study, some relevant airway parameters, such as the rigidity of soft tissue and the resistance of mucosa, could not be assessed in this trial. However, even if clinical parameters were not tested, the obvious differences in anatomic details, compared with actual patients, could influence simulation-based airway research and training. Furthermore, the anatomy of the upper airway changes throughout different stages of anesthesia and sleep and causes a narrowing of the pharyngeal structures.[35] As all patients included in this trial were conscious, applying general anesthesia, as required for airway management, would have caused a decrease in airway volumes and thus resulted in an even greater difference between patients' and manikins' anatomy. Although radiographic techniques have been used extensively to assess the anatomic proportions of the upper airway,[20,24,35,36,37,38] radiographic airway assessment does not appear to be predictive of difficult airway situations.[39] Furthermore, no standardized assessment method has been established up until now. Because of manufacturing details of the manikins, measurements found in the literature had to

be modified in part. Therefore, even though some parameters, such as the retropalatal airspace and the vertical distance from the base of the soft palate to the tip of the epiglottis, are in line with results reported by other researchers,[35,37,38] not all results of this trial can be directly compared.

In conclusion, the airway anatomy of four high-fidelity patient simulators and two airway trainers does not adequately reflect the anatomical proportions found in real patients. In particular, the pharyngeal airspace was larger in all manikins compared with actual patients. These anatomical inaccuracies can impact airway training and confound comparative airway device studies performed with adult patient airway simulators.

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