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- ² Simulation and education
- A radiographic comparison of human airway anatomy and airway
- manikins Implications for manikin-based testing of artificial
- ₃ airways[☆]
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ABSTRACT

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Obiective: The air

Objective: The aim of this prospective, single-center, observational study was to investigate the accuracy of modeling and reproduction of human anatomical dimensions in manikins by comparing radiographic upper airway measurements of 13 different models with humans.

Methods: 13 commonly used airway manikins (male or female anatomy based) and 47 controls (adult humans, 37 male, 10 female) were investigated using a mediosagittal and axial cervical spine CT scan. For anatomical comparison six human upper airway target structures, the following were measured: Oblique diameter of the tongue through the center, horizontal distance between the center point of the tongue and the posterior pharyngeal wall, horizontal distance between the vallecula and the posterior pharyngeal orifice length of epiglottis distance at the narrowest

part of the trachea. Furthermore, the cross-section of the trachea in axial view and the cross-section of the upper oesophageal orifice in the same section was calculated. All measurements were compared gender specific, if the gender was non-specified with the whole sample.

Results: None of the included 13 different airway manikins matched anatomy in human controls (*n* = 47) in all of the six measurements. The Laerdal Airway Management Trainer, however, replicated human airway anatomy at least satisfactorily.

Conclusion: This investigation showed that all of the examined manikins did not replicate human anatomy. Manikins should therefore be selected cautiously, depending on the type of airway securing procedure. Their widespread use as a replacement for in vivo trials in the field of airway management needs to be reconsidered.

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28 1. Introduction

Airway manikins are constructed as an artificial replication of the human airway and their use for training and research in airway management is widespread. They enable training of advanced airway skills and can be used to mimic clinical scenarios. When

http://dx.doi.org/10.1016/j.resuscitation.2015.05.001 0300-9572/© 2015 Published by Elsevier Ireland Ltd. designing a study there are no adverse effects that need to be taken into account. Such an investigation can be completed within a couple of days, rather than years. The fact that manikins can be used without placing patients in critical situations in repeated training sessions leads to the acquirement of vital skills.^{1,2} Timmermann and colleagues suggest that the applicability of acquired skills is highly dependent on a realistic setting, which also includes realistic anatomic structures of the manikins.³ Currently, more than 20 different manikins from different manufacturers are available. These manikins vary in design and complexity and the most suitable manikin for learning difficult airway management has so far not been identified. However, little evidence exists whether anatomic properties of manikins are similar to the human anatomy. This

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may have implications for the airway device evaluation as many preliminary studies are performed on manikins.

The aim of the present study was to investigate the accuracy 48 of modeling by comparing radiographic upper airway measure-49 ments of 13 different manikins with human anatomy to determine 50 if manikins are a reliable alternative when performing clinical air-51 way management studies in humans. 52

2. Methods

After approval by the Institutional Review Board, data (462/11) of all adult patients admitted with major trauma was collected during a 3-months period. None of the patients were endotracheal intubated or required cervical immobilization with a stiffneck device. As a routine they underwent a whole body Computed Tomography (CT) scan after being admitted to the emergency room in accordance with Advanced Trauma Life Support (ATLS) and institutional protocols for trauma care. Patients with diagnosed or obvious craniofacial or cervical dysmorphia, head, neck and face trauma and upper airway anomalies were excluded from the trial.

To establish which types of manikins were used in clinical studies a Pubmed, Medline and Oldmedline investigation using the following mesh terms "intubation, tracheal", "airway management", "laryngeal mask", "supraglottic airways" and "manikin" with an additive filter "clinical trials" was performed. All publications during the period 1960-April 2011 were screened for the terms mentioned above. 151 publications were identified and, after excluding pediatric airway manikin studies, 121 publications evaluating different intubation tools in manikins were analyzed. The most commonly used manikins were identified and included for further investigation if possible (Table 1).

As manufacturers base their manikins on male or female dimensions we classified the manikins into female, male and if no information was available into not applicable (n/a). The 13 manikins were either property of the University Hospital Frankfurt or Paramedic School of the Frankfurt Fire Department, Germany. One manikin was obtained from the manufacturer for investigational use only.

For comparison of the anatomic properties the mediosagit-82 tal and axial cervical spine CT scans were analyzed. All CT-scans 83 were performed with a Somatom Definition AS Sliding GantryTM 84 (Siemens, Erlangen, Germany) with a slice thickness of 3 mm. 85 For anatomical comparison of six human upper airway target 86 structures we used measurements as defined by Schebesta and 87**05** co-authors⁴ and additionally measured the narrowest tracheal 88 diameter^{5,6} (Fig. 1). To define this structure the epiglottis in the 89 sagittal reconstruction was identified and correlated with the axial 90 slices as some manikin are designed without cervical spine repli-91 cation 92

To compare the anatomic region of importance for the placement of supraglottic airway devices the upper oesophageal orifice (distance D in Fig. 1) was also measured.⁷ All distances were measured in the mediosagittal plane. Furthermore we calculated the cross-section of the trachea in the axial view and the cross-section of the upper oesophageal orifice in the same section (Fig. 2). In all manikins the CT scans were performed in the same manner as in our patients and results were compared gender specifically. In 100 manikins without gender specification anatomical comparison was 101 based on the results of all included male and female patients. 102

Statistical analysis was performed with GraphPad Prism5 for 103 Windows, Version 5.03 (GraphPad Software Inc., La Jolla/San Diego, 104 CA, USA). To assess data distribution a Shapiro-Wilk test was 105 performed. Results for the measurements in humans were summa-106 107 rized as mean \pm standard deviation. Each manikin was only scanned once and measurements were only performed once on each device. 108



Fig. 1. Anatomical measurements: (A) oblique diameter of the tongue through the center; (B) horizontal distance between the center point of the tongue and the posterior pharyngeal wall; (C) horizontal distance between the vallecula and the posterior pharyngeal wall; (D) distance of the upper oesophageal mouth; (E) epiglottic length; (F) distance at the narrowest part of the trachea.



Fig. 2. Anatomical measures of the tracheal cross-section at the narrowest part (G, mm²) and cross-section in the region of the upper oesophageal mouth (H, mm²).

Multiple scans were not considered necessary due to the fact that manikins were placed in the scanner in a standardized and fixed position. Measurements obtained from humans were compared to those obtained from manikins.

For comparison of the above-mentioned measurements the results obtained from human anatomy were set as baseline and the percentage difference of the distances measured in manikins was calculated and compared if applicable.

3. Results

During a three-month period 68 patients admitted to the trauma emergency room of our hospital were screened for eligibility. 109

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Table 1

List of the 13 manikins investigated with a sagittal and axial CT scan of the upper airway structures and comparison of the measurements in humans and manikins.

| | Nr. | Sex | A, mm | B, mm | C, mm | D, mm | E, mm | F, mm | G, mm ² | H, mm ² |
|--|------------|--------|-----------------------|------------------------|------------------|--------------------------|--------------------|------------------|---------------------------|--------------------|
| Human | | | | | | | | | | |
| All (n = 47) | | | $55 \pm 5 (4669)$ | $48 \pm 5 \; (37 60)$ | $10\pm 3(5-20)$ | $0.06 \pm 0.3 \; (01)$ | $30 \pm 5 (1439)$ | $16\pm 3(1023)$ | $207 \pm 66 (77 380)$ | 0.0 ± 0 |
| Male (<i>n</i> = 37) | | | 56±5(48–69) | $48 \pm 5 \; (37 60)$ | $10\pm 3~(6-20)$ | $0.05 \pm 0.2 \ (0{-}1)$ | $31 \pm 5(14 39)$ | $16 \pm 3(1023)$ | $210\pm70(77380)$ | 0.0 ± 0 |
| Female (<i>n</i> = 10) | | | $52 \pm 5 \ (46 59)$ | $44 \pm 4 (38 49)$ | $8\pm 2(5-12)$ | $0.1 \pm 0.3 (0{-}1)$ | $25 \pm 2 (2228)$ | $16\pm 2(12-18)$ | $194 \pm 41 \ (136 274)$ | 0.0 ± 0 |
| Manikin | | | | | | | | | | |
| Laerdal Airway Management Trainer TM | Dummy 1 | Male | 48 | 50 | 19 | 2 | 35 | 29 | 519 | 29 |
| (Stavanger, Norway) | | | | | | | | | | |
| Laerdal Resusci Anne Simulator TM | Dummy 2 | Female | 41 | 54 | 25 | 9 | 19 | 21 | 266 | 125 |
| (Stavanger, Norway) | Dummer 2 | NI/A | 10 | 50 | 20 | 2 | 7 | 10 | C12 | 101 |
| (CAE Healthcare Florida USA) | Dunning 3 | IN/A | 40 | 00 | 20 | 2 | 1 | 19 | 012 | 121 |
| VBM Atemwegssimulator BOB TM | Dummy 4 | Female | 50 | 69 | 24 | 17 | 25 | 24 | 264 | 430 |
| (Sulz-Neckar, Germany) | Dunnig I | remaie | 50 | | | | 20 | | 201 | 150 |
| Gaumard Scientific NOELLE Birthing | Dummy 5 | Female | 32 | 67 | 37 | 20 | 15 | 20 | 242 | 443 |
| Simulator™ (Miami, USA) | - | | | | | | | | | |
| AMBU Intubationstrainer Erwachsene TM | Dummy 6 | N/A | 38 | 52 | 16 | 11 | 20 | 16 | 208 | 334 |
| (Bad Nauheim, Germany) | | | | | ~ | | | | | |
| AMBU MegaCode W ^{IM} (Bad Nauheim, | Dummy 7 | N/A | 37 | 60 | 12 | 2 | 37 | 15 | 197 | 109 |
| Germany) | Dummer 0 | Female | 25 | 66 | 20 | 10 | 10 | - 20 | 550 | 222 |
| (Sulz Nockar Cormany) | Dunning 8 | Female | 30 | 00 | 30 | 10 | 16 | 20 | 228 | 332 |
| AMBLI Airway Man I TM (Bad Nauheim | Dummy 9 | N/A | 42 | 54 | 12 | 2 | 26 | 16 | 166 | 156 |
| Germany) | Dunning 5 | 14/24 | 72 | 54 | 12 | 2 | 20 | 10 | 100 | 150 |
| Laerdal Resusci Anne Advanced | Dummy 10 | Female | 46 | 59 | 24 | 12 | 17 | 21 | 224 | 379 |
| Skilltrainer [™] (Stavanger, Norway) | - | | | | | | | | | |
| Laerdal Sim Man TM (Stavanger, Norway) | Dummy 11 | Male | 46 | 44 | 7 | 6 | 36 | 17 | 206 | 113 |
| Laardal MagaCodo Kally ALSTM (Stavanger | Dummy 12 | Mala | 40 | E 2 | 15 | 10 | 24 | 10 | 167 | 224 |
| Norway) | Dunning 12 | Wale | 40 | CC. | 10 | 10 | 24 | 15 | 107 | 234 |
| Trucorn AirSim Multi TM (Belfast Northern | Dummy 13 | Male | 37 | 52 | 6 | 7 | 30 | 22 | 309 | 148 |
| Ireland) | 200000000 | | | | - | | | | | |

(A) Oblique diameter of the tongue through the center; (B) horizontal distance between the center point of the tongue and the posterior pharyngeal wall; (C) horizontal distance between the vallecula and the posterior pharyngeal wall; (D) distance of the upper oesophageal mouth; (E) epiglottic length; (F) distance at the narrowest part of the trachea (G, mm²) tracheal cross-section at the narrowest part and (H, mm²) cross-section in the region of the upper oesophageal mouth. Human data are represented as mean and standard variation. Human measurements are displayed as range, mean and standard deviation.

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Fig. 3. Comparison of the measurements (mm) in females with each manikin classified as female. (A) Oblique diameter of the tongue through the center; (B) horizontal distance between the center point of the tongue and the posterior pharyngeal wall; (C) horizontal distance between the vallecula and the posterior pharyngeal wall; (D) distance of the upper oesophageal orifice; (E) epiglottic length; (F) distance at the narrowest part of the trachea (G, mm²) tracheal cross-section at the narrowest part and (H, mm²) cross-section in the region of the upper oesophageal orifice.

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47 patients (37 male/10 female) met the inclusion criteria and 21 patients were excluded according to the study protocol. The patient age was 39.6 ± 13.5 years (21–67 years). A whole body CT scan including mediosagittal and axial cervical spine imaging was performed on all patients.

We compared each single manikin with the average anatomy 125 of either male or female patients and, if no specification was given 126 by the manufacturer, with the average anatomy of all 47 patients 127 (Table 1 and Figs. 3-5). None of the included manikins matched 128 human anatomy in all of the six measured distances and 2 mea-129 sured cross-sections. It became obvious that each manikin may 130 have advantages or disadvantages for different procedures in man-131 aging the airway. 132

Comparison by gender showed that female human anatomy 133 (Fig. 3) was best displayed by the Laerdal Resusci Anne Simula-134 tor and the Laerdal Resusci Anned Advanced Skilltrainer. Notably 135 only two distances were within range of the human measurements. 136 For insertion of a supraglottic device we focused on the upper 137 oesophageal orifice (distance D, Fig. 1) and its cross-section (cross-138 section H, Fig. 2). The Laerdal Resusci Anne Simulator resembled 139 female anatomy the closest. 140

141 The closest replication of male anatomy was observed in the Laerdal Sim Man and the Laerdal Airway Management Trainer 142 (Fig. 4). Five measured distances of the Laerdal Resusci Anne Simu-143 lator, Laerdal Resusci Anned Advanced Skilltrainer and the Trucorp 144 Airsim Multi were within the range of human measurements. The 145 upper oesophageal orifice (distance D, Fig. 1) and its cross-section 146 (cross-section H, Fig. 2) were best reflected by the Laerdal Airway 147 Management Trainer 148

All manikins without gender specification were classified as N/A 149 and compared to anatomic measurements of all participants. The 150 METI Human Patient Simulator and the AMBU Airman I present the 151 human anatomy best (Fig. 5). The METI Human Patient Simulator 152 was five times within the range and the AMBU Airman I followed 153 with four distances within the range of human measurements. The 154 upper oesophageal orifice (distance D, Fig. 1) and its cross section 155 (cross section H, Fig. 2) was reflected best by the AMBU Intubation 156 Trainer adults. 157

Considering all manikins tested, female anatomy was mimicked
 the closest by Laerdal Resusci Anne Simulator and the Laerdal
 Resusci Anned Advanced Skilltrainer, male anatomy by the Laerdal
 Airway Management Trainer and in unspecified by the METI Human
 Patient Simulator and the AMBU Airman I.

163 4. Discussion

Our obtained data demonstrated that the airway anatomy of 164 the most commonly used manikins rarely reflected human air-165 way anatomy in adults. In particular, the oesophageal orifice, an 166 anatomical landmark for the placement of supraglottic airway 167 devices and the narrowest part of the trachea differed significantly 168 in most of the manikins compared to human anatomy. Based on 169 our results supraglottic airway management training should ide-170 ally be performed with manikins reflecting the anatomy of the 171 oropharyngeal and oesophageal cross section. 172

Manikins or so called patient simulators are commonly used as
standardized airway models and were part of the process for the
evaluation of new airway devices and airway management techniques for routine and emergency situations in the past. Nowadays,
emphasis is set on teaching purposes and airway management
training for novices and experts.^{1,3,4,8-10}

It has to be taken into account that anatomy and physiology of a real patient cannot be replaced by simple manikins and
even sophisticated simulators.¹¹ Manikins cannot represent easy
or difficult anatomy in its vast diversity. In manikins the upper

airway is stiff, non-compliant, static and "open" rather than soft, fragile, dynamic or collapsible as in humans. Secretions, lubrications, bleeding, coughing reflexes and modeling of regurgitation are nearly impossible to simulate.¹²

Nevertheless, several manikin studies investigating different tools for tracheal intubation or supraglottic airway management, either in apparently normal airways or proposed difficult scenarios have been published in recent years.^{13–19} As informed patient consent is not required such studies are not impeded by administrative or ethical concerns. Rai criticized that many authors are aware of this issue and comment on the limitation of studies performed on manikins in their discussions and that verification in a clinical setting is necessary.¹⁰ However, the evaluation process of a new airway device is often solely limited to manikin studies, as independent subsequent clinical trials rarely follow the initial in vitro studies. Considering the enormous discrepancy between human and manikin anatomy, this issue should raise concern regarding validity and transferability of manikin trials.

The incidence of a difficult airway in an operating room setting and in emergencies has not changed much in the past decades. It remains a major cause for morbidity and mortality in clinical anesthesia and emergency medicine.^{20,21} Regular training of complex airway management scenarios to achieve familiarity when experiencing these obstacles in a clinical setting is therefore essential, especially for novices. This can be achieved by simulating these scenarios using manikins.

Jackson and colleagues⁸ evaluated the performance of eight supraglottic airway devices in four different manikins (Airway Management TrainerTM – Ambu, UK; Airway TrainerTM – Laerdal, Norway; AirsimTM – Trucorp, Ireland; Bill1TM – VBM-Germany). Insertion of the respective supraglottic airway was graded with a defined score, in which ease of insertion, ability of ventilation and persistence in the midline after insertion were graded from 0 (impossible), 1 (difficult) to 2 (easy). In contrast to our study, Jackson primarily focused on the practical applicability and subjective grading of the devices and manikins. In accordance with the results of the present study they concluded that no manikin performed "best" for all individual supraglottic airway devices and performance for a particular supraglottic airway device varied. This becomes relevant when selecting a manikin for training and evaluation of a specific airway device.

Jordan evaluated the performance of 16 non-surgical Difficult Airway Society (DAS) Guideline techniques and 9 non-DAS techniques in the mentioned manikins. Among other techniques, intubation with different blades, application of external laryngeal manipulations, application of different fiber optic techniques, simulation of a difficult airway and insertion of different supraglottic airway devices were performed and graded by ten experienced participants.⁹ The following grading was used: ability to perform with a sufficient amount of realism, to perform, ability to perform or unable to perform. Similar to Jackson they concluded, without formally investigating anatomic properties, that there were significant differences between the respective manikins. Differences were either of a subjective nature or on the basis of anatomical differences in crucial regions of interests. In contrast to our study anatomical differences were only described briefly but not measured using diagnostic imaging. A priori knowledge which supraglottic airway performs well or poorly in a specific manikin will allow for a better interpretation of previous manikin studies comparing different SAD and will contribute to improved and more valid future trials.

Although the performance of specific SAD-techniques was not investigated in our trial, we reached a similar conclusion. In terms of lifelike anatomical reproduction, the Laerdal Airway Management Trainer matched most anatomical landmarks, distances and cross sections of live patients. This is in accordance with the results 184

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Fig. 4. Comparison of the measurements (mm) in males with each manikin classified as male. (A) Oblique diameter of the tongue through the center; (B) horizontal distance between the center point of the tongue and the posterior pharyngeal wall; (C) horizontal distance between the vallecula and the posterior pharyngeal wall; (D) distance of the upper oesophageal orifice; (E) epiglottic length; (F) distance at the narrowest part of the trachea (G, mm²) tracheal cross-section at the narrowest part and (H, mm²) cross-section in the region of the upper oesophageal orifice.

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Fig. 5. Comparison of the measurements (mm) in all patients with each not classified manikin. (A) Oblique diameter of the tongue through the center; (B) horizontal distance between the center point of the tongue and the posterior pharyngeal wall; (C) horizontal distance between the vallecula and the posterior pharyngeal wall; (D) distance of the upper oesophageal orifice; (E) epiglottic length; (F) distance at the narrowest part of the trachea (G, mm²) tracheal cross-section at the narrowest part and (H, mm²) cross-section in the region of the upper oesophageal orifice.

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published by Jordan and may serve as an explanation for the favorable grading of this simulator when evaluating SAD-techniques.

The presented study has limitations. A merely comatose patient 251 who is about to undergo intubation may present a loss of muscular 252 tone and therefore altered anatomy. With current technical limi-253 tations a manikin will be unable to simulate such variations. We 254 evaluated only one of each manikin. Possible variations in design 255 between individual manikins of the same type and from the same 256 manufacturer may not be accounted for. In addition, possible errors 257 during the CT scans may have been missed or underestimated. As 258 manikins were placed in a standardized and fixed position, multi-259 ple scans were not considered necessary. Furthermore, this study 260 simply examines the dimensions of the manikins and not their per-261 formance. Therefore, a device that mimics the real life insertion of 262 an SAD the closest for a practitioner may deviate considerably from 263 human anatomy. Such difference may be due to the materials used 264 for construction of the manikin. 265

With this investigation we were able to show that most of the 266 investigated manikins did not reflect actual human anatomy and 267 thus their widespread use as a replacement for in vivo trials in 268 the field of airway management needs to be carefully debated. 269 270 Manikins for training have to be chosen with care and consideration for the airway management tool to be trained. Their use as a train-271 ing tool is unquestioned, but as a research tool for the evaluation 272 of airway devices they are insufficient. 273

274 5. Conclusion

This investigation shows that all of the investigated manikins did not reflect human anatomy. Manikins should therefore be selected cautiously depending on the type of airway securing procedure. Their widespread use as a replacement for in vivo trials in the field of airway management needs to be reconsidered.

280 **Conflict of interest statement**

The investigation was solely funded by departmental sources. 281 However, R.S. and C.B. receive material support for research from 282 VBM Medizintechnik GmbH and Karl Storz GmbH & Co. KG. the 283 manufacturers of the laryngeal tube and the C-MAC video laryngo-284 scope and Bonfils intubation fiberscope, respectively. C.B. received 285 educational grants from Karl Storz GmbH & Co. KG, and C.B. is a 286 member of the Karl Storz advisory board. None of the other authors 287 has any conflict of interest with products and/or companies men-288 tioned in the manuscript. 289

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