Editorial

Simulation-based airway research: The fast-track recipes?

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Simulation-based training is rapidly evolving with the changing healthcare landscape and airway training is no exception.To keep pace with the scenario, the field of simulation-based research has grown rapidly over the last decade and two types of simulation-based research studies have been described: 1) Studies that assess the efficacy of simulation as a training methodology (as an educational intervention) and 2) studies where simulation has been used as an investigative methodology.[1] Several articles describing the attributes of simulation-based research and the simulation-based educational interventions are available.[2]

As per the mandatory requirement of the regulating council, establishment of a 'Skill and Simulation Lab'in a medical college is mandatory and this has opened the doors and has also provided a platform for both simulation-based education and simulation-based research.

Simulation-based airway management training in a Skill and Simulation Lab is an integral part of the new competency-based curriculum.[3-6] The airway manikins have slowly evolved over time since the 1960s, when Resusci Annie was first introduced and currently, some manikin models with face and airways are connected to artificial lungs. Evaluation of airway equipment and respiratory variables of a person such as lung compliance, airway resistance, etc.can be done on such manikins that simulate the entire respiratory system.[7] Nevertheless, when a new airway device is developed, it is tested and evaluated in various steps, firstly in a manikin, and this is followed by clinical trials focussing on different aspects and situations.

Though training of rare and difficult scenarios has been the initial necessity for the development of manikins, they have slowly invaded the field of research too. Manikins/part task trainers form the majority of simulation-related research and practising with equipment forms the commonest objective of these research studies.[8] Nevertheless, the recommended tidal volume of 500ml during cardiopulmonary resuscitation was derived from a patient simulator study.[9] Currently, manikin-based research is trending in the difficult airway and respiratory system domains. Manikin-based research studies use either normal airway or difficult airway models or simulator apps depending on the research hypothesis.

The research studies conducted in manikins are often based on hypotheses involving airway assessment, airway obstruction, airway skills including airway maintenance manoeuvres, bag-mask ventilation, giving the optimal position for intubation, application of manoeuvres to improve glottic exposure, the application of cricoid pressure, endotracheal intubation by various routes, insertion of oropharyngeal and nasopharyngeal airway, insertion

of supraglottic airway device, front of neck access and fibreoptic bronchoscopy.These studies involve the measurement of parameters such as intubation time, laryngeal visualisation scores, first-pass success rate, airway trauma, etc. The comparison of different airway devices in the manikins has always been a favourite of airway researchers.

Research on objective assessment of biomechanical parameters of trainees while performing procedures on manikins has also been conducted.[10] Manikins with different stages of neck flexibility and mouth opening, different tongue sizes including both, normal tongues and tongue swollen by inflating with air are available. Manikins with different positions of vocal cords eg-during laryngospasm, edentulous manikins and manikins with different types of teeth including upper incisors that can break off or buck teeth when excessive force is applied are also available. A simulated difficult airway can be created with an inflated tongue, cervical collar or elevation of the occiput. Replaceable airway parts like swollen posterior cartilages, elongated or notched epiglottis are available and these can be interchanged easily. In a prospective randomised controlled study published in this issue of the Indian Journal of Anaesthesia (IJA), a simulated difficult airway was created with a Philadelphia collar by the researchers in real-life patients requiring one lung ventilation for thoracotomy and the efficacy of Airtraq DL™ and Macintosh laryngoscope for double lumen tube placement was compared.[11]

The more realistic the manikin, the more is its value in training and research. Manikins and simulators, though now occupy an important place in airway and respiratory research, there are various intricate facts that researchers using manikins should know.

MANIKIN STUDIES: APPEALING TO RESEARCHERS?

In real-life patients, the need for informed consent from participants is important, whereas, patient consent is not required in manikin-based research. A manikin offers a standardised patient with no physiological implications or contraindications. In fact, manikin-based studies provide an option for research in situations where ethical issues pose a barrier, as in cases of objective assessment of technical competency of novices, where exposing the patients to the risk of invasive procedures is avoided.There are many misconceptions about the need for ethics committee approval for manikin-based research; however, one has to remember that any study that is performed on the manikin will in all likelihood be extrapolated to real-life scenarios and this may possibly compromise the patient safety and can lead to enhanced morbidity and mortality.Hence, ethics committee approval is justified for manikin-based research studies.

The nuances of patient recruitment, risk of adverse effects and patient harm do not exist in manikin research. Manikins are readily available unlike real-life patients. Modern manikins and simulators are strong and can withstand repeated use and application unlike real-life patients who would get hurt, fatigued and may feel exploited.

CHALLENGES IN MANIKIN/SIMULATION-BASED RESEARCH

Procurement of appropriate high fidelity manikins can incur additional costs especially in resource-poor countries.The characteristics of the manikin such as intrinsic resistance and airway dead space may vary from model to model and these can impact peak pressure, tidal volume and other variables.[7] According to studies, cervical spine mobility and anatomical proportions such as the oral airspace, retro-palatal airspace and pharyngeal airspace may be different in different airway trainer manikins. There can be variations between manikins from the same manufacturer.[12-15] Manikin plasticity can change with repeated use and this can affect the force required for laryngoscopy.[16] Manikins can become stiff and non- compliant.[17] It is said that the manikin's anatomy, material compliance and haptic qualities can affect the forces exerted by the distal laryngoscope blade during laryngoscopy and intubation.[12,18] Researchers have measured forces applied during laryngoscopy in different manikins, cadavers and humans with the help of strain gauges and sensors attached to the laryngoscope handle or blade.[16,19] In addition, the manikin anatomy is fixed. However, in humans, there exists a wide clinical variability. Also, a variety of clinical scenarios including copious oral secretions, oropharyngeal bleeding, fogging caused by body temperature and gag reflex can be encountered in real-life clinical practice, but simulation cannot replicate these huge variations.[20]

The degree of realism too can vary between manikins.[16] Thus, the manikin used in the study may not accurately simulate human real-life conditions and the results of manikin studies need to be interpreted

with a pinch of salt. Eventually, the transferability of these manikin-based validation studies in the human subjects remains questionable. Furthermore, the evidence of effectiveness of this manikin-based research in real-life scenarios is mixed. Nevertheless, in a study, even with time as a dependent measure, there was no correlation between performance in simulation and clinical practice when training for fibreoptic bronchoscopy.[21]

WHAT TO KEEP IN MIND WHEN DOING MANIKIN/ SIMULATION-BASED STUDIES?

The performance of an airway device in a manikin is affected by the physical attributes of the manikin. Blackburn *et al*. found that low-fidelity airway manikins are not accurate when compared with adult humans. The airway space between the epiglottis and posterior pharyngeal wall was too large in these manikins.[17] The resemblance of the manikin to human morphometrics is important. Thus, the type of manikin that is selected can be an important factor that can affect the performance of the device that is being evaluated or researched upon.[17] Nevertheless, low fidelity manikins are most commonly used for device development.[17] Evaluation of the intrinsic resistance of the manikin is crucial for a comparative study or for evaluation of a single ventilation device. Whenever compared, manikins of the same model and produced by the same manufacturer should be used. The manikin used should replicate the anatomy of the human airway accurately and should be capable of providing a highly realistic experience. Also, one has to be careful while interpreting results of training and device evaluation in a single manikin.[16]

The value of simulation in airway management has now been proven beyond doubt. An increasing number of studies are being conducted using manikins and simulators as sources of data and as venues for research. Manikin-based studies including those related to coronavirus disease 2019 have been published in the IJA too in the last few years.[23-27] However, it is time that more research takes place on the characteristics of the numerous airway manikins and their correlation with characteristics of the real-life human airways and their influence on respiratory and ventilatory parameters. This will help develop more accurate and realistic manikins and the research study conclusions and clinical outcomes obtained from studies using these manikins will be more practical and reliable. Guidelines and protocols on manikins and simulation-based research need to be developed. Manikins with distorted airway anatomy due to thyroid or neck swellings, mediastinal mass, airway tumours need to be developed. The obstetric airway provides a rich fertile ground for research, but is unfortunately not much touched upon. Obstetric manikins with the anatomical changes of pregnancy, including oedematous airways with fragile airway linings need to be developed.

Though modern manikins are developed with the latest technology and are made to accurately resemble the human being,[17] the end users of manikin and simulation-based research should be aware of the associated limitations. At this point of time, several questions arise: Will the manikin be able to replace live animals, cadavers and real patients in device testing, training and research? Can the results of manikin-based studies be directly translated to actual clinical practice? Are these manikin-based studies, pilot studies whose results need to be further validated? It is time that we endeavour to produce high fidelity manikins, able to reproduce the airway anatomy and mechanics accurately. Nevertheless, manikin-based research should not become a fast-track (easy and fast to conduct) research in tune with the current trend of fast track publications. Research on the human airway has to go on, whether it is manikin or non-manikin-based. Meanwhile, the question arises: Where precisely do manikin-based and simulation-based studies lie in the hierarchy pyramid of evidence-based medicine? They are certainly non-human studies which should occupy the bottom part of the pyramid, but filtered (critically appraised) information is always placed at higher levels of evidence than non-filtered (not critically appraised) information and hence the systematic reviews or meta-analyses of well-structured and well-conducted scientific studies of simulation-based research provide top quality evidence for evidential clinical practice. With the incorporation of sophisticated technology and artificial intelligence, are not modern manikins almost human too?

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