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ORIGINAL RESEARCH

A special face mask with integrated angle meter to optimize the head position for bag-valve-mask ventilation—a prospective simulated proof-of-concept study

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Abstract

The supine position in unconscious patients resulted in the tongue falling back because of the loss of muscle tension which obstructed the upper airway. The head reclination opened the airway, however unexperienced rescuers faced difficulties in performing bag-valve-mask ventilation as it was hard to detect the optimal head position for opening the airway. The bag-valve-mask ventilation could be optimized if it indicated an optimized head angle to the rescuer. A digital sensor was attached to the face mask for measuring the degree of head reclination. Moreover, the face mask was equipped with an airway trainer and sealed *via* adhesive tape. The airway trainer was connected to a test lung and ventilated through pressure-controlled standard anesthesia machine (Pmax = 10 mbar, Positive End Expiratory Pressure (PEEP) = 0 mbar, f = 12/min). The head of airway manikin was tilted to 42 degrees starting from neutral position with a gradient of 2 degrees. The primary endpoint was the correlation of preset angles and digitally measured head position angles *via* the mask. In addition, the tidal and minute volumes were evaluated based on the head reclination. The preset and the digitally measured head position angles depicted correlation (R^2 = 0.9895855684; $p < 0.001$). The tidal volume was 150 mL in head position angle of <10 degrees, 200 mL at 18 degrees, 450 mL at 25 degrees, and it levelled with about 500 mL at 30 degrees. In conclusion, digital head position angle was measured to detect the correct head position. A signal in the face mask could indicate the optimized head position to the first respondents or inexperienced rescuers in emergency ventilation.

Keywords

Airway obstruction; Emergency ventilation; Face mask; Head reclination; Unprotected airway; Ventilation

1. Background

Bag-valve-mask (BVM) ventilation was employed in the emergency, however it posed psychomotor challenges to the rescuers [1–3]. There was a loss of muscle tension in the tongue and pharynx which resulted in the obstruction of upper airway in unconscious patients with supine position. Re-opening of obstructed airway (the so-called "A-problem") was the highest priority in emergency algorithms. "Tilting of the head and lifting of the chin" was the standard method for opening the airway [4]. Failure to open the airway resulted in ineffective bag-mask-ventilation which was life-threatening and might lead to death in minutes. However, the most experienced anesthesiologists did not know the difficulties and the trainings required for simultaneously tilting the head into correct position, sealing the facemask and providing tidal volumes with a bag valve device [5–7]. The proper BVM ventilation could improve its performance particularly for the less experienced rescuers [6, 8, 9]. A tilted head position to 43 degrees compared to the horizontal plane had been effective in opening the upper airway, as observed in magnetic resonance tomography based studies [10, 11]. Designing an easily applicable device such as facemask equipped with angle meter to indicate the head tilting angle might help rescuers in tilting the head for airway patency. It was unclear if measuring the head position with face mask was comparable to the measurements of magnetic resonance tomography, however it was vital to develop and technically validate such a device.

In this proof-of-concept study, a digital angle meter was fixed to the standard face mask for measuring the angle of mask position in relation to horizontal plane. The modified mask was assessed in a ventilation simulation made on an airway manikin trainer. The objective was to correlate a mechanically preset head position angle to the digitally measured angle through the face mask. Moreover, the tidal and ventilation minute volumes were measured on account of the preset head position angle.

2. Materials and methods

2.1 Experimental setup

The study was conducted at the Department of Anesthesiology, Intensive Care Medicine, Pain Therapy and Emergency Medicine, Friedrichshafen Regional Hospital, Germany. An anatomically shaped standard airway trainer (Airway Larry, 3B Scientific, Hamburg, Germany) was employed in this study. The airway trainer had an occluded airway that got opened in relation to the head tilt angle as in humans. A mechanical test lung (Michigan Instruments, DA 3 Adult Test Lung, Grand Rapids, MI, USA) was adjusted with the airway trainer. A standard face mask (Ambu Ballerup, Denmark) was fixed to the airway trainer. An adhesive tape (Tesa Gewebeband, Beiersdorf, Germany, Hamburg) was used to seal the mask with manikin's face for minimizing the leakage as confounding element in technical simulation. The position and sealing of the mask were same in the entire study.

An accelerometer (ADXL345, DollTek, Hong Kong) was fitted to the facemask for determining the angle between underlying surface (horizontal plane) and face mask. Accelerometers were the standard tools in smartphones, sports watches, pulse meters, *etc*. They could detect the vibrations or minimal changes in position. The main element was a micromechanical comb structure with fixed and mobile parts. One fixed and one mobile part were paired to build a condensator. The distance between these two structures was based on the factors such as acceleration and tilt angle. This resulted in the specific capacity of condensator which could be measured and transferred into a signal. The sensitivity of this sensor was less than one degree. A microcontroller (ATMega4809, Nano Every Arduino, Arduino, Boston, MA, USA) amplified the signal. The software was based on the open-source library Adafruit ADXL45 sensor test and the software serial. The signal output from microcontroller was transmitted *via* a Bluetooth transmitter (HM-10, DSDTech, Berlin, Germany). The signal from face mask was received by a development board (Raspberry Pi 4, Cambridge, England) through standard Bluetooth Low Energy Universal Serial Bus (BLE-USB) adapter fixed onto the board like all the other parts to form a single unit (Fig. 1). The signal was taken up *via* pygatt/Gattool module (Python, Software Foundation, Wilmington, DE, USA) and processed by Python based program to save the data in text files. A second accelerometer of the same type was connected to the development board for higher accuracy, attained by calibrating the slope of surface patient was lying on. The measurement of head tilt was thus possible against the surface even if this was not the horizontal plane. Both signals were processed, computed and transferred to the respective units of measurements and displayed *via* a graphical user interface (TKInter, Python, Wilmington, DE, USA).

User received the head position angle in degrees and in easily interpretable bar mower. The whole bar was presented in red at the head position angle of <30 degrees (Fig. 1A). The first of four subunits turned green at 30 degrees angle, the second at 35 degrees, the third at 39 degrees, and the whole bar was green at >42 degrees (Fig. 1B). These preset values were selected based on the previous studies [11]. The placement of face mask and head positioning were shown in the Two Videos placed in (**Supplementary videos 1,2**).

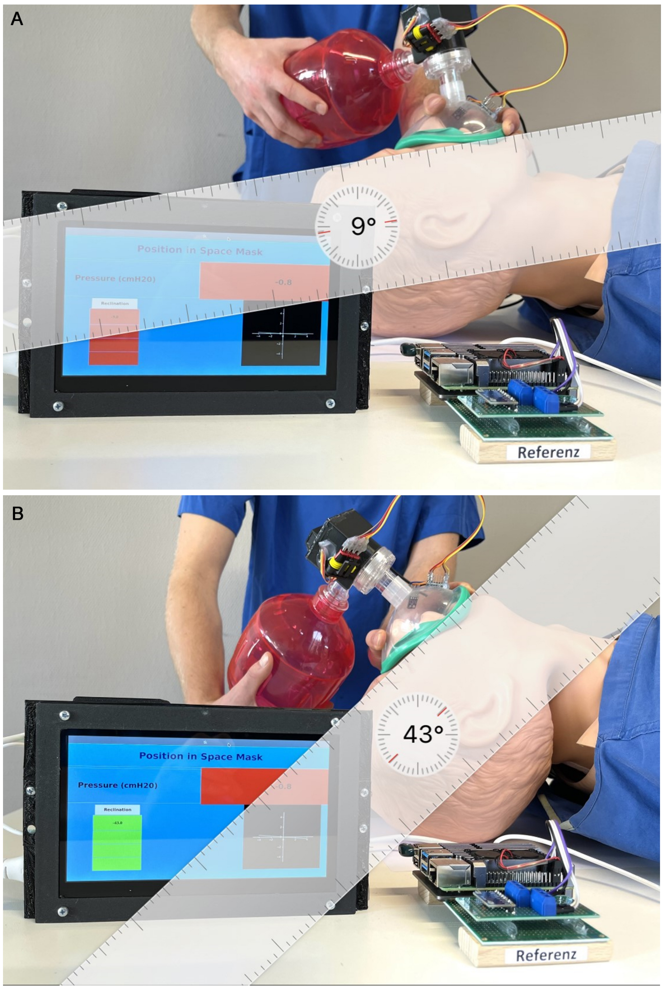

FIGURE 1. Experimental setting with photo digital measuring principle of head position angle in the neutral (A), and tilted position (B).

2.2 Experimental procedure

2.2.1 Evaluation of the head position angle

The head tilt (measured at a reference line between forehead and chin, Fig. 1) was increased stepwise in the gradient of 2 degrees, starting from 2 till 50 degrees tilt towards the horizontal plane. A classical angle meter (K-Classic, Obi, Wermelskirchen, Germany) was utilized to adjust the head position. The manikin was placed on a rubber mat and the head was manually fixed to avoid accidental changes in preset head position. A digital photo was taken from each setting, and the angle between reference line and horizontal plane was determined by iPhone (Apple Inc., Cupertino, CA, USA). The result was compared for the measurement of sensors in the face mask when mechanically preset angle and electronically measured angle were congruent. Each value was determined in duplicate.

2.2.2 Determination of ventilation based on head angle

The face mask was sealed to manikin's face through adhesive tape. Ventilation in pressure-controlled mandatory settings was provided *via* a standard anesthesia machine (Leon, Heinen & Löwenstein, Bad Ems, Germany) to avoid any bias from manual operation. The test lung (50 mL/mbar) was ventilated in pressure-controlled mode (Pmax = 10 mbar, PEEP = 0 mbar, f = 12/min). This was performed at each position between 3 and 43 degrees in the steps of 2 degrees for 1 minute. The minute ventilation volume was determined in this pilot study, and the average tidal volume was computed once for each preset angle.

2.3 Statistical analysis

Linear regression was employed to correlate each mechanically and photographically determined angle with electronically measured angle. Coefficient of determination was calculated, and F-test was used to determine the overall significance (SPSS 26; IBM, Armonk, NY, USA). Values for the ventilation volumes were evaluated in simple diagrams.

3. Results

There was no air leakage and the mask remained at the same position in whole experiment because of the tight fixation by the tape. The mechanically preset angle of head position compared to the horizontal plane had significant correlation (R^2 = 0.9895855684; $p < 0.001$, Fig. 2). The ventilation volume per minute and tidal volume were insufficient in the beginning of experiments at angles close to neutral position. There was an increase in the beginning at 18° angle and reaching a plateau without further improvement at ~28° angle (Fig. 3A,B).

4. Discussion

The preset head position angle was correlated with the angle measured by sensors in the face mask which could determine the optimized head position during face mask ventilation. Therefore, it might be a valid surrogate parameter. The angle between face mask and head position was correlated to humans as per this manikin model, however it must be subjected to futures studies in humans for validating the technical questions through bench studies.

The measured minute ventilation and the average calculated tidal volume were increased with the higher head tilting angle. These tidal volumes were added for the better comparison of results regarding dead space ventilation and to see the ventilation efficacy at each angle.

BVM ventilation was a complex psychomotor procedure. The loss of soft tissue tonus in unconscious patients resulted in obstructed upper airway because of the tongue falling back. Therefore, the rescuer had to tilt the head for keeping airway in patent state, to seal the face mask onto patient's face, and to push the ventilation bag. It was thus not surprising if this procedure often resulted in the insufficient ventilation by less experienced rescuers, especially in emergency [8, 12]. This procedure was further complicated if one of the steps was insufficiently carried out, which in turn might complicate another one and *vice versa*. For instance, if the head was not adequately tilted, this could increase the airway pressure because of semi-obstructed airway, resulting in mask leakage and stomach inflation. The increased stomach inflation might impair circulatory hemostasis [13], increase the risk of regurgitation and aspiration, and reduce the pulmonary compliance [14]. The experienced anesthesiologists thus considered the face mask ventilation as the most difficult challenges in anesthesia and emergency medicine. However, face mask ventilation was lifesaving as well as a basic procedure. It was a preferred measure for experienced rescuers if securing the airway was impossible by other procedures [6, 15].

Face mask ventilation was often impaired by the inadequate tilting of patient's head. It was suggested herein that the mask ventilation might be facilitated by a signal indicating if the head was sufficiently tilted, especially for less experienced rescuers. The angle could be presented on the analogy of traffic light system where red light indicated insufficient angle while green marked the sufficient angle. Such simplified device could be integrated into standard face masks such as those used in first aid kits.

In our previous studies, 21° was measured as a neutral position in adults whereas extension meant 42° [10, 11]. In this study, four trigger steps were chosen for our traffic lights with the first light displaying at 30°, the second at 35°, the third at 39°, and the last at aforementioned optimum of 42°. Sufficient airway opening started at 21° because of the constructed manikin design. A tidal volume of 150 mL was achieved at 18°, whereas 25° angle was sufficient in opening the upper airway to attain the tidal volumes of 450 mL. Thus, the traffic light system starting at 30° would not be useful in this airway trainer scenario as the airway was already open while the lights had yet not revealed the best position. This value must be verified through clinical studies for its integration into future traffic light system of our angle meter. Various maneuvers had been described to keep the upper airway open such as jaw thrust, sniffing position, and head tilt. A combination of these methods might achieve the best results. Applying jaw thrust or sniffing position might result in lower angles necessary to open the upper airway of some patients, while in other patients, 42° might not be sufficient without another method. Controlling the head tilt position with technical and convenient device could find an optimal adjustment for opening the airway. In addition, there would not be adverse effects if the head was tilted more than the minimum requirement. Head tilt was thus a basic maneuver which would be improved by the additional procedures.

The magnetic resonance tomographic studies revealed that an opening diameter of few millimeters was sufficient for adequate ventilation [15]. However, the optimal angle of minimum airway opening for the adequate ventilation in majority of patients was not known. Further studies in humans pertaining to this special face mask were thus necessary to precisely determine this minimum angle. Consequently, the

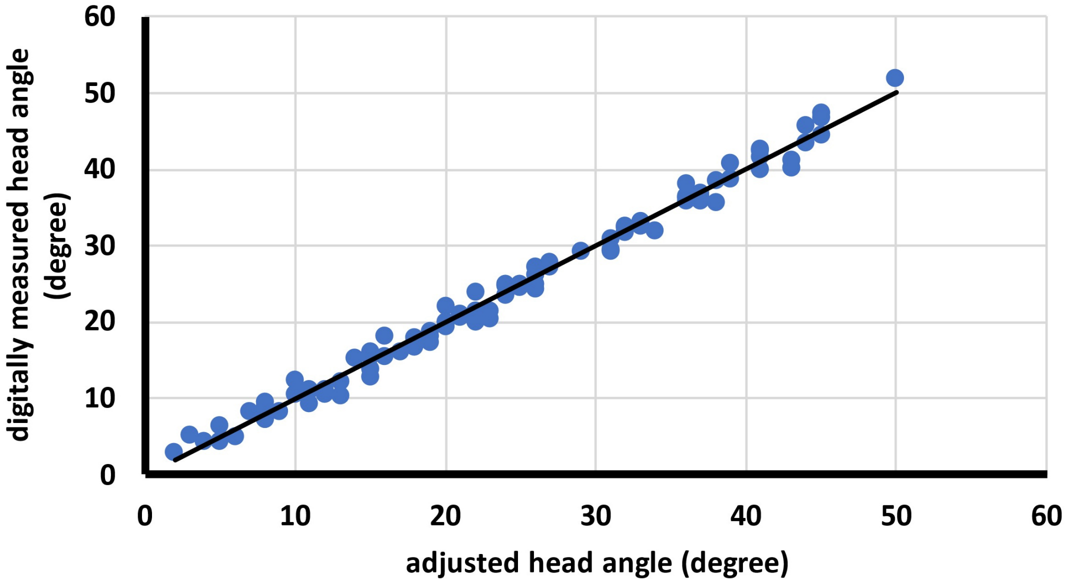

FIGURE 2. Correlation of angles measured *via* our face mask, and mechanically and photo-digitally controlled adjusted angles.

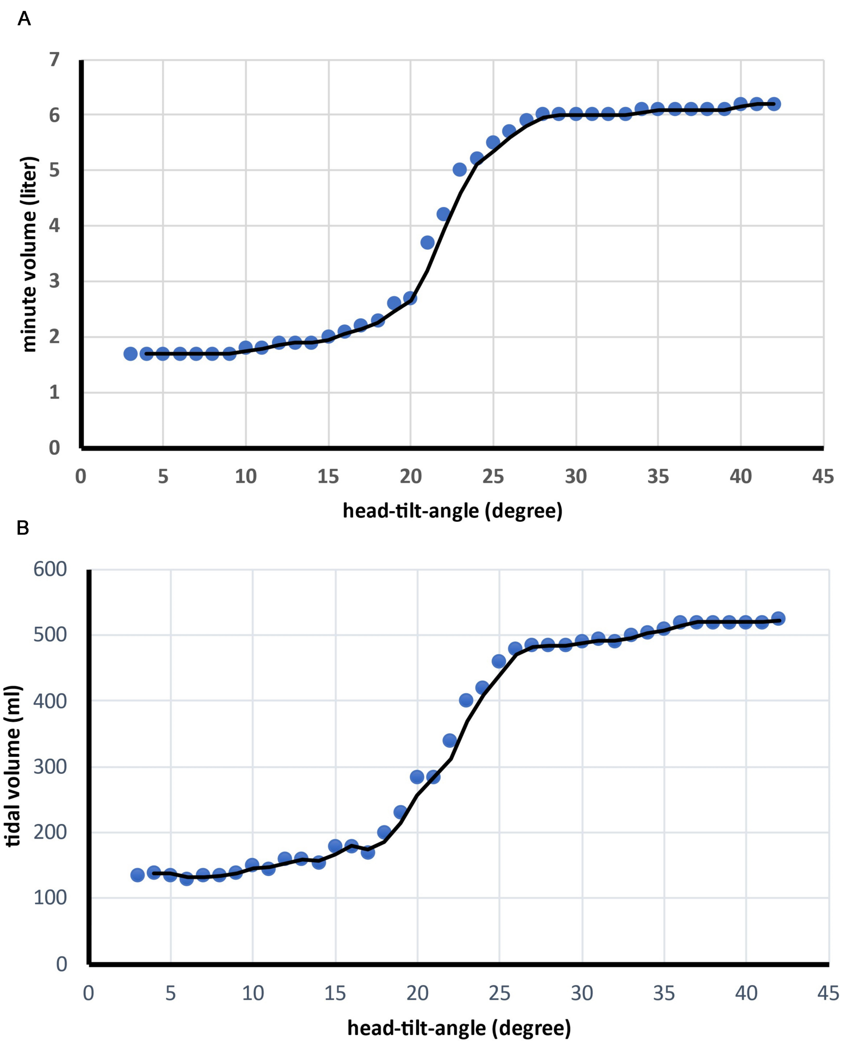

FIGURE 3. Minute (A) and tidal volumes (B) *vs.* head position angles. Points are the exact measurements whereas lines are the trendlines extrapolated based on the data.

developed bag valve mask ventilation "traffic light system" could precisely be adjusted to more realistic angles at the clinical level for sufficient opening of the airway. This face mask could further be employed for teaching the anesthesia beginners in operation theatres who were studying face mask ventilation to adequately tilt the patient's head for minimizing the possible sources of errors.

The angle meter technique might not be available everywhere. However, any future commercial device should be miniaturized for its convenient application compared to this prototype. The less sophisticated versions might be designed based on the simple principles.

A laboratory study had always been limited and it might allow only the pilot studies, *e.g.*, this model precisely opened the airway at 21° because of its specific construction. The manikin airway was standardized herein and the situation in human anatomy might be altogether different. This was a preliminary proof of concept study that evaluated the technical function of electronic angle meter. Could the device measure for what it was designed? Its utility in simulation settings was not addressed as it might have overloaded the study design. Further manikin studies on diverse users by especially focusing on mask leakage, gastric inflation and other handling issues were mandatory to evaluate its clinical function and clinical value. The system must be tested in patients before its routine usage. The situation might change even in a single human. The airway might open in one situation while the same angle might be insufficient in the next minute depending on chin lift. Moreover, this was a completely standardized model regarding ventilation through the face mask fixed to manikin with duct tape. This fixing was made to avoid the confounding effects such as mask leakage, multiple mask positions due to diverse grips being used by the care providers and because of applying mechanical ventilation [16, 17]. A higher number of participants would be required to control such confounding elements in a clinical study. This proof-of-concept study was focused on the principle of angle meter and above-stated confounding factors were controlled through tight fixation. These specified conditions pertaining to ventilation method, manikin position and mask fixation were focused for their technical development and feasibility, which made its clinical application difficult.

Similarly, the measured ventilation values were not evaluated statistically. This technical proof-of-concept study only compared the preset head position angles with those measured *via* the face mask. The leakages were up to 30% in previous bag valve mask ventilation studies. The mask was tightly sealed to manikin's face for avoiding this phenomenon, however, this was not conducive in reality. In this study, any such leakage was not found, nonetheless this could not be proved from the collected data due to pressure-controlled ventilation. The evaluation of mask leakage must be mandatory in future studies since the device adjusted to face mask might disturb the rescuer and result in the increase of leakage compared to standard device. The chin lift was an additional method to open airway in humans. This factor was erased from the study as its simulation was difficult in manikin study. Moreover, chin lift was manually handled which could alter the angel between mask and face, that required to be constant throughout the study. In patients, the chin lift might be helpful in reducing the angle needed for opening the upper airway. Thus, patient studies were mandatory in this regard.

The tidal volumes regarding head tilt angles evaluated the specific manikin opening at specific angle due to its design. The measured degrees of angles were not part of this evaluation, however they should be addressed as some threshold head tilt angles were effective in opening the airway. There might be different angles necessary to open the airway in another manikin, and same was applicable to humans. Thus, the study must be repeated on multiple volunteers, ventilating different manikins, and ideally to apply in operation theatres on humans to assess the clinical value of these face masks.

5. Conclusions

The digital head position angle measurement correctly detected the head position in this study. A signal from a face mask could be helpful to the first responders or relatively inexperienced rescuers in indicating the optimized head position.

AVAILABILITY OF DATA AND MATERIALS

All data generated or analysed during this study are included in this published article.

AUTHOR CONTRIBUTIONS

FS—developed the original idea to prepare and programme all the devices and built the experimental setting, helped in data acquisition and created all figures. NO—helped to construct the device, to build the experimental setup, to measure values and to create figures. PP—invented the concept to measure head position angles as surrogate parameter for patent airway state and helped to construct the face mask and study design. UP—helped in data acquisition and writing the original draft. WW—helped in data analysis, manuscript preparation, writing and editing. VW—helped to construct and improve the angle meter concept, organised funding and helped in building up the experimental setting and in statistical analysis. HH—helped in study concept and design, data analysis, first writing of the original draft and coordination of all corrections. All authors contributed to the data interpretation. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript and declared the responsibilities.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Since this was a completely technical simulation with no participants, no ethical approval was required as stated by the ethics committee of medical association of Baden-Wuerttemberg and consent to participate was not applicable.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.signavitae.com/mre-signavitae/article/1765977098833281024/attachment/Supplementary%20material.zip.

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