Developing a special face mask with an angle meter to optimize the head position while performing bag–valve–mask ventilation—a prospective simulated proof-of-concept study

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Abstract

Background

In unconscious patients in the supine position, the loss of soft tissue tension results in obstruction of the upper airway. Unexperienced rescuers may be unable to perform efficient bag–valve–mask ventilation due to difficulties in detecting the optimal head position to open the airway. If the ventilation mask were to indicate an optimized head position to the rescuer, bag–valve–mask ventilation could possibly be optimized.

Methods

A digital sensor was attached to a face mask to measure the degree of head reclination. We attached this face mask to an airway trainer and sealed the mask to its face with tape; the airway trainer was connected to a test lung and ventilated in a pressure-controlled mode by a standard anesthesia machine (Pmax 10 mbar, PEEP 0 mbar, F 12/min). Its head was extended starting from the neutral position to 42 degrees in steps of 2 degrees. The primary endpoints were the correlation of preset angles and our face mask’s digitally measured head position angles. We further evaluated the tidal and minute ventilation volume depending on head reclination.

Results

The preset head position angles correlated significantly (R² = 0.9895855684; P<.001) with the digitally measured head position angles. In head position angles <10 degrees, the tidal volume was 150 mL; at 18 degrees, it was 200 mL; at 25 degrees, it was 450 mL; and it levelled off at 30 degrees with about 500 mL.

Conclusion

Digital head position angle measurement correctly detected the head position in this study. A signal in a face mask could be a helpful tool to indicate to first responders or relatively inexperienced rescuers the optimized head position during emergency ventilation.

Background

Bag–valve–mask (BVM) ventilation is often used in emergency situations; however, it poses several psychomotor challenges to rescuers [1], with the loss of soft tissue tension in the pharynx resulting in obstruction of the upper airway in unconscious patients in the supine position being one of the most important challenges. The standard method to open the airway in this situation is “tilting of the head and lifting of the chin”[2]. However, even the most experienced anesthesiologists know about the difficulties of simultaneously tilting the head into the correct position while adequately sealing the facemask and providing adequate tidal volumes with a bag valve device [3–5]. In this regard, any feature that simplifies bag–valve–mask (BVM) ventilation could help to improve the performance of, in particular, lesser experienced rescuers [4, 6, 7]. In previous studies, a tilted position of the head equal to 43 degrees
compared to the horizontal plane has been proven to be the most effective position in opening the upper airway [8, 9]. A signal indicating this angle might help rescuers to tilt the head adequately and concentrate on other challenges while performing BVM ventilation.

We fixed a digital angle meter to a standard face mask and constructed and programmed a piece of special measuring equipment to indicate the head position compared to the horizontal plane. In this proof-of-concept study, we evaluated this prepared mask in a ventilation simulation on an airway manikin trainer. The main objectives were the correlation of a mechanically preset head position angle to the digitally measured head position angle. As part of a second attempt, we further measured the tidal and minute ventilation volume depending on the preset head position angle.

**Materials and Methods**

**Ethics approval**

This study is a completely technical simulation with no participants; thus, no ethical approval was required, as stated by the responsible ethics committee of the medical association of Baden-Wuerttemberg. The study was conducted at the Department of Anesthesiology, Intensive Care Medicine, Pain Therapy and Emergency Medicine, Friedrichshafen Regional Hospital, Germany.

**Experimental setup**

We used a standard anatomically shaped airway trainer (Airway Larry, 3B Scientific, Hamburg, Germany) that opens the airway in relation to the human anatomy if the head is tilted to a certain degree; otherwise, it is partially obstructed. The airway trainer was adjusted to a mechanical test lung (Michigan Instruments, Grand Rapids, MI). We fixed a standard face mask (Ambu Glostrup, Denmark) to the airway trainer. In order to minimize mask leakage as a confounding element in this technical simulation, a special tape was used (Tesa Gewebeband, Beiersdorf, Germany, Hamburg) which also sealed the mask onto the airway trainer. Furthermore, by using this method, the position of the mask on the airway trainer never changed.

To determine the angle between the underlying surface (in this experiment, it was always the horizontal plane) and the face mask, a surrogate parameter for the head position, we fixed a special accelerometer to the facemask (ADXL345, DollTek, Hong Kong). Accelerometers are standard tools in many applications such as smartphones, sports watches, or pulse meters, and they are able to detect vibrations or even minimal changes in position. The main element is a micromechanical comb structure with fixed and mobile parts. One fixed part and one mobile part pair together to build a condensator. The distance between these two structures depends on influences such as the acceleration and tilt angle, which results in a specific capacity in the condensator that can be measured and transferred into a signal. The sensitivity of this sensor element is described as being less than one degree. The signal is amplified using a microcontroller (ATMega4809, Nano Every Arduino, Boston, MA); the software used is based on the open-source library Adafruit ADXL45 sensor test and software serial. The signal output from the
microcontroller was carried out via a Bluetooth transmitter (HM-10, DSDTech, Berlin, Germany). It is a low-energy Bluetooth chip that is especially effective in saving energy and can thus be used for more than 100h in this application. The signal was transmitted from the face mask and received by a development board (Raspberry Pi 4, Cambridge, England) via a standard BLE-USB adapter that, as with all of the other parts, was fixed to a board forming a single unit (Fig. 1). The signal was received via a pygatt//Gattool module (Python, Software Foundation, Wilmington, DE) and processed by a program based on the programming language Python that saves data in text files. To achieve a higher exactness, a second accelerometer of the same type was connected to the development board which can be used to calibrate the slope of the surface the patient is lying on. Thus, the determination of head tilt is possible against the surface upon which the patient is lying, even if this is not the horizontal plane, as was the case in this experiment. Both signals are processed, computed, and transferred into the respective units of measurement and put out via a graphical user interface (TKInter, Python, Wilmington, DE).

The user receives the angle of the head position in degrees and a bar mower that can be easily interpreted: at a head position angle of less than 30 degrees, the whole bar is presented in the color red (Fig. 1A). At an angle of 30 degrees, the first of the four subunits turns green, the second changes at 35 degrees, the third changes at 39 degrees, and the whole bar is green above an angle of 42 degrees (Fig. 1B). These preset values were chosen based on previous studies and could be changed to any other value if the evidence suggests to do so [9].

Experimental procedure:

A—Evaluation of the head position angle

Starting from a position of the head at an angle of two degrees between the horizontal plane and the reference line between the forehead and chin (Fig. 1), the head was increasingly tilted in steps of two degrees to fifty degrees. To adjust the head position, we first used a classical angle meter (K-Classic, Obi, Wermelskirchen, Germany). To avoid any involuntary changes in the preset head position, it was placed on a rubber mat and manually fixed. In a second step, we took a digital photo of the setting and determined the angle between the reference line and the horizontal plane by using standard iPhone apps (Apple Inc., Cupertino, CA). When both the mechanically preset angle and the electronically measured angle were the same, the result was compared to our measurement face mask. Each value was determined twice.

B—Determination of ventilation with regard to the preset head position angles

The face mask was adjusted with tape to attach it to the airway trainer, and to avoid any confounding elements caused by bag–valve–mask ventilation, the test lung was ventilated with a standard anesthesia device (Leon, Heinen & Löwenstein, Bad Ems, Germany). The test lung (compliance 50ml/mbar) was ventilated in a pressure-controlled mode (Pmax 10mbar, PEEP 0 mbar, F 12/min). This was carried out at every position between 3 and 43 degrees in steps of 2 degrees for 1 minute. In this pilot study, we
determined the minute ventilation volume and computed the average tidal volume for each preset angle once [10].

**Statistical analysis:**

We correlated each mechanically and photographically determined angle with the electronically measured angle by using linear regression. The coefficient of determination was calculated and the overall significance was determined by the F-test (SPSS 26; IBM, Armonk, NY). The values for ventilation volumes were evaluated in simple diagrams.

**Results**

There were no problems with mask fitting connected to the manikin and anesthesia device that may have resulted in any mask leakage. Furthermore, the mask remained in the same position throughout the whole experiment due to the tight fixation provided by the tape. The mechanically preset angle of the head position compared to the horizontal plane correlated significantly ($R^2 = 0.9895855684; P < .001$, Fig. 2). The ventilation volume per minute and the tidal volume were insufficient from the beginning in the neutral position, with it increasing at the beginning at an angle of 18° and reaching a plateau without further improvement at an angle of approximately 28° (Fig. 3A and B).

**Discussion**

The preset head position angle correlated significantly with the head position angle measured via our face mask. Furthermore, the measured minute ventilation and, as a consequence, the average calculated tidal volume increased with the higher angle of head tilting. We deliberately added these calculated tidal volumes to better compare the results to dead space ventilation and to thus see how effective ventilation was at each angle. The angle measured by the sensor in the face mask might be a valid surrogate parameter to determine the optimized head position during face mask ventilation. Bag–valve–mask ventilation is a complex psychomotor procedure: the loss of soft tissue tonus in unconscious patients results in an obstructed upper airway due to the tongue falling back. Therefore, the rescuer has to tilt the head to keep the airway in the patent state. Furthermore, the rescuer has to seal the face mask onto the patient’s face via a C-grip and, lastly, the rescuer must push the ventilation bag. In summary, it is not surprising that this entire procedure often overtaxes less experienced rescuers, especially in emergency situations [6, 11]. This entire procedure is further complicated by the fact that if one of the steps is carried out insufficiently, it may complicate another one and vice versa, e.g., if the head is not tilted adequately, this increases airway pressure due to the airway being semi-obstructed which may result both in more mask leakage and stomach inflation, subsequently impairing ventilation efforts. Furthermore, increased stomach inflation may impair circulatory hemostasis [12], increase the risk of regurgitation and aspiration, and may reduce pulmonary compliance [13]. Thus, it is not surprising that many experienced anesthesiologists call face mask ventilation one of the most difficult challenges in anesthesia and emergency medicine. However, face mask ventilation is a life-saving tool and is an absolutely basic
procedure, e.g., even as a fallback measure for experienced rescuers if securing the airway is impossible with more sophisticated procedures [4, 13].

Since face mask ventilation is often impaired by inadequate tilting of the patient’s head, we speculate that a signal indicating if the head is tilted sufficiently might be a useful tool to facilitate mask ventilation, especially for lesser experienced rescuers. The angle might be presented in a simplified traffic light system: insufficient angle—red light; sufficient angle—green light. Such a simplified device could even be integrated into standard face masks, e.g., those used in first aid kits.

In previous studies of our working group, we measured 21 degrees as a neutral position in adults whereas extension meant 42 degrees [8, 9]. Based on these data, in this study, we chose four trigger steps for our traffic lights with the first light displaying at 30°, the second light displaying at 35°, the third light displaying at 39°, and the last light displaying at the aforementioned optimum of 42°. Due to the construction of the manikin in this study, sufficient opening of the airway started at 21°. While we achieved a tidal volume of 150 mL at 18°, an angle of 25° was completely sufficient in opening the upper airway resulting in tidal volumes of 450 ml. Thus, our traffic light system starting at 30° would not have been very useful in this airway trainer scenario, since the airway was already open while our lights still did not reveal the best position. Thus, this value must be verified in further clinical studies, and these results will have to be integrated into a future traffic light system of our angle meter. Furthermore, there are different maneuvers described to keep the upper airway open, e.g., jaw thrust, the sniffing position, and head tilt. Most probably a combination of these methods may achieve the best result. Applying jaw thrust or the sniffing position may on one hand result in lower angles that may make it necessary to open the upper airway of some patients, while in other patients, even 42° may not be sufficient without another method. Controlling the head tilt position with a technical and easily usable device could help to find an optimal adjustment for the head tilting parameter facilitating the whole procedure of opening the airway. In addition, even if the head is tilted more than the necessary minimum, this will not have any adverse effects. We see head tilt as a basic maneuver that will only be improved by additional procedures.

We know from MRT studies that even an opening diameter of a few millimeters is sufficient to allow adequate ventilation [14]. However, we do not actually know at which angle the majority of patients may have a minimum airway opening that is sufficient for adequate ventilation. Therefore, we believe that further studies in humans with our special face mask are necessary to more precisely determine the minimum angle that is sufficient to open the airway in the majority of patients. Subsequently, we might be able to adjust our BVM ventilation “traffic light system” more precisely to clinically more realistic angles that are sufficient to open the airway. A further indication for the use of our face mask may be teaching anesthesia beginners in the operating theatre who are studying face mask ventilation to tilt the patient’s head adequately and to thus reduce possible sources of error.

The technique of using an angle meter could of course not be made available everywhere. Any future commercial device, however, should be miniaturized to be applied more easily than this prototype version. Possibly less sophisticated versions based on the simple spirit level principle may be further options. A
laboratory study is always a limitation in itself and it may only allow pilot studies, e.g., our model opened the airway precisely at 21° due to its specific construction. While the airway of the manikin was standardized, the situation in human anatomy may be completely different. Even in a single human, the situation may change; while it may open the airway in one situation, the same angle may be insufficient the next minute. Furthermore, this was a completely standardized model in regard to ventilation with the face mask being fixed to the manikin with duct tape to avoid any confounding effects such as mask leakage or different mask positions due to different grips being used by different care providers and by applying mechanical ventilation [15]. To control for such confounding elements in a clinical study, we would need a far higher number of participants. Since this was not the purpose of this proof-of-concept study, we controlled these factors with tight fixation and concentrated on the working principle of the angle meter. In the same context, we did not explicitly evaluate the measured ventilation values statistically. We only evaluated the main objectives by comparing the preset head position angles with those measured via the face mask in this technical proof-of-concept study. In previous BVM ventilation studies, we saw leakages of up to 30%. To avoid this phenomenon, the mask was really tightly sealed to the manikin's face; however, this would not be possible in reality. As a result, we did not see and, in particular, hear any relevant leakage. However, due to ventilation taking place in the pressure-controlled mode, we were not able to prove this based on our data. As a result, to determine the effects in a field setting, the study must be repeated with multiple volunteers ventilating manikins or, even better, in an operating theatre in humans to assess the clinical value of our face mask.

Conclusions

Digital head position angle measurement correctly detected the head position in this study. A signal in a face mask could be a helpful tool to indicate to first responders or relatively inexperienced rescuers the optimized head position during emergency ventilation.

Declarations

Ethics approval and consent to participate

Since this was a completely technical simulation with no participants, no ethical approval was required and consent to participate is not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated used or analyzed during this study are included in the published article.

Competing interests
The authors declare that they do not have any conflict of interest.

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**Author contributions**

FS developed the original idea, to prepare and programme all the devices and built the experimental setting, helped in data acquisition and to create all figures. NO helped to construct the device, to build the experimental setup, to measure all values and to create figures. PP originally 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. 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 data interpretation. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript and declare responsibility.

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**Authors’ information - Doctoral Thesis**

This manuscript contains significant parts of the doctoral thesis of F. Schumacher, MD.

**References**


Figures
Figure 1

Experimental setting with the photo digital measuring principle of the head position angle in the neutral (A) and tilted position (B).
Figure 2

Correlation of angles measured via our face mask and adjusted angles controlled both mechanically and photo-digitally.
Figure 3

Minute (A) and tidal volumes (B) vs. head position angles. Note that the points are exact measurements whereas the lines are trendlines extrapolated based on these data.