Developing a special face mask with 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 supine position, 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 to detect the optimal head position for opening the airway. If the ventilation mask indicates the rescuer an optimized head position, bag-valve mask ventilation could be possibly optimized.

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

Results Preset head position angles correlated significantly ($R^2 = 0.9895855684; P<.001$) to digitally measured head position angles. In head position angles<10 degrees, tidal volume was 150 mL, at 18 degrees 200 mL, at 25 degrees 450 mL and levelled off at 30 degrees with about 500 mL.

Conclusion Digital head position angle measurement correctly detected head position. A signal in a face mask could indicate first responders or relatively inexperienced rescuers an optimized head position during emergency ventilation.

Background

Bag-valve-mask (BVM) ventilation is often used in emergency situations; however, it poses several psychomotoric challenges to rescuers,[1] with 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. Standard method to open the airway in this situation is "tilting of the head and lifting off the chin".[2] However, even the most experienced anesthesiologists know about the difficulties of simultaneously tilting the head in the correct position while adequately sealing a facemask and providing adequate tidal volumes with the bag valve device.[3–5] In this regard, any feature that simplifies bag-valve mask (BVM) ventilation could help to improve the performance especially of lesser experienced providers.[4, 6, 7] In previous studies, a tilted position of the head of 43 degrees compared to the horizontal plane proved to be most effective in opening the upper airway.[8, 9] A tool indicating this angle might help rescuers to tilt the head adequately and to concentrate on the other challenges while performing BVM ventilation.

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

**Methods**

**Ethics approval**

This study is a completely technical simulation with no participants. Thus, no ethical approval was required which was stated by the responsible ethics committee of the medical association 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 analogy to the human anatomy if the head is tilted to a certain degree; otherwise it is partially obstructed. This airway trainer was adjusted to a mechanical test lung (Michigan Instruments, Grand Rapids, MI). We fixed a standard face mask (Ambu Glostrup, Denmark) to this airway trainer. In order, to minimize mask leakage as a confounding element in this technical simulation, this was done by using a special tape (Tesa Gewebeband, Beiersdorf, Germany, Hamburg) which also sealed the mask on the airway trainer. Further, the position of the mask on the airway trainer never changed using this method.

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

The user receives the angle of the head position in degrees and a bar mower that could be easily interpreted: at a head position angle of less than 30 degrees the whole bar is presented in red color (Figure 1A). At an angle of 30 degrees the first of the four subunits turns green, the second at 35 degrees, the third at 39 degrees and the whole bar is green above an angle of 42 degrees (Figure 1B). These preset values were chosen based on previous studies and could be changed to any other value if 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 forehead and chin (Figure 1), the head was increasingly tilted in steps of two degrees to 50 degrees. To adjust the head position, we first used a classical angle meter (K-Classic, Obi, Wermelskirchen, Germany). To avoid any involuntary changes of a preset head position, it was placed on a rubber mat and manually fixed. In a second step, we took a digital foto of the setting and determined the angle between reference line and the horizontal plane by using standard I-phone Apps (Apple Inc., Cupertino, CA). When both mechanically preset and electronical angle were the same, this result was compared to our measuring face mask. Each value was determined twice.

**B Determination of ventilation in regard of preset head position angles**

The face mask was adjusted with tape to the airway trainer and the test lung ventilated with a standard anesthesia device (Leon, Heinen & Löwenstein, Bad Ems, Germany). The test lung (compliance 50ml/mbar) was ventilated in pressure controlled (Pmax 10mbar, PEEP 0 mbar, F 12/min). This was done at every position between 3 and 43 degrees in steps of two degrees for one minute. We determined minute ventilation volume and computed the average tidal volume for each preset angle once in this pilot study.[10]

**Statistical analysis**

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

The mechanically preset angle of the head position compared to the horizontal plane correlated significantly ($R^2 = 0.9895855684; P < .001$, Fig. 2). Ventilation volume per minute and tidal volume were insufficient from the beginning in neutral position, increased beginning at an angle of $18^\circ$ and reached a plateau without further improvement at an angle of approximately $28^\circ$ (Fig. 3A and B).

Discussion

The preset head position angle correlated significantly with the head position angle measured via our face mask. Thus, the angle measured by the sensor in the face mask might be a valid surrogate parameter to determine the head position during face mask ventilation. Bag valve mask ventilation is a psychomotoric complex procedure: 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 patent state. Further, the rescuer has to seal the face mask on the patient’s face via C-grip and lastly, the rescuer must push the ventilation bag. In summary, it is not surprising that this whole procedure often overtaxes less experienced rescuers, especially in emergency situations.[6, 11] This whole procedure is further being complicated since if one of the measures is done insufficiently, it may complicate another one and vice versa: e.g. if the head is not tilted adequately this increases airway pressure due to a semi-obstructed airway which may result both in more mask leakage and stomach inflation, subsequently impairing ventilation efforts. Further, 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 of the airway is impossible with more sophisticated measures.[4, 13]

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

In previous studies, tilting the patient’s head to 40 degrees resulted in sufficiently patent airway states,[8, 9] therefore, our traffic lights in this study had four trigger steps with the first green light burning at 30°, the second light at 35°, the third at 39° and the last at 42°. In our model, we saw an opening angle of 21 degrees due to the specific construction of the manikin in this study. While we achieved a tidal volume of 150 mL at 18°, an angle of 25° was completely sufficient in opening the upper resulting in tidal volumes of 450 mL. Thus, the traffic light system would not have been very useful in this airway trainer scenario, since the airway was already open while our lights were still not revealing the best position.
We know from MRT studies that even an opening diameter of a few millimeters is sufficient to allow adequate ventilation.[14] However, we actually do not know at which angle the majority of patients may have a minimum airway opening being sufficient for adequate ventilation. Therefore, we believe that further studies in humans are necessary with our special face mask to determine the minimum angle more precisely 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 being sufficient to open the airway. A further indication for our face mask may be teaching of anesthesia beginners in the operating theatre in face mask ventilation to tilt patient’s heads adequately and thus to reduce possible sources of error.

A laboratory study is always a limitation by itself and may only allow pilot studies, e.g. our model opened the airway precisely at 21° due to its specific construction. This angle might be less exact even in a single human: while it may open the airway in one situation, the same angle may be insufficient the next minute. Further, this was a completely standardized model in regard of ventilation with the face mask being fixed to the manikin with duct tape to avoid any confounders such as mask leakage or different mask positions due to different grips by different care providers and by applying mechanical ventilation.[15] Thus, we did not explicitly evaluate measured ventilation values statistically. We only evaluated the main objectives comparing the preset head position angles with those measured via face mask in this technical proof of principle study. In result, to determine the effects in a field setting the study has to be repeated with multiple volunteers ventilating manikins or even better in the operation theatre in humans to assess the clinical value of our face mask.

**Conclusion**

Digital head position angle measurement correctly detected head position. A signal in a face mask could indicate first responders or relatively inexperienced rescuers an optimized head position during emergency ventilation.

**Declarations**

**Ethics approval**

Since this was a completely technical simulation with no participants, no ethical approval was required.

**Consent to participate**

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**

All authors contributed to the study conception. The angle meter concept was invented by Volker Wenzel and Fabio Schumacher. Fabio Schumacher constructed and programmed all the devices. All authors contributed to the study conception and design. Material preparation and data collection were performed by Fabio Schumacher, Natalia Oberhanss, Urs Pietsch and Volker Wenzel. Statistical analysis was performed by Holger Herff, Volker Wenzel and Peter Paal. All authors contributed to data interpretation. The first draft of the manuscript was written by Fabio Schumacher, Volker Wenzel and Holger Herff; all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript and declare responsibility. This manuscript contains significant parts of the doctoral thesis of Fabio Schumacher.

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**References**


Figures

Figure 1

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

Correlation of angles measured via our face mask and adjusted angles controlled both mechanically and digitally.

Figure 3

Minute (A) and Tidal Volumes (B) vs. head position angles.