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A COMPARISON OF TWO-HANDED VERSUS SINGLE-HANDED BAG VALVE MASK VENTILATION DURING TWO-RESCUER CPR ON A SIMULATION MANIKIN

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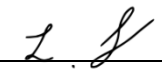
431359

A Research Report submitted to the Faculty of Health Sciences of the University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Science in Emergency Medicine

Johannesburg, 2020

DECLARATION

I, Louis Gerber, hereby declare that this research report is my own work and has not been submitted or presented for any other degree or professional qualification at this or any other Institute. This research was undertaken in the Division of Emergency Medicine, University of the Witwatersrand, Johannesburg.

Signature of Student:  Date: 10/11/2020

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SUBMISSION FORMAT OF THIS RESEARCH REPORT

As per University of the Witwatersrand Faculty of Health Sciences guidelines, this research report is being submitted in the following format: submission for publication ready format.

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ABBREVIATIONS

BVM: Bag-valve-mask

CCF: Cardiac compression fraction

CPR: Cardiopulmonary resuscitation

Double TE: Double thenar eminence grip (figure 2)

EC: Referring to figure 1

IHCA: In-hospital cardiac arrest

mL: Milliliter

mm: Millimeter

OHCA: Out-of-hospital cardiac arrest

QCPR: Quality cardiopulmonary resuscitation software and hardware package (Laerdal Medical; Stavanger, Norway)

ROSC: Return of spontaneous circulation

SD: Standard deviation

US: United States

MANUSCRIPT FOR SUBMISSION

TITLE OF MANUSCRIPT

A comparison of two-handed versus single-handed bag valve mask ventilation during two-rescuer CPR on a simulation manikin.

RUNNING TITLE

Two-handed versus single-handed bag valve mask ventilation during CPR

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LG: guarantor of the manuscript and responsible for the integrity of the data and the accuracy of the data analysis; data collection, statistical analysis and interpretation of the data; and drafting, writing, review and incorporating co-author feedback, revision, and final approval of the submission, corresponding author.

MB: contributed to the concept and design, analysis and interpretation of the data, and the drafting, writing, review, revision and approval of the manuscript, research supervisor.

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SUBMISSION LETTER TO THE EDITOR

Dear Editor- "Emergency Medicine Australasia"

Thank you for considering our manuscript entitled: *"Modified two-rescuer CPR with a two-handed mask-face seal technique is superior to standard two-rescuer CPR: A comparative experimental study"*

Cardiopulmonary resuscitation (CPR) is the mainstay of basic life support during cardiac arrest. Various studies have reported better outcomes when ventilatory breaths are administered during CPR. During bag-valve-mask (BVM) ventilation, a two-handed mask-face seal (double EC grip or double thenar eminence grip) has been shown to be superior to a one-handed mask-face seal (single EC grip). Current CPR guidelines advocate that when there are only two rescuers present, one rescuer should perform chest compressions, while the other performs BVM ventilation by creating a mask-face seal with one hand and compressing the BVM resuscitator bag with the other hand during ventilatory pauses.

In this potentially practice changing study, we compared a modified method of two-rescuer CPR using a two-handed mask-face seal to standard two-rescuer CPR using a one-handed mask seal. In the modified method, one rescuer performed a mask-face seal using both hands while the other rescuer performed chest compressions and squeezed the BVM resuscitator bag twice during every ventilatory pause. Our results showed that with the modified technique, participants were able to deliver higher volumes of rescue breaths without compromising the quality of chest compressions.

We are confident that this manuscript will appeal to the readership of ***Emergency Medicine Australasia.*** Furthermore, it carries a high citation potential, as the findings are potentially practice changing.

A comparison of two-handed versus single-handed bag valve mask ventilation during two-rescuer CPR on a simulation manikin.

ABSTRACT

Background: During cardiopulmonary resuscitation (CPR), using two hands to create a mask-face seal has been shown to be superior to using one hand. Current CPR guidelines advocate that when there are only two rescuers present, one rescuer should perform BVM ventilation by creating a mask-face seal with one hand while using the other hand to compress the BVM resuscitator bag.

Methods: In this simulation manikin based experimental study, 40 CPR trained participants compared standard two-rescuer CPR using a one-handed mask-face seal to a modified method of two-rescuer CPR where one rescuer performed a mask-face seal using both hands while the second rescuer performed chest compressions and also squeezed the BVM resuscitator bag twice during every ventilatory pause.

Results: The mean delivered volume for the standard two-rescuer CPR (one-handed mask-face seal) and modified two-rescuer CPR (two-handed mask-face seal) methods were 190.2±50.5 ml and 319.4±71.4 ml respectively ($p<0.0001$). There were no statistically significant differences between the two methods regarding the a) mean compression rate (118.08 ± 9.67 vs 117.05 ± 10.99 compressions/min; $p=0.477$), b) mean compression depth (52.77 ± 6.77 mm vs 52.80 ± 5.57 mm; $p=0.980$), c) ventilatory pause time (4.56 ± 0.43 vs 4.62 ± 0.64 seconds; $p=0.288$), d) chest compression fraction (76.57 ± 2.57 vs 75.92 ± 2.14; $p=0.186$) and e) Borg scale for perceived exertion scores (12.51 ± 1.69 vs 13.05 ± 2.02; $p=0.174$).

Conclusions: With the modified technique, participants were able to deliver higher volumes of rescue breaths without compromising the quality of chest compressions.

KEY WORDS

cardiopulmonary resuscitation; CPR; bag-valve-mask ventilation; BVM, two-handed mask-face seal, modified technique

INTRODUCTION

There are approximately 600 000 cases of cardiac arrest in the United States (US) every year. Survival to hospital discharge after in-hospital cardiac arrest (IHCA) and out-of-hospital cardiac arrest (OHCA) has been reported as 26.4% and 10.8% in adults and 49.5% and 10.7% in children respectively.[1] The data for Africa is limited with a Uganda study reporting return of spontaneous circulation (ROSC) in 7.4% of IHCA and a South African study reporting ROSC in 18% of OHCA with no long term outcome data available.[2,3]

Cardiopulmonary resuscitation (CPR) is the mainstay of basic life support during cardiac arrest.[2] Since the focus has shifted to increasing the effectiveness of CPR, a number of quality markers have been advocated. These include maintaining a chest compression fraction (CCF) of >60%, achieving a chest compression rate of between 100 to 120 compressions/ min, obtaining a chest compression depth of ≥50 mm (2 inch), allowing for full chest recoil, providing positive-pressure ventilation and avoiding hyperventilation.[2–4]

Various studies have reported improved outcomes when ventilatory breaths are administered during CPR.[5–7] However, chest compression only CPR is unable to generate sufficient tidal volumes during chest recoil to facilitate optimal gas exchange.[8–10] Several studies have indicated that compared to chest compression only CPR, 30:2 compression ventilation CPR is associated with better CPR metrics.[6,11–14]

During bag-valve-mask (BVM) ventilation, a two-handed mask-face seal technique (double EC grip or double thenar eminence grip) has been shown to provide superior ventilation than a one-handed mask-face seal technique (single EC grip).[15–17] Current CPR guidelines advocate that when there are only two rescuers available, one rescuer should perform chest compressions, while the other performs BVM ventilation by creating a mask-face seal with one hand and compressing the BVM resuscitator bag with the other hand during ventilatory pauses.[18,19]

In this study, we compared a modified two-rescuer CPR method using a two-handed mask-face seal to the standard two-rescuer CPR method using a one-handed mask seal. We hypothesized that with the modified technique, participants would achieve

greater volumes of rescue breaths without compromising the quality of chest compressions. Hence, the objectives of this study were to compare the volume of delivered rescue breaths and chest compression quality metrics between the two methods of CPR.

METHODS

This study used a non-randomized, self-controlled, experimental and questionnaire design. Participants were non-randomly selected from among second, third- and fourth-year paramedic students who were enrolled in a four-year professional degree in Emergency Medical Care at the University of Johannesburg, South Africa. All participants had successfully completed a basic life support course in CPR as part of their training. The study was approved by the Research Ethics Committee of the University of Johannesburg (REC-01-103-2018) and the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (M170738).

Prospective participants were invited to participate in the study and were provided with both verbal and written information regarding the study prior to being requested to sign consent for participation. The participants were blinded to the hypothesis and objectives of the study. During data collection, clothing was standardized to operational uniform, ambient temperature was regulated at 21°C and CPR was performed on the ground with a single blanket as knee padding. Data collection was conducted on a strict time schedule to standardize for confounders such as rest and exertion. On the morning prior to data collection, participants attended a refresher lecture and practical session presented by the researchers.

The BVM device utilized comprised a standard adult Laerdal Silicone Resuscitator (LSR, Laerdal Medical; Stavanger, Norway) that was fully assembled and tested prior to data collection and a standard size 5 adult Ambu Silicon Face Mask (Ambu A/S; Ballerup, Denmark). No fresh gas flow was provided. Delivered respiratory volume (volume delivered to the artificial lung) was measured by internal volume sensors located on the simulation manikins (SimMan 3G, Laerdal Medical; Stavanger, Norway) artificial lung.

Chest compression rate and depth was measured by QCPR[20,21] (Laerdal Medical; Stavanger, Norway) sensors located in the manikin's thorax. The QCPR software program uses sensor feedback to calculate and display the mean compression rate, mean compression depth, mean chest compression fraction and delivered volume to the artificial lung. A stopwatch and interval timer were used to manually calculate the chest compression fraction by dividing the total hands-on compression time by the total CPR time.

Using a random number generator, participants were randomly paired into groups. Each pair was then randomly assigned to begin with either standard two-rescuer CPR or the modified two-rescuer CPR method (supplementary video). Each method was performed for 8 minutes with a 5-minute refreshment break between methods. During each method, participants alternated roles (chest compressions and BVM ventilation) every 2 minutes. After completing both sessions of CPR, participants were asked to complete a questionnaire.

For standard two-rescuer CPR (figure 1), the first rescuer performed 30 chest compressions with the second rescuer thereafter delivering two rescue breaths by creating a mask-face seal around the simulation manikin's nose and mouth with one hand and compressing the BVM resuscitator bag with the other hand (single EC grip technique). The first rescuer thereafter immediately resumed with performing chest compressions and the cycle was repeated.

For modified two-rescuer CPR (figure 2), the first rescuer performed 30 chest compressions and thereafter immediately delivered two rescue breaths by squeezing the BVM resuscitator bag, while the second rescuer created a mask-face seal around the simulation manikin's nose and mouth using two hands (double thenar eminence grip technique). The first rescuer thereafter immediately resumed with performing chest compressions and the cycle was repeated.



Figure 1: Standard two-rescuer CPR. The first rescuer performs 30 chest compressions and the second rescuer thereafter delivers two rescue breaths by creating a mask-face seal around the simulation manikin's nose and mouth with one hand and compressing the BVM resuscitator bag with the other hand (single EC grip technique). The first rescuer thereafter immediately resumes with performing chest compressions and the cycle is repeated.



Figure 2: Modified two-rescuer CPR. The first rescuer performs 30 chest compressions and thereafter immediately delivers two rescue breaths by squeezing the BVM resuscitator bag while the second rescuer creates a mask-face seal around the simulation manikin's nose and mouth using two hands (double thenar eminence grip technique). The first rescuer thereafter immediately resumes with performing chest compressions and the cycle is repeated.

Quantitative data was collected by the primary investigator from the QCPR feedback monitor, the stopwatch and the interval timer. In addition, readings from the above were continuously recorded using a video camera (GoPro HERO 3; San Mateo, California, US) which was reviewed to ensure accuracy of the collected data. Collected data during simulated CPR included participant gender, participant age, delivered respiratory volume (mL), chest compression time (seconds), ventilatory pause time (seconds), total CPR time (seconds), chest compression rate (compressions/min) and chest compression depth (mm). Participants were blinded to the above findings. Data collected from the questionnaires included perceived exertion and was rated on a Borg scale. The Borg scale is a validated tool used to quantify perceived exertion during physical activity.[22–24] In addition data from the questionnaire pertaining to which of the two methods was associated with better rescuer comfort, better mask-face seal, better overall quality of CPR were also collected.

Data was analyzed using the R studio (RStudio Team, 2015) software program.[25] Results were described using frequencies, means, standard deviations and a quantile-quantile plot. Pearson's Chi-squared test and the Fisher's exact test were used to compare differences in the standard and modified CPR methods. The categories compared included: delivered respiratory volumes between the standard and modified CPR methods. The mean (SD) differences in delivered respiratory volume, compression rate, compression depth, ventilatory pause time, cardiac compression fraction and Borg scale rating were compared using the Student's t-tests. Binary data from the questionnaire was tested for difference in proportions. The Shapiro-Wilk test was used to assess and describe whether differences in delivered respiratory volumes between the standard and modified CPR methods were normally distributed among study participants. The level of significance was set at $\alpha=0.05$.

RESULTS

A total of 67 paramedic students were invited to participate in the study, of which 40 participants comprising 19 females and 21 males consented to study participation and were included in the final sample. The mean age of participants was 21.3±1.57 years. The mean delivered respiratory volumes for the standard and modified CPR methods

were 190.2±50.5 ml and 319.4±71.4 ml respectively, with a mean difference of 132.2±98.3 ml (p<0.0001) between the 2 methods. Figure 3 illustrates that differences in delivered respiratory volumes between the standard and modified CPR methods were normally distributed (p=0.354). The total number of failed ventilation attempts (alveolar volume of <150 ml) was 230/800 (28.7%) for the standard CPR method and 63/800 (7.9%) for the modified CPR method (p<0.00001).

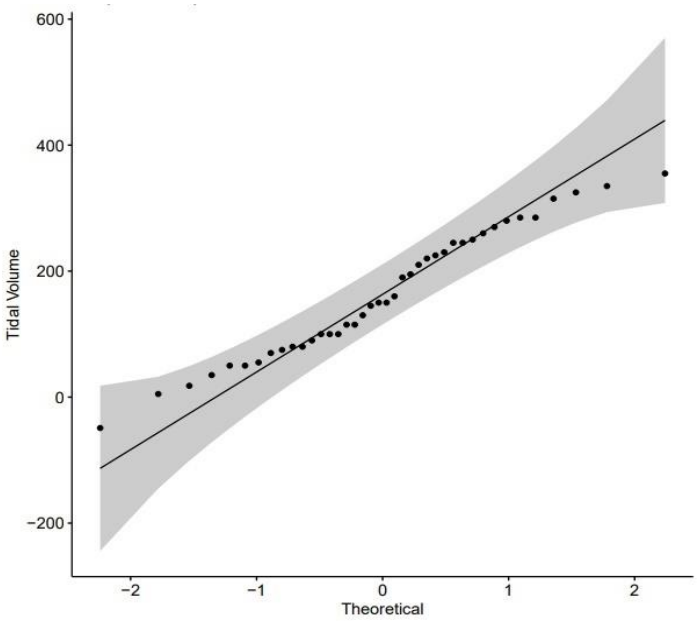

Figure 3: Quantile-quantile plot illustrating that differences in delivered respiratory volumes between the standard and modified CPR methods were normally distributed among study participants (p=0.354).

Table 1: Comparison of various chest compression quality metrics and Borg scale ratings between the standard and modified 2-rescuer CPR methods.

	Standard 2-rescuer CPR (mean±SD)	**Modified 2-rescuer CPR (mean±SD)**	**Mean Difference (mean±SD)**	**P-value**
Chest compression rate (compressions/ min)	118.08 ± 9.67	117.05 ± 10.99	1.03 ± 9.03	0.477
Chest compression depth (mm)	52.77 ± 6.77	52.80 ± 5.57	0.03 ± 6.25	0.980
Ventilatory pause time (sec)	4.56 ± 0.43	4.62 ± 0.64	0.06 ± 0.54	0.288
Chest compression fraction (%)	76.57 ± 2.57	75.92 ± 2.14	0.62 ± 2.14	0.186
Borg scale rating	12.51 ± 1.69	13.05 ± 2.02	0.55 ± 2.51	0.174

Table 1 describes the differences in the chest compression rate, chest compression depth, ventilatory pause time, chest compression fraction and Borg scale rating between the standard and modified CPR methods. Of note, there were no statistically significant differences in any of the above quality metrics between the two methods.

Majority of participants (n=33, 82.5%) recommended the modified CPR method over the standard CPR method, while 82.5% (n=33) also indicated that the modified CPR method provided an overall superior quality of CPR and 72.5% (n=29) indicated that the mask-face seal was better during the modified CPR method. Half the number of participants (n=20, 50%) indicated that chest compressions were more comfortable during the modified CPR method.

DISCUSSION

This study demonstrates a novel method of delivering effective rescue breaths without compromising the quality of chest compressions during simulated two-rescuer CPR. Several studies have reported improvements in survival and neurological outcomes following CPR with rescue breaths compared to CPR without rescue breaths (hands only CPR).[7–9,28] Furthermore, a number of studies have reported the delivery of significantly larger tidal volumes with a two-handed compared to a one-handed mask-face seal.[17–19,29] To our knowledge, this is the first study to compare differences in delivered respiratory volumes as well as chest compression quality metrics with perceived exertion in a simulated manikin between the standard two-rescuer and modified two-rescuer CPR methods.

The differences in mean delivered respiratory volumes between the standard CPR method (one handed mask-face seal) and the modified CPR method (two-handed mask-face seal) correlated with three manikin-based and two human-based studies. Among the manikin based studies, Hart et al. recorded expired median respiratory volumes for the two-handed and one-handed mask-face seal techniques of 538 ml and 428.4 ml respectively,[18] while Otten et al. recorded volumes of 480 ml and 186 ml respectively.[17] In a similar CPR based study by Shim et al. the median tidal volumes recorded were 657.5 ml and 320 ml for the two-handed and one handed mask-face seal techniques respectively.[30] In the human based studies, Gerstein et al. recorded

mean tidal volumes between the two-handed and one-handed mask-face seal techniques of 339 ml and 221 ml respectively,[19] while Joffe et al. recorded volumes of 8.60±2.31 ml/kg and 6.80±3.10 ml/kg respectively.[31] Unlike our study, where rescue breaths were manually delivered using a BVM resuscitator, four of the above studies utilized a mechanical ventilator to deliver set tidal volumes,[17–19,31] while the study from Shim et al. used a BVM resuscitator but did not report failed ventilations,[30] which may contribute to the higher volumes in these studies.

In this study, the number of failed ventilation attempts (alveolar volume of <150 ml) was significantly higher with the standard CPR method compared to the modified CPR method (28.7% vs 7.9%, p<0.00001). This corelates with a similar study by Root et al. which reported a failed ventilation rate of 20% (IQR 10-30%) and 0% (IQR 0-10%) respectively, no ventilation volumes were reported.[32] Joffe et al. also reported a lower rate of failed ventilations with a two-handed mask-face seal technique (14% vs 5%; p=0.013).[31] Since tidal volumes of 300-500ml are required for recognizable chest rise during positive-pressure ventilion[33] and the first ± 150 ml of tidal volume (anatomical dead space) does not participate in gaseous exchange,[34] it can be inferred that performing rescue breaths with a one-handed mask-face seal technique may result in the ineffective delivery of tidal volume.

It is noteworthy that there were no statistically significant differences in the chest compression rate, chest compression depth, ventilatory pause time or chest compression fraction between the standard and modified CPR methods. This correlates with two manikin-based studies which found no statistically significant difference between the CPR fractions or characteristics of the standard or modified methods.[30,32] Root et al. reported a similar compression fraction of 72% (IQR 69.5–75.7%) and 73.2% (IQR 69.1-76.1%) comparted to our study's 76.57±2.57% and 75.92±2.14% for the standard and modified methods respectively.[32] Similarly, Shim et al. showed no statistically significant differences between the methods but reported lower compression depths of (45.3±3.4mm vs. 45±3.2mm) and rate (112.6±8.6 vs. 112.0±8.1 per minute) compared to our studies compression depth (52.77±6.77mm vs. 52.80±5.57mm) and rate (118.08±9.67 vs. 117.05±10.99 per minute) for the standard and modified methods respectively.[30] The study by Shim et al. was methodologically different as the participants only completed 5 cycles each (mean completion time 109.7±9.8s and 110.1±9.3s) and as such could not report on the CCF

between the standard and modified methods.[30] Neither study commented on the perceived exertion, preference or comfort of either the modified or standard methods. In our study, there were no statistically significant differences in the overall perceived exertion during CPR (Borg scale) between the two methods. The Borg scale ratings in this study were similar to two other studies by Trowbridge et al.[15] and Kwak et al.[16] that reported scores of 13.3±0.2 and 14.62±2.23 respectively among participants performing standard CPR.

Overall, results of this study indicate that the modified 2-rescuer CPR method allows for the delivery of significantly higher volumes of rescue breaths without compromising the quality of chest compressions. The modified CPR method may also be of value when used in low resourced settings where training, skills or equipment to provide advanced airway management is lacking.

LIMITATIONS

A limitation is that this study was conducted outside the clinical environment on manikin models in a simulation laboratory. Other limitations include the relatively small sample size and that differences in gender, hand size, muscle strength and body mass index among participants were not considered. Nevertheless, the positive results of this experimental study are promising, and we are confident that it will pave the way for the design of similar human-based studies in both the pre-hospital as well as in-hospital environments.

CONCLUSION

In a simulation manikin model, modified two-rescuer CPR with a two-handed mask-face seal compared to standard two-rescuer CPR with a one-handed mask-face seal provided a statistically significant increase in delivered respiratory volumes without compromising the quality of chest compressions. Pending similar studies among humans, the modified two-rescuer CPR method may be recommended during two-rescuer CPR.

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FIGURE LEGENDS

Figure 1: Standard 2-rescuer CPR. The first rescuer performs 30 chest compressions and the second rescuer thereafter delivers two rescue breaths by creating a mask-face seal around the simulation manikin's nose and mouth with one hand and compressing the BVM resuscitator bag with the other hand (single EC grip technique). The first rescuer thereafter immediately resumes with performing chest compressions and the cycle is repeated.

Figure 2: Modified 2-rescuer CPR. The first rescuer performs 30 chest compressions and thereafter immediately delivers two rescue breaths by squeezing the BVM resuscitator bag while the second rescuer creates a mask-face seal around the simulation manikin's nose and mouth using two hands (double thenar eminence grip technique). The first rescuer thereafter immediately resumes with performing chest compressions and the cycle is repeated.

Figure 3: Quantile-quantile plot illustrating that differences in delivered respiratory volumes between the standard and modified CPR methods were normally distributed among study participants (p=0.354).

TABLE LEGEND

Table 1: Comparison of various chest compression quality metrics and Borg scale ratings between the standard and modified 2-rescuer CPR methods.

SUPPLEMENTARY VIDEO (for publication as online data supplement)

Modified CPR comparison demo

Available at:
https://drive.google.com/open?id=1edhJBc4V_uvEB2u858NBGC5kNK8L7djW

RESEARCH PROTOCOL

A comparison of two-handed versus single-handed bag valve mask ventilation during two-rescuer CPR on a simulation manikin.

Research protocol in partial fulfilment of the degree for Master of Science in Emergency Medicine

Louis Gerber

Student No. 431359

Supervisors: Prof. Abdullah E. Laher

Mr. Martin Botha

INTRODUCTION

South Africa had a total of 460 236 deaths during 2015. Of these deaths, non-communicable diseases accounted for 55.5%, communicable diseases 33.4% and injuries represented 11.1%.[1] Non-natural causes of death were the highest in the youth, especially among males with middle-aged and elderly patients predominantly succumbing to non-communicable disease.[1]

Modern emergency care practice recommends that CPR is immediately performed once it is discovered that a patient has become pulseless or suffered cardiac arrest.[2] CPR in itself has developed since Kouwenhoven et al. first described it in 1960 with the proposed cardiac pump model. Two newer models have also been suggested including the thoracic pump model by Weisfeldt & Halperin in 1986 and the lung pump model by Shaq et al. in 1997.[3,4] The models create a framework for the theoretical mechanism of action and have led to a number of improvements in how CPR is physically performed with the development of CPR quality markers.[5]

ILCOR (International Liaison Committee on Resuscitation, the American Heart Association and other resuscitation councils have recommended several CPR quality markers to decrease mortality and disability.[5] These quality markers have been grouped under the "Good quality CPR" umbrella and include: compression rate of 100 to 120 beats per minute, allowing full chest recoil, compressing the chest to a depth of at least 5 cm but no more that 6cm, and a compression ratio of 30 compressions to 2 ventilations while minimizing hands-off time with early defibrillation if required.[5] Ventilation during CPR has recently been emphasized with specific focus on delivered tidal volume and targeted end tidal carbon dioxide (EtCO2).[5]

The unresponsive patient presents several unique challenges with regards to providing rescue breaths or ventilation during CPR. Many methods exist to provide these rescue breaths and include basic interventions such as mouth-to-mouth and bag-valve-mask (BVM) resuscitator ventilation.[5] Bag-valve-mask ventilation, although categorized as a basic manoeuvre, requires both practice and time to be performed adequately and can be regarded as a difficult skill.[5,6] The difficulty encountered by the rescuer during BVM ventilation can be influenced by a number of other variables including the patient's position, airway resistance, excessive soft tissue and structural issues influencing mask seal.[7]

One solution that has been proposed in the field of airway management is that of using a modified or two-handed grip on the BMV face mask to gain an adequate seal during positive pressure ventilation.[6] This has been shown to decrease the number of "failed breaths" delivered by the rescuer and to increase the delivered tidal volume. Subjective data also suggests that rescuers found two handed mask seal techniques more comfortable with a greater sense of adequate ventilation.[6]

There is however no current data available on using a modified two-handed mask seal technique during CPR. This study is aimed at assessing if a modified two-handed mask seal technique is comparable to standard CPR ventilation in delivering adequate tidal volume, providing adequate mask seal and increasing rescuer comfort. The

secondary aim of the study is to assess whether this simple modification in two-rescuer CPR alters the quality of CPR provided by the two rescuers.

STUDY AIM

To compare a two-handed versus single-handed bag-valve-mask ventilation technique during two rescuer CPR on a simulation manikin.

STUDY OBJECTIVES

1. To compare the quality of chest compressions (chest compression fraction (CCF) and adequate chest compressions) between the two ventilation techniques
2. To compare delivered tidal volume and chest rise between the two ventilation techniques
3. To compare participant feedback on perceived effort, preferred BVM ventilation technique and CPR comfort between the two techniques.

METHODOLOGY

Study Design

Prospective manikin based experimental observational and questionnaire based transverse study

Study Site

Simulation centre at the Faculty of Health Sciences, University of Johannesburg, Johannesburg

Study Population

The population will include 2nd, 3rd and 4th year Bachelor of Health Science in Emergency Medical (BEMC) students from the University of Johannesburg.

Inclusion Criteria

BEMC 2nd, 3rd and 4th year students

Exclusion Criteria

1. Participants who have any form of physical disability or injury that would hinder CPR performance.
2. Participants who are unable to perform physical activity on the study data collection day for any medical/physiological reason, e.g. pregnant, ill etc.

Sample Size

This convenience sample will aim to include at least 40 subjects from the 2nd, 3rd and 4th year BEMC groups.

Data Collection

- Data collection will commence once the protocol has been approved with permissions (APPENDIX A) and ethical clearance obtained.
- Data collection will involve a contact session every fortnight at the University of Johannesburg simulation laboratory.
- To ensure that student academic activities are not disrupted, data collection will be conducted during non-academic times and at convenient times for the student.
- Participants will be approached in a group setting where the studies aim, objectives and structure will be explained.
- The participants will be given a study information sheet (APPENDIX B) and consent form (APPENDIX C) (which will include consent for video recording) after the introduction session.
- The video recording will be used to review both timing and real time CPR feedback on the simulation manikin monitor. Recording will be destroyed after review by the researcher.
- All participants who have agreed to participate in the study will be contacted via a phone call to schedule a data collection day for each group of 12 students and a single reminder SMS/email will be sent the week prior to the data collection day.
- The participant contact information will only be known to the researcher to maintain anonymity after data collection on an encrypted spread sheet. This

will allow any participant to withdraw from the study if they wish. Participant information will be destroyed after the report is submitted for assessment.

- During the data collection days, consenting participants will be requested to present at the University of Johannesburg Health science simulation laboratory.
- The participants will be given their participant number while receiving a basic briefing. This will be followed by a short lecture and physical skills refresher in basic life support, BVM mask grips and CPR.
- Ambient temperature will be standardised at 21°C, standard operational uniform will be worn.
- Prior to subjects commencing the CPR simulation, the video recorder will be commenced for timing and review purposes, the video recorder will only be recording the simulation monitor feedback and audio.
- Each group will consist of 2 participants, the participants will be paired randomly.
- Each participant in each group (2 participants) will then be given a random generated number between 1 (standard CPR with one-handed ventilation technique) and 2 (Two-handed ventilation technique with CPR) to allocate the ventilation technique used first by each participant in the group.
- The standard ventilation technique will encompass a one-handed CE grip on the BVM facemask to create a seal between the manikin's face and the facemask while the participant's second hand squeezes the bag section of the BVM to deliver positive pressure ventilation. The two-handed ventilation technique will require the participant at the patients head to use both hands in a double thenar eminence grip to secure the BVM face mask on the manikin's face while the second participant squeezes the bag to perform positive pressure ventilation after 30 chest compressions.
- The first group of 2 participants will be called into the simulation room and asked to perform the BVM and chest compression technique allocated to each of them on a medical simulation manikin (SimMan® 3G, Laerdal Medical, Norway), each participant will perform 5 cycles of CPR (2 min). After each 2 min interval, subjects will be asked to swop roles, i.e. The participant holding the BVM mask will switch to chest compressions and the participant performing the chest compressions will switch to BVM ventilation. This

participants will complete 4 rounds of CPR as a team, (2 rounds or 2 min per ventilation/CPR technique) this will total 8 min of continues CPR.

- The total compression time and total time for completion of the 4 rounds will be recorded to assess each groups chest compression fraction.
- The ventilation technique, average tidal volume per 2 rescue breathes and the time to deliver 2 rescue breaths in between sets will be recorded.
- After the two participants have performed their initial allocated set of CPR, they will be allocated a 5 min break to rest prior to repeating the scenario using the second allocated BVM ventilation technique each.
- At the end of the 2nd scenario, participants will be handed a questionnaire to complete. The questionnaire will cover aspects relating to the participants preferred ventilation technique, best perceived ventilation technique as well as their perceived exertion for each combination during CPR using the Borg scale.[9]
- The participant's data will be captured on a paper data sheet and transcribed into an encoded spread sheet (Microsoft® Excel).
- Data variables to be collected will include the participant's demographic data and feedback on preferred ventilation techniques (questionnaire). The participant's quality of CPR will be recorded as the compression depth, compression rate and cardiac compression fraction. The average delivered volume will be recorded as a ventilation variable.

DATA ANALYSIS

The time period for data collection is estimated to be over 4 months and will include 6 data capture days. All data recorded in the data collection sheets will be entered an electronic spreadsheet (Microsoft® Excel) and imported into R studio (RStudio Team, 2015) software program for statistical analyses. Statisticians from the University of the Witwatersrand will be approached for assistance in both processing the data and ensuring relevant statistical analysis. The data will be presented in both a descriptive form and graphically. Comparative tests will be used to statistically analyse the date, a paired student T-test will be used for normally distributed date or alternatively a Wilcoxon signed-rank test will be used for skewed data. Categorical data will be analyzed with a Fisher exact test.

The data sets (one-handed and two-handed ventilation technique) will be compared using descriptive statistics to assess for difference and statistically significance of the ventilation, CCF and average CPR quality markers. The subjective data from the questionnaire will be encoded numerically to allow for direct comparison of the mean between the two data sets, this will include the Borg scale to assign a perceived exertion scale to each ventilation and CPR technique. The remaining subjective data is configured in a binary question and may be commented on during the discussion.

LIMITATIONS

The study will draw data from a relatively small sample of novice students and the data may not be applicable to experienced healthcare providers. The study will use a simulated manikin, which may not provide comparable anatomical data compared to a human model.

ETHICS AND PERMISSION

Ethical approval for this study will be obtained from the University of the Witwatersrand human research committee. Permission to conduct the study will be obtained from the Dean, HOD of EMC at the University of Johannesburg and if required be assessed by the appropriate ethics committee. Informed written consent will be gained from the participants once the participants have agreed to participate in the study.

FUNDING

The study will be self-funded with the majority of the equipment required being sourced from the University of the Witwatersrand simulation centre after obtaining permission. Estimated cost of the study is as follows:

Printing – R1000

Travel expenses (petrol) – R700

Phone calls (HOD, participant arrangements, scheduling, SMS reminders) – R700

Total estimated cost – R2400

TIMING

The study once approved is scheduled to commence in May 2018. Data collection will be spread over 6 months. Other components of the study are charted below.

	Mar	Apr -	Jul -	Sep -	Jan -	Jan –	Mar -	Oct -	Jan
Preparing protocol									
Protocol Assessment									
Ethics Application									
Data Collection									
Data analysis									
Preparing report									

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APPENDIX A: PERMISSION

Re: Request for permission from academic H.O.D of the Department of Emergency Medical Care, and Dean of the faculty of Health Sciences, University of Johannesburg

To: Prof André Swart

Prof Craig Lambert

I am an Emergency care practitioner (ECP, BTech EMC, UJ) and am currently a postgraduate student registered at the University of the Witwatersrand, Johannesburg, South Africa.

I humbly request permission to carry out a research study in the Faculty of Health Science simulation laboratory using the Laerdal Simman 3G, which is a part requirement of my MSc degree in Emergency Medicine.

My proposed research study is entitled: **A comparison of two handed versus single handed bag valve mask ventilation during two rescuer CPR**(see attached proposal).

If granted permission, the research is a prospective experimental observational and questionnaire based transverse study and will be administered to the 2nd, 3rd and 4th year BEMC students at the University of Johannesburg.

Informed consent will be obtained before enrolment in the study.

The students who choose to enrol in the study will have their anonymity and confidentiality respected.

The study will take approximately 30 min and will not interfere with the normal academic activity.

There will be no major expense involved. All minor expenses for the study will be borne by me.

Yours Sincerely

_____

Louis Gerber (Researcher) Date……

Pending the University of Johannesburg ethics review board approval, I _____ (name, HOD EMC) hereby grant permission to Louis Gerber to carry out the research study outlined above.

_____

Prof Craig Lambert Date……

Pending the University of Johannesburg ethics review board approval, I _____ (name, Executive Dean Faculty of Health sciences) hereby grant permission to Louis Gerber to carry out the research study outlined above.

_____

Prof André Swart Date……

APPENDIX B: PARTICIPANT INFORMATION SHEET

INFORMATION SHEET

Title of Study: *A comparison of two-handed versus single-handed bag-valve-mask ventilation during two rescuer CPR on a simulation manikin.*

Introduction

Good day, my name is Louis Gerber, I would like to invite you to take part in this study. I am required to conduct research as part of my studies in Master of Medicine Degree (Msc EM) at the University of the Witwatersrand, Faculty of Health Sciences, and Department of Emergency Medicine.

What is the purpose of this Research Study and why have I been chosen?

I am inviting you take part in this simulation based experimental study as you have a basic understanding of cardiopulmonary resuscitation (CPR) and are likely to perform it many times during your professional practice. The key outputs of high-quality CPR have been established from multiple clinical and simulation-based studies and a drive to further refine the practice is ongoing.

The purpose of this study is to evaluate how a simple change in standard CPR influences the quality of CPR when used in a simulated environment as well as your perceived comfort and exertion.

What will happen to me if I take part in this study and what do I have to do?

In this research study, I would like to collect information about you by conducting a CPR simulation in which you, together with a randomly allocated partner, will perform CPR on a simulation mannequin. The performance of your CPR will anonymously be assessed via the mannequin software and a questionnaire will be given to you after the simulation to gain subjective data.

You will be asked to perform 2 rounds of standard CPR compressions rotating with your partner every 2 min. This will take 8 min and will be followed by a 5 min break, the same procedure with a minor modification to standard CPR will then be repeated for a further 8 min. I will then ask you to fill in a short questionnaire to rate your perceived comfort and exertion.

The simulation mannequin's user interface will be recorded for timing purposes and the recording will be destroyed after the study has concluded. Your data will be available to you directly after the simulation and will be anonymized.

What are the side effects or risks of taking part?

Due to the physical nature of CPR, minor physical discomfort may be present due to physical exertion.

What are the benefits for participating in the study?

There are no direct benefits to the participant in this study, but the data may provide evidence to improve the quality and comfort of CPR for both the practitioner and patient in the future.

Is there reimbursement for study participation?

You will not be paid to participate in this study. There will be no costs to you for any of the procedures or tests in participating in the study.

Do I have to take part?

Your participation in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this Information Sheet to keep and will be asked to sign an informed consent form/ should you wish to discontinue participation, you may do so freely at any time and without giving a reason. If you choose not to participate or to withdraw from the study, there will be no repercussions.

Will my taking part in this study be kept confidential?

All information obtained during this study will be kept confidential. All your personal information and simulation data will be captured on separate encrypted spreadsheets and only the researcher (Louis Gerber) will have access to this information. Data may be reported in scientific journals and will not include any information that identifies you as a participant in this study. Data will be kept for two years if published or six years if not published, after this period they will be destroyed. In the event of data sharing with other researchers for academic purposes, written permission will be sought from Human Research Ethics Committee (Medical) of the University of the Witwatersrand, which has approved this study.

Will my performance be recorded?

Your performance will be recorded indirectly via a video recorder capturing the feedback data from a simulation monitor for timing purposes and to allow for follow up on missing data points. No identifiable audio or visuals will be recorded except for the participant numbers who were involved in the simulation. This recording will be destroyed as soon as the research report is compiled.

Who is organizing and funding the research?

I have organized the study, as stated above this study is for degree purposes. This study is not funded, nor will it be used for commercial gain. If participation runs after hours i.e …. pm, you will be reimbursed for travel expenses by the Principal Investigator.

Whom do I call if I have questions or problems?

If you would like more information, have any questions about the study, or experience research related injuries, please contact me:

- Louis Gerber on cell: 074 176 9275/ email: louisgerber121@googlemail.com or alternatively my Supervisor:
- Dr. Abdullah Laher at cell: 084 840 2508 / email: abdullahlaher@msn.com

If you have any concern over the manner in which the research is conducted, please contact the Human Research Ethics Committee (Medical), University of the Witwatersrand

- Chairperson: Professor CB Penny Tel 011 717 2301, e-mail Clement.Penny@wits.ac.za

Secretariat: Ms Z Ndlovu/ Mr Rhulani Mkansi 011 717 2700/1234, e-mail zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za;

APPENDIX C: CONSENT FORM

Consent from participant in research

I, _____ , consent / do not consent to participate in the research project entitled; *A comparison of two handed versus single handed bag valve mask ventilation during two rescuer CPR*

The procedures have been explained to me and I understand and appreciate their purpose, and the extent of my involvement.

I have read and understand the attached study information leaflet.

I understand that the research forms part of a research project, and may not provide any direct benefit to me or the patient.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. Any queries may be directed to the Chairperson; Professor CB Penny, Tel 011 717 2301, e-mail Clement.Penny@wits.ac.za

I am aware that participation is voluntary, and that I am free to withdraw from the project at any time without any consequences.

I am aware that a my performance will be indirectly recorded but my anonymity will be maintained by the researcher and the recording will be destroyed after the research report is completed.

Participant name …..... Date ……

Researcher……..... Date ……

Participant signature …….. Researcher Signature……

Researcher contact detail; Cell: 0741769275

E mail; **louisgerber121@googlemail.com**

APPENDIX D: QUESTIONNAIRE

Participant number

Please indicate below with an X how you would rate your perceived exertion level during the specific CPR manoeuvre (when you were doing compressions)
Please view the attached information sheet (Appendix F) on the Borg scale for numerical classification

Borg Scale	M1 (Single-handed mask grip)		Describe your exertion
	6		(None)
	7		Very, very light
	8		
	9		Very light
	10		
	11		Fairly light
	12		
	13		Somewhat hard
	14		
	15		Hard
	16		
	17		Very hard
	18		
	19		Very, very hard
	20		

Borg Scale	M2 (Double-handed mask grip)		Describe your exertion
	6		(None)
	7		Very, very light
	8		
	9		Very light
	10		
	11		Fairly light
	12		
	13		Somewhat hard
	14		
	15		Hard
	16		
	17		Very hard
	18		
	19		Very, very hard
	20		

Which mask seal provided the most comfortable grip? (Please mark with X)

M1 ☐ M2 ☐

Which mask grip provided better patient ventilation in your opinion?

M1 ☐ M2 ☐

After finishing a set of compressions during manoeuvre 2, did taking your hands of the patient's chest and compressing the BVM increase your overall perceived comfort?

YES ☐ NO ☐

Which manoeuvre do you believe provided the best quality overall CPR?

M1 ☐ M2 ☐

Which manoeuvre would you use again or recommend to a fellow lay person or professional?

M1 ☐ M2 ☐

APPENDIX F: QUESTIONNAIRE ADJUNCT

How you might describe your exertion	Borg rating of your exertion	Examples (for most adults <65 years old)
None	6	Reading a book, watching television
Very, very light	7 to 8	Tying shoes
Very light	9 to 10	Chores like folding clothes that seem to take little effort
Fairly light	11 to 12	Walking through the grocery store or other activities that require some effort but not enough to speed up your breathing
Somewhat hard	13 to 14	Brisk walking or other activities that require moderate effort and speed your heart rate and breathing but don't make you out of breath
Hard	15 to 16	Bicycling, swimming, or other activities that take vigorous effort and get the heart pounding and make breathing very fast
Very hard	17 to 18	The highest level of activity you can sustain
Very, very hard	19 to 20	A finishing kick in a race or other burst of activity that you can't maintain for long

Table adapted from Harvard T.H. Chan, School of public health

APPENDIX E: DATA COLLECTION SHEET

Group	Participant	Age	Sex	BVM hold	1TV1	1TV2	1TV3	1TV4	1TV5	Mean 1TV C1	1TV6	1TV7	1TV8	1TV9	1TV10	Mean 1TV C2

Group	Participant	2TV1	2TV2	2TV3	2TV4	2TV5	Mean 2TV C1	2TV6	2TV7	2TV8	2TV9	2TV10	Mean 2TV C2

Group	Participant	Mean depth 1	Mean rate 1	PCPR T 1	PCPR T 2	CPR Frac 1	Mean depth 2	Mean rate 2	PCPR T 3	PCPR T 4	CPR Frac 2	Borg 1	Borg 2	Mask seal	Mask grip	Break	Quality	Recommend

APPENDIX 1: ETHICS CLEARANCE CERTIFICATE

FACULTY OF HEALTH SCIENCES
RESEARCH ETHICS COMMITTEE

NHREC Registration: REC 241112-035

ETHICAL CLEARANCE LETTER
(RECX 2.0)

Student/Researcher Name	Gerber, L	Student Number	-
Supervisor Name	Dr A Laher	Co-Supervisor Name	Mr M Botha
Department	EXTERNAL		
Qualification	MSc Med (Emergency Medicine)		
Research Title	A Comparison of Two Handed versus Single Handed Bag Valve Mask Ventilation during Two Rescuer CPR on a Simulation Mannequin		
Date	3 September 2018	Clearance Number	REC-01-103-2018

Approval of the research proposal with details given above is granted, subject to any conditions under 1 below, and is valid until 31 January 2019.

1. **Conditions:**
None

2. **Renewal:**
It is required that this ethical clearance is renewed annually, within two weeks of the date indicated above. Renewal must be done using the Ethical Clearance Renewal Form (REC 10.0), to be completed and submitted to the Faculty Administration office. *See Section 12 of the REC Standard Operating Procedures.*

3. **Amendments:**
Any envisaged amendments to the research proposal that has been granted ethical clearance must be submitted to the REC using the Research Proposal Amendment Application Form (REC 8.0) prior to the research being amended. Amendments to research may only be carried out once a new ethical clearance letter is issued. *See Section 13 of the REC Standard Operating Procedures.*

4. **Adverse Events, Deviations or Non-compliance:**
Adverse events, research proposal deviations or non-compliance must be reported within the stipulated time-frames using the Adverse Event Reporting Form (REC 9.0). *See Section 14 of the REC Standard Operating Procedures.*

The REC wishes you all the best for your studies.

Yours sincerely.



Prof. Christopher Stein
Chairperson: REC
Tel: 011 559 6564
Email: cstein@uj.ac.za

RECX 2.0 – Faculty of Health Sciences
Research Ethics Committee

Secretariat: Ms Raihaanah Pieterse
Tel: 011 559 6073 email: rpieterse@uj.ac.za

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
WITWATERSRAND
JOHANNESBURG

R14/49 Mr L Gerber

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170738

NAME: (Principal Investigator)	Mr L Gerber
DEPARTMENT:	School of Clinical Medicine Department of Medicine Division of Emergency Medicine Medical School University
PROJECT TITLE:	A comparison of two-handed versus single-handed bag-valve-mask ventilation during two rescuer CPR on a simulation manequin
DATE CONSIDERED:	28/07/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr A Laher
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	19/09/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in July and will therefore reports and re-certification will be due early in the month of July each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

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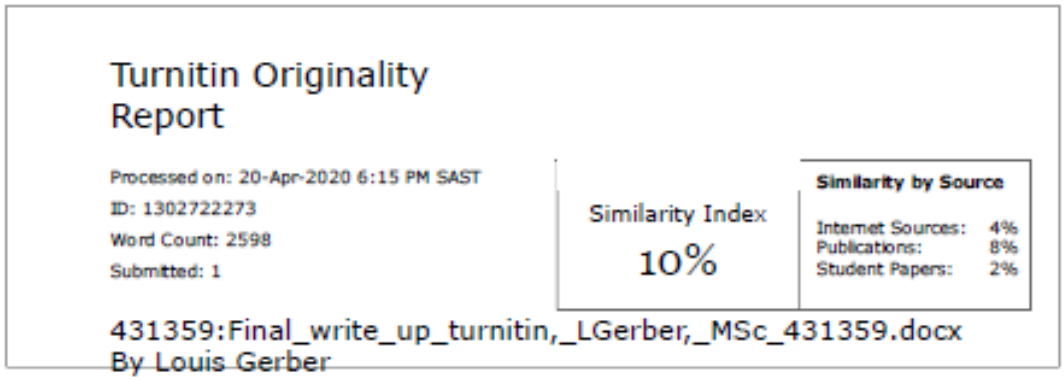

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