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Department of Anesthesiology
American University of Beirut Medical Center
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The Middle East Journal of Anesthesiology (Middle East J. Anesth), commonly known as MEJA, was first published in June 1966. It received its International Standard Serial Number (ISSN 0544-0440) in 1981. MEJA was licensed by the Lebanese Ministry of Information Decision No. 84 that was published in the Lebanese Official Gazette No.22 in 28/5/1992. MEJA was accepted for inclusion in the Index Medicus and MEDLARS databases in 1976.

The Middle East Journal of Anesthesiology was first published in June 1966 by Dr. Bernard Brandstater, Chairman and Professor in the Department of Anesthesiology at the American University of Beirut – Medical Center and School of Medicine. Dr. Brandstater assumed the role of the first Editor-in-Chief of the journal and gave it the famous motto "For some must watch, while some must sleep" (Hamlet – Act III, Sc. Ii). He also chose its symbol, the poppy flower (Papaver Somniferum), because the poppy flower was first cultivated in the Middle East and has given a unique service to the suffering of humankind for thousands of years. The journal is a non-profit publication of the Department of Anesthesiology at the American University of Beirut and is managed by volunteer staff from the department.

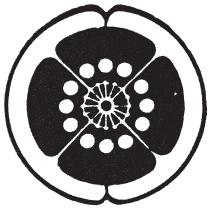
MEJA is published three times a year (February, June, and October) and has an Editorial Executive Committee consisting of faculty members from the department in addition to consultant editors from various parts of the world. MEJA has a worldwide circulation and was made available electronically since 2008.

The main objective of the journal is to act as a forum for publication, education, and exchange of opinions by promoting basic science and clinical research publications in the field of Anesthesiology.

MEJA has followed a policy to dedicate total issues for regions in the Middle East. To date, 17 regional issues have been published: Iran (June, 1969), Egypt (June, 1970), Lebanon I (February, 1971), Syria (October, 1971), Turkey (June, 1973), Saudi Arabia I (February, 1979), USA I (October, 1979), Lebanon II (February, 1984), Saudi Arabia II (June, 1985), USA II (February, 1986), Qatar (October, 1986), Jordan I (June, 1987), Jordan II (October, 1988), Saudi Arabia III (October, 1993), Saudi Arabia IV (February, 1999), Lebanon III (February, 2004).

It is important to recognize the February and June issues of 1983 that were dedicated to the experiences of the American University of Beirut – Medical Center staff during the tragic Lebanese war. These two issues also inaugurated the new cover design that uses the name of the journal and its symbol the poppy flower depicted in the colors of the Lebanese national flag. Furthermore, to celebrate the arrival of the third millennium (Year 2000), a special issue on the history of anesthesia in the Middle East was published (Vol. 15, No.4, February 2000). With increased awareness and challenges imposed by the COVID-19 pandemic, a special issue was dedicated (Vol. 27, No. 2, June 2020).

The Middle East Journal of Anesthesiology gained a posture of excellence as evidenced by the "Book Review", which appeared in the journal Anesthesia & Analgesia (Volume 63, p. 704-708, 1984) in which Dr. Nicholas Green, Professor and Chairman of the Department of Anesthesiology at Yale University School of Medicine, USA while describing MEJA wrote "…this journal has consistently proven to be one of the most interesting and educationally rewarding of the 30 or so regional journals about anesthesiology published throughout the world…".



*"For some must watch, while some must sleep"*

(Hamlet-Act. III, Sc. ii)

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SPECIAL ARTICLE

# PREPARATION FOR NATIONAL MEDICAL EDUCATION DISASTER LESSONS FROM COVID-19 PANDEMIC EFFECT ON SAUDI ANESTHESIA TRAINING: TRAINERS VIEW - A DESCRIPTIVE REPORT

Baraa O. Tayeb,[1,2*] MBBS, MS, D. ABA, ABHPM, CHSE, Wadeeah K. Bahaziq,[1,2] MBBS, FRCPC, Usamah S. Alzoraigi, MBBS[3,4] and Abdulaziz M. Boker,[1,2,5] MBBS, FRCPC, Med

## Abstract

**Background:** COVID-19 pandemic was declared as a global emergency affecting all aspects of clinical practices including medical education. In this study, we surveyed the staff trainers of the Saudi Arabia residency anesthesia program 6 months into the COVID-19 to formulate an assessment plan of the residency training program during the pandemic.

**Aims:** The aim of this project was to study the effects of COVID-19 disaster on the Saudi Anesthesia Training program as assessed by the trainers and synthesize recommendations to address the identified gaps in the current and any future disasters.

**Methods:** We deployed a survey 6 months into the pandemic targeting trainers of the Saudi residency program. Using a mixed design method, our survey had 3 main sections: 1) COVID-19 pandemic impact on the residency program, 2) interventions to decrease the impact, 3) and demographics.

**Results:** We had 55 responses including 33 program directors (%83 of programs in the kingdom). More than 50% reported the clinical exposure for trainees as inadequate. The core and obstetrics rotation were the least interrupted while subspecialties rotations were the most interrupted. Our respondents suggested online teaching, small group discussion and simulation as the top methods to adopt for the deficiencies. Also, they suggested changing the assessment and evaluation methods. Stress level among residents, as per trainers, was 7 out of 10 despite the available wellbeing resources.

**Conclusion:** The real lesson to be learned and the eye opener from COVID-19 pandemic year to medical education institutes is the importance of establishing disaster backup plans for continuous education during a crisis.

**Keywords:** Anesthesia; postgraduate training; Disaster; COVID-19

1 Department of Anesthesia and Critical Care, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia.
2 King Abdulaziz University Hospital, Jeddah, Saudi Arabia.
3 Department of Anesthesia and Perioperative Medicine, King Fahad Medical City, Riyadh, Saudi Arabia.
4 Center of Research, Education and Enhanced Training, King Fahad Medical City, Riyadh, Saudi Arabia.
5 Department of Anesthesia and Critical Care, Faculty of Medicine, and Clinical Skills and Simulation Center, King Abdulaziz University, Jeddah, Saudi Arabia.
* **Mailing address of the corresponding author**: Baraa Tayeb, MBBS, MS, D.ABA, ABHPM, CHSE; Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabi. Telephone number: +96626401000 (1-10199/10209). E-mail: btayeb@kau.edu.sa. Mailing Adress: P.B. Box 80215, Jeddah 21589

## Main Messages:

- Global disasters and Emergencies like pandemics have wide effects on medical education and graduation of competent clinicians.

- The 3 most important ways to compensate for missing clinical training and rotations are online learning, simulation, and small group discussion.

- It is important to monitor trainee's wellbeing and offer resources as these disasters have profound emotional, social and personal effects on the medical community and personnel.

- Medical education experts and medical councils need to establish a disaster educational continuity plan including methods of teaching, assessment, competencies, and completion of training.

## Research Questions:

- Are our medical education institutes have plans to be able to absorb effects of global disasters?

- Is it time to change trainee's evaluation to competency-based instead of time-based to ensure the graduation of competent clinicians?

- What is the potential of further integration of distant learning in medical education?

## Introduction

In March 2020, the first case of COVID-19 was declared in Saudi Arabia and all public and private efforts were directed toward public protection and minimizing the exposure and potential devastating consequences of COVID-19 pandemic. [1] Consequently, several effects were expected to impact routine medical education activities and in particular anesthesia training in Saudi Arabia. In a national level survey by Bahaziq et. al. 2020 [2] the effects on the Saudi anesthesia residency programs from the resident point of view during the first 3 months of the pandemic were explored. The survey showed that there are high stress levels of average 6.5/10 among residents with high concerns about personal and family safety and the progress in training.

The Saudi Commission For Health Specialties (SCFHS) and The Scientific Council of the Saudi Anesthesia Residency Program (SCSARP) prepared guidelines and recommendations for appropriate changes to adapt to COVID-19 challenges. These recommendations included increase in online education, small group workshops and Personal Protective Equipment PPE training among many other steps to help the residents go through this period and acquire the competency needed for graduation. Graduating safe, competent, and well-trained physicians is paramount for patient and public safety as well to support and strengthen the medical teams combating the pandemic.[3]

The aim of this study was to survey the staff trainers of the Saudi Arabia Anesthesia residency programs 6 months into COVID-19 pandemic. Comparing and contrasting the trainers' survey at 6 months with the trainees' survey at 3 months previously conducted by our team[2] will help in assessing the changes and to prepare for future changes to support postgraduate anesthesia medical education in Saudi Arabia and draw lessons for around the world.

## Methods

The study was approved by King Abdulaziz University Hospital (KAUH) Ethical Committee (reference no. IRB-No.412-20). We collected data using an electronic survey (appendix 1) on Google Forms. Data collection started August 2020, 6 months after the first COVID-19 case was diagnosed in Saudi Arabia.[1] The research team designed, reviewed, and piloted a survey to ensure the validity of the tool. Our survey was anonymous, we did not collect personal data. Any identifying data kept separate from the data set and no response were traced to individuals, hospitals, or regions. We kept the data confidential and password protected with restricted access to the research team only.

Using a mixed methods design,[4] our questions were both qualitative and quantitative including open ended questions to address any missed elements. We

designed the survey into multiple sections, namely COVID-19 pandemic impact on the residency program, interventions to decrease the impact, and demographics.

We extracted the quantitative data to Excel Sheets and manually coded the qualitative data. At least 2 authors independently reviewed and categorized the data. We employed a descriptive analysis for qualitative data, using cross-tabulations and multiple measures of dispersion. Also, we presented quantitative data for categorical variables as numbers, averages, sums, percentages, or frequencies as appropriate.

## Results

We had a total of 55 responses to the survey with combined 600 years of anesthesiology practice and 397 years of residents' supervision. Of the respondents, there were 33 program directors which represents 83% of the programs in the kingdom, 7 department chairs and 2 deputy program directors (Table 1).

*Table 1*
*Demographics of Respondents*

| **Distribution by gender** | | |
|---|---|---|
| **Male** | 36 | 65% |
| **Female** | 17 | 31% |
| **Prefer not to say** | 2 | 4% |
| **Distribution by region** | | |
| **Central** | 17 | 31% |
| **West** | 30 | 55% |
| **East** | 8 | 15% |
| **Distribution by role** | | |
| **Program Director** | 33 | 60% |
| **Mentor** | 12 | 22% |
| **Department chair** | 7 | 13% |
| **Deputy program director** | 2 | 4% |
| **Fellowship director** | 1 | 2% |

Starting with non-clinical didactical education our data showed an increase in online teaching and small group workshops instead of in-person teaching over the last 6 months as trainers believed self- learning and online teaching to be the most important during the pandemic period (Tables 2 and 3).

*Table 2*
*Importance of various interventions to utilize/ help residency program training in a pandemic period:*

| | **Personal self-study** | **Interactive E-learning platforms** | **Online group oral case discussion** | **Conducting research** | **Engagement in specialty related quality projects** | **Being front liners and handling emergency cases** | **Simulation workshop-based training** |
|---|---|---|---|---|---|---|---|
| 6 Extremely important | 43 | 34 | 32 | 5 | 9 | 13 | 15 |
| 5 | 4 | 16 | 14 | 14 | 20 | 20 | 20 |
| 4 | 2 | 5 | 8 | 15 | 15 | 9 | 13 |
| 3 | 6 | 0 | 0 | 9 | 4 | 11 | 1 |
| 2 | 0 | 0 | 1 | 8 | 3 | 0 | 2 |
| 1 Not important | 0 | 0 | 0 | 4 | 4 | 2 | 4 |

*Table 3*
*Interventions done by hospitals to decrease COVID-19 impact on medical training*

| **What interventions did your department institute to decrease the impact on residents' medical training?** | |
|---|---|
| Online teaching | 14 |
| Small group discussion | 8 |
| None | 5 |
| One to one teaching | 4 |
| Redistribution to other rotation and emergencies | 4 |
| Increase grand rounds and lectures | 4 |
| Self-learning | 2 |
| Reassurance and support | 2 |
| Other | 3 |

When asked about what rotation were uninterrupted due to COVID-19 for more than 3 months, we found that regional and pain anesthesia rotations were the most interrupted while on the other end of the spectrum core and obstetric anesthesia were the least interrupted (figure 1). At the time of the survey, 19 respondents reported resuming all subspeciality rotations while 18

respondents still had more than one rotation interrupted (figure 2).

Clinically, residents' exposure to cases during the last 6 months reported to be adequate by 8 respondents (14.5%), fair by 18 respondents (32.7%), inadequate by 29 respondents (52.7%), and no exposure by 0 respondents. To compensate for missing rotations 38 respondents suggested online learning, 39 suggested using simulation, 25 suggested small group discussion, 2 suggested self-learning, and 3 suggested other ways including delaying graduation. These findings reflect the actual interventions done by different hospitals (Table 3). Our respondents suggested long term changes to the anesthesia residency program for this and subsequent years residents to adapt to the current circumstances (Tables 4 and 5) which included among others change in graduation requirements, change to competency-based evaluation and delay graduation if needed.

Forty two respondents had a COVID-19 airway team in their hospitals; however the majority of respondents 71% thought residents should not be part of that team or be a second line provider at most.

Respondents rated the residents stress level to be of a mean and mode of 7 out of 10 (Figure 3). The highest concern of our participants is the extension of the pandemic for a long period, followed by a significant gap in residents' competency, and finally delay in certification and graduation while some respondents indicated no concerns at all since this pandemic is affecting everybody equally (Figure 4). The 3 most methods used to address wellbeing support were wellbeing clinics, social media groups and small group discussion, decreasing duty hours among other wide range of wellbeing interventions offered to residents (Table 6).

*Table 4*

*Suggestion to current year graduates*

| **What changes do you suggest to current year graduates to help their certification and education process?** | |
|---|---|
| None | 13 |
| Simulation based education | 11 |
| Online based education | 9 |
| Small group discussion | 7 |
| Extension of program / keep residents until cases log completed | 7 |
| One to one counseling and discussion | 6 |
| Study-hard | 4 |
| Long term strategic plans | 2 |
| Mini exams followed by targeted workshop | 2 |
| Uncertain | 2 |
| Join program and distribute the residents as per requirement to fulfill their schedule | 1 |
| Decrease requirements for graduation | 1 |
| Continue the work-based assessment | 1 |

*Fig. 1*

*Rotation uninterrupted for more than 3 months.*

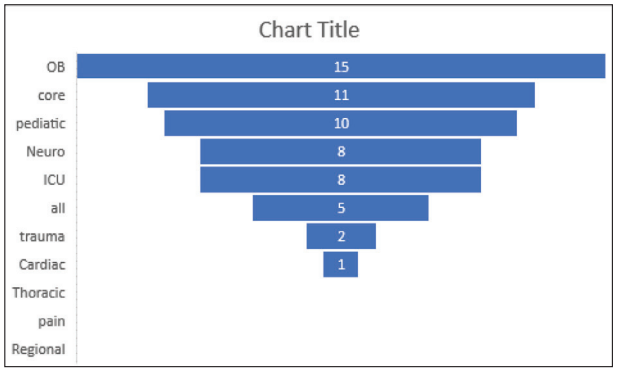


*Fig. 2*

*Anesthesia rotations not offered anymore to residents at the time of the study.*

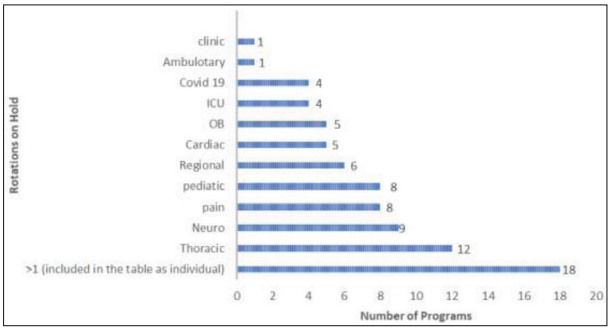

*Fig. 3*
*The mean stress levels among residents (0-10).*

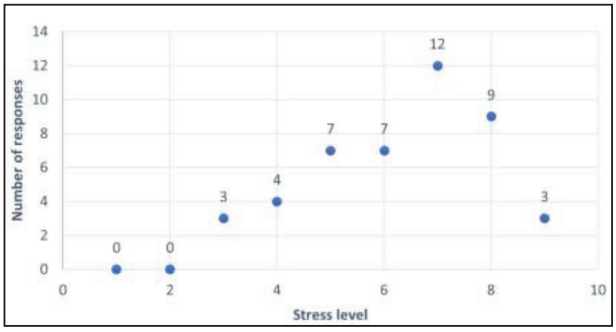


*Fig. 4*
*Highest concerns about residents.*

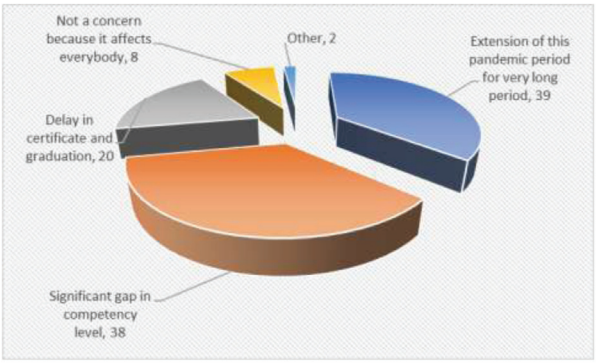


*Table 5*
*Suggestions to anesthesia residency program subsequent year's graduates*

| **What changes do you suggest to anesthesia residency program subsequent years graduates to help their certification and education process?** | |
|---|---|
| Nothing | 14 |
| Simulation learning and skills workshops | 9 |
| Depend more on continuous evaluation | 8 |
| E-learning | 7 |
| Appropriate/ increase utilization of teaching opportunities and review of the curriculum | 7 |
| Delete or re-evaluate the need /concept of subspeciality and non-anesthesia rotations | 6 |
| Small group education | 5 |
| One to one learning during cases | 3 |
| Increase working hours | 3 |
| Employ competency related evaluation as basis of completion of rotation instead of time. | 3 |
| Engage them early and provide safe learning | 2 |
| Work on residents' privilege | 2 |
| Delay graduation | 2 |
| Decrease to 4 years program | 2 |
| Separate each city into clusters | 1 |
| case based discussion | 1 |
| using logbooks to follow up their progress | 1 |

*Table 6*
*Wellbeing support for the residents offered by departments*

| **In your institute/ Department, any wellbeing support have been provided to support the residents?** | Number |
|---|---|
| Wellbeing clinic | 28 |
| Social media group support | 17 |
| Small group Discussion | 17 |
| Mentorship for residents | 16 |
| Decrease the working hours | 13 |
| One to one counseling | 10 |
| None | 9 |
| Psychological/psychiatry supports | 7 |
| Stop rotations from and to our institution | 3 |
| Residents were not allowed to do any suspected or confirmed COVID-19 cases. | 3 |
| Supportive Zoom meetings by MOH | 2 |

## Discussion

COVID-19 pandemic has brought to the specialty and practice of anesthesia many important opportunities as well as challenges. Opportunities like increased demands and reliance on anesthesiologist's expertise to manage surge in critical cases, support health care systems and provide highly needed leadership and training stewardship. Many of these opportunities also created more challenging situation to the specialty. One of these key challenges is to provide the needed balance between increased clinical demands and stressors and the need to train and graduate future

anesthesiologists.

During the early phases of the COVID-19 pandemic, like many other national training boards, SCSARP forecasted potential issues and solutions including the deployment of a national trainee's survey[2] to mitigate the possible negative impacts of the crisis on national anesthesia training programs. This study followed the first survey in a continuous effort to monitor and assess progress of the learning process from the trainer's point of view.

Our survey indicated the most important ways to compensate for missing anesthesia residents' rotations and exposure. These include activation of online learning, utilization of simulation, and small group discussion. As for online education, our study showed a spike in the use of electronic and social media-based education among most of the respondents. This is facilitated by the vast and developed technical infrastructure and computer science evolution during the 21st century which eased access to online teaching tools while keeping social distancing possible.[5]

The use of online teaching has been very important during this crisis worldwide and its incorporation into medical education and practice might last beyond the pandemic time.[6] For example, in one study,[7] more than 70% of participants (faculty and students) have increased confidence in the effectiveness of online teaching after using it.

Similarly, small group discussion is an easy and safe way of maintaining social distancing during pandemics when practiced appropriately; and there are available guidelines to help construct a positive small group discussion environment as the one published by Edmunds et. al. 2010[8] and Meo et. al. 2013.[9] Small group discussions have been practiced for decades and is found to be preferable by medical learners.[10]

Simulation has shown success historically in training anesthesia residents.[11] Interestingly simulation was not a highly used interventions even though it was highly suggested by our participants. This could be due difficult access to simulation centers, uncertainty of how to safely use simulation during pandemic or unavailability of simulation mentors.[12] In addressing these gaps, the Ministry of Health MOH in cooperation with SCFHS has supported simulation over the last few years as a way of medical education, patient safety, and quality improvement. The Saudi Society for Simulation in Healthcare (SSSH) was established two years ago and is in the process of accrediting and supporting simulation centers around the country to achieve the intended goals. Also, SCSARP has incorporated simulation into the anesthesia residency curriculum. Finally, the SSSH published the SSSH Guidelines for Simulation Based Education During and Beyond COVID-19 Pandemic [13] to help guide the local scientific community on safe use of simulation-based education during COVID-19 pandemic. These changes will help in any future medical education disaster to overcome any obstacles in using simulation as an essential or back up for residents training to achieve needed competencies.

As for anesthesia subspecialties training, the impact of COVID-19 interrupted mainly elective-based sub-specialized rotations at tertiary hospitals, in contrast to emergency-based services like Core (general/trauma) anesthesia and Obstetrical anesthesia were less impacted or interrupted due to continuing need for service despite the pandemic. Interestingly, the need for some of these rotation was questioned by our participants as they suggested to re-assess the need for subspecialties and non-anesthesia rotations compared to core rotations during the primary residency program; while other participants suggested using simulation to address the deficiencies in subspeciality rotations that are difficult to encounter during disasters. Simulation has already shown to have positive results in subspeciality training in multiple studies including thoracic[14] and cardiac[11,15] among others.

Residents' assessment during the pandemic was one of the challenges reported in our study due to concerns in term of offering socially distant space to conduct national level exam, as well as the possible effect of decreased clinical exposure. One of the participants' suggestions was to move more toward formative assessment and competency mastering rather than time-based evaluation. Formative assessment was suggested to replace current ongoing part of promotion criteria which include conducting annual national level written, clinical and case-based discussion exams in addition to fulfilling other requirements like rotations, work base discussion and program director recommendation. This suggestion goes in parallel with

the future transition of the Anesthesia Training in Saudi Arabia towards Entrustable Professional Activities (EPA). Even before the pandemic, there was a school calling for the change of medical training evaluation from time based to competency based to adapt to our evolving healthcare system needs.[16] Competency based evaluations can be a substitute for prolonging training, as suggested by few participants, as during disasters we might need to graduate competent clinicians on urgent basis to help the community and this was done successfully in the United States and multiple other countries during this pandemic.[3,17] One of the remaining unanswered questions, if those residents who did not complete training requirements to be graduated with limited privileges.

Our participants rated the mean stress among the residents to be 7 out of 10, which is comparable to the 6.5 out of 10 resident self-reported stress in the Bahaziq et. al. 2020 study.[2] The continued unchanged high stress level could be explained with the continued uncertainty about the end of the pandemic, the approaching residency graduation exam, and/or the restricted social distance measures at the time. Since then, wide community COVID-19 vaccination has started, there have been increase in elective surgery and improvement in the training environment for residents and the residency exam has been completed, which in turn might have decreased the residents' stress levels. Due to all of that we expect that by the time of writing the manuscript the stress levels are improving. Nevertheless, we recommend for program directors to keep monitoring wellbeing and involve well-being specialists, as social workers and psychiatry specialists when needed. Physician well-being and needs are essential to acknowledge on national level by medical societies to support and prevent physician burn-out.[18]

The real lesson to be learned and the eye opener from COVID-19 pandemic year to medical education institute is the importance of establishing disaster backup plans for continuous education during a crisis using experts in medicine, education, and simulation as we do in any other high stake medical emergency. After all, medical education is the basis of future medical practice.[19,20]

Limitations to our study include the use of survey instead of more robust methods. Surveys in medical research have known limitations that we tried to avoid by peer testing the design, using open ended questions, and avoiding non-response bias during the design and deployment of the survey.[21] Also, another limitation is the continuously changing dynamic nature of the pandemic situation which makes the analysis and results variable and changing with time. An ongoing and continuous process for the changing needs assessment and gap identification and/or remediation steps are suggested strategies to overcome this limitation.

## Conclusion

In time of global disaster, e.g., COVID-19 pandemic, medical education residency/fellowship programs could be affected. Anesthesia Educator experts and medical councils need to establish a disaster educational continuity plan including methods of teaching, assessment, competencies, and completion of training. One of the questions remaining unanswered, if those residents who did not complete training requirements to be graduated with limited privileges.

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# RESIDENT'S PUSHED TO THE BRINK: A WAKE-UP CALL TO CHANGE THE HEALTHCARE CURRICULUM

Sara Farsi,[1*] MD, Abdulhameed Ardawi,[1] MD,
Waleed A. Alghamdi,[2] MD, Wadeeah Bahaziq,[1] MD,
Abrar Faden,[1] MD, Nora Albarti,[1] MD,
Abdulrahman A. Almazrooa,[1] MD

## Abstract

**Background:** Anesthetists experience a lot of stress on a daily basis and they take charge during a health crisis. Unfortunately, mindfulness and coping strategies are rarely taught during training. With the appearance of the COVID-19 pandemic, some might struggle to cope. Our goal was to uncover the prevalence of moderate-severe anxiety, stress, and depression among anesthesia residents during the crisis.

**Methods:** This is a cross-sectional study. We sent a questionnaire to the anesthesia residents enrolled in the Saudi Commission for Health Specialties anesthesia residency program in the western region of Saudi Arabia. This questionnaire included demographic data, concerns and coping methods. We also included questionnaires for stress, anxiety and depression.

**Results:** We achieved a 77% (93 residents) reply rate. Around 25% of the residents had trouble coping. There was a high prevalence of moderate-major stress and depression at 89% and 50% respectively. The biggest concern was contracting the virus (66%), infecting their family members (81.5%), and a delay in graduation as a result of the pandemic (59.8%). There was a statistically significant relationship between living alone and depression.

**Conclusions:** A health crisis can have a serious impact on psychological well-being of anesthetisia residents. It is essential that they are provided with support services ans well as incorporating well-being training into their curriculum.

**Keywords:** Anesthesia, curriculum development, mindfulness, resident well-being, pandemic, coping, medical education, COVID-19.

## Introduction

From the start of medical school, healthcare workers are constantly exposed to high levels of anxiety and stress. About 50% of American physicians have reported burnout,1 and anesthesiologists are no exception. Their profession involves quick decision making, a stressful working environment, and high expectations with very little gratification and recognition. Depression is

1 Department of Anesthesia and Critical Care, King Abdulaziz University Hospital, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia.

2 Department of Psychiatry, King Abdulaziz University Hospital, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia.

*** Mailing address of the corresponding author:** Sara Farsi, MD, Department of Anesthesia and Critical Care, King Abdulaziz University Hospital, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia. Mailing Address: Department of Anesthesia, KAUH, P.o.box 80215, Jeddah, 21589, Saudi Arabia
Email: sfarsi@kau.edu.sa Telephone number: +966012 640 8335

twice as high among anesthetists as it is in the general population.2 Even during residency, a study by Sun et al. revealed that 51% of anesthesia residents had burnout, 36% had distress, and 12% screened positive for depression.3 These disturbances have been shown to lead to carelessness, lack of commitment, and risky behavior.4 All of this emphasizes the importance of incorporating a mindfulness and resilience curriculum in the training years.

Mindfulness-based stress reduction (MBSR) program for medical schools has been around since 1985.5 Despite that, a study by Dobkin et al. in 2013 revealed that only 14 medical schools actually taught mindfulness. These programs have already shown to reduce negative emotions and stress, and enhance empathy and self-compassion.6 Having support services that help physicians deal with stress and burnout isn't enough. We must try to prevent it by building their resilience, developing their coping strategies, and encouraging self-care.

With the onset of the COVID-19 pandemic, physicians are being asked to increase their productivity. At the same time, they are socially isolated from family and friends to prevent cross-infection. Without the proper skills to deal with the uncertainty, high-stress environment, and poor outcomes, physicians can be pushed to the brink. They become more and more at risk for succumbing to the negative effects of high anxiety and stress with the consequences of not being able to deliver the high-quality healthcare is expected of them.7

This study is a cross-sectional questionnaire-based study conducted to assess the mental well-being and coping strategies of anesthesia residents in the Western Region of Saudi Arabia during the COVID-19 crisis, which was conducted in April 2020. The primary aim of our study was to identify the residents' ability to cope by screening for high levels of stress, and depression and try to uncover the associated risk factors.

## Methods

Ethical approval was obtained from the King Abdulaziz University Hospital bimedical ethics committee. The study population were all anesthesia residents enrolled in the Saudi Commission for Health Specialties (SCFHS) Western Region's anesthesia residency program. We excluded residents that were on leave during the pandemic.There are 120 residents actively enrolled in the SCFHS anesthesia program. Of those residents, 45 (35.8%) are female and 75 (62.5%) are male. A survey was generated using Survey Monkey© that comprised of the predeveloped PHQ-9 questionnaire for depression, and the Perceived Stress Scale. An additional 11 demographic questions were added. These 11 questions were developed through a collaborative and iterative process by the research team after reviewing the existing literature for identified risk factors. The survey was sent out electronically on the 15th of April, and the residents were invited to complete the questionnaire voluntarily. The objective and goal of the trial was explained to the participants and we obtained a verbal consent. Participants' names were not included to maintain anonymity.

The PHQ-9 is a nine-item questionnaire used for producing a criteria-based diagnosis of depression. Major depression is diagnosed if five or more of the nine items in the questionnaire have been present for "more than half of the days" for the last two weeks. One of the items must be depressed mood or anhedonia. Other types of depression are diagnosed if 24 depressive symptoms have been present for at least "more than half the days" in the past two weeks, and one of the symptoms is depressed mood or anhedonia.8

The Perceived Stress Scale is a 10-item questionnaire designed to determine how unpredictable, uncontrollable, and overloaded respondents find their lives. It contains four positively stated items and six negatively stated items. The scores are obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing across all scale items.9 The score ranges from "013" indicate low stress, from "1426" moderate stress and from "2740" high perceived stress."

We included two open-ended questions that asked residents to reflect on their biggest concerns during the crisis. The answers to those questions were analyzed, and common themes were identified.

The results were analyzed using SPSSv21©. The

results of the questionnaires were tallied individually to determine each resident's level of depression, anxiety, and stress. The number of cases was then computed to determine the prevalence of each disorder. Cronbach's alpha was used to determine whether a relationship existed between the demographic variables and the questionnaire's results.

## Results

Of the 120 residents actively enrolled in the program, we received 93 responses, which give us a response rate of 77%. Of those, 39% (n=36) were female and 61% (n=57) of the respondents were male. See (Table 1) for the characteristics of respondents. Of the respondents, 20 (22%) had a chronic medical condition that made them more vulnerable to COVID-19, 75 (81%) were living with their family, and 47 (51%) had quarantined themselves. In addition, 15 residents (16 %) had already been in contact with a confirmed COVID-19 patient, and 12 (13%) of those had isolated themselves from their families..

*Table 1*

*Baseline Characteristics of Respondents*

| Variable | N | % |
|---|---|---|
| **Gender:** | | |
| Male | 57 | 61 |
| Female | 36 | 39 |
| **Year of training** | | |
| 1 | 21 | 23 |
| 2 | 23 | 25 |
| 3 | 20 | 21 |
| 4 | 15 | 16 |
| 5 | 14 | 15 |
| **Marital status** | | |
| Married | 48 | 52 |
| Single | 45 | 48 |
| **Have children** | | |
| Yes | 33 | 35 |
| No | 60 | 65 |
| **History of anxiety** | | |
| Yes | 7 | 8 |
| No | 86 | 93 |
| **Risk factor for COVID-19** | | |
| Yes | 20 | 22 |
| No | 73 | 78 |
| **Living with family** | 75 | 81 |
| **Isolated themselves from family** | 47 | 51 |

Stress:

Seventy-nine residents (89%) fulfilled the Perceived Stress Scale criteria for moderate to severe stress. A higher percentage of female residents achieved a moderate-severe stress score than males, although it was not statistically significant. Seventy residents (79.5%) scored within the moderate stress range, and nine residents (10%) scored within the severe stress range. We did not find a significant difference when comparing the stress level with other variables (see Table 2).

## Depression:

Twenty-nine (33%) of the residents fulfilled the questionnaire's criteria for major depressive disorder. Furthermore, 25 residents (27%) fulfilled the criteria for mild depression, 20 (22%) fulfilled the criteria for moderate depression, and 19 (22%) fulfilled the criteria for moderate-severe depression. We did find a significant increase in moderate-severe depression among residents who lived alone and those who had quarantined themselves (see Table 2). More than half of the residents (58%) who had actually been in contact with a COVID-19 patient had symptoms of moderate to severe depression. The question "Have you had Thoughts that you would be better off dead or of hurting yourself in some way", 17% of the residents have answered "several days", 5% have answered "more than half the days", and 6% have answered "almost every day". Of these residents, 7 lived alone and 6 didn't communicate regularly with their family using online platforms.

Concerns and Coping:

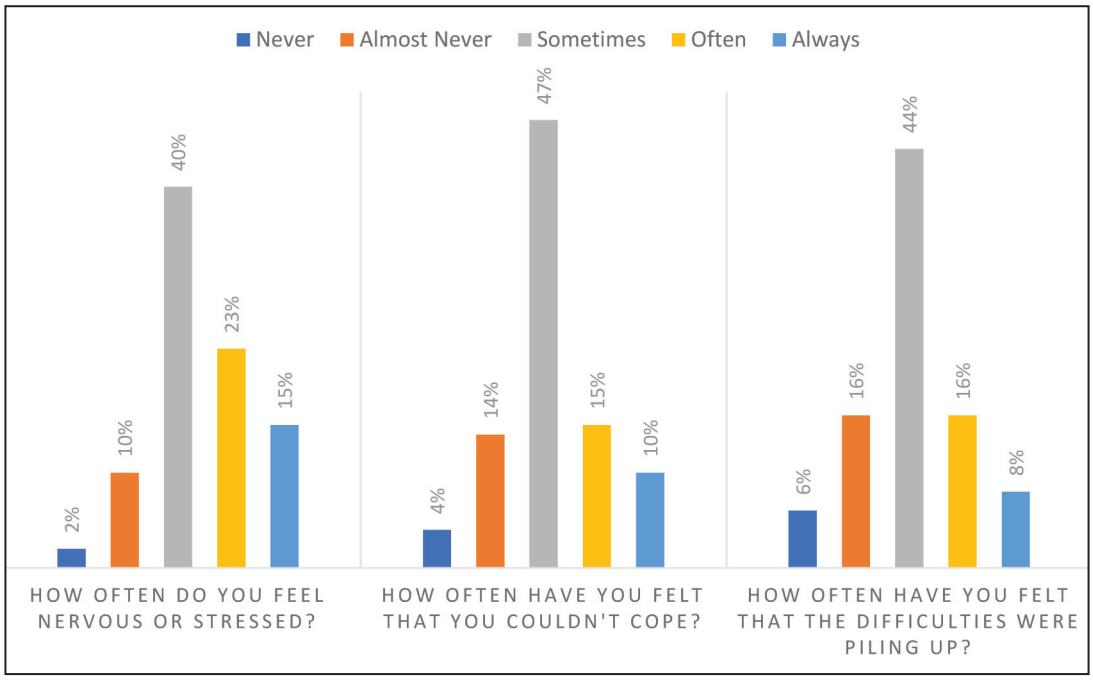
Twenty five percent of the residents were struggling to cope (Figure 1). The most common concerns among the trainees were contracting the virus (66%) or passing the virus on to their families (82%). This was significantly higher among the female and senior residents. About 80% of the residents who

*Table 2*
*The prevalence of Stress and Depression by variable*

| | n (%) | p-value | n (%) | p-value |
|---|---|---|---|---|
| | Residents That Had Moderate-Severe Stress (n=79) | | Residents That Had Moderate-Severe Depression (n=43) | |
| Gender | | | | |
| Male | 47(59) | 0.6 | 29 (67) | 0.1 |
| Female | 32 (41) | | 14 (33) | |
| Level of Training | | | | |
| 1 | 18(23) | 0.9 | 8(19) | 0.2 |
| 2 | 21(27) | | 14(33) | |
| 3 | 17(22) | | 7 (16) | |
| 4 | 10(12) | | 5(12) | |
| 5 | 13 (16) | | 9 (20) | |
| Marital Status | | | | |
| Married | 39(49) | 0.7 | 19(44) | 0.28 |
| Single | 40 (51) | | 24 (56) | |
| Children | | | | |
| Yes | 27(34) | 0.9 | 13(30) | 0.3 |
| No | 52(66 | | 30 (70) | |
| Health Conditions | | | | |
| Yes | 15 (19) | 0.3 | 5 (12) | 0.9 |
| No | 64 (81) | | 18 (88) | |
| Come in contact with COVID-19 patient | | | | |
| Yes | 14 (18) | 0.16 | 7 (16) | 0.017 |
| No | 65 (82) | | 16 (84) | |
| Living with family | | | | |
| Yes | 62 (78) | 0.4 | 30 (70) | 0.015 |
| No | 17 (22) | | 13 (30) | |
| Self-quarantined | | | | |
| Yes | 41 (52) | 0.8 | 27(60) | 0.05 |
| No | 38 (48) | | 8 (39) | |

We found no difference between the level of stress and other variables. Moderate to severe depression was higher among residents who had come in contact with a COVID-19 patient, living alone and who self-quarintined. *n= Number of residents. (%) is the percentage from that category.

*Fig. 1*
*Level of coping in participating anesthesia residents*




The majority of residents felt stressed, inability to cope and having difficulties piling up at lease some of the times.

were worried about getting infected had quarantined themselves. Another concern among the residents (60%) was the academic implications of the COVID-19 crisis and whether or not they would be able to be promoted to the next level of training or even graduate. Many residents (76%) were also concerned about the financial implications of the crisis (see Table 3). In the open-ended questions, common themes in coping where family support 16%, friends 12%, and religion 13%. 55% of residents exercised regularly.

## Discussion

This study uncovered a great deficiency in preparing anesthesia trainees in the Western Region of the Kingdom of Saudi Arabia for a health crisis. During the early days of the COVID-19 pandemic, a large number of anesthesia residents had already started to show signs of high stress and depression. In our study, 25% of residents felt that they often couldn't cope, and 21% felt that the difficulties were piling up. Concerningly, 33% of them fulfilled the criteria for major depressive disorder. If left unchecked, they can lead to a detrimental outcome, such as interpersonal relationship difficulties, drugs, alcohol, and even suicide.[10]

The appearance of the COVID-19 crisis has affected trainee's well-being in several ways. Previous studies on anesthesia staff and residents show that major sources of stress are lack of control over work, high demand, overtime, lack of support, and feeling helpless.[11,12] All of these factors certainly increased during the COVID-19 crisis. The pandemic already increased their workload and working hours, endangered their health, isolated them from their families, altered their normal routine, and appeared at the time where most of them were studying for their end-of-the-year exams. Furthermore, in a study by Hayanga et al. (2017), only 17% of residents felt that their program provided them with adequate training for an influenza pandemic and only 50% had emergency preparedness training.[13] There are already many reports of healthcare worker fatigue, anxiety, and burnout during this COVID-19 pandemic.[14,15]

The workplace may not be the only source of stress for residents. They may also be experiencing stress in their personal lives. Indeed, in our own study, we have found that the majority (81.5%) of

*Table 3*

*Residents' Biggest Concerns During the Pandemic in Association with Other Variables*:*

| | Residents Highly Concerned About Contracting Virus (n=61) | | Residents Highly Concerned About Infecting Family (n=75) | | Residents Highly Concerned About Finances (n=55) | | Residents Highly Concerned About Training (n=70) | |
|---|---|---|---|---|---|---|---|---|
| | n (%) | p | n(%) | p | n(%) | p | n (%) | p |
| Gender | | | | | | | | |
| Male | 32 (57) | 0.02 | 41(73) | 0.01 | 29 (51.7) | 0.51 | 42(75) | 0.7 |
| Female | 29 (80) | | 34 (94) | | 26 (72.2) | | 28(77.7) | |
| Level of Training | | | | | | | | |
| Junior (R1-R2) | 24 (54) | 0.022 | 32 (72) | 0.037 | 28 (63.6) | 0.47 | 34(77.2) | 0.79 |
| Senior (R3-R5) | 37 (77) | | 43 (89) | | 27 (56.2) | | 36(75) | |
| Marital Status | | | | | | | | |
| Married | 31 (65.9) | 0.14 | 40 (85) | 0.36 | 29(61.7) | 0.71 | 35(74.4) | 0.71 |
| Single | 30 (66.6) | | 34 (77.7) | | 26 (57.7) | | 35(77.7) | |
| Children | | | | | | | | |
| Yes | 23 (71.8) | 0.4 | 28 (87) | 0.2 | 20(62.5) | 0.698 | 21(65.6) | 0.08 |
| No | 38 (63) | | 47 (78.3) | | 35 (58.3) | | 49 (81.6) | |
| Living with family | | | | | | | | |
| Yes | 50 (67.5) | 0.6 | 63(85.1) | 0.2 | 47 (63.5) | 0.139 | 55(74.3) | 0.42 |
| No | 38 (63) | | 12 (66.6) | | 8 (44.4) | | 15 (83.3) | |
| Self-quarantined | | | | | | | | |
| Yes | 38(80) | 0.003 | 41(87.2) | 0.14 | 27 (57.4) | 0.64 | 36(76.5) | 0.9 |
| No | 23 (51.1) | | 34 (66.9) | | 28 (62.2) | | 34(75.5) | |
| Total | 61 (66) | | 75 (81.5) | | 55 (59.8) | | 70 (76.1) | |

* Residents were asked to rate how often they worry about these issues from 1 (Never) and 5 (All the time). This table includes the number of residents that gave these items a high rating (4-5). There was a statistically significant higher number of female and junior residents concerned about contracting the virus as well as passing it on to their families. There was a statistically significant relationship between residents who self quarantined and concern for contracting the virus.

residents' main concern was infecting a member of their family. A study out of Wuhan, China, revealed that 41% of COVID-19 cases might have originated in healthcare facilities.[16] In particular, anesthetists are at high risk of contracting the disease due to their involvement in aerosol-generating procedures. A study by El-Boghdadly et al. showed that 1 in 10 anesthetists displayed signs of the disease after intubating a COVID-19 patient.[17] That may have driven 47% of our own anesthesia residents to isolate themselves from their families. This could have the inadvertent effect of worsening their well-being, as 16% of the residents

considered family their biggest support, and we found a statistically significant relationship between depression and living alone. One alarming finding was that 6% (7 residents) thought about hurting themselves almost everyday, six of those resident lived alone. The concern with infecting family members was higher among senior residents. This could be due to the bigger responsibilities and close involvement in patient care given to them during a crisis. Furthermore, this crisis is predicted to lead to a drop in salaries and employment rates. Many of the residents (approximately 60%) were concerned with the long-term financial implication the crisis would have on their future.

Most training facilities do provide support service. In Saudi Arabia, the SCFHS has a support service for residents enrolled in their training programs. Residents can signup online, and then they are contacted by a psychologist who will provide confidential support and guidance. This service is completely free for any resident enrolled in a SCFHS training program. Most hospitals also have onsite supportive services to help physicians dealing with stress and burnout. Our own site provided a 24-hour helpline during the crisis. But, shouldn't we be trying to prevent burnout from happening in the first place?

Long ago, the majority of medical training programs emphasized on improving clinical skills and knowledge. In 1993, after an outcry from the public on dissatisfaction with the healthcare system,[18,19] the medical curriculum around the world was modified to fit the society's needs and expectations.[20] Teaching in the UK, Canada, and the USA was transformed to improve patients' well-being. But, what about the physicians' well-being?

Unfortunately, little has changed to improve physicians' mindfulness and coping ability. Mindfulness addresses physicians' self-awareness and has been shown to reduce negative emotions and stress.[21,22] Even a physician's approach to a problem can affect their well-being. For example, seeing a difficult situation as a challenge rather than a threat may mobilize more positive emotions such as eagerness and curiosity.

The limitations of our study include a small sample size, and it was restricted to anesthesia residents. It may not be applicable to other specialties. We also lack information on the level of stress, anxiety, and depression in anesthesia trainees prior to the pandemic. We also have not inquired in our study whether the participants acquired well-being training or support at any time during their training.

In conclusion, while it is essential that hospitals have the necessary equipments to face a health crisis, mentally preparing healthcare workers is just as important. This would include revising medical training programs to incorporate mandatory courses in mental well-being and disaster management as well as ensuring adequate sources of support for struggling healthcare workers. It's about time to remove the stigma surrounding "seeking mental support" from health specialties. Training program directors must regularly meet with the staff and trainees to uncover emerging concerns and signs of burnout. By doing this, we may improve the global outcome of any future crisis and hopefully avoid a repeat of the heart-breaking consequences of the COVID-19 pandemic may be improved.

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# EFFECT OF LOW TIDAL VOLUME VENTILATION ON DYNAMIC PRELOAD PARAMETERS DURING GRADED HEMORRHAGE AND RETRANSFUSION: AN ANIMAL MODEL

Simon M[1], MD, Hueter L[2], MD, Schwarzkopf K[3*], MD

## Abstract

**Background:** Dynamic preload parameters as systolic pressure variation (SPV) and stroke volume variation (SVV) are established monitoring tools for volume responsiveness during critical care therapy. The impact of ventilator settings on SPV/SVV is still under research.

**Methods:** We studied the impact of two different ventilator settings (low tidal volume ventilation (LTVV) (6ml/kg bodyweight) and normal tidal volume ventilation (NTVV) (12ml/kg bodyweight)) on SPV/SVV-measurements during graded hemorrhage (-15% and -30% blood volume) and retransfusion of the blood in an animal model.

**Results:** Cardiac output decreased significantly during volume depletion compared to baseline. Dynamic preload parameters increased during graded hemorrhage both during LTVV and NTVV. Changes in dynamic preload parameters show a tidal volume dependency: During NTVV values of SVV an SPV were higher and differed significantly from values obtained during LTVV.

**Conclusions:** The cardiac volume responsiveness in critical care is a surrogate of intravascular volume status and positive intrathoracic pressure induced by mechanical ventilation. Dynamic preload parameters are more sensitive monitoring tools for ventilation-induced changes in volume responsiveness than static preload parameters. The use of SPV/SVV for calculation of volume responsiveness depends on comparable ventilator settings during the measurements.

**Keywords:** Hemodynamic monitoring; Fluid management; Systolic pressure variation (SPV); Pulse pressure variation (PPV); Stroke volume variation (SVV); Ventilation

1 Department of Anesthesia and Intensive Care Medicine, Friedrich-Schiller-University Jena, Germany.
2 Department of Anesthesia and Intensive Care Medicine, Klinikum Burgenlandkreis GmbH / Saale-Unstrut-Klinikum Naumburg, Germany.
3 Department of Anesthesia and Intensive Care Medicine, Klinikum Saarbruecken, Germany.
*** Mailing address of the corresponding author:** Konrad Schwarzkopf MD, Klinik für Anästhesiologie und Intensivmedizin, Klinikum Saarbrücken, Germany. Telephone number: +49-681-9632640. E-Mail: kschwarzkopf@klinikum-saarbruecken.de.

## Introduction

Static preload parameters like central venous pressure (CVP) and pulmonary capillary wedge pressure (PCWP) are unreliable markers of intravascular volume state in ICU patients. Therefore dynamic preload parameters (systolic pressure variation (SPV), pulse pressure variation (PPV), and stroke volume variation (SVV)) have been established as parameters for evaluating intravascular fluid balances and volume responsiveness.[1-5] However, the question to what extent dynamic preload parameters are influenced by tidal volume and fluid load is still a matter of discussion.

Our study was conducted to measure the impact of mechanical ventilation on SPV and SVV during graded hemorrhage and retransfusion using low tidal volume ventilation (LTVV) (6ml/kg) compared with normal tidal volume ventilation (NTVV) (12ml/kg) which is still used in many intensive care facilities.[6]

## Methods

With approval of the regional Governmental Animal Care Office, eight female German Landrace pigs (26-32kg) were anesthetized with propofol (2-3mg/kg i.v.) and rocuronium (1.2mg/kg i.v.) to facilitate oral intubation. NTVV using an ICU respirator (Evita 2, Draeger, Luebeck, Germany) was adapted by adjusting respiratory frequency to ensure normocarbia ($PaCO_2$ 4,1-4,7kPa). PEEP was set to zero. Anesthesia was maintained with propofol (30-60mg/kg/h) and remifentanil (15-30µg/kg/h).

For measurements of pulmonary capillary wedge pressure (PCWP) and mean pulmonary artery pressure a 7F pulmonary artery catheter (Baxter, Irvine, USA) was introduced into the pulmonary artery. A central venous catheter was advanced into the superior vena cava. For analyzing arterial pressure waveform, cardiac output (CO), and stroke volume variation (SVV), a 4F fibreoptic thermistor catheter (Pulsicath, Pulsion medical systems, Munich, Germany) was positioned into the abdominal aorta. Thermodilution curves were analysed using a PiCCO® Plus monitor (Pulsion medical systems, Munich, Germany). CO data were collected by means of a PiCCO®-Plus System calculating the mean of three consecutive measurements of 10ml iced saline 0.9% injected into the central venous catheter.

Via a serial port the arterial pressure curve was transmitted to a notebook computer. Using a custom-made software a computerized online analysis of the systolic pressure variation was realized (GJB Datentechnik, Ilmenau, Germany). Beside SPV a calculation of the delta up/ delta down component of the SPV was possible once the system was calibrated by implementing a 10 sec interval of apnea. Systolic pressure variation was calculated during a 30sec interval by dividing it into four parts of 7.5 sec each. The highest and the lowest systolic pressure during each time window were determined. The mean value of the maximum systolic pressures of all time windows (7.5 sec) was subtracted from the systolic arterial pressure during apnea to calculate the delta up/ delta down component.

After a 30 min of steady state, four study steps were undertaken:

**Phase 1:** Hemodynamic parameters at baseline (normovolaemia) were collected with NTVV and LTVV. Respiratory frequency was adapted to ensure normocarbia. The equilibration time after changing the tidal volume was 10min before performing the next measurements.

**Phase 2:** Animals were bled through the arterial catheter by 15% of their estimated blood volume (calculated as 7% of body weight) within 10min followed by a 5min interval for hemodynamic stabilization. Hemodynamic measurements at both ventilator settings were done as at baseline.

**Phase 3:** Animals were bled by another 15% of their estimated blood volume, (i.e. total volume depletion 30%) within 10min followed by a 5min interval for hemodynamic stabilization. Measurements and modification of respiratory parameters were done as at baseline.

**Phase 4:** The pigs were re-transfused the shed blood within 10min. Hemodynamic measurements and modification of respiratory parameters were done as at baseline.

At the end of the experiment the animals were euthanized.

*Statistical analysis*

Values are expressed as mean ± standard error (SEM). One-way analysis of variance was performed for repeated measurements. A p-value of 0,05 was considered to be statistically significant.

## Results

All animals completed the protocol. During volume depletion 225 ±13ml (-15%) and 450 ±٢٧ml (-٪٣٠) of blood were removed and retransfused.

Each step caused a significant decrease in CO, MAP, CVP and PCWP compared to the preceding step. Dynamic parameters (SPV, SPVddown, SVV) significantly increased during graded hemorrhage. Ventilation at different tidal volumes caused significant changes in dynamic parameters but not in CO, MAP, CVP, and PCWP (Table 1).

For systolic pressure variation and SPVddown the mean values at baseline during NTVV were higher than at baseline and even at graded hemorrhage during LTVV. During retransfusion CO always increased by more than 15%. Dynamic preload parameters decreased significantly during LTVV. During NTVV the changes in SPV, SPVddown and SVV were more pronounced.

Static preload parameters showed a significant increase during retransfusion that was not significantly affected by the applied tidal volume.

## Discussion

Our study demonstrates significant changes of dynamic preload parameters during graded hemorrhage both during LTVV and NTVV. CO was significantly decreased during volume depletion compared to baseline as a result of a clinical relevant blood loss. The changes in dynamic preload parameters show a tidal volume dependency. During NTVV values of SVV, SPV, SPVddown were higher and differed significantly from values obtained during LTVV.[7]

After graded hemorrhage (-30% of intravascular fluid amount) all animals were volume responsive as demonstrated by the significant increase of cardiac output after retransfusion. During this phase the tendency to higher CO during LTVV compared to cardiac output using NTVV at same volume loading step was also seen. This is in contrast to older data that showed lower cardiac output during retransfusion using LTVV.[8]

Cardiac volume responsiveness is a surrogate of intravascular volume load as well as positive intrathoracic pressure induced by mechanical ventilation. Under certain circumstances the effect of positive pressure ventilation even seems to exceed the effect of changes in intravascular fluid load. Dynamic preload parameters are more sensitive to monitor these ventilation-induced changes in volume responsiveness than static preload parameters. Therefore, influence of mechanical ventilation on SPV/SVV cannot be interpreted as limitation of the parameters. However, the question to what extend both, intravascular fluid load and respiratory settings contribute to the volume responsiveness of a certain individual cannot be clearly differentiated.

## Conclusion

Our experiment demonstrates that the interpretation of chances in SPV/SVV as a marker of fluid responsiveness has to be done with a close look on the ventilator settings.[9] Changes of SPV/SVV should only be interpreted as marker of volume responsiveness if the ventilator settings during the measurements are comparable.[10]

**Financial disclosures:** None

**Conflicts of interest:** None

*Table 1*
*Hemodynamic variables at baseline, during 15% and 30% volume depletion respectively and after retransfusion at two different tidal volumes (TV)*

| | Normovolemia TV 6ml/kg | Normovolemia TV 12ml/kg | Volume depletion -15% TV 6ml/kg | Volume depletion -15% TV 12ml/kg | Volume depletion -30% TV 6ml/kg | Volume depletion -30% TV 12ml/kg | Retransfusion TV 6ml/kg | Retransfusion TV 12ml/kg |
|---|---|---|---|---|---|---|---|---|
| CO | 4.21 ±0.26* | 3.98 ±0.23* | 3.69 ±0.21* | 3.51 ±0.19* | 2.96 ±0.22* | 2.76 ±0.21* | 3.87 ±0.29* | 3.58 ±0.33* |
| MAP | 67.50 ±4.54* | 74.00 ±4.49* | 59.88 ±4.57* | 61.63 ±3.33* | 50.88 ±4.75* | 51.63 ±4.14* | 57.71 ±5.77* | 75.71 ±5.67* |
| PCWP | 10.38 ±1.68* | 10.88 ±1.99* | 8.38 ±1.36* | 8.13 ±1.33* | 7.13 ±1.20* | 6.75 ±1.23* | 10.29 ±1.04* | 10.14 ±0.98* |
| CVP | 8.13 ±1.27* | 8.88 ±1.60* | 7.25 ±1.08* | 6.88 ±1.00* | 6.50 ±1.29* | 6.00 ±1.08* | 9.71 ±1.34* | 9.00 ±1.38* |
| SPV | 5.50 ±1.19*+ | 9.01 ±1.09*+ | 6.75 ±0.50*+ | 12.15 ±1.20*+ | 7.85 ±0.73*+ | 19.51 ±1.74*+ | 6.89 ±0.98*+ | 9.68 ±1.19*+ |
| SPVdd | 5.04 ±1.28*+ | 7.16 ±1.10*+ | 5.93 ±0.745*+ | 11.01 ±1.22*+ | 6.62 ±0.53*+ | 16.88 ±1.21*+ | 4.55 ±0.89*+ | 8.06 ±1.10*+ |
| SVV | 7.00 ±0.82*+ | 7.87 ±1.09*+ | 7.87 ±0.93*+ | 12.62 ±1.70*+ | 10.25 ±1.46*+ | 16.62 ±2.06*+ | 7.37 ±1.03*+ | 13.37±1.98*+ |
| PIP | 18.88 ±1.46+ | 23.63 ±1.97+ | 19.50 ±1.28+ | 24.50 ±1.66+ | 17.88 ±1.17+ | 23.38 ±1.05+ | 19.14 ±1.72+ | 23.43 ±1.27+ |
| PAW | 9.63 ±0.49+ | 15.38 ±1.22+ | 11.00 ±0.82+ | 16.63 ±1.25+ | 9.75 ±0.52+ | 16.13 ±1.09+ | 10.00 ±0.65+ | 17.00 ±1.27+ |

* significant changes during fluid load

* significant changes at different tidal volumes

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# EVALUATION OF EFFICACY OF VARYING DOSES OF 0.5% BUPIVACAINE HEAVY WITH FENTANYL IN SPINAL ANESTHESIA IN PATIENTS UNDERGOING LOWER EXTREMITY SURGERIES: A COMPARATIVE, RANDOMIZED PROSPECTIVE STUDY

Anjum Naz[1], MD, Ramapati Sanyal[2*] MD,
Vishal Agarwal[1], MD

## Abstract

**Background:** Hypotension is a side effect often associated with spinal anesthesia which can be detrimental in certain clinical situations.Lesser doses of bupivacaine have been associated with lower incidence of hypotension and associated complications. Fentanyl when used intra-thecally enhances the sensory block of local anesthetics. We have evaluated the effect of three different doses of 0.5% heavy bupivacaine along with intrathecal fentanyl on intraoperative hypotension and recovery profiles.

**Methods:** 45 patients were randomly divided in three groups. Group A received 7.5 mg (1.5 ml) 0.5% heavy bupivacaine, 25 µg fentanyl and 0.5 ml of normal saline; Group B received 9 mg (1.8 ml) 0.5% heavy bupivacaine, 25 µg fentanyl and 0.2 ml of normal saline; and Group C received 10 mg (2 ml) 0.5% heavy bupivacaine and 25 µg fentanyl. All the groups were assessed for non-invasive blood pressure, two segment sensory regression, motor regression and the level of sensory block.

**Results:** Group C had a significant fall of blood pressure compared to Group A and B. The time to two segment sensory regression and time to motor regression was significantly longer in group C compared to the other two groups. Highest level of sensory block was up to T10 in group A, T7 in group B and T4 in group C.

**Conclusion:** Lower bupivacaine doses (9 mg and 7.5 mg)along with fentanyl 25 µg provide reliable spinal anesthesia with better hemodynamic stability and early recovery in lower limb orthopedic surgeries of duration two hours or less.

**Key words:** Spinal anesthesia; Bupivacaine; Low-dose; Intrathecal; Fentanyl

1 Department of Anesthesiology and Intensive Care, KPC Medical College and Hospital, Kolkata, West Bengal, India.
2 Department of Anesthesiology and Intensive Care, Tomo Riba Institute of Health and Medical Sciences , Naharlagun, Arunachal Pradesh, India.
*** Mailing address of the corresponding author:** Ramapati Sanyal, MD, Department of Anesthesiology, Tomo Riba Institute of Health and Medical Sciences, Old Assembly Complex, Naharlagun, Arunachal Pradesh, India. Telephone number: +919830163182. E-mail address: sanyalramapati@gmail.com

## Introduction

Spinal Anesthesia (SA) is a commonly used technique to anesthetize patients for lower extremity surgeries; however, it is associated with some unwanted side effects like hypotension, bradycardia intra-operatively, urinary retention, and prolonged immobility in the postoperative period.[1] In elderly and in patients with cardiovascular and respiratory diseases, hypotension can be particularly hazardous. White *et al.*[2] have demonstrated a significant correlation between hypotension, mortality and dose of intrathecal local anesthetic.

Hypotension during SA can be treated or prevented with the use of vasopressors and intravenous fluids which are associated with their own set of ill effects.[3,4] Lower doses of bupivacaine have been found to be associated with reduced incidence of hypotension and other complications during SA.[5]

The synergism of intrathecal fentanyl and local anesthetics is well established. Intrathecal fentanyl provides a rapid onset of sensory block and decreases the rebound pain without increasing the intensity of motor block contributing to early recovery.[6-8]

The present study was designed to compare three doses of heavy bupivacaine 0.5% with fentanyl 25 µg in SA with respect to incidence and degree of hypotension (systolic and mean) and time to recession of sensory and motor block. Comparison of level of sensory block and Bromage score was also done as a secondary outcome.

## Methods

This was a prospective randomized controlled study conducted in a tertiary care health center. The study was approved by institutional ethics committee (KPCMCH/IEC/870) and was prospectively registered with clinical trial registry, India (Registration No-CTRI/2018/01/011593).

Forty-five patients of age more than 18 years and ASA physical status I and II scheduled for lower limb orthopedic surgery were included in the study. A written informed consent was obtained from all the study subjects prior to enrollment. Patients with a history of spine surgery, spine deformities, skin infection and abnormal coagulation profile were excluded from the study. Patients were randomized into three groups using a sealed envelope technique to receive one of the three subarachnoid doses of 0.5% hyperbaric bupivacaine. Group A received 7.5 mg (1.5 ml) 0.5% heavy bupivacaine, 25 µg fentanyl and 0.5 ml normal saline; Group B received 9 mg (1.8 ml) 0.5% heavy bupivacaine, 25 µg fentanyl and 0.2 ml normal saline; and group C received 10 mg (2 ml) 0.5% heavy bupivacaine and 25 µg fentanyl.

After a thorough preoperative assessment and appropriate aspiration prophylaxis, patients were taken to the operation room. An intravenous infusion was started and monitoring of non-invasive blood pressure, oxygen saturation and electrocardiogram were established. Before the block, all patients were given a rapid infusion of 5- 8 ml/kg of ringer lactate as most patients posted for elective surgeries are on 7-8 hours of fasting. Subarachnoid block was given in sitting or lateral position as appropriate with the use of 25 or 26 G spinal needle at L3-L4 or L2-L3 interspace, and the patients received the drug as per randomization and were immediately placed in a supine position. The patients and physicians were blinded regarding the dosage of 0.5% heavy bupivacaine administered. The drug was prepared by one anesthesiologist who was not part of the study, and the commencement of anesthesia, assessment of patient and recording of study data were done by another anesthesiologist. Patients received intravenous midazolam 2 mg for sedation and amnesia. Patient's complaint of pain was treated with a bolus of intravenous fentanyl 1 µg/kg.

The following parameters were measured in all patients: Non-invasive blood pressure – Pre-procedure baseline blood pressure (mean of three readings taken at five minutes interval on the operation table) and then at five minutes interval for 30 minutes and throughout surgery. and throughout surgery. Hypotension was considered as a drop of more than 20% of the preoperative systolic blood pressure or a systolic pressure less than 90 mm Hg.

Sensory assessment–Height of sensory block achieved after the block and time to two dermatomal sensory regression was recorded.

Motor assessment– Final Bromage scale score

achieved after the block and time to motor recovery (one grade improvement in Bromage scale) was recorded.

## Statistical analysis

Based on previous studies, the probability of occurrence of hypotension with the use of normal dose bupivacaine in spinal anesthesia is 90%. Taking the confidence level of 95% and a power of 80% and assuming a clinical significance of 4%, the minimum number of sample required is 13.We recruited 15 patients in each group.

Data obtained was tabulated and analyzed by using Statistical Package for Social Sciences (SPSS) version 17 (New York). Statistics applied for the interpretation of results was mean and standard deviation, two way ANOVA with post hoc Bonferroni test for continuous variables and Chi square test for non-parametric and grouped variables. P value <0.05 was considered statistically significant.

## Results

A total of 57 patients were enrolled for the study and final analysis was done for 45 patients with 15 patients in each group (Figure 1). The three groups were comparable with respect to the demographic variables of the patients, and type and duration of surgeries (Table-1). One case of spinal failure in group B (9 mg of bupivacaine with fentanyl) and two cases of group A (7.5 mg of bupivacaine with fentanyl) which required conversion to general anesthesia in the later part of surgery were excluded from the study.

The baseline systolic and mean blood pressures of the three groups were comparable. After giving SA there were drops of systolic and mean blood pressures in group B and group C. The mean and systolic blood pressure in group C was significantly lower compared to group A at all time points (P<0.05; Figures 2, 3). In group B the mean blood pressure was significantly lower compared to Group A at 20, 25 and 30 minutes (Figure 2). However, the consumption of vasopressors was lesser in group B compared to group C. Patients in group A did not have a significant fall of blood pressure

*Fig. 1*
*Consort diagram of the study*

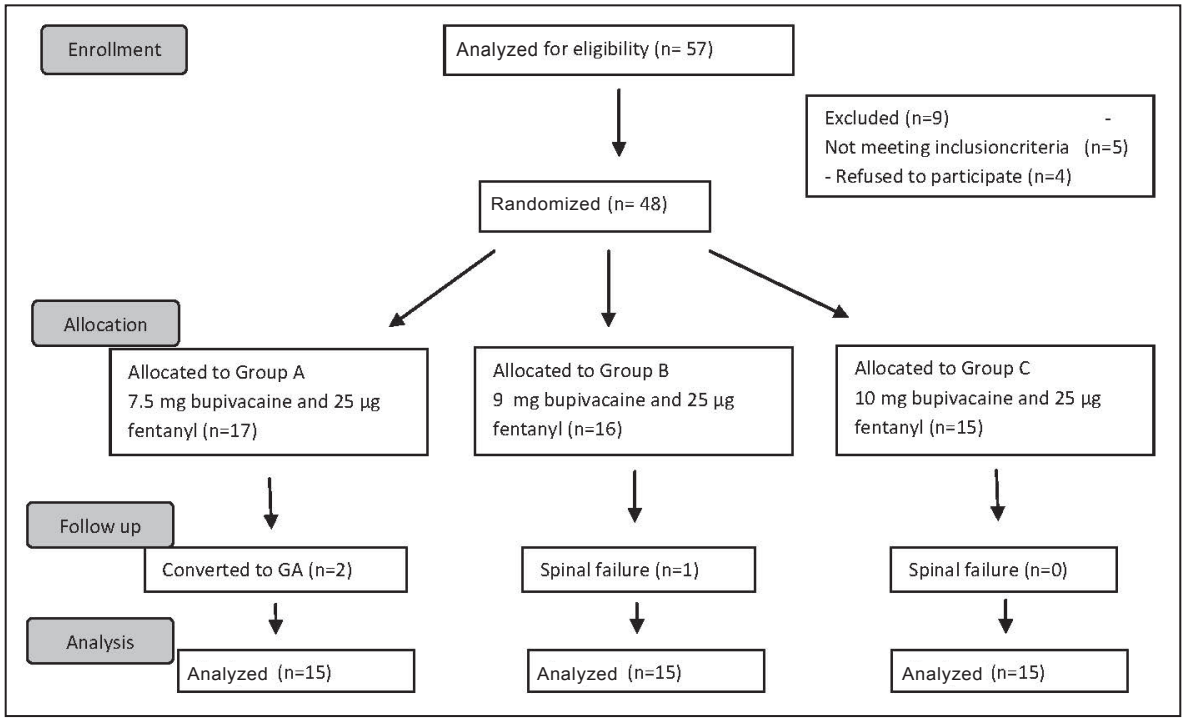


*Table 1*

*Demographics of the patients recruited for the study.*

| Parameters | Group A (n=15) | Group B (n=15) | Group C (n=15) | p Value |
|---|---|---|---|---|
| Age (yrs) | 56.6±15 | 52.5±13 | 47.1±16 | 0.233 |
| Weight (Kg) | 68±10 | 65±11 | 69±9 | 0.82 |
| Height (cm) | 163.2±8.9 | 163.4 ± 8.7 | 164.2 ± 7.8 | 0.244 |
| Sex(male/female) | 6/9 | 7/8 | 7/8 | 0.914 |
| Duration of surgery (mins) | 90±25 | 93±20 | 85±30 | 0.69 |

Data are mean ± SD or number of patients.

at any time points throughout the study period.

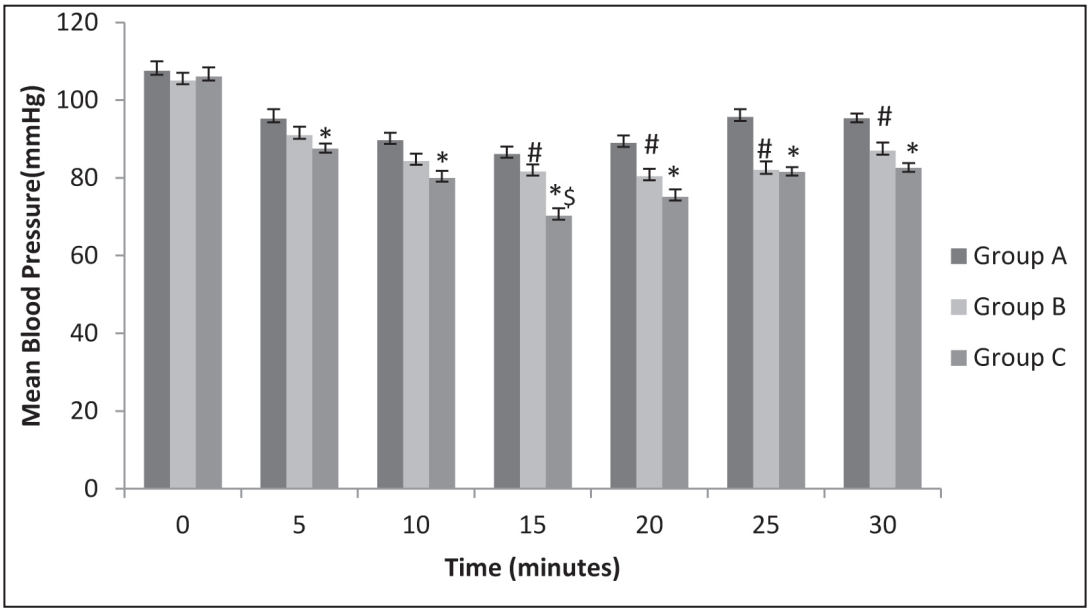
The two segment sensory regression time in group C was significantly longer than group A and group B ($p<0.05$), whereas it was comparable for group A and group B ($p> 0.05$). Similarly the time for one grade improvement in Bromage scale (motor recovery) was significantly longer in group C as compared to group A and group B ( $p< 0.05$; Table-2), whereas it was comparable in group A and group B ($p>0.05$).

The highest level of sensory blocks achieved in group A, group B and group C were T9-T11, T7-T9 and T4-T6 respectively (Table-2). Bromage scale scoring achieved in Group A was only 1 and 2; none of the patients had a score of 3. In group B and Group C the scores were mainly 2 and 3 (Table-2).

Regarding side effects, postoperative vomiting was observed in only two patients in group C and one patient in group B and none in group A. Hypotension was observed in six patients in group C and two patients in group B. Two patients in group A required general anesthesia at a later phase of the surgery and one patient in group B had a failed spinal. Pruritis was

*Fig. 2*

*Comparison of mean blood pressure of the three groups.*




* Significant - Group C to Group A, # Significant - Group B to Group A, $ - Significant Group C to Group B.

*Table 2*

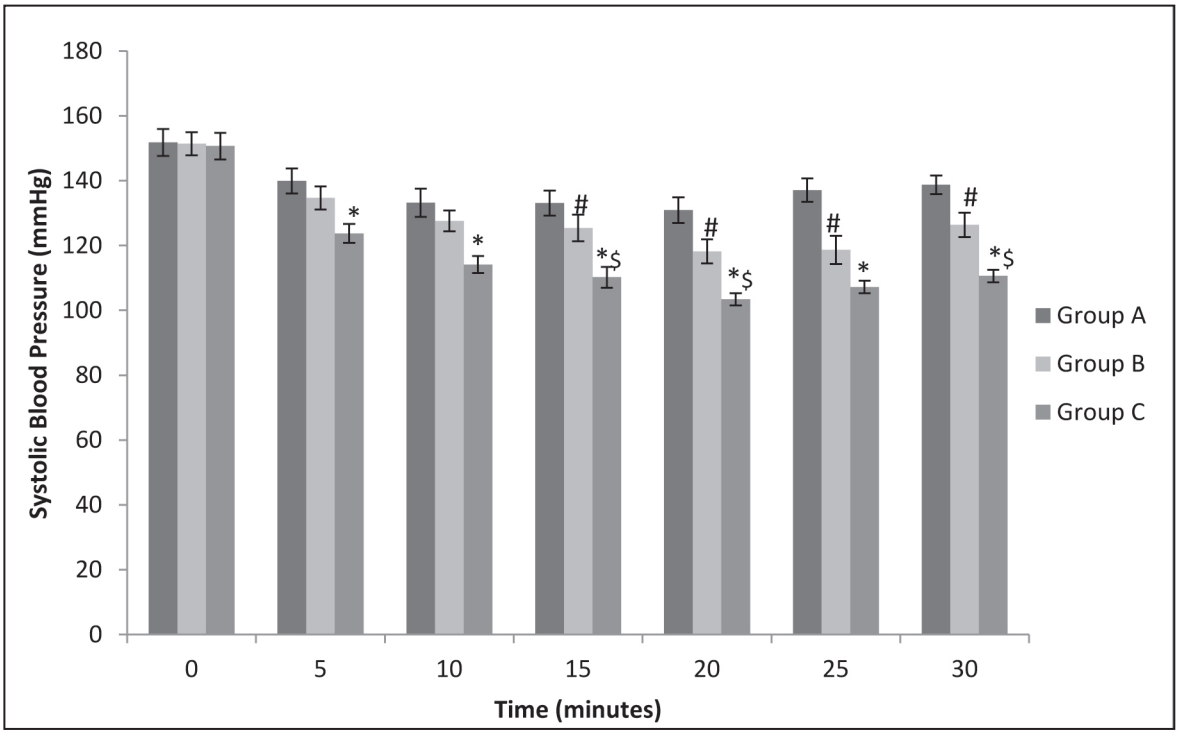
*Sensory and motor blockade characteristics.*

| parameters | Group A (n=15) | Group B (n=15) | Group C (n=15) | p Value |
|---|---|---|---|---|
| **Highest level of sensory block** | T9-T11 | T7-T9 | T4-T6 | NA |
| **Bromage Score (0/1/2/3)** | 0/8/7/0 | 0/0/10/5 | 0/2/8/5 | 0.003 |
| **Time to two dermatomal sensory regression (minutes)** | 122.6±10.79 | 119.7±10.27 | 132.3±7.32 | 0.002 |
| **Time to motor recovery (minutes)** | 93.2±12.53 | 99.2±9.80 | 119.0±3.60 | 0.0001 |

Data is expressed as numbers or mean±standard deviation. NA: Not applicable.

*Fig. 3*

*Comparison of systolic blood pressure of the three groups.*




* Significant - Group C to Group A, # Significant - Group B to Group A, $ Significant - Group C to Group B.

*Table 3*

*Side effects and complications among the three groups.*

| Side effect | Group A (n=15) | Group B -(n=15) | Group C (n=15) |
|---|---|---|---|
| **Vomiting** | 0 | 1 | 2 |
| **Hypotension** | 0 | 2 | 6 |
| **Failure** | 2 | 1 | 0 |
| **Pruritis** | 7 | 6 | 7 |

Data is expressed as numbers.

observed in 47% of patients in group A, 40% of patients in group, and 47% of patients in group C (Table-3).

## Discussion

This dose finding study was designed to find the lowest effective dose of bupivacaine which can be given along with 25 µg fentanyl to provide satisfactory anesthesia without the cardiovascular side effects in lower limb orthopedic surgeries. The optimum dose of intrathecal fentanyl as an adjuvant of local anesthetic is not clearly defined and have been used in the range of 10 µg to 25 µg.[8-12] Though, some authors have claimed the lesser doses to be effective with no incidence of respiratory depression and pruritis, the most commonly used dose of intrathecal fentanyl with minimal side effects is 25 µg.

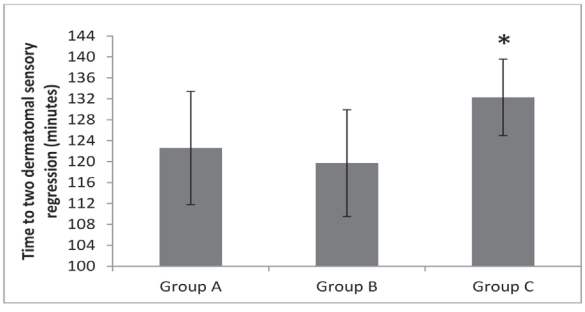
In the present study, the groups A and B showed better hemodynamic stability compared to group C. This is evident by the findings of marked reduction in blood pressure values in group C, despite the calculated use of vasopressors. The blood pressure was recorded every 5 minutes for 30 minutes after administering the spinal block. The drug gets fixed to the spinal cord in 20-30 minutes after administration, so maximum sensory level and sympathetic block will be achieved during that time. There was a significant fall in the mean blood pressure and systolic blood pressure in group C compared to group A at all time points. Similarly in group B significantly lower blood pressures (mean and systolic) were observed at 15 and 20 minutes compared to group A. However the requirement of rescue vasopressors was much lesser in group B compared to group C. Patients in group A didn't have a significant fall in blood pressure at any time point.

Ben-David compared 4 mg of bupivacaine along with 20 µg fentanyl with 10 mg of bupivacaine and found a significant difference in the incidence and severity of hypotension with no failures in patients undergoing hip fracture repair.[10] Similar findings were experienced by Hoda *et al*.[11] in patients undergoing surgical repair of hip fracture with 6 mg of bupivacaine and 20 µg fentanyl. In both the studies, the study population included elderly patients and there was no failure or conversion to general anesthesia. In elderly patients there is a delayed pharmacokinetics of drug which may be the reason for zero failure rates with the mini-doses of bupivacaine.

In the current study, the study population included both young adults and elderly patients so the dose lesser than 7.5 mg was not used. Intrathecal bupivacaine in a dose of 7.5 mg along with 10 µg fentanyl have been demonstrated to provide a reliable neuraxial block for patients subjected to percutaneous nephrolithotomy, with stable hemodynamics, good post-operative analgesia and acceptable patient and endoscopist satisfaction by Atallah *et al* .[12]

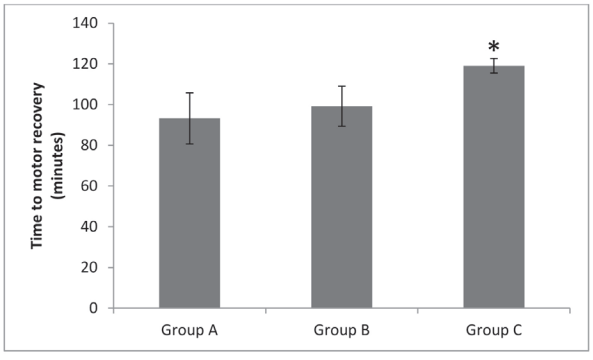
Hypotension due to pharmacological sympathectomy is the most common and serious side effect of SA with the use of conventional doses of local anesthetics. Large surveillance studies have observed

*Fig. 4*
*Comparison of the two dermatomal sensory regression of the three Groups.*




* Significant compared to Group A and B.

*Fig. 5*
*Comparison of the motor recovery of the three Groups. * Significant compared to Group A and B.*



incidences of hypotension around 33% in non-obstetric populations.[1]

Elderly, pregnant patients and patients with cardiovascular disease are susceptible to the negative impact of the hypotension. Besides, the usual dose of bupivacaine might delay the recovery of motor functions and can cause urinary retention, leading to delayed ambulation and discharge of the patient.[1,2]

Several techniques are adopted to prevent or treat the spinal anesthesia induced hypotension with varying results. The most common is preloading or co-loading with the crystalloid or colloid. This technique is much debated with not much convincing literary evidence.[3] Fluid loading, whether with crystalloids or colloids, alone is not effective to prevent sympathectomy induced hypotension and needs to be coupled with vasopressors. Excessive fluid loading can lead to other complications like pulmonary edema and full bladder requiring urinary catheterization. Nonetheless, 8 ml/kg of Ringer's lactate was used to preload all the study patients as they remained nil per oral for more than six hours before surgery.

Vasopressors which are commonly used in our institution to prevent and manage spinal anesthesia induced hypotension are the directly acting selective α1 receptor agonist phenylephrine and both direct and indirectly acting mephentermine. The best vasopressor for the treatment of spinal anesthesia induced hypotension is still unclear. Each vasopressor is associated with its own set of side effects and mandates a judicious use.[4]

Though, the use of low doses of local anesthetics may reduce the incidence and severity of hypotension, but may not provide adequate and reliable anesthesia. Opioids and local anesthetics administered together intrathecally have a potent synergistic analgesic effect. Intrathecal opioids, lipophilic as well as hydrophilic enhance analgesia from sub therapeutic doses of local anesthetic without prolonging motor block and recovery while making it possible to achieve successful SA using otherwise inadequate doses of local anesthetic. As intrathecal fentanyl does not cause depression of efferent sympathetic activity either alone or in combination with local anesthetic, it is possible to enhance the sensory blockade without altering the degree of sympathetic blockade.[6,7]

Chambers *et al*.[13] have demonstrated that an increase in the volume of 0.5% bupivacaine not only increases the cephalad spread of the drug but also the duration of action significantly. Many authors have demonstrated that addition of fentanyl to spinal anesthesia with diluted small-dose bupivacaine intensifies and increases the duration of sensory blockade without increasing the intensity of motor blockade or prolonging recovery to micturition or street fitness.[6,9,11,12] In the present study the dose of fentanyl was the same in all the groups. The maximium upper level of block was much higher in the group where 10 mg of bupivacaine was used compared to the other two groups and the time for sensory and motor recovery was also significantly more in the same group.

Many factors have been shown to be involved in the cephalic spread of the intrathecal drug. The concentration, dose and volume of the local anesthetic, and their interplay with the lumbosacral volume of cerebrospinal fluid are some of the aspects which determine the level of spread and the duration of the block. In a well-controlled study designed to understand the effects of volume, dosage and concentration on the intrathecal distribution of plain bupivacaine, Sheskey *et al*.[14] observed that dosage rather than volume or concentration was the important determinant. Patient posture and baricity of the drug are among the other factors which can affect the spread of the drug. It has been demonstrated that glucose concentration in excess of 0.8% in local anesthetic behaves as hyperbaric solution for all practical purposes. Though normal saline was added to the drugs used in group A and B to make the volumes identical in all the three groups, the bupivacaine had remained hyperbaric.[15] With lower concentration of glucose, the time of spread of the local anesthetic increases, which can be due to drug gliding off the slope of the lordotic lumbar curve towards the thoracic spine more 'lazily' compared to its more hyperbaric counterparts. As the lower limb is innervated by lumbar and sacral plexuses, levels up to T4 may not be required for the surgery.

There was a significant delay in two dermatomal sensory regression in group C compared to the other two groups. Similarly time of motor regression (recovery of one grade on Bromage scale) was significantly delayed in group C. Since the amount of

fentanyl used was constant, so the dose of bupivacaine is responsible for the delayed regression.

Nausea and vomiting associated with hypotension can be an unpleasant sensation for the patient. Venkata *et al.*[16] reported a significantly reduced incidence of nausea and vomiting with the use of lower dose of bupivacaine and 25 µg fentanyl compared to the conventional dose of bupivacaine due to the lesser hypotension associated with the lower dose of bupivacaine which concurs with the present study.

None of our patients in any group had cardiovascular instability requiring resuscitation. Intrathecal opioids are associated with late respiratory depression. Fentanyl is said to have lesser incidence of such events compared to morphine due to its shorter half life. There was no incidence of late respiratory depression in the present study which is consistent with the findings of other studies.[8,9]

All our patients were admitted at least one day before surgery and were not to be discharged on the same day so the assessment for street fitness was not taken into consideration. Urinary retention in the postoperative period is a common occurrence following SA. But time to urination though an important aspect of recovery from SA was not taken into consideration as many patients especially elderly males were catheterized preoperatively. This can be a limitation of our study.

Failed spinal was observed in one patient of the group where medium dose (9 mg) of bupivacaine was used. The etiology of a failed spinal is multi-factorial and is dependent on technical, drug and patient-related factors.[17]

Two patients in the group where low dose bupivacaine was used needed conversion to general anesthesia in the later parts of the surgery as the surgery got prolonged than the anticipated time. The speed and experience of the surgeon plays an important role in the outcome when lower doses are used. *Niar et al.* in a systematic review have established that the low dose spinal anesthesia has a high efficacy in ambulatory surgery. They found the lowest effective doses of bupivacaine for knee arthroscopy surgery was 4 mg and a reasonable discharge times were achieved using bupivacaine in doses 7.5 mg. They stressed that the type of surgery and the duration of surgery are very important factors influencing the efficacy of low dose SA.[18]

Pruritis is the most common side effect of intrathecal fentanyl but seldom requires treatment.[1] In the present study also mild pruritis was observed in 44% of patients but none needed treatment.

## Conclusion

Lower limb orthopedic surgeries of duration of 2 hours or less can be done with lower doses of bupivacaine (7.5 mg and 9 mg) with fentanyl as adjuvant. The incidence of hypotension is nearly absent with 1.5 ml (7.5 mg) and minimal with 1.8 ml (9mg) of 0.5% bupivacaine with 25 µg of fentanyl and can be beneficial in circumstances where intraoperative hypotension can be detrimental for the patient outcome. However, a dose of 7.5 mg may be associated with lower Bromage scale scores, higher rates of conversion to general anesthesia and lesser patient satisfaction, and therefore needs an extra consideration for the type and duration of surgery.

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# INCIDENCE, CAUSES, AND FINANCIAL IMPACT OF DELAY OF TRANSFERS FROM THE INTENSIVE CARE UNIT: A PROSPECTIVE OBSERVATIONAL STUDY

Adil Suleiman Al Kharusi,[1] MD, Nilay Chatterjee,[2] MD, DM, DESA, Samaresh Das,[2*] MD, DESA

## Abstract

**Objectives:** Delay of transfers are relatively common in busy intensive care units (ICU) because of many reasons. This study aims to analyse the incidence, causes, and financial impacts of delay of transfer from ICU.

**Methods:** A prospective observational study was conducted between January and December 2019. All the patients transferred from the ICU were included in the study. Data were collected for patients who were medically fit for transfer but remained in the ICU for one or more extra days. Reasons for delay were noted, extra costs associated were estimated, and the correlation between hospital admissions and overstay in ICU was calculated.

**Results:** Transfer from ICU was delayed in 6.33% (n = 50) of the 789 patients. Delays ranged from 1 to 7 days (mean 3.84 +/- 1.62). The most common reasons for the delay of transfer were i) unavailability of appropriate isolation beds (48%), ii) unavailability of bed in the wards (24%), iii) unavailability of suitable beds in the peripheral hospitals (24%), and iv) social or administrative reasons (4%). A positive correlation was found between the monthly hospital census and the ICU bed occupancy (Spearman rho = 0.87, p=0.041). Extra costs associated with delays of transfers were OMR 28800 (USD 74902) during the entire study period, translating a per patient excessive cost of OMR 576 (USD 1498).

**Conclusions:** Delay of transfer from ICU is common and incurs an unnecessary healthcare expenditure. A high hospital admission rate is associated with a delay in transfer of ICU patients to the wards.

**Keywords:** intensive care unit; patient transfer; patient isolation; beds; financial

1 Intensive Care Unit, Khoula Hospital, Mina Al Fahal, Muscat, Sultanate of Oman.

2 Department of Anaesthesia and Intensive Care Medicine, Yeovil District Hospital NHS Foundation Trust, Yeovil, United Kingdom.

*** Mailing address of the corresponding author: Samaresh Das, MD, DESA,** Consultant in Anaesthetics and Intensive Care Medicine, Yeovil, District Hospital NHS Foundation Trust. Mailing address: Yeovil, Somerset, BA21 4AT, United Kingdom. Telephone number: +44 7960 532682, Email address: drsamareshdas@gmail.com, samaresh.das@ydh.nhs.uk

## Introduction

Treatment in intensive care unit (ICU) is uniformly expensive all over the world[1,2]. As such, administrative and clinical efforts are focused to contain expenditures in order to use these precious resources wisely. Delayed discharges from ICU pose significant constraints on optimising hospital resources and results in financial and administrative burdens to the hospital. We conducted a prospective observational study to quantify the incidence and identify the causes responsible for delay of transfers from our ICU. We also attempted to find any association between hospital census with ICU overstay and the financial impact for each day of delay of transfers from ICU. To the best of our knowledge, this is the first study from the Sultanate of Oman addressing the extent of delay of transfers from ICU in a tertiary care hospital, its financial implications and the possible remedies towards a better healthcare utilisation and equitable distribution of resources.

## Methods

The study took place in a 30 bedded ICU of Khoula Hospital, a tertiary care teaching hospital in Muscat, Sultanate of Oman. After obtaining approval from the research and ethics committee, a prospective observational study was conducted between January and December 2019 in our ICU. Individual informed consents were not required and there was no deviation in terms of intensive care management of these patients.

All patients admitted to the ICU between January and December 2019 were included in the study. Patients who died during this period in the ICU, those who left ICU against medical advice and patients transferred to hospitals abroad for further treatment were excluded as they did qualify for ICU overstay. Data were collected for patients who were medically ready for transfer to the wards but remained in the ICU for one or more extra days for any reason other than medical. We recorded the reasons for each delay of transfer and calculated extra costs associated with the delay. We also calculated the correlation between hospital admissions and ICU overstay.

Our ICU runs on a semi-closed model where intensive care consultants and specialists are primarily responsible for patient care. The decision to transfer a patient to the wards or peripheral hospitals (from where the patient was referred to our tertiary care centre) was based on ICU discharge criteria and a broad consensus amongst consultant intensivist, the primary team consultant, and the ICU nurse in charge.

Data was collected about ICU transfers and delays of transfers from the ICU admissions and discharge register. The reasons causing delay of transfers from ICU for each patient were identified. On-call intensive care specialist collected and updated the register everyday midnight whenever any discharged patient was not transferred out of ICU to the respective destination due to any non-medical reason. The total duration of extra ICU stay, decision time of discharge from ICU, the actual date and time of transfer from ICU, cause of delay in transfer and additional expenses due to ICU overstay were obtained.

### *Data analysis:*

Data obtained from the study was analysed for each quarter of the study period. Data were expressed as numbers, percentage, and mean +/- SD. Spearman's correlation coefficient was calculated to determine a relationship between hospital admissions and higher ICU bed occupancy. A p-value $<0.05$ was considered as statistically significant. SPSS 25 (IBM SPSS Statistics, IBM Corporation) was used for data analysis.

## Results

Altogether 869 patients were admitted to our ICU (3.7% of all hospital admissions) between January and December 2019. During this period, 789 patients were transferred after treatment in ICU to different hospital wards or peripheral hospitals. Delays of transfers from ICU were recorded in 6.33% (n = 50) of the transfers (Table 1). A seasonal trend in ICU overstay was observed during the study period. The first quarter of the year had the maximum number of delay of transfers, whereas the second and last quarter of the year had the least (Table 1). Delay of transfer from the ICU ranged from 1 to 7 days (3.84 ± 1.62 days). The most common reasons for delay of transfers in

*Table 1*
*Intensive Care Unit admissions, discharges and transfer delays*

| Quarter | Total hospital admissions, n | Total ICU admissions, n (%) | Total transfers from the ICU, n | Total transfers for treatment outside/ LAMA, n | Total ICU deaths, n | Delay of transfer from ICU in days, (mean +/- SD) | Number of patients with delays, n (%) |
|---|---|---|---|---|---|---|---|
| Jan-Mar | 6,074 | 210 (3.45) | 187 | 4 | 19 | 4.22 +/-1.77 | 22 (11.76%) |
| Apr-Jun | 5,580 | 208 (3.72) | 195 | 2 | 11 | 3.75 +/- 1.83 | 08 (4.1%) |
| Jul-Sep | 5,839 | 217 (3.71) | 196 | 7 | 14 | 3.5 +/- 1.16 | 12 (6.12%) |
| Oct-Dec | 5,966 | 234 (3.92) | 211 | 6 | 17 | 3.87 +/-1.8 | 08 (3.79%) |
| Total | 23,459 | 869 (3.7) | 789 | 19 | 61 | 3.84 +/- 1.62 | 50 (6.33%) |

*LAMA: left hospital against medical advice

our ICU were 1) unavailability of appropriate isolation beds/rooms in the wards, 2) unavailability of beds in the wards, 3) unavailability of suitable beds in the peripheral hospitals, and 4) social or administrative reasons (Table 2). There was a positive correlation between hospital census (admitted in-patients) and ICU bed occupancy (Spearman rho; r=0.31, p=0.041). The average extra cost associated with each day of ICU overstay was estimated to be 576 Omani Rial equivalent to USD 1,498 (Table 2).

*Table 2*
*Incidence, causes, and financial impact of delay of transfer from the Intensive Care Unit*

| | |
|---|---|
| Common reasons for ICU overstay, n (%) | 1. Unavailability of isolation beds in wards: 24 (48.0%)<br>2. Unavailability of beds in wards: 12 (24.0%)<br>3. Unavailability of suitable beds in peripheral hospitals: 12 (24.0%)<br>4. Social/administrative reasons: 2 (4.0%) |
| Cost associated with ICU overstay (in OMR and USD) | Over entire study period: OMR 28,800, USD: 74,902<br>Average extra cost per overstay: OMR: 576, USD: 1,498 |
| Hospital census (correlation between hospital admissions versus ICU occupancy) | Spearman Rho=0.98, p=0.041 |

* OMR=Omani Rial, USD=United States Dollar (1OMR=2.6USD)

## Discussion

The present study revealed an average delay of transfer of 3.84 days among eligible patients (ready for discharge) in 6.33% of the ICU transfers in Khoula Hospital. Unavailability of isolation beds/rooms (appropriate for patients requiring infectious contact precautions) in the wards was the principal reason accounting for almost half of the delays. The delay in timely transfers resulted in a combined loss of OMR 28,800 (USD 74,902) during the study period.

An Australian study in 2004 found that 27% of ICU transfers were delayed (median delay time was 21.3 hours; range, 10 minutes to 26 days)[3]. Unavailable ward beds (81%) were the main reason for the delay in discharge[3]. Edenharter G et al. reported delayed transfer from the ICU to the wards in 24.8% of the transfers. Lack of appropriate bed in the ward was responsible for 91.7% of those delays. In their study, the internal cost calculation showed 1 min of delay corresponds to 0.75 Euro (1,080 Euro/day), which led to a total cost of Euros 199,268 (~ USD240,000) for the study period[4]. Ofoma and colleagues explored the associations between hospital occupancy, ICU transfer delay and hospital mortality. They showed that a hospital occupancy level above 80% was associated with longer transfer delays, which might be

associated with increased hospital mortality[5]. Johnson and colleagues conducted a prospective observational study on incidence, causes, and financial impact of delay of transfer from the intensive care unit[6]. Their study showed transfer from surgical ICU to the floor was delayed in 22% of patients with delay ranged from 1 to 6 days (mean 1.5 days). The extra costs associated with delays were estimated to be USD 21,547/week (USD 3,078/day). The two most common reasons for the ICU overstay were lack of available surgical-floor bed (71%) and lack of isolation bed/room (18%)[6]. Similar to the findings of Ofoma et al.[5], Johnson DW and colleagues also showed an association between the daily hospital census and the daily number of Surgical ICU beds occupied by patients delayed in transfer[6].

We had multiple compelling reasons for delays in the timely transfer of patients from our ICU. First, our hospital is a tertiary referral centre catering to the entire country for neurosurgical, spine and neurological complex cases; therefore, availability of beds in wards and particularly beds appropriate for patients requiring contact precautions for their infections (isolation room/ beds in the wards) is a perpetual problem. Together they accounted for 72% of the delay of transfers. Second, the logistics of transfer to a peripheral hospital (i.e., availability of beds in peripheral hospitals, transfer arrangements within a reasonable time frame within the day) once their management in our centre is over was also an important reason responsible for delay in 24% of the transfers, and third, social and administrative issues, although small but could delay 4% of the transfers.

As per the hospital protocol and established guidelines, patients infected or colonised with multidrug-resistant organisms or Clostridium difficile must have single rooms or share a room with patients infected with the same organism[7]. In Khoula Hospital isolation beds (single room or in the wards) outside ICU were minimal. Therefore, in our study, the main reason for the delay of transfer from ICU unavailability of isolation beds/room. Evidence in published studies is divided regarding the efficacy of contact precautions; however, it is still recommended to keep infected patients isolated. The trend is unlikely to change soon[8,9]. The main reasons for unavailability of floor beds were delay in transferring ready to discharge patients from the wards to home, delay in decision-making by the admitting physician, hesitation of the ward nurses about optimum care of tracheostomised patients, and at times administrative reasons resulted delayed transfer. Being a tertiary care national centre for trauma, spine, and neurological diseases Khoula Hospital encounters tremendous constraints regarding availability and turnover of in-patient beds in the wards. We do not have a high dependency unit or surgical step-down unit in the hospital, which compounded the bed availability problem by many folds. Delay of transfer due to beds unavailability in peripheral (referring) hospitals is a unique finding in our study. The reason behind this is multifactorial: scarcity of specialised workforce (trained doctors and nurses) in smaller peripheral hospitals situated in different corners of the country, low bed turnover, and inadequate infrastructure for follow-up of complex cases in such hospitals are some of the factors that caused a delay in 24% of the transfers. At times, lack of communication and shared decision-making with patients' relatives or next of kin resulted in poor compliance (on their part) while we were planning a transfer to a peripheral hospital, which resulted in a delay in 4% of the transfers. Despite all these contributing causes described above the present study showed that the delay of transfer from our ICU (6.33% of total transfers) is comparable or better than many of the published studies[3-6].

Delays of transferring from ICU have considerable financial burden on the healthcare system. ICU care is expensive globally because of staffing pattern (doctor to patient and nurse to patient ratio), expensive equipment, infrastructure, and consumables. Therefore, the duration of ICU overstays disproportionately increases the overall costs compared to ward-based care. It also prevents judicious utilisation of precious ICU resources by obstructing ICU admission of some of the sickest but salvageable patients; the impact of which can not be computed in terms of money. In a recently published study (2020), Bagshaw and colleagues showed that 6.4% of total ICU cost is attributable to the avoidable time patients spent in the ICU[10]. Our internal cost analysis which revealed an increased cost of OMR 28,800 (USD 74,902) associated with delay of transfers over the entire study period or OMR 576 (USD 1,498) for each day of ICU overstay. Published studies have shown similar estimates for each day of

ICU overstay[4,6,10].

Our study had some limitations. It was a single centre study in a tertiary care surgical ICU. Available staffing in the hospital wards and peripheral hospitals might have affected the outcome. We did not analyse the reasons behind seasonal trends in the delay of transfers. We estimated the average cost; however, it is not uniform over the period. In a study, Dasta and colleagues demonstrated the higher expenses during the initial two days of ICU care[11]. We counted the time of delays in days, but it could have been more realistic to count in hours. Our cost estimates expenses are accurate only for hospitals governed by the Ministry of Health, Sultanate of Oman, and may not be applicable for private hospitals.

The present study brought some remarkable changes. Creation of more isolation bed for patients requiring contact precautions, revamping day-care surgery, timely discharge of patients from wards, training of bedside nurses to recognise ready to discharge patients, educating junior doctors regarding the discharge process, and better liaison with peripheral hospitals: are some of the direct impacts.

## Conclusion

Delay in discharge from the ICU is common in every hospital, increasing the hospital expenses and quality of healthcare. Timely intervention and proper planning could help to reduce the delay. Healthcare workforce should be trained to identify the cause and mitigate the issue.

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# EFFICACY OF FORCED AIR WARMING VERSUS WARMED IRRIGATION FLUID FOR PREVENTION OF HYPOTHERMIA AND SHIVERING DURING TRANSURETHRAL RESECTION OF PROSTATE UNDER SPINAL ANESTHESIA

Tarek I. Ismail[1*], MD, Mohammed Hasan[2], MD

## Abstract

**Background:** Hypothermia is a common observation in elderly males undergoing transurethral resection of prostate (TURP) under spinal anesthesia. Warmed irrigating solutions have been shown to reduce heat loss and the resultant shivering. Prewarming and intraoperative warming with forced air-warming system prevents perioperative hypothermia and shivering in many surgical procedures. The aim of this study was to test the hypothesis that intraoperative forced air-warming alone could prevent hypothermia and shivering in elderly patients undergoing TURP under spinal anesthesia when compared to warmed irrigation fluid.

**Methods:** One hundred and twenty elderly patients scheduled for TURP under spinal anesthesia were randomly assigned to one of 2 groups. Group 1 received intraoperative forced-air skin warming and group 2 received warmed irrigation fluid. Core temperature and shivering scores were recorded at 15-min intervals during intraoperative period. Incidence and severity of hypothermia also recorded from admission to operating room till end of surgery.

**Results:** Demographic and surgical data were similar between study groups. Patients on warmed fluid irrigation had significantly lower mean core temperature than those on forced-air warming at 45-, 60-minutes intraoperative as well as at the end of surgery ($p<.05$). 76.7% of patients who received warmed irrigation fluid developed shivering compared to 26.7% of patients assigned to forced-air warming ($p<.001$).73.3% of patients on warmed irrigation fluid experienced hypothermia (core body temperature< 36 °C) Of them, 23.3% were mild, 45% were moderate and 5% were profound. 25% of patients on forced-air warming had hypothermia. Of them, 11.7% developed mild and 13.3% developed moderate hypothermia while none of patients were categorized as profound ($p<.001$).

**Conclusion:** Intraoperative forced-air warming is effective in decreasing the incidence of intraoperative hypothermia and shivering during TURP when compared to warmed irrigation fluid.

**Keywords:** Hypothermia; Spinal anesthesia; Warmed irrigation; Forced-air warming

1 Department of Anaesthesia and Surgical Intensive Care, Faculty of Medicine, Helwan University, Egypt.
2 Department of Urology, Faculty of Medicine, Helwan University, Egypt.
* **Mailing address of the corresponding author:** Tarek I. Ismail, Department of Anaesthesia and Surgical Intensive Care, Faculty of Medicine, Helwan University, Egypt. Mailing address: 152 Tiba st. Sporting, Alexandria, Egypt. Telephone number: +2001001467166. Email address: drtarek.anesth@gmail.com , tarek.ismaeel@med.helwan.edu.eg

## Introduction

Perioperative hypothermia is an accidental decrease in core body temperature < 36 °C during intra or immediately postoperative period.[1] Impairment of thermoregulatory mechanism from anesthesia, surgical factors and/or environmental conditions in the operating theatre are the main causes of perioperative hypothermia.[2] Heat redistribution from the core to the periphery secondary to anesthesia induced vasodilation is the most important cause of perioperative hypothermia.[3] The temperature gradient between the core and the peripheral compartments quantifies the amount of heat redistribution.[4] Skin pre warming with forced air warming system before induction of anesthesia can decrease this gradient by increasing the heat content of the peripheral tissue.[5]

Perioperative hypothermia can lead to detrimental sequels such as blood loss, surgical wound infection, myocardial ischemia and delayed recovery from anesthesia.[6] Hypothermia also induces shivering which is a potentially serious complication as it increases patient oxygen consumption nearly five folds.[7] In low cardiac reserve patients, this elevation of oxygen consumption increases risk of myocardial ischemia, cardiac arrhythmia and myocardial infarction in the first postoperative day.[8] Transurethral resection of prostate (TURP) is a very common surgical procedure of elderly male. Many TURP patients have chronic pulmonary or cardiac diseases.[9] Hypothermia and subsequent shivering is very common during TURP surgery. In addition to the anesthesia role in induction of hypothermia, the TURP procedure entails bladder irrigation with large amounts of fluids that result in heat loss and drop of core body temperature by 1-2°C.[10] Many methods were investigated to avoid heat loss and to reduce the risk of unintentional hypothermia associated with anesthesia and surgical technique. Warming of irrigation fluids was proven to prevent drop of body temperature during TURP.[11]

On the other hand, pre-operative warming of skin surface using forced –air warming devices for different short periods of time were examined. It has been reported to decrease the temperature gradient and heat redistribution between the core and the periphery with subsequent reduction of shivering and prevention of hypothermia.[12]

We hypothesized that intraoperative skin surface warming using a forced- air warming device after spinal anesthesia might reduce perioperative hypothermia and shivering when compared to warm irrigation fluids during TURP. Thus the aim of this prospective, randomized study was to compare temperature changes in patients undergoing TURP under spinal anesthesia either using intraoperative forced air warming or warm irrigation fluids.

## Methods

This randomized, controlled, clinical trial was approved by the research ethics committee of faculty of medicine, Helwan university and was registered in Pan African Clinical Trial Registry (PACTR 201907657139393). Written informed consent was obtained from all study participants. The study was conducted at Andalusia Smouha hospital, Alexandria during the period from 1 March 2019 to 31 December 2019.

Patients scheduled to undergo TURP and who were between 60-80 years old, American Society of Anesthesiologists (ASA) physical status Ⅰ-Ⅲ were considered for the study. Patients with chronic major respiratory, cardiovascular or endocrinal diseases, electrolyte abnormality, preoperative anemia, fever (core temperature >37.5 °C), preoperative coagulopathy or on anticoagulant therapy were excluded from the study. A detailed preoperative evaluation was done for all patients. No premedication was given to any patient.

Upon arrival to the operating room (OR) an intravenous (IV) access was established, and all patients received ringer acetate at a dose of 10 ml/kg. All IV fluids used during operation were kept at room temperature. Standard monitoring including electrocardiogram (ECG), pulse oximetry (SpO2) and noninvasive blood pressure (NIBP) were attached to all patients. Core temperature of the patient was measured via mouth with the use of digital medical infrared thermometer (Anchen, Gdt 3008, Jiangsy, China). Operating room temperature was kept at 21-22 °C and relative humidity around 40%. Randomization of patients was done using computer

generated methods into 2 groups: Intraoperative forced air warming (FA) group (60 patients), and intraoperative warmed irrigation fluids (WF) group (60 patients). A person not involved in this study allocated the groups to the envelopes labeled with consecutive numbers. The research nurse opened the sealed envelopes in numerical order after observing the patient's written consent. All patients were instructed to stay in the sitting position. Subarachnoid block using 23 G spinal needle and 12.5 mg 0.5 % hyperbaric bupivacaine (Heavy Marcine, Astra Zeneca, Egypt) was given to all patients. After that, patients were turned to supine position and adequate block level was confirmed by pinprick method. Then patients were turned to lithotomy position and were covered with one layer of surgical drapes over upper limbs, neck, chest, abdomen till umbilicus, thigh and calves. IV ringer acetate at constant rate of 6 ml/kg/h in both groups was started immediately after spinal anesthesia. Surgical intervention was the same for all patients using bipolar resection with well lubricated resectoscope (Olympus, Hamburg, Germany). The average sizes of prostate for all patients were comparable. The height of the irrigation fluid was kept around 60 cm for all cases. With the beginning of the surgery, the active warming group patients received active warming with forced air blanket (Bair-Hugger, USA). The blanket was over body type covering neck, chest, abdomen till umbilicus, and thigh. The thermostat of the warmer was set at 38 °C. The active warming period continued till the end of the surgery. If the patient became over warmed or started sweating, the temperature of the warming cover was reduced accordingly. Patients in this group received irrigation fluids at room temperature. In the WF group, with the beginning of the surgery, patients received only warmed irrigation fluids that were maintained throughout the surgical procedure. Normal saline solution 1 liter bottle (Otsuka, Egypt) was used as irrigation fluid. It was warmed by using water bath warmed incubator (El Shames Company Ltd, Alexandria, Egypt). The irrigation fluids were immersed and kept at constant temperature of the incubator at 38 °C. The temperature of the irrigation fluids was measured with mercury thermometer put inside the water bath. The irrigation fluids were taken from the incubator to be used immediately to avoid drop of their temperature. During the study period, heart rate, peripheral oxygen saturation and arterial blood pressure were observed. When systolic blood pressure fell to 80% below base line value, ephedrine (10 mg) was given at 3 min intervals. At the end of surgery, all patients were transferred to post anesthesia care unit (PACU) and after fulfilling discharge criteria from PACU, patients were transferred to their rooms.

One investigator blinded to the study estimated the perioperative outcomes, patient characteristics including age, weight, ASA status, duration of surgery, prostatic volume, amount of irrigation fluids, IV fluids, and ambient temperature in the operating room.

Core temperature and shivering scores were recorded on arrival to the operating room (baseline), immediately after induction of spinal anesthesia, and every 15 min till the end of surgery. Incidence of hypothermia from admission to operating room till end of surgery was collected. Hypothermia was defined as decrease of core temperature to less than 36 °C and severity of hypothermia were graded to mild (35.5-35.9°C), moderate (35.0-35.4°C) and profound (34.5-34.9°C).[13] Rating of shivering was achieved by using Bedside Shivering Assessment Scale (0=no shivering; 1=shivering localized to neck and thorax; 2=shivering involving the upper extremities with or without shivering in the thorax; and 3=shivering involving the entire body).[14] IV meperidine (25 mg) was given to any patient with shivering score of 2 or more.

## Statistical Analysis

A minimum required total sample size of 120 patients undergoing TURP under spinal anesthesia was divided to 60 patients assigned to receive intraoperative warmed irrigation fluids and 60 patients receive Intraoperative forced air warming to achieve 80% power (PASS 14 Power Analysis and Sample Size Software (2015). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass) and to detect a mean difference of 0.2 Celsius based on the hypothesis that mean core temperature change from baseline is 0.6 °C among patients with intraoperative forced air warming and 0.8 °C in patients undergo intraoperative warmed irrigation fluids with estimated group standard deviations of 0.3 and 0.3 respectively. Calculation was

performed at 0.05 significance level (alpha) using a two-sided two-sample t-test.[15,16]

The primary outcomes were core temperature changes during the intraoperative period, incidence and severity of hypothermia.

Data are expressed as mean± standard deviation, and numbers or percentages as appropriate. Chi-square test was performed to study significant association between categorical variables. Monte-Carlo significance was used if more than 20% of total expected cell counts <5 at .05 level of significance. We used independent sample t test to detect significant difference in the mean quantitative variables between two treatment groups of patients based on normal distribution of variables by Kolmogorov-Smirnov test and large sample size >30 per group. We conducted mixed design repeated measures ANOVA to study if statistically significant main effect of time, main effect of treatment whether Forced air warming and warmed irrigation fluid and if interaction is present in form of pattern change of mean core temperature along different points of time between both two treatment groups. Adjusted post hoc-pairwise comparisons were employed by Bonferroni tests.[17] Statistical significance was considered at $p<0.05$ level using IBM SPSS statistics program version 21 and Microsoft Excel[18].

## Results

120 patients were included in our study with no patients were lost follow-up, (Figure 1). 60 patients were randomized to receive forced air warming and 60 patients were randomized to receive warmed irrigation fluid.

Table 1 illustrates the baseline characteristics of included participants. There were no significant differences in mean age, weight, and prostate volume between the two groups. Also, the mean duration of surgery, mean irrigation volume, mean amount of IV fluids and mean ambient room temperature were not different between the two groups. Around one-third of patients were classified as ASA grade II per each arm of treatment.

Mean core temperatures were measured in patients assigned to forced-air warming and warmed irrigation fluid groups at different time intervals. There were no statistically differences between the two groups at baseline, after spinal anesthesia, at 15- and at 30-minutes intraoperatively. However, patients who received warmed fluid irrigation had significantly lower mean core temperatures at 45-, 60- minutes

*Table 1*
*Baseline characteristics of included participants in Forced air warming and warmed irrigation fluid groups.*

| | Forced Air Warming (n=60) | Warmed Irrigation Fluid(n=60) | p-value |
|---|---|---|---|
| Age (Years) | 68.93±2.79 | 68.73±2.27 | 0.667 |
| Weight (Kg) | 70.32±3.42 | 70.0±3.12 | 0.597 |
| Duration of Surgery (min) | 69.383±5.91 | 69.97±6.19 | 0.599 |
| Prostate Volume (CC) | 64.03±6.19 | 64.28±6.42 | 0.829 |
| Irrigation Volume (Liters) | 49.12±6.10 | 49.683±6.02 | 0.610 |
| IV Fluids (ml) | 623.33±186.50 | 628.33±209.18 | 0.890 |
| Ambient Room Temp (C) | 21.87±.34 | 21.78±.41 | 0.233 |
| ASA | | | 0.699 |
| I | 39(65.0%) | 41(68.3%) | |
| II | 21(35.0%) | 19(31.7%) | |

*Table 2*
*Comparison of mean core Temperature between patients assigned to Forced air warming and warmed irrigation fluid groups at different time points.*

| | | **Forced air warming (n=60)** | **Warmed irrigation fluid(n=60)** | **p-value** |
|---|---|---|---|---|
| Core Temperature | Baseline | 36.77±0.13 | 36.77±0.14 | 0.839 |
| | After spinal Anesthesia | 36.70±0.13 | 36.68±0.15 | 0.363 |
| | At 15-minutes | 36.52±0.22 | 36.47±0.18 | 0.193 |
| | At 30-minutes | 36.35±0.22 | 36.21±0.25 | 0.001 |
| | At 45-minutes | 36.21±0.25 | 35.98±0.30 | <0.001 |
| | At 60-minutes | 36.07±0.29 | 35.75±0.36 | <0.001 |
| | At end of surgery | 36±0.34 | 35.53±0.40 | <0.001 |

*Fig. (2a):*
*Change of mean core temperature*
*for Forced air warming group.*

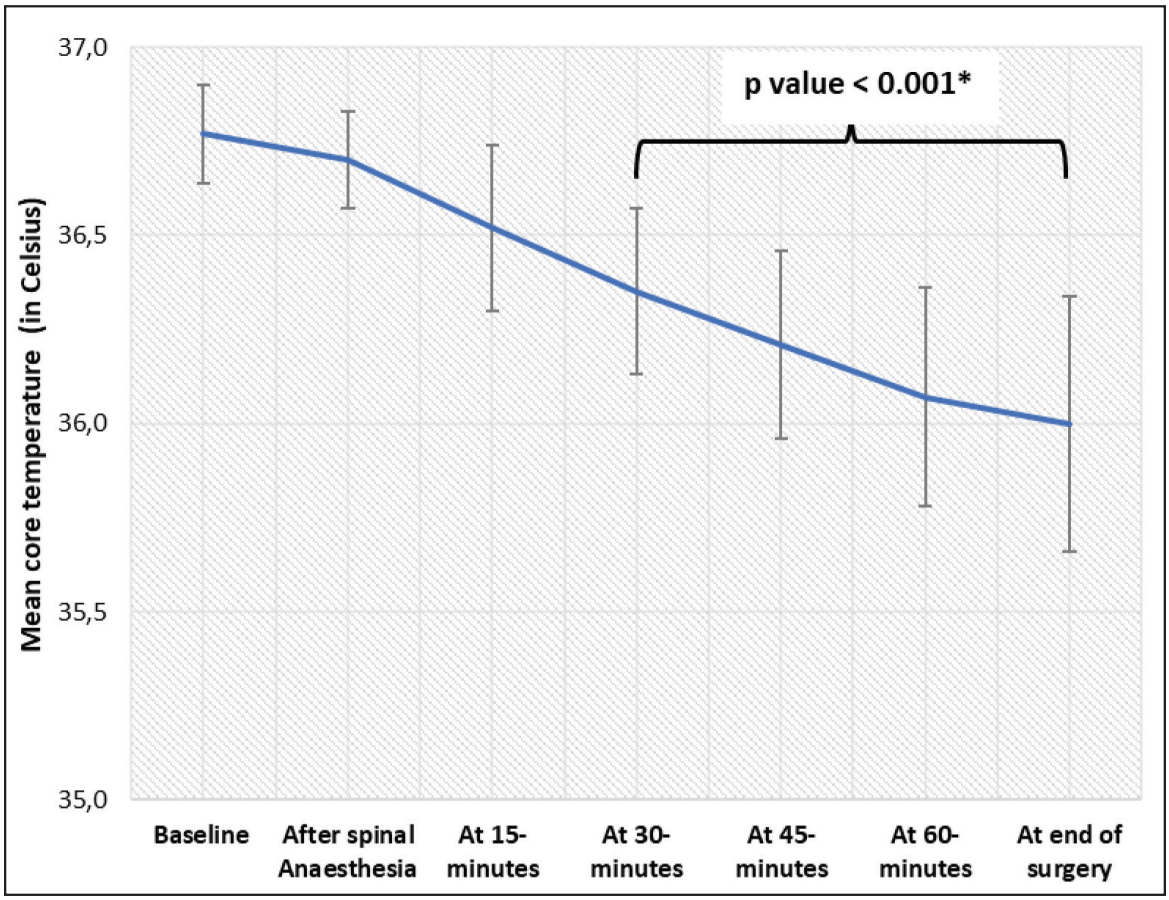
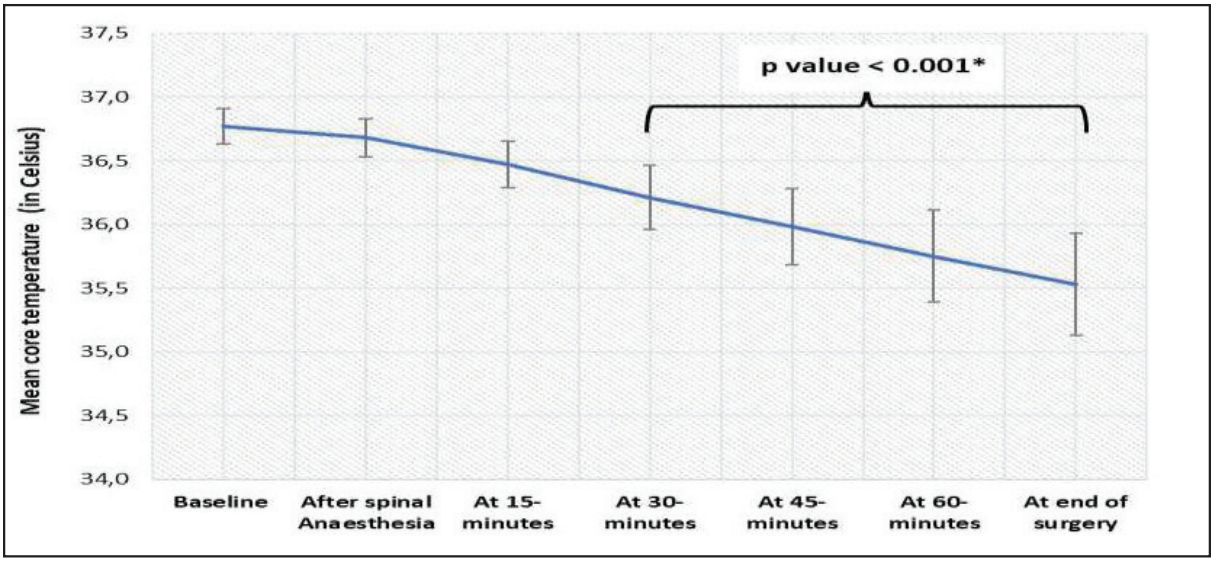



*Fig. (2b):*
*Change of mean core temperature*
*for warmed irrigation fluid group.*



intraoperatively as well as at the end of surgery compared to patients in the forced air warming group (Table 2). Also, mean core temperature significantly declined relative to baseline per each group (Figures 2a-b).

The incidence and severity of shivering were significantly lower in patients who received forced air warming compared to patients who received warmed irrigation fluid (Table 3). Similarly the incidence and severity of hypothermia were significantly lower in patients who received forced air warming compared for patients who received warmed irrigation fluid (Table 3).

## Discussion

Our trial confirmed the effectiveness of intraoperative skin surface warming using forced-air warming device in preventing perioperative hypothermia and shivering when compared to warm irrigation fluids. We observed fall of core temperature in both groups toward the end of surgery, however these changes were significantly less in forced air group when compared to warm irrigation group. The mean core temperature in the warming group around the end of surgery was 36 °C, which was 0.47°C higher than the mean core temperature in the other group; moreover, incidence of hypothermia was only 25% of patients in the warming group compared with 73.3% in the other group. The incidence and severity of shivering in the intraoperative period were significantly lower in the active warming group when compared to the other group.

*Table 3*
*Comparison of incidence and severity of shivering and hypothermia between Forced air warming and warmed irrigation fluid groups.*

| | **Forced air warming (n=60)** | **Warmed irrigation fluid (n=60)** | **p-value** |
|---|---|---|---|
| Incidence of Shivering | | | |
| Shivering | 16 (26.7%) | 46 (76.7%) | <0.001 |
| No Shivering | 44 (73.3%) | 14 (23.3%) | <0.001 |
| Severity of shivering | | | |
| 1 | 9 (15.0%) | 26 (43.3%) | <0.001 |
| 2 | 7 (11.7%) | 20 (33.3%) | <0.001 |
| Incidence of hypothermia | | | |
| Hypothermia | 15 (25%) | 44 (73.3%) | <0.001 |
| No hypothermia | 45 (75.0%) | 16 (26.7%) | <0.001 |
| Severity of hypothermia | | | |
| Mild | 7 (11.7%) | 14 (23.3%) | <0.001 |
| Moderate | 8 (13.3%) | 27 (45.0%) | <0.001 |
| Profound | 0 | 3 (5.0%) | <0.001 |

TURP entails using large amounts of irrigating fluids in order to open the mucosal spaces and to get rid of prostatic tissue slices and blood clots from the operating filed. Cold irrigation fluids are an important cause of heat loss and core body temperature drop by 1-2°C.[19] Absorption of large amounts of irrigation fluids were also previously mentioned as a cause of the resultant hypothermia.[20] Moreover, spinal anesthesia, the recommended technique of TURP surgeries also cause deterioration of the thermoregulatory function of the autonomic nervous system in addition to peripheral vasodilation in the blocked dermatomes that result in heat redistribution from core to peripheral compartment with subsequent hypothermia.[21]

Warming of skin surface using forced air transfers real amounts of heat to the whole body.[22] If body heat content increases, temperature gradient between peripheral and core compartment decreases i.e. the quantum of this heat redistribution depends mainly on the temperature gradient between the core and the peripheral compartment. This decrease will prevent hypothermia irrespective to its cause[22] in the same way, the optimal temperature of irrigation fluid to use during TURP has been a source of debate in many clinical trials.[23-25] following intense calculation of patients' basal metabolic heat production and heat energy achieved from warm irrigation fluids(heat balance calculations), Allen reported that other factors must have more strong effects on body temperature than irrigation fluid temperature during intraoperative period in TURP surgeries.[23] Hahn also in his study of hypothermia following TURP confirmed the same belief. HE found that increase volumes of irrigation fluids were associated with significant drop of core

body temperature when compared with lesser amounts of irrigation fluids.[26] This finding confirms the idea that the principal mechanism of heat loss during TURP may be more related to irrigation fluid absorption than to its temperature. Hahn later on reported that limiting surgical duration to 60 minutes may prevent hypothermia due to lesser fluid absorption irrespective to its temperature.in our trial,[27] we believe that using intraoperative active forced air warming may have a greater impact on preventing drop of core body temperature secondary to use irrigation fluid at room temperature and more effective than using warm irrigation fluid alone. The mechanism of perfection of the surface warming machines relies mainly on heat transfer per unit area. Even defective wormers may do well when available surface area for warming is enough.[28]

in our study we used over body warm blanket that cover the whole upper body till umbilicus in addition to the thighs, so the body surface area exposed to forced air warming was relatively high and this could explain the positive effect of forced air warming. On the other hand we believe that failure of pre warmed irrigation fluid to prevent perioperative hypothermia was related to their flushing into the urinary bladder as a part of the procedure with subsequent drop of its temperature and so using of large amounts of irrigation fluids in the current trial (>40 liters) was the leading cause of the progressive cooling in the second group.[29]

Jaffe et al closely agree to our results, they observed that warmed irrigation fluid was not enough to avoid core body temperature drop in patients undergoing TURP.[30] They suggested that other variables could be responsible for perioperative hypothermia such as the duration of stay in the operating room and its ambient temperature, amount of irrigation fluid absorbed and resection time. They recommended that limiting resection times, proper nursing care, and strict use of warming blanket intra and postoperatively are essential to help the patients in preserving their core body temperatures. The results of the current study contrast with those of Butwick et al.[31] They concluded that intraoperative forced air warming did not prevent intraoperative hypothermia and shivering in women undergoing caesarean delivery under spinal anesthesia, however in their study forced air warming was applied to lower limbs just distal to the inguinal fold while the remaining part were not warmed. Moreover, sensory block >T4 dermatome was achieved for all case which resulted in more extended vasodilation secondary to sympathetic block when compared to only T10 dermatome height block in our trial.

Tyvold also contrasts our results. He reported that forced air warming reduced heat loss to a certain extent when compared to self-warming blanket, but it was insufficient to prevent perioperative hypothermia. However, the blanket used in his trial was under body type.[32] Posterior surface warming is also limited by the restricted perfusion in dependent capillaries and subsequent reduced ability to distribute heat to the rest of the body. Moreover, the exposed skin surface in his trial was relatively high as in many cases surgical procedure was involving the whole abdomen and lower extremities and the blanket was then applied to upper thorax and upper extremities only.

In our trial, the incidence and severity of shivering in the intraoperative period could be related to the fact that patients in the first group did not reach the shivering threshold which is 35.5±0.5°C like the other group.[33]

In agreement to the results of the present study, Agamia et al, reported that intraoperative forced air-warming blanket is an effective way in decreasing the shivering incidence by preserving core body temperature during caesarean section under spinal anesthesia.[34] Sessler, showed that warming of the patient through forced air systems was very successful in preventing postoperative shivering.[35] In contrast to the results of the present study, Cobb et al found that active warming is ineffective to prevent hypothermia and shivering during cesarean delivery,[36] this is maybe because using the blanket in their study was to cover only the lower extremities.

This study had some limitations: (1) we used oral infrared thermometer to measure temperature changes. Core temperature is the only single best indicator of body temperature. Despite the oral route is known to be a (near-core) site for monitoring of temperature,[37] it was suitable for measurement when compared to other routes of measurement like esophageal probe which would be difficult to use as all patients were under spinal anesthesia. Infrared systems can provide

accurate measurements of surface temperatures and reduces measurement error.[38] Moreover, we assumed that any measurement bias was equally distributive between the two groups. (2) we tried to maintain patients' and investigators' blinding during the study period, however this could not be easily done as the forced air warmer device produced relatively noisy sounds when switched during surgery (3). We did not take any further protective steps towards any patient developed hypothermia during study period for fear of limitation of final core temperature values in our study.

To conclude, the results of our study revealed that using intraoperative forced air warming was more effective for preventing hypothermia and shivering in elderly patients undergo TURP under spinal anesthesia when compared to warmed irrigation fluid.

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**Conflicts of interest:** None.

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# COMPARING THE EFFECTIVENESS OF INTRAVENOUS MORPHINE VERSUS FENTANYL FOR IMMEDIATE POST-OPERATIVE PAIN AFTER MAJOR SPINAL SURGERY UNDER REMIFENTANIL-BASED GENERAL ANESTHESIA

Lily Hii[1], MD, Nadia Md Nor[2], MBBChBaO , MMed (Anaes),
Siti Nidzwani Mohamad Mahdi[2], MBBS, MMed (Anaes),
Azlina Masdar[2], MD, FCAI, Ahmad Fairuz Abdul Shokri[2], MBBChBaO,
Syarifah Noor Nazihah Sayed Masri[3], MD,
Azarinah Izaham[2*], MD, MMed (Anaes)

## Abstract

**Background**: Post-operative pain management in major spine surgery is important to ensure early ambulation and good functional outcome. This study compared the effectiveness of intravenous (IV) fentanyl 4 μg/kg to IV morphine 0.1 mg/kg for immediate post-operative pain after major spinal surgery under remifentanil-based anesthesia.

**Methods**: Seventy-eight patients undergone major spine surgery were randomly assigned to two groups: Group A received IV fentanyl 4 μg/kg and Group B received IV morphine 0.1 mg/kg given at skin closure. Total dosage of intra-operative remifentanil and the time taken for extubation were recorded. The immediate post-operative pain was assessed using the behavioural pain score (BPS) or visual analogue scale (VAS). The time to the first rescue analgesia, total cumulative morphine given and number of patients required rescue analgesia, pain score and sedation score were recorded. The assessments were done at 10 minutes interval upon patient arrival at recovery for one hour. The side effects of fentanyl or morphine were recorded.

**Results**: There was a delayed time for extubation in Group A compared to Group B (23.39 ± 6.1 *vs* 14.78 ± 6.8 minutes; p<0.001). The median time to the first rescue analgesia was longer in Group A compared to Group B (30(20-60) *vs* 20(10-60) minutes; p<0.001). The number of patients required rescue analgesia and the total cumulative morphine dosage in the first 30 minutes in the recovery were both less in Group A compared to Group B (24 *vs* 34 patients, p=0.027; 1(1-7) *vs* 2(0.5-4) mg, p<0.001). Median sedation score up to $T_{40}$ showed statistically significant difference between two groups (p<0.05). At $T_{10}$ and $T_{20}$, median BPS was lower in Group A compared to Group B (1(1-1) *vs* 1(1-2), p<0.01; 0(0-0), 2(0-2), p<0.022). However, there was no statistically significant difference in VAS from 20 minutes to 60 minutes for both groups. No other opioids side effects were noted.

1 Department of Anaesthesiology & Intensive Care, Hospital Umum Sarawak, Sarawak, Malaysia.
2 Department of Anaesthesiology & Intensive Care, Faculty of Medicine, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia.
3 Department of Anaesthesiology & Intensive Care, Hospital Umum Sarawak, Sarawak, Malaysia.
* **Mailing address of the corresponding author:** Azarinah Izaham, MD, MMed(Anaes), Department of Anaesthesiology & Intensive Care, Faculty of Medicine, Universiti Kebangsaan Malaysia. Mailing address: Jalan Yaakob Latif, 56000 Kuala Lumpur, Malaysia. Telephone number: +60391455555, Email address: azaizaham@yahoo.com

**Conclusion**: Fentanyl provided comparable analgesia and safety properties compared to morphine as immediate post-operative analgesia after remifentanil-based anesthesia despite delayed in extubation without any adverse effects. However, fentanyl significantly delayed awakening from anesthesia.

**Keywords**: Fentanyl, morphine, remifentanil, spine surgery

## Introduction

Major spinal surgeries are generally associated with considerable post-operative pain as it often involves extensive dissection of subcutaneous tissues, bones and ligaments. Adequate pain management is important to ensure early ambulation and good functional outcome.[1,2] Anesthetic challenges presented by major spinal surgery include the need to provide profound intra-operative analgesia and to facilitate intra-operative neurophysiologic monitoring of the spinal.[3,4] Intra-operative infusion of remifentanil is an established technique that is commonly used to meet this need.

Remifentanil is a potent, selective 4-anilidopiperidine μ-opioid receptor agonist that has a rapid onset and short duration of action independent of the duration of infusion with a context sensitive half-time of 4 minutes.[4-7] The pharmacokinetics properties of remifentanil result in termination of analgesic effect within minutes of discontinuing an infusion.[8] Thus, a transition must be made from remifentanil to some other longer-acting analgesics.[9] The most commonly used opioids for surgical pain are morphine and fentanyl, with the former being the mainstay of pain management after spine surgery.[10] It offers a good balance between the speed of action onset (15-30 minutes) and the maintenance of analgesia as it is relatively hydrophilic with a long duration of action.[11] Fentanyl also has favourable pharmacokinetics, theoretically having a more rapid onset ( <60 seconds) with a half-life of 90 minutes and duration of action close to 30-60 minutes.[12] This may allow the reduction of total opioid dosage used, thus reducing the dose-dependent opioid-related side effects.

Furthermore, an important concern with intra-operative infusion of remifentanil is the possible development of opioid induced hyperalgesia, causing as increased post-operative analgesic requirement, especially with potent opioids.[13] Crawford et al. demonstrated that the initial 24-hour post-operative morphine consumption was increased by 30% in adolescents who had received infusion remifentanil for scoliosis repair compared with those who received intermittent morphine alone.[3] Previous study showed that intravenous (IV) morphine bolus of 0.25 mg/kg administered 30 minutes before the end of major surgery significantly reduced Verbal Pain Score (VPS) at 60 minutes compared to 0.15 mg/kg ($p<0.001$).[14] However, three cases of post-operative respiratory depression occurred in 0.25 mg/kg group. In their study, they also suggested that an acute tolerance had occurred during remifentanil infusion or rapid offset of remifentanil. The postulation of the phenomenon was the opioid receptor coupled with the slower attachment of opioids with lesser affinity, and hence, causing the pain and agitation seen following cessation of remifentanil.

The present study was conducted with the objective of comparing the effectiveness of IV fentanyl 4 μg/kg versus IV morphine 0.1 mg/kg for immediate post-operative pain after major spinal surgery under remifentanil-based general anesthesia. We also evaluated the incidence of opioids side effects such as post-operative nausea and vomiting (PONV), pruritus, respiratory depression and over sedation.

## Methods

This prospective double-blind and randomised study was conducted after obtaining approval by the Research Committee of Department of Anaesthesiology & Intensive Care, Universiti Kebangsaan Malaysia Medical Centre and the Medical Research & Ethnics Committee UKMMC (FF-2018-083).

Patients aged 12 to 60 years old with American Society of Anesthesiologists (ASA) I or II classfications and scheduled for major spine surgery requiring patient-controlled analgesia (PCA) post-operatively were included in the study. The exclusion criteria were patients with known allergies to the study drugs, history of substance abuse, chronic use of opioids and patients who could not understand the Visual Analogue

scale (VAS). Patients were recruited one day prior to the operation and were kept fasting for at least 6 hours prior to their surgery. The written informed consent was taken and all patients did not received premedication. The VAS (Appendix 1) was explained to all patients and the baseline VAS was assessed and recorded. Patients' demographic data, which included age, gender, race, ASA physical status, weight, height, diagnosis and surgical procedure planned, were recorded. Patients were randomly assigned into one of the two study groups by using a computer-generated randomization table. Group A received IV fentanyl 4 µg/kg (lean body weight) while Group B received IV morphine 0.1 mg/kg (lean body weight) 30 minutes before the end of surgery (defined as starting of skin closure). The specified drug was prepared by the primary investigator and was given to the patients by the medical officer in the operating theater (OT), who was blinded to the study.

**Appendix 1**
**Visual Analogue Scale (VAS)**
0 mm (no pain) to 100 mm (unbearable pain)

In the OT, standard monitoring which included non-invasive or invasive blood pressure, electrocardiography, pulse oximetry and capnography were applied. The IV access was established using a 18G branula and IV Hartmann's solution was commenced followed by the Holliday Segar formula for maintenance fluid requirements.[15] All patients were induced and maintained using total intravenous anesthesia (TIVA) with target-controlled infusion (TCI) of propofol and remifentanil using the Schnider and Marsh model, respectively. The intra-operative TIVA infusion dose was according to the anesthesiologist in charge. Patients were intubated with an appropriately sized endotracheal tube and positioned prone for the spine surgery. Intravenous dexamethasone 8 mg and IV paracetamol 15 mg/kg were given after induction of anesthesia.

At skin closure, all patients were given the study drug prepared earlier, depending on randomisation, with TCI propofol discontinued and 1mg of granisetron administered as PONV prophylaxis. The TCI remifentanil was discontinued when dressing was applied to the surgical wound. All patients were extubated following the standard extubation criteria and sent to recovery area for monitoring. Total dose of remifentanil used intra-operatively was recorded. The time for extubation which was defined as the time from the termination of remifentanil infusion to removal of endotracheal tube was also recorded. Patient was considered drop-out from the study if he/she failed to be extubated 30 minutes after discontinuation of remifentanil infusion.

At 10 minutes after arrival at recovery area ($T_{10}$), patient's sedation score was assessed using the Ramsay sedation scale (Appendix 2). Should the score be ≥4, pain assessment was done using the Behavioural Pain Score (BPS) (Appendix 3). If the Ramsay sedation score was <4, pain was evaluated using the VAS. Similar assessment was done every 10 minutes for a 60-minute duration, recorded as $T_{20}$, $T_{30}$, $T_{40}$, $T_{50}$ and $T_{60,}$ respectively. A BPS of ≥ 2 or VAS ≥ 40 mm was considered as inadequate analgesia, following which an IV morphine 1 mg bolus was given as a rescue analgesia and titrated to effect until a VAS ≤ 40 mm or BPS < 2 was reached. The time to the first rescue analgesia and total cumulative morphine given as rescue analgesia in the recovery area were also recorded. All patients were given a PCA morphine before being discharged to the ward upon fulfilling the standard discharge criterias. The presence of opioid side effects such as nausea, vomiting, respiratory depression and pruritus were also recorded during the first hour in the recovery area and treated accordingly.

**Appendix 2**
**Ramsay sedation score**
1- agitation and uncomfortable
2- cooperated and orientated
3- do simple directions
4- sleep and strongly reply to stimulation
5- sleep and slowly reply to stimulation
6- sleep and do not reply to stimulation

**Appendix 3**
**BPS**
0- calm patient with no verbal or behavioural manifestation of pain
1- behavioural or verbal expression of pain
2- intense behavioural or verbal manifestation of pain (cry, extreme agitation).

The sample size was calculated using the PS Software version 3.0 (Dupont & Plummer, 2011) based on Schlesselman's (1982) formula.[15,16] Fletcher et al. showed that there was a significant difference between patients with a VPS of ≥2 who received intra-operative IV morphine 0.25 mg *vs* 0.15 mg/kg (40.5% *vs* 70.5%), 60 min after discontinuation of remifentanil.[14] A sample size was designed based on these results, with an α value of 0.05 and a power (1-β) of 0.80. It was calculated that each group required 38 subjects. We therefore enrolled 86 patients (43 per group) to allow for 10% dropouts. Data analysis was performed using SPSS for Windows version 23.0 (IBM Corp, Armonk, NY. USA). Independent t-test or Mann-Whitney U test were used for normally distributed continuous data and not normally distributed data, respectively. The qualitative data (e.g Race, Gender, ASA status) was analysed using Chi-square or Fisher exact test if insufficient numbers were present. A *p* value of <0.05 was considered statistically significant.

## Results

A total of 86 patients who underwent major spinal surgery were recruited in this study. Eight patients dropped out from the study: five patients from Group A because of delayed extubation and three patients from Group B due to massive blood loss and were kept ventilated post-operatively. The demographic data of both groups were comparable (Table 1).

There was a statistically significant delay for time to extubation after remifentanil infusion discontinuation between Group A (23.39 minutes) and Group B (14.78 minutes) ($p<0.001$). In addition, the median time to the

to Group B (30 minutes *vs* 20 minutes; $p<0.001$). The median of total cumulative morphine dosage in Group A showed a statistically significant lower dose compared to Group B for the first 30 minutes in the recovery area (1(1-7) *vs* 2(0.5-4) mg, ($p<0.001$) (Table 2). Similarly, the number of patients that required rescue analgesia in the first 30 minutes in the recovery was significant lower in Group A compared to Group B, 24 (63.2%) *vs* 34(85.0%) ($p=0.027$).

There were a statistically significant difference in the median Ramsay sedation score between Group A and Group B for the first 40 minutes in the recovery area (Table 3).

The difference in median BPS at $T_{10}$ between Group A (1(1-1)) and Group B (1(1-2)) was statistically significant (Table 4). Two types of assessment were conducted according to the Ramsay sedation score at $T_{20}$. The median BPS score in Group A was significantly

*Table 1*
*Demographic characteristics of study patients*

| | **Group A (n= 38)** | **Group B (n= 40)** | **p-value** |
|---|---|---|---|
| Age, years | 17.6 (12-34) | 16.0 (13-33) | 0.0415 |
| Gender, n (%)<br>Female<br>Male | <br>33 (86.8)<br>5 (13.2) | <br>36 (90.0)<br>4 (10.0) | 0.734 |
| BMI, kg/m$^2$ | 18.1±2.5 | 18.0±2.6 | 0.820 |
| Duration of surgery (min) | 128.5±38.0 | 138.0±43.9 | 0.312 |
| ASA, n (%) 1<br>2 | 33 (86.8)<br>5 (13.2) | 30 (75.0)<br>10 (25.0) | 0.185 |
| Surgical procedure, n (%) Scoliosis<br>Non-scoliosis | 36 (94.7)<br>2(5.3) | 40 (100.0)<br>0(0) | 0.234 |

Values are expressed as median (25$^{th}$ percentile – 75$^{th}$ percentile), mean ± SD or number of patients (percentage)

*Table 2*

*Intra- and post- operative anesthesia properties*

| | **Group A** (n=38) | **Group B** (n=40) | **p value** |
|---|---|---|---|
| Baseline VAS score, mm | 0 (0-7) | 0 (0-5) | 0.945 |
| Total dose of intra-operative remifentanil (ng) | 1555 ± 584 | 1757 ± 647 | 0.153 |
| Time to extubation (minute) | 23.39 ± 6.1 | 14.78 ± 6.8 | <0.001 |
| Time to first rescue analgesia (minute) | 30 ( 20-60) | 20 (10-60) | < 0.001 |
| Total cumulative morphine dose in recovery (mg)<br>0- 30 minute<br>30-60 minute | 3.0 (0-9)<br>1 (1-7)<br>3.5 (2-9) | 3.5 ( 0-6)<br>2 (0.5-4)<br>4 (1-6) | 0.164<br><0.001<br>0.156 |
| Number of patient requiring rescue analgesia in first 30 minutes, n (%) | 24 ( 63.2) | 34 ( 85) | 0.027 |

Values are expressed as median ($25^{th}$ percentile – $75^{th}$ percentile) or mean ± SD

*Table 3*

*Post-operative Ramsay sedation score at recovery*

| | **Group A (n=38)** | **Group B (n=40)** | **p value** |
|---|---|---|---|
| $\mathbf{T_{10}}$ | 5 (5-5) | 4 (2-4) | <0.001 |
| $\mathbf{T_{20}}$ | 5 (4-5) | 2 (1-4) | <0.001 |
| $\mathbf{T_{30}}$ | 4 (2-4) | 2 (2-2) | <0.001 |
| $\mathbf{T_{40}}$ | 2 (2-4) | 2 (2-2) | 0.001 |
| $\mathbf{T_{50}}$ | 2 (2-2) | 2 (2-2) | 0.234 |
| $\mathbf{T_{60}}$ | 2 (2-2) | 2 (2-2) | 0.284 |

* Values are expressed as median ($25^{th}$ percentile - $75^{th}$ percentile)

*Table 4*

*Postoperative Behavior Pain Score (BPS) and Visual Analogue Scale (VAS)*

| **Time** | **Group A (n=38)** | | **Group B (n=40)** | | **p-value** |
|---|---|---|---|---|---|
| | BPS,median ($25^{th}$-75th percentile) | VAS, median ($25^{th}$ percentile - $75^{th}$ percentile) | BPS,median ($25^{th}$-75th percentile) | VAS, median ($25^{th}$ percentile - $75^{th}$ percentile) | |
| $T_{10}$ | n=38<br>1 (1-1) | n=0 | n=40<br>1 (1-2) | n=0 | <0.01 |
| $T_{20}$ | n=30<br>0 (0-0) | n=8<br>4 (1-6) | n=5<br>2(0-2) | n=35<br>6 (5-8) | $0.022_{BPS}$<br>$0.078_{VAS}$ |
| | VAS, median ($25^{th}$ percentile - $75^{th}$ percentile) | | | | |
| $T_{30}$ | 5 (0-9) | | 5 (0-8) | | 0.215 |
| $T_{40}$ | 6 (0-9) | | 5 (1-9) | | 0.620 |
| $T_{50}$ | 5 (0-8) | | 5 (2-8) | | 0.207 |
| $T_{60}$ | 4 (0-7) | | 4 (2-8) | | 0.366 |

Values are expressed as median ($25^{th}$ percentile - $75^{th}$ percentile)

lower compared to Group B at $T_{20}$ (0 (0-0) *vs* 2(0-2), *p* =0.022). However, there was no significant difference in VAS from 20 to 60 minutes for both groups.

There were no side effects (nausea, vomiting, pruritus and respiratory depression) noted among the participants.

## Discussion

The current study showed that fentanyl could be considered as a post-operative analgesia after remifentanil-based anesthesia in major spine surgeries. The time required to first rescue analgesia was longer while the cumulative morphine dosage for 30 minutes in the recovery room was lower when fentanyl was given as a post-operative analgesia after remifentanil was discontinued. A delay in time to extubation and higher sedation scores were also seen when fentanyl was administered.

A study by Kochs et al. found that there was no differences in median time to extubation after equi-potent dose of morphine or fentanyl were given to patients undergoing major abdominal surgery, 25 minutes before terminating remifentanil-based anesthesia.[16] However, our result showed that there was a delay in extubation time when fentanyl was given as post-operative analgesia after remifentanil-based anesthesia. The study by Kochs et al. used a fixed dose of fentanyl and morphine whereas the dosage used in the present study was according to body weight.[16] We postulated that fentanyl's greater lipophilicity and potency allowed it to rapidly cross the blood-brain barrier, contributing to the peak effect of fentanyl at the time of extubation.[17] Contrary to the present findings, Kochs et al. showed no difference between morphine and fentanyl as a post-operative pain management after remifentanil-based anesthesia, regarding the time to first rescue analgesia in patients. A study by Albrecht et al., who compared the effectiveness of approximately equipotent doses of morphine and fentanyl given 20 minutes before the end of remifentanil-based anesthesia for major abdominal surgery, also showed similar median time to administration of first rescue opioids.[17] However, both studies used fixed dose of fentanyl and morphine instead of according to body weight which was in contrast to our study.

The current study showed that fentanyl had better analgesia property at the first 10 minutes in the recovery area. However, patients who received fentanyl were more sedated compared to morphine. At 20 minutes into recovery, 79% of the patients in the fentanyl group who were assessed using BPS had median score of 0 suggesting that fentanyl had better analgesic property at 20 minutes after remifentanil-based anesthesia. For the last 30 minutes into recovery, patients who received either drug showed moderate pain scores, requiring rescue analgesia. To the best of our knowledge, there has been no prior study assessing pain scores by using time intervals while in recovery. Kochs et al. showed a lack of difference in analgesic property between fentanyl and morphine after remifentanil-based anesthesia, with the pain score only being assessed once an Aldrete score of ≥ 9 was achieved.[16] At 60 minutes we found that patients had moderate pain with median pain score of 4, which was similar to the study done by Fletcher et al. who used 0.15 mg/kg morphine. We used 0.1 mg/kg morphine as a post-operative analgesia, which was comparable to the dosage used by Fletcher et al.[18]

We didn't observe any side effects when either drug was used for post-operative analgesia after remifentanil-based anesthesia in which both appeared to be safe. As the patients recruited were less than 40 years of age, the findings here cannot be extrapolated for patients > 40 years old. The assessment of respiratory components is also important in evaluating the effect of morphine and fentanyl. This includes time to spontaneous respiration, time to response to verbal command and time to achieve an Aldrete score ≥ 9. However, this was not taken into account in the present study.

In conclusion, fentanyl provided comparable analgesia and safety properties compared to morphine as immediate post-operative analgesia after remifentanil-based anesthesia. However, fentanyl 4μg/kg significantly delayed awakening from anesthesia.

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# TRANSLATION, CROSS CULTURAL ADAPTATION AND VALIDATION OF ROLAND MORRIS LOW BACK PAIN TOOL IN LEBANON

Fadia Shebbo[1], Bassam Farhat[1], Maha Makki[2], Ghassan Kanazi[1*]

## Abstract

**Background:** The Roland-Morris questionnaire is one of the most widely used questionnaires, which have been designed for back pain. It has been shown to yield reliable measurements valid for inferring the level of disability in low back pain patients. The aim of this study is to validate the Roland-Morris questionnaire in patients with low back pain after translation and adaptation to the Lebanese population.

**Methods:** The questionnaire was translated from English to Arabic and back translated using two separate Lebanese translators with English as their mother tongue. The questionnaire was applied on 122 patients with low back pain and then analyzed for reliability and validity.

**Results:** Patients' mean age was 61.43±17.22. Cronbach's alpha, which was used to assess the internal consistency of the questionnaire, measured 0.778. Pearson correlation between the RMQ and NRS was $r=0.407$, $p<0.0001$. A three factors exploratory factor analysis was done. There was a high and significant correlation between the questions related to physical activity and NRS.

**Conclusion:** The Lebanese version of the RMQ is a reliable and valid tool for the evaluation of low back pain.

**Keywords**: Low back pain, Arabic version, Roland Morris questionnaire, reliability, validity

## Introduction

Low back pain constitutes an important public health problem[1] with an estimated worldwide one month prevalence of 30.8%.[2]

A recent study, among Lebanese workers, have shown that the prevalence of LBP ranged around 45%.[3] Female workers had higher incidence of LBP due to their complex daily life activities and this was also demonstrated in other studies.[4,5]such as natural menopausal transition, physical strain to the lower back, and psychosocial and lifestyle stress, for low back pain (LBP

Back pain is defined as pain extending from the bottom of the rib cage to the gluteal sulcus. The etiology for back pain could be secondary to a musculoskeletal disorder, spine injury, disc related, or a medical disease affecting the spine.[6] The type and intensity of back pain varies among individuals and its severity depends greatly on the underlying etiology.

1 Department of Anesthesiology, American University of Beirut Medical Center, Beirut, Lebanon
2 Clinical Research Institute, American University of Beirut Medical Center, Beirut, Lebanon
* Mailing address of the corresponding author: Ghassan Kanazi, M.D. Department of Anesthesiology, American university of Beirut Medical Center; Mailing address: Cairo Street P.O. Box 11-0236, Riad El Solh 1107 2020, Beirut, Lebanon; E-mail: gk05@aub.edu.lb; Telephone number: 00 961 350 000 - 6380.

LBP stands as an obstacle against performing daily life activities and is associated with high financial burden i.e loss of days of work, medical expenses.[7]

It is very important to have a tool that evaluates the severity of low back pain in a reliable, easy and feasible approach, and its effect on daily activities of the individual.

The Roland Morris questionnaire[8] is a common instrument used in the assessment of patients with low back pain that has been translated and validated in several countries. It is also an efficient tool that is be used to evaluate the efficacy of medical or interventional treatment protocols. Although RMQ questionnaire was translated and validated in Saudi Arabia, the difference in culture and dialect have prompted us to translate and validate the questionnaire to Lebanon. The objective of this study is to translate and validate the Lebanese version of the RMQ.

## Materials and Methods

The Roland Morris questionnaire was translated by two different translators, with one of them aware of the study while the other served as a control. Cultural sensitivity was tested through an expert panel consisting of 2 pain physicians, a nurse and a spine surgeon. A single version was selected after an anesthesiologist (practicing pain specialty) and the two translators had agreed on. Then, a back translation of this final version was done by two translators whose mother tongue language is English. The Arabic version was used throughout the study without any modification.

One-hundred twenty two patients were included in this study. The patients were screened through the outpatient Pain Center or from in-patient consultations at the American University Medical Center. The inclusion criteria included Lebanese nationals, older than eighteen years admitted for chronic low back pain due to any etiology.

Most of the patients were receiving a pharmacological treatment such as Non-steroid anti-inflammatory drug, Opioid, Paracetamol and/or Gabapentin/Pregabalin medications. Oral informed consent was obtained from all the patients before the administration of the questionnaire. Verbal analogue scale (VAS) was used to measure the pain intensity after the questionnaire had been administered and the score was recorded.

The RMQ consists of 24 items, where a total score of 0 indicates no disability and a score of 24 implies severe disability.[8] It includes questions related to daily life functions and common physical activities.

Descriptive statistics were summarized by presenting the number and percentage for categorical variables and the mean ± standard deviation (SD) for continuous ones. The correlation between two continuous variables (RMQ and NRS) was assessed by using Pearson correlation coefficient. An exploratory factor analysis (EFA) was conducted to evaluate the factor structure of the 24 items. Factors were extracted by the principal component method, and a Varimax (orthogonal) method of rotation was applied to the results. Cronbach's alpha was measured to assess the reliability (internal consistency) of a set of items. P-value $< 0.05$ was used to indicate statistical significance. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS, version 24).

## Results:

One-hundred twenty two patients with low back pain were included in this study, with average weight 61.43 kg, with a predominance of females to males ratio. Hypertension was the prevalent comorbidity in these patients. Participants' demographics and baseline characteristics are present in Table 1. Descriptive information of the RMQ is present in Table 2. Data are presented as frequencies and percentages of positively answered questions. The most common pain medication consumed by the patients was paracetamol, which was followed by NSAIDs, opioids and Gabapentin/Pregabalin. There was no predominance in drug combinations over one another.

The internal consistency, measured with Cronbach's alpha, was 0.778.

Two factor EFA was eliminated because it dropped out several items, while the three factor EFA retained most of the items and had a Cronbach's Alpha of 0.71 and 0.72 for the first two factors (Table 3). The

*Table 1*
*Sample Demographics*

| | **Total N=122** |
|---|---|
| **Gender** | |
| Male | 47 (38.5) |
| Female | 75 (61.5) |
| Age | 61.43 ± 17.22 |
| Weight | 75.08 ± 13.18 |
| BMI | 26.93 ± 4.44 |
| Medical history | |
| HTN | 53 (44.2) |
| DM | 17 (14.8) |
| CAD | 7 (6.1) |
| Dyslipidemia | 15 (13.0) |
| Osteoporosis | 1 (0.9) |
| Medications | |
| Gabapentin/Pregabalin | 37 (34.3) |
| Paracetamol | 71 (61.2) |
| NSAID | 58 (52.7) |
| Opioid | 38 (36.9) |

first factor consisted of 10 questions that included Q8, Q9, Q11, Q16, Q19, Q1, Q6, Q3, Q5, and Q24. The highest loading factor 0.6 was retained by Q8 "Because of back, I try to get other people to do things for me". The second factor included Q17, Q10, Q2, Q12, Q20, Q21, and Q23 with a load factor ranged between 0.45 and 0.77. The highest rank was in Q17 "I only walk short distances because of my back pain" with a load factor of 0.776. The third factor included Q7, Q13, and Q14 with a load factor ranged from 0.46 to 0.58.

Pearson correlation of the EFA with the NRS demonstrated that pain score significantly associated with the three factors constructs. The highest correlation was shown to be with factor 2. This factor comprises the following questions: 2, 10, 12, 17, 20, 21, and 23.

Questions in factor 1 and questions in factor 2 showed a Cronbach's alpha of 0.71 and 0.72 respectively. The linear relation between the questionnaire and NRS was measured. The RMQ mean of the entire sample was 16.75 ± 4.25, and the NRS mean was 2.54 ± 0.55 on a scale of 0-10. The Pearson correlation between RMQ and NRS was r=0.41, p<0.0001. Correlation between each factor and NRS was also assessed; the highest and most significant correlation appeared to be between NRS and the second factor (alpha=0.56, p<0.0001).

*Table 2*
*Descriptive of the RMQ*

| | Total N=122 |
|---|---|
| **Total score** | 69.77 ± 17.69 |
| **Q1** | 74 (60.7) |
| **Q2** | 97 (79.5) |
| **Q3** | 110 (90.2) |
| **Q4** | 98 (80.3) |
| **Q5** | 88 (72.1) |
| **Q6** | 90 (73.8) |
| **Q7** | 90 (73.8) |
| **Q8** | 86 (70.5) |
| **Q9** | 86 (70.5) |
| **Q10** | 96 (78.7) |
| **Q11** | 98 (80.3) |
| **Q12** | 93 (76.2) |
| **Q13** | 79 (64.8) |
| **Q14** | 89 (73.0) |
| **Q15** | 52 (42.6) |
| **Q16** | 90 (73.8) |
| **Q17** | 91 (74.6) |
| **Q18** | 84 (68.9) |
| **Q19** | 29 (23.8) |
| **Q20** | 72 (59.0) |
| **Q21** | 104 (85.2) |
| **Q22** | 93 (76.2) |
| **Q23** | 101 (82.8) |
| **Q24** | 52 (42.6) |

## Discussion

Several tools were established to evaluate low back pain and are easy accessible. The RMQ is an established tool used to evaluate low back pain. It is one of commonly and widely used questionnaires to assess disability in low back pain patients. Several

*Table 3 Exploratory Factor Analysis Load Factors and internal reliability measures of RMQ*

| | Factors | | | Alpha coefficient |
|---|---|---|---|---|
| | 1 | 2 | 3 | Cronbach's Alpha |
| **First factor** | | | | |
| **Q8** | **0.602** | | | 0.71 |
| **Q9** | **0.593** | | | |
| **Q11** | **0.582** | | | |
| **Q16** | **0.534** | | | |
| **Q19** | **0.477** | | | |
| **Q1** | **0.463** | | | |
| **Q6** | **0.441** | | | |
| **Q3** | **0.440** | | | |
| **Q5** | **0.406** | | | |
| **Q24** | **0.396** | | | |
| **Second factor** | | | | |
| **Q17** | | **0.776** | | 0.72 |
| **Q10** | | **0.699** | | |
| **Q2** | | **0.584** | | |
| **Q12** | | **0.504** | | |
| **Q20** | | **0.501** | | |
| **Q21** | | **0.498** | | |
| **Q23** | | **0.451** | | |
| **Third factor** | | | | |
| **Q7** | | | **0.582** | 0.37 |
| **Q13** | | | **0.510** | |
| **Q14** | | | **0.460** | |

studies illustrated that RMQ was reliable and valid.[9–18]culturally adapted questionnaire.\\n\\nOBJECTIVE: Argentinean Roland-Morris Disability Questionnaire (RMDQ

In this study, we translated and validated this questionnaire in Lebanese patients with LBP. The questionnaire, answered by yes/no, was short, easy to administer and understand. Most of the patients required assistance in filling the questionnaire but some of them were able to fill it solely. There were no difficult sentences needed to be changed for its clarity after piloting.

According to the descriptive of our questionnaire, Questions 15, 19, and 24 are the least representable. These three questions cover three aspects, the appetite, dependence, and prolonged bed rest.

The internal consistency of our questionnaire version was found to be acceptable with a Cronbach's alpha coefficient of 0.78, similar to the Spanish[18] (0.83) and Guajarati[19]validity, sensitivity and specificity of the Gujarati version of the RMDQ for use in Non Specific Chronic low back pain.\\n\\nSTUDY DESIGN: A

reliability, validity, sensitivity and specificity study of Gujarati version of the Roland-Morris Disability Questionnaire (RMDQ (0.75) versions, lower than the Columbian[12]but a validated version is not available in our country. Methods. The RMQ 24-item scale ranges from 0 (no disability (0.86), Chinese[11] (0.87), Korean[15] (0.89), and Argentinian[9] (0.9).

The Pearson correlation between RMQ and pain score is rated as moderate (r=0.41) with a highly significant correlation (p<0.001). Based on the literature review, our result was found to be similar to the Columbian[12]but a validated version is not available in our country. Methods. The RMQ 24-item scale ranges from 0 (no disability (r=0.43), Japanese[20] (r=0.44), and Korean[15] (0.45) versions, lower than the Argentinian (r=0.5)[9], Chinese (0.68) and Hungarian[21] (r=0.61) versions, but higher than the Moroccan[14] (r=0.32) and Spanish[18] (r=0.35) versions.

We believe that RMQ is a multi-dimensional tool, therefore it was interesting to check which factor would highly correlate with the patients' pain scores. Factor 2, describing physical activity performance, was associated with the highest correlation with pain score. Therefore, we can tell that the questionnaire reflects the relation between the intensity of pain through the NRS and its effect on physical activity. Moreover, this questionnaire could function as a tool to evaluate the treatment modalities in such patients.

In conclusion, our study showed that the Lebanese version is suitable, well received, and easy to use. Thus, it is reliable and valid to assess disability in low back pain in the Lebanese population.

Limitations in this study included: lack of measurement of repeatability and sensitivity due to limitations in time and resources; bias might have been introduced since a research member was assisting some patients in filling the questionnaire.

Conflicts of Interest: None.

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