Effect of Mechanical Ventilation Mode Type on Prioperative Blood Loss in Patients Undergoing Posterior Lumbar Inter body Fusion Surgery: A Randomized Controlled Trial

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Research Article

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Abstract

Background

this study has examined modes of mechanical ventilation, pressure or volume-controlled ventilation (PCV or VCV) on intra- and post-operative surgical bleeding in posterior lumbar inter body fusion (PLIF) surgery

Methods

This research was a randomized, single-blinded, and parallel study, that 78 patients were selected. They mechanically ventilated using either PCV or VCV in PLIF surgery. In this regard, a permuted block randomization was used with a computer-generated list. After induction of anesthesia in supine position, the hemodynamic and respiratory parameters were measured

Results

The mean bleeding was 431.281 ± 361.04cc in the PCV group and 465.26 ± 338.16 cc in the VCV group (p = 0.669). Moreover, blood transfusion rates in the PCV and VCV groups were 0.40 ± 0.74 and 0.43±78 0.78 pack cell (p = 0.836), respectively. Notably, surgeon satisfaction was more observed in the PCV group (82.1% vs. 74.4%, p = 0.548). In addition, the other variables were similar in these two groups.

Conclusions

The mean bleeding volume was higher in the VCV group compared to the PCV group; however, no significant difference was observed between these two groups. Hemoglobin levels in the patients included before and after surgery showed that the two groups were in a similar condition.

Background

It was indicated that posterior spinal fixation surgery is often associated with heavy bleeding that sometimes requires a blood transfusion or blood product (1, 2) The need for blood transfusion in spinal fusion surgeries without any implantation of the device was reported in 70% of the cases and in case of using the device, it was up to 50% of the cases. Additionally, the estimated bleeding rates have been reported in studies to be between 80 and 3100 cc. (3, 4, 5, 6, 7, and 8)

In spinal deformity correction surgeries performed using posterior reversal methods, the amount of bleeding has been reported to be from 1 to 3 liters (9, 10, 11, 12, 13 and 14). Accordingly, there are similar reports in interior correction (15, 16). Reduction of intraoperative bleeding is important for maintaining hemodynamic stability and the desirability of the surgical field. On the other hand, it was found that the convenience of the surgeon reduces the duration of the operation, which is accompanied with a reduction

in the amount of bleeding (2, 17). Moreover, reducing bleeding reduces the need for blood transfusions and blood products, which consequently decreases the risks of hemolytic and non-hemolytic complications, lung damage, viral and bacterial infections, and hypothermia and coagulation disorders caused by blood transfusions (2, 18 and 19).

The techniques used to reduce intraoperative bleeding and the suitability of the surgical field are divided into two groups as follows: 1- Reduction of bleeding by reducing intravenous blood flow such as the controlled hypotension and local vascular contraction, and 2- Accelerating and stabilizing coagulation using chemical and biological agents such as desmopressin, aprotinin, and tranexamic acid; estrogen; and bone wax. Correspondingly, these techniques have been widely studied as contradictory results, and finally many contradictory findings have been obtained (19, 20, 21, 22, 23 and 24).

Mechanical ventilation increases the pressure inside the chest, reduces vascular return, and increases venous pressure, which finally increase bleeding. Few studies in this regard have shown that reducing intrathoracic pressure in mechanical ventilation by maintaining spontaneous respiration over the controlled respiration can be effective on reducing site bleeding (10). On the other hand, changes in CO2 can affect the central arteries and the pressure inside the skull can also affect the amount of bleeding in the fixation of the spine (10, 25, 26 and 27).

Due to the limited studies conducted on the effect of respiratory ventilation on the reduction of intraoperative bleeding as well as the positive effects that can have on the outcome of patients, which lead to the reduced loss and transfusion of blood and blood products during spinal surgery, in the present study, the effects of two types of Mechanical ventilation including volumetric ventilation (VCV) and compression ventilation (PCV) were evaluated on intraoperative surgical bleeding in patients undergoing spinal surgery.

Methods

Ethics and patients

This study protocol was approved by the Ethics committee of Kashan University of Medical Sciences (Ghotb-e-Ravandi Blvd, 5th Km, Kashan Road, 8715988141, Kashan, I. R. Iran- Postal code: 8715988141). All methods were carried out in accordance with relevant guidelines and regulations and with CONSORT recommendations. The study was registered in Kashan University of Medical Sciences (The link for the study registry: https://irct.ir/user/trial/24834/view, Trial Id: 24834, IRCT Id: IRCT2016122731611N1, Registration date: 18/03/2017).

In this prospective, randomized, parallel and one-way blinded clinical trial, 78 patients with ASA class 1 and 2, aged between 18 and 75 years old, who were candidates for posterior spinal fixation surgery, were included and then randomly divided into two groups of 39 subjects after obtaining the written informed consent.

This study was prospective, randomized, and parallel (allocation ratio = 1:1).

For the participants' allocation, the permuted block randomization was used by applying a computer-generated list of random numbers and using sealed envelopes. Although surgeons and nurses who were involved in patient care, were aware of the study they were blinded to the details of the study's protocol. The surgical procedure was performed by one surgeon and a single surgical team using the same method.

The permuted block randomization was used for the participants' allocation (allocation ratio=1:1). in this regard used random numbers that extracted from computer-generated list and sealed envelopes.

Anesthetic protocol:

Anesthesia was induced and then maintained by the attending anesthesiologist, who managed anesthesia using a standard regimen in the study protocol; however, he was blinded to the details of the study protocol. After establishing routine patient monitoring (Heart rate, noninvasive blood pressure, pulse oximetry, and end tidal CO2), anesthesia was induced with an intravenous premedication of 2μg/kg fentanyl, 0.03 mg/kg midazolame, 5 mg/kg sodium thiopental, and 0.5 mg/kg atracurium. Endotracheal tube with a suitable size, a high-volume, and a low-pressure cuff was inserted for the patients.

Anesthesia was maintained with infusion of propofol 100-200Mic/Kg/min as well as 30/70% of O2/N2O mixture to maintain 70 mmHg of MAP, if any additional drug was necessary to maintain 70 mmHg of MAP labetalol infused. In the PCV group, mechanical ventilation begun with PIP=15 mmHg, RR=12/min, I/E= ½, and PEEP=0 and then the PIP was adjusted to achieve a tidal volume that was calculated as the ideal body weight (50 [female: 45.5] + 0.91 [height − 152.4]) × 7 ml. In addition, the respiratory rate was controlled. Using the end-tidal carbon dioxide pressure (ETco2) ranged from 35 to 40 mmHg. In the VCV group, TV=7ml/IBW and RR, I/E, and PEEP were chosen as one group. Afterward, anesthesia was reversed with 0.04 mg/Kg neostigmine and 0.02 mg /Kg atropine.

Measurements hemodynamic changes BP, HR, MAP, amount of blood loss, and transfusion were recorded intera and post-operative duration of surgery was recorded as well.

In this study, the amount of bleeding was calculated based on the volume of blood lost in the suction, the number of completely impregnated gases (4 x 4 cm, 15 cc each), large amount of completely impregnated blood (30 x 30 cm per 50 cc), and the amount of blood in the hemovac drain of the patients and then registered until the end of the operation.

Additionally, the amount of blood and blood products injected during the operation along with blood pressure and heart rate were recorded before the induction, immediately after the intubation, after being in the prone position, during the operation every 15 minutes, at the end of the operation, after being in the supine position, and after endotracheal tube exit and recovery time.

Afterward, postoperative hemoglobin levels were checked after the arrival to general ward.

Surgeon’s satisfaction from the field of surgery was also questioned and recorded as good, moderate, and weak, which were stated based on the volume of bleeding, the bleeding conditions of the operation field, and the surgeon's personal opinion.

All the obtained data were measured and recorded by one trained observer who was not aware of each group. All the patients operated by one surgeon who was not informed of the method of ventilation.

Statistical analysis

The findings were described with central and environmental indicators and then displayed with the related tables and graphs. The findings analyzed using Kolmogorov-Smirnov test, parametric t-test and Fisher’s exact test and also with Chi-square tests. SPSS-16 software was used to analyze data.

In this study, details of the protocol were blinded for surgeons and nurses. A surgeon was applying surgical procedure and a single surgical team used the same method

Patient’s inclusion criteria

The patient’s inclusion criteria were as follows:

1. Patients with ASA class 1 or 2,
2. Ages between 18 and 75 years old,
3. Patient consent to enter the study

The patient’s exclusion criteria were as follows:

1. Respiratory diseases like Asthma, and chronic obstructive pulmonary diseases.
2. Severe heart diseases such as heart failure, myocardial infarction, and valvular diseases.
3. Coagulation diseases or anticoagulation drug consumption.
4. Severe hemodynamic instability preoperative, And
5. History of any previous lumbar surgery

This study was done from 2017 to 2019 at the university teaching hospital and gave the approval of the Institutional Review (95051) of Kashan University of medical science. (Ethical code IR.KAUMS.REC.1395.50)

Result

In this study, 78 patients who were candidates for posterior spinal fixation surgery were studied in the two groups of volume control ventilation and pressure ventilation in terms of the amount of bleeding caused by the operation. The variables of sex, age, height, weight, and body mass index (BMI) of the studied patients showed that these were not significantly different between these two groups (Table 1).

According to Table 1, 38.5% of the patients in the VCV group and 41.0% of the patients in the PCV group were Male, and 61.5% of the patients in the VCV group and 59%of the patients in the PCV group were Female. The difference between two group was not statistically significant (p = 0.82). The mean age of the patients enrolled in the VCV group was 42.41±10.45 years old and in the PCV group was 43.77±11.38 years old (p = 0.53). The mean height of the patients enrolled in the VCV group was 1.65±.9 meter and in the PCV group was 1.66±.1 meter (p = 0.54). The mean weight of the patients enrolled in the VCV group was 76.11±11.47 kg and in the PCV group was 78.77±19.71 kg (p = 0.13). The mean BMI of the patients enrolled in the VCV group was 27.92±4.89 and in the PCV group was 28.42±7.10 (p = 0.93).

The mean bleeding volume in the studied groups was shown in table 2. the volume of bleeding due to surgery in the VCV group was 465.26 cc and in the PCV group, it was 431.28 cc; however, no significant difference was observed between these two groups (p = 0.67) (Table 2).

Most of the patients in both treatment groups required no blood transfusions. In the VCV Group 17.9% and in the PCV Group 15%, although the patients needed two pack cells of blood. The difference between these two groups was not statistically significant (p = 1) (Table 3).

Surgeon evaluation of the surgical field in 74.4% of the patients in the VCV group and 82.1% of the patients in PCV Group has shown good results (p = 0.58) (Table 4).

The frequency of the need for antihypertensive drugs during surgery in the VCV group was 10.3% and in the PCV Group was 5.1%, which were not statistically significant (p = 0.22) (Table 5).

Comparison of hemoglobin levels of patients before and after surgery showed that these two groups were in a similar condition. After removing the effects of age, sex, body mass index, duration of operation, and basal hemoglobin no changes were observed in hemoglobin levels between the two groups. (Table 6).

Discussion

This study reported that the mean volume of bleeding due to surgery in the ventilation group with volume control was 465.26 cc, and in the ventilation group with pressure control, it was 431.28 cc, but no significant difference was observed between these two groups (p = 0.67). The results of the Kang’s study showed that the rate of intraoperative bleeding in the PCV group was lower than the VCV group in patients undergoing similar surgery (253 and 382 ml), respectively (28). However, in the study of Le Guen and et al (2019) that examined the effect of mechanical ventilation modality, showed no bleeding in trans sphenoidal pituitary surgery (29). Accordingly, the difference can also be related to the impact of some other factors such as the length of surgery and the number of surfaces that should be operated. The average duration of surgery in Kang's study was 156 minutes and in the present study, it was 146 minutes. In addition, another variable was the age of the include patients that was less than 46 years old in both groups, but in the Kang’s study, it was more than 64 years old. It was indicated that age alone with

cardiovascular changes can have a great impact on the amount of bleeding directly or indirectly by exacerbating the other factors.

The Guen's study challenged the possible effect of ventilation type as well as the increased intrathoracic pressure on venous return in positive pressure ventilation and as a result rejected its clinical effect, which is consistent with the results of the present study. However, the sitting position could still be considered as a contributing factor in these differences.

Comparison of hemoglobin levels of the patients before and after surgery showed that the two groups were in a similar condition. This finding is similar with the findings of other studies (11, 18, 19 and 27). Although the amount of intraoperative bleeding was different between these two groups, the measured hemoglobin and hematocrit were not significantly different between them at any time. Therefore, this indicates that hemoglobin and hematocrit are not good indicators of intraoperative bleeding, which can be due to various causes like fluid shifts. Furthermore, there was no difference in the amounts of postoperative bleeding at 24 and 72 hours between the two groups.

In the present study, most of the patients in both treatment groups required no blood transfusions. Notably, in the ventilation group with volume control of 74.4% and in the ventilation group with pressure control of 75%, the difference between the two groups was not statistically significant (p=1).

The surgeon evaluated the surgical field in 74.4% of the patients in the ventilation group with volume control and 82.1% of the patients in the ventilation group with a good pressure control (p = 0.58). This finding is in agreement with a similar study (27).

Due to the limited studies performed similar to our study, the comparison of most of the results of this study with other studies was limited.

Conclusion

The mean volume of bleeding due to surgery was higher in the volume-controlled ventilation group compared to the pressure-controlled ventilation group, but no significant difference was observed between these two groups. Due to the inconsistencies in few studies available, the role of ventilation type in the rate of bleeding cannot be confirmed as an independent variable, so it needs further investigations.

Abbreviations

PCV: Pressure controlled ventilation

VCV: Volume controlled ventilation

PLIF: Posterior lumbar inter body fusion

Declarations

Acknowledgements

This study was done after obtaining the approval of the Institutional Review (95051) of Kashan University of medical science.

Authors' contributions

Salimian Manoochehr collected and analyzed the data and wrote the paper. *Hajijafari Mohammad* analyzed the data. *Fakharian Esmaeil* helped with the clinical anaesthesia management. *Meghdad Rahati* helped with the study design and revision of the paper. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request. The corresponding author: Salimian Manoochehr, Email: drmsr_44@yahoo.com.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Kashan University of Medical Sciences.

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Consent for publication

Written informed consents were obtained from all participants' parents. All experiment procedures (consisted of invasive manipulation) and data collection were conducted with prior informed consent.

Competing interests

All authors declare that they have no conflicts of interest.

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Tables

Table 1: Demographic and bleeding

	VCV group	PCV group	p-value
Male	15(38.5%)	16(41%)	**0.82**
Female	24(61.5%)	23(59%)	
Age (year)	42.41±10.45	43.77±11.38	0.53
Height(meter)	1.65±.9	1.66±.1	**0.54**
Weight(kg)	76.11±11.47	78.77±19.71	**0.13**
BMI	27.92±4.89	28.42±7.10	**0.93**

* Independent T test

Table 2: Mean bleeding volume in the studied groups

Group	Mean	SD	P value*
VCV	465.26	33.81	**0.67**
PCV	431.28	36.10	

* Independent T test

Table 3: Frequency of injectable pack cell in the studied groups

Group	0	1	2	Sum	P value
VCV	29(74.4%)	3(7.7%)	7(17.9%)	39(100%)	**1***
PCV	30(75%)	3(10%)	6(15%)	39(100%)	
Sum	59(74.7%)	6(8.9%)	13(16.5%)	78(100%)	

* Fisher's Exact test

Table 4: Satisfaction surgeon from the surgical field

Surgeon satisfaction	VCV Group	PCV Group	Sum
Good	29(74.36%)	32(82.1%)	**61(78.2%)**
Moderate	9(23.8%)	7(17.9%)	**16(20.5%)**
weak	1(2.56%)	0	**1(1.3%)**
Sum	39(100%)	39(100%)	**78(100%)**
P Value	*58/0		

Table 5: Frequency of need to use antihypertensive drugs in the studied groups

Group	Need for Blood pressure-lowering drugs	No Need for Blood pressure-lowering drugs	Sum
VCV	4(10.3%)	35(89.7%)	**39**(100%)
PCV	2(5.1%)	37(94.9%)	**39**(100%)
Sum	6(7.7%)	72(92.3%)	**78**(100%)
P Value	***22/0**		

* Chi Square

Table 6: Mean hemoglobin of patients before and after surgery in the study groups

Time	Group	Mean	SD	P value*
Before surgery	VCV	13.39	1.47	0.772
	PCV	13.48	1.41	
After surgery	VCV	11.92	1.43	0.775
	PCV	12.01	1.41	

* Independent T test