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Randomised Controlled Trial

Comparative study of the effect of two different doses of remifentanil on bleeding control in lumbar fusion surgery: A randomized clinical trial☆

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ABSTRACT

Objectives: Spinal fusion surgery completely prevents movement or friction between the two vertebrae. Remifentanil, a selective drug agonist, suppresses and decreases the vasomotor system upon release of histamine. In this study, the efficacy of remifentanil infusion at doses of 0.1 and 0.3 μg/kg/min in the control of low blood pressure was compared.

Methods: In this randomized clinical trial, 110 candidates for selective spinal fusion surgery were entered and randomized into 2 groups. The first group received 0.1 μg/kg/min and in the second group 0.3 μg/kg/min remifentanil. The systolic and diastolic blood pressure, pulse rate, SPO2, and surgeon's satisfaction were measured and compared between groups.

Results: the systolic blood pressure was significantly lower in patients receiving 0.3 μg of remifentanil by the time 30, 45, 60, and 90 min during the surgeries ($P < 0.05$). No significant difference was observed in terms of PR ($P = 0.19$) and SPO2 ($P = 0.41$) between the two groups. We also observed significantly higher duration of surgeries ($P = 0.002$), duration of anesthesia ($P = 0.009$), significantly higher bleeding volume ($P < 0.001$), higher fluid intake ($P = 0.01$) and higher transfused blood ($P = 0.01$) in patients that received 0.1 μg remifentanil compared to other patients.

Conclusion: Here we showed that administration of 0.3 μg/kg/min remifentanil was associated with significantly lower systolic blood pressure during the surgeries. On the other hand, patients that received 0.1 μg/kg/min remifentanil had significantly higher duration of surgeries, duration of anesthesia, significantly higher bleeding volume, higher fluid intake, and also higher transfused blood.

1. Introduction

Spinal fusion surgery is a surgical procedure that causes a permanent connection between two or more vertebrae [1]. This procedure prevents movement or friction between the vertebrae and is often performed on the lumbar spine [2]. Spinal fusion could also be performed on other spinal levels such as cervical and thoracic [3,4]. Selective fusion surgery is performed in adolescents in cases of curvature [5]. The benefit of this surgery is the limitation of fusion levels, therefore decreasing the limitation of motion [6]. Three types of surgical procedures are performed for spinal fusion, which are posterior, anterior, and posterior-anterior fusion. Indications for spinal fusion include spinal deformity due to cerebral palsy, neuromuscular disease, scoliosis, trauma, vertebral tumors [7], and mechanical injuries due to spinal instability, and some reoperations [8,9].

Bleeding is known as an important intraoperative complication during spinal fusion that interferes with the success of the operation and increases the complications during and after the operation [10]. This

☆ The study protocol was approved by the Research Committee of Isfahan University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR.MUI.MED.REC.1399.1025, Iranian registry of clinical trials (IRCT) code: IRCT20200217046523N12).

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complication depends on various factors such as the type of anesthesia, the type of injury, the type of fusion, the skill of the surgeon, and the patient's characteristics [11,12]. Excessive bleeding during surgery is one of the most important problems during lumbar fusion surgery [13].

By defining a reduction in blood pressure and heart rate, the goal of clearing the surgical field can be achieved [14]. Excessive bleeding during surgery, in addition to reducing the surgeon's view of the surgical field, causes more trauma to the surrounding tissues, and the longer the period, the better the recovery period [15]. Controlled hypotension reduces bleeding from the surgical incision, thereby providing technical freedom and better vision for the surgeon in terms of operating more accurately [16,17]. In controlling hypotension, drugs such as Trimetaphan and pentolinium, vascular wall muscle relaxants such as hydralazine, sodium nitroprusside, and beta-blockers including propranolol [18–20].

Remifentanil suppresses and decreases the vasomotor system upon release of histamine [21]. Compared to other narcotic drugs such as fentanyl and alfentanil, remifentanil can provide better hemodynamic stability in stressful surgical events and alter cerebral blood flow changes. On the other hand, such treatment should be performed with great care because there is a possibility of heart failure or bronchoconstriction [22]. Controlled hypotension should be used with caution to minimize the risk of damage to vital organs. Important risks of controlled hypotension include the possibility of coronary, cerebral, or renal circulatory failure [23,24]. Previous studies have shown the effectiveness of remifentanil in controlled hypotension but different dosages have been reported [25]. To date, no previous studies have compared the effects of 0.1 and 0.3 μg/kg/min dosages of remifentanil in reducing bleeding. As a result, using the optimized dosage of remifentanil has great importance, especially in patients undergoing special surgeries including selective fusion. Therefore, in this study, the efficacy of remifentanil infusion at doses of 0.1 and 0.3 μg/kg/min in the control of low blood pressure in patients undergoing dual lumbar fusion surgery was compared.

Methods and material.

This is a triple-blinded randomized clinical trial that was performed in 2020 in Al-Zahra hospital affiliated to Isfahan University of Medical Science. The current study was conducted on patients that were candidates for posterior spinal fusion surgery under general anesthesia. The study protocol was approved by the Research Committee of Isfahan University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR. MUI.MED.REC.1399.1025, Iranian registry of clinical trials (IRCT) code: IRCT20200217046523N12).

The inclusion criteria were age between 16 and 70 years, candidates for posterior spinal fusion surgery at the level of 1 and 2, American Society of Anesthesiologists (ASA) classification equal to 1 or 2 and signing the written informed consent to participate in this study. The exclusion criteria the use of hypotensive induction anesthesia, the occurrence of unwanted hemodynamic complications due to surgical technique, having severe cardiovascular diseases and patients with the history of hypertension.

Required Sample size was calculated with using the sample size estimation formula to compare the means with considering the 95% confidence level, 80% test power, standard deviation of mean blood pressure in controlled hypotension which was about 1.5 [15] and the effect size was 0.8 in 55 patients in each group. Also, the data collector and the statistical analyst were also unaware of the dose of fentanyl injected into patients. After analyzing the data, the codes were opened and comparisons are made between groups. Sampling method was convenient.

The names of the patients were entered to the SPSS software (I·B.M., IL Chicago) and were randomized into two groups. The blinding method was such that the patient and the researcher were unaware of the type of injectable drug to the patients. The drugs were prepared in the same coded syringes by one of the operating room staff who was not aware about the study and were given to the researcher for injection.

A total number of 114 patients entered based on inclusion criteria and were randomized into two groups. At the initial examination, vital signs such as blood pressure, heart rate, blood oxygen saturation were measured and recorded. General patient information including age, sex, type of operation and underlying diseases and patients' weight were recorded in the data collection form.

All patients under general anesthesia after pre-oxygenation and premedication with 0.05–0.03 mg/kg midazolam and 3–4 μg/kg fentanyl and 100 mg lidocaine and for induction from thiopental sodium 5–7 mg/kg and 0.1 mg/kg and *cis*-atracurium were used. Patients were injected with 0.1 mg/kg morphine during surgery. Also, if there was no contraindication, 1 g of tranexamic acid was infused within 30 min. From the beginning, propofol was infused at a rate of 50–150 μg per kilogram for patients.

After positioning the patient and ensuring the patient's constant hemodynamic status, in the first group 0.1 μg/kg/min and in the second group 0.3 μg/kg/min remifentanil (manufactured by Hamelen Pharmaceutical Company) was infused. In case of failure to develop control hypotension with the mentioned doses (failure to bring systolic blood pressure to 50–60 mm Hg), the dose of propofol was increased or labetalol with an initial dose of 5 mg and then 10 or 20 mg was used. Requiring additional morphine injections was also noted.

From the beginning of anesthesia, systolic and diastolic blood pressure, heart rate, and blood oxygen saturation percentage were monitored and recorded every 30 min during the operation and recovery [26,27]. Incidence of any hemodynamic disorder including hypotension (systolic blood pressure less than 70 mm Hg), hypertension (systolic blood pressure above 140 mm Hg), tachycardia (heart rate greater than 100 beats per minute), and bradycardia (heart rate lower than 45 times per minute) during operation and recovery. In case of hypotension, 5–10 mg of ephedrine, and in case of bradycardia, atropine in the amount of 0.5 mg was injected.

The volume of bleeding during the operation was calculated by the weight of gauze used and the amount of suctioned blood during the operation. Other required information such as duration of operation (from the time of surgical incision to the time of the last suture), duration of anesthesia (from the start of injection to discontinuation of anesthesia), time of extubation (from time to closure of anesthesia to the exit of the tube Chip) and the length of stay in recovery were determined and recorded in all patients. After the operations, the patients were discharged from the recovery according to the modified Aldrete criteria [28]. If morphine was needed, the dose and frequency of injections were recorded.

To remove the bias, all surgeries were performed by a single neurosurgeon. Surgeon satisfaction at the end of the operation was measured using the 5-point Likert scale. The above criterion is a 5-part criterion that divides satisfaction from 1 to 5, which included completely satisfied [5], satisfied [3], dissatisfied [3], dissatisfied [2] and completely dissatisfied [1]. The occurrence of postoperative complications such as nausea and vomiting was monitored and recorded. The severity of nausea in patients was classified from zero to 3 using the Apfel criterion, which was zero as no nausea, 1: as mild nausea, 2, as moderate nausea, and 3 as severe and persistent nausea. If the patient had a complication, he was not excluded from the study.

Data analysis: The obtained data were entered into the Statistical Package for Social Sciences (SPSS) version 24. We used independent *t*-test and repeated measure tests to compare data between different timelines and also different groups. P-value$<$ 0.05 was considered a significant threshold.

Unique identifying number (UIN) of your study: Researchregistry7111.

The work has been reported in line with the CONSORT criteria [29].

2. Results

A total number of 114 patients entered this study and were

randomized into 2 groups of 57 patients. 4 patients (2 patients in each group) were excluded due to changes in the surgical plan. Data are indicated in Fig. 1. The primary analysis of demographic data showed no significant differences between the two groups regarding age, weight, and ASA classification, level of surgeries, gender, and past medical histories ($P > 0.05$ for all items). These data are indicated in Table 1.

Further analysis showed that the systolic blood pressure was significantly lower in patients receiving 0.3 μg of remifentanil by the time 30, 45, 60, and 90 min during the surgeries ($P < 0.05$) but no significant differences could be observed among patients regarding diastolic blood pressure and MAP (Table 2).

According to Table 3, no significant difference was observed in terms of PR ($P = 0.19$) and SPO2 ($P = 0.41$) between the two groups.

We also evaluated further variables among groups. These data showed a significantly higher duration of surgeries ($P = 0.002$), duration of anesthesia ($P = 0.009$), significantly higher bleeding volume ($P < 0.001$), higher fluid intake ($P = 0.01$), and higher transfused blood ($P = 0.01$) in patients that received 0.1 μg remifentanil compared to other patients. We also showed that the surgeon's satisfaction was significantly higher in patients that received 0.3 μg remifentanil ($P = 0.001$). There were also no significant differences between groups regarding other variables. These data are indicated in Table 4.

No significant differences could also be observed between the two groups regarding nausea and vomiting.

Table 1
Comparison of demographic data between groups.

group			N	Mean	Std. Deviation	p-value
Age	0.1 μg		55	41.56	14.29	0.23
	0.3 μg		55	44.57	11.64	
Weight	0.1 μg		54	70.77	9.74	0.06
	0.3 μg		54	74.24	9.11	
			1.00	2.00		
ASA	0.1	Number	48	5	53	0.07
	μg	Percent	90.6%	9.4%	100.0%	
	0.3	Number	39	11	50	
	μg	Percent	78.0%	22.0%	100.0%	
Level of surgery	0.1	Number	9	44	53	0.26
	μg	Percent	17.0%	83.0%	100.0%	
	0.3	Number	5	49	54	
	μg	Percent	9.3%	90.7%	100.0%	
			Female	Male		
Gender	0.1	Number	30	25	55	0.84
	μg	Percent	54.5%	45.5%	100.0%	
	0.3	Number	28	27	55	
	μg	Percent	50.9%	49.1%	100.0%	
			Yes	No		
past medical histories	0.1	Number	45	10	55	0.81
	μg	Percent	81.8%	18.2%	100.0%	
	0.3	Number	43	12	55	
	μg	Percent	78.2%	21.8%	100.0%	

Using independent *t*-test and chi-square tests.

3. Discussion

A comparison of two different dosages of remifentanil in patients undergoing spinal surgeries with the possibility of massive bleeding was associated with decreased amounts of bleeding. In this study, the efficacy of remifentanil infusion at doses of 0.1 and 0.3 μg/kg/min in the control of low blood pressure in patients undergoing dual lumbar fusion surgery was compared. Here we showed that the patients that received 0.3 μg/kg/min remifentanil had significantly lower systolic blood pressure by the time of 30, 45, 60, and 90 min during the surgeries. On the other hand, patients that received 0.1 μg/kg/min remifentanil had significantly higher duration of surgeries, duration of anesthesia, significantly higher bleeding volume, higher fluid intake, and also higher transfused blood. Similar findings are reported in our study.

In a study by Hadi and colleagues in 2010, 30 candidates for spinal fusion surgery were divided into two groups and received 0.2 μg/kg/min remifentanil with or without ketamine and were evaluated for 24 h in the post-anesthesia care unit. It was reported that patients that received only remifentanil had significantly lower blood pressure and heart rate. The patients had also lower bleeding volumes which led to better hemodynamic stability [30]. Rahimzadeh and colleagues also compared the results of remifentanil and dexmedetomidine injections among patients undergoing posterior spinal fusion surgery. They evaluated 60 patients and explained that patients that received remifentanil with the dosage of 0.1 μg/kg/min had decreased blood pressure but the patients receiving dexmedetomidine had lower hemodynamic indexes at 30, 60, 120, and 360 min after extubation [31]. The findings of our study were in line with these results showing the effectiveness of remifentanil injection. An important point of the current study was that we compared two different dosages of remifentanil and the clinical outcomes of patients during and after surgeries. We observed that administration of 0.3 μg/kg/min has better effectiveness compared to conventional dosage (0.1 μg/kg/min).

Ghodraty and others performed another study in 2014 on 39 patients undergoing spine surgery. It was declared that injection of 0.25 μg/kg per minute of remifentanil was associated with a significant reduction in blood pressure and bleeding volume during the 5 h of post-anesthesia care. The study recommended that higher dosages could have better effects on patients [32]. These data are also in line with our findings.

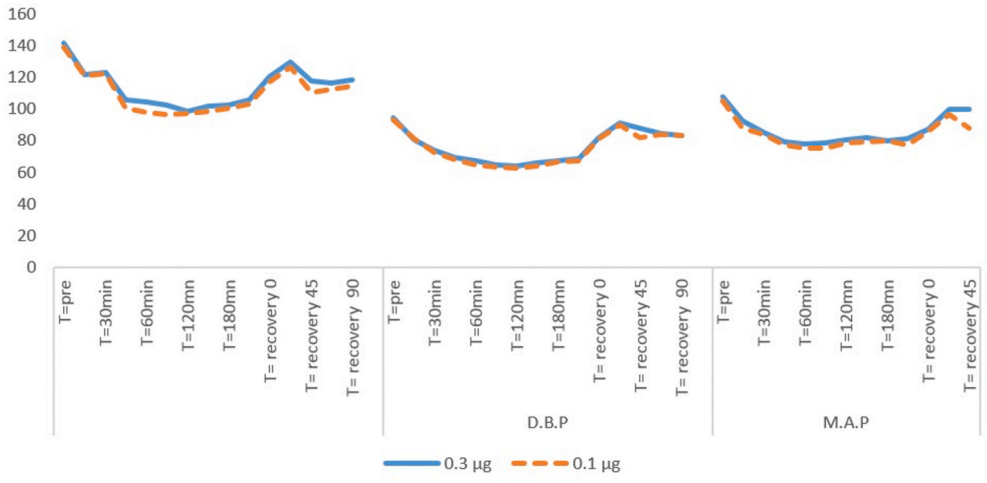

Fig. 1. Evaluation of blood pressures between groups.

Table 2
Evaluation of blood pressure changes by time and group therapy.

group		T = pre	T = 0	T = 30min	T = 45min	T = 60min	T = 90min	T = 120mn	T = 150mn	T = 180mn	T = 210mn	T = recovery 0	T = recovery 30	T = recovery 45	T = recovery 60	T = recovery 90	P1	P2	P3
SIS 0.1 μg	Mean	138.7091	120.8364	122.4000	98.7455	116.1091	112.4909	100.9818	102.3922	102.4894	103.1522	117.2909	126.7455	110.2333	116.6566	118.3662	0.001	0.15	0.63
	S.D	19.60411	16.19301	12.96805	18.01051	14.31481	9.36477	13.71602	6.95724	6.92152	8.56081	11.15990	11.39561	13.91274	15.32365	10.32220			
0.3 μg	Mean	141.6364	121.7273	123.1636	96.7636	111.3818	108.6182	98.8909	101.7455	102.4808	105.7000	120.4545	129.9818	117.8438	112.3842	114.3663	0.001		
	S.D	16.96659	10.01380	14.12086	12.51512	9.51313	9.72490	10.80753	9.54758	9.92223	11.61851	13.53161	11.73234	29.36106	12.21320	11.36687			
	P4	0.40	0.72	0.76	0.50	0.04	0.03	0.37	0.69	0.90	0.22	0.18	0.14	0.20	0.23	0.19			
DIAS 0.1 μg	Mean	93.5091	81.0909	72.7091	69.4727	67.5273	64.7455	63.8000	65.9216	67.4286	68.3830	82.0000	90.9818	82.1786	84.6332	83.5420	0.001	0.34	0.78
	S.D	16.10368	14.85519	11.88630	11.07693	13.13865	8.29149	11.73535	7.66510	6.91616	8.66666	9.58973	10.68486	13.43587	10.25007	11.28770			
0.3 μg	Mean	94.8727	80.9455	74.2727	67.9455	64.4364	63.4364	62.8182	66.1818	66.7547	67.3600	81.4364	90.1455	87.9667	84.1556	83.3560	0.001		
	S.D	13.68705	10.91112	12.92780	9.64829	9.06308	7.95302	9.89592	9.90901	9.88181	11.25540	10.15758	10.56097	11.93801	11.59203	10.20478			
	P4	0.63	0.95	0.51	0.44	0.15	0.40	0.63	0.88	0.69	0.61	0.76	0.68	0.08	0.20	0.17			
MAP 0.1 μg	Mean	104.8727	87.9818	83.8727	80.3636	89.0727	86.6364	85.6727	73.8627	75.2041	76.0426	88.6000	96.7778	88.0714	101.6302	100.2557	0.001	0.23	0.051
	S.D	16.95971	17.97580	12.39482	13.21526	11.04512	7.90772	10.15811	7.66817	7.07101	8.21705	9.96958	13.14314	11.03170	11.32870	10.26300			
0.3 μg	Mean	108.0182	92.5455	84.9455	78.3455	85.4545	84.0000	88.3455	79.3636	79.6852	77.2000	88.0364	99.9636	99.9667	95.2014	94.5870	0.001		
	S.D	14.93379	9.40019	11.81559	9.70341	9.53516	8.95669	7.74171	10.13129	10.25123	11.22861	10.80974	9.41819	12.43877	10.26587	11.23698			
	P4	0.30	0.09	0.64	0.36	0.06	0.10	0.12	0.002	0.01	0.50	0.77	0.14	<0.001					

Table 3
Comparison of PR and SPO2 among patients.

group		T = pre	T = 0	T = 30min	T = 45min	T = 60min	T = 90min	T = 120mn	T = 150mn	T = 180mn	T = 210mn	T = recovery 0	T = recovery 30	T = recovery 45	T = recovery 60	T = recovery 90	P1	P2	P3
PR 0.1 μg	Mean	91.1091	88.9636	81.5636	82.9091	80.6909	78.0000	79.2727	78.7059	79.0408	77.9149	81.3273	79.6111	75.2069	68.3551	69.241	0.001	<0.001	0.19
	S.D	13.11441	14.58940	17.05847	11.91214	12.93556	17.79409	11.60532	12.64167	11.23603	12.75493	13.78412	12.61987	10.37641	13.22540	12.36724			
0.3 μg	Mean	95.0182	90.0727	85.4909	81.4727	80.3818	82.8545	77.2182	75.8182	77.2778	78.7800	81.4000	80.2909	80.6000	67.7421	68.2360	0.001		
	S.D	15.47099	13.91755	12.65332	12.75387	13.27556	45.13249	12.67206	15.06294	12.82011	13.16503	14.87429	13.05639	15.74933	11.25741	11.30870			
	P4	0.15	0.68	0.17	0.54	0.90	0.46	0.37	0.28	0.46	0.74	0.97	0.78	0.12	0.64	0.87			
SPO2 0.1 μg	Mean	97.8909	98.7091	98.8545	99.2182	98.8909	98.8364	98.5849	99.2549	98.5490	98.5102	98.4231	98.3617	98.7857	98.7921	98.7834	0.001	0.009	0.41
	S.D	2.38570	1.34264	1.00771	1.06616	.97511	1.01404	1.13398	1.07412	1.10116	1.06306	1.82946	1.89307	1.49039	1.84205	1.63277			
0.3 μg	Mean	97.6000	98.5455	98.8182	99.0182	98.7636	98.7636	98.6182	99.0182	98.6182	98.5926	98.3148	98.1915	98.4474	98.4526	98.4723	0.001		
	S.D	2.90338	1.54941	1.09021	1.17837	1.10493	1.10493	1.16255	1.16255	1.17837	1.17391	2.23036	2.23255	1.87007	1.96387	1.25387			
	P4	0.56	0.55	0.85	0.35	0.52	0.72	0.88	0.28	0.75	0.71	0.78	0.69	0.37	0.39	0.42			

P1 (Time), p2 (interaction), p3 (intervention) at a significant level of repeated measure test.
P4 at the 5% level of independent *t*-test.

Table 4
Evaluation of surgical duration, anesthesia duration, recovery duration, bleeding volume and fluid intake and other variables.

	group	N	Mean	Std. Deviation	P-VALUE
Surgical duration (hour)	0.1 μg	50	3.6382	.58280	0.06
	0.3 μg	51	3.8700	.67620	
Anesthesia duration (hour)	0.1 μg	55	4.5000	.75768	0.009
	0.3 μg	55	4.8473	.60975	
Extubation duration (hour)	0.1 μg	51	39.1176	12.23544	0.11
	0.3 μg	50	35.3000	12.13908	
Recovery duration (hour)	0.1 μg	51	1.3333	.43205	0.42
	0.3 μg	50	1.2700	.35298	
Bleeding volume (ml)	0.1 μg	52	536.5385	223.19327	<0.001
	0.3 μg	55	372.7273	201.11223	
Fluid intake (L)	0.1 μg	52	2.4904	1.51622	0.01
	0.3 μg	54	1.7037	1.70050	
Transfused blood (L)	0.1 μg	51	.5294	.85681	0.01
	0.3 μg	47	.1702	.43335	
Atropine (mg)	0.1 μg	7	1.2500	1.86474	0.28
	0.3 μg	12	.4429	.45408	
Ephedrine (mg)	0.1 μg	13	2.3889	3.08486	0.41
	0.3 μg	18	3.3846	3.65897	
Propofol (mg)	0.1 μg	50	301.7105	255.93569	0.72
	0.3 μg	51	337.9688	580.74182	
Remifentanil (mg)	0.1 μg	53	5.3395	2.41141	0.01
	0.3 μg	53	4.0154	1.67778	
Extra morphine (mg)	0.1 μg	25	7.0833	6.20056	0.33
	0.3 μg	6	4.1667	4.91596	
Extra labetalol (mg)	0.1 μg	18	14.8328	1.54125	0.07
	0.3 μg	6	3.37291	0.21405	
Surgeon's satisfaction	0.1 μg	55	2.2000	.91084	0.001
	0.3 μg	54	1.4815	.77071	

Using independent *t*-test and chi-square tests.

Some other previous studies have also declared the effectiveness of remifentanil injections with the dosage of 0.1 μg/kg/min during spinal surgeries [33–35] and reported lower blood pressure, lower bleeding, lower surgery and recovery, and also limited fluid intake compared to other agents. In the present study, we showed that administration of 0.3 μg/kg/min is associated with better results during and after surgical operations and also with no difference in complications.

In 2008, a study was conducted by Kim and colleagues in Korea on 60 patients that were candidates for endotracheal intubation and reported that 1 μg/kg/min remifentanil followed by an infusion of 0.1 μg/kg/min is more effective than 1.5 mg/kg esmolol for inhibiting the cardiovascular responses following endotracheal intubation during the induction of general anesthesia. They also explained that higher dosages of remifentanil might have better results. However, the study evaluated these parameters from 1 to 5 min before intubation and 1–5 min after intubation [36]. We believe that administration of 0.3 μg/kg/min remifentanil could have significant clinical outcomes in other medical interventions.

Our study is the first one to provide evidence regarding two different doses of remifentanil for managing bleeding among spinal surgery patients along with intraoperative and postoperative parameters. It can also be deduced that 0.1 μg/kg/min may be less to achieve the desirable results. The limitations of the current study were restricted number of patients and also not evaluating the hemoglobin levels of patients and also the amounts of administered muscle-relaxants in patients. Therefore, we suggest that further studies on larger populations should be performed with evaluating the mentioned factors.

4. Conclusion

Here we showed that administration of 0.3 μg/kg/min remifentanil was associated with significantly lower systolic blood pressure by the time of 30, 45, 60 and 90 min during the surgeries. These data indicate the effectiveness and beneficial outcomes of 0.3 μg/kg/min remifentanil injection in patients undergoing posterior spinal fusion surgery under general anesthesia. These data show that administration of 0.3 μg/kg/min remifentanil during surgeries is associated with significant positive results compared to other patients.

Availability of data and materials

All relevant data and materials are provided with in manuscript.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Author statement

Dr. Seyedeh Hamideh Hashemiyazdi and Dr. Mohammad Aryafar: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Mehrdad Masoudifar and Dr. Azim Honarmand: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. Dr. Zahra Rahimi: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Registration of research studies

Name of the registry: IRCT20200217046523N12.

Unique Identifying number or registration ID: IR. MUI.MED. REC.1399.1025.

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Guarantor

Dr. Seyedeh Hamideh Hashemiyazdi.

Consent

Not applicable.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Human and animal rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

Declaration of competing interest

The authors deny any conflict of interest in any terms or by any means during the study.

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