

ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Comparative analysis of effects of three different doses of fentanyl and standard dose of bupivacaine on a spinal block in patients with hip endoprosthesis surgery

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SUMMARY

Introduction/Objective Spinal anesthesia is often used for hip endoprosthesis surgery. Significant surgical stress response consisting of hormonal, metabolic and inflammatory changes can be initiated by the hip replacement surgery. Intrathecal opioids, as adjuvants to local anesthetics, make spinal block sufficient even with lower doses of the local anesthetics, and the incidence of the side effects reduce to minimum.

Methods This study included 162 patients of either sex, American Society of Anesthesiology classification (ASA) 1–2, scheduled for total hip arthroplasty. The patients had spinal anesthesia with 10 mg of 0.5% bupivacaine with 20 µg (Group I), or 25 µg (Group II) or 30 µg fentanyl intrathecally (Group III).

Results Mean time to achieve maximum motor and sensory blockade was with no significant difference among the groups. Time of motor block duration was shorter in the Group III. Four hours after the operation, patients in the Group I had significantly higher cortisol serum levels. Blood glucose levels were with no significant difference among the groups. Levels of CRP increased remarkably postoperatively in the Group I. Incidence of hypotension, bradycardia, nausea and vomiting was significantly higher in the Group III. Pruritus and shivering were not recorded among the groups. The first time an analgetic was needed postoperatively was the longest in the Group III.

Conclusion The dose of 10 mg of bupivacaine combined with 25 µg fentanyl was the optimal option to achieve hemodynamic stability, sufficient sensory and motor blockade, and reduce the stress response and incidence of the opioids side effects such as vomiting, nausea, pruritus etc.

Keywords: spinal anesthesia; bupivacaine; fentanyl; postoperative analgesia

INTRODUCTION

Significant surgical stress response consisting of hormonal, metabolic and inflammatory changes can be initiated by the hip replacement surgery [1, 2]. The controlled trauma of a surgical insult activates the afferent nerve signals from the surgical site and stimulates the production of corticotrophin-releasing hormone and arginine vasopressin. These peptides stimulate secretion of adrenocorticotrophic hormone which stimulates cortisol secretion [3]. The effects of cortisol in the setting of surgical stress include suppression of insulin and mobilization of energy stores, increased proteolysis, sodium and water retention leading to preservation of blood pressure, suppression of the immune inflammatory response and delayed wound healing through its effects on collagen synthesis. Cortisol enables the synthesis and release of catecholamines and contributes to normal vascular permeability, vascular tone, and myocardial contraction by regulating β -receptor synthesis and regulation [4, 5].

Spinal anesthesia is often used for hip endoprosthesis surgery. During a spinal anesthesia

there are many side effects as a result of sympathetic nervous system blockade. Post spinal anesthesia hypotension is caused by the decrease in the sympathetic outflow causing arterial vasodilatation, a decrease in venous return and consequently the activation of the Bezold–Jarisch reflex that elicits a triad of bradycardia, vasodilatation and further hypotension [6]. The incidence of hypotension during the spinal anesthesia is about 16–33% [7]. Compensatory mechanisms are generally more effective in young patients [8]. In elderly patients there are reduced physiological reserve and associated comorbidities [9]. Acute hypotension reduces cerebral perfusion, which leads to transient ischemia and activates the vomiting center [10]. To reduce the incidence and severity of hypotension, various strategies have been developed: preloading/co-loading fluids, use of vasoconstrictors and low doses of local anesthetics [11, 12].

Spinal anesthesia can provide good perioperative pain control. The pre-surgery block contributes to intra-operative analgesia and reduces the need for other analgesics [13].

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The use of the lower doses of local anesthetics combined with opioids, while providing a spinal block, may result in a better hemodynamic response of the patients and minimal incidence of the side effects [14, 15]. Besides analgesia, this anesthetic technique protects patients by reducing the immune response and the incidence of the postoperative complications.

The aim of this study is to compare the efficiency of three different intrathecal doses of fentanyl (20 µg, 25 µg and 30 µg) added to standard dose of local anesthetic (2 mg 0.5% bupivacaine) during the elective hip replacement surgery. The efficiency of the opioid used refers to less surgical stress, less side effects and longer duration of analgesia.

METHODS

All procedures performed in the study involving human participants were done in accordance with the ethical standards of the Helsinki declaration and its later amendments. Furthermore, the research was approved by the Ethics Committee of the Faculty of Medicine of the University of Niš on September 12, 2017; ref. No.: 12-8765/ 8. Informed consent was obtained from all individual participants included in the study.

This study included 162 patients of either sex, American Society of Anesthesiology physical status classification 1–2, scheduled for total hip arthroplasty. All patients had surgical treatment in the morning. The patients were randomized into three groups:

Group I: Patients that received 10 mg (2 ml) 0.5% bupivacaine and 20 µg (0.4 ml) of fentanyl intrathecal;

Group II: Patients that received 10 mg (2 ml) 0.5% bupivacaine and 25 µg (0.5 ml) of fentanyl intrathecal;

Group III: Patients received 10 mg (2 ml) 0.5% bupivacaine and 30 µg (0.6 ml) of fentanyl intrathecal.

Sensory blockade was evaluated by the bilateral pinprick method. Motor blockade was evaluated by the modified Bromage test (0 – without paralysis; 1 – unable to lift extended legs; 2 – unable to flex knee; 3 – unable to flex feet or complete motor blockade).

Serum levels of cortisol, glucose and C-reactive protein (CRP) were measured in all groups preoperatively and four, 12, and 24 hours after surgery.

The cardiovascular status of the patients was monitored by non-invasive methods such as: ECG monitoring, systolic, diastolic and mean arterial pressure, in five-minute intervals.

The side effects on the central nervous system and gastrointestinal system such as: shivering, nausea, vomiting, and pruritus were followed up and recorded intra-operatively or postoperatively.

The intensity of pain was assessed in the 30th, 60th, 90th, 120th, 180th, 240th, and 300th minute after the anesthesia was given in two ways:

- visual analog scale (0 – without pain to 10 – the worst pain);
- numerical scale (0 – without pain to 10 – the worst pain).

Duration of sensory blockade and the first time an analgesic drug was needed postoperatively were also recorded.

RESULTS

There was no statistically significant difference regarding ages, body mass index and the duration of surgery in all groups ($p < 0.05$) (Table 1).

Table 1. Patient characteristics

Group (number of patients)	Age (years)	Sex (M/F)	BMI (kg/m ²)	Duration of surgery (min)
I (n = 54)	69.1 ± 8	30/24	25.5 ± 3.1	104.4 ± 9.6
II (n = 54)	66.6 ± 7.5	38/16	24.3 ± 3.8	106.9 ± 8.6
III (n = 54)	67.5 ± 7.7	34/20	24.4 ± 3.4	105.6 ± 8.6

There was no statistically significant difference regarding age, body mass index (BMI) and the duration of surgery in all the groups ($p < 0.05$)

There was no significant difference between the groups' mean time to achieve maximum motor blockade. The time of motor blockade duration was significantly shorter in Group II ($p < 0.05$) (Table 2).

Table 2. Motor blockade characteristics

Group	Time to achieve motor blockade I (min)	Time to achieve motor blockade II (min)	Time to achieve motor blockade III (min)	Time to achieve motor blockade IV (min)	Time duration of motor blockade (min)
I	2.2 ± 0.6	3.2 ± 0.8	4 ± 1	4.7 ± 1	166.0 ± 7.8
II	2.4 ± 0.7	3.4 ± 0.7	4.5 ± 0.6	4.6 ± 0.6	141.7 ± 15.3
III	2.1 ± 0.6	3 ± 0.7	3.9 ± 0.7	5 ± 0.6	128.7 ± 15.1

Mean time to achieve maximum motor blockade was with no significant difference among the groups; the time of motor blockade duration was significantly shorter in Group II ($p < 0.05$)

The mean time to achieve maximum sensory blockade was comparable among the three groups ($p < 0.05$) (Table 3). It was with no significant difference among the groups.

Table 3. Characteristics of sensory blockade

Group	Time for distribution of sensory blockade until T10 (min)	Time to achieve maximal sensory blockade (min)
I	4.3 ± 0.5	6.4 ± 0.4
II	4.4 ± 0.8	6.6 ± 0.7
III	4 ± 0.7	6.2 ± 0.9

Mean time to achieve maximum sensory blockade was with no significant difference among the groups ($p < 0.05$)

At the fourth, 12th and 24th postoperative hour, the hormones of the surgical stress response were recorded. The study showed that patients in Group I had significantly higher cortisol serum levels at the fourth hour after surgery (Table 4).

Blood glucose levels were not significantly different among the groups. Levels of CRP increased remarkably postoperatively in the Group I (Table 5).

Table 4. Average serum cortisol levels (nmol/l) in the groups with 20 µg, 25 µg, and 30 µg intrathecal fentanyl, four, 12, and 24 hours postoperatively

Group	Preoperatively (nmol/l)	Postoperatively (nmol/l)		
		4 hours	12 hours	24 hours
I	472.4 ± 167.6	593.2 ± 277.3	850 ± 265.1	698 ± 105.3
II	692.6 ± 219.7	636.7 ± 184.2	789 ± 278.2	490.3 ± 170.6
III	558.5 ± 353.1	441.8 ± 249.4	765 ± 149.4	441.6 ± 277.3

Patients in Group I had significantly higher cortisol serum levels at the fourth hour after the surgery ($p < 0.05$)

Table 5. Levels of C-reactive protein (mg/L) four, 12, and 24 hours postoperatively

Group	Preoperatively (mg/L)	Postoperatively (mg/L)		
		4 hours	12 hours	24 hours
I	18.9 ± 3	108.4 ± 1.1	78.7 ± 26.6	65.3 ± 28.9
II	5.9 ± 2.2	5.3 ± 1.7	21.3 ± 11.2	11.2 ± 8.9
III	16.1 ± 2.5	18.7 ± 1.6	56.8 ± 15.6	44.9 ± 21.4

Levels of C-reactive protein increased remarkably postoperatively in Group I ($p < 0.05$).

Table 6. Prevalence of side effects

Group	Hypotension		Bradycardia		Nausea		Vomiting	
	Number of patients (n)	%	Number of patients (n)	%	Number of patients (n)	%	Number of patients (n)	%
I	17	31.5	11	20.4	0	0	0	0
II	18	33.3	13	24.1	2	3.1	0	0
III	25	46.3	18	33.3	4	7.4	2	3.7

Incidence of hypotension, bradycardia, nausea and vomiting were significantly higher in Group III ($p < 0.05$).

Incidence of hypotension, bradycardia, nausea and vomiting were significantly higher in Group III ($p < 0.05$) (Table 6). Pruritus and shivering were not recorded among the groups.

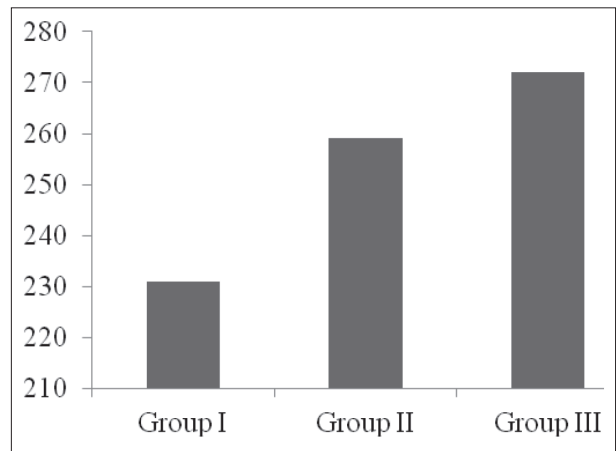
The longest time until new analgetic was needed postoperatively was in the Group III (Figure 1).

DISCUSSION

The intensity of sympathetic nervous system blockade depends on the local anesthetic dosage. A degree of sympathetic blockade and consequent hypotension after spinal anesthesia can be reduced by using small doses of local anesthetic. On the other side, a more breakthrough pain was reported with bupivacaine doses of 5 mg or less [16]. This tendency to adopt a higher dose approach is likely to be attributable to concerns that duration of spinal anesthesia may not be sufficient for the proposed surgery when bupivacaine < 10 mg is used [17].

The success of spinal anesthesia with low dose of local anesthetic can be improved by addition of opioids. Intrathecally fentanyl doses not make additional effects on the sympathetic blockade, but makes duration of analgesia longer [18, 19].

In this study, the maximum dose of the intrathecal solution of 0.5% bupivacaine was 2 ml (10 mg) with 30 µg (0.6 ml) fentanyl. This dose was defined by the results of the previous studies [19, 20]. Lower doses of local anesthetics combined with opioids may result in

**Figure 1.** New analgesic needed postoperatively; the longest time until new analgesic was needed postoperatively was in the Group III ($p < 0.05$).

inadequate sensory or motor blockade. Intra-operatively, analgesia was adequate in all groups. Similar results had Ben et al. [20] with intrathecal dose of 4 mg bupivacaine with 20 µg fentanyl.

Bibhush [21] compared three different doses (12.5 mg, 10 mg and 5 mg) of 0.5% bupivacaine, with 25 µg fentanyl. The results of this study showed that the dose of 5 mg of bupivacaine in combination with

25µg of fentanyl intrathecally had inadequate motor blockade, while the dose of 10 mg of bupivacaine increased intensity and duration of both, sensory and motor blockade. The time was 241.96 minutes. In this study the duration of motor blockade was 141.67 ± 15.3 minutes.

In this study, increasing the dose of fentanyl from 0.4 ml (20 µg) to 0.5 ml (25 µg) and 0.6 ml (30 µg) resulted in the increase of the maximum level of sensory blockade. The time of achieving maximum analgesia was with no significant difference among the groups. Kuusniemi [22] had similar results.

Cortisol has been researched in order to find the best anesthetic approach to reduced surgical stress response. Opioids, fentanyl and morphine, can reduce surgical stress response. Kwon et al. [23] hypothesized that circadian rhythm of cortisol might affect postoperative cortisol levels depending on the surgery start time. Cortisol recovery to preoperative level was faster in the afternoon surgery than in the morning surgery group. In this study, all patients had surgical treatment in the morning. Postoperative cortisol increased, similar to previous studies, except in the Group II, where the values were the same as before surgery. Cortisol serum level was significantly higher in the Group I at the fourth postoperative hour. Postoperatively, at 12th hour, there was a remarkable increase of the cortisol serum levels in all groups.

CRP serum levels were without any significant differences among the groups. At the fourth postoperative hour, the level of serum CRP was significantly higher in the Group I. Even after 12 hours it showed higher levels.

Impaired metabolism of glucose has influence on wound infection, and can cause cardiac and thromboembolic complications. Hahn et al. [24] mention the reduction of the postoperative complications in patients who were not diabetics. Glucose blood level is very important peri-operatively and postoperatively. In this study, blood glucose levels were not significantly different among the groups.

As a result, Knigin et al. [25] described spinal hypotension in 43.4% of patients. Rao et al. [26] described hypotension in seven out of 30 patients in a group with 8 mg bupivacaine combined with 25 µg fentanyl. Malhotra et al. [27] reported that the highest incidence of hypotension had a group with 12.5 mg of bupivacaine combined with 25 µg fentanyl. In this study, hypotension was described in 60 patients (37%). In Group I it was described in 17 (31.5%) patients. In Group II hypotension was described in 18 (33.3%) patients, and in Group III in 25 (46.3%). Better hemodynamic stability was observed in patients with 10 mg bupivacaine and 20 µg fentanyl. Ali et al. [28] reported pruritus with higher doses of fentanyl (25 µg). Akanmu et al. [29] described pruritus and shivering only in patients who received 10 mg of bupivacaine with 25 µg of fentanyl. Pruritus and shivering were not recorded among the groups in our study.

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CONCLUSION

Spinal anesthesia using standard doses of local anesthetics for hip endoprosthesis surgery in geriatric population, often causes hemodynamic instability due to reduced physiological reserve and comorbidities of patients. In order to prevent negative side effects and complications, but achieve an appropriate sensory and motor blockade, the use of lower doses of local anesthetics combined with opioids was implemented in practice.

The dose of 10 mg (2 ml) of bupivacaine combined with 25 µg (0.5 ml) fentanyl, in this study, was the optimal option to achieve hemodynamic stability, sufficient sensory and motor blockade, and reduce the stress response and the incidence of the opioids side effects such as vomiting, nausea, pruritus, etc.

Conflict of interest: None declared.

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Компаративна анализа три различите дозе фентанила у комбинацији са стандардном дозом бупивакаина код спиналног блока код болесника подвргнутих елективној операцији уградње вештачког кука

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САЖЕТАК

Увод/Циљ Спинална анестезија честа је анестезиолошка техника која се користи током хируршке интервенције уградње вештачког кука. Овај хируршки третман може изазвати системски одговор на хируршки стрес, односно хормонске, метаболичке и запаљенске промене. Интратекално дати опиоиди као адјувант локалног анестетика остварују синергистички ефекат са њим чинећи спинални блок потпунијим чак и при примени нижих доза локалног анестетика, а инциденцу нежељених ефеката своде на минимум.

Метод Студијом су обухваћена 162 болесника, оба пола, из групе 1–2 по класификацији ASA (Америчког друштва анестезиолога), подељена у три групе методом случајног избора. Испитаници су добијали 10 mg 0,5% раствора бупивакаина и 20 µg (Група I) или 25 µg (Група II) или 30 µg (Група III) фентанила интратекално.

Резултати Није било статистички значајне разлике у времену потребном за постизање потпуне моторне и сензитивне блокаде међу групама, док је време трајања моторне блока-

де било знатно краће у Групи III. Постоперативно, током прва четири сата болесници Групе I имали су највећу вредност кортизола у серуму. Ниво гликемије у крви није имао статистички значајну промену вредности. Током постоперативног периода вредности CRP биле су највише код болесника Групе I. Инциденца хипотензије, брадикардије, мучнине и повраћања била је највећа у Групи III. Свраб и дрхтање нису описани ни у једној од испитаних група. Постоперативно, најдужи период до потребе за аналгетиком описан је код болесника Групе III.

Закључак Применом 25 µg фентанила, као адјуванта локалног анестетика, 10 mg 0,5% бупивакаину, постиже се адекватна хемодинамска стабилност, моторна и сензитивна блокада, смањује одговор организма на хируршки стрес и редукује инциденца нежељених ефеката опиоида, мучнина, повраћање, свраб итд.

Кључне речи: спинална анестезија; бупивакаин; фентанил; постоперативна аналгезија