Comparison of Hemodynamic Changes in Unilateral Spinal Anesthesia Versus Epidural Anesthesia Below the T10 Sensory Level in Unilateral Surgeries: a Double-Blind Randomized Clinical Trial

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ABSTRACT

Background: Unilateral spinal anesthesia is used to limit the spread of block. The aim of the present study was to compare hemodynamic changes and complications in unilateral spinal anesthesia and epidural anesthesia below the T10 sensory level in unilateral surgeries. Materials and Methods: In this double-blind randomized clinical trial in total 120 patients were randomly divided into a unilateral spinal anesthesia group (Group S) and an epidural anesthesia group (Group E). Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rates were measured before and immediately after the administration of spinal or epidural anesthesia and then at 5-, 10-, 15-, 20-, 25-, and 30-min intervals. The rates of prescribed ephedrine and intraoperative respiratory arrest were recorded, in addition to postoperative nausea and vomiting, puncture headaches, and back pain during the first 24 h after the surgery. Results: SBP, DBP, and MAP values initially showed a statistically significant downward trend in both groups (p = 0.001). The prevalence of hypotension in Group S was lower than in Group E, and the observed difference was statistically significant (p < 0.0001). The mean heart rate change in Group E was greater than in Group S, although the difference was not statistically significant (p = 0.68). The incidence of prescribed ephedrine in response to a critical hemodynamic situation was 5.1% (n = 3) and 75% (n = 42) in Group S and Group E, respectively (p = 0.0001). The incidence of headaches, back pain, and nausea/vomiting was 15.3%, 15.3%, and 10.2% in Group S and 1.8%, 30.4%, and 5.4% in Group E (p = 0.017, 0.07, and 0.49, respectively). Conclusion: Hemodynamic stability, reduced administration of ephedrine, a simple, low-cost technique, and adequate sensory and motor block are major advantages of unilateral spinal anesthesia.

Keywords: Spinal anesthesia, Epidural anesthesia, Hemodynamic, Unilateral

1. INTRODUCTION

The type of anesthesia technique used depends on various factors, such as the anesthesiologist’s and patient’s preferences, in addition to the patient’s age, type of surgery, underlying diseases, intraoperative body position, duration of the surgery, and pain-management methods (1, 2). Regional anesthesia (spinal and epidural) is often preferred for surgeries involving the lower abdomen or extremities to induce required sensory levels while exerting minimum effects on the sympathetic nervous system (3, 4). Contraindications to spinal and epidural anesthesia include patient refusal, sepsis, infection at the site, elevated intracranial pressure, allergies to local anesthetics, and inability to maintain the required body position (5). Since spinal analgesia was first described in 1909, various spinal analgesia techniques, including unilateral spinal anesthesia, have been described (6). In unilateral spinal anesthesia, the anesthetic is administered to just one side of the body. The aim of unilateral spinal anesthesia, which is generally used in orthopedic surgeries, is to restrict the spread of somatic and sympathetic block. In unilateral spinal anesthesia, a hypobaric solution is administered into the subarachnoid space, with the patient placed in the

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lateral decubitus position (7-9). Limiting the spread of the spinal block offers many clinical advantages, including greatly reducing the hemodynamic impact of spinal anesthesia (10). In addition, unilateral spinal anesthesia can be useful in elderly patients who have low cardiac output and a risk of early postoperative embolization (10).

There have been few comparative studies of the incidence of hypotension and associated complications in unilateral spinal anesthesia and epidural anesthesia. The aim of the present study was to compare hemodynamic changes and complications in unilateral spinal anesthesia versus epidural anesthesia below the T10 sensory level in patients undergoing unilateral surgeries.

2. PATIENTS AND METHODS

Study design
This study was a double-blind randomized clinical trial. After obtaining ethics committee approval and informed consent of the patients, 120 patients admitted to Imam Khomeini Hospital, Sari, Iran between 2014 and 2015 were included in the study. The patients were randomly divided into two groups: a unilateral spinal anesthesia group (Group S) and an epidural anesthesia group (Group E). This study was registered in the Iranian Registry of Clinical Trials Database (IRCT: 2016020819771N2).

Inclusion and exclusion criteria
The inclusion criteria were aged between 18 and 70 years, ASA I-II, and scheduled to undergo unilateral surgery below the T10 sensory level. The exclusion criteria were any contraindications of spinal and epidural anesthesia, including patient refusal, inability to maintain the required body position during needle puncture, elevated intracranial pressure, coagulopathy, sepsis, localized infection at the site of needle insertion, hypertension, severe allergies to local anesthetics, peripheral neuropathy, neurological disorders, severe hypotension (mean arterial pressure < 50 mm/Hg), cardiovascular diseases (ejection fraction < 30%), liver diseases (liver enzyme levels 1.5 times higher than normal levels), and renal diseases (creatinine > 1.5 mg/dl).

Randomization and blinding
One hundred-twenty patients who met the inclusion criteria were randomly assigned to Group S or Group E based on a random number table. The statistician, nurse anesthetist, and patients were unaware of which patients were assigned to which treatment groups. In addition, the nurses who completed the data collection forms were blinded to the treatment status of the patients.

Anesthesia technique
Group S
Thirty minutes before the administration of anesthesia, crystalloid serum (7 ml/kg) was injected into a suitable peripheral cubital vein. Fentanyl (50 µg) was then injected intravenously as premedication. Each patient in Group S was placed in a sitting position, and spinal puncture was performed at the L2-L3 and L3-L4 space using a midline approach and G25 Quinke spinal needle. Then, 3 cc of Marcaine 0.5% was injected into the subarachnoid space. The patient was then immediately placed in a supine position and tilted about 45 degrees toward the surgical site.

Group E
An epidural catheter was inserted in the L2-L3 or L3-L4 space through a G17 Tuohy needle, with the patient in a sitting position. The space was identified using the loss of resistance technique. An epidural dose containing 3 ml of lidocaine 2% and 5 µl/ml of epinephrine was first administered to ensure the accuracy of the epidural space. Marcaine 0.5% (15 ml) was then injected, and the patient was placed in a supine position.

Primary outcomes
Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rates were measured and recorded using an X110 monitor (Saadat Co., Iran) before and immediately after spinal or epidural anesthesia and then at 5-, 10-, 15-, 20-, 25-, and 30-min intervals.

Secondary outcomes
The amount of prescribed ephedrine and respiratory arrest intraoperatively, in addition to postoperative nausea, vomiting, puncture headaches, and back pain during the first 24 h after surgery, were recorded in a data form.

Statistical analysis
The Shapiro-Wilk test was conducted to test whether the data were normally distributed. Descriptive baseline characteristics for two group comparisons were tabulated as the mean (standard deviation [SD]) or as percentages. A chi-square or Fisher’s exact test was performed for comparisons between two groups of categorical data. Continuous data were statistically analyzed using a t-test or Mann-Whitney U test. Primary efficacy data were examined using an intention-to-treat analysis.

Using a general linear model, hemodynamic changes and complications between the two groups were compared using a repeated measurement ANOVA test, with the baseline values (age and sex) used as covariates in the model. The time of the evaluation was considered a within-subject factor, and the intervention (unilateral spinal anesthesia or epidural anesthesia) was considered a between-subject factor. The time groups (interaction term) were considered as group differences (between the unilateral spinal anesthesia and epidural anesthesia groups) in their response over time.

Mauchly’s sphericity test was performed to test the compound symmetry assumption. The ephedrine prescription over time was analyzed using the log rank test and Kaplan-Meier survival curves. A p value of 0.05 or less was considered statistically significant, and a p value of less than 0.1 was considered marginally statistically significant. The data were analyzed using IBM SPSS statistics, version 16 and Stata version 10.

3. RESULTS

Participants
In total, 147 patients who were referred for surgery to our hospital were screened during the study period. Of these, 19 patients did not meet the inclusion criteria, and 8 patients declined to participate in the study. Of 120 pa-
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Basic demographic and clinical characteristics of the patients in the two groups are presented in Table 1.

| Variables               | Type of anesthesia | P-value |
|-------------------------|--------------------|---------|
|                         | Epidural, N = 56   | Unilateral spinal, N = 59 |
| Age                     | 52.27 ± 17.45      | 45.52 ± 17.17          | 0.09    |
| Sex (male/female)       | 25/31              | 26/33               | 0.31    |
| Body mass index         |                    |                     |         |
| Underweight             | 1 (1.8)            | 3 (5.1)             | 0.42    |
| Normal                  | 20 (35.7)          | 26 (44.1)           |         |
| Overweight              | 30 (53.6)          | 23 (39)             |         |
| Obese                   | 5 (8.9)            | 7 (11.9)            |         |

Table 1. Demographic and clinical characteristics of the patients in the two groups

Outcomes

Trend in changes in SBP

Figure 2 shows the mean and SD values for pre- and postoperative SBP in each group. SBP showed a statistically significant time trend (a within-subject difference or time effect) (p = 0.001). Regardless of the time of follow up, the level of SBP in Group S was higher than in Group E, and this difference was statistically significant (a between-subject difference or group effect) (p = 0.007). The trend in changes in SBP levels was statistically significant between the two groups (group × time interaction or an interaction effect) (p < 0.001).

Trend in changes in DBP

As shown in Figure 3, there was a statistically significant time trend (a within-subject difference or time effect) for DBP (p = 0.001). Regardless of the time of follow up, the level of DBP in Group S was higher than in Group E, and this difference was statistically significant (a between-subject difference or group effect) (p = 0.001). The results of the comparison of the trend in changes in the DBP levels of the two groups were statistically significant (a group × time interaction or an interaction effect) (p = 0.007).

Trend in changes in MAP

As shown in Figure 4, MAP showed a statistically significant time trend (a within-subject difference or time effect) (p = 0.04). Regardless of the time of follow up, the level of MAP in Group S was higher than in Group E, and this difference was statistically significant (a between-subject difference or group effect) (p = 0.001). The between-group trend in changes in MAP levels was sta-
Disadvantages include the potential need for a more gradual and less severe increase in blood pressure, which can result in nausea, urinary retention, back pain, and hypoventilation (16-17). Previous studies of patients who received spinal anesthesia prior to undergoing a sympathectomy reported that vasodilatation and hypotension, with a subsequent reduction in arterial pressure, was the most common side effect (observed in more than 30% of patients) (12-14). Hypotension was reported to be more gradual and less severe in epidural anesthesia than in spinal anesthesia when a comparable level of anesthesia was administered (12).

Hypotension is defined as a fall greater than 30% in baseline levels, and bradycardia is defined as a heart rate of less than 60 beats/min. The administration of a high volume of crystalloid solution, placement of the patient in the Trendelenburg position, and administration of intravenous ephedrine and atropine are used to reduce hypotension (18). In the present study, no significant hemodynamic disorders occurred in the unilateral spinal anesthesia group (Group S). In contrast, significant changes were observed in the epidural anesthesia group (Group E), with a reduction in SBP and sharp gradients, followed by an upward trend after the administration of ephedrine. In Group S, systolic hypotension exhibited a gentle downward gradient, and there was no statistically significant between-group difference. Diastolic hypotension was severe in Group E and then increased relatively. In contrast, we observed only a small increase in diastolic hypotension in Group S, followed by a gentle downward gradient. The between-group difference in diastolic hypotension was statistically significant.

MAP was significantly higher in Group S as compared to Group E, consistent with the results of other studies in this field (11-19). In the present study, unilateral spinal anesthesia was associated with greater intraoperative hemodynamic stability, which is in line with the results of other research (9, 16, 20). Nausea and vomiting are known consequences of spinal anesthesia. In the present study, although these side effects were more common in Group S than Group E, the difference was not statistically significant. This finding is in line with the results of other studies (21-22). In a comparative study of bilateral and unilateral spinal anesthesia, the incidence rate of nausea was lower when using the unilateral method (16). Other comparative studies of bilateral spinal anesthesia and epidural anesthesia reported no between-group difference in the incidence of postoperative nausea and vomiting when sufentanil and morphine were used in conjunction with epidural anesthesia.

Table 2. The incidence of complications in the two groups

| Variables            | Type of anesthesia | P-value |
|----------------------|--------------------|---------|
|                      | Epidural, N (%)    | Unilateral spinal, N (%) |        |
| Headaches            | 1 (1.8)            | 9 (15.3)   | 0.017   |
| Back pain            | 17 (30.4)          | 9 (15.3)   | 0.07    |
| Respiratory arrest   | 0                  | 0        | 1       |
| Nausea and vomiting  | 3 (5.4)            | 6 (10.2)   | 0.49    |

Heart rate

As depicted in Figure 5, there was no statistically significant trend in heart rate changes (the effect of time) (p = 0.41) over time, and there was no statistically significant between-group difference (no interaction effect) (p = 0.74). Although the mean heart rate change was higher in Group E than Group S, the difference was not statistically significant (p = 0.68).

Complications in spinal and epidural anesthesia

The proportion of headaches in Group S was higher than in Group E (15.8% and 1.8%, respectively; p = 0.017). The incidence of other complications in Group S compared to those in Group E was not statistically significant (p > 0.05), as shown in Table 2.

Prescribed ephedrine

The rate of prescribed ephedrine in Group E was higher than in Group S (75% and 5.1%, respectively; p < 0.001). The mean (SD) time of ephedrine prescription was 65.18 (12.72) and 143.22 (3.82) min in Group S and Group E, respectively (log-rank test p < 0.001), as shown in Figure 6.

4. DISCUSSION

Despite the many similarities between spinal and epidural anesthesia, their physiological and pharmacological effects differ, and they induce different side effects. The advantages of epidural anesthesia include reducing the risk of headaches, ensuring a low level of hypotension, creating segmental sensory blockade, and controlling the intensity of sensory and motor block (11, 12). Disadvantages include the potential need to replace the epidural catheter and the possibility of prolonged anesthesia, in addition to postoperative analgesia (11-13). Related complications are epidural hematomas; accidental dural puncture (wet tap); headaches; systemic hypotension, systemic absorption; accidental intravascular, subarachnoid, or subdural injections; and nerve damage (12-13).

As compared to the epidural method, spinal anesthesia is a simple technique, which takes less time. Although spinal anesthesia can cause severe motor and sensory block, this can be avoided by ensuring that the needle is injected into the subarachnoid space (14-15). Complications of spinal anesthesia include double vision, tinnitus, neurological symptoms, hypotension, and bradycardia and asystole, in addition to headaches after hole at Doral (16-17). Furthermore, a high level of spinal anesthesia can result in nausea, urinary retention, back pain, and hypoventilation (16-17). Previous studies of patients who received spinal anesthesia prior to undergoing a sympathectomy reported that vasodilatation and hypotension, with a subsequent reduction in arterial pressure, was the most common side effect (observed in more than 30% of patients) (12-14). Hypotension was reported to be more gradual and less severe in epidural anesthesia than in spinal anesthesia when a comparable level of anesthesia was administered (12).

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spinal anesthesia (23, 24). However, the use of pethidine resulted in a reduced incidence of nausea and vomiting in a spinal anesthesia group (25). In the present study, ephedrine was administered for the treatment of hypotension. The need to prescribe ephedrine because of the critical hemodynamic status of the patient was significantly higher in Group E than Group S, which is in accordance with the findings of previous studies in this field (9-10).

No incidences of cardiorespiratory arrest, which is another consequence of spinal anesthesia, occurred in the present study. Headaches, another complication of spinal anesthesia, were more common in Group S than Group E. Back pain, an additional side effect of anesthesia, occurred in 15.3% of patients in Group S and 30.4% of patients in Group E. In general, unilateral spinal anesthesia is used for lower limb surgery (26). Unilateral spinal anesthesia offers a number of benefits, including fewer hemodynamic effects; block selected for associated members, prevention of unnecessary limb paralysis on the other side, better mobility during recovery, a lower incidence of urinary retention, and increased patient satisfaction (9, 26).

A number of studies have evaluated the advantages of bilateral spinal anesthesia and epidural anesthesia, or even a combination of these two methods. Most of these studies reported that hemodynamic changes, such as systolic and diastolic hypotension, MAP, headaches, nausea, and back pain, were less common in bilateral spinal anesthesia groups than epidural anesthesia groups. The main difference between our study and reports in the literature was that we used unilateral spinal anesthesia instead of the bilateral method and compared the outcomes with those in patients who received epidural anesthesia. The results revealed fewer side effects and improved hemodynamic stability in the unilateral spinal anesthesia group as compared to the epidural anesthesia group.

5. CONCLUSION

In the present study, the hemodynamic stability of the unilateral spinal anesthesia group was better than that of the epidural anesthesia group. In addition, fewer complications were observed in the unilateral spinal anesthesia group as compared to the epidural analgesia group. Importantly, unilateral spinal anesthesia is easier to perform than epidural anesthesia, with lower health care costs. Thus, unilateral spinal anesthesia can be expected to be of interest to anesthesiologists. In the present study, we did not evaluate between-group differences in some variables, such as the duration of hospitalization, need for analgesics, occurrence of itching, incidence of urinary retention, level of patient satisfaction, and level of muscle relaxation. These factors should be considered in future studies.

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• Author’s contributions: Study conception and design: AZK, AB, AA, SM, and AGB. Acquisition of data: AZK, SM, AGB. Statistical analysis and interpretation of data: AZK, AA. Drafting of the manuscript: AZK, AB, AA, SM, and AGB. Critical revision of the manuscript for important intellectual content: AZK, AB, AA, SM, and AGB.

• Clinical trial registration number: IRCT2016020819771N2.

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