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The effects of Adding Meperidine to Heavy Intrathecal Lidocaine on Hemodynamic Changes and Blood Loss in Open Prostatectomy: A Randomized Double-Blind Clinical Trial

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This article has Continuous Medical Education (CME) credit for Iranian physicians and paramedics. They may earn CME credit by reading this article and answering the questions on page 67.

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Abstract

Background: Clinical investigations have reported several anesthetic properties of intrathecal injections of meperidine. The purpose of this study was to investigate the effect of adding meperidine to intrathecal heavy lidocaine on hemodynamic changes and blood loss in patients undergoing elective suprapubic open prostatectomy.

Methods: In a randomized double-blind clinical trial, 77 patients candidate for elective suprapubic open prostatectomy were allocated to two equal groups. All patients in the control and experimental groups received heavy lidocaine intrathecally. A low dose of meperidine was added to lidocaine in the experiment group. Changes in blood pressure and heart rate were measured and documented in several intervals. Blood loss, transfusion rate, shivering, nausea, vomiting, need to an analgesic drug, and transient neurologic symptoms were also recorded.

Results: No significant difference was observed between the two groups in regards to blood pressure changes in operating room. Blood pressure increase was more prevalent among patients of the control group immediately in post-operating period .There were significantly ($P<0.0001$) less post-operative bleeding and need to transfusion in the experimental group.

Conclusion: Adding low dose of meperidine to lidocaine induces minimal effect on blood pressure change in operating room, but prevent increasing of blood pressure in post-operative period with a reduction of bleeding.
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Keywords ● Blood loss ● intrathecal ● lidocaine ● meperidine

Introduction

Although the practice of anesthesia has had a very fast pace in recent years and a number of drugs and techniques are available in this regard, maintaining hemodynamic stability and preservation of blood volume during surgery still remain a concern, especially in high risk patients.[1,2] Patients who are candidates for open

prostatic surgery are elderly with co-morbid cardiovascular and respiratory diseases and high risk for intraoperative bleeding.[3-5] Hemodynamic instability and major blood loss may predispose these patients to cardiac incidents during peri-operative period.[5]

Spinal anesthesia is a popular technique for managing patients in need of open prostatic surgery. Lidocaine is the most popular local anesthetic drug utilized in diminutive surgical procedures, which may have adverse effects after the injection.[6-8] Opioids bind to well established receptors in the central nervous system (CNS) capable of producing long-time postoperative pain relief.[9] However, there are several investigations on the effects of intratechal opioids added to local anesthetics on hemodynamic stability, but there are still a lot of controversies and no definite answer.[10,11] The aim of this study was to examine the effect of adding meperdine to heavy intratechal lidocaine on blood pressure (BP) changes and blood loss. Comparisons were made to standard heavy intrathechal lidocaine.

Methods and Materials

The study was approved by the Ethics Committee of Bushehr University of Medical Sciences, and was registered with the Government Database for Clinical Trials (reference no: IRCT138903061936N2). It was performed in keeping with the requirements of the Declaration of Helsinki. Seventy seven males (45 to 75-year-old), who were candidate for elective suprapubic prostatectomy, and classified as American Society of Anesthesiologist I-III (ASA I-III) were included in this prospective randomized double-blind clinical trial. The exclusion criteria of the study were patients with uncontrolled hypertension, disinclination to the procedure, infection at the injection site, disorders of coagulation, history of headache, neurologic diseases, or hypersensitivity to amide local anesthetics or meperidine, and uncooperative patients were eliminated. No premedication was given to the patients before the surgery. Data regarding age, weight and pre-operation hemoglobin was documented. Patients were randomly divided into two equal experimental and control groups for spinal anesthesia according to numbers inserted in sealed envelopes. After routine monitoring and infusion of 10 ml/kg of 0.9% sodium chloride solution, a measurement of baseline hemodynamic values including heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were recorded. Spinal anesthesia was induced using midline approach by injecting local anesthetic into the L4-L5 interspace using a 25 G Quincke needle while the patients were kept in sitting position. Another anesthesiologist prepared the solutions so that the anesthesiologist inducing the spinal block was blind of the injected drugs. In the experiment group, patients received 0.4 ml/kg meperidine plus up to 2 ml of heavy lidocaine (5%), and in the control group, patients received heavy lidocaine (5%) plus normal saline in equal volume to that of meperidine. A blind observer was assigned to collect the data. Blood pressure, ECG, HR, and oxygen saturation (SpO_2) were continuously monitored. Any reduction of more than 30% from the baseline SAP or a SAP lower than 90 mmHg was treated using incremental intravenous (IV) boluses (5 mg) of ephedrine. Moreover, bradycardia (HR<50) was treated with IV (0.5 mg) atropine. Supplementary oxygen (5 L/min) was given via a nasal cannula, if SpO_2 was less than 95% with patient surroundings air respiration. Sensory anesthesia was evaluated using pinprick at intervals of one min for 10 min, intervals of five min for the next 30 min, and intervals of 10 min until regression to L_4 level. If noted, any complication or adverse effects as nausea, vomiting, chest discomfort, pruritis, shivering, and respiratory depression treated in appropriate ways. According to pinprick, if pain sensation was lost at the T_8 level, anesthesia was regarded adequate for surgery. Patients were then placed in the supine position and operation was started. All operations were done by one surgeon. Time to reach T_8 sensory block, sensory block's highest level was documented. Estimated blood loss (EBL), non-autologous transfusion rates, and change of hemoglobin (Hb) levels between two groups were compared to investigate the effect of adding meperidine to lidocaine on blood loss. The EBL in the operating room and recovery unit, and non autologous blood transfusion was recorded.

Motor block (MB) was assessed according to the Bromage scale,[12] 1: unable to move feet, 2: able to move feet only, 3: just able to move knees, and 4: full flexion of knees and feet. Complete motor block was defined as a Bromage score of three. Pain was assessed in operating room, recovery room, and the ward for 12 hours using the 10-score visual analog scale (VAS). If a patient complained of a pain score over three, (1.5 µg/kg) IV fentanyl would be prescribed, and in the event of failed spinal block, general anesthesia would be performed. Midazolam was given intravenously in 0.5 mg increments as was indicated for anxiolysis. All patients were asked about the presence of

headache, backache, paraesthesia, pain in thighs, buttocks, or leg, etc during the first and second post-operative days. Assuming that the incidence of hypotension by meperidine to be 8% percent and that of lidocaine to be 33%, it was predicted that the study would require 38 patients in each group to provide a power of 80% to detect a 35% differences in the incidence of hypotension. The data obtained were analyzed using the Statistical Package for Social Sciences software, version 11.0 (SPSS Inc, Chicago, IL, USA). Descriptive statistics were computed for the characteristics of the patients, and preoperative and postoperative hemodynamic changes. Repeated measure test ANOVA Student's *t* test, and paired *t* test were used for between and within-group comaprisons. Bonferroni procedure to P value to avoid committing type 1 error after repeated measure ANOVA Chi square and Fisher exact tests were used to analyze nominal variables. A P value of <0.05 was considered statistically significant.

Results

Thirty eight patients in the experimental group and 39 patients in the control group finished the study. The two groups were not statistically different with regards to the age, weight, or duration of operation (P>0.05). Baseline hemodynamic data and pre-operative hemoglobin were not significantly different between the two groups (table 1). The hemodynamic effects of subarachnoid block were studied among all patients in the two study groups. Heart rate in the patients receiving intrathecal meperidine was not significantly (P=0.08) different from the baseline value (table 2). The systolic and diastolic blood pressures in the two groups were significantly (P<0.0001) different from the baseline values after the induction of anesthesia. Moreover, the percent of patients, who experienced over 30% decrease in mean blood pressure, was significantly (P<0.0001) higher in the control group (56.4%) compared to that of the experiment group (7.9%) after induction of anesthesia (table 3).

No patient in the two groups experienced transient neurological symptoms. The highest level of sensory block in all patients was T4. Moreover, the time to reach maximum sensory extension was not significantly (p value=0.002) different between the two groups. Duration of maximum sensory block to regress to L1 was significantly (P<0.0001) different between the two groups. Duration of complete motor block was not different between the two groups (P =0.82). The mean duration of analgesia in the control group was 88.89 minutes while in the experimental group was 137.28 minutes. The difference of analgesia duration in the two study groups was statistically significant (P<0.0001) (table 4). There was no significant difference (P>0.05) between the size and volume of prostate between the control and experimental groups.

The incidence of hypotension (more than 30% decrease in SBP), which required ephedrine administration, in the experimental group was 18.4% and in the control group was 66.7%.The incidence of nausea and vomiting in the experiment group was 23.7% and in the control group was 5.1%.The incidence of pruritus in the control group was 0% and in the experimental group was 12.8%.The two groups

Table 1: The demographic and baseline hemodynamic data (mean±SD) of patients in the control and experiemntal groups

	Experimental group	Control group	P value
Age (year)	68.11±8.11	67.23± 8.36	0.64
Weight (Kg)	73.68±9.58	70.97±12.32	0.28
Preop-hemoglobin (g/dl)	13.5±1.96	13.43±2.07	0.88
Duration of operation (min)	74.24±11.6	72.42±11.68	0.49
Heart rate (beats/min)	79.08±13.11	80.10± 10.88	0.71
SBP (mmHg)	139.74±31.70	141.59±28.72	0.78
DBP (mmHg)	77.92±14.81	78.26±12.40	0.91

Preop: preoperative; SBP: systolic blood pressure; DAP: diastolic blood pressure

Table 2: Heart rate (beats/min) of the experimental and control groups during the operation and in recovery room

Heart rate	Experimental group	Control group	P value
HR5†	82.0±11.2	93.1±10.6	0.0001
HR10†	84.3±8.7	94.0±12.2	0.0001
HR20†	79.3±8.4	78.8±6.9	0.78
HR30†	78.3±7.1	81.3±7.9	0.08
HR60†	78.9±6.9	77.7±6.5	0.44
HR R15‡	78.0±7.9	78.4±8.2	0.84
HR R30‡	78.4±10.5	89.0±11.4	0.0001

†Heart rate at 5, 10, 20, 30 and 60 minutes after the injection of meperidine (in the experimental group) or normal saline (in the control group); ‡Heart rate at minutes 15 and 30 of arrival in recovery room

Table 3: Comparison of systolic and diastolic blood pressures of the experimental and control groups during the operation and in recovery room

Blood Pressure	Experimental group	Control group	P value
SBP5¶	112.1±20.8	90.0±13.2	0.0001
DBP5**	69.9±13.6	57.0±12.1	0.0001
SBP10¶	112.9±13.9	94.7±18.5	0.0001
DBP10**	69.8±10.6	60.3±14.1	0.001
SBP20¶	122.8±11.0	112.5±14.6	0.001
DBP20**	69.8±16.7	60.3±9.6	0.02
SBP30¶	122.8±21.2	112.5±21.4	0.13
DBP30**	75.2±9.2	67.9±10.5	0.39
SBP60¶	140.1±18.6	133.1±18.4	0.09
DBP60**	78.6±9.5	75.2±8.8	0.11
SBPR15†	133.5±17.8	156.3±18.5	0.0001
DBPR15‡	76.7±9.4	82.5±9.5	0.009
SBPR30†	139.7±22.8	163.5±14.0	0.0001
DBPR30‡	76.9±11.9	85.8±7.4	0.0001

¶ Systolic blood pressure (mm Hg) at 5, 10, 20, 30 and 60 minutes after the injection of meperidine (in the experimental group) or normal saline (in the control group); **Diastolic blood pressure (mm Hg) at 5, 10, 20, 30 and 60 minutes after the injection of meperidine (in the experimental group) or normal saline (in the control group); †Systolic blood pressure (mm Hg) atminutes 15 and 30 of arrival in recovery room; ‡Diastolic blood pressure (mm Hg) at minutes 15 and 30 of arrival in recovery room

Table 4: Analgesia characteristics of experimental and control groups

	Experimental group	Control group	P value
Time to reach maximum sensory sensation†	5.73±1.42	4.82±1.04	0.002
Duration of maximum Sensory block to regress to L1†	118.86±13.62	87.17±10.8	0.0001
Duration of complete Motor block†	76.02±5.51	78.28±4.54	0.82
Duration of analgesia†	137.28±23.58	88.89±8.12	0.0001

were only significantly (P<0.0001) different in terms of hypotension and ephedrine use, but not the incidence of nausea, vomiting or pruritis.

The incidence of the needs to analgesia in the experimental group (10.5%) was insignificantly (P=0.22) lower than that of the control group (23.1%). However, the incidence of shivering in the control group (2.6%) was insignificantly less than that in experimental group (17.9%) (table 5). No patient in the two groups experienced respiratory depression and no individual needed mask ventilation. There was significant difference in the changes (decrease) of hemoglobin concentration (p <0.001) or blood loss (P<0.001) of the experimental and control groups. The transfusion rate in the experimental group (13.2%) was half of that of the experimental group (25.6%). Moreover, the transfusion rate or post-operation hemoglobin was not statistically significant between the two groups. Moreover, no significant (P>0.05) difference was found between the size or volume of prostate in the control and experimental groups.

Discussion

This study revealed that adding 0.4 mg/kg of meperidine to heavy intrathechal lidocaine 5% not only had no effect on hemodynamic stability during the operation, but also prevented the increase of patients' BP in recovery room. This might have been due to the induction of a long post-operative analgesia, which avoids the need to pain killer drugs. There was no significant difference in blood loss in operative room between the two groups (P=0.98), although significantly (P<0.0001) less bleeding was observed in patients in the meperidine group in the recovery room. Post-operative nausea and vomiting and pruritus were more common in the meperidine group (P<0.02), but shivering was less frequent in that group (P<0.056). None of the patients in any group had transient neurological symptoms. The addition of meperidine to spinal lidocaine slowed down

Table 5: The number and percentage of side effects occurred in experimental and control groups

Side Effect	Experimental group	Control group	P value
Hypotension and ephedrine use	7 (18.4)	16 (41)	0.0001
Nausea and vomiting	9 (23.7)	2 (5.1)	0.025
Shivering	1 (2.6)	7 (17.9)	0.056
Pruritus	5 (12.8)	0 (0)	0.055
Need of analgesia	4 (10.5)	9 (23.1)	0.22
Post operation Hemoglobin (gr/dl)	11.9±1.76 *	10.7±1.6 *	0.002
Hemoglobin difference (after-before)	1.6±1.2 *	2.8±1.8 *	0.001
Blood loss in operating room (ml)	234.2±65.1	238.9±75.1	0.98
Blood loss in recovery (ml)	183.4±65.6	371.8±171.9	0.0001

the onset of sensory and motor block, improved intraoperative analgesia, and delayed the demand for analgesic drug without affecting motor block (P=0.82). The sensory and motor blockades in all patients in the two groups were adequate for surgery. No respiratory depression was observed in the two groups.

Although transurethral resection of prostate (TURP) has been described as the gold standard treatment for the treatment of patients with prostatic hypertrophy, and over 90% of prostatectomy operations for benign prostatic hyperplasia are performed by TURP, open prostatectomy is still regarded as one of the most satisfactory procedures which cause excellent relief and symptomatic improvement in the majority of patients with prostatic hyper trophy.[13,14]

Aging alters both pharmacokinetic and pharmacodynamic aspects of anesthetic actions.[15] The functional capacity of organs declines, and co-existing diseases further contribute to this decline. In terms of cardiac function, geriatric patients have decreased beta-adrenergic responsiveness, increased reliance on Frank-Starling mechanism for cardiac output, and increased incidence of hemodynamic changes.[15,16] It is, therefore, important to consider fluid administration carefully. In a non compliant older heart, small changes in venous return produce large changes in ventricular preload and cardiac output.[16,17] Due to diastolic dysfunction and decreased vascular compliance, the elderly patient compensates poorly for hypovolemia.[17] Similarly, exaggerated transfusion is poorly tolerated.[2,17]

Murto et al.[18] investigated the effects of the addition of low dose meperidine to spinal lidocaine on the sensory and motor blockade profiles, and the quality and duration of postoperative analgesia. They conducted a randomized double-blind prospective study on 40 patients undergoing transurethral prostatectomy with spinal anesthesia and compared three treatment protocols. These protocols included 75 mg lidocaine 5% intrathecally as the sole agent (group A), co-administration of 75 mg lidocaine 5% intrathecally with 0.15 mg/kg meperidine (group B) and co-administration of 75 mg lidocaine 5% intrathecally with 0.30 mg/kg meperidine (group C). They found no significant difference in the latency or duration of the motor block among three groups. Patients in group C had a lower VAPS over time than those in groups A and B. Time to first analgesia was longer (429±197 minutes) in group C than in group A (254±157 minutes). Fewer patients in group C required parenteral opioid postoperatively than in group A. The incidence of bradycardia was higher in the groups receiving meperidine. No symptoms of transient radicular irritation (TRI) were reported in the groups receiving meperidine. It was concluded that the addition of 0.3 mg/kg of meperidine to spinal lidocaine extended postoperative analgesia, and did not postpone the discharge from post anesthetic care unit. It also reduced the requirements for parenteral analgesics. Our findings agree these finding, except for bradycardia that did not occur in our study. Our findings receive support from those of Murto et al.[18] in a number of aspects. First of all, their study was similar to ours; then, the sensory level in both studies was the same; and next, similar dosages of meperidine were administered in both studies. However, no measurement of blood loss was performed in that study. Our findings also agree with those of Nguyen et al.[19] who found that adding meperidine to intrathecal bupivacaine improved post-operative analgesia. Conway et al.[20] studied the hemodynamic effects of intrathecal meperidine (0.8 mg/kg), meperidine (0.4 mg/kg) plus 1.5 ml of heavy bupivacaine 0.5% or 3 ml of heavy bupivacaine 0.5% in 42 Chinese patients (59-87 years) scheduled for transurethral bladder or prostate surgery. Non-invasive SAP and MAP, central venous pressure and cardiac index, stroke index and HR were measured. The onset of sensory and motor block was also evaluated. The onset of block was slower in the meperidine group. Decreases in SAP, MAP, and systemic vascular resistance index (SVRI) occurred within five minutes of drug administration in all three groups. Due to inadequate block, six patients receiving meperidine and two patients receiving the mixture required general anesthesia. The incidence of nausea and vomiting was higher in the patients receiving meperidine alone. They concluded that the administration of intrathecal meperidine, alone or mixed with bupivacaine, had no intra-operative advantage over heavy bupivacaine 0.5%. Unfortunately, the amount of blood loss was not reported for the three groups in that study.

Kafle compared,[21] intrathecal meperidine with heavy lidocaine in 50 full-term pregnant women, with ASA physical status I or II, who were candidates for elective caesarean under spinal anesthesia. He found that the sensory and motor blockades in all patients except two in each group, who required sedation at the time of skin incision, were adequate for surgery. None of the mothers suffered from any major side effects. The incidence of hypoten-

sion was higher in the lidocaine group compared to the meperidine group. In the meperidine group, pruritus and drowsiness were more common than in the lidocaine group. The mean duration of postoperative analgesia was six hours in the meperidine group, and one hour for the lidocaine group. Postoperative analgesia requirement was less in the meperidine group compared to that in the lidocaine group. They concluded that intrathecal 5% meperidine in a dose of 1 mg/kg was superior to 5% heavy lidocaine because of the prolonged postoperative analgesia. Some findings of this study confirm our results, but some others do not.

Norris et al.[22] compared the anesthetic potency, duration, and side effects of subarachnoid meperidine and lidocaine in twenty healthy unpremedicated postpartum women, who were candidates for postpartum tubal ligation. They found that sensory or motor block developed slightly faster in the lidocaine group. Patients who received meperidine experienced more pruritus. Patients receiving lidocaine had more postoperative pain, and required supplemental analgesia. No patient's oxygen saturation fell below 95%. Patients expressed equal satisfaction with both agents. The study concluded that subarachnoid meperidine had no advantage compared to lidocaine for postpartum tubal ligation except for meperidine providing longer postoperative analgesia.

The only investigators, who studied the hemodynamic effects of intrathecal meperidine, were Cozian et al.[23] They exercised some invasive monitoring on eight patients, and measured radial arterial pressures and cardiac output. They found statistically insignificant decreases in MAP, CVP and left atrial pressure with no change in CI and HR. Level of sensory block in that study was the same as that in ours (T8). The findings of Cozian et al.[23] are similar to our findings in operative room, and suggest that intrathecal meperidine causes a sympathetic block similar to intrathecal local anesthetics with no significant effect on BP.

In the present study no patient showed respiratory depression, which might be due to the use of a low dose of meperidine (0.4 mg/kg). However, the previous study by Nguyen et al.[19] showed that respiratory depression could occur with doses as low as 0.5 mg/kg. Maurette et al.[24] investigated the mechanisms leading to respiratory depression after lumbar administration of opioids. They studied plasma and ventricular cerebrospinal fluid (CSF) pharmacokinetics of intrathecal meperidine (1 mg/kg) in five head-injured patients undergoing surgery for lower limb fracture. Meperidine was detected both in the plasma (arterial catheter) and in the ventricular CSF (intracranial catheter) soon after intrathecal administration. The study concluded that the putative risk of respiratory depression appears to be mainly related to the absorption into the systemic circulation and redistribution back into the CSF.

The post-operative hypertension usually begins within 30 min from the end of operation and lasted about two hours. The principal factors possibly contributing to the pressure elevations are pain, hypercarbia and emergence excitement.[25] Excessive autonomic cardiovascular drives, such as large changes in cardiac output, heart rate and pre-ejection period, can be the first signs of acute post operative pain.[26]

Preoperative hypertension is a common problem encountered by anesthesiologists, surgeons, internists, and there are some investigations confirming the relation between preoperative hypertension and pain or bleeding.[27-29] Basali et al.[28] examined the relation between preoperative blood pressure elevation and postoperative intracerebral hemorrhages using a retrospective case control design. Preoperative, intraoperative, and postoperative (up to 12 hours) blood pressure records were examined. It was revealed that acute blood pressure elevations occur frequently prior to post craniotomy intracranial hemorrhage. Patients, who develop post craniotomy intracranial hemorrhage are more likely to be hypertensive in the intraoperative and early postoperative periods. These findings explain and confirm higher postoperative bleeding and transfusion rates in the control group in our study. Patients in the experimental group showed more extended period of sensory block and analgesia as well as minimal increases of blood pressure and heart rate in recovery period compared to patients in the control group (tables 2-4).

In another study the incidence and etiology of postoperative intracerebral hemorrhages were examined.[29] Major etiologies underlying postoperative intracerebral hemorrhages were uncontrolled bleeding from a blind area, difficult dissection of a tumor from the brain, retraction injury, vessel injury from a needle, bleeding from a residual tumor. Hypertension during recovery from anesthesia was another important factor.

Arterial supply to prostate is derived mainly from branches of the internal iliac (hypogastric) artery, the inferior vesicle and middle rectal arteries.[29,30] Bleeding during open prostatectomy arises from venous structure in majority

of cases.[30,31] Although there are limited investigations to find risk factor of bleeding as one of the most common early complication of open prostatectomy, no literature was found on the effect of BP changes in immediately post operative period.[2,31,32] It seems that in patients of the control group EBL had a significant relationship with BP increase immediately in postoperative period. Moreover, it seems to have an association with hemoglobin decrease immediately in postoperative period. It is assumed that in the control group, pain can stimulate sympathetic nervous system, and causes an increase in BP. Perhaps this unwanted increase of BP is due to pain in immediately postoperative period, which induces the vein to bleed.

Conclusion

The findings of this study indicate that adding 0.4 mg/kg meperidine to heavy intrathecal lidocaine has no effect on the hemodynamic stability during surgery. The advantage of such an addition is a long time postoperative analgesia with less BP rise in immediately postoperative period and the reduction of postoperative bleeding. It does not modify the efficacy of sensory and motor block, but is associated with increased incidence of other side effects, which could be easily treated.

Conflict of Interest: None declared

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