Unilateral Spinal Anesthesia In Knee Arthroscopy: Clinical And Pharmacoeconomic Effects Of Application Of Hyperbaric Bupivacaine
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Citation

Abstract
Purpose: The study was designed to compare the efficacy and cost-effectiveness of unilateral spinal anesthesia using 0.5% hyperbaric bupivacaine with conventional spinal anesthesia using normal 0.5% (isobaric) bupivacaine when performing knee arthroscopy.

Material and methods: The study included 60 patients allocated in two groups of 30 patients. Group A patients received spinal anesthesia with 0.5% hyperbaric bupivacaine and group B patients - identical anesthesia with 0.5% isobaric bupivacaine. All changes in the patients' pulse and blood pressure were monitored; we also recorded the quantity and type of infusion solutions, the time for regaining motor function and sensitivity in the lower limbs and the time to discharge of patients from the clinical unit. The patients were followed up for possible unwanted early postoperative complications. The cost of anesthesia and the length of postoperative hospital stay were estimated.

Results: The unilateral spinal anesthesia with hyperbaric bupivacaine caused minimal changes in the hemodynamics and thermal regulations, reduced the infusion therapy volume, shortened the time for recovery after anesthesia and the stay in the orthopedic surgery unit. This reduced the cost of anesthesia by about 22 Euro per patient.

Conclusions: Unilateral spinal anesthesia with hyperbaric bupivacaine is a clinically effective and economically beneficial method of intraoperative analgesia. It can be recommended as a safe and financially expedient technique in operations of lower limbs.

INTRODUCTION
Spinal anesthesia is an anesthetic technique that is easy, fast and relatively inexpensive to perform for lower limb operations. For a very long time the major anesthetic agent that was used for it was lidocaine [1]. After becoming known that it is associated with some unwanted transient neurologic symptoms [2], regional anesthesia changed. In the last decade, bupivacaine has become the most frequently used agent to induce spinal and epidural anesthesia. Spinal anesthesia produces some adverse effects, the commonest being the intraoperative hypotension and bradycardia, and post-operative headache [3,4] which makes it necessary to use additional infusion solutions and sympathomimetics, thus prolonging the hospital stay and increasing the cost of therapy. The hyperbaric solutions introduced in the induction of spinal anesthesia allow reduction of the anesthetic agent dosage (if the type of surgery allows it) and achieving pain relief only in specific necessary anatomic sites for the operative intervention [5,6]. Such an approach should, theoretically, reduce cardiovascular complications, the amount of the anesthetic agents used and the volume of the infusion solutions and therefore bring faster recovery of patients.

The present randomized study was designed to compare the efficacy, adverse effects and cost-effectiveness ratio of unilateral spinal anesthesia induced with hyperbaric 0.5% bupivacaine (Markain heavy – AstraZeneca) with the conventional (bilateral) spinal anesthesia using normal (isobaric) 0.5% bupivacaine (Markain spinal – AstraZeneca) in patients undergoing knee arthroscopy.
PATIENTS AND METHODS

The study included 60 patients after their informed consent was obtained. The patients were randomly assigned by a computer program to one of two groups of 30 patients each: group A patients received unilateral spinal anesthesia and group B patients - bilateral spinal anesthesia.

All patients underwent operative knee arthroscopies. The day before surgery laboratory tests of the patients’ hemoglobin, erythrocytes, thrombocytes, leukocytes and serum total protein were done. Electrocardiography was carried out for men over 40 years of age and women over 50 were and if any pathologic abnormalities were detected or there was a history of cardiovascular disorder the patients were consulted by a cardiologist. If there was a history of allergic disorders we tested the patients’ sensitivity to local and general anesthetic agents. Only patients of ASA grade I were included in the study.

The anesthesia was induced as follows:

On arrival in the anesthesia induction room, a peripheral i.v. access was established using an 18-gauge cannula and 150 mL of Ringer lactate was infused for approximately 10 min. Blood pressure, pulse and saturation were monitored from this moment on till the patient was taken away from the operation theatre. In the operation theatre the patient was positioned in a lateral position lying on the side to be operated. If the patient experienced pain syndrome, 2 mL of fentanyl were infused prior to the induction of anesthesia. The lumbar region was disinfected twice with a non-iodine agent (Skinsept). The puncture was performed with a 25 gauge Quinke spinal needle. Once free flow of CSF was recognized we injected:

- in group A patients - 1.5 mL of hyperbaric 0.5% bupivacaine (Markain heavy – Astra Zeneca), the patient remaining in the same posture for 12-15 min, then after achieving a block and checking its level the patient was placed in supine position.

- in group B patients - 4 mL of isobaric 0.5% bupivacaine (Markain spinal – Astra Zeneca) and the patient was then immediately placed in the supine position.

Surgical intervention began after complete sensory block was induced. The infusion therapy continued with administration of Ringer lactate. If, after infusing 1000 mL of the solution, the patient needed more to maintain circulation we added 500 mL of 10% hydroxyethyl starch (HAES-steril 10% - Fresenius, Germany) and then we reverted again to water electrolyte solutions (Ringer lactate). Sedation with midazolam 3-5 mg i.v. was used to manage the emotional stress. In both groups we recorded the changes in the pulse and blood pressure, the amount and type of infusion solutions to maintain normal circulatory parameters, determined the degree of sensory block by Bromage scale \[7\], time for regression of the motor functions and the sensitivity of lower limbs, and the time to discharge of the patients from the hospital unit. The patients were monitored for possible early adverse postoperative side effects such as headache, urine retention, and orthostatics.

The pharmacoeconomic analysis took into account:

1) the cost of anesthesia – which included the disposables used (spinal needles, syringes, syringe needles, sterile gauze, i.v. cannula, infusion set, ECG electrodes), drugs (bupivacaine – hyperbaric or isobaric, infusion solutions), disinfecting solutions for the skin around the spinal puncture and sterilization of instruments, and sterile operation drapes, necessary for the induction of spinal anesthesia; 2) the averaged cost of a 24-hour hospital stay.

The cost analysis did not include the direct expenses made for the operation for sterile materials, disposable endoscopic consumables, sterilization, price and amortization of instrumentarium, etc. nor the infusion solutions for disinfection of the operation theater.

Statistical analysis was performed using the programme StatSoft, Inc. (1995). STATISTICA 5.0 for Windows, StatSoft, Inc., Tulsa, OK, USA. The distribution of data was tested with the Kolmogorov-Smirnov test. In normal distribution we used the analysis of variance and the Student's t test, and in all other cases – the Mann–Whiney test. Categorical data were analyzed by chi-square test. A value of $p < 0.05$ was considered significant.

RESULTS

In all patients the induced anesthesia was sufficient to perform the operation; no additional anesthetic medication was used.

The statistical analysis of the sex, age and body weight parameters using the $\chi^2$ analysis and the t-test for independent variables yielded no significant differences ($p>0.05$), which indicates that the whole sample of patients
was homogenous (Table 1).

Table 1: Demographic data

<table>
<thead>
<tr>
<th>Sex (male/female)</th>
<th>Group A (n=30)</th>
<th>Group B (n=30)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>16/14</td>
<td>17/13</td>
<td>&gt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

The hemodynamic changes in both groups were identical (Fig. 1). In group A patients, the systolic and diastolic pressure dropped significantly compared with these variable at baseline 5 minutes after beginning of anesthesia (p<0.05). They remained low until the end of operation without reaching critical levels (the mean systolic blood pressure was about 120 mm Hg, and the mean diastolic – 65-75 mm Hg). In group B, significant differences in the systolic and diastolic pressures were recorded at intervals of 15 minutes, not 5 minutes; they remained low until the end of operation, but unlike group A, the systolic pressure drop here was greater (about 100 mm Hg at 15 and 30 min), which rendered the difference between the two groups in this parameters statistically significant (p<0.05). There were no significant differences between the two groups in the diastolic pressure and heart rate (p>0.05).

Figure 1: Hemodynamic changes during anesthesia

Figure 2

Group A received 598.33±232.11 mL in the infusion therapy to maintain intraoperative hemodynamics within normal limits which was significantly less than the amount of infusion received by group B – 1870.00±427.42 ml (p=0.000).

The changes in skin temperature in the course of anesthesia are presented in Table 2. There were no changes in group A patients while in group B it dropped at 5 minutes (p<0.05) and the differences with group A (where the temperature was higher by about 1.5°C throughout the operation) were statistically significant (p<0.05).

Table 2: Skin temperature (°C) in the two groups during the anesthesia.

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32.0±10.51</td>
<td>32.2±10.82</td>
<td>0.67087</td>
</tr>
<tr>
<td>5</td>
<td>32.3±10.55</td>
<td>32.4±10.59</td>
<td>0.00911</td>
</tr>
<tr>
<td>15</td>
<td>32.7±10.55</td>
<td>32.7±10.57</td>
<td>0.00070</td>
</tr>
<tr>
<td>30</td>
<td>32.7±10.55</td>
<td>32.7±10.57</td>
<td>0.00070</td>
</tr>
<tr>
<td>60</td>
<td>32.7±10.55</td>
<td>32.7±10.57</td>
<td>0.00070</td>
</tr>
</tbody>
</table>

The anesthesia in both groups lasted enough to perform all operative interventions, but it was significantly longer in group B (146.67±13.30 min) than it was in group A (86.97±13.85 min) (p=0.000).

The postoperative period for group A patients was 7.33±3.70 hours which was significantly shorter than the length of stay of group B patients – 23.03±2.81 hours (p=0.000).

Two patients of group A and two patients of group B developed a postoperative headache which successfully resolved within 3 days after operation with administration of non-steroid analgesics – ketoprofen and paracetamol and did not delay the patients' discharge or cause rehospitalisation for none of the patients.

In both groups the cost of the anesthetic procedure with the 500 mL of lactated Ringer solutions for preoperative hydration, but without the intraoperative infusion therapy were respectively per patient of group A – 7.295 Euro and per patient of group B – 10.475 Euro. The difference was due to the different anesthetic agent used in the respective groups: 1.5 mL of hyperbaric bupivacaine in group A and 4 mL of isobaric bupivacaine in group B.

The difference in the cost of the intraoperative infusion therapy between the two groups was also significant. For group A patients we used a total of 36 ampoules of 500 mL.
of lactated Ringer’s solution and 1 ampoule of 500 mL HAES-steril 10% at a total cost of 39.3 Euro or an average of 1.311 Euro per patient. In group B we infused 84 containers of Ringer’s solution and 28 containers of HAES-steril 10% at a total cost of 352.51 Euro or in the average of 11.75 Euro per patients. Total cost of anesthesia (drugs, infusion solutions and disposables) averaged 8.608 Euro per patient of group A and 22.224 Euro per patient of group B.

The cost of the postoperative stay for both groups was calculated on the basis of the average cost of the first postoperative day of knee arthroscopy patients in the Department of Traumatology and Orthopedics which was 12.53 Euro/24 hours or 0.522 Euro/hour. At an average length of stay for group A of 7.33 hours the cost amounted to 3.827 Euro per patient, while for group B, at a mean length of stay of 23.033 hours it was 12.0283 Euro per patient. All patients of group A spent in the hospital a total of 220 hours which cost 116.907 Euro, and group B patients – 691 hours which cost 360.702 Euro.

The total cost (which include anesthesia and infusion therapy and hospital stay) for all patients of group A was 373.041 Euro, and for group B – 1027.50 Euro, that is, 654.46 Euro more was spent for group B patients. The economic effectiveness was calculated to be 21.82 Euro per patient.

**DISCUSSION**

In this study spinal anesthesia in both groups was sufficiently efficient to enable the performance of surgery, which reinforces other authors’ reports about the efficiency of achieving analgesic effect by unilateral spinal anesthesia with small doses of hyperbaric bupivacaine. [8]

The hemodynamic changes were more extensive in group B which accounts for the larger volume of infusion solutions in order to maintain the circulatory parameters. Our results are consistent with those reported by Casati and Faneli [9], although in other studies the hemodynamic changes have been reported to be almost identical but there are no data reported in them about the volume type of infusion therapy.

Mild hypothermia is relatively frequent in spinal anesthesia. Often underestimated, it can cause some untoward side effects [10] associated with the increased oxygen demands, especially in patients with limited cardiac and ventilation resources [11]. The absence of changes in skin temperature during hyperbaric bupivacaine anesthesia in our study can be considered as an advantage of the technique.

In the available literature reports [10], the unilateral anesthesia, like in our study, is shorter than conventional anesthesia. In operations such as knee arthroscopy, inguinal herniorrhaphy, and other operations, this is rather an advantage which means less need of postoperative observation and earlier discharge of patients, as seen in our study.

Spinal anesthesia is economically efficient alternative of total analgesia in operations of lower body parts and limbs [12-14]. We found no reports in the literature review we did that compare the cost effectiveness of unilateral and conventional (bilateral) spinal anesthesia. In our study, unilateral spinal anesthesia with hyperbaric bupivacaine 0.5% was associated with considerably reduced cost at a similar clinical effect. The reasons for the lower cost are the less pronounced hemodynamic changes which requires less extensive infusion therapy, the faster recovery and earlier discharge from the orthopedic clinic in group A patients. In this study the induction of spinal anesthesia of this type saved about 22 Euro per patient.

**CONCLUSIONS**

This study has shown that unilateral spinal anesthesia with hyperbaric bupivacaine induces adequate analgesia comparable clinically with the effect of conventional anesthesia in knee arthroscopy. It caused significantly less hemodynamic changes and no changes in body temperature. The faster recovery of motor and sensory functions, the shorter hospital stay and the reduced infusion therapy brought about a considerable economic effect – cost reduction of about 22 Euro per patient. For this we can recommend the unilateral spinal anesthesia with hyperbaric bupivacaine as an economically beneficial and clinically effective alternative in operations of lower limbs.

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