Ropivacaine for Unilateral Spinal Anesthesia; Hyperbaric or Hypobaric?

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Summary: Cantürk M, Kılçi O, Ornek D, Ozdogan L, Pala Y, Sem O, Dikmen B – Ropivacaine for Unilateral Spinal Anesthesia; Hyperbaric or Hypobaric?

Background and objectives: The aim of this study was to compare the unilaterality of subarachnoid block achieved with hyperbaric and hypobaric ropivacaine.

Methods: The prospective, randomized trial was conducted in an orthopedics surgical suite. In all, 60 ASA I-III patients scheduled for elective total knee arthroplasty were included in the study. Group Hypo (n = 30) received 11.25 mg of ropivacaine (7.5 mg.mL⁻¹) + 2 mL of distilled water (density at room temperature was 0.997) and group Hyper (n = 30) received 11.25 mg of ropivacaine (7.5 mg.mL⁻¹) + 2 mL (5 mg.mL⁻¹) of dextrose (density at room temperature was 1,015). Patients in the hyperbaric group were positioned with the operated side down and in the 15° Fowler position, versus those in the hypobaric group with the operated side facing up and in the 15° Trendelenburg position. Combined spinal epidural anesthesia was performed midline at the L₃₋₄ lumbar interspace. Hemodynamic and spinal block parameters, regression time, success of unilateral spinal anesthesia, patient comfort, surgical comfort, surgeon comfort, first analgesic requirement time, and adverse effects were assessed.

Results: Time to reach the T10 dermatome level on the operated side was shorter in group Hyper (612.00 ± 163.29 s) than in group Hypo (763.63 ± 208.35 s) (p < 0.05). Time to 2-segment regression of the sensory block level on both the operated and non-operated sides was shorter in group Hypo than in group Hyper.

Conclusion: Both hyperbaric and hypobaric ropivacaine (11.25 mg) provided adequate and dependable anesthesia for total knee replacement surgery, with a high level of patient and surgeon comfort. Hypobaric local anesthetic solutions provide a high level of unilateral anesthesia, with rapid recovery of both sensory and motor block, and therefore may be preferable in outpatient settings.

Keywords: Anesthesia, Epidural; Anesthesia, Spinal; Anesthetics, Local/ropivacaine; Specific Gravity.

INTRODUCTION

Unilateral spinal anesthesia is becoming more popular for surgical procedures that are limited to one side of the body, especially in orthopedic lower limb surgery. Probably the most important advantage of the technique is the reduced incidence of hypotension during spinal anesthesia, in addition to facilitating faster recovery, and a good level of patient and surgeon satisfaction 1-4. Unilaterality of spinal anesthesia is dependent on those factors, including baricity of the local anesthetic solution, patient position, rate of injection of local anesthetic solution into the subarachnoid space, dose-concentration-volume properties of the local anesthetic solution, and the design of the spinal needle used when performing spinal anesthesia 1-5,7.

The main goal of this prospective, randomized study was to evaluate the differences in the incidence of unilaterality of subarachnoid block between hyperbaric and hypobaric low-dose ropivacaine.

MATERIAL AND METHODS

The study included 60 patients (American Society of Anesthesiology [ASA] physical status I-III) aged 18-60 years that received combined spinal epidural anesthesia (CSEA) for elective total knee arthroplasty (TKA). The study protocol was approved by the local ethic committee and written informed consent was obtained from all the patients.

Exclusionary criteria were as follows: younger than 18 years or older than 75 years, ASA risk group > III, mental disturbance, pregnancy or the possibility of pregnancy, contraindication for regional anesthesia, having participated in another clinical study within the last 30 days, previously participating in the present clinical study, and a history of local anesthetic allergy.
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Standard monitoring included heart rate, non-invasive blood pressure, respiration rate, pulse oximetry, and 3 lead electrocardiograms (Peta K800). Data were recorded at 5-minute intervals and data collected before the CSEA procedure were considered baseline.

The pain visual analog scale (VAS) was introduced to the patients and they were informed about patient-controlled epidural analgesia (PCEA). The patients were pre-hydrated with 500 mL of lactated Ringer solution 30 minutes prior to surgery. No premedication was administered to any of the patients.

Using a list of random numbers, the patients were assigned by an anesthetic nurse to one of the treatment groups. The patients were positioned with the surgery side down in the 15° Trendelenburg position in the hypobaric group, and with the surgery side up in the 15° Trendelenburg position in the hyperbaric group. CSEA was performed in the midline at the L3-4 lumbar interspace. The epidural space was localized with the loss of resistance technique using the Tuohy needle supplied by the Spinal Needle Kit. After observing the free flow of cerebrospinal fluid at room temperature. Patients in both groups were kept in the lateral position for 10 min.

The study solutions were prepared in 4 mL volumes as follows: 3 mL of each study solution were injected into the subarachnoid space at the rate of 1 mL.min⁻¹. The opening of the spinal needle was performed through the Tuohy needle. After observing the free flow of cerebrospinal fluid, the study solution was injected into the subarachnoid space at the rate of 1 mL.min⁻¹. The opening of the spinal needle was performed to face lowermost in the hyperbaric group and uppermost in the hypobaric group. Following the removal of the spinal needle, an epidural catheter was introduced into the epidural space as the opening of the Tuohy needle facing lowermost in hyperbaric group and uppermost in the hypobaric group. In all, 3-4 cm of the catheter was positioned in the epidural space and the rest of the catheter was fixed to the skin.

The study solutions differed equally from the density of cerebrospinal fluid, without aspiration or barbotage. The density of the study solutions differed equally from the density of cerebrospinal fluid at room temperature. Patients in both groups were kept in the lateral position for 10 min.

Table I – Modified Bromage Scale

<table>
<thead>
<tr>
<th>Scale (Bromage)</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>No Motor Block.</td>
</tr>
<tr>
<td>1</td>
<td>Can flex knee, move foot, but cannot raise leg.</td>
</tr>
<tr>
<td>2</td>
<td>Can move foot only.</td>
</tr>
<tr>
<td>3</td>
<td>Cannot move foot or knee.</td>
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Table II – The Patient Comfort Scale

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
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<tbody>
<tr>
<td>Very good</td>
<td>The patient is satisfied and comfortable during the CSEA procedure.</td>
</tr>
<tr>
<td>Good</td>
<td>Analgesia is sufficient, but the patient is agitated during the CSEA procedure and intra-operative intravenous sedative medication is needed.</td>
</tr>
<tr>
<td>Inadequate</td>
<td>Analgesia is not sufficient and analgesic medication (fentanyl) is needed.</td>
</tr>
<tr>
<td>Unsuccessful</td>
<td>Analgesia is not sufficient and general anesthesia is needed.</td>
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CSEA: combined spinal epidural anesthesia.
Surgical comfort was evaluated according to verbal answers provided by the surgeon to the following questionnaire (0-3):

0: It is impossible to operate under these circumstances;
1: It is possible to operate, but we are not comfortable;
2: It is possible to operate and we are comfortable, but conditions are not as good as with general anesthesia;
3: It is possible to operate and conditions are as good as with general anesthesia.

The first analgesic requirement time was the elapsed time from the administration of the intrathecal local anesthetic solution to when the patient required analgesic medication for pain relief. Postoperative analgesia was supplied by a patient-controlled analgesia (PCEA) device. The analgesic solution was prepared with 5 µg mL⁻¹ of fentanyl citrate. The PCEA device was set for a 5 mL bolus dose without infusion, lock out time of 30 min, and a 4 h limit of 30 mL. The quantity of analgesic solution used by the patients was recorded in mL. The level of demand by the patients, the amount of bolus dose supplied by the PCEA device, and maximum pain VAS scores (0-10) on demand by the patients, the amount of bolus dose supplied by the device were recorded in mL. The level of demand by the patients, the amount of bolus dose supplied by the PCEA device, and maximum pain VAS scores (0-10) on the 1st and 2nd postoperative days were recorded.

Nausea, vomiting, bradycardia, hypotension, and decreased oxygen saturation based on pulse oximeter were recorded and consecutively treated, when present, with ondansetron hydrochloride dehydrate 4 mg i.v., atropine 0.5 mg i.v., intravenous fluid infusion, ephedrine 10 mg i.v., and breathing 2 L min⁻¹ of oxygen with a face mask.

**Statistical analysis**

Group means and standard derivation were used to compare the measurable data; age, weight, time to reach the T10 dermatome level, motor block regression time, and operation times were analyzed with Student’s t-test. Other demographic data, motor block, sensory block, and hemodynamic parameters were analyzed with the Mann-Whitney U test. Inter-group data for both sides were analyzed with the Wilcoxon test. The Chi-Square test was used to analyze data obtained for gender, ASA classification, and the number of patients in which successful unilateral spinal anesthesia was achieved. The Mann-Whitney U test was used for inter-group comparison of the patients that achieved a sensory block level above the T10 dermatome on the non-operated side. Remaining data were analyzed by median testing. The results were interpreted as median, percentage, or mean ± SD. The cut-off point for statistical significance was accepted as p < 0.05.

**RESULTS**

Patient demographic data and the duration of the operations are shown in Table III. There were no statistically significant differences in patient age, height and weight, or the duration of surgery between groups.

Time to reach the T10 dermatome level on the operated side was shorter in group Hyper (612.00 ± 163.29 s) than in group Hypo (763.63 ± 208.35 s) (p < 0.05). Patients whose sensory block dermatome level reached T10 on the non-operated side were compared between groups; the time to reach T10 was shorter in group Hyper than in group Hypo (p < 0.05) (Figure 1). While in the lateral position sensory block was completely unilateral in 25 patients in group Hyper (83.3%) and in 29 patients in group Hypo (96.6%) (p < 0.05). After placing the patients in the supine position, spinal block redistributed toward the non-operated side and at the 15th min spinal anesthesia was still unilateral in 20 patients in group Hyper (66.6%) and in 22 patients (73.3%) in group Hypo (p > 0.05). Time to 2-segment regression of the sensory block level on the operated side was shorter in group Hypo than in group Hyper (p < 0.05). On the non-operated side, time to 2-segment regression of the sensory block level was shorter in group Hypo than in group Hyper (p = 0.001). Time to reach the maximum sensory block level was similar in both groups (Figure 2).

No patients in either group required general anesthesia as a result of failed spinal anesthesia, nor did they require sedation due to discomfort. All patients reached the T10 sensory block level on the operated side.

Hemodynamic parameter changes were similar in both groups. One patient in the hyperbaric group and one patient in the hypobaric group required treatment for hypotension and both were given 250 mL of NaCl intravenously over the

<table>
<thead>
<tr>
<th>Table III – Patient Demographic Data and the Duration of Surgery</th>
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<tr>
<td><strong>Group 1 (n = 30)</strong></td>
</tr>
<tr>
<td>Age (years)¹</td>
</tr>
<tr>
<td>Weight (kg)²</td>
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<tr>
<td>Height (cm)³</td>
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<tr>
<td>Gender (F/M)</td>
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<tr>
<td>ASA (I/II/III)</td>
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<tr>
<td>Operation time (min)⁴</td>
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<tr>
<td>CSEA level</td>
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<td>(L₃/₄ / L₄/₅)</td>
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CSEA: combined spinal epidural anesthesia; values are mean ± SD.

**Figure 1 – Time to Reach the T10 Dermatome Level on the Operated and Non-Operated Sides.**

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course of five minutes. The two patients were subsequently given 10 mg ephedrine i.v. when this failed. None of the patients in either group needed treatment with 0.5 mg atropine (Figure 3).

The quality of anesthesia and the patients’ and surgeons’ answers to the questionnaires are shown in Tables IV and V. All of the patients in the hyperbaric group and 96% of the patients in the hypobaric group indicated that they would choose the same anesthetic technique in the future for a similar operation. One patient in the hypobaric group stated that he would choose general anesthesia in the future for a similar surgery, as he was disturbed by the sounds he had heard when the prosthesis was implanted.

None of the patients in either group complained about postdural puncture headache or urinary retention. First analgesic requirement time was similar in both groups. There were no complaints of backache or pain in the buttocks or legs at the 2nd postoperative day follow-up.

![Figure 2](image.png)

**Figure 2** – Sensory Block Curves for the Operated and Non-Operated Sides.
1: <L5; 2: L3-4; 3: L1-2; 4: T11-12; 5: T9-10; 6: >T8; SblkD Group 1: Sensory block dermatome level on the operated side in group 1; SblkD Group 2: Sensory block dermatome level on the operated side in group 2; SblkND Group 1: Sensory block dermatome level on the non-operated side in group 1; SblkND Group 2: Sensory block dermatome level on the non-operated side in group 2.

![Figure 3](image.png)

**Figure 3** – Heart Rate Curves.

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<th>Table IV – Spinal Block Characteristics I</th>
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*USA*: unilateral spinal anesthesia; **values are mean ± SD.

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after intrathecal administration. Moreover, it is reported that doses of intrathecal local anesthetic solution, it is reported that Kaya et al. 11 reported that unilateral spinal anesthesia in their study, the ropivacaine dose administered intrathecally for total knee replacement surgery was the smallest ropivacaine dose ever reported. In a study reported by Kaya et al. 11 0.5% hyperbaric bupivacaine and 0.18% hypobaric bupivacaine were compared for achieving unilateral spinal anesthesia in lower extremity orthopedic surgery. The incidence of unilateral spinal anesthesia was 80% in the lateral position and unilateral reduced to 68% 15 minutes after patients were placed in the supine position in the hyperbaric group; whereas in the hyperbaric group, the incidence of unilateral spinal anesthesia was 76% in the lateral position and 24% in the supine position. In the present study, the incidence of unilateral spinal anesthesia was 76% in the lateral position and 24% in the supine position. In the present study, the ropivacaine dose administered intrathecally for total knee replacement surgery was the smallest ropivacaine dose ever reported. In a study reported by Kaya et al. 11 0.5% hyperbaric bupivacaine and 0.18% hypobaric bupivacaine were compared for achieving unilateral spinal anesthesia in lower extremity orthopedic surgery. The incidence of unilateral spinal anesthesia was 80% in the lateral position and unilateral reduced to 68% 15 minutes after patients were placed in the supine position in the hyperbaric group; whereas in the hyperbaric group, the incidence of unilateral spinal anesthesia was 76% in the lateral position and 24% in the supine position. In the present study, the incidence of unilateral spinal anesthesia was 76% in the lateral position and 24% in the supine position. In the present study, the incidence of unilateral spinal anesthesia in the hyperbaric group - when patients were in the lateral position - was 96.6% and reduced to 73.3% after they were placed in the supine position. In the hyperbaric group, the incidence of unilateral spinal anesthesia while patients were in the lateral and supine positions was 83.3% and 66.6%, respectively. The unilateral spinal anesthesia incidence rate was higher in the hyperbaric group in our study because the densities of the local anesthetic solutions differed equally from the density of cerebrospinal fluid at room temperature. The nerve-blocking properties of hyperbaric and hypobaric solutions are compared, the difference in density between cerebrospinal fluid and hyperbaric solution is much greater than that of hypobaric solutions. To the best of our knowledge the present study is the first in which the baricity of hyperbaric and hypobaric ropivacaine (11.25 mg) differed equally from the baricity of CSF at room temperature.

Casati et al. 9 reported that the use of local anesthetic solution in different concentrations affects the outcome of unilateral spinal block. Therefore, the present study used equal concentrations of ropivacaine. Kuusiniemi et al. 10 compared 6 mg of 0.5% isobaric bupivacaine and 6 mg of 0.5% hyperbaric bupivacaine in 8% dextrose for achieving unilateral spinal anesthesia; unilaterality was 83.3% in the hyperbaric group, whereas unilateral spinal block was 37% in the isobaric group. Kaya et al. 11 reported that unilateral spinal anesthesia in their hyperbaric group was 80%. In the present study, unilateral spinal anesthesia in the hyperbaric group was 83.3%, in accordance with the literature.

Maintaining patients in the lateral position after the administration of either hyperbaric or hypobaric local anesthetic solution intrathecally might influence the distribution of the local anesthetic solution. However, there is no consensus as to the optimal duration that patients should be kept in the lateral position, though it is greatly affected by the dose of local anesthetic solution. Following the administration of high doses of intrathecal local anesthetic solution, it is reported that local anesthetic migration is observed as much as one hour after intrathecal administration. Moreover, it is reported that when small doses of local anesthetic solution are administra-

### DISCUSSION

In this randomized, prospective double-blind study 11.25 mg of hypobaric and hyperbaric ropivacaine provided satisfactory levels of anesthesia at the operated extremity during unilateral total knee replacement surgery. The difference in specific gravity between cerebrospinal fluid and the anesthetic solution was the same in the hypobaric and hyperbaric groups. The use of anesthetic solutions with densities that were equally different from the density and specific gravity of cerebrospinal fluid provided similar distributions of nerve blockade.

The present results appear to contradict the literature 6,8, but, in fact, they support it. Because the study solutions in both groups differed equally from the specific gravity and density of cerebrospinal fluid, neural blockade distribution was similar; however, according to the literature, when the nerve-blocking properties of hyperbaric and hypobaric solutions are compared, the difference in density between cerebrospinal fluid and hyperbaric solution is much greater than that of hypobaric solutions. To the best of our knowledge the present study is the first in which the baricity of hyperbaric and hypobaric ropivacaine (11.25 mg) differed equally from the baricity of CSF at room temperature.

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### Table V – Spinal Block Characteristics II

<table>
<thead>
<tr>
<th></th>
<th>T10D (sec)</th>
<th>T10ND (sec)</th>
<th>SBRD (min)</th>
<th>SBRND (min)</th>
<th>MBRD (min)</th>
<th>MBRND (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>763.63 ± 208.35</td>
<td>1086.67 ± 250.0</td>
<td>89.53 ± 25.49</td>
<td>57.33 ± 26.05</td>
<td>195.0 ± 58.29</td>
<td>111.0 ± 43.97</td>
</tr>
<tr>
<td>Group 2</td>
<td>612.00 ± 163.29</td>
<td>850.91 ± 189.39</td>
<td>98.50 ± 16.93</td>
<td>73.00 ± 22.19</td>
<td>203.0 ± 64.81</td>
<td>113.5 ± 44.68</td>
</tr>
<tr>
<td>p</td>
<td>0.003</td>
<td>0.016</td>
<td>0.046</td>
<td>0.001</td>
<td>0.617</td>
<td>0.828</td>
</tr>
</tbody>
</table>

T10D: Time to reach the T10 dermatome level on the operated side; T10ND: Time to reach the T10 dermatome level on the non-operated side; SBRD: 2-segment regression time of sensory block on the operated side; SBRND: 2-segment regression time of sensory block on the non-operated side; MBRD: Motor block regression time on the operated side; MBRND: Motor block regression time on the non-operated side.
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was achieved, the hypobaric local anesthetic solution became more hypobaric and the hyperbaric local anesthetic solution’s baricity approximated that of the cerebrospinal fluid.

Stienstra et al. 21 reported that small changes in the baricity of local anesthetic solution affect its distribution in the cerebrospinal fluid, regardless of the injection rate. It is yet unclear at which density and it is not possible to foresee at what rate a local anesthetic behaves hyperbaric 18. Several factors affect this rate, including: the patient’s, the ingredients in the local anesthetic solution, needle design, injection rate and level, volume, viscosity, protein content of the cerebrospinal fluid, and, although excluded in the present study, obstruction of the inferior vena cava in pregnant women 22. These factors in the present study may have affected the hyperbaric behavior of ropivacaine.

Kuusinami et al. 10 and Casati et al. 23 reported that the incidence of hypotension was lower with unilateral spinal anesthesia than with conventional spinal anesthesia. Pre-hydration is one of the factors that minimize hypotension following spinal anesthesia. In the present study, all patients were pre-hydrated with 500 mL i.v. of lactated Ringer’s solution. We considered hypotension as a 30% decrease from baseline mean arterial blood pressure or mean arterial blood pressure < 60 mm Hg; one patient in each group had hypotension. The patient with hypotension in group 1 was hydrated with 250 mL of 0.9% NaCl solution i.v. and the patient with hypotension in group 2 required an additional 10 mg of ephedrine i.v. Bradycardia was considered as < 50 beats.min⁻¹ in the present study and none of the patients had bradycardia.

Pencil-point needles provide a laminar flow during the injection of local anesthetic solution into the cerebrospinal fluid, which probably helps to achieve limited unilateral spinal anesthesia 24,25. Another factor that helped us to achieve successful unilateral anesthesia was that the ropivacaine dose used in the present study was the smallest ropivacaine dose ever reported for total knee replacement surgery. The injection rate of the local anesthetic solution was 1 mL.min⁻¹, which helped us render the block on the operated side. Patients were placed in position just before the administration of spinal anesthesia and the position helped to limit the cranial spread of unilateral spinal anesthesia.

In the present study, sensory and motor block recovery characteristics were similar to those of studies that used low-dose bupivacaine. The 2-segment regression time of sensorial block on the operated side in the hypobaric group was 89.5 ± 26.05 min, versus 98.53 ± 16.93 min in the hyperbaric group. On the non-operated side, the 2-segment regression time of sensory block was 57.33 ± 26.05 min in the hypobaric group and 73.0 ± 22.19 min in the hypobaric group. The difference in 2-segment regression time of sensory block between the two groups was statistically significant, both on the operated and non-operated sides. The number of patients that achieved a sensory block level > T10 on the operated side was higher in group Hypo, which means that ropivacaine distributed within the cerebrospinal fluid over a larger area in group Hypo than in group Hyper. This helps explain the statistically significant difference in sensory block regression time. The regression time of motor block was similar in both groups: both for the operated and the non-operated sides, and all patients completely recovered from motor block within 180 minutes. Although total knee replacement surgery is not ambulatory surgery, early recovery of motor block facilitates early mobilization. None of the patients complained of clinical neurological change, postdural puncture headache, or radicular irritation during the follow-up period.

Urinary retention is a frequent side effect of spinal anesthesia, which is due to bilateral blockade of the sacral parasympathetic plexus innervating the detrusor muscle and over-hydration to treat hypotension due to spinal anesthesia. As the hemodynamic stability provided by unilateral spinal anesthesia does not necessitate over-hydration, another advantage of unilateral anesthesia is that unilateral sacral parasympathetic plexus blockage does not completely disturb the detrusor muscle function. In the present study, two patients in group Hypo and 7 patients in group Hyper complained of urinary retention and were catheterized once, micturating spontaneously 6,10.

Postoperative analgesia was achieved using an epidural PCEA device. First analgesic requirement time was shorter in group Hypo than in group Hyper. Due to the sensory and motor block regression times being shorter in group Hypo, these patients faced postoperative pain earlier than those in group Hyper. Total analgesic solution volume used and the number of patient demands returned by the PCEA device were similar in both groups. However, it is worth noting that the number of patient demands in group Hypo was much higher than in group Hyper (Figure 4). This may be an important disadvantage of the hypobaric technique, as compared to the hyperbaric technique.

In conclusion, both hyperbaric and hypobaric ropivacaine (11.25 mg) provided adequate and dependable anesthesia for total knee replacement surgery, with a high level of patient and surgeon acceptance. The hemodynamic parameters were well preserved in both groups. Indeed, hypobaric local anesthetic solution provided a higher percentage of unilateral anesthesia with faster recovery properties, both for sensory and motor block. Therefore, even not being the concern of this study, it may be preferable in outpatient settings.

Figure 4 – Number of Demands and the Number of Demands Provided by PCEA.

*Demand: Number of analgesia demand from PCEA; **Provided: Number of analgesia provided by PCEA.
REFERENCES