Spinal anaesthesia with articaine 5% vs bupivacaine 0.5% for day-case lower limb surgery: a double-blind randomized clinical trial

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Background. A local anaesthetic with fast onset and short reliable duration of anaesthesia may be preferable for out-patient lower limb surgery. Articaine is believed to act faster and to have a shorter duration of action than bupivacaine, but there are no conclusive data available. The purpose of this study was to compare articaine and bupivacaine for day-case lower limb surgery.

Methods. Eighty patients planned for day-case lower limb surgery enrolled in this study. Patients were randomized to receive hyperbaric articaine 80 mg or plain bupivacaine 15 mg intrathecally. Primary outcome variable was recovery time from motor block. Secondary outcomes were: onset of sensory and motor block, maximum spread of sensory block, time to micturition, discharge from the hospital, and complications.

Results. The groups were comparable for the medians and the range of the maximum blocks after 30 min. Median time to complete regression of motor block was 101 min (range 80–129) for articaine compared with 307 min (range 225–350) for bupivacaine (P<0.0005). First spontaneous micturition occurred after 257 min (210–293) in the articaine group and after 350 min (304–370) in the bupivacaine group (P<0.0005). In the articaine and bupivacaine groups, patients were discharged after 300 min (273–347) and 380 min (332–431), respectively (P<0.0005). There was no significant difference in the occurrence of complications between the groups.

Conclusions. Spinal anaesthesia with 80 mg of hyperbaric articaine has a shorter duration than a spinal anaesthesia with 15 mg of plain bupivacaine in lower limb surgery of approximately 1 h duration.

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Keywords: anaesthetic techniques, regional; anaesthetic techniques, spinal; anaesthetics local, articaine; anaesthetics local, bupivacaine; surgery, day-case

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A decade ago several local anaesthetics were licensed for intrathecal use. Nowadays, only one commercially available anaesthetic is licensed for intrathecal use in The Netherlands, namely bupivacaine. Faster onset and shorter elimination time may favour a short-acting local anaesthetic for spinal anaesthesia for day-case lower limb surgery.

A number of short-acting local anaesthetics have been found useful for spinal anaesthesia for day-case surgery, such as lidocaine and articulate. These are, however, not licensed for spinal anaesthesia. Lidocaine has a shorter duration of action than bupivacaine, but the occurrence of transient neurological symptoms (TNS) has raised concerns.¹⁻⁶

Hyperbaric articulate may act faster and may have a shorter duration of action than isobaric bupivacaine, but there are not enough conclusive data available.⁻⁷⁻⁸ In addition, it is important to establish that articulate is as safe as bupivacaine.¹⁰ The purpose of this study was to
Spinal anaesthesia with articaine or bupivacaine for day-case lower limb surgery. The primary outcome is recovery time from motor block.

Methods

The ethics committee of the Reinier de Graaf Hospital approved the study and patients gave their written informed consent. Eighty patients planned for day-case lower limb surgery (e.g. knee arthroscopy, foot, and surgery for varicose veins) under spinal anaesthesia were included in this investigator initiated, prospective, randomized, observer, and patient-blinded trial.

Inclusion criteria were age between 18 and 70 yr, a height of 1.60–1.90 m, and a BMI of 18.5–35 kg m\(^{-2}\). Exclusion criteria were contra-indications for spinal anaesthesia, a history of allergic reactions to amide-type local anaesthetics, and estimated operation duration of more than 1 h. Patients were randomized in blocks of 10 to receive either hyperbaric articaine hydrochloride 80 mg or plain bupivacaine hydrochloride 15 mg intrathecally. The articaine ampoules were prepared by the hospital pharmacy. The ampoules contained articaine 5% (100 mg=2 ml) and dextrose 8%. The bupivacaine ampoules (20 mg=4 ml) used were commercially available in The Netherlands (Marcaine\textsuperscript{R} 0.5% spinal, AstraZeneca). Consequently, volumes of injection were 1.6 ml for articaine and 3.0 ml for bupivacaine. The anaesthesiologist injected the local anaesthetic intrathecally, but did not participate in the further assessment of the patient. The patients, the investigators, and the nurses were blinded regarding the study group. Premedication consisted of oral midazolam 7.5 mg. On arrival in the pre-induction room, continuous monitoring of ECG, non-invasive arterial pressure, and pulse oximetry were started. During and after the procedure, Ringer’s solution 500 ml was administered i.v. for hydration. Additional fluids were only administered to replace intraoperative fluid losses. The puncture was performed at the L2–L3 or L3–L4 interspace with a 27-G pencil-point needle, in the sitting position, preferably with a paramedian approach. If it was not possible to perform the intrathecal puncture according to protocol, this was noted on the results form. The patient was placed in the supine position immediately after injection. The time to sensory block T12 dermatomal level (analgasia to pinprick and cold pack) and motor block modified Bromage scale 3 were assessed (modified Bromage scale: 0, full movement; 1, inability to raise extended leg, can bend knee; 2, inability to bend knee, can flex ankle; and 3, no movement\textsuperscript{10}). After the measurements, the patient was transferred to the operating room for surgery. Sedation during surgery was provided with midazolam 2.5 mg i.v. with a maximum of 5 mg on patients’ request. Hypotension, defined as a decrease in systolic pressure >30% from baseline, was treated with i.v. ephedrine 10 mg as often as needed. After 30 min, the maximum spread of the sensory block was measured and if a difference in height of block between left and right occurred, the mean was recorded. After the operation, patients were asked to record time to recovery from sensory and motor block. Recovery from motor block was defined as ability to bend knees and to raise extended legs for 5 s in a 30º angle (corresponding with modified Bromage scale 0). After 90 min, the extent of the sensory block and degree of lower limb motor block were tested by the investigator. The bladder volume was measured by bedside imaging and bladder catheterization was performed only if indicated. In addition, patients were asked to record the time of first micturition and discharge from the hospital. All patients were contacted at home by telephone on days 1 and 10 after surgery by a blinded investigator. A structured interview using a questionnaire was conducted about adverse effects, that is (post-spinal) headache, pain, backache, and possible signs and symptoms of TNS. TNS was defined as pain or dysaesthesia in the buttocks, thighs, or lower limbs occurring after recovery from the anaesthetic and outside the surgical area. Recovery time from motor block was defined as the primary outcome variable. Secondary outcomes considered were: onset of sensory and motor block, maximum spread of sensory block (30 min after spinal injection of anaesthetic), spread of sensory block after 1.5 h, recovery time from sensory block, time to micturition, and adverse events.

Statistics

The sample size calculation was based on detecting at least a 15 min difference between the groups in motor block recovery. Assuming a power of 80%, a level of significance of 5%, SD of 21.3 min, it was estimated that 80 patients would be required. Data on age, weight, height, and BMI are given as mean (SD). Other continuous variables are reported as median (range). Continuous variables such as onset and recovery time from sensory and motor block and time to micturition were compared using the Mann–Whitney U-test. This test was also used if the data were not normally distributed. In the case of other continuous numeric values, the groups were compared using the t-test. Non-continuous numeric values, such as block height at 30 and 90 min, are expressed as medians (range), and were tested with the Mann–Whitney U-test. Binominal data were compared using the \(\chi^2\) or Fisher’s exact test. When sensory onset times at T12 were tested, patients not reaching T12 were assessed as right-censored variables and compared using the log-rank test. A P-value of <0.05 was considered statistically significant. The calculations were performed with SPSS version 15.0 for Windows.

Results

Of the 80 patients enrolled in the study, one patient in the articaine group and two patients in the bupivacaine group were excluded, because they did not meet the inclusion criteria (too old, tall, and short). Patient and surgical characteristics (Table 1) did not differ between the groups. The L2–L3 instead of the L3–L4 inter-space was used for
the puncture in four patients in the articaine group and for 
one patient in the bupivacaine group. A Quincke type 
needle instead of a pencil-point needle was used in seven 
patients in the articaine group and 10 patients in the bupi-
vacaine group. These were not considered to be relevant 
differences. In the bupivacaine group, two patients 
required a second spinal injection, most probably due to 
technical failure. Two patients in the bupivacaine group 
and one in the articaine group needed bladder catheterization. 
Sixteen patients in the articaine group and 15 in the 
bupivacaine group requested intraoperative sedation with 
midazolam, but verbal contact was maintained at all times. 
One patient in the bupivacaine group did not develop a 
block suitable for surgery and required additional analge-
sia (alfentanil i.v.). None of the patients manifested an 
over-extensive cephalad spread of the block or severe 
hypotension and none required general anaesthesia. Two 
patients in the bupivacaine group were hospitalized for 
the night. They went for surgery in the late afternoon and did 
not meet the discharge criteria early in the evening.

Table 1 Patient characteristics and surgical data for the two groups. Results 
are given as number of patients, mean (range) for age, mean (SD), and median 
(range) for duration of surgery. There were no significant differences

<table>
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<tr>
<th></th>
<th>Articaine (n=39)</th>
<th>Bupivacaine (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female</td>
<td>18/21</td>
<td>17/21</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>47 (40–57)</td>
<td>48 (42–55)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>79 (12.2)</td>
<td>82 (13.7)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>175 (8.2)</td>
<td>177 (8.4)</td>
</tr>
<tr>
<td>BMI (kg m⁻²)</td>
<td>26 (4.1)</td>
<td>26 (3.8)</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee arthroscopy, n (%)</td>
<td>16 (41)</td>
<td>20 (54)</td>
</tr>
<tr>
<td>Varicose vein surgery, n (%)</td>
<td>17 (44)</td>
<td>8 (22)</td>
</tr>
<tr>
<td>Other orthopaedic surgery, n (%)</td>
<td>6 (15)</td>
<td>9 (24)</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>30 (20–43)</td>
<td>30 (25–35)</td>
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Sensory block
The onset of pinprick analgesia at T₁₂ was short in both 
groups (3–4 min). The onset was more rapid with arti-
caine (P<0.005). Figure 1 presents the maximum extent of 
cephalad spread measured with pinprick after 30 min. 
The two groups were comparable for the medians and the 
range of the maximum blocks after 30 min. Articaine 
produced a median spread of analgesia to T₆ with a range 
of T₄.₅–T₉.₅. Bupivacaine had a median spread to T₇ with 
a range of T₄.₅–T₉. The median block height after 90 min 
was significantly lower with articaine L₄ (L₂–L₅) in com-
parison with bupivacaine T₁₀ (T₇.₅–T₁₁) (P<0.0005) 
(Fig. 1). The sensory block measured with cold pack

<table>
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<tr>
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<th>Articaine 30 min</th>
<th>90 min</th>
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<tbody>
<tr>
<td>C₃</td>
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<tr>
<td>C₄</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>T₂</td>
<td>★ ★</td>
<td></td>
<td>★ ★ ★</td>
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<td>★★ ★★</td>
<td>★★ ★★</td>
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<tr>
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<td>★★★★</td>
</tr>
<tr>
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<td>★★★★</td>
<td>★★★★</td>
<td>★★★★</td>
</tr>
<tr>
<td>T₁₂</td>
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<td>★★★★</td>
<td>★★★★</td>
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</tr>
<tr>
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<tr>
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<tr>
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<td>★★★★</td>
</tr>
<tr>
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<td>★★★★</td>
<td>★★★★</td>
<td>★★★★</td>
</tr>
</tbody>
</table>

Fig 1 Extension of sensory block in the two groups of patients after 30 min (maximum block) and 90 min with pinprick.
showed a comparable figure with data not statistically significantly different from the pinprick data. The cold pack figure is therefore not shown. The total duration of sensory block was significantly shorter with articaine 197 min (range 127–241) compared with bupivacaine 323 min (range 263–358) (Table 2).

**Motor block**

The onset of motor block Bromage scale 3 was more rapid with articaine (P=0.019). Median time to complete regression of motor block was 101 min (range 80–129) with articaine compared with 307 min (range 225–350) with bupivacaine (P<0.0005). First spontaneous micturition occurred after 257 min (210–293) in the articaine group and after 350 min (304–370) in the bupivacaine group (P<0.0005). In the articaine and bupivacaine groups, patients were discharged after 300 min (273–347) and 380 min (332–431), respectively (P<0.0005) (Table 2). The overall duration of motor block parameters was shorter in the articaine group and, notably, the difference in time until complete recovery was statistically significant.

**Adverse events**

There was no significant difference in the occurrence of adverse events at days 1 and 10 between the two groups. In the interviews on days 1 and 10 after operation, six persons complained of a slight headache in both groups, which was managed by acetaminophen. Three patients in the articaine group and two in the bupivacaine group complained of back pain at the puncture site. One patient in the articaine group and two in the bupivacaine group developed post-dural puncture headache. The patient in the articaine group required an epidural blood patch. One patient in the articaine group reported symptoms compatible with TNS on day 10 (Table 2).

**Discussion**

The present study shows that articaine is an alternative to bupivacaine as a short-acting spinal anaesthetic. Articaine and bupivacaine produce a similar quality of spinal anaesthesia but hyperbaric articaine 80 mg resulted in significantly faster recovery from both motor and sensory block, and shorter time to first spontaneous micturition and discharge, in comparison with plain bupivacaine 15 mg. Onset of both sensory and motor block are also faster, but the difference is clinically not relevant. The occurrence of adverse events was comparable. The T 12 level of analgesia was chosen as an arbitrary study parameter assumed to represent sufficient block level for patients undergoing day-case surgery of the lower extremities. In this respect, adequate level of analgesia was achieved in all patients in the articaine group, and in all patients in the bupivacaine group except one, who needed rescue opioid during the operation. With spinal anaesthetics used for day-case surgery, potency differences remain a controversial issue. In this study, the two groups were comparable for the medians and the range of the maximum blocks after 30 min. This is an indication that there is a dose equivalence for the articaine 80 mg and bupivacaine 15 mg, regardless of

<table>
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<tr>
<th>Sensory block</th>
<th>Articaine</th>
<th>Bupivacaine</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset at T12 pinprick (s)</td>
<td>180 (140–257)</td>
<td>234 (170–520)</td>
<td>0.0028</td>
</tr>
<tr>
<td>Max cephalad spread (dermatome) pp</td>
<td>T2 (T1.5–T0)</td>
<td>T2 (T1.5–T0)</td>
<td>NS</td>
</tr>
<tr>
<td>Block height at 90 min (dermatome) pp</td>
<td>L3 (L2–L3)</td>
<td>L3 (L2–L3)</td>
<td>NS</td>
</tr>
<tr>
<td>Total duration (min)</td>
<td>197 (127–241)</td>
<td>323 (263–358)</td>
<td>&lt;0.0005</td>
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<table>
<thead>
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<th>Motor block</th>
<th>Articaine</th>
<th>Bupivacaine</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to grade 3 block (s)</td>
<td>135 (99–200)</td>
<td>180 (124–270)</td>
<td>0.019</td>
</tr>
<tr>
<td>Total duration (min)</td>
<td>101 (80–129)</td>
<td>307 (225–350)</td>
<td>&lt;0.0005</td>
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<th>Adverse events Day 1</th>
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<td>Transient neurological symptoms</td>
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<td>0</td>
<td>NS</td>
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<tr>
<td>Back pain general</td>
<td>2</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Back pain at puncture site</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Normal headache</td>
<td>2</td>
<td>6</td>
<td>NS</td>
</tr>
<tr>
<td>Post-dural puncture headache</td>
<td>1</td>
<td>1</td>
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<th>Other factors</th>
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<th>Bupivacaine</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Time to first micturition (min)</td>
<td>257 (210–293)</td>
<td>350 (304–370)</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>VAS score by discharge</td>
<td>2.0 (1.0–4.0)</td>
<td>1.5 (0.0–2.0)</td>
<td>0.006</td>
</tr>
<tr>
<td>Time to discharge (min)</td>
<td>300 (273–347)</td>
<td>380 (332–431)</td>
<td>&lt;0.0005</td>
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</table>
Baricity and volume. The rationale for selection of the
dose articaine was our own clinical experience. A recent
study of Kallio and colleagues11 confirmed our clinical
impression. They found that spinal anaesthesia with hyper-
baric articaine 60 and 84 mg was suitable for 1 h surgery
of the lower extremities. More rescue opioid was needed
with the 60 mg dose, but the difference was not signifi-
cant. The use of 108 mg was not recommended because of
frequent extensive cephalad spread of the block,
accompanied by hypotension and nausea.11

Fifteen milligrammes of bupivacaine was chosen on the
basis of our experience that bupivacaine 12.5 mg without
opioids gives an unpredictable and an insufficiently exten-
sive enough block for surgery with a maximum operation
duration of 1 h, but this is not stated by literature. Some
anaesthesiologists might consider hyperbaric bupivacaine
a more feasible alternative than plain bupivacaine.
Alston10 found a shorter duration of action for hyperbaric
bupivacaine than for plain bupivacaine. On the downside,
however, the block was less reliable. The articaine used in
the study was also hyperbaric. This was based on a
product formulation that was commercially available until
a couple of years ago. We do have extensive clinical
experience with this product. Different volumes of bupiva-
caine and articaine were used, but there is convincing
evidence that the dose and not the volume predicts the
duration of motor block.3 12 13 A long-lasting sensory and
motor block does affect voiding capability. Articaine is
clearly superior to plain bupivacaine with a clinically
highly relevant difference in time to first micturition, thus
reducing the chance of urinary retention. If voiding is
required before the patient is allowed to leave the hospital,
the use of bupivacaine will clearly delay discharge.14 In
this study, patients were discharged from hospital much
earlier, after the use of articaine. This observation may be
confounded by the fact that other factors, such as avail-
ability of transportation or time of the surgical discharge
visit, may have influenced this outcome. The incidence of
complications for both local anaesthetics was comparable
during hospital admission and on days 1 and 10 post-
discharge. The study population, however, was not large
enough to discover any difference in the occurrence of
rare side-effects such as TNS. A much larger study would
be required to quantify this. Of note is the occurrence of a
rare case of TNS after articaine use, reported on day 10
post-discharge. In previously published studies on arti-
caine in spinal anaesthesia, there was no description of
any symptoms resembling TNS.7 8 11 When evaluating TNS,
it is critical to have an observation period sufficiently long
beyond day 1 as otherwise this side-effect will be missed.
We conclude that spinal anaesthesia with 80 mg of hyper-
baric articaine results in a shorter duration of action than a
spinal anaesthesia with 15 mg of plain bupivacaine in
lower limb surgery of approximately 1 h duration.
Articaine is an alternative with a favourable recovery
profile for use in ambulatory surgery.

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nursing and surgical staff of the Reinier de Graaf Groep, Dr Paul Mulder
for statistical and Mrs Karina de Klerk Wolters for logistical support.

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