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Chloroprocaine 40 mg produces shorter spinal block than articaine 40 mg in day-case knee arthroscopy patients

J. G. Förster[1], P. H. Rosenberg[2], A. Harilainen[3], J. Sandelin[3] and M. T. Pitkänen[1]
[1]*Department of Anaesthesia, Orthopaedic Hospital Orton, Helsinki, Finland,* [2]*Department of Anaesthesiology and Intensive Care Medicine, Helsinki University Central Hospital, Helsinki, Finland and* [3]*Department of Orthopaedics, Orthopaedic Hospital Orton, Helsinki, Finland*

Background: Articaine and chloroprocaine have recently gained interest as short-acting spinal anaesthetics. Based on previous work comparing articaine 60 mg with chloroprocaine 40 mg, we hypothesised that articaine 40 mg and chloroprocaine 40 mg would produce similar spinal anaesthesa regarding block onset, maximal spread, and recovery.
Methods: In this randomised, double-blind study, adult patients (18–70 years, American Society of Anaesthesiologists physical status I-III, BMI < 36 kg/m^2) scheduled for day-case knee arthroscopy received either articaine 40 mg (20 mg/ml) (group A40, $n = 16$) or chloroprocaine 40 mg (20 mg/ml) (group C40, $n = 18$) intrathecally. Telephone interviews were performed on the first and seventh postoperative day to disclose possible side effects, e.g. transient neurological symptoms (TNS).
Results: The groups were comparable regarding demographic data, onset and maximal spread of spinal anaesthesia, and duration of surgery. Surgery could be performed successfully under spinal anaesthesia except once in A40 (insufficient block) and once in C40 (prolonged surgery). Complete recovery was significantly slower in A40 vs. C40 for both motor block (105 (94/120) vs. 75 (71/90) min) [$P < 0.001$, Mann–Whitney *U*-test (MW-*U*)] and sensory block [135 (109/176) vs. 105 min (90/124)] ($P < 0.02$, MW-*U*), respectively [data are median (25th/75th percentiles)]. One patient from A40 showed mild TNS.
Conclusion: Both A40 and C40 provided mainly adequate spinal anaesthesia for day-case knee arthroscopy. While onset and maximal spread were comparable, the recovery from motor block was clearly faster with chloroprocaine after equivalent doses of spinal articaine and chloroprocaine.

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The suitability of the rapid and short-acting local anaesthetics articaine and chloroprocaine for day-case spinal anaesthesia has recently been discussed.[1] These two drugs seem advantageous substitutes for spinal lidocaine which disturbingly often causes transient neurological symptoms (TNS) in up to 20–30% of patients.[2–4] The first direct comparison of spinal articaine and chloroprocaine in ambulatory surgery (knee arthroscopy) showed that recovery from both motor and sensory block was significantly slower with articaine 60 mg than with chloroprocaine 40 mg.[5] Based on these results, we presumed that articaine 40 mg and chloroprocaine 40 mg would produce similar spinal anaesthesia regarding block onset, maximal spread, and recovery in day-case knee surgery. The null hypothesis was that there would be no significant intergroup difference in complete recovery from motor blockade.

Methods

This prospective, randomised, double-blind study received approval from the National Committee on Medical Research Ethics (TUKIJA no. 55/06.00.01/2011) and the National Agency for Medicines (EudraCT no. 2011-000062-35). All patients gave written consent. It was performed within the same clinical setting as described before.[5] In short, the inclusion criteria were age 18–70 years, American Society of Anaesthesiologists (ASA) physical status I–III; while the exclusion criteria were allergy to one

The study was carried out at the Orthopaedic Hospital Orton, Helsinki, Finland
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of the study drugs, contraindications to neuraxial anaesthesia, previous neuropathy of the lower extremities, body mass index > 36 kg/m^2.

Treatment allocation was by blocked randomisation (block sizes 10, 10, and 16 patients; closed envelope method). One of the anaesthetists broke the seal of the randomisation envelope and administered the spinal anaesthesia according to the named drug. This anaesthetist did not disclose the treatment allocation to anybody and did not take part in the further treatment or follow-up of the patient. A second anaesthetist assumed responsibility for the case along with the specially trained research nurse. The procedures were performed by one of two orthopaedic surgeons experienced in knee arthroscopy. A thigh tourniquet (250 mmHg) was used during arthroscopy. Postoperative telephone interviews were carried out by the study nurse.

Perioperative monitoring consisted of pulse oximetry, electrocardiogram, non-invasive blood pressure measurement. An intravenous access was assured but care was taken not to infuse more than 50–100 ml of Ringer's acetate solution before the application of spinal anaesthesia.

Spinal anaesthesia was performed with the patient in the lateral decubitus position, side of surgery downwards, spine column horizontal, lumbar puncture preferably midline at L3–L4, preferably pencil point G27 needle. With the orifice of the needle facing downwards, the study drug was injected (1 ml/10 s). Then, a stopwatch was started (= time zero) and the patient was turned supine without delay and, if needed, the operating table was adjusted horizontally.

Patients received intrathecally either articaine hydrochloride 40 mg [1.0 ml Ultracain® D ohne (i.e. without) adrenalin 40 mg/ml, Aventis, Frankfurt am Main, Germany, diluted with 1.0 ml of sterile saline 0.9%] (group A40, $n = 18$), or chloroprocaine hydrochloride 40 mg (2.0 ml Nesacaine®-MPF 20 mg/ml, APP Pharmaceuticals, Schaumburg, IL, USA) (group C40, $n = 18$). With densities of 1.0012 g/ml in A40 and 1.0013 g/ml in C40* both study solutions are considered slightly hyperbaric (the lower limit of hyperbaricity is defined as three standard deviations (SD) above the mean density of the cerebrospinal fluid, i.e. 1.00119 g/ml).[6]

Midazolam or fentanyl was administered intravenously (i.v.) at the time of lumbar puncture and during surgery, as needed. Hypotension (systolic < 90 mmHg or systolic decrease > 30% of baseline): i.v. ephedrine 5 mg; bradycardia (pulse < 50/min): i.v. atropine 0.5 mg.

The cranial spread of the sensory blockade was recorded bilaterally as the highest dermatome level without a sharp sensation to a pinprick needle at 2, 4, 6, 8, 10, 15, 20, 25, and 30 min, then at 15-min intervals until the sensory blockade had regressed to dermatome S2. Motor blockade was evaluated with a modified Bromage scale (Fig. 2) at 5, 10, 15, 20, 25, and 30 min, then every 15 min until the patient could lift both legs.

Every patient was observed at the post-anaesthesia care unit (PACU) for at least 1 h. Postoperatively, when the sensory blockade had regressed to at least the dermatome L1 on one limb the patient was permitted to drink fluid. All patients had a cooling ice pad on the operated knee for the first hour in the PACU. The postoperative pain treatment was tailored individually and included either paracetamol or a non-steroidal anti-inflammatory drug combined with on demand codeine or oxycodone. Within 30 min after surgery, the urinary bladder was ultrasound scanned and single catheterisation was performed, if necessary (for decision guide, see Table 3). The time of first spontaneous voiding was registered. After return to the surgical ward, further treatment was according to the hospital's standard procedure.

On the first and seventh postoperative day, the patients were interviewed by telephone (standardised questionnaire) for possible side effects such as headache and TNS. The latter was defined as a bilateral mild to severe pain occurring in the gluteal region and legs, appearing no more than 24 h after complete recovery from the spinal anaesthesia.[4]

Sample size and statistics

The articaine and chloroprocaine dosages were based on an earlier study.[5] With full recovery from motor block as the primary outcome, and assuming a clinically meaningful minimum difference of 30 min (SD 25 min), we calculated that 15 patients per group would suffice to confirm or reject the null hypothesis ($\alpha = 0.05$, power = 90%). To allow for possible dropouts, 18 patients were allocated to each group.

Normally distributed, parametric data are presented as mean (SD) and the groups are compared with the *t*-test. Non-parametric data are given as median with percentiles or range, as appropriate, and the groups are analysed with the Mann–

**As compared with the density of distilled water at 37°C; uncertainty of measurement 0.0002 g/ml; measured at 36.8°C (± 0.2); measurement protocol: M-09D025, 2009, the National Standards Laboratory, Centre for Metrology and Accreditation, Espoo, Finland.*

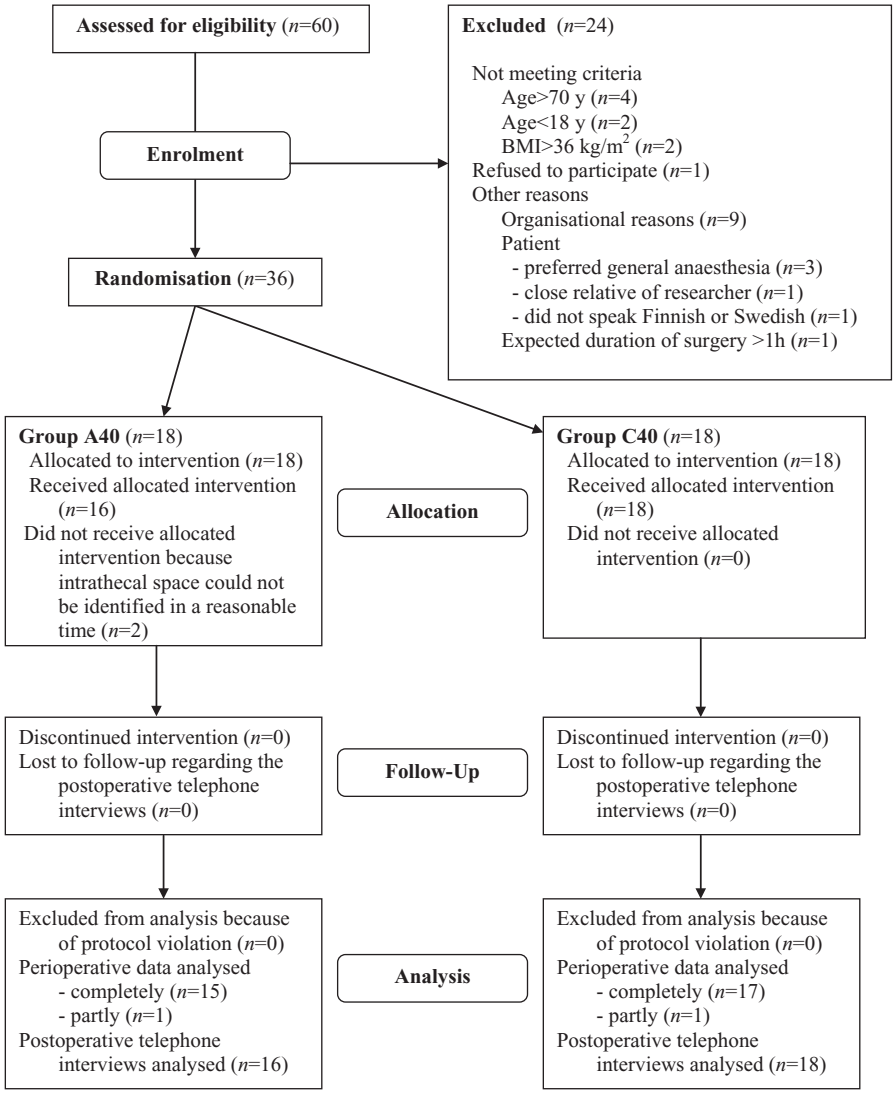

Fig. 1. CONSORT flow diagram.

Whitney *U*-test (MW-*U*). Categorical data are presented in absolute numbers with percentages and the differences between the groups are assessed using the χ^2 test. *P*-values < 0.05 are considered statistically significant. The StatView® for Windows® computer program (version 5.0.1, SAS Institute Inc., Cary, NC, USA) was used for the analysis. As appropriate, 95% confidence intervals (95% CI) were computed with the software Confidence Interval Analysis (version 2.1.1, Bryant TN, University of Southampton, Southampton, UK, 2000).

Results

The data were collected from May 2011, to November 2011. As shown in Fig. 1, two patients in group A40 dropped out because their intrathecal space could not be identified in a reasonable time. The study groups were comparable regarding the demographic data, oral diazepam premedication, or surgery related results (Table 1). A few patients received small doses of midazolam or fentanyl i.v. during the application of the spinal block (Table 2). Supplemental i.v. anaesthesia (propofol and fentanyl combined with a laryngeal mask) was applied two times, once in A40 because of an insufficient block depth and once in C40 due to prolonged surgery (start of procedure 37 min after lumbar puncture, duration of surgery 69 min). The data of these two individuals were, however, included in the analysis as regards the period before induction of general anaesthesia and then the telephone interviews. Another patient from C40 received twice supplementary fentanyl 50 µg i.v. intraoperatively (Table 2).

Table 2 shows the onset times of sensory block at dermatome L1, the number of patients where the

Table 1

Data related to demographics, premedication, and surgery.

	Group A40 ($n = 16$)	Group C40 ($n = 18$)
Male/female	10/6	10/8
ASA physical status I/II/III	12/4/0	11/7/0
Age (years)	52 (13.4)	48 (14.9)
Weight (kg)	73 (8.2)	80 (13.5)
Height (cm)	173 (8.1)	175 (8.9)
Premedication diazepam 10 mg p.o. (yes/no)	5/11	5/13
Time from spinal anaesthesia to ready-to-cut (min)	20 (5.0)	23 (5.8)
Time from spinal anaesthesia to start of surgery (min)	31 (8.3)	32 (9.0)
Duration of surgery (min)	22 (9.7)	26 (12.8)
Type of arthroscopic knee surgery*		
Diagnostic arthroscopy	0	1
Lateral capsular discission	1	1
Removal of osteosynthesis material	0	1
Arthroscopic synovectomy	1	2
Revision of osteochondritis lesion	0	4
Refixation of meniscus	1	0
Repair of joint cartilage	0	3
Resection of meniscus	14	12

Data are numbers of patients or mean (SD).
*One patient in group A40 and six patients in group C40 with two codes.
A40, spinal articaine 40 mg; C40, spinal chloroprocaine 40 mg; ASA, American Society of Anaesthesiologists; SD, standard deviation; p.o., per oral.

Table 2

Details related to the administration and progress of spinal anaesthesia.

	Group A40 ($n = 16$)	Group C40 ($n = 18$)	*P*-values, statistical test
Midazolam 1–2 mg i.v. during			
Administration of spinal anaesthesia	3	4	
Surgery	2	2	
Fentanyl 50–100 μg i.v. during			
Administration of spinal anaesthesia	1	1	
Surgery	0	1	
Sensory block at dermatome L1			
At least level L1 reached (yes/no)	14/2	17/1	
Time to onset (min)	6 (4/10)	4 (2/10)	
Duration (min)	54 (37/73)	54 (41/61)	
Sensory block reached at least level T10 (yes/no)	6/10	8/10	
Maximal extension of sensory block (dermatome)	T8 (T12/T6)	T8 (T10/T7)	
Time to onset (min)	20 (10/25)	18 (15/25)	
Time from start of spinal anaesthesia to two-dermatome regression from maximal sensory block level (min)	75 (49/75)	60 (45/60)	0.07, MW-*U*
Time to full motor block recovery (min)	105 (94/120)	75 (71/90)	< 0.001, MW-*U**
Time to full sensory block recovery (min)	135 (109/176)	105 (90/124)	< 0.02, MW-*U**
Needle 27G Pencil point/Quincke type	14/2	17/1	
Level of puncture L III–IV/L IV–V/L II–III	14/1/1	18/0/0	
Median/lateral approach	12/4	16/2	
Number of bone contacts (0/1/2/≥3)	10/2/2/2	11/4/2/1	
Paraesthesia during puncture (no/yes)	13/3	18/0	
Pain on injection	0	0	
Needle slightly bent	0	1	

Data are numbers of patients or median (25th/75th percentiles).
*Median differences (95% CI) 30 (15–45) and 30 min (0–60) for motor and sensory block recovery, respectively.
A40, spinal articaine 40 mg; C40, spinal chloroprocaine 40 mg; i.v., intravenously; MW-*U*, Mann–Whitney *U*-test; CI, confidence interval.

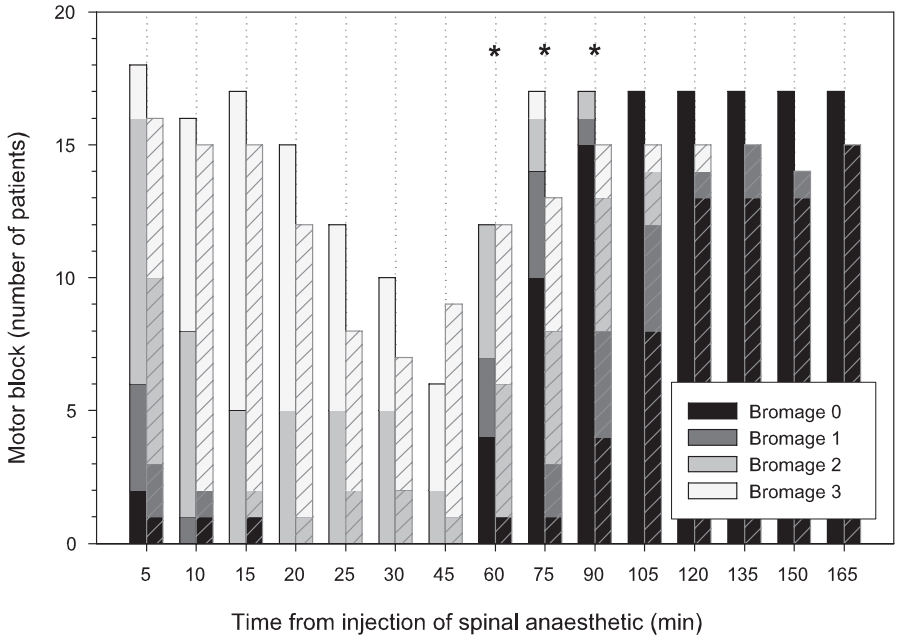

Fig. 2. Time-dependent course of motor block on side of arthroscopy for group A40 and group C40. A40 = Spinal articaine 40 mg. C40 = Spinal chloroprocaine 40 mg. Stacked bars filled with plain colour represent C40, bars with shading A40; grade of motor block according to colour scale (modified Bromage scale: 0 = able to raise entire leg; 1 = unable to raise whole leg but able to flex knee; 2 = unable to flex knee, only foot moving; 3 = unable to move knee or foot). Time points with statistically significant differences are marked with an asterisk ($P \leq 0.045$, MW-U). As regards the ditch during the first hour, it should be noted that motor block was not necessarily measured during the arthroscopy.

sensory block reached a level ≥ L1 and ≥ T10, and the maximum extension of the sensory block with no significant difference between the groups. The motor block developed similarly fast in both groups ($P > 0.13$ at 5 and 10 min, MW-*U*; Fig. 2).

There were no intergroup differences in the interval from spinal anaesthesia until the two-dermatome regression from the maximum sensory block or the median duration of the sensory block at level L1 (Table 2). Nevertheless, complete recovery from sensory block was significantly slower in A40 vs. C40 ($P < 0.02$, MW-*U*; Table 2).

Figure 2 presents the grades of motor block over time with significantly slower regression in A40 vs. C40 at 60, 75, and 90 min after spinal puncture ($P \leq 0.045$, MW-*U*). Correspondingly, complete recovery from motor block was significantly slower in A40 vs. C40 ($P < 0.001$, MW-*U*). The median differences (95% CI) were 30 (15–45) and 30 min (0–60) for motor and sensory block regression, respectively.

Vital parameters did not differ between the groups before induction of spinal anaesthesia or intraoperatively (data not shown). In a few patients, hypotension and bradycardia developed intraoperatively; i.v. ephedrine and atropine were given as per the protocol (Table 3). Two of these persons, one in each group, experienced mild, short-lasting nausea (Table 3).

The time from spinal anaesthesia to first oral fluid intake was comparable between the groups (Table 3). There were trends towards a higher urinary bladder volume at the initial bladder scan and a longer time to the first spontaneous voiding in A40 as compared with C40 (Table 3). However, no patient required catheterisation of the urinary bladder. The proportion of patients who received weak or strong opioids on demand, postoperatively, did not show a significant intergroup difference (Table 3). One subject from group A40 encountered a short-lasting orthostatic hypotension on the ward (more than 5 h after the block) without any further sequelae. One patient of C40 remained in hospital overnight because of nausea.

There were no significant differences between the study groups when considering posture-independent headache, backache, and postoperative nausea and vomiting which occurred in a few patients in both groups (Table 4). There were no cases of postdural puncture headache. Lumbar puncture was easily performed in the majority of patients (Table 2). Especially, the procedure was completely uneventful in the patient from group A40 who presented with mild TNS (Table 4). This patient (53-year-old female, 160 cm, 59 kg, ASA physical status I) had good spinal block (maximum level dermatome T7 after 15 min) that regressed within 105 min. About 8 h after recovery from the spinal anaesthesia, her back started to ache and to be touch sensitive. These sensations crept down to both buttocks and thighs over the next 3 days. The discomfort was the strongest on the second and third

Table 3

Intra- and postoperative data related to hypotension, bradycardia, nausea, urinary bladder function, and pain medication given in hospital on day of surgery.

	Group A40 ($n = 15$)	Group C40 ($n = 17$)	*P*-values, statistical test
Patients receiving intraoperatively			
Ephedrine i.v. (yes/no)	2/13	4/13	
Cumulative dosage of ephedrine (mg) [range]	10–15	5–25	
Atropine 0.5 mg i.v. (yes/no)	2/13	1/16	
Patients with mild nausea intraoperatively (yes/no)	1/14	1/16	
Time to first oral fluid intake (min)	89 (72/97)	89 (77/97)	0.73, MW-*U*
Urinary bladder volume at first ultrasound (ml)	211 (136/578)	164 (76/313)	0.15, MW-*U*
Time to first spontaneous voiding (min)	236 (152/279)	171 (163/197)	0.27, MW-*U*
Urinary retention needing catheterisation*	0	0	
Weak and strong opioids on demand postoperatively (no/codeine in combination with paracetamol/oxycodone)	7/7/1	8/5/4	0.35, χ^2-test

Data are numbers of patients or median (25th/75th percentiles), unless stated otherwise.
*At first urinary bladder ultrasound: volume 0–400 ml of urine, no intervention and follow-up until spontaneous voiding; 400–500 ml of urine, patient asked to void and reassessment after 1 h as needed; > 500 ml of urine, single catheterisation of the bladder if spontaneous voiding was not possible.
A40, spinal articaine 40 mg; C40, spinal chloroprocaine 40 mg; MW-*U*, Mann–Whitney *U*-test.

Table 4

Data gathered during postoperative telephone interviews.

	First POD		Seventh POD	
	Group A40 ($n = 16$)	Group C40 ($n = 18$)	Group A40 ($n = 16$)	Group C40 ($n = 18$)
PONV	5	5	1	4
Non-PDPH	2	3	3	1
PDPH	0	0	0	0
Non-radicular backache	0	1	0	0
TNS	1	0	0	0
Satisfaction with spinal anaesthesia technique (grade 0/1/2/3)			6/9/0/0	11/7/0/0

Data are number of patients. Grading for satisfaction with spinal anaesthesia: 0, very satisfactory; 1, satisfactory; 2, unsatisfactory; 3, very unsatisfactory.
A40, spinal articaine 40 mg; C40, spinal chloroprocaine 40 mg; POD, postoperative day; PDPH, postdural puncture headache, i.e. posture-dependent headache which is worsened on standing up and alleviated on lying down; non-PDPH, posture-independent headache which does not worsen on standing up and is not alleviated on lying down; TNS, transient neurological symptoms, for definition see Methods; PONV, postoperative nausea and vomiting.

postoperative day and ceased on the fourth postoperative day. The patient did not report any other neurological symptoms. When asked on the seventh postoperative day, the patients stated to be either satisfied or very satisfied with their anaesthesia (no intergroup difference, Table 4).

Discussion

The equivalent doses of 40 mg of articaine and chloroprocaine produced mainly adequate spinal anaesthesia for knee arthroscopy. While onset and spread of anaesthesia were similar, block regression was faster with chloroprocaine. This was particularly distinct regarding the motor block with a median difference (95% CI) of 30 min (15–45). Such a difference can be considered clinically significant in ambulatory surgery.

The earlier direct comparison of spinal articaine and chloroprocaine utilised 60 and 40 mg, respectively. It showed that recovery was clearly faster for both motor [median difference (95% CI) 45 (45–60)] and sensory [45 min (30–60)] block with chloroprocaine.[5] The question arouse whether the observed difference was attributable mostly to the 1.5 times higher articaine dose. This prompted the present study where we applied equivalent dosages of these two short-acting local anaesthetics. Obviously, now the difference in recovery times was smaller but still remained statistically and clinically significant. The

study design here does not allow conclusions in how far the different recovery times were dependent on the pharmacokinetic properties of the applied local anaesthetics (e.g. lipid solubility, protein binding, and inactivation of both chloroprocaine and articaine through hydrolysis).[7,8]

Although not always directly comparable for methodological reasons, it appears that, at least in group C40, the motor block regression times were equal to or shorter than those from numerous studies aiming at a swift recovery from spinal anaesthesia after ambulatory surgery of the lower extremities.[9–20] A recent paper described the successful use of selective sensory spinal anaesthesia for knee arthroscopy by means of a low dose (4 mg) of the long-acting local anaesthetic levobupivacaine combined with fentanyl 10 µg.[21] With this technique, most patients had regained motor function and proprioception already immediately after surgery and 80% of the subjects fulfilled the criteria to bypass the PACU. Besides, the short time to first walking [median (range) 45 min (23–120)][21] appears very competitive as compared with the complete recovery from motor block in group C40 here [median (25th/75th percentiles) 75 min (71/90)]. On the other hand, many of the so-called selective/unilateral/low-dose spinals combined the local anaesthetic with a small dose of an opioid which introduces possible adverse effects such as pruritus,[11,13,15,22–24] nausea,[13,24] and urinary retention.[13,24] From that perspective, it may be warranted to compare chloroprocaine 40 mg with a low-dose combination of a long-acting local anaesthetic and an opioid. Besides, it would be important to investigate spinal chloroprocaine (e.g. 40 mg) with or without fentanyl (e.g. 10–20 µg) in a clinical setting because such has been studied only in volunteers so far.[25] In any case, such studies should not only compare the ambulation times but also register the aforementioned adverse effects and hospital discharge times. Achieving an accelerated hospital discharge or testing for possible PACU bypass was not part of the present study design.

Onset times, spread of sensory block, and depth of motor block were comparable in the groups A40 and C40 (Table 2, Fig. 2). With articaine 60 mg, the onset of motor block was more intense at 5 and 10 min from injection;[5] such a difference was not evident any more with A40 vs. C40 (Fig. 2). Nevertheless, onset times were fast enough in relation to the ready-to-cut intervals (Table 1).

The requirement for supplemental intraoperative sedation or pain medication was small and did not distinguish from what has been described in similar investigations (e.g.[11,12,15,16,20,21,26]). Nevertheless, both articaine 40 mg and chloroprocaine 40 mg may be at the lower end of the clinically feasible dose range; this is suggested by the observations that the sensory block did not even reach dermatome L1 a few times (Table 2) and that the spinal block did not spread and deepened sufficiently once in A40. Another point is that even with a sufficient primary block and a smooth operating theatre scheduling, it may happen that the effect of the short-acting spinal anaesthetic wears off too early in relation to the duration of surgery, as seen once in C40.

Encouraged by our previous results[5] – where spinal anaesthesia with articaine 60 mg or chloroprocaine 40 mg produced mostly very well tolerated blocks combined with stable vital parameters – we decided here to refrain from the routine intravenous fluid challenge before application of the block. Thus patients received only approximately 50–100 ml of Ringer's acetate solution prior to lumbar puncture. In spite of this, no deteriorations of blood pressure or heart rate were observed. The few observed episodes of hypotension and bradycardia were relatively mild and reacted adequately to i.v. ephedrine and atropine. It is worth noting that ephedrine and atropine were given partly due to the protocol instructions rather than because of complaints by the patients. The avoidance of larger fluid challenges might be of importance as regards possible urinary retention.[27] The longer sensory and motor block in A40 might go hand in hand with a slower recovery of the voiding capacity (only trend; Table 3); however, no patient required catheterisation of the urinary bladder. Earlier, 2 of 39 patients required catheterisation of the urinary bladder after spinal articaine 60 mg.[5] Possible urinary retention should not be forgotten in future trials looking at various anaesthetic techniques in ambulatory surgery.[5,27–29]

This study adds to earlier data indicating that TNS are rare with spinal articaine[20,26,28,30,31] and even more so with chloroprocaine.[1,16,32,33]

The anaesthesiologist who performed the spinal block was not blinded with regard to the group allocation and this might have introduced some intervention bias. Here, we consider this risk to be of minor importance; at least, this study design should not have caused any selection or measurement bias. In retrospect, it would have been interesting to register also the time to first ambulation rather than only the time to full regression of motor block (with the patient still supine in bed during measurement). Finally, the small numbers do not allow far-reaching

inferences about secondary parameters or safety issues.

In conclusion, the equivalent doses of 40 mg of articaine and chloroprocaine provided mainly adequate spinal anaesthesia for day-case knee arthroscopy; however, block regression was clearly faster with chloroprocaine.

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Conflict of interest: The authors have no conflicts of interest.

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Address:
Johannes G. Förster
Department of Anaesthesia
Orthopaedic Hospital Orton
Tenholantie 10
00280 Helsinki
Finland
e-mail: johannes.forster@orton.fi