Dose response study of lidocaine 1% for spinal anaesthesia for lower limb and perineal surgery

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Purpose: To compare the sensory and motor block produced by three different volumes of intrathecal lidocaine 1% and thereby determine the appropriate volume to administer for surgery of the lower limbs and perineum.

Methods: Forty-eight patients scheduled for perineal or lower limb surgery were randomly assigned to receive 4, 6 or 8 ml lidocaine 1% intrathecally. The onset, spread, duration and regression of analgesia and motor block and side effects were evaluated (by a blinded observer whenever possible).

Results: The maximum cephalad spread in the 6 ml ($T_8 \pm 3$) and 8 ml ($T_4 \pm 1.7$) groups were higher than the 4 ml group ($T_{12} \pm 2.2$, $P < 0.01$). In the 4 ml group, six patients (33%) did not achieve analgesia to T_{12} and four (22%) did not have complete motor blockade. Patients given 8 ml had longer duration of block (duration at T_{12}: 104 ± 23 *vs* 60 ± 24, 67 ± 14 min, $P < 0.01$; 8 ml *vs* 4, 6 ml) and slower recovery times (sensory recovery: 188 ± 27 *vs* 142 ± 27, 157 ± 28 min, $P < 0.01$; 8 ml *vs* 4, 6 ml). Two patients (18%) from the 8 ml group and one (5%) from the 6 ml group had transient hypotension.

Conclusion: Four millilitres intrathecal lidocaine 1% is adequate for perineal surgery but for lower limb procedures, 6 ml is more appropriate as it consistently provides sensory analgesia above L_1 dermatome and complete motor block. Eight ml gives an unnecessarily high block with higher incidence of hypotension.

Objectif : Comparer le blocage sensitif et moteur produit par trois différents volumes de lidocaïne intrathécale à 1 % et déterminer ainsi le volume approprié pour une chirurgie des membres inférieurs et du périnée.

Méthode : Quarante-huit patients devant subir une chirurgie des membres inférieurs ou du périnée ont été choisis au hasard pour recevoir 4, 6 ou 8 ml de lidocaïne intrathécale à 1 % . Le début, l'étendue, la durée et la régression de l'analgésie et du blocage moteur et les effets secondaires ont été évalués (par un observateur impartial autant que possible).

Résultats : Dans les groupes ayant reçu 6 ml ($T_8 \pm 3$) ou 8 ml ($T_4 \pm 1,7$) l'extension maximale en direction céphalique a été plus haute que dans le groupe ayant reçu 4 ml ($T_{12} \pm 2,2$; $P < 0,01$). Dans le groupe à 4 ml, chez six patients (33 %) l'analgésie n'a pas atteint T_{12} et quatre (22 %) n'ont pas eu de blocage moteur complet. Les patients à qui on a donné 8 ml ont eu un blocage de plus longue durée (durée à T_{12} : 104 ± 23 *vs* 60 ± 24, 67 ± 14 min, $P < 0,01$; 8 ml *vs* 4, 6 ml) et une récupération plus lente (récupération sensitive : 188 ± 27 *vs* 142 ± 27, 157 ± 28 min, $P < 0,01$; 8 ml *vs* 4, 6 ml). Deux patients (18 %) du groupe à 8 ml et un (5 %) du groupe à 6 ml ont eu de l'hypotension transitoire.

Conclusion : Quatre millilitres de lidocaïne intrathécale à 1 % constituent une dose appropriée pour une chirurgie du périnée, mais pour une intervention aux membres inférieurs, 6 ml sont plus efficaces, puisqu'ils fournissent régulièrement une analgésie sensorielle au-dessus du dermatome de L_1 et un blocage moteur complet. Huit millilitres produisent un blocage inutilement haut accompagné d'une plus grande incidence d'hypotension.

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THERE are several reports of adverse reactions to spinal administration of lidocaine 5%. Cauda equina syndrome[1,2] associated with continuous spinal anaesthesia and transient radicular irritation[3,4] after single dose spinal anaesthesia illustrate the need to use the lowest effective concentration of local anaesthetic agent to avoid potential concentration-related[5,6] neurotoxic effects. Although lidocaine 1% is not commonly employed as a spinal anaesthetic, we have administered it intrathecally for brief procedures below the L_1 dermatome and found it to be effective and safe.

Since Stout and Toma[7] first reported the use of lidocaine 1% as a spinal anaesthetic (mean dose 137 mg) for abdominal surgery, there have been no studies which evaluated the dose response characteristics of intrathecal lidocaine 1%.

Our study compared three different volumes of intrathecal lidocaine 1% with respect to onset, spread, duration and regression of sensory and motor blockade and side effects. The results will enable us to determine the optimal dose range to use for surgery of the lower limbs and perineum.

Methods

Forty-eight ASA 1- 2 patients, 20 to 50 yr, scheduled for surgery below the L_1 dermatome estimated not to exceed 60 min, took part in the study. Patients with spinal deformities, neurological disease or mental disorder were excluded. Surgical procedures deemed suitable include anal fistulectomy, sphincterotomy, haemorroidectomy, incision and drainage of perianal abscess, removal of ankle or tibia implants and diagnostic ankle or knee arthroscopy. The study was approved by the Hospital Ethics Committee and informed consent was obtained from all participants.

Each subject was randomly assigned to receive 4, 6 or 8 ml of lidocaine 1%.

Plain aqueous solution lidocaine hydrochloride 1% (Xylocaine, Astra) which is both glucose and preservative free was used. Its specific gravity, determined by refractometry in our clinical laboratory, was found to be 1.008 at 23°C.

Just before the spinal injection, blood pressure, heart rate and oxygen saturation were recorded in each patient and an infusion of lactated Ringer's solution was started. With the patient in the left lateral position, a lumbar puncture was performed at the L_{3-4} interspace through a midline approach with a 25-gauge Quincke needle. After free flow of cerebrospinal fluid was obtained, the lidocaine solution was injected without barbotage at the rate of one millilitre every five seconds. The patient was then turned supine and left undisturbed for 10 min before further positioning, if required, was carried out.

Immediately after the injection, the level of sensory analgesia was evaluated by pin-prick with a 23-gauge needle every three minutes for the first 30 min, every five minutes for the next 30 min and at 15 min intervals thereafter until complete regression of sensory block. At the same time intervals, the degree of motor block was assessed using a scoring system. The movements assessed were hip flexion with the leg in the extended position, knee flexion and ankle flexion. Inability to perform any of the three movements on either side was scored as one point, thus the sum of scores represents the intensity of motor blockade with a score of 0 indicating no motor block and a score of 6 implying complete bilateral motor block. As far as possible, the assessment of the block was performed by an independent doctor (usually an anaesthetic resident assigned to the operation list) who was unaware of the local anaesthetic solution given. However, due to manpower constraints, on some occasions, the investigator administering the spinal evaluated the block as an independent doctor was not available.

The ECG and pulse oximetry were continuously monitored and measurements of heart rate, oxygen saturation (Ohmeda Biox 3700e) and blood pressure (Dinamap, Criticon) were recorded at the same time intervals as the sensory and motor assessments. Hypotension, defined as a decrease in systolic blood pressure of 30% below baseline value was treated with intravenous fluids and small doses of ephedrine if necessary. Other complications such as bradycardia (heart rate < 50 bpm), chills and shivering, desaturation (SpO_2 < 95%) and inadequate analgesia were also noted and appropriate treatment instituted as necessary.

After surgery, the patients were monitored in the recovery room until complete recovery from the spinal block and they were allowed to ambulate not earlier than one hour after their return to the ward. Follow-up interviews were conducted on the fifth postoperative day (by telephone) and patients were asked specifically for symptoms of headache and backache as well as any other problem perceived to be related to the spinal anaesthesia.

Statistical analysis of the data from the three groups was performed either using analysis of variance (ANOVA) followed by Student-Newman-Keuls test or, in the case of non-parametric data, Kruskall-Wallis test followed by Dunn test. Paired t test was used for comparison of data within the same group. All results were expressed as mean and standard deviation except for the maximum sensory level achieved which was expressed as median and standard deviation. A P value of < 0.05 was considered statistically significant.

Results

Of 48 patients, 18 received 4 ml, 19 received 6 ml and 11 received 8 ml lidocaine 1%. Halfway through the study, we performed a preliminary data analysis and decided to discontinue the 8 ml group after we found that this dose gave a consistently high sensory block which was inappropriate for patients undergoing surgery below the L_1 dermatome. The three groups of patients were similar with regard to age, height, weight and sex (Table I). The average duration of surgery was 34 ± 18 min.

Onset and Spread

The onset of sensory anaesthesia to T_{12} and onset to complete motor block were slower in the 4 ml group than in the 6 and 8 ml groups (Table II). Of the 18 patients in the 4 ml group, 33% did not reach T_{12} sensory level and only 78% had full motor blockade. All patients from the 6 and 8 ml groups reached T_{12} sensory level and only one from the 6 ml group did not achieve complete motor blockade.

There was no difference among the three groups in the time taken to reach maximum analgesic levels which occurred at 13 - 16 min (Table II). However, the maximum cephalad spread of analgesia increased with increasing volume of lidocaine used. The difference in maximum cephalad spread among the three groups was significant ($P < 0.01$) (Table II).

TABLE I Patient characteristics

Group	*4 ml* (*n = 18*)	*6 ml* (*n = 19*)	*8 ml* (*n = 11*)
Sex (M:F)	10 : 8	15 : 4	10 : 1
Age (yr)	35 ± 9	30 ± 9	36 ± 15
Height (cm)	164 ± 2	169 ± 9	170 ± 6
Weight (kg)	60 ± 13	68 ± 12	69 ± 11

Values for age, height and weight are mean ± SD.

TABLE II Onset and spread

Group	*4 ml*	*6 ml*	*8 ml*	*P*
T_{12} Sensory Level				
Onset time (min)	11 ± 7	5 ± 3	4 ± 2	< 0.01*
Frequency	12/18	19/19	11/11	
Full motor block				
Onset time (min)	14 ± 6	9 ± 5	8 ± 2	< 0.01*
Frequency	14/18	18/19	11/11	
Maximum cephalad spread				
Onset time (min)	16 ± 7	13 ± 5	16 ± 5	NS
Dermatomal Level †	T_{12} ± 2	T_8 ± 3	T_4 ± 2	< 0.01*

Values for onset times are mean ± SD
† Values are median ± SD
* 4 ml *vs* 6 and 8 ml groups
NS - not significant

TABLE III Duration and regression

Group	*4 ml*	*6 ml*	*8 ml*	*P*
Duration at/above T_{12} (min)	60 ± 24	67 ± 14	104 ± 23	< 0.01*
Duration of full motor block (min)	59 ± 21	65 ± 23	100 ± 33	< 0.01*
Onset of sensory regression (min)	44 ± 17	40 ± 16	33 ± 16	NS
2-segment regression time (min)	18 ± 8	16 ± 10	11 ± 7	NS
Complete sensory recovery (min)	142 ± 27†	157 ± 28†	188 ± 27†	< 0.01*
Complete motor recovery (min)	105 ± 30	113 ± 43	158 ± 34	< 0.01*

Values are mean ± SD
* 8 ml *vs* 4 and 6 ml groups
NS - not significant
† $P < 0.01$ compared with time taken for complete motor recovery within the same group

Duration and Regression

The duration of sensory anaesthesia at or above T_{12} and the duration of complete motor blockade were longer in the 8 ml group than in the 4 ml and 6 ml groups ($P < 0.01$) (Table III).

The regression of sensory analgesia began between 33 - 44 min after intrathecal injection. The onset times of sensory regression and the 2-segment regression times were similar in all three groups (Table III). The times taken for complete regression of sensory and motor block were longer in the 8 ml group than in the 4 ml and 6 ml groups ($P < 0.01$). In each of the three groups, the recovery of full motor power was significantly faster than complete recovery from sensory blockade ($P < 0.01$).

Quality of Analgesia

In the 4 ml group none complained of pain during surgery, but during the postoperative interview, one patient admitted to having mild discomfort during the procedure (incision and drainage of perianal abscess) but it was tolerable.

Two patients from the 6 ml group experienced intraoperative pain because surgery took longer than expected (83 min and 94 min respectively from time of intrathecal injection). The first patient complained of pain 75 min after spinal injection and was given fentanyl

iv. Fortunately, the procedure (knee arthroscopy) ended eight minutes later. The second had pain 90 min after intrathecal injection towards the end of skin closure. Supplementary analgesics were not given.

None from the 8 ml group experienced pain or discomfort during surgery.

Side Effects

Hypotension occurred in one patient from the 6 ml group and in two from the 8 ml group at about 18 - 21 min after intrathecal injection. In all three, it was transient, easily reversed with intravenous fluids and did not require use of vasopressors. One patient from the 6 ml group received atropine because of bradycardia (heart rate < 50 bpm). Despite the high level of sensory analgesia in some patients from the 6 and 8 ml groups, none had difficulty in breathing and only one patient from the 6 ml group had SpO_2 that decreased to 94% while breathing room air.

Chills and shivering were common in all three groups occurring in 17% (3/18), 47% (9/19) and 59% (6/11) of the 4, 6 and 8 ml groups respectively (*P*:NS). Treatment with small doses of pethidine *iv* was effective in all cases.

Forty seven patients were interviewed on the 5th postoperative day as one of the patients from the 4 ml group could not be contacted. The most common problem encountered was mild backache, the incidence was 24% (4/17), 44% (8/19) and 36% (4/11) in the 4 ml, 6 ml and 8 ml groups respectively (*P*:NS). The mean duration of backache was 2.4 ± 1.3 days. Two patients, one each from 4 ml and 6 ml groups had symptoms suggestive of post-dural puncture headache after discharge but the headaches were mild and resolved spontaneously by the 3rd postoperative day without the need to seek medical assistance. There were no complaints of lower limb pain or paraesthesia.

Discussion

The results of our study show that lidocaine 1% can provide adequate spinal anaesthesia for short surgical procedures involving the lower limbs and perineum. The onset of action was rapid and the intensity of motor block, maximum cephalad spread and duration of action were dose dependent. The incidence of side effects was acceptable with hypotension seen only with the 8 ml dose. We found a 4% incidence of postdural puncture headache which was self-limiting. Mild backache was common but there were no complaints of symptoms of transient radicular irritation.

The onset times for the 4 ml group were slightly slower than the 6 and 8 ml groups, however, on average, the onset of lidocaine 1% was fast and comparable to that of lidocaine 2% or 5%.[8–10] Almost all patients given 6 ml or 8 ml lidocaine 1% achieved full motor block whereas only 78% in the 4 ml group had complete motor blockade. Kristensen *et al.*[9] using equivalent doses of lidocaine 2% reported similar frequencies of motor blockade, indicating that dose rather than concentration is important in determining intensity of motor block.

Although the maximal cephalad spread increased with increasing volumes of local anaesthetic used, the time taken to reach the highest analgesic level was similar for all three groups. Our mean value of 15 min is comparable with those from studies[8,11] using lidocaine 2% or 5% indicating that time taken to reach maximal cephalad spread is a pharmacological characteristic of lidocaine and is independent of the dose or concentration used.

In agreement with previous studies of bupivacaine,[12,13] the duration of sensory anaesthesia at or above a particular dermatomal level varied with the dose of local anaesthetic used. We examined the duration of sensory analgesia at T_{12} as well as the duration of full motor blockade because they give a good indication of the effective duration of anaesthesia for surgery below L_1. Both 4 ml and 6 ml lidocaine 1% provided about one hour of complete motor block and sensory analgesia at or above T_{12} while the 8 ml dose lasted much longer (~ 100 min). However, we would not recommend administering only 4 ml intrathecal lidocaine 1% for procedures of the lower limbs in which an upper thigh tourniquet is required or complete immobility preferred as not all patients at this dose will achieve a T_{12} analgesic level (67%) or complete motor block (78%).

The onset of sensory regression and the 2-segment regression times for all three groups were similar. Axelsson *et al.*[14] also found that in his patients given different volumes of bupivacaine 0.5%, two segment regression occurred at about the same time (105 min) after injection and progressed in a relatively parallel way in the different volume groups. This suggests that the regression characteristics of subarachnoid block are largely dependent on the local anaesthetic used and are independent of drug dosage. It can also be deduced that, given the same onset and speed of regression, the time taken for complete sensory regression will be longer for larger volumes of intrathecal lidocaine 1% because the starting point of regression, the maximum analgesic level is higher when larger doses are administered. Consistent with this theory, we found that the 8 ml group took a longer time for complete sensory regression than did the 4 and 6 ml groups. Similar to previous studies of

lidocaine[9] and bupivacaine,[12] we also found that full motor recovery was slower with larger doses of local anaesthetic used.

The incidence of hypotension increased when larger volumes of 1% lidocaine were used. Even though as high as 18% in the 8 ml group experience some degree of hypotension, this was not a serious problem as the hypotensive episodes were transient and responded well to fluids without the need for vasopressor. A few of our patients had high sensory analgesic levels (T_1 - T_3) but none experienced subjective respiratory difficulty. We attribute this to differential blockade, somatic motor fibres being more resistant to blockade than somatic afferent sensory fibres. Our findings of high sensory block without accompanying respiratory muscle weakness has also been reported in studies using high volume, low concentration bupivacaine for spinal anaesthesia.[13,15] Differential nerve block could also be used to explain the faster recovery of full motor power compared to the longer time taken for complete sensory recovery seen in all three groups of patients.

One potential criticism of our practice is the use of 25-gauge Quincke needle in our young study population. The use of smaller gauge Quincke needles or pencil-point needles such as the 25-gauge Whitacre may result in less postdural puncture headache. However, despite the young age group and early ambulation, our 4% incidence of postdural puncture headache is comparable to the 3.5% incidence reported by Phillips *et al.*[16] from a large series using mainly 25-gauge or 26-gauge spinal needles and lower than the 7.5% incidence reported following the use of 26-gauge Quincke needles in day-care surgery.[17] The overall incidence of postoperative backache has been reported to be approximately 20% and appears to be primarily related to the duration of surgery with no difference in frequency following general anaesthesia or spinal anaesthesia.[18,19] Considering the short duration of surgery, we were surprised to find that about one third of our patients had backache. However, this was acceptable as all the symptoms were mild and none of the patients requested nor required any treatment for it.

In view of the recent studies showing no difference in the incidence of transient radicular irritation after spinal anaesthesia with isobaric lidocaine 2% or hyperbaric lidocaine 5%,[20,21] we were pleased to find that none of our patients had any neurological symptoms after lidocaine 1%. *In-vitro* studies[5,6] have shown that lidocaine neurotoxicity is concentration dependent. In fact, Bainton and Strichartz[6] have found that lidocaine induces a non- reversible loss of impulse activity in frog nerve in a progressive fashion with increasing drug concentration beginning at 40 mM (~1%) but the range of lidocaine that produces such changes in mammalian nerve awaits determination. In the absence of any reported cases of transient radicular irritation associated with lidocaine 1%, it is possible that the 1% solution is the 'safe' concentration to use for spinal anaesthesia.

In conclusion, this study shows that intrathecal lidocaine 1% is suitable for surgery of the lower limbs and perineum estimated not to exceed one hour. Its rapid onset, efficacy and short duration of action should make it particularly useful in spinal anaesthesia for day-care surgery. We found that subarachnoid injection of 4 ml lidocaine 1% was adequate for perineal surgery but for surgery of the lower limbs, 6 ml may be a better choice as it provided a more complete motor block and consistent sensory anaesthesia above L_1 dermatomal level. We do not recommend administering 8 ml lidocaine 1% for lower limb or perineal surgery as it produces an inappropriately high analgesic level accompanied by a greater incidence of hypotension and the correspondingly slower recovery time is a disadvantage in short procedures.

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