Headache after lumbar puncture: randomised crossover trial of 22-gauge versus 25-gauge needles

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ABSTRACT

Objectives To compare the frequency of headache and the procedure time following lumbar puncture (LP) using a 25-gauge needle compared to a 22-gauge needle.

Design 4-period crossover blinded randomised controlled trial.

Setting Oncology unit, Royal Children’s Hospital, Melbourne.

Patients Children aged 4–15 years at enrolment having LPs as part of their treatment for leukaemia.

Interventions Each child was allocated a random sequence of four LPs, two with a 22-gauge and two with a 25-gauge needle.

Outcome measures The presence of post-LP headache. Secondary outcomes included the presence of any headache, procedure time and impact of headache on the family.

Results Data on 341 procedures in 93 randomised children were analysed. There was little difference in the incidence of post-LP headache between the two needle sizes (22-gauge 7.2%, 95% CI 3.8 to 12.2; 25-gauge 4.6%, 95% CI 2.0 to 8.9, p=0.3) or in the incidence of any headache (22-gauge 18% 95% CI 12.5 to 24.6; 25-gauge 15%, 95% CI 10.0 to 21.1, p=0.4). Use of the 25-gauge needle was associated with longer procedure times. The incidence of post-LP headache showed little evidence of an age effect (OR =1.1, 95% CI 0.98 to 1.3) and was higher in girls than in boys (11% vs 3%, respectively, OR=3.3, 95% CI 1.3 to 8.4, p=0.014). Fifty-five per cent of families with a child with a post-LP headache assessed the overall functional impact as moderate or severe.

Conclusions There was little difference in the occurrence of post-LP headache or any headache between procedures carried out using the 22-gauge or 25-gauge needles. Depending on the circumstances of the procedure and the experience of the operator, either gauge may be appropriate for an LP in a child.

In children, the optimal needle for diagnostic or therapeutic LPs, such as in the emergency room or oncology ward, is less clear. They are usually performed with 22-gauge needles because of concerns that smaller needles are technically more difficult, with longer procedure times and higher failure rates.2 Reported rates of LP headache vary between 8% and 25%.4–9 Two studies, a randomised comparison of 22-gauge cutting needles with 22-gauge pencil point needles4 and a non-randomised comparison of 22-gauge cutting needles with 25-gauge ‘atraumatic’ needles,9 found little evidence of a difference in the rate of LP headache between the treatment groups.

In children requiring spinal anaesthesia without CSF collection, 25-gauge or smaller needles are often used, with a reported rate of LP headache of 0.4% to 5%.10–13 This suggests that there may be a benefit of using needles smaller than 22-gauge. However, these data are confounded because spinal anaesthesia is usually performed by doctors with more experience than many of the doctors doing diagnostic LPs. Four randomised trials in children having spinal anaesthesia with 24-gauge or smaller needles found little evidence of a difference in the rate of LP headache between different needle sizes and needle designs.10 12 14 15 The benefit, if any, of using 25-gauge needles for LPs compared with the standard 22-gauge needle therefore remains unclear.

INTRODUCTION

Frequent lumbar punctures (LPs) for diagnostic and therapeutic reasons are part of standard treatment protocols for children with leukaemia. These LPs are occasionally followed by headache. These headaches are recognised as ‘post-LP headache’ if they have a characteristic postural component. LP headache occurs in the first week after the procedure and may be due to persistent leakage of cerebrospinal fluid (CSF) from the puncture site. In adults, studies have shown that the incidence of LP headache can be reduced significantly by using smaller diameter needles and needles with a blunt, pencil-type point rather than the traditional cutting point.1–3
To make informed decisions about LP strategies to minimise headache in children, it is also important to consider the functional impact of LP headache. We could not find any studies looking at the impact these headaches have on family functioning.

The aim of this study was to use a randomised crossover design to compare 22-gauge and 25-gauge needles of standard cutting point design. We hypothesised that the use of a smaller needle (25-gauge) would reduce the frequency of LP headache in the week following LP.

**METHOD**

**Study design**

The study was a 4-period crossover randomised controlled trial of 22-gauge versus 25-gauge needles. This design maximised the information available from participants and was possible as we did not expect a carry-over effect between LPs.

**Recruitment**

Children having LPs as part of their standard treatment protocol for leukaemia were eligible. They were recruited during visits to the Day Surgery Unit of the Royal Children’s Hospital (RCH), Melbourne, between May 2005 and May 2007. Children needed to be aged 4–15 years inclusive at the time of their first procedure. Ethics approval was given by the RCH Research Ethics Committee (Australia and New Zealand Clinical Trials Registry 12605000052639). Consent was obtained from parents for all participants.

**Exclusion criteria**

Children were excluded if they had insufficient LPs remaining in their planned treatment, had significant coexisting medical problems causing headache or were routinely using 25-gauge needles at parental request, or if there were significant social or communication problems.

**Procedures**

Following informed consent, children were allocated a random sequence of four LPs, two with a 22-gauge and two with a 25-gauge standard LP needle (Portland), that is, AABB, BBAA, ABAB or BAAB, where A=22-gauge and B=25-gauge needles. The treatment allocation was computer-generated by an independent statistician. Patients were allocated a sequential study number which corresponded to a large envelope containing four smaller sealed envelopes, labelled a, b, c and d, containing details of the needle sizes to be used for four procedures. All LPs were performed under general anaesthesia by the same experienced doctor (CC) who was given the relevant sealed envelope immediately before the procedure. This doctor was not involved in data collection after the procedure. All other staff and study participants were blinded to the needle gauge. For each procedure, the needle was inserted with the orientation of the bevel parallel to the long axis of the dural fibres.

Each child contributed up to four procedures, not necessarily consecutive as not all LPs on a child enrolled in the study were eligible for inclusion, for example if an additional procedure such as bone marrow aspiration was being done under the same anaesthetic.

**Data collection**

A study researcher blinded to the needle size recorded the time from first needle insertion to successful commencement of CSF collection and the time required for collection of 22 drops of CSF (approximately 1 mL). The sum of these two gave the ‘total procedure time’. If multiple needle attempts were needed, the total procedure time included the time taken for all attempts.

Following each procedure, parents were given a one-page questionnaire to take home which asked them to record details of any headache in the child on days 1, 3 and 7 following the procedure. Data were collected on whether the headache was postural, whether any analgesia was required and the impact of the headache on family functioning (missing school, adults missing work). A researcher also phoned families on days 1, 3 and 7 after each procedure to ensure the data were recorded, and confirm the nature of any headache.

**Outcome measures**

The primary outcome was the presence of LP headache, defined as occurring within 7 days after the procedure, being worse within 15 min of standing up and improving within 30 min of lying down. Secondary outcomes were the presence of any headache within 7 days, the CSF collection time, the total procedure time, the number of failed needle attempts and the impact of headache on the family and the child.

**Sample size**

Because of the paucity of data in the literature on which to base a formal sample size calculation and the difficulty of estimating a sample size due to the crossover nature of this study, a sample size of 100 patients was chosen based on feasibility.

**Analysis**

Analysis was by intention-to-treat where outcome data were available. Data were analysed using Stata release 12.0 (StataCorp, College Station, Texas, USA). Age at baseline is presented as median and IQR and gender as absolute and relative frequencies.

The primary outcome was summarised as absolute and relative frequencies of LP headache across all procedures by needle size, with the comparison between the needle size groups presented as an OR and its 95% CI obtained using mixed effects logistic regression with a random effect for individual to allow for the repeated measures within participants and a fixed effect for period to allow for the possibility of period effects. A period-by-group interaction was added to check for possible carry-over effects. Age at procedure and sex were assessed as predictors of LP headache using mixed effects logistic regression with a random effect for individual. Covariates included in the models were period, age, gender and needle size. As a post hoc analysis, we explored whether the effect of needle size on LP headache occurrences varied by sex and by the addition of an interaction term.

The secondary outcome of any headache within 7 days was analysed similarly.

Secondary continuous outcomes of time to start CSF collection, CSF collection time and total procedure time are summarised as means and SDs on the logarithmic scale across all observations because these data are highly skewed, as expected. For ease of interpretation, geometric means are given. Comparisons between the groups were via mixed effect regression carried out on the natural logarithmic scale, with a random effect for participant and allowing for possible period effect. Comparisons between the groups are presented as the mean difference on the log scale and its 95% CI.

Secondary categorical outcomes (severity rating and general impact of headache on the families’ functioning) are reported as absolute and relative frequencies for the cases where either a
normal headache or an LP headache occurred, combining results from both needle groups.

RESULTS

Of 133 children considered for the study, 40 were excluded (insufficient LPs remaining (24), communication problems (10), using 25-gauge for all procedures (2), continuous headache (1), family declined to take part (3)). As the number of children meeting exclusion criteria was higher than anticipated, the target aim of 100 participants was not met. Ninety-three children were randomised and took part in the study. Demographic information of the study participants is presented in table 1. Of note, two children had their last LP after their 16th birthday. A further 16 did not complete all four procedures for reasons such as moving interstate or finishing their treatment protocol, giving a total of 341 procedures (167 with the 22-gauge and 174 with the 25-gauge needle).

Headache

Headaches were recorded after 56 of the 341 procedures (16%), and 20 of these (in 19 children) were classified as LP headaches (table 2). Ninety per cent of headaches and 90% of LP headaches began within 3 days of the procedure. There was little evidence of a difference in the incidence of LP headache between the two groups (p=0.3) or in the incidence of any headache (p=0.4). There was little evidence of a carry-over effect for LP headache (global p=0.4) or any headache (global p=0.4).

In a secondary analysis, the rate of any headache (26% vs 12%, OR=2.3, 95% CI 1.1 to 4.9, p=0.036) and LP headache (11% vs 3%, OR=3.3, 95% CI 1.3 to 8.4, p=0.014, table 3) was greater in girls than in boys. There was also evidence that the OR of any headache increased with age (OR=1.2 per year increase in age, 95% CI 1.1 to 1.4, p=0.001), but not for LP headache (OR=1.1, 95% CI 0.98 to 1.3, p=0.1).

In a post hoc analysis, we assessed whether the effect of needle size varied by sex, but found little evidence of any such interaction (p=0.4 and p=0.6 on occurrences of LP headache and any headache, respectively). There was also little evidence that the effect of needle size varied with age (p=0.2 and p=0.5 on occurrences of LP headache and any headache, respectively).

Technical execution

Of the 341 LPs, 337 used sevoflurane inhalation anaesthetic and four used propofol. Except in four procedures, intrathecal methotrexate was given after CSF collection. A single needle attempt was used in 320 procedures (94%). Multiple needle attempts were required in 21 procedures, 9 (5%) with 22-gauge needles (table 4). The overall rate of LP headache in our study was 5.9%, lower than previously reported. 4–9 The rate of LP headache with a 25-gauge needle (4.6%) was slightly lower than with a 22-gauge needle (4.6%) was slightly lower than with a 22-gauge needle (4.6% vs 3%, OR=3.3, 95% CI 1.3 to 8.4, p=0.014, table 3).

A summary of procedure times according to needle size is presented in table 4. The ‘time to start CSF collection’ and the ‘CSF collection time’ were shorter with the 22-gauge needle, meaning the total procedure time was also shorter with the 22-gauge needle (mean difference 0.47 (95% CI 0.37 to 0.58) on the log scale, p<0.001).

Quality assessment on family and child

Table 5 shows a summary of the severity rating and general impact of headache on family functioning in the 56 cases where a headache occurred.

Discussion

Our study helps address the question of whether 25-gauge needles rather than 22-gauge needles should be routinely used for diagnostic/therapeutic LPs in children. This decision requires consideration of several factors including the technical aspects of the procedure, the rate of subsequent headache and the effect of these headaches on family functioning.

The success rate in our study for the first needle attempt was equally good with the 25-gauge (93%) and the standard 22-gauge needle (95%), and there was little clinical difference in the time to get the first drop of CSF (table 4). Despite these findings, the operator (CC) found the thinner needles more flimsy and more difficult to use. Achieving this high success rate of first attempts (94% overall) is likely to require considerable expertise. As expected from fluid physics, the average time required to collect 22 drops of CSF was almost doubled with the smaller bore needle (table 4).

The overall rate of LP headache in our study was 5.9%, lower than previously reported. 4–9 The rate of LP headache with a 25-gauge needle (4.6%) was slightly lower than with a 22-gauge needle (4.6% vs 3%, OR=3.3, 95% CI 1.3 to 8.4, p=0.014, table 3).
A final factor required to make an informed decision about needle size is the effect the headaches have on the family. Among families with a child with an LP headache, three-quarters rated the severity of the headache as moderate or severe, one-fifth required an adult to take time off work, half had activities such as sport or school disrupted and half assessed the overall functional impact on the family as moderate or severe (table 5).

Our study has limitations. Our data may vary from centres where LPs are performed under different conditions from those in this study. The qualitative data did not use a standardised family impact questionnaire and gives only limited detail on the specific problems experienced by the families.

Our data can be used to guide general recommendations for diagnostic and therapeutic LPs. Assuming the rate of LP headache is reasonably small (4%–8%) in either group, we do not think this risk should lead to a technically more difficult procedure. In a situation, where children are sedated or held, rather than anaesthetised, patient distress can be significant and the aim should be for a rapid procedure with easy detection of fluid flashback and straightforward fluid collection. A 22-gauge needle is a reasonable choice. For anaesthetised children with experienced operators, either a 22-gauge or 25-gauge needle is reasonable. When our data are combined with the data from adult studies and from spinal anaesthesia in children, the case for using a smaller needle bore becomes more persuasive with highly experienced operators and in children who will need repeated LPs over long periods.

CONCLUSION

In this study, we found little evidence that the rate of LP headache is different after LPs using 22-gauge and 25-gauge needles in children, with approximately 4% to 7% suffering an LP headache. There was little evidence of an age effect on LP headache. Fluid collection time was doubled using the thinner needle. Over half of the families with a child with an LP headache assessed the overall functional impact on the family as moderate or severe.

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Contributors Each author has made a substantial contribution to conception and design, acquisition of data or analysis and interpretation of data, in addition to assisting with critical revision of, and approving, the manuscript.

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Competing interests None.

Ethics approval Royal Children's Hospital Research Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES


Table 4 Effect of needle size on lumbar puncture (LP) procedure

<table>
<thead>
<tr>
<th></th>
<th>Needle 22 g</th>
<th>Needle 25 g</th>
<th>Mean difference (95% CI)*</th>
<th>p</th>
<th>Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to start CSF collection (s)</td>
<td>2.9 (0.7)</td>
<td>3.1 (0.7)</td>
<td>0.17 (0.03 to 0.31)</td>
<td>0.017</td>
<td></td>
</tr>
<tr>
<td>Geometric mean</td>
<td>18</td>
<td>21</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSF collection time (s)</td>
<td>3.2 (0.6)</td>
<td>3.9 (0.4)</td>
<td>0.68 (0.57 to 0.79)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Geometric mean</td>
<td>25</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total procedure time (s)</td>
<td>3.9 (0.6)</td>
<td>4.3 (0.4)</td>
<td>0.47 (0.37 to 0.58)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Geometric mean</td>
<td>47</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Reported on the log scale. Covariates included in the models: period and needle size. CSF, cerebrospinal fluid.

Table 5 Quality assessment of the impact of headache on family and child

<table>
<thead>
<tr>
<th></th>
<th>Non-LP headache</th>
<th>LP headache</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=36</td>
<td>N=20</td>
</tr>
<tr>
<td>Severity of headache as rated by family</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>26 (72%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 (19%)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (8%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Time off work needed for adults in the family</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 (11%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Disrupted activity for the child</td>
<td>12 (33%)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Functional impact rated by family</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>26 (72%)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 (19%)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (8%)</td>
<td>2 (10%)</td>
</tr>
</tbody>
</table>

Results are number and percentage for the given type of headache. LP, lumbar puncture.


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