Reviewer's report

Title: A positioning pillow to improve lumbar puncture in paediatric haematology-oncology patients: A randomized controlled trial.

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Reviewer: Johann Hitzler

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A randomized controlled study of the use of a positioning device to improve the results of lumbar punctures without deep sedation in children and adolescents was conducted in two centres. The impact of the intervention on the technical success of the procedure, on the patients’ level of pain and anxiety and on the level of satisfaction among patients, parents, nursing steam and physicians performing the procedure was assessed. No significant differences were detected between the experimental and control group. A subgroup analysis of children older than 6 years of age showed a higher rate of technically successful lumbar puncture (58% vs. 41%) and no significant difference of the patients’ perception of pain and satisfaction with the procedure.

Major compulsory revisions

This is a well conducted study in an area of significant clinical relevance. The strength of the study is that the analysis of procedural success includes both the technical aspect and the subjective experience of patients and families.

1. Some inconsistencies in the data need to be corrected or clarified.
   a. Three patients without analyzable CSF specimens were excluded from the analysis of the primary outcome. It is not clear whether they were randomized to the experimental and control group.
   b. Why are the cohort sizes and results of the analysis of children's satisfaction in the age group >6 years different in table 2 and 3?
   c. The percentages calculated for primary outcomes and child satisfaction in both control and pillow group in table 3 are incorrect if calculated based on the data provided (e.g. successful LP, pillow group: 24/38 = 63% not 58.3%; 17/34=50% not 41.5% etc.)
   d. The overall success rate of lumbar puncture is described as 62%. Yet 19% required more than one attempt, 21% had a traumatic LP and in an additional 3% the LP goal was not achieved, accounting together for 43% without success (page 9, third paragraph).
   e. In table 1, 7 patients in the pillow group and 5 in the control group had no prior LP. Yet in both groups 7 patients are listed under diagnostic LP (presumably without prior lumbar punctures).

2. The tables describing outcomes mention the absence of differences between
control and experimental group with regard to the patient’s pain, anxiety and satisfaction as well as the nursing team’s and physicians’ satisfaction. Why is the perception by parents (see page 10, second line before last) of a higher level of pain and anxiety in the experimental group omitted from table 2?

3. A pertinent comparison of LP success for this study are LPs performed under deep sedation. Some information and discussion is warranted to be able to decide how best to improve outcomes.

Minor essential revisions
1. Why did the authors use a red cell concentration of 50/mm3 to define a traumatic lumbar puncture rather than the 10/mm3 used in large trials (e.g. Gajjar 2000, Burger 2003)?
2. How was post-LP syndrome defined for the purpose of the study?
3. ‘LP duration’, ‘number of attempts’ and ‘number of attending persons’ in table 1, base line characteristics, appear to be outcomes and should be moved to table 2. P values are provided for LP duration but not for use of EMLA, N2O, number of attempts, number of attending persons and CSF amount collected.
4. “Caregiver” is used ambiguously and sometimes seems to denote nursing staff and sometimes parents.
5. A reference should be given for the success rate of LPs performed without deep sedation (page 10, third paragraph, line 6).
6. The discussion states there was less bleeding in the experimental group. Was this defined as macroscopic or microscopic hemorrhage? No data are provided for this in the result section.
7. The photo is very helpful. It appears to show a lumbar puncture. The misleading and unfortunate part is that the operator wears neither mask nor gloves in the picture.
8. suggested edits : “ cytological” for “biochemical” analysis (page 7, second paragraph, line 4); “that the LP pillow …could not only increase …but would decrease pain” in stead of “that the LP pillow …could not only increase …but would be less painful” (page 10 second paragraph, line 4); “traumatic” for “hemorrhagic” LP (page 10, third paragraph, line 4; table 2, second line, operating physician % satisfaction in control group “(84)” instead of “(8)”); clarify and correct “carer” (page 11, third paragraph, line 3); table 2, remove “a” in “0.85 a” (fourth row); define or remove “nb” for number in tables; define or remove “***” in figure 1.

Discretionary revisions
1. The presence of a parent during the procedure was significantly less frequent in centre 2 than centre 1. Did the parent’s presence have an effect on technical success and anxiety level/self perception of pain of the patient? If so, were the effects in both areas concordant?
2. It is interesting that the LP success rate dropped from 70% during the
preceding two years to 56% in the study setting (control group). Is it possible that the study setting itself has a negative impact on LP success rates?

3. Information regarding the diagnoses among participating patients, the minimal required platelet count prior to LP, the consent rate and identification of participating centres would be useful.

Overall this is a valid and well conducted study of a highly relevant clinical issue that should trigger further investigations of how to improve lumbar punctures in children.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.