Author’s response to reviews

Title: Fascia iliaca compartment block as a preoperative analgesic in elderly patients with hip fractures – effects on cognition. A prospective randomised trial.

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Version: 2 Date: 15 May 2019

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Örebro, 15 May 2019

Response to the reviewers’ comments on our manuscript “Fascia iliaca compartment block as a preoperative analgesic in elderly patients with hip fractures – effects on cognition. A prospective randomised trial” (BGTC-D-19-00056R1).

Your comments are well balanced and contribute to the effective development of the text. Please find our reply to your comments below.

Changes in the manuscript are highlighted in yellow.

Reviewer reports:
Margareta Hedström, MD PhD Ass prof (Reviewer 1):
Reviewer comments Our response
Reviewer #1
This is an important study however I have some concerns, mainly about the methods used.

Thank you, we like to think it is important too. We would like to thank the reviewer for showing interest in our work and helping us to improve it. All the comments are greatly appreciated. We have taken the liberty of organising your comments below.

Please describe: 35-42 % had a diagnosis of dementia prior to enrollment (was it found in the medical records?)

The diagnosis of dementia prior to enrolment was extracted from the patients’ medical records = previous diagnosis. We felt it was relevant to present this, as an imbalance between the two groups could have been regarded as a confounder. This information has now been added on page 7 in the
Reduced SPMSQ scores are not equivalent to a dementia diagnosis. A reduction in SPMSQ scores merely reflects the cognitive status at the present time. Persons with dementia will have a reduced SPMSQ score – but probably not a large variation in SPMSQ scores over time. A person with delirium will probably have a fluctuating score over time. The text on page 8 in the measurements section has been updated.

Table 2 shows that the control group had more patients in group 8-10 compared (51->57) to baseline and to the intervention group (58-49). It was better result for the control group?

In the case of patients changing to group 8-10, the control group had a better result. We used the four groups of SMPSQ scores, as they have been used in other studies. We felt it was relevant to analyse the movement between all four groups. If a patient had moved up in the groups, he/she was reported to have increased in Table 3. If a patient had moved down in the groups, he/she was reported as decreased. Unchanged is somewhat self-explanatory and was the largest group. This is why we reported the change in scores in Table 3.

In Table 3 was the group with SPMSQ 0-2 "the dementia group", could you please explain your subgroups and their definitions. Because your conclusion is drawn from the fact that you suddenly compare the group with 0-2 to all the other patients (instead of 0-2 and 3-5)

The subgroups are described on page 8 in the Measurements section. We agree that the step from four to two groups comes suddenly. We have now added a new table (Table 4) and an explanation in the text on pages 11 & 12.

In Table 3, none of the four SPMSQ groups is displayed separately. Table 3 only presents whether or not the patients changed SPMSQ group. Could you please describe more about the given FICB, the technique and how many persons were included in this.

This is now described in the manuscript on page 7.

The dose given in mg, Robivacain and was it adjusted to the weight of the person.

No, the study dose was reduced to ¼ of the maximum dose and therefore not adjusted. The nerve block is a volume-based block. The aim of the dose reduction was primarily to reduce the risk of intoxication. The study dose was recommended by the Swedish Medical Products Agency. Text revised on page 6.

Is it possible to add the hours between the given FICB and the second measurement of SPMSQ, probably this is of importance...?

This information has now been added to Table 1.

Adjustments for fracture type? A patient with an undisplayed fracture has less pain compared to displaced fractures.

We have not adjusted for displaced fractures, as we do not have data on displaced fractures. The fracture type is reported in Table 1. We have added a section in the limitations section on page 16.

Use patients with hip fractures (instead of hip fracture patients)

This awkward formulation has been deleted and changed according to your suggestion throughout the manuscript.

Hip fracture repair - > surgery?
Yes, this is correct. “Hip fracture repair” has been changed to “surgery”.
Check the references and use numbers consistently
This has now been corrected.

Ami Hommel (Reviewer 2):

Reviewer comments  Our response
Reviewer #2
Thank you, even though it is old data it is an interesting article, however, it needs revision especially the method section.
   We thank the reviewer for taking the time to help us improve our work.
   We have listened to your many good suggestions and attempted to comply in the text.

Page 3 line 5 you need to check what the reference shows.
   We have now extended the statement on page 3.
Page 5 line 8 You have not used the symbol ® after Ropivacaine nor after Morphine in your text, sometimes you start with uppercase and sometimes with lowercase. You need to be consequent.
   We have now changed to lower-case letters in the manuscript. We have not used the ® symbol because ropivacaine and morphine are not registered trademarks.
Page 6 line 9 you describes whom was paged for study inclusion during office hours and after office hours until midnight. So you did not include patients from midnight until office hours starts? Why? If you had included all patient, could that affect the study result?
   Between midnight and office hours there was no orthopaedic surgeon in the hospital to pursue the inclusion. This could theoretically have affected the study results. We have added a sentence about it in the limitations.
Page 6 line 16 you mention the pain assessment instrument and on page 8 line 12 you mention a pain instrument with a reference but you need to explain the instrument. It seems not to be a well-known instrument. You also mention VAS did you use VAS or NRS?
   An explanation has now been added on page 9 in the Measurements section.
Page 9 table 1, the number of patients with diagnose of dementia seems to be high in the intervention group and very high the control group. How sure can you be that your result regarding incidence of delirium? Regarding the diagnosis of dementia, it was retrieved from the patients’ medical records. They had a diagnosis prior to enrolment. A statement has been added on page 7 in the section on patient characteristics. Regarding the incidence of delirium, we do not claim that SPMSQ scores define delirium in patients. A low SPMSQ score may imply delirium, but it may also imply dementia or both. The results do not verify delirium or dementia. A statement has been added on page 8 in the Measurements section.
Page 10 table 2 the numbers looks mixed up in the postoperative SPMSQ higher percentage of patients with 8-10 in the control group compared to the intervention group. We understand the assumption, but the figures are correct. The increase in the proportion of patients with 8-10 is more prominent in the control group.
Page 11 table 4 why have you changed from reporting 4 groups of SPMSQ to 2 groups.
   The difference was non-significant between scores of 3-10. However, patients with SPMSQ scores of 0-2 received significantly lower doses of morphine in the ambulance than patients with 3-10. This is actually a secondary finding and is not a part of the original study aim. The results emerged
when controlling doses of pain relief before study enrolment. We felt it was important to report this. We agree that the step from four to two groups can be discussed. We have now added a new table (Table 4) and an explanation is given in the text on page 11.

Page 11 line 9 No serious adverse events were reported. Which AE and SAE were you looking for? Did you have any in your protocol? Typical symptoms of AE which the investigators were instructed to look for were hypotension, bradycardia, nausea, vomiting, paraesthesia, dizziness and headache connected to the injection. The severity of the AE was judged according to the definition of SAE. The protocol had routines for how to report AE and SAE, but there were no specific questions regarding the above-mentioned symptoms.
A statement has been added on page 6 in the “Intervention and data collection” section.

Page 13 line 1 and 3 you suddenly uses name as references instead of numbers
This has now been corrected.