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Anesthesiology and Pain Medicine
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Peer Review Report for "Four-Week Pain Profile and Patient Non-Adherence to Pharmacological Pain Therapy After Day Surgery"

Author(s): Steffe Jorissen, Ina Callebaut, Caroline Pelckmans, Noor Berends, Martijn Droogmans, Maxime van Rossum, Marijke Nulens, Bjorn Stessel

Review Timeline:

Submit Date: 25 Feb 2020
Revised Date: 18 Apr 2020
Accepted Date: 18 Apr 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (0)

4 Mar 2020

Dear AE,
Comments for the authors:
- Abstract: The abstract is structured, and the content and word count are adequate. Keywords were selected through MESH.
- Introduction: The introduction does not include a clearly written section that addresses the question "What do we not know?"
- Methodology: Please provide a more detailed description of the interscalene block (plexus identification method, anesthetic used, adjuvants?) Has data been collected on the use of Tramadol as a backup analgesic?
- Results: Is there data linking how the severity of postoperative pain affected patient adherence? It may be a very important factor. How much was Tramadol consumption in each patient group?
- Discussion: Indicate steps for future research.

- Conclusion: No comment.
- References: The references are mostly recent and properly written.
Thanks

Alireza Abdullahzadeh-Baghaei: Reviewer | **Revision** (0) 4 Mar 2020

Dear AE,
I found this work valuable considering try to shed light neglected part of ambulatory surgeries. Also it has good discussion covering a few of problems facing postoperative pain management.
I have some views for a better presentation:
1- Extension of exclusion criteria to preoperative pharmacological treatment of pain or history of chronic pain is not good idea as shoulder or knee arthroscopy was frequently done in patients with chronic pain. It might be consider duration of this parameters as limiting factors.
2- Please explain assessment method for satisfaction evaluation briefly.
3- Measurement of Some outcomes such as “short term and long term surgical fear” or “impact pain of daily life” presented in tables 1 and 3, have not any delineation in method and need to be explained.
Thanks.

Reza Aminnejad: Reviewer | **Revision** (0) 31 Mar 2020

Dear AE,
I read this fluently written manuscript with great interest and I can recommend the authors to improve the quality of their valuable work with the following points:
1- Please address the 4 surgical procedures in the method section of the abstract.
2- Please correct your keywords to Postoperative pain, Treatment adherence, and ambulatory surgery.
3- In the method section please clarify which kinds of surgeries are allowed in an ambulatory setting? Is it allowed for a patient with ASA-PS 3 to have surgery in an ambulatory setting?
4- Isn't there any relationship between profession or level of education and treatment adherence?
5- Some diseases affect the perception of pain. Diabetes Mellitus is one of them. Since you had some patients with ASA-PS III, it was better to refer to the disease as well, and those with suspected neuropathy were excluded.
6- What was the content of oral and written instructions regarding prescribed medications? Have you explained to patients the concept of preemptive analgesia?
7- Did you only ask about drug use during follow-up or did you emphasize regular drug use?
Thanks.

REFEREE: Reviewer | **Revision** (0) 4 Apr 2020

Dear AE,
In my opinion, the design of the study is clear and well-defined. It has got a useful topic that needs more work on it as early discharge and pain control ability and modalities at home

lead to less cost and patients' comfort.
It has demonstrated accurate data and chose patients as well.
but still a little bit of revision. The inclusion and exclusion criteria should be more clarified and we need more diagrams to show better the aim and result of the study .please revise these matters and send them again
Thank you

REFEREE: Associate Editor | **Revision** (0) 4 Apr 2020

Dear EIC,
Based on reviewer comments this manuscript needs some corrections before publishing.
Regards

REFEREE: EIC | **Revision** (0) 4 Apr 2020

Dear Author,
Your article is reviewed by the reviewers carefully. According to their comments, this document needs minor revision. Please follow their comments as requested.
Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Hasselt, 16th April 2020

Manuscript ID: 101669

Title: Four week pain profile and patient non-adherence to pharmacological pain therapy after painful day surgery: secondary analysis of a randomized controlled trial

To: Editorial Office of Anesthesiology and Pain Medicine

Dear Prof. Imani,

We wish to thank you for your positive response and the constructive comments on our manuscript 101669, submitted on 6th February 2020. We have followed the very helpful suggestions from reviewers and incorporated a number of improvements based on our response to the reviewers suggestions and comments. These improvements are indicated in yellow in the revised manuscript.
As we have met all the requirements needed, we now hope that this resubmission is acceptable for publication in Anesthesiology and Pain Medicine.

Kind regards,
Dr Björn Stessel

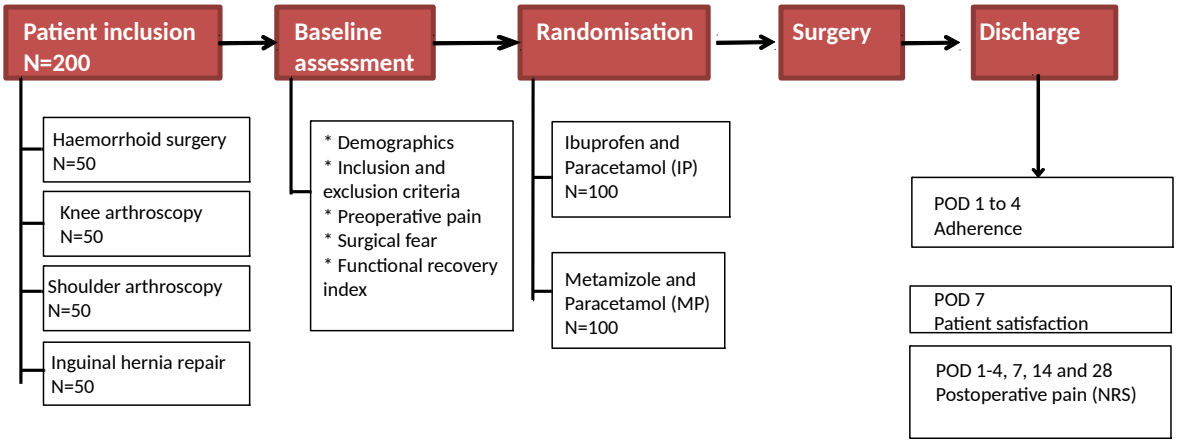
Point by point response to reviewer comments:

Reviewer 1

In my opinion the design of the study is clear and well defined.It has got a useful topic that needs to more work on it as early discharge and pain control ability and modalities at home leads to less cost and patients comfort.
It has demonstrated accurate data and chose patients as well.
but still a little bite revision.The inclusion and exclusion criteria should be more clarified and we need more diagrams to shows better the aim and result of the study .please revise this matters and send them again
Thank you

We thank the reviewer for his positive comments and clarified the inclusion and exclusion criteria in the revised manuscript op page 5 lines 10-25.

We have added an detailed scheme of the study set up (figure 1 in the revised manuscript).



Reviewer 2

Hi
I found your work valuable considering try to shed light neglected part of ambulatory surgeries. Also it has good discussion covering a few of problems facing postoperative pain management.

We thank the reviewer for this positive comment.

I have some view for better presentation:
1- Extension of exclusion criteria to preoperative pharmacological treatment of pain or history of chronic pain is not good idea as shoulder or knee arthroscopy was frequently done in patients with chronic pain. It might be consider duration of this parameters as limiting factors.

As suggested by reviewer 1, we clarified the inclusion and exclusion criteria in the revised manuscript on page 5 lines 10-25. Patients with chronic pain that was not associated with the reason they had to undergo surgery were excluded, as for patients with fibromyalgia and Complex Regional Pain Syndrome (CRPS). Preoperative treatment with opioids was also an exclusion criterion in this trial.

2- Please explain assessment method for satisfaction evaluation briefly.

Patients were asked about their satisfaction concerning the study medication on postoperative day 7 with a 11-point Numeric Rating Scale (NRS) where 0 indicating not satisfied at all and 10 indicating fully satisfied. This was stated on page 7 lines 21-23.

3- Measurement of Some outcomes such as "short term and long term surgical fear" or "impact pain of daily life" presented in tables 1 and 3, have not any delineation in method and need to be explained.

We agree with the reviewer that the terms short term and long term surgical fear as well as the impact of pain on the daily life were not fully explained in the manuscript. The fear of the surgical procedure was evaluated with the Surgical Fear Questionnaire, which is a validated eight-item instrument for the assessment of self-reported surgical fear, covering a range of short-term (SFQ-s, item 1–4, i.e. afraid of operation, anaesthesia, postoperative pain, side effects) and long-term (SFQ-l, item 5–8, i.e. health deterioration, failed operation, incomplete recovery, and long duration of rehabilitation) surgery-related fears (1). All items are scored on an eleven point numeric rating scale (NRS) ranging from 0 (not at all afraid) to 10 (very afraid). This results in a score of 0–40 for each subscale and a total score of 0 to 80.

The impact on pain on the daily life was a preoperative measurement evaluated with an 11-point NRS scale, with 0 indicating no influence at all and 10 indicating the maximum influence of pain on the daily life.

We adapted the revised manuscript accordingly on page 6 lines 2-7 and 9-10.

Reviewer 3

Manuscript Full Title: 4-week pain profile and patient non-adherence to pharmacological pain therapy after painful day surgery: a secondary analysis of a randomized controlled trial Date: 04.03. 2020th

Title: I think it is better that the title does not start with a number but with a word (four instead of 4). The title should be up to 100 characters. Running title is not clearly defined.

We agree with the reviewer and adapted the title accordingly.

Abstract: The abstract is structured, the content and word count is adequate. Keywords were selected through MESH.

We thank the reviewer for this positive comment.

Introduction: The introduction does not include a clearly written section that addresses the question "What do we not know?"

More than 35% of patients undergoing typical painful ambulatory surgical procedures, for example, inguinal hernia repair, haemorrhoid surgery, arthroscopic knee, and shoulder surgery are still suffering from moderate to severe pain on the fourth post-operative day. Therefore, the scope of research on postoperative pain should be expanded to the first week and by extension the first month after painful types of day surgery. Moreover, an optimal characterization of the acute postoperative pain trajectory over the first postoperative month after painful surgical procedures can be a valuable asset for the development of future procedure-specific pain-treatment schedules. This was stated in the manuscript on page 3 lines 14-21.

Methodology: Please provide a more detailed description of the interscalene block (plexus identification method, anesthetic used, adjuvants?) Has data been collected on the use of Tramadol as a backup analgesic?

Interscalene blocks were performed according to the extra-plexic technique described by Spence et *al* (2). An in-plane ultrasound-guided puncture was made through the middle scalene muscle. The tip of the needle was placed inferoposterior to the C6 root without making contact with the neural structures (extraplexic technique). After confirming the extravascular position of the needle tip, 20 ml of 0.75% ropivacaine was incrementally injected under continuous ultrasound vision. This was added to the revised manuscript on page 6 lines 17-21.

The use of tramadol as a backup analgesic was not recorded in this trial.

Results: Is there data linking how the severity of postoperative pain affected patient adherence? It may be a very important factor. How much was Tramadol consumption in each patient group?

It is known that the proportion of non-adherent patients decreases as average postoperative pain intensity increases. However, in our hands, we did not detect any differences in average postoperative pain on postoperative day 1 to 4 between patients in non-adherence and patients in the adherent group.

On postoperative day 1, 21.4% of patients in de non-adherence group reported the intake of tramadol whereas this was 31.2 % in the adherence group. On postoperative day 2, this decreased to 9% in the non-adherence group compared to 24.6% in the adherence group, while on postoperative day 3, 14.2% of patients in non-adherence group and 15% in the adherence group reported the intake of rescue mediation. On postoperative day 4, 7% in the non-adherence and 13% in the adherence group reported the intake of tramadol.

This was added to the revised manuscript on page 10 lines 9-14.

Discussion: Indicate steps for future research.

Further research may involve personalized e-health interventions at home triggered by alarm signals elicited by patient-derived information which may decrease mean postoperative pain levels after painful day surgery in the future. This in stated on page 11 lines 21-23. Moreover, it is important to explore different types of ambulatory surgery since we suggest that each type of surgery has its own unique pain trajectory and as a consequence this can add to a better postoperative pain treatment schedule after surgery. At last, it is important to evaluate the adherence of patients undergoing ambulatory surgery in a standardized manner with the use of e-health interventions together with tele monitoring based medication boxes. This was added to the revised manuscript on page 13 lines 19-23.

Conclusion: No comment.
References: The references are mostly recent and properly written.
My final decision: Major revision.

Reviewer 4

I read this fluently written manuscript with great interest and I can recommend the authors to improve the quality of their valuable work with the following points:
1- Please address the 4 surgical procedures in the method section of the abstract.

We added the four types of surgical procedures, i.e. haemorrhoid surgery, knee or shoulder arthroscopy and inguinal hernia repair to the Methods section of the revised Abstract on page 1 lines 9-10.

2- Please correct your keywords to: Postoperative pain, Treatment adherence, ambulatory surgery.

We adapted the keywords accordingly.

3- In method section please clarify that which kind of surgeries are allowed in an ambulatory setting? Is it allowed for a patient with ASA-PS 3 to have a surgery in an ambulatory setting?

As also mentioned by 1 and 2, we clarified the inclusion and exclusion criteria page 5 lines 10-25.

Patients with ASA III were allowed to have surgery in an ambulatory setting in our hospital. Extra care is taken during these surgeries and these patients are usually scheduled early in the morning.

4- Isn't there any relationship between profession or level of education and treatment adherence?

We evaluated the level of education and profession of patients being fully adherent to their medication and patients being not or partial adherent to their medication in table 3. However we did not find any differences in our hands.

5- Some diseases affect the perception of pain. Diabetes Mellitus is one of them. Since you had some patients with ASA-PS III, it was better to refer to the disease as well, and those with suspected neuropathy were excluded.

In line with the comments of the other reviewers, we clarified the inclusion and exclusion criteria page 5 lines 10-25. We thank the reviewer for this constructive remark, as this will be of value in future trials.

6- What was the content of oral and written instructions regarding prescribed medications? Have you explained to patients the concept of preemptive analgesia?

All patients received oral instructions from a member of the study team, stating that correct adherence to the pain medication can prevent postoperative pain. Together with these instructions, patients received a detailed treatment schedule with the exact time points and days the patients were required to take their medication. Last, they were phoned daily to evaluate adherence to the predefined treatment schedule. This was adapted accordingly in the revised manuscript on page 7 lines 9-12.

7- Did you only ask about drug use during follow-up or did you emphasize regular drug use?

The importance of adhering to the treatment schedule was emphasized during the daily follow-up telephone calls with the patients. The use of the IP/MP, paracetamol and rescue medication was evaluated together with the reasons why the schedule was not followed.

References

1. Theunissen M, Peters ML, Schouten EG, Fiddelers AA, Willemsen MG, Pinto PR, et al. Validation of the surgical fear questionnaire in adult patients waiting for elective surgery. PloS one. 2014;9(6):e100225.
2. Spence BC, Beach ML, Gallagher JD, Sites BD. Ultrasound-guided interscalene blocks: understanding where to inject the local anaesthetic. Anaesthesia. 2011;66(6):509-14.

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (1) 18 Apr 2020

Dear AE,
Thank you for inviting me for revised manuscript ID#101669 . The author considers the majority of recommendations, and could corrected them.
Sincerely yours

REFEREE: Associate Editor | **Revision** (1) 18 Apr 2020

Dear EIC,
Based on reviewer comments this revised manuscript is acceptable for publishing at Anesth Pain Med.
Regards

REFEREE: EIC | **Revision** (1) 18 Apr 2020

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.