Author’s response to reviews

Title: Comparison of single-dose radial extracorporeal shock wave and local corticosteroid injection for treatment of carpal tunnel syndrome including mid-term efficacy: A prospective randomized controlled trial

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Response to reviewers’ comments

Thank you, the editorial staff and the reviewers for their useful comments on our manuscript. We have addressed each of them specifically below and have modified our manuscript accordingly. Modifications in the manuscript have been edited under track changes. We believe the manuscript has been substantially improved because of the comments that we have received. We trust that you and the editorial staff will agree.

Reviewer#1 comments:

General comments: Shock wave therapy has recently been increasingly used in conservative treatment of CTS. So far, all the studies have shown beneficial effects of shock wave therapy. However, there are large methodological discrepancies, so further studies of shock wave efficiency in conservative CTS treatment are needed. It is also important to evaluate how a single shock wave therapy session affects the symptoms, function, pain, and nerve conduction that is the subject of this article, and how long these changes persist.

Response: The authors are grateful to the reviewer for positive and encouraging comments.
Abstract:

Comment 1: The summary is written correctly and contains all the necessary information.

Response: We appreciate the positive feedback from the reviewer.

Introduction:

Comment 2: In general, the introduction introduces well to the subject matter in this article. However, in the second paragraph, the authors cite only some of the work on the effectiveness of corticosteroid use in conservative treatment of CTS. On this basis, authors of this article suggest that treatment with corticosteroids gives only short-term improvement. However, there are some works that point to the positive long-term effects of this type of therapy (Hagebeuk 2004, Ayhan-Ardiç 2000). In these studies, beneficial effects persisted 6 months or even 1 year after therapy. It would be useful to explain why in this work the effect of using corticosteroids had only short-term?

Response: Thank you for your suggestion. We have reviewed the study from Hagebeuk et al. in 2004 “Clinical and electrophysiological follow-up after local steroid injection in the carpal tunnel syndrome”. We found the reason why their result was different from this project was the different methodology. The study of Hagebeuk et al. included the patients who received the repeated injection if the patient had more complaints or got higher Boston self-assessment questionnaire score. They also reported 50% of their patients had repeated injection at 3 months and they did not eliminate these patients from the study, therefore the clinical symptoms were improved from repeated injection. Compared to our study, we classified patients who need repeated injection as the failed treatment and eliminate from the study.

Compared to study of Ayhan-Ardiç et al. in 2000, their primary outcomes were severity of symptoms which were paresthesia, nocturnal pain, pain, proximal pain, sensory and motor deficit, Tinel’s and Phalen’s test. In each parameter, they measure as 0=absent, 1=very mild, 2=mild, 3=moderate, 4=marked. While this study used Boston self-assessment questionnaire score as the primary outcome which included not only the severity but also duration and frequency of symptoms and severity in performing functional activity. We thought that the different from the clinical symptoms was from the different outcome measurement. We also review the systematic review in Cochrane Database of systematic reviews 2007 in topic “Local corticosteroid injection for carpal tunnel syndrome”. The result from 12 studies with altogether 671 participants. Two high quality randomized controlled trials included 141 participants showed clinical improvement of carpal tunnel syndrome at one month or less following local corticosteroid compared to placebo injection. This systematic review excluded the study from Hagebeuk et al. in 2004 according to no control group and did not mention the study from Ayhan-Ardiç et al. in 2000.

Subject and method
Design: No comments.

Participants:

Comment 3: I do not understand why only a hand with more severe symptoms was being treated? Why did not therapy be given to both hands? This needs clarification.

Response: Thank you for your comment. To prevent the confusion of which hand when patients did the Boston-self assessment questionnaire, we decided to let them choose more severe hand symptom to be treat. All patient in our study also agree with us because the other hand usually had minimal symptom which we can detect by the provocative test. Other publication such as Hagebeuk et al. in 2004 also chose the most affected hand to be treat in bilateral symptom.

Comment 4: Why the description of who performed the study and when it was done and who was eliminated from the study is in the "Participants" section. Could it be better to create a section called "Randomization and allocation" or "Blinding procedures"? It is assumed that in this type of work enrolled, allocation and lost to follow-up is shown on the flow diagram.

Response: Thank you for your suggestion. We have created" Randomization and allocation " section (Randomization and allocation section, line 109, page 4) and explain the details. The flow diagram was created (please see the attached file “Fig. 1”).

Intervention: No comments.

Outcome measures: No comments.

Data analysis: No comments.

Results

Comment 5: The first paragraph can replace the flow diagram (see the comment above). There is no information in Table 1 how many unilateral and bilateral CTS were. There is also no p-value for gender and severity. This could be check by a Chi2 test.

Response: Thank you for your suggestion. We added the Fig.1 as the flow diagram and explained in line 160-164, page 6. We have added the number of unilateral and bilateral CTS in Table 1. P-value for gender was 0.16 and the p-value of severity was >0.99 (the detail was showed in Table 1).

Discussion

Comment 6: Discussion is well written and compares the results obtained with own studies with results from other studies. Authors also see the limitations of the study.
Response: We appreciate the positive feedback from the reviewer.

Conclusion: No comments.

References

Comment 7: References relevant to the topic of work.

Response: We appreciate the positive feedback from the reviewer.

Reviewer#2 comments:

Comment 1: When using abbreviations, make sure that your readers will be familiar with them. If they aren't, then write out the full name (with the abbreviation in parentheses) on the first use. Please check "AAOS (Line 76)" / "NSAIDs (Line 102)" / "use only abbreviation in line 106 for both of visual analogue scale and Boston self-assessment questionnaire" / "use only abbreviation in line 125 for Boston self-assessment questionnaire" / "use only abbreviation in line 130 visual analogue scale " / " SD in line 147" in the text.

Response: Thank you for your suggestion. We have corrected as American Academy of Orthopaedic Surgeons (AAOS) in line 76-77, page 3 and Nonsteroidal anti-inflammatory drugs (NSAIDs) in line 106, page 4. We use only abbreviation in line 117, page 4 for Boston self-assessment questionnaire" / "use only abbreviation in line 150, page 5 visual analogue scale " / " SD in line 167, page 5" in the text.

Comment 2: You may prefer "LCsI" instead of "LCSI" for "local corticosteroid injection."

Response: Thank you for your suggestion. I have changed to LCsI in line 38, 40, 44, 46, 49 page 2; line 75, 79, 81, 85, 90 page 3; line 120, 134 page 4; line 185, 187, 193, 195, 198, 202, 204 page 5; line 222, 223, 227, 239, 242 page 6; line 268, 269 page 7; line 290, 297 page 8.

Comment 3: Please give more information about randomization method. Any Software used in randomization? / What was the block size?

Response: In randomization method. We use free program from “www.randomization.com” to create the blocks of four using a random number generator (number of subjects per block = 4, number of block = 7). The notes in each treatment was prepared and put them into envelopes according to the allocation orders. After that, nurse assistant who did not take the responsibility in the allocation method would open the envelope and informed PA or SP to do the treatment. Please see Randomization and allocation section, line 118-128, page 4.

Comment 4: Please check your statistical analysis section. Author’s claimed that "the independent t-test used for normally distributed continuous variables" but I could not find any parametric data in this trial. Mentioned non-parametric tests are suitable for the analysis.
Response: Thank you for your suggestion. We used Shapiro–Wilk W test and histogram to check the normality of the data. The results showed age, baseline symptom severity score, baseline functional score, baseline Boston questionnaire score, baseline peak sensory distal latency, baseline motor distal latency were normally distributed continuous variables. Therefore, independent t-test was used to calculate. While, BMI, baseline visual analogue scale, baseline SNAP amplitude, baseline CMAP amplitude were non-normally distributed continuous variables. So, Mann-Whitney U test was used to calculate.

Comment 5: Please check your analysis for comparison of the gender between two groups. In group one, the percentage of the females was 38%, and in the second group, that ratio was 92%. Any significant differences detected between two groups?

Response: Thank you for your suggestion. The Fisher’s exact test was used to evaluate the significant differences of gender between both groups. The result showed no significant differences detected between two groups (p=0.16) as in Table 1.

Comment 6: Please explain your each step in your process with a Flowchart.

Response: Thank you for your suggestion. We create “Fig.1” as the flow chart (please see the attached file “Fig. 1”) and explain in “Results section, line 179 page 5- line 188 Page 6.

Comment 7: Please explain "why you did not exclude your dropouts?"

Response: Thank you for your comment. In 3 patients who rejected to provide electrodiagnostic measurement at week 12 after the treatment. We excluded the evaluation in electrodiagnostic part, however the Boston-self assessment questionnaire score and Visual analogue scale could be evaluated because all 3 patients still came to the follow up period at week 12 after treatment. For 2 patients who loss follow-up at week 24 after treatment according to travelling problems, we excluded them when comparing the evaluation of Boston-self assessment questionnaire score and Visual analogue scale between baseline and week 24 after treatment. Conversely, we could evaluate the evaluation of Boston-self assessment questionnaire score and Visual analogue scale between baseline and the week before week 24.