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OPEN PEER REVIEW

Low-intensity Extracorporeal Shock Waves for Treatment of Erectile Dysfunction in Patients Not Responding to Phosphodiesterase Type 5 Inhibitors, Its Durability, and Factors That May Influence the Outcome: A Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

0 comments

No public comments in this round.

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Reply to Reviewer

1. It needs English language revision

Answer: The English language revision was done.

2. Abbreviations should be written in complete form for first time in the text (not title) including abstract

Answer: It is done.

3. Please name urologic clinics which were involved

Answer: A Private Sexual Dysfunction Clinic and Urology Clinic of Razi University Hospital

4. It is better to exclude patients with history of any cardiac diseases and all risk factors of those, se of beta-adrenergic medications, patients with psychologic erectile dysfunction, radiation therapy to pelvis, any pelvic surgeries, all form of prostatectomy

Answer: In this study, patients with a history of neurological diseases such as MS, stroke, spinal cord injury, Parkinson's and a history of positive NPT in the last three months and a history of taking drugs such as beta-adrenergic and diuretics were excluded.

5. It is better to mention all patients who were referred because of ED and then exit whom with exclusion criteria

Answer: We are agreed in this matter and it is revised in the manuscript.

6. "the total number of shocks per session was 6000 so that each time 2000 shock waves were applied to the corpus cavernosum on each side, and 1000 shock waves were applied to both sides of corpora" is this correct? Please explain more

Answer: The implementation protocol was defined according to the standard, for the device and confirmed during the studies. It is explained in the full study implementation method.

7. You should consider patients satisfaction as a variable before and after treatment

Answer: Subjectively, the majority of patients were satisfied with the treatment results. It was added to the manuscript.

8. It would be better if you study your variables after each session of ESWT, then you were able to assess the optimum number of therapy sessions

Answer: This treatment method has been carried out according to a pre-specified protocol in previous studies and the result of the procedure has been evaluated at certain time intervals.

9. for studying ED, you should approve it by NPT-Riggi scan

Answer: Patients were people who did not have NPT.

2 Revision 1

1 comment · 13 Mar 2023

Referee 1 Reviewer

MAJOR REVISION 13 Mar 2023

Thanks to the authors for considering NUM for their submission.
Regarding the title of the study, it can be mentioned that many studies, including meta-analyses, have been conducted in this field, and the effectiveness of the intervention is almost certain. However, there are discussions about the length of treatment and how long the effect of treatment lasts. However, since there was no study in this field in Iran, the results of this study can be useful. But the following points should be considered:
1. CONSORT: The manuscript should be written according to the CONSORT guidelines.
2. Title: Efficacy should be replaced with effectiveness.
3. Abstract: It should be written according to the journal's instructions.
4. Abstract methods: The study design, which is a before-after design, inclusion criteria, the amount and duration of the intervention, the type of outcomes, the tool for evaluating the outcomes, statistical analysis, and the level of significance should be briefly described.
5. Abstract results: When an outcome value is compared between two time points, in addition to the significance level, the value at each time point should also be presented in parentheses. Also, the effects of other variables, such as diabetes, smoking, severity of erectile dysfunction (ED), etc., on the response to treatment should be described.
6. Abstract conclusion: This sentence should be deleted: "Therefore, despite the need for further studies to confirm the results of this study and further understand the mechanism, we recommend to use this therapeutic method in patients with erectile dysfunction who are nonresponders to PDE5-Is."
7. Full-Text methods: It should be written according to the CONSORT guidelines. All items in the guidelines, such as outcomes, follow-up, questionnaire, etc., should be clearly described.
8. Statistical analysis: For the score variable, the median and interquartile range (IQR) should be calculated. For a normal quantitative variable such as age, the mean and standard deviation (SD) can be calculated. For a qualitative variable such as gender, the number and percentage should be reported. Instead of measuring the change in response to treatment in relation to variables such as age, smoking, etc., it is better to measure response versus nonresponse to treatment, as well as the durability and nondurability of treatment after 6 months, according to these variables using an independent t-test, Chi Square, or Fisher's exact measure. Moreover, it is better to provide detailed information about the software used (SPSS), including its name, in the last sentence, along with the significance level.
9. English editing is needed.
10. Results: The results section was written in an inappropriate style. For example, "Scores obtained from the IIEF questionnaire in patients with erectile dysfunction during the study period, before treatment, at the end of treatment, three months after treatment, and six months after treatment, were 30.38±8.37, 37.92±10.12, 37.21±9.7, 35.9±9.51 respectively. The IIEF questionnaire scores had statistically a significant difference in the periods analyzed. (P=0.0001)." These two sentences can be merged and summarized as follows: "ED score statistically changed from 30.38±8.37 to the 37.92±10.12, 37.21±9.7, and 35.9±9.51, respectively from before treatment, at the end of treatment, three months after treatment, and six months after treatment (p=0.0001)".
11. The results section should be rewritten completely. This well-structured paper, "Low-Intensity Extracorporeal Shock wave Therapy Can Improve Erectile Function in Patients Who Failed to Respond to Phosphodiesterase Type 5 Inhibitors", can be used as a template for editing the results and all sections of this manuscript.
12. Tables: They are presented in an inappropriate manner. Please redraw the tables using the aforementioned

article.
13. The title of Figure 1 is available in the manuscript file, but no figure can be seen.
Please reply to the questions one by one in a separate file, and mark changes in the manuscript in green.

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Reviewers' Comments:

With the best regard: We announced that, we made a major revision to the attached manuscript and answered all the following revisions; also, we revised the manuscript as similar as to the published clinical trials in your journal; therefore we are recommended, to study the attached manuscript again

Reviewer 1:

Thanks to the authors for considering NUM for their submission.

Regarding the title of the study, it can be mentioned that many studies even meta-analysis were conducted in this field and the effectiveness of the intervention is almost certain. However, there are discussions on the length of the treatment, and how long the effect of the treatment remains. However, since there was no study in this field in Iran, the result of this study can be useful. But, the following points should be considered:

1. CONSORT: Manuscript should be written according to COSORT guideline. The manuscript was revised according to CONSORT guidelines, and the Consort flowchart figure was added.

2.Title: Efficacy should be replaced with effectiveness. It was replaced

3. Abstract: It should be written according to journal instruction. Major revision was done to the abstract.

4. Abstract methods: It should be briefly explained about the design of the study, which is before-after, inclusion criteria, the amount and duration of the intervention, the type of outcomes, the tool for evaluating the outcomes, statistical analysis, and the level of significance. Major revision was done to the abstract method.

5. Abstract results: When the result value is compared between two time points, in addition to the significance level, the value of each time should also be presented in parentheses. Also, it should be written about the effect of other variables such as diabetes, smoking, severity of erectile dysfunction (ED), etc. on the response to treatment. Major revision was done to the abstract results.

6. Abstract conclusion: This sentence should be deleted "Therefore, despite the need for further studies to confirm the results of this study and further understand the mechanism, we recommend to use this therapeutic method in patients with erectile dysfunction who are non-responders to PDE5-Is.". Major revision was done to the abstract conclusion.

7. Full-Text methods: It should be written according to CONSORT guideline. All items of guideline such as outcomes, follow-up, questionnaire, … should be clearly described. Full-text method was revised based on CONSORT guidelines.

8. Statistical analysis: For the score variable, the median and interquartile range (IQR) should be calculated. For a normal quantitative variable such as age, the mean and standard deviation (SD) can be calculated. For a qualitative variable such as gender, the number and percentage should be reported. Instead of measuring the change of response to treatment, in terms of variables such as age, smoking, etc., it is better to measure the response versus non-response to treatment as well as the durability and non-durability of treatment after 6 months according to the variables using independent t-test, Chi Square or Fisher's exact measure. Moreover, it is better to write the detailed data and name of the used software (SPSS) as the last sentence along with a significance level. Statistical analysis was revised by the statistical counselor.

9. English edition is needed. Full-text was also revised in terms of native English revision.

10. Results: The results section was written in an inappropriate style. For example, "Scores obtained from the IIEF questionnaire in patients with erectile dysfunction during the study period, before treatment, at the end of treatment, three months after treatment, and six months after treatment, were 30.38±8.37, 37.92±10.12, 37.21±9.7, 35.9±9.51 respectively. The IIEF questionnaire scores had statistically a significant difference in the periods analyzed. (P=0.0001)."It can be merged and summarized two sentences as this manner "ED score statistically changed from 30.38±8.37 to the 37.92±10.12, 37.21±9.7, and 35.9±9.51, respectively from before treatment, at the end of treatment, three months after treatment, and six months after treatment (p=0.0001)". Major revision was done to the full-text results.

11. The results section should be re-written completely. This good structured paper "Low-Intensity Extracorporeal Shock wave Therapy Can Improve Erectile Function in Patients Who Failed to Respond to Phosphodiesterase Type 5 Inhibitors" can be used as template for edition of results and all section of this manuscript. Major revision was done to the full-text results.

12. Tables: It presented in an inappropriate manner. Please redraw the tables using the aforementioned article. We made a major revision to the tables, and revised them in three new table.

13. The title of Figure 1 is available in the manuscript file, but no figure can be seen. Figure 1 is

consort flowchart. Figure 2 indicating the IIEF through the time was added.

Please, reply to the question in separate file one by one, and apply changes in the manuscript with green color. With the best regard: Due to making a major revision to the manuscript, the possibility of highlighting was difficult for us; therefore, we are recommended to study the attached manuscript again.

3 Revision 2

2 comments · 3 Jun 2023 – 4 Jun 2023

Referee 2 Reviewer

ACCEPT 3 Jun 2023

1. Please check your keywords against the MeSH database. It seems that the keywords need some revisions.
2. Please mention the weak and strong points of your study.
3. Please write about the limitations of your survey. Are there any limitations to this study? If yes, please mention all limitations of the current study within the discussion section, too.

Associate Editor

MINOR REVISION 4 Jun 2023

Minor Revision

4

Revision 3

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

The authors did not provide a point-by-point response to the reviewers' comments in this round.

4 Revision 3

1 comment · 10 Jun 2023

Associate Editor

ACCEPT 10 Jun 2023

Accept