Author's response to reviews

Title: Outcome and patients' satisfaction after functional treatment of acute lateral ankle injuries at emergency departments versus family doctor offices: a prospective randomized study

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Author's response to reviews: see over
To the editors of the BMS family practice:

Dear Editors,

Thank you for having our paper considered in the review process for your journal. We have tried as extensive as possible to answer all the reviewers' questions and remarks point by point. For the sake of clarity, all changes in text are underlined. We hope we have answered all open questions to your satisfaction and now fulfil your criteria for publication.

With kind regards

Lorin M Benneker

-Answers to the reviewers see below:
Dear reviewers,

Thank you for reviewing our manuscript. We have tried to answer each of your questions and have changed the text where appropriate.

**Reviewer:** Nicola Maffulli  
**Reviewer's report:**  
This is a well designed randomised controlled trials bridging primary and secondary care.  
The fact that the use of orthotics was not standardised, and that a large proportion of patients bought their own somewhat detracts from the study, and should be better highlighted  
*A:* The use of orthotics was actually standardized (we did not prescribe any at all) but the fact that patients feel more comfortable in an ankle brace even if there is no mechanical necessity is worth a mention and can help practitioners guiding their patients.

**CONSORT Statement:** is lacking, and is an absolute necessity  
*A:* The trial was performed according to the CONSORT checklist: details of the randomization implementation and a respective statement are now added in the method section.

**Level of interest:** An article of importance in its field  
**Quality of written English:** Needs some language corrections before being Published  
*A:* Translation into English was performed by a professional translator, medical terms have been adapted by the authors. According to the reviewer comments the manuscript now has undergone another language checking by a native English speaking and minor corrections are implemented.

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.  
**Declaration of competing interests:**  
*I declare that I have no competing interests*
Reviewer: Jan A Verhaar

Reviewer's report:

This article describes the satisfaction of patients with lateral ankle injuries, who have initially seen at a university emergency room, but were referred to their general practitioner compared with a group, who were further treated in the hospital. Both group had 50 groups and no differences were found between the groups two months after initially treatment.

Major Compulsory Revisions

Many questions remain unanswered and need to be clarified:
- Why did the authors not use the internationally accepted Ottawa rules but their own Bernese rules?
  A: As explained near the end of the introduction section the Bernese ankle rules are a adaptation of the Ottawa rules with a higher specificity and are routinely applied at our hospital for lateral ankle injuries.
- How many radiographs were made? Was there any difference between the two groups?
  A: Since we wanted to be sure not to miss any fractures that would falsify our results all patients had a biplanar radiograph (see text page 4). No patients with fractures or unclear findings were included so no differences between the groups were possible.
- Were the patients randomized after clinical diagnoses or after clinical diagnoses and radiograph?
  A: The randomization was performed after clinical examination and after radiological confirmation that no fractures were present.
- What was the method of randomization?
  A: Method of randomization: if a patient fulfilled all inclusion criteria he was asked to pull a number from a black box; this number has previously been assigned to one of the study arms and was prior not accessible to the actual examiner – so both examiner and patient were blinded. Details of the randomization implementation and a respective statement are now added in the method section.
- What was the null hypothesis (H0) of this study and on which power the number of patients. The reviewer has a strong impression that the study was underpowered to find differences between the two groups.
  A: H0 was that there is no difference in (subjective) satisfaction of patients if aftercare is performed by GPs or at ER doctors. Outcome variable was satisfaction on a simple 3 grade scale (very satisfied, satisfied, not satisfied) for the same treatment (no intervention, only control), our power calculation for sample size showed that a significance level of p < 0.05 should be reached with N = ? (100). If the functional results were objective of the study a larger number of patients and a longer follow up might would have been necessary.
- Why was a follow-up of two months chosen? Follow-up studies show that the overall long-term results are less well, than generally assumed. A 12 months follow-up seems to be more reasonable.
  A: Objective of the study was to determine the effect of GP vs ER aftercare on patients satisfaction and not functional results of the injury itself. For simple lateral ankle injuries patients usually are only seen for aftercare within the first weeks. If we
would have chosen a 12 Mth control most patients would be out of treatment for months already but the patients with persistent problems and so biasing the results.

- How many patients refused to participate to the study?
  A: none (see change in methods section)

- Were patients informed about the study and how were they treated when they refused to participate?
  A: see answer above

Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a
Reviewer: Sita M Bierma-Zeinstra

Reviewer's report:
This paper as it stands, presents the patient satisfaction after functional treatment of acute lateral ankle injuries. Whilst it is important to shine light on the patient satisfaction of different treatment strategies, I have some serious concerns about the presentation and analysis of the results and, consequently on the outcome and interpretation of this study.

The writing can certainly be improved, perhaps an English native speaker can be consulted?

A: Translation into English was performed by a professional translator, medical terms have been adapted by the authors. According to the reviewer comments the manuscript now has undergone another language checking by a native English speaking and minor corrections are implemented.

Further, one of my major concerns is the contrast between both intervention groups. Both groups received the same treatment, the only difference is that one intervention group visited the GP and the other visited the ER once. So what is the reason that you expect a difference in patient satisfaction?

A: Patients satisfaction is not equal to the functional outcome of the treatment; whereas there is no difference to expect in functional outcome we wanted to investigate if patients are not satisfied if their ankle injury is treated by a GP. In our country (and many others) patients are still free to choose whether they see their GP or if they present themselves at an ER even for minor injuries as lateral ankle injuries. Obviously many of these patients present themselves at ER wards and expect to be seen and treated by a specialist and so block resources that can be used for ‘real’ emergencies. Goal of the study was to bring evidence that patients satisfaction after such a minor trauma is not depended on where the treatment is taking place. Such data can help to implement rules like you already have in your country where its mandatory to see a GP first. In our and other countries we are faced with a lot of opposition about this topic as many patients only trust in (expensive) specialists and with our study we hope to support such regulation to outsource minor trauma to GPs.

Introduction:
In the introduction you mention the increasing number of patients seeking help directly at the emergency department. However, you refer to a study from 1995 and I have some serious questions about this number nowadays. Later on, you refer to a Scandinavian study (Viljakka 1983) that shows a high percentage of ER admittances.

Further, such statements might only be applicable to certain countries. For example, in the Netherlands patients first have to visit their GP or a GP cooperative (out of office hours). Because of this reason, I have some concerns about the actual number of patients visiting the ER for ankle traumas nowadays. Please present more recent published numbers or percentages.

A: We have changed the text here, taking your comment in account - see also answer above.

I miss a clear rationale for this study. Why is this important and of interest for the reader? Do you expect that treatment satisfaction differs depending on receiving care in different settings? In line with this, I am wondering why there are 6 lines in the introduction about surgery and the consequences of surgery, while this isn’t related to the subject of this study.
Please formulate a clear objective for this study.
**A:** Please see changes at the end of the introduction and answers above.

Methods

General:
I would like to suggest organizing the methods section into subheadings with ‘patient selection’, ‘data collection and measurements’ and ‘analysis’. This would make the methods section much more readable.
**A:** If this is also the editor’s request we have no objection to add these subheadings.

How many patients were approached for this study and what percentage of these agreed to participate?
**A:** We did not collect data of all ankle injuries for the 6 month period of probands recruitment.

“All grades are included”. Please clearly describe what grades of injuries are included in this study, because there is a contrast with the abstract and introduction where you mention grade 1 and 2 and in the methods section “all grades are included”. What about grade 3?
**A:** we treat all grades 1-3 non-operatively and without immobilization or brace. Please see changes at the introduction section. All patients receive an information sheet and instructions for autotherapy. Some patients that were insecure were transferred to a physiotherapist for initial instruction (less than 10%).

How was the randomization procedure performed? And was the allocation concealed?
**A:** Method of randomization: if a patient fulfilled all inclusion criteria he was asked to pull a number from a black box; this number has previously been assigned to one of the study arms and was prior not accessible to the actual examiner – so both examiner and patient were blinded. Details of the randomization implementation and a respective statement are now added in the method section.

Page 5, line 6-9: Should this section not be described in the results? And how many patients demanded physiotherapeutic guidance and how was this divided over the two groups?
**A:** As already to be read in the results section and table 3 only 9 patients needed physiotherapeutic guidance; 3 in the GP group and 6 in the ER group. The respective passage has been deleted/moved to the results section.

Page 5, second paragraph: patient characteristics must be described in the results section. Besides, a table with baseline characteristics is missing (comparison between both intervention groups).
**A:** the groups were comparable for age and gender distribution, we do not think another table gives additional information. The respective passage has been moved to the results section.

Please clearly describe your measurements and how these were performed. For example, how was the physical examination performed and what were the outcomes? And ‘there was room left’ is very vague.
**A:** Initial examination according the ‘Bernese ankle rules’ were performed by the resident on duty at the ER. All residents had instructions for clinical examination and
the use of the rules; the ‘Bernese ankle rules’ were published in JOT 2005. The FU examination was performed by the first author PS. Pain at palpation at predetermined areas was noted as well as swelling (comparison to the not injured site). This and the results are cited in text and in table 2 and figure 3.

Analysis: why are the analysis not adjusted for potential confounders. This is a major concern to me because of the potential influence on the outcome of the patient (for example pain on a VAS scale) onto the patient satisfaction. Additionally, the grade of the injury could influence the outcome and satisfaction. Therefore I would suggest a regression analysis with adjustment for potential confounders.

A: Potential confounders are probably relevant for the functional outcome of the ankle joint but not for the satisfaction with regard to treatment modality (GP and ER both implemented the same treatment (functional as explained before). We explicitly differed between satisfaction about the functional outcome and the treatment modality. No patient had problems with that differentiation as it was explained from the beginning (when asking them to participate in the study). Since we did not collect any potential confounders a regression analysis now is not possible (and not required as explained before)

Table 1. What is the exact difference between satisfaction about the treatment and therapy and treatment outcome? Was this clear for the patients?

A: See answer above

Results
Page 7: ‘Satisfaction regarding treatment outcome’. Was there a difference between the patients who visited a physiotherapist and the patients who did not? I have some great concerns about this outcome because the analysis is not adjusted for this potential confounder. Therefore I am seriously concerned about the interpretation of this result. Aren’t you measuring the ‘outcome’ of the patient instead of the ‘satisfaction’ of the patient?

A: See answer above

Page 7: ‘pain and swelling’. These items are not announced in the methods section. How did you measure these?

A: See answer above

Page 7: “There was a tendency…(p=0.129).” What do you mean? Very unclear sentence.

A: A tendency describes a non-significant trend for more self-aquired otheses in the GP group. No other reviewer found that sentence unclear.

General:
In the results section you refer to an objective data collection. How is this possible? And was the assessor blinded to the intervention of the patients?

A: Here the term objective was chosen to differentiate the physical examination from the subjective answers of the patients (how satisfied they were with the treatment). If that term causes confusion it can be deleted if this is the editors wish.

Discussion
Page 10, second paragraph drops out of the blue. Are these medication prescribed? Missing in the methods section.
A: A respective notion is added at the methods section.

Page 11, “These results are consistent…” So this is already investigated in other studies? Why isn’t this mentioned in the introduction?
A: Yes, as referenced there are other studies investigating that topic for other minor injuries.

Study limitations section is missing.
A: Has been added

Page 11, last section: New results are presented here and should first at least be mentioned in the results chapter.
A: These results are already presented at p7 in the results section. Other data discussed are data from literature and have no place in our own results section.

Level of interest: An article of limited interest
Quality of written English: Needs some language corrections before being published
A: Translation into English was performed by a professional translator, medical terms have been adapted by the authors. According to the reviewer comments the manuscript now has undergone another language checking by a native English speaking and minor corrections are implemented.

Statistical review: Yes, and I have assessed the statistics in my report.

with kind regards

Lorin M Benneker