Author’s response to reviews

Title: Wrist fractures and their impact in daily living functionality on elderly people. Prospective cohort study

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Author’s response to reviews:

Reviewer 1

General comments;

This is a very interesting paper on an understudied area of wrist fracture.

I would recommend a number of changes and clarifications in the paper;

The aim needs to be rephrased to make it more focused to the scope of the paper, , this should be done in the abstract and the introduction/background sections.

For example the aim of this study was to describe…..

Author’s response: thank you for the recommendation. The aim was cited but not clearly enough.

Author’s action: Following this suggestion, the abstract and the introduction sections have been modified in order to introduce this missing aspect.

Page 2 line 42 and page 4 line 98.
Line 106, how were the 6 hospitals comparable – how was this determined by the researcher team?

Author’s response: The six hospitals are part of the Basque public health system. Mean sociodemographic characteristics of the population of reference, and service use and quality indicators of the centers are similar and comparable to each other. If needed, information can be found in the official web page of Basque public health system – Osakidetza (https://www.osakidetza.eus/)

Did the one ethics committee give ethical approval for all of the 6 participating hospitals, please clarify if this was the case.

Author’s response: Yes, at the time the project was set up, this was the regular procedure. The ethics Committee of Galdakao Hospital provided the approval and it was valid for all the hospitals under the same organization.

Line 112/113 – it is not clear who conducted the assessments, this would be helpful, was it a nurse doctor, researcher – please add this detail

Author’s response: The assessment was conducted by two psychologists members of the research team, who had experience in conducting interviews.

Author’s action: This clarification has been included as proposed. Page 5 line 117.

Line 120 – clarify which scales were self report.

Author’s response: As stated in the methods section, social support network, level of education, income, health-related quality of life (HRQoL) and functionality (Barthel Index and Lawton IADL Scale)) were patient-reported.

Author’s action: In order to better clarify this point, the name of the scales has been added in the text. Page 6 line 127.

Line 127/128 – add details relating to who conducted the assessments at baseline and follow-up?

Author’s response: Two psychologists members of the research team carried out all the interviews. Interviews lasted approximately 40 minutes. Psychologists had been previously trained on interview skills and the battery of tests.

Author’s action: This information has been included in the manuscript. Page 5 line 117.

Line 129 – the authors refer the reader to reference 10 with more details of the methodology but the reference describes a hip fracture study – please review.

Author’s response: It is not a mistake. These results are part of a bigger study aimed to describe the treatment provided to elder patients presenting fractures (hip and wrist) due to accidental
falls. The methodology of the overall project was described in the referred previous article were the results regarding hip fractures were presented.

Author’s action: This information has been included in the manuscript. Page 6 line 138.

Line 130 – clarify the definition of ‘functionality’ do the authors mean functional independence – review the use of this term throughout the manuscript.

Author’s response: The assessed concept is functional capacity. This capacity can also be classified in functional capacity for the basic daily living activities BADL (measured by Barthel Index) and functional capacity for instrumental daily living activities IADL (measured by Lawton Scale). Scoring below specific cut points in these scales is translated in clinical terms as dependence.

Author’s action: Following this suggestion, this concept has been reviewed and consistently modified through the manuscript.

Line 142/143 – provide references for the Spanish versions of the scales referred to.

Author’s response: Spanish references have been provided after each specific scale.

Author’s action: Barthel Index ref number 8; Lawton Scale ref number 10; SF12 ref number 17; Quick DASH ref number 15.

Line 151-160 – provide additional detail regarding the cut off scores used by the authors, how were these determined?

Author’s response: Regarding the Barthel Index, patients’ condition was considered to have deteriorated if they obtained post-fall scores of <90 points or their score decreased by more than 10%, given that 90 points is defined as a threshold for moderate dependency and that a 10% decrease may imply in some cases, a change in the level of independence (ref 7).

With the Lawton IADL Scale, post-fall values of <5 points or a decrease of 2 points were considered to indicate deterioration, taking into account the responsiveness of this test (ref 9). Other authors have also associated a <5 score with worse outcomes (Sacanella E. at al. Intensive Care Med (2009); 35:550-555), whereas a 2 point difference actually means that the subject has lost 2 IADL activities during the follow up. Such a difference was considered as highly relevant, given that losing 2 out of 8 IADL activities may imply a change in independence level. The same cut-off points have been considered in a previous publication (Ref: Vergara I, Vrotsou K, Orive M, Gonzalez N, Garcia S, Quintana JM: Factors related to functional prognosis in elderly patients after accidental hip fractures: a prospective cohort study. BMC Geriatr 2014, 14: 124)

Line 161-165 – provide additional detail regarding the cut off scores used by the authors for the PRO measure, how were these determined? Are these established cut offs – were they determined following statistical advice
Author’s response: For a detailed explanation please see our reply to the previous question. We wish to clarify that statistical input existed in all phases of the current project. From protocol planning to data collection and obviously in data analysis and writing up of the current article. A number of experienced statisticians and epidemiologists form part of our research group and thus statistical issues have been thoroughly considered during the whole study process.

Line 194 – what was the typical duration of a treatment session? How was this variable collected, was it from charts, for example for those referred to rehab was a typical duration 15-20 minutes? Is it possible to add more details relating to the treatment and rehabilitation variables?

Author’s response: Since this is an observational study performed at 6 hospitals, rehabilitation indication and treatment sessions varied from patient to patient, physician to physician and centre to centre, as it can be expected in a real life study. Rehabilitation treatment was considered for this study in a global way, taking into account if the patient was receiving some kind of rehabilitation treatment or not. Given the high variability of rehabilitation interventions, no further detail about the specific techniques used in each case was collected.

Line 231 – the use of the term ‘autonomous’ is confusing, do the authors mean independent/related, might be preferable to use another term.

Author’s response: Thank you for the proposal. It is a bad translation of the most frequent term used in Spanish.

Author’s action: We have changed it through the manuscript to the term independent.

Line 268 – what types of ‘treatment’ were used, could more detail be added here? Assume this refers to surgical vs. conservative management of the fracture. Please ensure that is clear in the manuscript.

Author’s response: Yes. The treatment alternatives considered were conservative versus surgical.

Author’s action: This information is presented in page 6 line 125.

Line 286 – the authors refer to frail patients, how do they propose that an assessment of frailty could be incorporated in the management of wrist fracture patients?

Author’s response: Frailty could be assessed in patients suffering a fracture using, for example, the Tilburg Frailty Indicator proposed and validated by Gobbens et al. This is a self-reported questionnaire with good psychometric characteristics that doesn’t imply any physical performance measure. The assessment of frailty would allow medical services to identify patients with high risk of becoming dependent after a wrist fracture and to tackle their specific health and social needs in order to reduce this risk. This idea was presented in page 12 line 288

Minor changes
Abstract, Methods section, suggested change to the line 46… A prospective cohort study, rather than the phrase was set up, suggest this be changed to ‘was conducted’.

Suggestion incorporated.

Methods section of abstract – last line add follow-up ‘period’? Line 53

Suggestion incorporated.

Keywords – suggest add the word ‘elderly’ to the list of key words line 66

Suggestion incorporated.

Acknowledgments – suggest change the line 76 to ‘The authors wish to thank….

Suggestion incorporated.

Line 99 A study …. ‘was conducted’ rather than ‘put in place’

Suggestion incorporated.

Line 103 – correct English, where they ‘sought’ medical attention

Suggestion incorporated.

Line 108, due to a previous syncope episode, add the word ‘episode’

Suggestion incorporated.

Line 111, change losses to ‘lost to’

Suggestion incorporated.

Line 181 change studied patients to ‘The study participants’

Suggestion incorporated.
Reviewer 2

The authors present an observational study of older patients suffering a wrist fracture. They report on 6 month results regarding BADL and IADL.

The study is well-written however there are concerns regarding the presentation of the results.

Throughout the manuscript it remains unclear and confusing what the primary end point is / are. In the abstract it is defined as BADL and IADL. (p. 3, line 50). In the method section again (p.6 line 131. In the statistics presented both outcome parameters are studied separately with different models. During presentation and discussion of result this is not always clear Example: p. 9 line 202, p10 lines 219-228. P11 line 239/240, line 249 and so on. I would recommend to report each outcome variable separately, or to pool both outcome parameters.

Author’s answer: The main outcome to be assessed is functional capacity considering both, basic activities of daily living (BADL) (measured by Barthel Index) and instrumental activities of daily living (IADL (measured by Lawton Scale). Both aspects are studied separately even though in the discussion section, sometimes are considered jointly from a comprehensive perspective.

Author’s action: Both outcomes are reported separately through the article.

Abstract page 3 line 51; methods page 4 lines 147; results page 9 lines 212 and 231 and discussion page 11 line 252 and page 12 line 261

It is not clear whether the two endpoints are independent from each other. Considering the similarities in those with deterioration of IADL and BADL I would suspect that there is a great overlap of participants in both models that needs to be considered. (p. 9 line 200).
Author’s answer: Functional capacity is a complex concept that includes advanced activities, instrumental activities of daily living (IADL), and basic activities of daily living (BADL). These components are hierarchically ordered, an ability to develop activities at the highest levels imply the preservation of the lower levels. But, as the reviewer points out, when IADL is affected, BADL is affected too. In this study, 18% of all patients presented functional decline in both considered outcomes. In any case, and being completely aware of this overlap, throughout the study our aim was to explore these two endpoints (IADL and BADL) separately. We wished to examine what factors may affect the one and the other, focusing on the similarities and discrepancies as far as significant factors were concerned. The derived results make sense from a clinical point of view and we present them as hypotheses generating basis for future research.

This is an observational study and regression analyses provide associations and not causality. This is not very clear. Please re-write some passages accordingly (e.g. page 2 line 43, page 3 line 62, page 12, line 282). The Conclusion needs to be rephrased (...have a direct role...). It is not unlikely that those suffering deterioration in ADLs would have some deterioration without a wrist fracture due to their underlying conditions.

Author’s answer: Thank you for the comment.

Author’s action: The proposed rephrases have been made accordingly at page 2 line 42, page 3 line 64 and page 12 line 304.

Furthermore, I would suggest to take out the discussion of the association with choice of treatment as the choice of treatment is influenced by other factors shown to be associated with functional decline. Page 12, line 268 ff.

Author’s action: following this suggestion the paragraph has been deleted.

Methodological comments

- Please provide Table 1 with characteristics of all participants

Author’s action: It has been included

- what do the authors define as wrist fracture. Please give ICD-10 codes for inclusion criteria.

Author’s answer: Fractures of the lower end of radius and ulna were considered. The included ICD-9 codes were 813.4 and 813.5.

Author’s action: This criterion has been clarified in the manuscript, page 5 line 104

- please explain what happened with patients suffering two different fractures (i.e. wrist + hip) – was a second fracture exclusion criteria? It should be so.
Author’s answer: Yes, patients with a second fracture were excluded.

Author’s action: This information has been included in the manuscript, page 5 line114

- why were patients with syncope excluded?

Author’s answer: The casuistic of fractures due to accidental falls are different from those presented by patients suffering syncope. The aim of the overall research project was to analyse the treatment provided to elder subjects suffering a fracture due to an accidental fall in order to describe the impact of the fracture in their quality of life.

- The choice of parameters is not clear. Why did the authors choose an item oft he Charlson Index – this appears arbitrary, What does „social network“ (p6 line 119) refer to?

Author’s answer: All pathologies incorporated in the Charlson Index were additionally studied on their own. The majority had low frequencies, but cardiovascular, pulmonary, cerebrovascular diseases and diabetes allowed for further explorations. Consequently as described in “Methods” those variables with $p$-value≤0.10 in the univariate stage were considered at the multivariate stage too. In this second stage Charlson and individual diseases were considered jointly and also separately (each on its own). Nonetheless only Cardiovascular disease resulted as statistically significant in the BADL model. Neither Charlson nor any of the others did, when considered with the rest variables.

Author’s action: A brief explanation that clarifies this point has been added in Methods section at page 8 line 177.

I miss information and association with cognition. Considering the very detailed evaluation I wonder why this is not included.

Author’s answer: Patients with severe and mild cognitive impairment were excluded from the study. The reason for this exclusion was the necessity to obtain all PRO measures, specially the functional condition prior to the fall, through a personal interview with the patients.

Author’s action: this aspect has been clarified in the method section page 5 line 115.

- Independent variables in a regression should be independent from each other – has this been checked?

Author’s answer: Thanks for your comment. Dependence among variables is an existing issue in most observational studies and in studies like ours, where many life style and age related questions are asked and analysed. Stating that all variables are independent and no relation exists is nearly never realistic. Interrelations among variables may be problematic as it may affect point estimation, their direction and their standard errors. However, certain data characteristics can condition the effect of these relations. The magnitude of those interrelations is a major factor, with correlations >0.80 considered as really problematic (Andy Field 2009, Discovering statistics
using SPSS). Secondly, sample size also plays an important role, as smaller samples (<150 subjects) result in more unstable estimations when related variables are present (Mason CH, Journal of Marketing Research 1991). But, none of these is the case in our study. More than 600 subjects were analysed in our project, N that provides sufficiently robust estimates, whereas the correlation matrix of the included variables showed a maximum estimated correlation of 0.55. Additionally univariate and multivariate estimations have been thoroughly checked and none of them changes direction. In other words, positive/negative effects remain such in the multivariate models irrespective of the other variables. And this is what interests us the most here, the direction of the included effects. In any case, based on the respective diagnostics, collinearity does not appear to be a problem for the derived models.

Author’s action: Info related to factor collinearity has been added in the methods and results section.

- Associations between fracture treatment and participants characteristics are not the purpose of this study – could be deleted (p9, line 191 – 198)

Author’s action: The paragraph at the discussion section has been deleted.

Please check references – they do not seem to match the meaning it refers to:

Ref 1: This reference has been confirmed. Table 1 presents data about the incidence of forearm fractures.

Ref 3: This reference has been confirmed. The information referenced is contained in the results section where the characteristics of women presenting wrist fractures are described.

Ref 6: This reference has been confirmed. The affirmation is withdrawn from the results section and is confirmed at the discussion section of this article.

Rephrasing suggested:

P 4 line 92: what does the „it“ refer to?

It refers to the functional impact. The sentence has been rephrased as suggested.

P 5 line 99: „set up“ instead „put up“

The sentence has been rephrased as suggested.

P5 line 99/100: „65 years and older“ instead „65 or more“

The sentence has been rephrased as suggested.
P5 line 100: „suffering“ instead „affected“

The sentence has been rephrased as suggested.

P6 line 122: „...evolution registered at the clinical record“

The sentence has been rephrased as suggested.

P8 line 177-80: could be rephrased

The paragraph has been rephrased.

P9 line 108: „Factors associated with this condition“ – not precise

The sentence has been rephrased to improve precision.

P10 line 233-235: second part of the sentence is confusing and could be deleted.

The sentence has been rephrased and kept considering the relevance of the comparison with the non-falling population.