Author's response to reviews

Title: Which factors influence the resort to a surrogate consent in stroke trials, and what are the patient outcomes in this context?

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Author's response to reviews: see over
Author's covering letter for initial submission

Title: Which factors influence the resort to a surrogate consent in stroke trials, and what are the patient outcomes in this context?

Authors:

Version: 1 Date: 4 March 2015

Comments: see over
Dear Colleagues

We have well received the comments on our paper ‘Which factors influence surrogate consent in stroke trials and what are the patient outcomes in this context?’. We are grateful to both reviewers to have considered our paper as an article of importance in its field.

We have noted that the reviewer 1 did not any change in the paper.

In contrast, the reviewer 2 has suggested several ways to improve our paper that we have integrated in a new version:

1- The comment of the reviewer highlights a lack of precision in the aim of the paper. Nevertheless, we did not study the willingness to provide a surrogate consent but the choice of the medical team (and not the choice of patient who is not able to judge) to collect the consent from patient or surrogate after the assessment of the ability of patient to give or not a consent. We have changed the title to give this precision as well as in introduction (l. 54 ; l.76) or discussion.

2- We know that a development of this paper should be a more qualitative study of psychological or sociological consequences on surrogate to have given a consent for others. We consider that the presented study remains the first step of a larger research program. We added this point in discussion as a limitation of our study that remains only quantitative study.

3- The reviewer suggested that the definition should be more precise
   a. We focused the population on the 395 patients of our 409 patient cohort. The 14 patients excluded from the analyzed were patients in who the consent was missing because they died before the consent has been signed while an acceptance has been orally obtained before patient worsened.
b. The population was not initially dedicated to study the factors influencing the collection of consent. It was initially a cohort constituted to study clinical, lesion and pharmacological factors influencing the severity of stroke. The collection of consent was a necessity to be included in this study. It appears us that this cohort could be interesting to study the choice of investigators to resort to a direct or surrogate consent while this study has no risk for the patient since it was a non interventional study. Nevertheless, we understand the comment of reviewer on the lack of study of patients or surrogate who did not accept to give their consent in this context. We added this point as a limitation.

4- The reviewer suggested to add some limitations of the study in the discussion of the paper
   a. We have changed the paper to take into account this comment, since we have no data to support this feeling. We have suggested that as an hypothesis for further studies.
   b. We have changed the sentence in accordance with this comment
   c. As we work on stroke-related dementia, we are aware to the pre-existing cognitive state of stroke patients. In our experience, pre-existing is not an exclusion criterion. It is often not introduced as a data in clinical trial while it is important in term of informed consent or in term of therapeutic response
   d. We are in a context of emergency (the context of Glasgow scale development in 1974) and during the clinical examination, it is clear that consciousness impairment is not related to normal sleep or resting, since patients are stimulated to perform neurological tasks necessary for the NIH Scale Score assessment.

5- We have substantially changed the discussion to suppress the notion of strength and we added some points in the discussion to highlight some limitations of the study.
   a. We have better balanced the discussion on the nature of the study.
   b. We have suppressed this point
   c. We have not the justification of the judgment of physicians since we wished to be in normal conditions of consent collection. Nevertheless, we agree that it is a limitation of the study and we added it in discussion.
   d. For us, it remains important to know what the pre-existing cognitive state was since it should be taken into account in the judgment of physician to collect directly or not the consent. We have suppressed the notion of strength.
   e. This point has never been addressed previously and we remains that it is important for the family to know that the poor outcome is not related to the study and the consent.
We agree that we have not data to support what the family's feeling could be. We have changed the discussion to explain that this paper can support further qualitative studies on the feeling of surrogate giving its consent.

6- We have changed the discussion to explicit links between papers and our data.

7- We have clarified the two passages in the paper.

Professeur Régis Bordet
on the behalf of co-authors