Author’s response to reviews

Title: Somatostatin receptor expression in Merkel cell carcinoma as target for molecular imaging

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Version: 5
Date: 26 March 2014

Author’s response to reviews:

RE: Manuscript 1953419757112834

Somatostatin receptor expression in Merkel cell carcinoma as target for molecular imaging

Dear Editors,

We thank you very much for your efficient and timely handling of our manuscript (No. 1953-4197-5711-2834) entitled “Somatostatin receptor expression in Merkel cell carcinoma as target for molecular imaging”.

We are pleased that the manuscript is close to acceptance and would like to address the remaining comments of the editor.

Editor’s Comments:

(1) You state that you did not require ethics approval for your study, if your study does not require approval we still require some further information. Your study should have been granted exemption from requiring ethics approval; this should be detailed in the manuscript (including the name of the local ethics committee that granted the exemption). If your study wasn’t granted exemption from an ethics committee, and it complies with national regulations we will require a reference to the specific regulation in your manuscript which supports this.
As requested by the editors, a paragraph has been included in the revised version of the manuscript highlighting the conformity of the PET-studies according to current regulations (page 5, 1st paragraph, “patients”).

Since 2009, German federal regulations accept the use of the radiotracers Gallium-68 DOTATATE or Gallium-68 DOTATOC under conditions of the pharmaceutical law. Before that time point, the use of Gallium-68 DOTATATE/-TOC was approved on a compassionate use base. Nevertheless, in all of our patients, written informed consent was obtained prior to the imaging procedure.

In general, the ethical committee of our institution (Ethics Committee, Medical Faculty of the University of Würzburg) exclusively discusses prospective clinical trials. Hence, for retrospective studies, the requirement for approval has been waived by the ethics committee. We have informed a representative of the local Ethics Committee (Vice president, Prof. Schneider). If requested by the editors, a certificate can be provided stating that an ethical vote has been waived by the Ethics Committee of the Medical Faculty Würzburg.

Therefore, it can be clearly stated that PET imaging in patients with Merkel cell carcinoma was in agreement with the regulations of regional and national authorities.

A PubMed search as of March 19, 2014 displayed 99 original papers and review articles including clinical data on the utility of Gallium-68 DOTATOC and 73 papers using Gallium-68 DOTATATE as the tracer. Just recently, colleagues of another Bavarian university (Ludwig-Maximillians-Universität Munich) have published a related paper using Gallium-68 DOTATATE in patients with neuroendocrine tumors (Haug et al., Radiology 2014). The legal basis for their retrospective trial is exactly the same as for our cohort. The pdf-file of this paper is attached. As you can see in their Material and Methods section (study population), a similar statement regarding the regulations in Germany has been mentioned. Recently, from our own group, a case report has been published with the provided DOTATATE-PET scan serving as cover illustration of the most recent edition of the journal (Lapa et al., J Clin Endocrinol Metab 2014).

We hope that this information fully addresses your concerns and that the revised manuscript is now acceptable for publication in BMC Cancer. All authors have read and approved the revised manuscript. This manuscript is not under consideration elsewhere.

On behalf of all co-authors, C. Lapa, A. Schirbel, K. Herrmann, M.C. Kreissl, A. Schnack, E.-B. Bröcker, M. Goebeler, A.K. Buck, and J.C. Becker.

Yours sincerely,