Reviewer’s report

Title: Optimal cut-off criteria for duplex ultrasound for the diagnosis of restenosis in stented carotid arteries: review and protocol for a diagnostic study

Version: 2 Date: 9 June 2009

Reviewer: Erwin Stolz

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Major Compulsory Revisions

The authors should comment on the SPACE and CAVATAS results, which show a high rate of in-stent stenosis, but on the other hand a low rate of clinical endpoints. This would make it easier for the reader to grasp the scope of the problem.

The systematic literature search had the aim to identify all studies which used ultrasound and a reference test. The result of this is, that currently not enough data exists to define clear cut-off criteria for duplex diagnosis of in-stent stenosis. On this background I cannot really understand why the study of Kwon was excluded since the aim of this search was to identify all material as a starting point and the proposed study should yield definite results. In the context of the proposed study it would also be necessary to comment on the accuracy of CTA in comparison to DSA in more depths, because CTA is planned to be used as reference.

I am not sure, whether it is unethical to use DSA instead of CTA as reference. It is known that the accuracy of CTA in comparison with DSA is limited. So in the long run, we would end up with a non-invasive method with new ultrasound cut-off values which are of very limited accuracy compared to DSA because already the initial “goldstandard” was second best. In this respect it would also be necessary to take into account, that a therapeutic intervention would very likely need preinterventional or interventional DSA anyway. On the other hand I understand, that it would be difficult to enrol enough patients to bring such a study to an end. The inaccuracy of ultrasound, which would be still acceptable obviously depends on the situation when a new therapeutic intervention is necessary. Perhaps the authors should comment on this last point and try to define “points of intervention” from the existing literature.

Although it is not intended to use DSA as the sole standard, at least the postinterventional DSA result and DSA at the point of a planned new intervention or perhaps at the point of in-stent stenosis > 70% according CTA could serve as some “anchor points”.

It seems that the authors intend to define velocity cut-offs only. However, since often in-stent stenosis is caused by intimal hyperplasia it might be better to try to also define additional duplex criteria. In-stent stenosis often is not localised such
as in atherosclerotic proximal ICA stenosis.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests