Clinical Radiology 74 (2019) 726–727

Contents lists available at ScienceDirect

Clinical Radiology

journal homepage: www.clinicalradiologyonline.net

Correspondence

Re: MRI in otology: applications in cholesteatoma and Ménière's disease

Sir — Recently, Lingam and colleagues published a review on the use of diffusion-weighted imaging (DWI) magnetic resonance imaging (MRI) in the imaging of middle-ear cholesteatoma.[1] In this review, as well as in the meta-analysis paper of 2017, Lingam and colleagues remark that a large multicentre randomised controlled trial (RCT) is needed to evaluate the cost-effectiveness of DWI compared to second-look surgery.[1,2]

In 2016, we set up such a multicentre study, including an RCT in the Netherlands, entitled Dutch Cholesteatoma Data (DCD; trial no.: NL5899). The main research question of this RCT was to determine the cost-effectiveness of MRI DWI compared to second-look surgery in the follow-up of cholesteatoma surgery. Alongside the RCT, we collected observational and quality-of-life data from all our participating centres.

We encountered difficulties throughout the conduct of the study, especially with the inclusion of patients, and were finally compelled to stop the RCT; however, the study is still ongoing to answer additional research questions. In reaction to the suggested research question, we would like to share the set-up of our study and the reasons why we could not succeed in answering this important research question.

In the DCD study, 16 hospital-based otolaryngology centres spread across The Netherlands are participating. Adult cholesteatoma patients were included in the RCT after their surgery. The inclusion criteria were (a) age >18 years; (b) canal wall-up surgery for cholesteatoma ≤ 11 months ago; and (c) a primary or recurrent cholesteatoma. Exclusion criteria were (a) pregnancy and (b) not willing or able to undergo DWI MRI. After inclusion, patients were randomised to two arms, either the MRI 3-year annually or second-look follow-up strategy. The presence of cholesteatoma, hearing, complications, complaints, and costs were all monitored.

We had to stop the RCT for three reasons: first, both the patient and the otolaryngology surgeon commonly prefer DWI MRI in the follow-up of cholesteatoma instead of second-look surgery. Patients view second-look surgery as stressful due to the impact of surgery on daily life, work situation, and the possible complications that can arise. This led patients who met the inclusion criteria to choose not to participate in the RCT as they almost all preferred MRI and did not want to have the study allocate them to surgery. Furthermore, the unknown cost-effectiveness question does not seem to concern the individual patient when offered participation in an important RCT. Lastly, it seems that second-look surgery has been caught up by the MRI technique, and the MRI technique is almost fully implemented as the standard follow-up method of choice. The set-up of our study was appropriate to address the research question, but by the time we obtained approval to start patient recruitment, it seemed that many otolaryngology surgeons had already counselled their patients in favour of MRI. In order to still pull off an RCT, the time of inclusion and the actual implementation of the MRI are crucial. Once the patient has the idea that MRI is an equal option to second-look surgery, they do not want to be randomised.

Although the RCT study was stopped, a few welcome side effects arose. An overview of current cholesteatoma care practice containing observational data from the multicentre DCD study has been achieved. In addition, we have established, by means of a consensus method, a framework for uniform registration of cholesteatoma care in The Netherlands.

All in all, we support the quest to find the answer to the cost-effectiveness question, but practical implementations of an RCT comparing a MRI versus surgery should have been done as soon as the new MRI method was gaining ground, not at the point when it is almost fully accepted and easily accessible.'

Conflicts of interest

The authors declare no conflict of interest.

https://doi.org/10.1016/j.crad.2019.05.021

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