



When East meets West

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A report entitled ‘Evaluation of HIFU Ablation for uterine fibroids: an IDEAL Prospective Exploration Study’ was led by Professor Jinghe Lang, a member of the Chinese Academy of Technology.

Chinese researchers have been leading the R&D of high-intensity focused ultrasound surgery technology and its clinical applications for more than 20 years, but worldwide clinical dissemination has been hindered by the lack of systematic and high quality clinical evaluation. The study by Lang et al. presents a snapshot of the rising emergence of evidence-based clinical research in China and represents a leap forward that has overcome the inadequacy in research methods to produce high-quality evidence-based outcomes.

The study benefitted from the collaboration with the Surgical Trial Unit at Oxford University for the trial design. It was designed as a prospective multi-centre patient choice cohort study (IDEAL Exploratory study). The IDEAL framework is an innovative clinical trial scheme developed specifically for the evaluation of new surgical technologies that require a different scheme of evaluation than the drug trials.

This study is the first state-funded multi-centre clinical trial for the post-marketing evidence-based evaluation of medical devices. It deployed 20 medical centres in China and enrolled 2411 Chinese women with symptomatic fibroids. The high quality of the trial was supported by the National Engineering Research Centre of Ultrasound Medicine (NERCUM) and the Chinese Cochrane Centre: NERCUM provided the technological support and clinical training of focused ultrasound surgery for the 20-centre study and the Chinese Cochrane Centre provided services in the trial registry, design, data collection, quality control, data analysis and evaluation.

Through the joint efforts of the 20 participating centres, the patients, NERCUM, the Chinese Cochrane Centre and IDEAL, this study demonstrates the feasibility of implementing this new surgical technology in a variety of clinical environments. It has produced, to date, the most convincing clinical research evidence establishing the efficacy, safety and social economic benefits of HIFU for the management of uterine fibroids, a worldwide health threat to

women’s health. However, this evidence, along with that generated collectively by the HIFU research community, are not sufficient to justify HIFU use over the current treatment modalities for the management of this disease. Nevertheless, the findings of this study support the need for an RCT to establish definitively HIFU as a standard of care for fibroids. In addition, long-term follow-up RCTs are required to determine the impact of HIFU treatment on the outcome of pregnancy in order to demonstrate the social economic advantages of uterine preservation using this technology over other treatments.

When East meets West in harmony, we witness the creation of a new international platform for accelerating the translation of innovations in medical technologies to the patients’ bedside by conducting high quality cost-effective clinical evaluations. This is just the beginning; the best is yet to come.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information. ■