

A call for expressions of interest in a comparative study of the options for pre-emptive aortic root surgery for people with Marfan syndrome

More than thirty patients have now had personalised external aortic root support. The evidence is that this strengthens and stabilises the aortic root indefinitely in people with Marfan syndrome.

- (1) The technique has successfully undergone technology appraisal by the National Institute for Health and Clinical Excellence (NICE).
- (2) It now requires comparative evaluation with other forms of surgery.
- (3) The British Heart Foundation has expressed interest in funding such an evaluation.
- (4) A requirement is that we can show sufficient interest and assemble a group willing to join in development of a suitable study design.

What we know so far:

- Efficacy and reproducibility of the technique have been demonstrated in a rigorous masked study of repeated MRI images.
- Perioperative and procedural advantages over root replacement have been quantified in a comparative study.
- The macroporous mesh becomes incorporated in the vascular adventitia creating a stable composite vascular structure. Dissection within the support appears unlikely as evidence accrues; this is not just an external “wrap”.
- We are submitting for publication 1- to 9-year results in the first 30 patients (average 4.4 years). No aortic, neurological or valve related events were seen in 140 patient years of follow-up.
- The results to date compare favourably with valve sparing root replacement.
- External aortic root support has favourable NICE technology appraisal.
- Comparison of EARS with valve sparing root replacement appears favourable.

The proposal to British Heart Foundation

We are proposing an inclusive Big Aortic Root Study (BARS). Already on board from the advisory/methodological point of view are:

- Imperial College/Clinical Trials and Evaluation Unit at Royal Brompton Hospital
- Colin Baigent in Oxford
- Graeme Hankey at the University of Western Australia

The proposed design includes documenting the assessment and information given to patients who are being monitored with a view to aortic root surgery. What is envisaged is an inclusive overarching observational study and within it, the option of random allocation at (two or more) decision making nodes where clinicians and patients recognise that there is uncertainty in the decision making algorithm.

What we now need are:

- (1) Expressions of support for this study being done from people involved in the care of people with Marfan syndrome.
- (2) Amongst those, a smaller core group who would be interested in developing the study with an appropriate and workable design.

All published papers can be found at <http://www.marfanaorticrootsupport.org/>

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