



BRISTOL HEART INSTITUTE
 University of Bristol
 Bristol Royal Infirmary



Clinical Trials and Evaluation Unit Newsletter

Long term monitoring of cardiac surgery patients

The long term monitoring programme continues to be successful with 4500 patients taking part. In 2004 82% of patients we wrote to returned a completed questionnaire. Many patients have used the questionnaire to give us feedback on their stay at the BRI and to let us know how their cardiac operation has changed their life. Comments include:

- ◆ 'I cannot praise enough the efforts of all those in the cardiac department'
- ◆ 'Please thank all those who helped with my recovery'
- ◆ 'Thank you for giving me years more life'
- ◆ 'Feel better than I have for many years since operation'
- ◆ 'Able to do things I haven't been able to undertake for considerable time'
- ◆ 'Going on 80 - feel like 18',

GPs are continuing to help us with our research. 94% of GPs have returned questionnaires to us where patients have given us permission to contact them for additional information. This, together with the information provided by patients, has allowed us to review the services we provide and show us where improvements in patient care can be made. We are very grateful to all those who are taking part as it is an invaluable aid to research.

BHACAS (Beating Heart Against Cardioplegic Arrest Studies)

The BHACAS studies took place between 1997 and 1999 and compared on and off pump surgery. Results published after 2 years of follow-up showed that off-pump surgery is associated with fewer complications. It is now at least 5 years since these patients had their operations, and we are in the process of performing further follow-up to see if off-pump surgery continues to be superior. This involves asking everyone who took part in BHACAS to complete a questionnaire about their current health and quality of life. We will also be performing non-invasive scans of the grafts so that the quality of the grafts at this stage can be compared.

What is on and off pump surgery?

Traditionally all open heart surgery was performed on a non-beating heart with the aid of the heart bypass machine pumping blood around the body. This is on-pump surgery. Recent advances in surgical techniques mean that some cardiac operations can be performed whilst the heart is still beating, and the heart bypass machine is not needed. This is termed off-pump surgery. Not all cardiac operations can be performed off-pump, but at the BRI about 60% of cardiac artery bypass graft operations are now performed off-pump.

The EXTENT trial: using science to improve existing surgical techniques

Bypass grafting using leg veins is a very effective surgical treatment for advanced coronary heart disease, but sometimes the initial benefits of the operation can be lost over the following years. This is because the vein grafts themselves can become blocked like the original coronary arteries. Many attempts have been made to prevent this, including variations in surgical technique and using drugs. Here at the Bristol Heart Institute a collaboration between basic

Why are trials randomised?

Randomisation is equivalent to tossing a coin to decide which treatment to give. This is the best way of comparing two treatments if it is not known which is better. This is because if the randomisation is done properly, the two groups of patients will be comparable in terms of age, gender and underlying disease etc. This means that any differences between the groups after the treatment should be due to the treatment received. If it is left to the researcher or doctor to allocate the treatment, they may have preconceived ideas of which is better and this may influence their decisions.

scientists and cardiac surgeons, stretching over the past 10 years, has resulted in a radical new therapy. This involves wrapping the vein in a stocking-like material during the bypass operation so that it will be continuously supported during its life as a graft. In experimental studies this has had a dramatic effect in reducing the thickening of the graft wall. Surgeons at the BRI are about to embark on the EXTENT trial which will evaluate this new therapy in patients for the first time. State of the art intravascular ultrasound equipment will be used to see if the new therapy improves the performance of the vein graft.

Update of ongoing trials in this department:



The CARDIA trial is the first randomised study comparing modern angioplasty using new drug eluting stents with cardiac artery bypass grafting for the growing diabetic population with coronary artery disease. Traditionally bypass surgery was recommended for diabetic patients with multiple narrowings in their arteries, but it is hoped that recent advances in angioplasty technology such as drug eluting stents will make angioplasty as effective as surgery in these patients. Drug eluting stents are small mesh tubes that are inserted where the artery was narrowed to help keep it open. They are coated with drugs that also help keep the artery clear, and these drugs can be given in tiny doses as they are delivered by the stent to the exact place they are needed. These new stents are now being used in routine clinical practice in the UK in accordance with government and hospital guidelines. CARDIA is coordinated by the Hammersmith hospital in London, with 22 participating centres in the UK and Ireland. At the moment 332 patients have been recruited, which is more than halfway to the target of 600 patients. At Bristol we have recruited 18 patients, and are actively looking for suitable patients on a daily basis.

EPIDURAL This study is looking at the potential benefits of using epidural anaesthesia alongside general anaesthesia for cardiac operations. It is hoped that 300 patients will be recruited on to this study, to be randomised between general anaesthesia alone or with epidural. We have almost 100 patients so far. Collaborators in Italy are also running a similar study, and we plan to pool our results to make the study even stronger.

Cardiac support groups

If you are interested in joining a cardiac support group in your area, the British Heart Foundation has about 300 affiliated groups in England and Wales. Activities vary from group to group, but may include a listening service, exercise classes, regular meetings or invited speakers on a wide range of topics. For more information about groups in your area, please contact the BHF Cardiac Care Administrator on 0207 487 7110 or if you have access to the internet you can use their Website: www.bhf.org.uk



We gratefully acknowledge the support of:

- The British Heart Foundation
- The Garfield Weston Trust
- NHS R&D Health Technology Assessment Programme

Clinical Trials and Evaluation Unit:

Lucy Culliford, Chris Rogers, Harpreet Seehra, Barney Reeves and Jan Wild