Manubrium Limited Mini Sternotomy Versus Conventional Sternotomy for Aortic Valve Replacement: A Randomised Controlled Trial

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Background
Open heart surgery to replace one of the valves in the heart (the aortic valve) is a commonplace NHS procedure. Patients needing this operation suffer symptoms of chest pain, shortness of breath and dizziness caused by the valve becoming narrow (aortic stenosis) or leaky (aortic regurgitation). To replace the valve, the operation usually involves cutting the breast bone completely (from the collar bone to the bottom of the breast bone); this is called a sternotomy. At least one in three patients who have this operation bleeds after the operation to the extent that they need a blood transfusion. This has risks for the patient such as difficulty breathing, confusion, an increased chance of getting an infection or dying, and a longer stay in hospital.

A new operation has been developed which means that a much smaller part of the breast bone needs to be cut to replace the valve; this operation is called a manubrium-limited ministernotomy. Early results from The James Cook University Hospital suggest that fewer patients need a blood transfusion after a manubrium-limited ministernotomy than after a conventional sternotomy. This means that patients may recover faster and be fit to go home sooner, which is better for patients and for the NHS. We now need more information to be sure whether or not the new operation is better.

Study aims

Primary objective
The primary objective is to determine the proportion of patients who receive a post-operative red blood cell transfusion within 7 days of aortic valve replacement (AVR) via manubrium-limited ministernotomy or conventional sternotomy.

Secondary objectives:
- the number and proportion of patients who receive a red blood cell transfusion and the number of units transfused,
- the number and proportion of patients receiving platelet transfusion or receiving fresh frozen plasma transfusion and the number of units transfused,
- postoperative blood loss,
- operative success as defined by echocardiographic assessment,
- post-operative changes in haemoglobin (Hb),
- post-operative changes in inflammatory markers,
- post-operative sternal wound pain,
- re-operation rates,
- rate of conversion to conventional AVR,
- changes in lung function tests,
- quality of life,
- time to which patients are fit for discharge from hospital,
- health care utilisation,
- cost and cost effectiveness,
- adverse event profiles.

Study design
A single centre, single-blind, randomised controlled trial comparing the proportion of patients undergoing AVR using manubrium-limited ministernotomy and conventional median sternotomy that require red blood cell transfusion.

The study aims to recruit 220 patients in a single NHS Trust in the North of England. Patient assessments will continue until 12 weeks after discharge from hospital following their index AVR operation.

Study procedures
Male and female patients undergoing isolated AVR surgery will be identified at the point of referral or from the inpatient waiting list and approached about participation in MANVIRC. Patients will be consented by a Consultant Cardiothoracic Surgeon or a Surgical Registrar. Eligible patients will be randomised to receive AVR by manubrium-limited ministernotomy or by conventional sternotomy. Patients will be eligible for the study if they are aged 18 or over at the time of consent, require first-time, non-emergency, isolated Aortic Valve Replacement surgery; and are able and willing to provide written informed consent. Patients will be excluded if they: require concomitant cardiac procedures; have a haemoglobin level < 90g/L; are pregnant; have received previous cardiac surgery; are unable to stop currently prescribed treatment affecting clotting; have a haematological condition that would affect participation in the trial; have infective endocarditis; are prevented from having red blood cells and blood products according to a system of beliefs; or have any other medical, psychiatric and or social reason that precludes participation.

For patients receiving manubrium-limited ministernotomy, the operation divides only the top quarter of the sternum from the sternal notch to 1cm below the manubro-sternal junction. For patients receiving conventional median sternotomy, the operation will involve a midline incision from the sternal notch to the xiphisternum. Procedures for both operations will be standardised; full details are included in the protocol.

This trial is currently open to recruitment at South Tires Hospitals NHS Foundation Trust

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