The Excel trial – BBC Newsnight, 9 December 2019

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On December 9th 2019, BBC Newsnight broadcast a 10 minute report about the Excel trial and its results. The Excel trial was a comparative trial of stents vs surgery in patients with disease affecting the left main coronary artery. Many NHS patients were enrolled in the trial, in a number of UK Hospitals. The Newsnight report raised concerns about the conduct and results of the trial, and in particular questioned whether stents can be safely recommended for the treatment of left main coronary artery disease.

Unfortunately, the limited time of the programme restricted explanation of the context of the Excel trial. This background information would facilitate informed discussion by patients and non-specialist cardiovascular physicians/surgeons. Regrettably, the BBC did not contact BCIS for comment and there was no informed counter discussion around the issues raised. The alarmist manner in which the trial was discussed has caused anxiety in patients with heart disease that have had stents and may cause confusion and concern for patients that are currently awaiting treatment with stents.

British Cardiovascular Intervention Society (BCIS)

BCIS has over 2000 members and it represents the specialist interventional cardiology community who provide care for patients with obstructive disease of their heart arteries. Members are both doctors and nurses and allied health professionals. BCIS encourages and facilitates the discussion of clinical trials through publications and providing forums for trial discussion.

Coronary stents

Coronary stents are devices used to relieve obstructive disease of the coronary arteries. They are commonly implanted as a day case procedure and outcomes are excellent. When implanted in patients with angina they are a safe way of reducing symptoms and when used in patients presenting with a heart attack they save lives and allow a rapid return to a good quality of live. Thousands of coronary stents are placed in the UK every week by dedicated medical teams working 24 hours a day, 7 days a week to care for some of the most acutely unwell patients. Historically coronary stents had some limitations but careful clinical trials performed together with the medical device industry have improved long term outcomes dramatically.

The Excel trial

As the clinical outcomes from stents have improved it has become apparent that many patients might be able to avoid bypass surgery and have stents instead. Having stents is a less invasive procedure and allows a quicker return to a normal life style. Deciding which patients should have stents and who should have surgery can be complex (especially when there are a number of narrowings in multiple arteries) and these decisions are usually shared by surgeons and cardiologists- the Multi-Disciplinary Team (MDT) or heart team.

The Excel trial randomised a proportion of patients with a specific pattern of heart disease – disease affecting the left main coronary artery (about 10-15% of all patients with coronary

disease requiring revascularisation). Historically, this pattern of disease was thought to be particularly suitable for bypass surgery but in view of the considerable progress with stent technology, it was felt appropriate to compare the two treatments- head to head. The conditions of an ethically approved trial are set out at the beginning and the comparison within Excel was agreed by teams of both surgeons and cardiologists. The main finding of the trial – the primary endpoint suggests that stents and surgery were similar in their safety and effectiveness for the treatment of left main coronary artery disease. The concerns about various definitions of heart attack raised by the BBC will not change this principal finding which has been published in the New England Journal of Medicine.

Although the trial was funded by a commercial stent company it was conducted by independent investigators and an independent trial organisation. It has already provided a wealth of information which has informed heart teams in their daily decision making.

Clinical Guidelines

Guidelines are created to inform clinicians about existing trials and to try and allow data from trials to be translated into clinical practice. The committee members are clinical scientists used to analysing data. The recent ESC/EACTS/EAPCI Guidelines cover the complete range of coronary disease and make a number of clear recommendations. Management of left main artery disease (the subgroup of patients studied in the Excel trial) is covered in the Guideline and a number of other trials were also considered including Syntax, Combat and Noble as well as Excel. After consideration of all of these trials, the Guidelines concluded that stents can be appropriately used to treat some patients with left main coronary artery disease. BCIS continues to endorse the existing ESC Guideline and that some patients with left main disease should be considered for stents, whereas others are optimally treated with bypass surgery. This decision should be made by a multi-disciplinary heart team in conjunction with each individual patient.

Medical devices industry

BCIS has a collaborative partnership with the devices industry. Both partners are dedicated to improving outcomes for patients. Without industry investment the dramatic improvements we have seen in technology and consequently outcomes would not have been possible.

Conclusion

Patients undergoing stent procedures in the UK can be reassured that stent technology is a safe and effective treatment. When their disease is complex and there is uncertainty about which treatment may be optimal, including specifically when they have left main disease, they will be discussed by a multi-disciplinary heart team. The outcome of this discussion will be shared with patients in order to reach a final decision.

Prof Adrian Banning
President of BCIS on behalf of BCIS Council

Prof Banning was an investigator in the Syntax , Noble and Excel trials of left main disease. He was a member of the recent ESC/EACTS/EAPCI Guideline Committee. He has received reimbursement from stent manufacturers for speaking at educational events.