Concerns over minimally invasive heart valve surgery

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A new type of heart valve surgery known as transcatheter aortic valve implantation "cannot be justified on medical or cost effectiveness grounds" warn experts in a paper published in BMJ today.

Hans Van Brabandt from the Belgian Health Care Knowledge Centre and colleagues describe the procedure as "risky and costly" and call for better regulation and transparency around the use of such high risk medical devices.

TAVI is a minimally invasive surgical procedure for patients with aortic valve disease who are too old or too ill for conventional open heart surgery. In patients who are suitable for conventional surgery, survival after TAVI is equivalent to conventional surgery, but the risk of stroke is higher. TAVI is also much more expensive than conventional surgery.

Since its introduction 10 years ago, around 40,000 procedures have been carried out worldwide.

TAVI is classed as a medical device. In Europe this means it needs only a simple quality certificate (CE mark) to gain access to the market, putting TAVI on the same footing as domestic appliances such as toasters. In contrast, the US Food and Drug Administration (FDA) demands trial evidence before it can license any innovative device. Thus TAVI was in use in Europe four years before the US.

However, guidance from the UK National Institute for Health and

Clinical Excellence (NICE) says that the evidence for TAVI in patients who are suitable for conventional surgery is "inadequate."

The authors agree. After rigorous analysis of all the available data, combined with a study of real world TAVI practice in Europe, they conclude that "the arguments supporting the widespread use of TAVI do not stand up to scrutiny."

They also raise concerns about access to full trial data on TAVI and a lack of disclosure of financial interests among trial investigators.

They believe that Europe's regulatory system "should require high quality randomised trials to show clinical efficacy and safety before granting marketing approval to innovative, high risk medical devices."

They also call for a major improvement in transparency of information "to allow clinicians to practise evidence based medicine, patients to make informed decisions, and health technology assessment agencies to make the right judgements."

More information: Paper online: www.bmj.com/cgi/doi/10.1136/bmj.e4710

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