NHS Commissioning Board

Clinical Commissioning Policy: Transcatheter Aortic Valve Implantation (TAVI) For Aortic Stenosis

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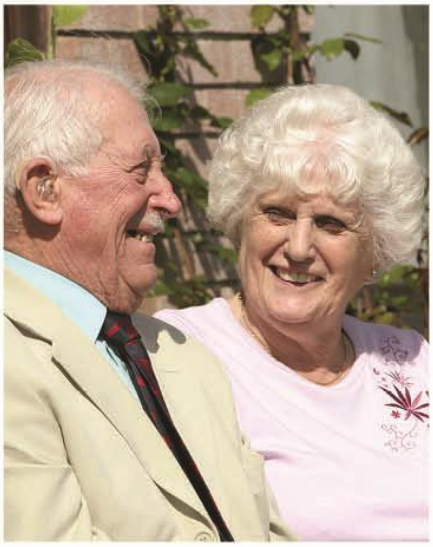

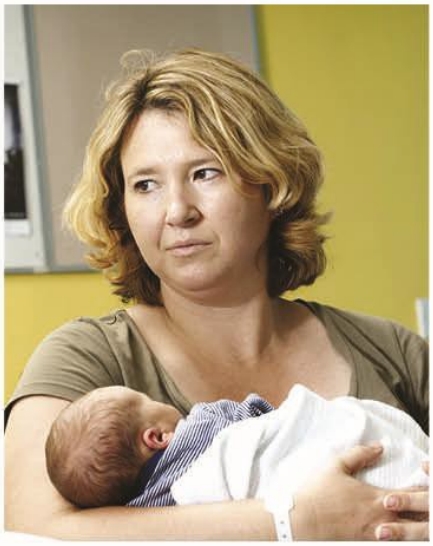

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NHS Commissioning Board

Clinical Commissioning Policy: Transcatheter Aortic Valve Implantation (TAVI) For Aortic Stenosis

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Specialised Cardiology

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Policy Statement

The NHS Commissioning Board (NHS CB) will commission Transcatheter Aortic Valve Implantation (TAVI) as an alternative to standard surgical aortic valve replacement in accordance with the criteria outlined in this document and in the context of ongoing research and evaluation. The continuation of services in future years will be dependent on the emerging evidence of benefit, safety and cost-effectiveness.

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

Patients whose aortic valve (one of several in the heart) is not functioning effectively, usually because of narrowing (or stenosis), require a valve replacement which is conventionally done through open heart surgery. For some patients the risk of surgery is too high. TAVI is an alternative and less invasive way of replacing a diseased aortic valve by using a catheter (a thin tube) and the body's blood system to access the heart.

The scientific evidence on the benefit of TAVI to date is uncertain. Long term outcomes and safety are not yet understood, nor is it clear which patients are likely to benefit as many elderly patients have other serious illnesses that will affect their chance of a successful long term outcome.

TAVI is funded for patients who are judged by a specialist team, in agreed cardiac centres, to be at too high a risk for open heart surgery, primarily as a result of other conditions (co-morbidities).

Information on the outcome of TAVI will be collected nationally and considered along with new scientific evidence when this policy is reviewed.

1. Introduction

Transcatheter Aortic Valve Implantation (TAVI) is a new therapy which may be used as an alternative to standard surgical aortic valve replacement. The procedure is performed on the beating heart without the need for a sternotomy or cardiopulmonary bypass and involves replacing a diseased aortic valve, usually one with narrowing or stenosis, with a new valve. Two TAVI devices have been CE marked up to 2012 and the procedure may be performed via the transfemoral, subclavian, direct aortic or transapical approaches.

While the opportunity for less invasive surgery with a shorter recovery period is always attractive to patients, the evidence of benefit to date for patients who might have TAVI is uncertain. The long term outcomes and safety of TAVI are not yet understood nor is it clear which patients are likely to benefit as many elderly patients have serious co-morbidities that will affect their chance of a successful long term outcome.

2. Definitions

Transcatheter Aortic Valve Implantation (TAVI) is a means of replacing a diseased aortic valve in the heart through a catheter-based approach rather than the conventional approach of open heart surgery. Surgical aortic valve replacement (AVR) is a major operation that requires that patients have a reasonable level of fitness to survive, and benefit from, the procedure.

The TAVI procedure is an elective one that requires detailed assessment of the patient and agreement from a multidisciplinary team (MDT) in a cardiac centre that a patient is appropriate for TAVI.

3. Aim and Objectives

In order to justify national commissioning of TAVI, the following questions need to be addressed:

- Do patients judged potentially suitable for TAVI, and unsuitable for surgery, do better than if they had received conservative or standard treatment?
- Will patients needing aortic valve replacement but judged to be at high risk for surgery do as well from having TAVI as if they had had surgery?
- Will ongoing evaluation of the procedure and the outcomes for patients (both short and long term) demonstrate that TAVI is beneficial for patients and good value for the NHS?

The overall aim of a TAVI service is to investigate and assess patients with severe

symptomatic aortic valve disease (including prosthetic valve stenosis) and to determine which patients are likely to benefit from a TAVI procedure. The anticipated benefit should be an improvement in both survival and quality of life. Patients considered fit for conventional aortic valve replacement surgery should still be offered surgery in the first instance although trials comparing TAVI with aortic valve replacement surgery in patients who are suitable for conventional surgery, but are at higher than average risk, are planned.

4. Criteria for commissioning

TAVI for aortic stenosis will be commissioned and funded through agreed cardiac centres that meet the requirements of the standards specified in this policy and the service specification covering this clinical area.

The number of TAVI procedures to be funded will equate to a level of 25 per million population across England, a total of at least 1,250 procedures.

TAVI services are at different stages of evolution across England. In 4 of the 28 cardiac networks, TAVI implant rates for 2011-12 are greater than 30 per million. For these areas, we recommend that commissioners consider commissioning at 2011-12 out-turn rates or consider individual referrals above the level of 25 per million.

Patient selection will be through a multidisciplinary team (MDT) and a set number of procedures will be funded for 2013-2014 at each centre. At each cardiac centre where TAVI is funded the MDT will need to prioritise patients that are most likely to benefit within the agreed annual number and should monitor referrals on a geographical basis. These cardiac centres will be expected to participate in any ongoing research trials.

TAVI can be funded in patients who are judged to be at too high a risk for operation if the inoperability is primarily the result of anatomical limitations and their life expectancy is not significantly compromised by concomitant severe medical conditions.

The MDT is the forum where a mix of the appropriate specialist interventional cardiologists, cardiac surgeons and other clinicians makes an assessment of whether a patient with severe aortic stenosis needs and is suitable for surgery, TAVI or optimal medical therapy. The decision making will be supported by appropriate investigations and risk assessment tools, such as the EuroSCORE or STS score, which are used to predict the mortality risk associated with surgery. Aortic valve replacement should not to be used as a “rescue” procedure where the patient has a limited life expectancy, possibly linked to other co-morbidities, and any interventional procedure is unlikely to change the patient outcomes or benefit the patient overall.

The key criterion for deciding which patients should have TAVI is that patients who are potential candidates are considered by an appropriate MDT. The MDT of a cardiac centre that meets the governance arrangements for TAVI will be expected to

decide upon, and schedule, the number of TAVI cases at regular intervals throughout the financial year so as to meet the agreed number of cases for that centre and not to exceed this limit nor to submit individual requests. Patients who might be eligible for TAVI will need to be prioritised so as to meet this scheduling requirement.

In the absence of definitive evidence and guideline recommendations, the determination of inoperability in any given patient depends on the judgment of the medical team. It is generally agreed that patients with limited life expectancy due to concurrent conditions such as malignancy, dementia, primary liver disease, chronic obstructive pulmonary disease (COPD), among others, are not appropriate for AVR.

Frailty and related conditions of debility and deconditioning are known to result in inability to recover from major heart surgery such as AVR, despite operative survival and hospital discharge. These conditions can potentially contribute to increased surgical mortality and morbidity in the elderly. A substantial percentage of patients with aortic stenosis (AS) are judged to be inoperable for surgery based primarily on the physician's or surgeon's determination of operative risk and survivability. Although some patients may be found to be inoperable for technical and surgical reasons, most inoperable patients are felt to be too ill from associated comorbid conditions.

TAVI can be funded in patients who are judged to be at too high a risk for operation if the inoperability is primarily the result of anatomical limitations, such as extensive aortic calcification (so-called "porcelain aorta"). These patients are relatively easy to identify clinically, their life expectancy is not compromised by concomitant severe medical conditions and they represent the population in whom TAVI is likely to be cost effective.

5. Patient pathway

Patients with aortic valve disease and heart failure who might be considered as eligible for aortic valve replacement should be referred from cardiologists or other specialists in district general hospitals to cardiac surgeons or interventional cardiologists in a specialist cardiac centre. This should be in line with the specialised service specification for cardiology and cardiac surgery.

Direct referrals to cardiac centres from primary care and general practice requesting consideration for TAVI are not expected. In the first instance these should be local referrals for specialist cardiac assessment of a patient.

6. Governance arrangements

The governance arrangements are based on the consensus statement of the British Cardiovascular Intervention Society (BCIS) and the Society of Cardiothoracic

Surgeons (SCTS), (March 2009)[1]

Transcatheter Aortic Valve Implantation (TAVI)

(1) TAVI should currently be reserved for patients who have been considered by a multidisciplinary team (including 2 surgeons and 2 interventional cardiologists) who consider the risk/benefit ratio of open heart surgery and TAVI to favour TAVI. The usual "high risk" patient will have a logistic Euroscore of >20 or an STS score of >10.

(2) In general TAVI should be performed for symptomatic severe degenerative aortic stenosis. Under exceptional circumstances and after full discussion within a multidisciplinary team, other forms of aortic valve disease such as a failing aortic bio-prosthesis may be treated.

(3) TAVI should be performed by a multidisciplinary team (MDT) drawn from a minimum of 2 interventional cardiologists, 2 cardiothoracic surgeons, cardiac anaesthetists and cardiac imaging specialists.

(4) Patients should be screened into a TAVI programme by this MDT team and not by any individual speciality.

(5) There should be formal training of the implanting team which should include:

- Didactic theoretical training.

- Simulator training if available.

- A visit to an experienced centre to observe TAVI cases.

- Support for the initial cases at any site by a proctor.

(6) Any hospital wishing to set up a TAVI programme should have the following minimum infra-structure available:

- The ability to set up an MDT (as above).

- Immediate availability of trans-thoracic and transoesophageal echocardiography.

- Availability of a dedicated cardiac catheter lab or hybrid theatre.

- A theatre with "C" arm screening facilities is generally not appropriate for TAVI procedures.

- CT scanning facilities.

- Immediate availability of perfusion services in case of the need for emergency femoro-femoral bypass.

- On-site availability of a surgical recovery area and intensive care with staff experienced in looking after patients following surgical aortic valve replacement.

- Robust arrangements for immediate renal support if necessary.

- Immediate access to vascular surgeons and interventional radiologists to

deal with major peripheral vascular complications.

- The above requirements will mean that this procedure should only be performed in a unit currently carrying out surgical aortic valve replacement.

(7) Any unit performing the procedure has to provide procedural, outcome and follow-up data, (in the form of the agreed BCIS/SCTS dataset), to a centrally held database for event tracking hosted by NICOR (National Institute for Cardiovascular Outcomes Research).

(8) It is the view of BCIS and SCTS that the TAVI procedure should be performed by centres which can provide the above infrastructure and that the procedure should only be carried out by highly experienced interventional cardiologists and cardiothoracic surgeons. We believe occasional practice and small volume TAVI units should be actively discouraged. It is difficult to stipulate a minimum number of cases per year for a TAVI programme. Competence is obviously more important than numbers. Given the learning curve and infrastructure needed we believe somewhere in the order of > 50 cases per year to be optimal.

(9) Finally we have carefully considered the question of the timing of further studies, in particular a randomised clinical trial. We believe that UK centres need to get beyond their learning curve before entering into a randomised trial. During this run-in phase centres must enter data using the agreed dataset so as to create a prospective cohort study (as described above). We believe that, at the correct time in the development of this technology, UK centres should be strongly encouraged to participate in a RCT. Equally we believe an RCT comparing TAVI with conventional AVR should be conducted before there is widespread dissemination of TAVI into a population who would be considered low/moderate risk for conventional AVR.

(10) In general we support the position paper produced and published by the European Societies (ESC & EACTS)

This position paper[2] concluded that TAVI is a promising technology but careful evaluation is needed to avoid the risk of uncontrolled diffusion.

7. Epidemiology and needs assessment

The natural history of aortic valve stenosis has changed in the past decades, possibly because more patients now survive long enough to develop symptomatic aortic stenosis. Patients presenting with severe symptomatic aortic stenosis present late in life, typically in their late 70s or older, and have predominantly fibrocalcific aortic stenosis (AS). The onset of symptoms heralds a rapid decline in functional status when treated with medical therapy alone. Despite substantial contemporary experience with successful surgical AVR in elderly patients, multiple series have documented that 30% to 40% of patients with severe AS do not undergo surgery owing to advanced age, left ventricular (LV) dysfunction, multiple coexisting conditions, patient preference or physician recommendation.

There are currently no reliable estimates of the number of patients in a population who might benefit sufficiently from TAVI as research has not yet delineated the characteristics of the these patients. A survey across the ten Specialised Commissioning Groups (SCGs) in 2010 showed that some SCGs were funding TAVI at a level equivalent to 16 per million of their population, whilst some regions had no formal funding arrangements. Figures for TAVI cases from the UK TAVI database suggest that there has been a progressive increase in cases.

Within the Clinical Reference Group (CRG) there were differing views about whether a recommendation should be made about the number of TAVI procedures to be commissioned. Some felt that NHS CB should fund ~~any~~ requests in line with the defined clinical selection criteria in the policy. The CRG members who held this view The argued that some areas of England already had well developed referral pathways for TAVI and might identify patients who fulfilled the defined criteria at a rate higher than 25 per million of population while other areas, with less well developed services, would identify fewer suitable patients. In this option, the numbers of procedures are not defined and the reliance is on clinical criteria alone to select suitable patients. This would lead to greater uncertainty around clinical and financial risks. The majority opinion of the CRG was that a number of procedures, probably around 25 TAVI procedures per million of population, should be identified in the commissioning policy at least until the evidence of which patient groups stand to benefit from the procedure is more clearly defined.

The SCTS database[3] provides a detailed analysis of the current outcomes with surgical AVR in the UK. Whilst overall mortality is low and the outcomes are good there are patients with a number of risk factors who have relative poor outcomes in terms of morbidity and mortality. It is the group of patients who are judged to be a high risk for surgery where the research interest around TAVI is currently focussed.

8. Evidence Base

When TAVI was first reported, the mortality appeared high. However, it was difficult to generalise as the patients in these series often appeared to have a high number of co-morbidities or the selection criteria were not clear. A number of clinical databases have now been established and are starting to generate important analyses of the patients currently undergoing TAVI. Morbidity and mortality appear to be improving; it is thought that some of this relates to improving operator technique but some of the improvement almost certainly relates to better patient selection by MDTs.

Two large Randomised Controlled Trials (RCTs), the PARTNER trials from the USA [4,5], and follow-up studies[6] to date are felt by some commentators to have demonstrated that TAVI does benefit patients at too high a risk to undergo surgery whilst AVR represents the best option for those patients fit enough for surgery.

PARTNER A[4] demonstrated similar rates of survival at one year but there are important differences in periprocedural risks. PARTNER B[5] , an RCT of TAVI in patients unable to undergo surgery reports better survival for TAVI but more side

effects and possibly biased selection of patients in favour of TAVI.

An earlier safety review[7] recommended that concerns preclude the use of TAVI outside of clinical trials.

A recent detailed review of published evidence[8] included comments from clinicians with expertise in the clinical area. One proposed option for commissioning recommended TAVI, in the context of the updated NICE IPG.[9] IPG421 identifies the evidence on the efficacy of TAVI for patients with aortic stenosis is adequate only for patients who are considered to be unsuitable for surgical aortic valve replacement. The potential for serious but well-recognised complications is noted.

Another evidence review did not recommend the use of TAVI in Scotland[10] but the authors will continue to review evidence.

A US Medicare statement[11] included an overview of the evidence for TAVI and caveats around its use for public funding in the USA through Medicare.

There are substantial criticisms of the PARTNER trials[12,13] particularly around whether the two groups that were randomised in the non-surgical randomised controlled trial (RCT) were equivalent and whether the rate of serious complications, such as stroke or major adverse cardiac events, is too high to be able to say that TAVI is reasonably beneficial.

> *Caution is advised when interpreting the findings of the PARTNER study. Critical analysis shows that, due to methodological shortcomings, the published results may have overestimated the clinical efficacy of TAVI. TAVI can only be considered in patients who are inoperable. If the inoperability is the result of anatomical limitations, then reimbursement of TAVI could be justified. These patients are easy to identify clinically, their life expectancy is not compromised by concomitant severe medical conditions and they represent the population in whom TAVI is the most cost effective…..*

The PARTNER trial does not provide an answer to questions regarding the efficacy of transapical TAVI in inoperable patients or the clinical efficacy of the CoreValve® prosthesis. No other sources were found that could change the KCE's standpoint with respect to its 2008 report [[14]]

Criticism of the growth of TAVI[12] states that the rate of increase in TAVI cases in a number of European countries is not justified by the current evidence. Many UK cardiologists involved in TAVI programmes agree that the implantation rates in some European countries seem high (and "ahead of the evidence base") but believe that the expansion of TAVI in England has been controlled and in line with the emerging evidence.

There are different techniques for delivering a TAVI device and it is not clear whether some of the different access approaches are justified in terms of benefit versus risk. Ongoing analyses from the database[15,16,17] may help to clarify some of this.

In terms of cost effectiveness there are an increasing number of analyses broadly suggesting that TAVI is cost effective. However, these analyses depend on the robustness of the clinical RCTs. There are still questions that need further clarification and more research is needed.

There are major RCTs looking at TAVI and a new trial is expected to be launched in the UK in Autumn 2012.[18] This is intended to be a pragmatic RCT looking at current NHS practice. This trial is particularly seeking to assess whether patients at high risk, but still eligible, for surgical AVR may benefit from TAVI as an alternative treatment. This trial is important as an analysis of clinical practice in the UK and has major implications for NHS funding. It is likely to be seen as complementary to the ongoing data collection for the UK TAVI database.

9. Rationale behind the policy statement

TAVI, as a relatively new intervention, is regarded as a procedure with an emerging evidence base. We recommend that TAVI is commissioned and funded as a number of procedures per million of the population as the evidence is not yet sufficiently mature to allow identification of the number of patients who are most likely to benefit from the procedure or to determine whether TAVI represents good value for the NHS. This is not the conventional approach to commissioning because the patient need ("the ability to benefit" from the intervention) is not yet fully defined and understood.

For those patients who are inoperable on the grounds of anatomical limitations, then reimbursement of TAVI is more easily justified. Their life expectancy should not be compromised by concomitant severe medical conditions and they represent the population in whom TAVI is a cost effective treatment.

TAVI services in England are at very different stages of evolution. Data for 2011-12 show a mean TAVI implant rate of approximately 20 per million for England. However, there is enormous geographical variance with implant rates in different cardiac networks varying from 4 per million to 46 per million.

We have recommended commissioning TAVI at a minimum rate of 25 per million pending further evidence. For most of England, this will represent controlled and clinically appropriate growth. However, the implant rate is already greater than 30 per million in 4 cardiac networks. This is likely to be a result of well developed services for identifying patients most likely to benefit. We recommend, therefore, that the rate of 25 per million should be regarded as a minimum and that commissioning of TAVI in areas where implant rates are already greater than 25 per million should be either be maintained at 2011-12 out-turn rates or commissioners should agree to consider individual requests above the level of 25 per million. Although TAVI is an elective procedure, there is a high mortality risk while awaiting the procedure. To restrict those areas of the country with higher implant rates to a figure of 25 per million would inevitably lead to longer waiting lists and to patient deaths while awaiting the procedure.

Given the current uncertainties and that there are ongoing RCTs, it is important that the overall funding of TAVI cases contributes to the evolving evidence base. The need for UK centres to participate in trials and to contribute high quality data to the UK TAVI database, hosted by NICOR, is a key part of this policy.

10. Mechanism for funding

Through the responsible Area Team

11. Audit Requirements

All TAVI cases should be submitted to the UK TAVI Registry in line with the dataset requirements http://www.bcis.org.uk/pages/news_box.asp?NewsID=19495422 .

This is hosted by NICOR (National Institute for Cardiovascular Outcomes Research).

12. Documents which have informed this policy

See references

13. Links to other policies

The mechanism operated by the NHS CB for funding requests outside of the clinical criteria in this policy is yet to be finalised.

14. Date of Review

During 2013

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