

## **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

### **Interventional procedures**

#### **Patient Organisation Submission**

### **Transcatheter valve-in-valve implantation for the treatment of aortic bioprosthetic valve dysfunction IP1013/2**

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

**Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.**

**NICE** National Institute for  
Health and Care Excellence

**NICE** National Institute for  
Health and Care Excellence

<b>About you</b>	
1. Your name	1. XX XXXX XXXXXXXX      2. XX XXXXXXXX XXXX  On behalf of British Cardiac Society / British Cardiac Intervention Society
2. Name of organisation	1. University Hospital Southampton 2. The James Cook University Hospital, Middlesbrough
3. Job title or position	1. Consultant Interventional cardiologist 2. Consultant Interventional cardiologist
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	NHS Foundation Trusts
<p>5. How did you gather the information about the experiences of patients and carers to help your submission? (For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)</p> <ol style="list-style-type: none"> <li>1. Both respondents have extensive personal experience of managing patients with symptoms relating to failure of tissue aortic bioprostheses. This includes initial clinical assessment, performance of relevant investigations and performing TAVI valve in valve procedures. Furthermore, respondents undertake active follow up of patients after valve in valve TAVI in order to assess clinical outcomes and symptom response.</li> <li>2. 4 patients who had undergone TAVI valve in valve procedures took part in telephone interviews, guided by a structured questionnaire. This was to assess the impact of procedures on everyday life from a patient centred perspective. The questionnaires and responses are attached as an appendix.</li> </ol>	

**NICE** National Institute for  
Health and Care Excellence

**NICE** National Institute for  
Health and Care Excellence

**Living with the condition**

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Transcatheter aortic valve replacement (TAVI) is used in the management of patients with degenerative aortic valve disease. The purpose of this document is to describe the application of TAVI valve technology to treat the subset of patients that have dysfunction of a pre-existing aortic valve surgical (or trans catheter) bioprosthesis. This may be stenotic or regurgitant.

Valve degeneration may be progressive and gradual, or sudden - usually as a consequence of non-infective leaflet failure. The symptoms of both stenosis and regurgitation are often similar. TAVI is generally not considered as a treatment for leaflet failure due to infective endocarditis, where surgical management is preferred.

The symptoms of a progressively failing valve are similar to native valve disease - namely gradual decline in exercise tolerance/capacity, breathlessness, chest pain, collapse (with associated loss of consciousness), and peripheral oedema. In cases of sudden leaflet failure, the onset of symptoms can be more acute, with rapid onset shortness of breath, associated with pulmonary oedema and occasionally haemodynamic collapse and shock.

Living with valvular heart disease is similar to other progressive debilitating illness, with a significant long term adverse prognosis. Patients will become increasingly limited in their day to day activities. This leads to frustrations, and a gradual decline in both physical and mental health as their care needs increase. Left untreated, severe bioprosthetic valve failure is fatal as a consequence of progressive heart failure. Both patients and carers will be made aware of this fact, and will need to prepare for this potential outcome.

Patients will have already undergone and recovered from one (or more) cardio-thoracic procedures, in the vast majority of cases requiring sternotomy. This often requires a minimum of 4-6 weeks convalescence with a phased return to normal day-day activities. The DVLA mandate 6 weeks off driving, and a 6 week period away from employment is usually recommended. Patients will often report that it takes around 3 months to feel well again after major cardiac surgery.

These are factors that are important to patients and their families/carers when clinicians identify that further valvular intervention is required. They have faced cardiac surgery before, and are acutely aware of the physiological and psychological impact that further surgery may have on the individual. Having discussed this with patients, they are often shocked that they will require further intervention, and may be disappointed with the longevity of the

currently implanted valve prosthesis. Re-do surgery carries with it an increased risk of major adverse complications, in a group of patients that are older, often frailer and more co-morbid than at the time of the original surgery. The risk of re-do cardiac surgery is often much more than double the risk of an identical patient undergoing first time surgery. Added to the older age group affected, the risk of second time surgical intervention is often considered prohibitive by health care professionals, patients and carers.

With respect to caring with a patient with established valvular heart disease, relatives will have observed the recovery from cardiac surgery, and the resolution of symptoms related to valve dysfunction. When these symptoms return, due to prosthetic valve failure, the patient is older, often with other associated co-morbidities, and may become more limited more rapidly. This can place additional burden upon carers, supporting patients through interventions that may be higher risk than previously undertaken.

In cases of sudden leaflet failure, symptoms may progress quickly, and become severe in a short period of time - often associated with haemodynamic compromise. In these circumstances, both patient and carers have to assimilate information rapidly, and make life changing decisions around patient care. Urgent surgery is associated with a further increase in procedural risk, and often the only realistic treatment option available to the heart team, is to recommend valve-in-valve TAVI.

In individuals with sudden leaflet failure, often intensive nursing and haemodynamic support is required before valve treatment and will usually require admission and treatment in a level 2 or higher cardiac unit. Correction of valve function with Valve in Valve TAVI, is less invasive than re-do cardiac surgery, and in our experience has a rapid recovery with associated reduction in hospital stay. There is however limited data in the literature in this particular population

**Advantages of the procedure or operation**

7. What do patients (or carers) think the advantages of the procedure or operation are?

The main advantages are:

- a) Less invasive approach, with a significantly shorter stay in hospital and quicker recovery time
- b) Rapid return to normal activities.
- c) Perception of decreased overall risk of major adverse complications - supported by registry data (ref J Int Cardiol 2018 Oct 31(5), JACC 2018;72:370-82)
- d) Equivalent mortality outcomes - although there has been no randomised data - and is unlikely to be.
- e) Low rates of TAVI related complications - lower risk of pacemaker implantation, lower major bleeding requiring blood transfusion, and lower rates of sternal complications.
- f) Ability to restore haemodynamics acutely.

**Disadvantages of the procedure or operation**



8. What do patients (or carers) think the disadvantages of the procedure or operation are?

The main disadvantages are:

- a) Uncertain valve longevity - physicians are unable to currently estimate valve longevity accurately due to a lack of longer term prospective data. To counter this point, VinV TAVI has been widely reported in the literature for over 10 years, with multiple large scale prospective registries having reported. There is no signal, to date, that V In V TAVI is associated with accelerated valve degeneration in the reported literature.
- b) Ongoing symptoms - a reflection of patient prosthesis mismatch. This is particularly relevant in patients in whom a small sized stented valve prosthesis has been implanted, and subsequently treated with TAVI. In particular, many 19mm and 21mm valve types are associated with an increased risk of high residual gradients due to the relative decrease in effective orifice area. This is a specific consideration for the heart team when making treatment recommendations. A new technique of balloon fracture of the original surgical valve at the time of TAVI has been described and is associated with greatly improved acute results, though the longer term risks and benefits are unclear at this time.
- c) Specific procedural risk - related to increased risk of coronary obstruction (depending upon prosthesis design), risk of aortic annulus disruption (particularly if valve fracture techniques are employed), and para/intravalvular regurgitation. That latter is less frequently observed than with native valve TAVI, but is a relative risk when compared to re-do surgery.

### Patient population

9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

1. Patients with very advanced age who have accrued multiple major comorbidities and / or who have become immobile may not derive improvements in overall quality of life.
2. There are some technical factors regarding the failing tissue valve which may increase the procedural risk of coronary occlusion or unsatisfactory valve gradients post TAVI.

The Heart Team / MDT is ideally placed to consider these factors once full investigations and assessments have been performed.

### Equality

10. Are there any potential [equality issues](#) that should be taken into account when considering this topic?

Yes. Older patients are more likely to be affected by bioprosthetic valve failure. There are two main reasons for this. First, traditional surgical practice has been to recommend mechanical valve replacements for younger patients with tissue valves being reserved mainly for older patients - commonly aged 65 or older. (Valve in valve procedures are not possible for mechanical valves). Surgical tissue valve lifespan is variable but often in the range of 10-15 years. Therefore tissue valve failure most often affects older patients than the average patient with severe native valve disease. Since the patients are both older and have higher risk due to prior sternotomy, repeat surgical valve replacement is often prohibitive and not offered. The above factors which increase risk of surgical intervention do not influence the risk of valve in valve TAVI to such an extent. If valve in valve TAVI were not endorsed, elderly patients would be disproportionately affected.

### Other issues

11. Are there any other issues that you would like the Committee to consider?

**Key messages**

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Bioprosthetic aortic valve failure is common, and is associated with major symptoms, reduced life expectancy and frequent hospitalisations.
2. Medical management is ineffective. If untreated, progressive heart failure causes major burdens on patients, carers and health care providers
3. Repeat cardiac surgery is associated with substantially higher risk than first time surgery – this is often prohibitive
4. Used in appropriate cases, valve in valve TAVI is associated with excellent clinical outcomes and improvements in quality of life.
5. Return to normal exercise capacity after valve in valve TAVI is commonly rapid and much quicker than after initial or re-do surgical valve replacement.

Thank you for your time.

Please return your completed submission to [ip@nice.org.uk](mailto:ip@nice.org.uk)

**NICE** National Institute for  
Health and Care Excellence

**NICE** National Institute for  
Health and Care Excellence

### **The experience of having the condition or caring for someone with the condition:**

- What were your symptoms before treatment?  
SOB, I just couldn't get my breath. I was gasping, I was very breathless on doing only small things like getting out of bed.
- How long did you have symptoms for before treatment?  
Quite a while, a few months I think, they tried lots of things first like tablets and did scans before I could have any treatment.
- What was it like living with your heart valve condition?  
It was awful; I was worried because it was my heart. I worried there was nothing they could do to fix it.
- Did your symptoms stop you doing any activities that you had previously enjoyed doing?  
I could only walk a few yards, so I couldn't do much housework and I couldn't really get out as much as I had done before.
- Did your symptoms affect your general mood/mental wellbeing?  
It made me feel upset that I couldn't do those things
- Did you have to ask for help from others because of your symptoms?  
I had to ask my daughter to come and do my housework and help with shopping.
- How did this make you feel?  
I didn't like it, I'm independent and don't like to rely on other people, she's busy enough with work and doesn't need to be running after me as well.

### **The experience of having the procedure or operation & the expectations about the risks and benefits of the procedure or operation:**

- How did you feel about having the procedure?  
Well, I felt like I had no choice, I wanted it done regardless so I didn't feel worried about it.
- Did you feel well informed about the procedure and what was going to happen?  
Yes, I was taken through it step by step before I went in to have it done. Everything was very clear.
- Did anyone talk to you about the risks of the procedure?  
The Dr told me straight away about all the risks before he told me about the procedure.
- Was there anything that particularly worried you about the risks?  
No because I knew I wanted it done, I didn't let it worry me
- Did anyone talk to you about the benefits of the procedure?  
Yes, it was all very clear
- Was there anything about the benefits that were important to you?  
Just to be able to breathe properly without gasping
- How did it feel to have the procedure done?  
It was great, I just wanted it done. It wasn't uncomfortable and I was made to feel at ease by everyone
- Was it as you expected or different?  
As expected, because it had all been explained to me
- Was there anything you didn't like?

no

- How did you find your stay in hospital?  
It was very good, it's a marvellous hospital, all the nurses and drs were lovely.

**The outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life):**

- How did you feel immediately after the procedure?  
It was lovely, I wanted to use the toilet about 2 hours after and the nurse helped me to the toilet, and I felt wonderful because I could walk, I didn't have any pain or discomfort.
- When you went home how did you feel?  
I felt fine, as all of a sudden I could breathe. I noticed straight away that I could do more without having to stop for breath. I walked down the hallway when I got in and didn't have to hold the handrail like I usually had to.
- What would you say was good/bad about having the procedure?  
No nothing, it was perfect

**The impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.):**

- What has been the biggest change on your day to day life after having the procedure?  
Being able to do my housework in one go, I'm independent again and can do things for myself
- What did your family and friends think about how you were after the procedure?  
They all thought I was marvellous, they couldn't believe how well I felt and looked
- Has it made a difference to your day-day activity or lifestyle?  
Yes just like I said before, there's nothing I can't do now
- Do you still need help at home (if applicable)?  
No but my daughter still rings every day to make sure I'm ok
- Did having the procedure make a difference to your general mood/mental wellbeing?  
Yes, I'm really enjoying getting out and seeing people again
- Did you have any problems or new symptoms after the procedure?
- I sometimes feel more tired but I think this is because I'm doing more.

### **The experience of having the condition or caring for someone with the condition:**

- What were your symptoms before treatment?  
The first thing I knew I collapsed in the bathroom, but deep down I had known there was a problem before that as I was very breathless and couldn't go up the stairs without having to pull myself up.
- How long did you have symptoms for before treatment?  
I had the symptoms for about 5 months before, but it was quite gradual, I just slowly got more and more breathless, I don't think I realised really.
- What was it like living with your heart valve condition?
- I was on my own because my husband had to go into a care home as he had dementia and I couldn't manage him anymore. I felt very stressed at that time and guilty because I was so breathless and couldn't look after him anymore. I actually felt relieved when they admitted me to hospital.
- Did your symptoms stop you doing any activities that you had previously enjoyed doing?  
It stopped me from looking after my husband, I couldn't be as active as I normally was. I'm an active person and like to be out but I couldn't do that anymore.
- Did your symptoms affect your general mood/mental wellbeing?  
Yes I think I was fed up and really stressed about what happened to my husband
- Did you have to ask for help from others because of your symptoms?  
Yes, I have 2 sons and 4 grandchildren, my sons and daughter in laws had to help with my shopping and cleaning.
- How did this make you feel?
- I didn't like it, I like to be independent

### **The experience of having the procedure or operation & the expectations about the risks and benefits of the procedure or operation:**

- How did you feel about having the procedure?  
Well I knew the risks were higher but I felt comfortable having it because I just wanted my life back, I didn't have any quality of life at that time. It wasn't a big decision for me.
- Did you feel well informed about the procedure and what was going to happen?  
Yes they went through everything with me in lots of detail and took time to explain everything to my two sons too.
- Did anyone talk to you about the risks of the procedure?  
Yes they went right through the risks and mentioned that they would be higher but the alternative wasn't a nice option either
- Was there anything that particularly worried you about the risks?  
Nothing, I couldn't let it worry me because I couldn't go on as I was
- Did anyone talk to you about the benefits of the procedure?  
Yes, that was the biggest thing, I just wanted to feel better again.
- Was there anything about the benefits that were important to you?  
Getting my quality of life back, I'm not bothered about living forever but for the time that I am here I want to be able to do things.
- How did it feel to have the procedure done?

- I couldn't believe how well I felt afterwards, when I compare it to how I was after open heart surgery it was a world of difference. I was up and down the stairs the very next day, and I wasn't in any pain. It was marvellous.
- Was it as you expected or different?  
No it was as expected, everyone was very nice
- Was there anything you didn't like?  
No
- How did you find your stay in hospital?  
All the staff were very nice, the consultant explained things really well after the operation too which made me feel at ease. From the cleaners to the top doctors they are all like your friends, they speak to you like a friend and you can understand everything; I had a good experience in Middlesbrough.

**The outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life):**

- How did you feel immediately after the procedure?  
I felt well, I was tired but was relieved it was done and had gone well. I was happy when I could get sat up.
- When you went home how did you feel?  
I went to my sons for a week, and I was tired and slept a lot. I felt good though, my great granddaughter even commented on how fit I looked. After a week I went shopping for food with my sister and then went back home and have been really good ever since. I've not got any SOB, I can walk up the stairs with my washing, I have no problems.
- What would you say was good/bad about having the procedure?  
I think I've got my life back, nothing bad to say.

**The impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.):**

- What has been the biggest change on your day to day life after having the procedure?  
I can't describe how well I feel, I keep going out walking and wondering why I feel ok. Just to have that freedom again is good.
- What did your family and friends think about how you were after the procedure?  
They just couldn't believe how well I looked. They let me do as much or as little as I wanted but when they saw me walking again without being breathless, they couldn't believe it.
- Has it made a difference to your day-day activity or lifestyle?
- Do you still need help at home (if applicable)?  
No I manage completely fine by myself. I do get my sons to do the very heavy work though, I'm 86 after all.
- Did having the procedure make a difference to your general mood/mental wellbeing?
- Absolutely, its changed my life, I feel wonderful



- Did you have any problems or new symptoms after the procedure?
- no