British Cardiovascular Society
'Promoting excellence in cardiovascular care'

British Heart Valve Society
For Education and Best Practice in Heart Valve Disease

SCTS
Society for Cardiothoracic Surgery in Great Britain and Ireland

Enhanced Follow-Up for Patients with Trifecta™ Aortic Valve Bioprostheses

A Statement from the British Heart Valve Society (BHVS), the Society for Cardiothoracic Surgery (SCTS) and the British Cardiovascular Society (BCS)

Dear Colleague

In July 2020, the Medicines and Health Regulatory Authority (MHRA) issued a Medical Device Alert regarding cases of structural valve degeneration (SVD) affecting the 1st Trifecta™ and Trifecta GT™ aortic bioprosthetic heart valves.[1] This follows publications of several reports from across the world about a higher than expected rate of premature SVD requiring re-intervention. The document states:

"Data accumulated by Abbott through their Trifecta™ long-term (10 year) follow-up and durability studies conclude acceptable clinical outcomes. However, the manufacturer acknowledges that the design of the 1st generation Trifecta™ valve may increase the likelihood of early degeneration. Specifically, the SVD seen may be a result of having a valve design with externally mounted leaflets, in combination with a stent that may be deformed during implant. Improvements to the valve leaflets and reinforcement of the stent, implemented in later designs, are expected to reduce this risk."

In 2019, the British Heart Valve Society (BHVS) and British Society of Echocardiography published joint guidance on frequency of echocardiography and follow-up for patients with replacement heart valves.[2] In this document, the two societies advocated **annual echocardiography** for patients that receive an aortic bioprosthesis for which adequate long-term durability data do not exist – this includes the Trifecta™ valves, which contain externally mounted bovine pericardial leaflets.

Valve type	Indications	Frequency
Mechanical valve in aortic, mitral or tricuspid position	Baseline echocardiogram normal	No routine follow-up usually required
Biological valve	TAVI, new designs for which adequate durability data do not exist, Ross procedure	Annual from implantation
Biological valve	Mitral or tricuspid position, aortic xenograft age <60 at implantation (or other major risk factors, e.g. renal failure, severe patient–prosthesis mismatch)	Annual from 5 years after implantation
Biological valve	Designs in the aortic position with proven longevity e.g. Edwards Perimount, Medtronic Hancock II in patients aged ≥60 at implantation	Annual from 10 years after implantation

Above: Table from the joint BHVS/BSE guideline on echocardiography after heart valve replacement surgery

As a result of the MHRA guidance, the BHVS wishes to re-emphasize **annual follow-up with annual echocardiography** for patients that have received a 1st generation Trifecta™ or Trifecta GT™ bioprosthesis. Provision for echocardiography remains restricted due to the COVID-19 pandemic, but we recommend that patients with Trifecta™ valves are prioritized. Finally, the BHVS, BCS and SCTS, as well as the MHRA, encourages cardiac surgeons and cardiologists to continue to report all adverse incident reports, including early events of SVD / NSVD (non-structural valve deterioration), to both the manufacturer and the MHRA.

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References

1. Abbott Trifecta / Trifecta GT bioprosthetic aortic heart valves: cases of structural valve deterioration (SVD). Medicines and Healthcare Products Regulatory Authority Medical Device Alert. MDA/2020/019. Issued July 6th, 2020.
2. Chambers JB, Garbi, Briffa NP *et al*. Indications for echocardiography of replacement heart valves: a joint statement from the British Heart Valve Society and British Society of Echocardiography. *Echo Res Pract* 2019; 6(1): G9-G15