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Abbott shifts to tricuspid repair

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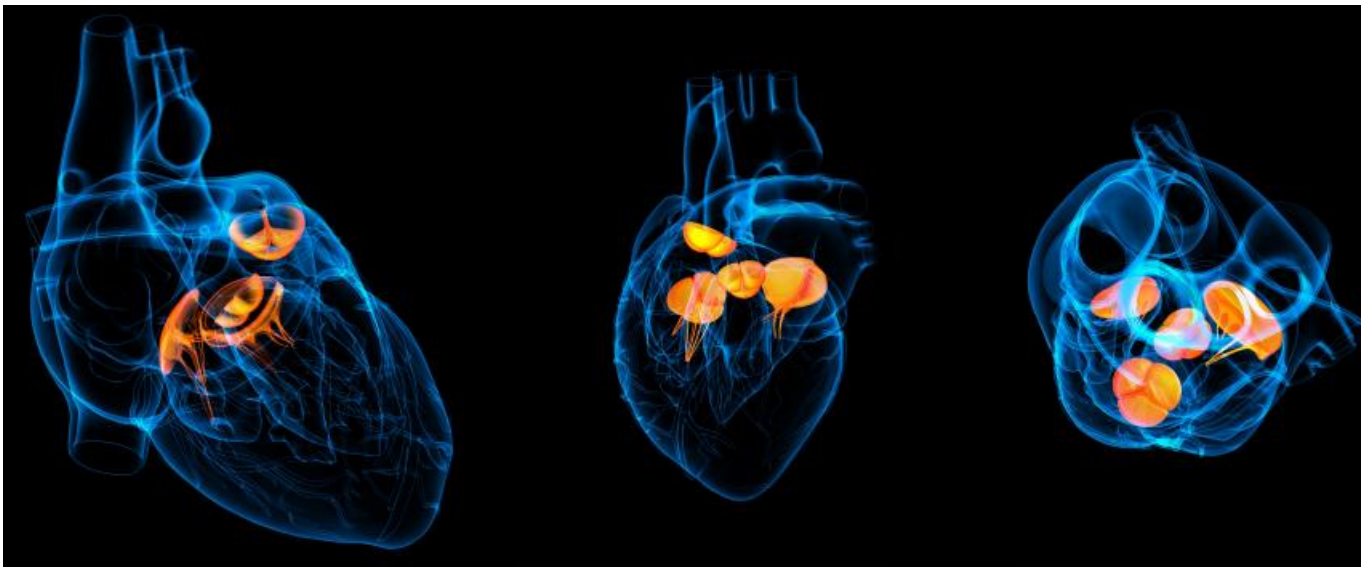

First-look data on Abbott’s tricuspid-focused MitraClip follow-on device are promising, but can TriClip emulate its predecessor’s success?

Abbott's transcatheter mitral valve repair device MitraClip succeeded impressively in the Coapt trial last year, and the company is developing a similar product for the tricuspid valve. Early data are positive, and European approval for TriClip could soon be within Abbott’s grasp.

Another group got to Europe first, however. Edwards Lifesciences’ minimally invasive Cardioband gained CE mark for tricuspid repair a year ago. Cardioband is in a 35-patient US feasibility trial, so the race to the American market might see a closer finish.

Data from Abbott’s Triluminate study were presented yesterday in a late-breaking session at the EuroPCR meeting in Paris. TriClip reduced regurgitation severity by at least one grade in 74 of 85 patients with symptomatic moderate or greater tricuspid regurgitation, one month after implantation.

At 30 days, significantly more patients (81%) were categorised as NYHA class I or II – the milder end of this heart failure scale – than at baseline (26%). The patients also had improved social abilities, symptoms and quality of life, according to Abbott.

The more important endpoint, major adverse event rate, will be determined at six months. If TriClip can show an acceptable profile on this measure – and there will likely be some discussion of what an acceptable profile looks like – it might soon gain its CE mark. MitraClip was approved in Europe in 2008, five years before it reached the US, and a similar delay could well occur with TriClip.

America

Abbott is, of course, already working towards US approval: the Triluminate Pivotal trial is due to start in July. This will compare the TriClip with drug therapy in 700 patients with severe tricuspid regurgitation, who would be at intermediate or greater risk of death were they to undergo tricuspid valve surgery.

This study will read out in July 2022 and then it will be over to the FDA. No device is yet approved in the US for tricuspid regurgitation – the only treatment is surgical repair of the valve, which is rarely performed owing to high mortality and morbidity rates. This might predispose the FDA to look on Abbott’s submission favourably.

But Abbott’s MitraClip, sales of which are forecast to reach an astonishing $1.8bn in 2024, according to *EvaluateMedTech*’s sellside consensus, is already being used off-label for tricuspid repair. Presumably Abbott has concluded that adding tricuspid repair to MitraClip’s label is a non-starter, necessitating the creation of a

separate product. The risk is that, if approved, TriClip could cannibalise some of Abbott’s own sales.