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ESC 2017 – Biotronik builds an impressive Castle

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Hard endpoints are increasingly what clinicians look for when deciding whether to use a medical device, and they do not come much harder than death. Data from the Castle-AF trial showed that using catheter ablation to treat atrial fibrillation patients with heart failure allowed a 38% reduction in a composite of all-cause mortality and hospitalisation for worsening heart failure five years after the procedure.

The trial was sponsored by Biotronik, but the data will likely boost sales of ablation catheters whether made by Biotronik or its competitors, among whom Abbott, Medtronic and Boston Scientific may be counted. But the German group has got the drop on its rivals in another area: according to the company, the data quietly back the use of its home monitoring tech.

First, though, the purpose of the study: the use of catheter ablation in heart failure patients with atrial fibrillation is now conclusively proven. At a median follow-up of just over three years the primary endpoint events occurred in 28.5% of patients in the ablation arm versus 44.6% in the control group, who received drug therapy, the standard of care in this population.

As well as the hit on the primary endpoint there were statistically significant improvements in both its components: a 47% reduction in the risk of death and 44% fall in the risk of hospitalisation for worsening heart failure.

This was driven by cardiovascular death and hospitalisation, said Dr Nassir Marrouche of the University of Utah, presenting the results at the European Society of Cardiology meeting in Barcelona today. The reductions here were 51% and 28% respectively.

Discussing the results, Dr Carina Blomström-Lundqvist of Uppsala University, Sweden, said the data were highly relevant to clinical practice, pointing out that this study was the first to use this hard primary endpoint; previous trials used freedom from fibrillation as their goal – a surrogate endpoint that does not prove that the technique can save lives.

Guidelines

Manuel Ortega, senior vice-president at Biotronik, told *EP Vantage* that the data ought to increase the use of catheter ablation. The atrial fibrillation market is worth around $4bn, and more than 30% of patients with heart failure either have the condition or will go on to develop it, so this is not a small market.

“There may not be total surprise about what the study says, but it will give peace of mind in the medical community that now there is a study that shows conclusively that it is working,” he said. “When it comes to ablation it will benefit anyone with a catheter. Biotronik, Medtronic, Biosense Webster – it’s not unique.”

Abbott’s ablation catheters and related products account for around 5% of the group’s total sales, according to Wells Fargo analyst Larry Biegelsen. For Medtronic, Boston Scientific and Johnson & Johnson, which sells through its Biosense Webster subsidiary, this figure is between 2% and 3% of total revenues. Biotronik is private and does not disclose revenues.

The speed at which sales of ablation catheters will grow depends on the treatment guidelines released by organisations such as the ESC.

After 10 years of investment in this trial Biotronik will be hoping that the Castle-AF data will lead to a change in these rules – the first patient was enrolled in January 2008. The ESC’s current guidelines, released in 2016, state that catheter ablation might be useful in this population, “but further data are needed”.

“We will see how this data is interpreted and how much urgency the ESC shows,” Mr Ortega said.

Monitoring

Biotronik’s decision to fund a trial that will boost its rivals’ sales as well as its own might almost look like an unusual business strategy were it not for the second technology backed by the Castle-AF data.

All the patients in the study were supplied with implantable cardioverter defibrillators (ICDs) or cardiac resynchronisation therapy defibrillators (CRT-Ds) – a fairly standard therapy for heart failure. But all those in the trial were made by Biotronik, and all employed Biotronik's home monitoring technology, which collects data from the patient's device and sends it to their doctor.

"The follow-up was done thanks to home monitoring," Mr Ortega says. "It reduces mortality using home monitoring versus no home monitoring. We believe this is going to benefit only Biotronik."

Study	Trial ID
Castle-AF	NCT00643188

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