St. Jude Medical has had its troubles with pacing leads over the years, so perhaps it is due some good news about these products. A presentation at the ESC delivered, with a trial in nearly 1,000 patients backing St. Jude’s Quartet lead, which has four electrodes, over older devices that have only two.

Quartet is already on the market, but the More-CRT trial was the first randomised study of any quadripolar lead. Despite this, four-electrode technology is already becoming the standard of care. But while Quartet appears to be better than bipolar leads, it is certainly more expensive, and the question now is whether these new data are positive enough to justify the cost.

Two poles good, four poles better

The trial hit its primary endpoint, proving that Quartet reduced lead-related adverse events occurring during or after the implantation of a cardiac resynchronisation therapy-defibrillator (CRT-D), compared with bipolar leads. One-third of the bipolar leads used in the trial were St. Jude products, and two-thirds were made by four different manufacturers – Medtronic, Boston Scientific, Biotronik and Sorin.

At six months, 86% of patients in the Quartet group did not experience these events, compared with 77% in the control group. There was a significant reduction in relative risk, with Quartet recipients 41% less likely to have an event. The number needed to treat was 11. The types of events were not specified, but are likely to include the inability to place a lead and the requirement to use a second one.

It was improvement during implantation of the leads and CRT-D device, rather than afterwards, that was mainly responsible for the endpoint win. Intra-operative complications were reduced by more than 50% in the quadripolar group: 5.98% vs 13.73%.

“I expect that [the trial data] will be important for some [doctors] who are justifying their current practice, and for some who may make their decisions based on, or give greater weight to, randomised clinical trials,” Mark Carlson, St. Jude’s chief medical officer, told EP Vantage. “For the late adopters, this may be a very important step.”

The advantage of a quadripolar lead is that it is more versatile than a bipolar one, said Giuseppe Boriani of the University of Bologna, Italy, presenting the More-CRT results. Nearly 10% of heart failure patients cannot be successfully implanted with bipolar left ventricular leads owing to anatomical challenges, phrenic nerve stimulation or poor electrical measurements.

The tip of the Quartet lead, with its four electrodes, is placed within the coronary sinus, and the cardiologist can decide which two to use to shock the heart. If two and only two electrodes are active, this gives six possible combinations.

Cost

Discussing the results, John Cleland of Imperial College London said that quadripolar leads are “already becoming the standard of care”, even though no large-scale randomised studies have hitherto been conducted. St Jude could increase its share of the market thanks to the More-CRT data – though it should be borne in mind that More-CRT was not blinded. Currently the US market for quadripolar leads is split between Medtronic and St Jude; Medtronic’s Attain Perfecta lead was approved in the US this month, adding to its arsenal.

“Right now we have a single quadripolar lead,” says Mr Carlson, “but we anticipate having additional designs.” He says that Medtronic’s designs differ significantly from St Jude’s.

If clinical data could increase adoption, the other factor which will decide whether it sinks or swims on the market is its price. Prof Cleland said that the product is four times as expensive as bipolar leads, and added that further research into its cost-effectiveness will need to be produced.

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