Potential benefits of remote follow-up of ICD patients

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Results from the EVATEL (EVAluation of TELe follow-up) trial are the first in Europe to demonstrate potential safety and efficacy benefits from the remote follow-up of ICD patients. The trial was conducted in France, with the financial support of the French Ministry for Health and independent of any manufacturer grants.

ICDs (implantable cardioverter defibrillators) are devices routinely implanted in patients at risk of sudden cardiac death as a result of rhythm disturbances. The expending indications for ICDs are expected to have an impact on follow-up strategy, as the number of patients with ICDs is increasing rapidly.

"Currently," explains investigator Dr Philippe Mabo form the University Hospital of Rennes, France, "regular in-clinic follow-up must be performed every three months, according to manufacturer guidelines. But there are two drawbacks to the in-clinic follow-up - they're time-constrained for both the patient and the clinic, and there's no link between the time of the appointment and the clinical event or device malfunction. So there's a clinical need to consider new follow-up strategy."

In response, several manufacturers have developed new technologies which allow the remote transmission of information from the device and on its therapeutic effect. Critical data can be transmitted at any time on system integrity or unexpected events - for example, lead integrity, battery status or ineffectively delivered therapy. Data stored in the

device are transmitted by phone from the patient's home to the implant centre, with website access to the data.

"In this context," said Dr Mabo, "remote device follow-up seems to be a promising technique for device follow-up. But the technology needed clinical validation in terms of safety, efficacy and cost-efficiency, which were the objectives of the EVATEL trial."

The study included 1501 patients from 30 French centres enrolled between January 2008 and January 2010. They were each followed-up every three months for an overall period of one year. The last follow-up was performed in January 2011. The characteristics of the subjects were comparable to those of an ICD trial or registry, with a mean age of 59 years and the majority male (85%). Half the patient received conventional follow-up at the implant centre, the other half were followed remotely. The primary end-point of the trial was a clinical composite of death (all causes), cardiovascular hospitalisation, and ineffective or inappropriate therapy delivered by the device.

The primary endpoint was validated in 28.5% of the control group and 30.2% of the remote group, thus indicating no difference in outcome between the groups. In addition, there were no statistically significant differences between the two groups in time to occurrence of the first primary endpoint (p=0.71) and the one-year survival rate (p=0.31). The number of inappropriate therapies was lower in the remote group (4.7%) as compared to the control group (7.5%) (p=0.03).

Nevertheless, the non-inferiority hypothesis of the trial with a strict non-inferiority margin of 5% was not confirmed, as the event rate difference between the two groups was 1.7%, with a 95% confidence interval of -0.3 to 6.4.

Commenting on the results, Dr Mabo said: "The remote follow-up of

patients implanted with an ICD seems to be a safe alternative to conventional in-office follow-up. However, for the widespread uptake of this new strategy - at least in France - reimbursement from the healthcare system will be needed. We hope that it will be available soon in France."

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