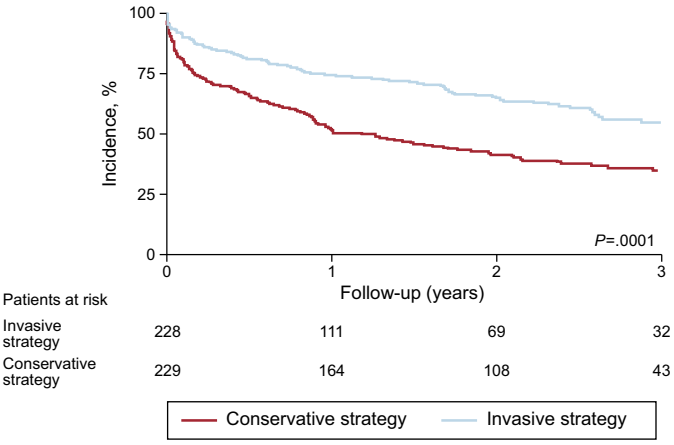

Figure. Cumulative incidence of acute myocardial infarction, urgent revascularization, stroke, and death during follow-up in the After Eighty trial.[1] Adapted with permission from Tegn et al.[1].

The prognostic impact of frailty in ACS has been confirmed in a registry[3] that included 202 patients aged 75 years or older with type I AMI treated in 4 Spanish hospitals. Frailty was evaluated using the SHARE-FI index, which evaluates self-perceived fatigue, appetite, functional difficulties, physical activity, and grip strength. In total, 71 patients (35.1%) met the criteria for frailty. The frail patients were older and had more comorbidities (mean Charlson Comorbidity Index, 8.4 vs 6.6; $P < .001$). Despite showing a higher-risk profile, with higher scores on the GRACE (154.4 vs 141.0; $P < .001$) and CRUSADE (48.2% vs 34.1%; $P < .001$) scales, frail patients underwent fewer coronary angiography studies (66.2% vs 93.1%; $P < .001$). The main endpoint (cardiac death or infarction during hospitalization) was more frequent in frail patients (9.9% vs 1.5%; $P = .006$), largely due to higher mortality. The incidence of major bleeding (a hemoglobin decrease > 3 g/dL or need for surgery or transfusion during hospitalization) was also higher in frail patients (19.7% vs 9.2%; $P = .032$). Despite the small sample size, frailty could predict mortality independently of age, sex, creatinine, diabetes mellitus, and GRACE score.

In a subsequent publication, González Salinas et al.[4] analyzed the ability of frailty to predict bleeding risk in 190 patients from the same series. Frailty predicted a higher incidence of bleeding complications, despite a lower use of dual antiplatelet therapy and the invasive strategy; this predictive ability was independent of age (hazard ratio, 2.7; 95%CI, 1.2-5.7; $P = .012$).

Thus, these findings strengthen the association of frailty with conservative treatment and worse prognosis in ACS. The question underlying all of these findings is whether frail patients should really be treated differently.[5] In an attempt to respond to this question, the LONGEVO-SCA registry[6] has been designed, with funding from the Geriatric Cardiology Section of the Spanish Society of Cardiology. The registry plans to include 500 patients aged 75 years or older with NSTEACS from more than 50 Spanish hospitals; a comprehensive geriatric assessment will be performed (frailty, comorbidities, functional and cognitive status, quality of life) and the researchers will analyze the association of these variables with treatment and prognosis at 6 months.

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Selection of the Best of 2016 on Cardiac Pacing: Leadless Pacing

Selección de lo mejor del año 2016 en estimulación cardiaca: estimulación sin cables

To the Editor,

Transvenous pacemaker implantation carries a not insignificant risk of adverse events. Most of these events are related to the generator pocket or the electrode.[1]

To avoid these complications, attempts have been made over the past 40 years or more to produce a system in which the electrode and generator constitute a single device that can be implanted within the heart; that is, a device known today as the leadless pacemaker (LPM). Initially, the available technology did not allow such a device to be created for clinical use and progress remained at a standstill for some time. However, advances in miniaturization, battery longevity, implantation equipment, and communication systems, among other factors, have since allowed the creation of the LPM models that are used today.

The first LPM system available for use in humans was the Nanostim device by St. Jude Medical (Figure 1). Subsequently, the

Figure 1. Nanostim leadless pacemaker (image courtesy of St. Jude Medical).

Micra device by Medtronic was introduced (Figure 2). Initial clinical studies involved very few patients but reported excellent safety and efficacy outcomes.

These studies also provided information on the possible adverse events associated with the devices.[2,3] The LEADLESS trial of the Nanostim device reported 6 cardiac perforations and 2 deaths, and the study was therefore terminated.[3] This led to a review and improvement of the implantation procedure, and the launch of a new registry named LEADLESS II.[4] With the Medtronic system, the most frequently-reported complications relate to vascular access.[2]

Over the past year, new data on leadless pacing have become available, and the most relevant information relates to 2 main areas of publication. First, the results of 2 clinical studies, LEADLESS II[4] and MICRA TPS,[5] were published, with a significantly higher number of patients and longer follow-up than in previous studies. Second, additional reports have been published on the combination of LPMs with subcutaneous implantable cardioverter-defibrillators (S-ICDs).

LEADLESS II[4] is a prospective registry of patients with an indication for single-chamber pacing who received a Nanostim device. This registry included more than 500 patients and evaluated efficacy and safety parameters at implantation and, in the first 300 patients, at 6 months postimplantation. This pacemaker was implanted successfully in 95.8% of cases. At follow-up, the rate of device-related adverse events was 6.7%: these included increased pacing threshold, cardiac perforation, arrhythmias, emboli, and vascular access problems. Total mortality was 0.44%. The authors concluded that, in the study, implantation was successful in most patients and the complications rate was 1 in 15 patients.

Figure 2. Micra transcatheter leadless pacemaker (image courtesy of Medtronic).

MICRA TPS[5] is also a multisite prospective study of patients with an indication for single-chamber pacing, who received a Micra pacemaker. It included 725 patients, and 99.2% of implants were successful. At 6 months, 98.3% of patients had stable pacing parameters and 96% were free from major complications. There were 28 major complications. The most frequent were pericardial hemorrhage, cardiac perforation, and complications related to the groin puncture site. One patient died due to metabolic acidosis. There were no dislodgments or infections. These data are from the first 300 patients who completed the 6-month follow-up, and similar results have recently been reported for all enrolled patients.

The second noteworthy point from publications over the past year is the possibility of combining an S-ICD with an LPM. This option could be useful because neither device requires intracardiac electrodes, and pacing cannot be performed with S-ICD alone. Tjong et al.[6] published the results of a small study involving animal experiments and implantation of this combination in 1 patient: no sensing or pacing disturbances were observed, and defibrillation did not affect the LPM function. However, more robust safety studies are needed for this device combination.

This information seems to show that we are in a transition period between conventional pacing and the pacing techniques of the future. In the coming years, we expect to witness further progress in leadless pacing. Significant advances and improvements in its current limitations will herald a new era of pacing.

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