CLINICAL TRIAL HIGHLIGHTS

SUP2 Trial: Selection Algorithm Benefits Patients With Recurrent Reflex Syncope

Written by Emma Hitt Nichols, PhD

Conducting a testing algorithm of patients with severe, recurrent, unpredictable syncope to receive a dual-chamber (DDD) pacemaker provides clinical benefit by reducing syncopal recurrence. Michele Brignole, MD, Ospedali del Tigullio, Lavagna, Italy, presented data from the prospective, observational SUP2 trial [Brignole M et al. *Eur Heart J*. 2015].

It is not yet established whether cardiac pacing with an implanted DDD pacemaker is beneficial in patients with reflex syncope. The purpose of the SUP2 trial was to determine if DDD pacemaker implantation is effective in reducing recurrent reflex syncope in patients with severe, recurrent, unpredictable cardioinhibitory (CI) reflex syncope.

The primary end point was to evaluate the efficacy of the diagnostic algorithm by measuring the time to first syncopal recurrence. Patients were enrolled if they were aged > 40 years and had severe, recurrent, unpredictable syncopes, which included CI carotid sinus syncope (CSS), Vasovagal Syncope International Study (VASIS) 2B response, or type 1 asystole. The algorithm began with cardiac sinus massage to detect CSS; if negative, patients underwent tilt testing for VASIS 2B response, and if this was negative, patients received an implantable loop recorder (ILR) to detect asystole. Patients positive for any of the above received pacing; all other patients were followed clinically.

Severe syncope was defined as unpredictable with or without short (< 10 seconds) prodromes that affected quality of life. Recurrent syncope was defined as ≥ 2 episodes within the past year or ≥ 3 episodes during the past 2 years. Suspected reflex syncope was defined as reflex syncope without severe structural heart disease, severe abnormalities, rhythm disturbances, orthostatic hypotension, and nonsyncopal causes of transient loss of consciousness.

After algorithm testing, 66 of 253 had CI CSS, 34 of the remaining 185 had a VASIS 2B response, and 25 of the remaining 134 had type 1 asystole, all of whom received a DDD pacemaker. Thus, in total, 125 out of 253 patients (47%) finally received a pacemaker. Among those who did not receive a pacemaker, 10 were lost to follow-up, 82 were ongoing with clinical observation, 4 had tachyarrhythmia, and 13 had no rhythm variations. At baseline, the mean age was 70 years, mean age of first syncope was 61 years, and the proportion of syncopes without or with prodromes < 10 seconds was 89%.

DDD pacemaker implantation was associated with significantly greater survival rates compared with patients who received only an ILR (15% vs 37% at 24 months; $P = .004$). DDD was not particularly more efficacious in any specific indication subgroup.

Prof Brignole highlighted that the data suggest that about 50% of patients with severe recurrent syncope have an asystolic reflex, and pacing resulted in a low recurrence rate. In conclusion, the SUP2 trial data indicate that using a testing algorithm to select patients who are candidates for pacing is feasible and provides clinical benefit.

Official Peer-Reviewed Highlights From

Cardiac Implantable Electronic Devices Also Benefit Women, Sometimes More So

Written by Emma Hitt Nichols, PhD

The influence of sex on the beneficial effect of cardiac implantable electronic devices (CIEDs) has recently been appreciated, but remains poorly characterized. For example, implantable cardiac defibrillators (ICDs) may be less effective in women, whereas cardiac resynchronization therapy (CRT) defibrillators may be more effective. Importantly, women receive fewer implants than men in clinical practice and are underrepresented in clinical trials that evaluate CIEDs, making these questions difficult to answer.