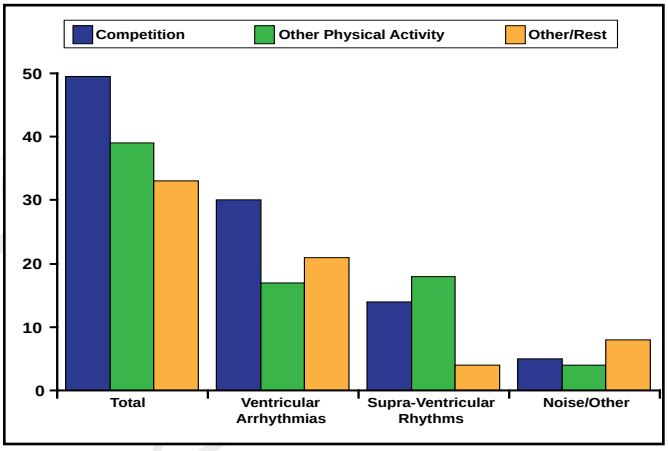
At 1 year, 315 athletes had shocks, with a 95% CI of 1% to 1.2%, and at 2 years, 243 athletes had shocks, with a 95% CI of 0% to 1.5%. Since the number of athletes that were studied is small, the upper bounds of the 95% CIs (1.2% and 1.5%) are meaningful.

In total, the number of shocks for competitive sports was higher than those for other physical activities or noise/other (Figure 1). The investigators concluded that shocks were not rare during sports. No serious health consequences occurred, and most participants returned to sports despite shocks. "Whether or not patients with ICDs return to sports should be an individual decision," Dr. Lampert said.

Figure 1. Shocks Received.



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Subcutaneous ICD Proven Safe and Effective

Written by Rita Buckley

An investigational, fully subcutaneous implantable cardioverter defibrillator (S-ICD) that senses, detects, and treats malignant ventricular tachyarrhythmias exceeded prespecified safety and efficacy endpoints in a recent clinical trial, potentially paving the way for a paradigm shift in ICD technology. Martin C. Burke, DO, University of Chicago, Chicago, Illinois, USA, reported findings from this study.

Investigators enrolled 330 patients at 33 centers in the United States, New Zealand, the Netherlands, and the United Kingdom to perform a prospective, single-arm comparison of the S-ICD to objective performance criteria. Patients were aged ≥18 years, met guidelines for ICD implantation or replacement of an existing ICD system, and had appropriate preoperative electrocardiograms. The S-ICD system was used for primary prevention in 79% of the patients. Characteristics of the population are shown in Table 1.

Table 1. Baseline Characteristics of S-ICD Subjects.

	Mean (SD)
Total	330
Age (years)	52±16
Male (%)	244 (74%)
Female (%)	86 (26%)
NYHA class 1 (%)	68 (21%)
NYHA class II (%)	146 (45%)
Body mass index (kg/m²)	30±7
Ejection fraction	36±16%
Congestive Heart Failure	197 (61%)
Hypertension	187 (58%)
Myocardial Infarction	133 (41%)
Diabetes	90 (28%)
Atrial fibrillation	49 (15%)
Percutaneous Coronary Intervention	92 (29%)
Coronary Artery Bypass Graft	48 (15%)
Transvenous ICD	43 (13%)

NYHA=New York Heart Association; SD=standard deviation; S-ICD=subcutaneous implantable cardioverter defibrillator.

Devices were implanted in 321 patients; only anatomical landmarks were used in 95% of patients. During the follow-up period, no electrode or pulse generator movement was detected in 99% of patients. Of 18 (5.6%) suspected or confirmed infections, 14 (4.4%) were superficial or incisional and were managed without explantation. The 4 that required explantation occurred early in the study.

The primary efficacy endpoint was an acute ventricular fibrillation (VF) conversion rate that was greater than 88%. The S-ICD system successfully converted 100% of investigator-induced VFs, surpassing the prespecified target. The primary safety endpoint was the complication-free rate at 180 days, with a prespecified goal of at least 79%. In the study, the 180-day Type 1 complication-free rate was 99%.

The 180-day performance goal of freedom from all device-, labeling-, and procedure-related complications was 79%; the observed rate in the study was 92.1%. All spontaneous episodes were successfully converted with 80J or spontaneously converted, and unnecessary therapy was avoided. No patients experienced a shock because of discrimination error in the conditional shock (dual) zone, and the rate of inappropriate shocks was similar to that of standard transvenous devices.

According to Dr. Burke, the S-ICD system exceeded all objective performance criteria for safety and efficacy.