The PRAETORIAN Trial

S-ICD VS. TV-ICD: THE LANDMARK HEAD-TO-HEAD STUDY

The PRAETORIAN Trial[1] is an investigator sponsored study (ISR)* initiated, designed and led by Academic Medical Center in Amsterdam (AMC) and Reinoud E. Knops, MD, PhD. It is the first randomized head-to-head trial comparing the performance of S-ICD and TV-ICD.

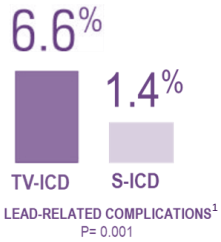
Study Hypothesis

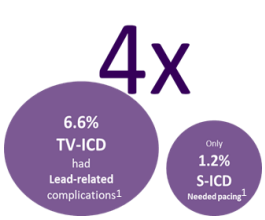
The trial hypothesis was that the S-ICD is non-inferior to the TV-ICD with respect to major ICD-related adverse events, including:

- Inappropriate shocks
- ICD-related complications that require intervention
    - Lead-related complications

The trial enrolled 849 patients between March 2011 and January 2017 within the EU and US.

Primary & Secondary Endpoints





Mortality rates[1]

No significant difference in overall arrhythmic mortality rates between the two groups. Mortality rate was low in both groups, even though:

- 90% had ischemic (68%) or non-ischemic heart failure
- ~20% of patients had secondary prevention
- Median EF was 30%
- Median age was 63 years

Lead-related complications[1]

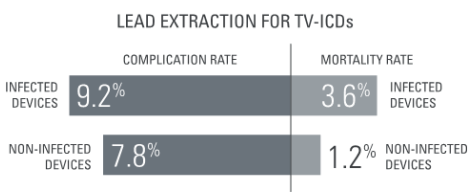
Data showed a statistical difference in lead-related complications, with TV-ICD patients experiencing more than 4 times as many as S-ICD patients.

Lead complications 4-times more likely than need for pacing or ATP[1]

Patients were more than four times as likely to need an intervention for a lead-related complication than they were to develop a need for pacing or ATP.

Infections requiring device extraction[1]

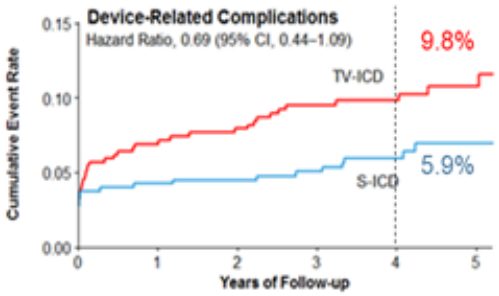
TV-ICD patients experienced twice as many infections that required extraction compared to S-ICD patients (8 pts vs 4 pts at 4 years)



Reducing infection can lower mortality rates – and costs[2]

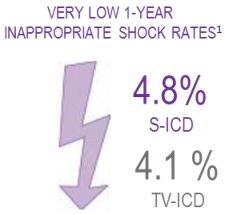
Data in >91,000 transvenous lead extractions demonstrated that those extracted for TV-ICD infection had a higher in-hospital complication and mortality rate compared to those without infection[2]

In this same study, the median cost of lead extraction was $39,308 for infected devices and $14,916 for non-infected devices[2]



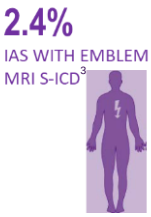
Device-related complications[1]

No statistical difference (P=0.11) in device-related complications at the median 4-year follow-up. The trial authors have initiated an extended follow-up, in PRAETORIAN XL. The hypothesis in PRAETORIAN XL is that at the 8-year median follow-up, the S-ICD will demonstrate superiority to TV-ICD for all device-related complications.



Inappropriate shock rates[1]

No significant difference in inappropriate shock rates. The study used mainly devices available prior to 2016. Studies using modern S-ICDs like the EMBLEM™ MRI S-ICD have demonstrated even lower rates of IAS.



EMBLEM MRI S-ICD with SMART Pass™ further reduces inappropriate shock rates (IAS)[3]

In the UNTOUCHED study[3], the 1-year IAS rate was 3.1%, and 2.4% for those with an EMBLEM family of devices with SMART Pass, which is comparable to or lower than the rate observed with TV-ICDs in other studies, including the PRAETORIAN trial.

S-ICD: A smart alternative to TV-ICD

Because it avoids some of the more major complications associated with the TV-ICD, including serious infection and lead-related complications, data shows that the S-ICD is an appropriate and potentially desirable alternative for primary and secondary ICD-indicated patients who do not require pacing.

1. Knops R. et al. A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial. .
2. Deshmukh A, Patel N, Noseworthy PA, et al. Trends in Use and Adverse Outcomes Associated with Transvenous Lead Removal in the United States Circulation. 2015;132(25):2363-2371.
3. Gold M. Understanding Outcomes With The S-ICD In Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial Primary Results.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

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