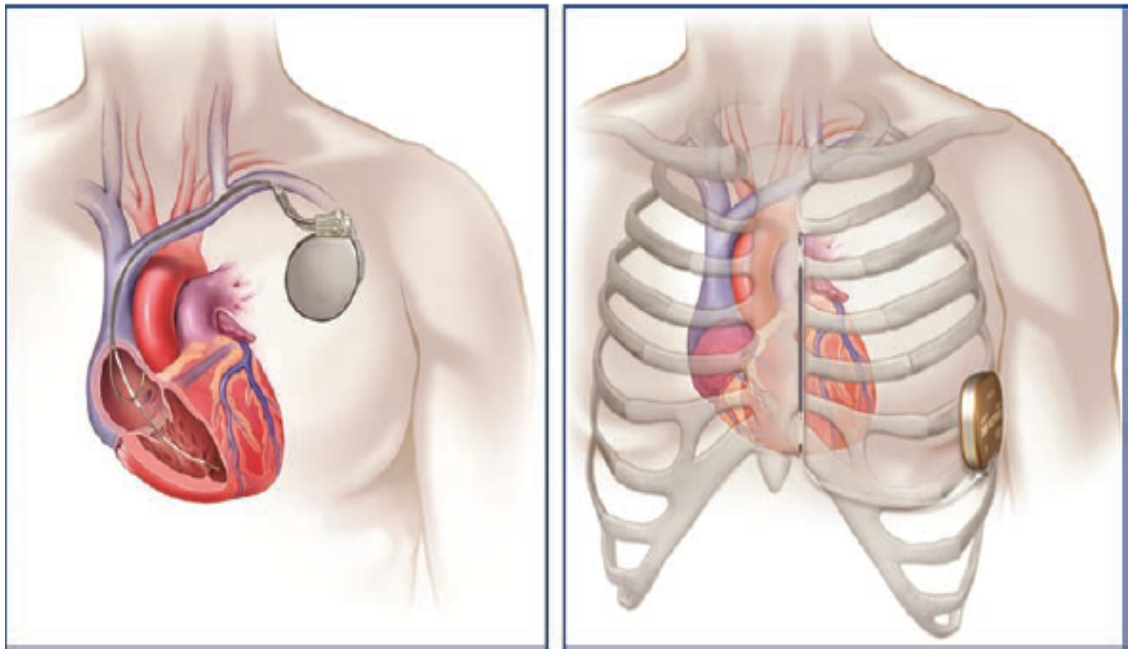
SUBKUTAN ICD (SICD)

Dr. Ümit GÜRAY

Ankara Numune EAH

Transvenöz ICD



Sorunlar:

- İmplanatasyon sırasında : Pnömotoraks, hemotoraks, hemoperikardiyum, hematom, venöz tromboz
- ***Transvenöz lead problemleri: 10 yıl içerisinde %20.***
- ***Cep enfeksiyonu, bakteriyemi, infektif endokardit***
- ***Transvenöz lead ekstraksiyonu gereksinimi***

SICD

- SICD ani ölümü önlemede TV-ICD alternatiftir.
- VT/VF'yi saptar ve sonlandırır.
- Tamamen subkutan ve intravasküler lead gereksinimi yoktur.
- İmplantasyon sırasında sadece anatomik göstergeler kullanılır (Sıfıra yakın floroskopi ihtiyacı)
- **S-ICD:**
  - **CE Mark approval in Europe in 2009**
  - **FDA approval in US in 2012.**

SICD: SİSTEM BİLEŞENLERİ

SQ-RX™ Pulse Generator

- Volum: 69 cc
- Ağırlık: 145 gram
- Kalınlık: 15.7 mm
- Enerji: 80J ; 10 sn şarj zamanı
- Dalgaformu: Bifazik

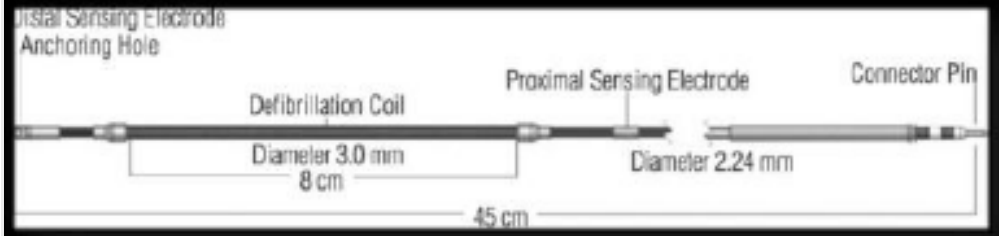
Q-GUIDE™ Electrode Insertion Tool

- tek kullanımlık
- 36cm total uzunluk
- 3mm çap

Q-TRAK™ Elektrot

•Lümensiz

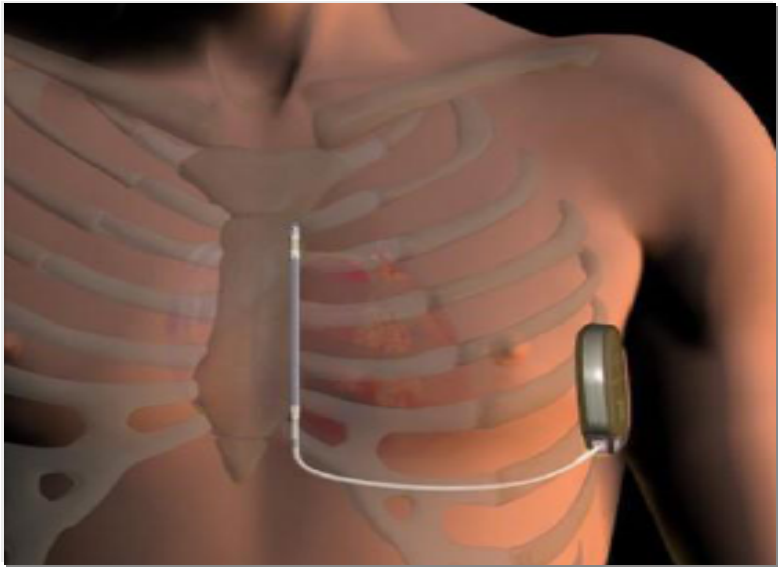
- Dayanıklı poliüretan insülasyonlu
- CPR yapılmasına uygun şekilde dizayn edilmiş

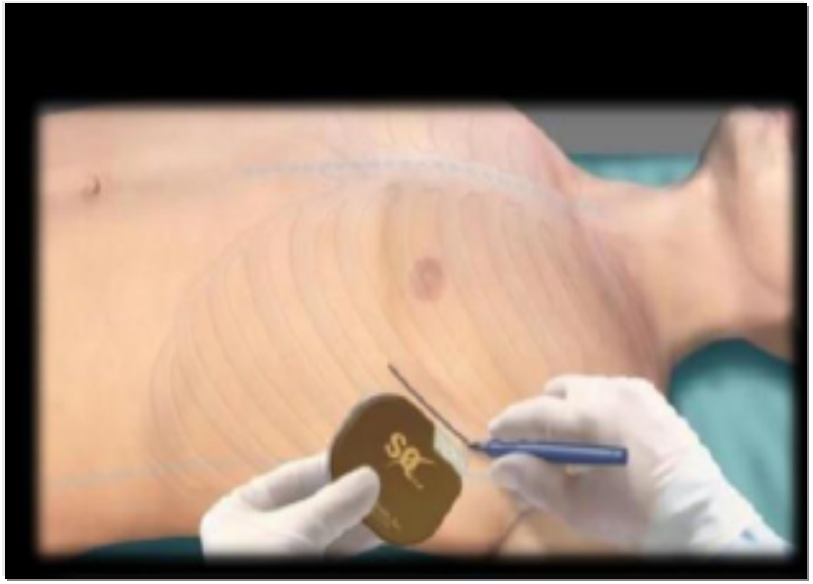


Q-TECH™ Tablet Programlayıcı

- RF telemetrili
- Kablosuz yazıcı bağlantılı
- Micro SD card

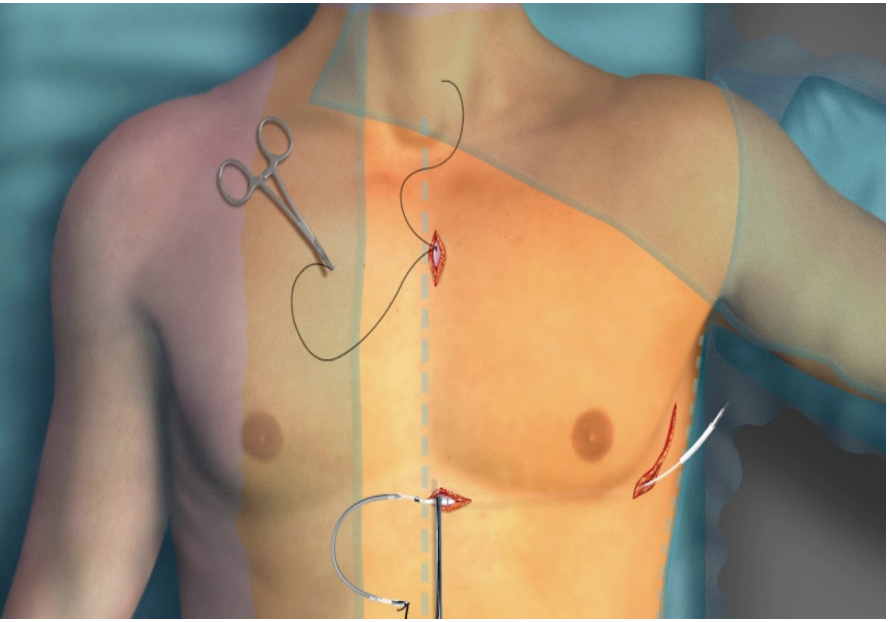
SICD: İmplantasyon



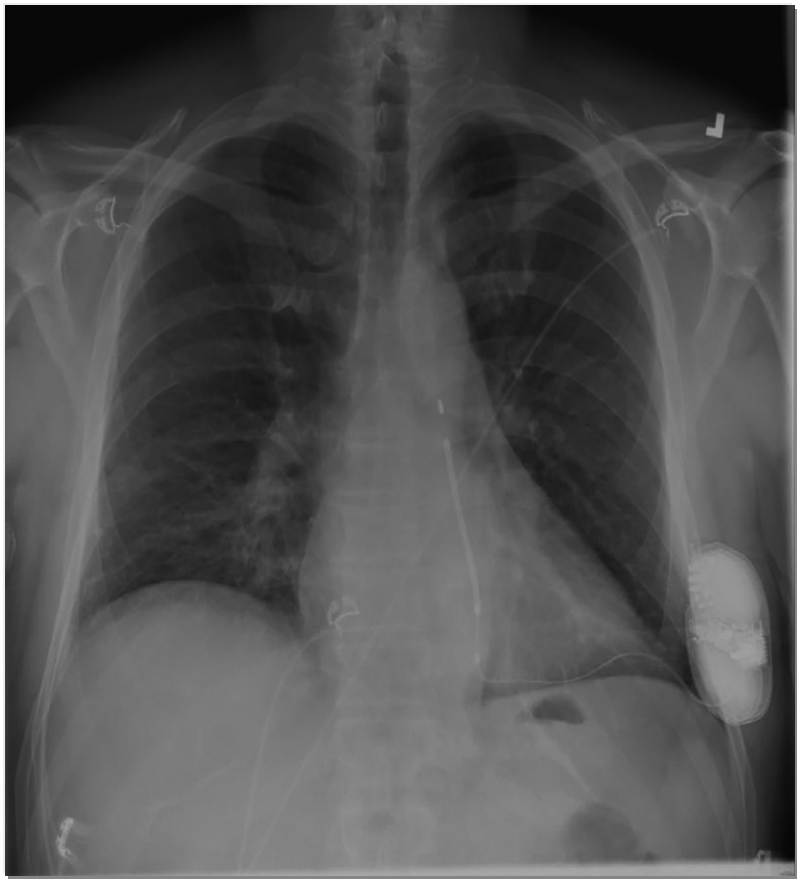


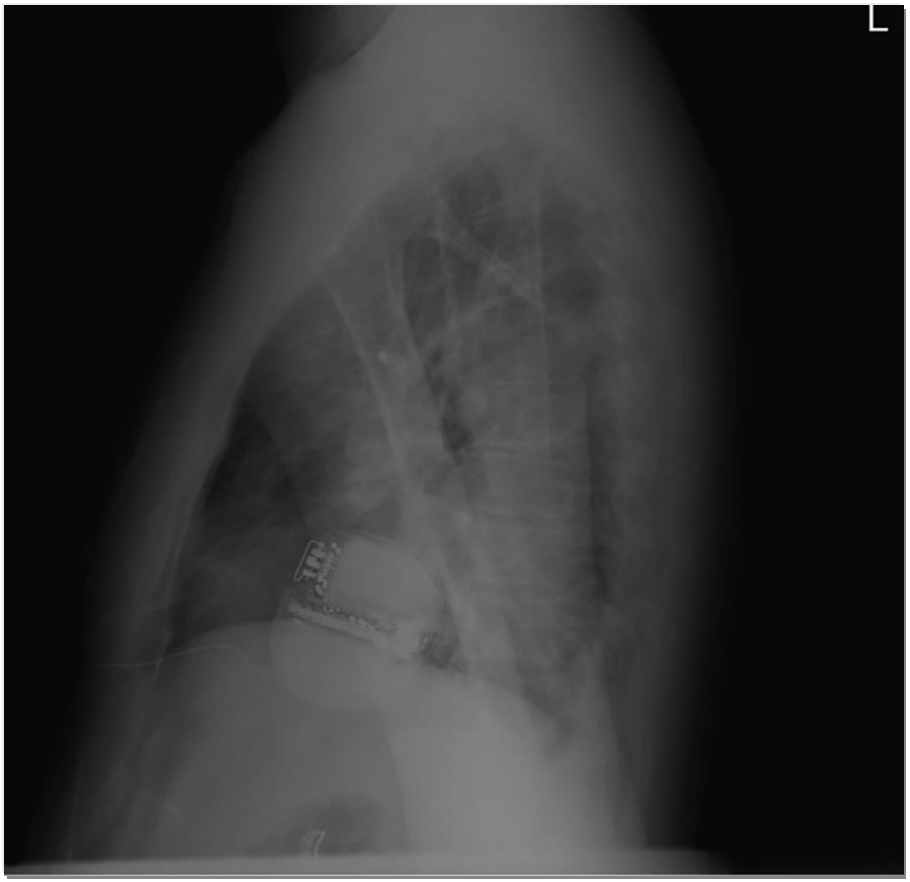
- Pulse jeneratörü sol lateral pozisyonda anterior ve midaksiller hatlar arasına sol ventrikül apeks komşuluğuna yerleştirilir.
- Algılama (*sensing*) ve defibrilasyon için tek bir lead, oluşturulan tünel yardımı ile lateral cepten mediale (ksifoid çıkıntı) sonra sterunumun 1-2 cm solunda ve paralel şekilde distal ucu manubrium sterni ve sternum bileşkesinde kalacak şekilde yerleştirilir.
- ICD leadi *8 cm şok coil*'u ile ayrılmış iki sensing elektrodundan oluşur.

SICD: İmplantasyon

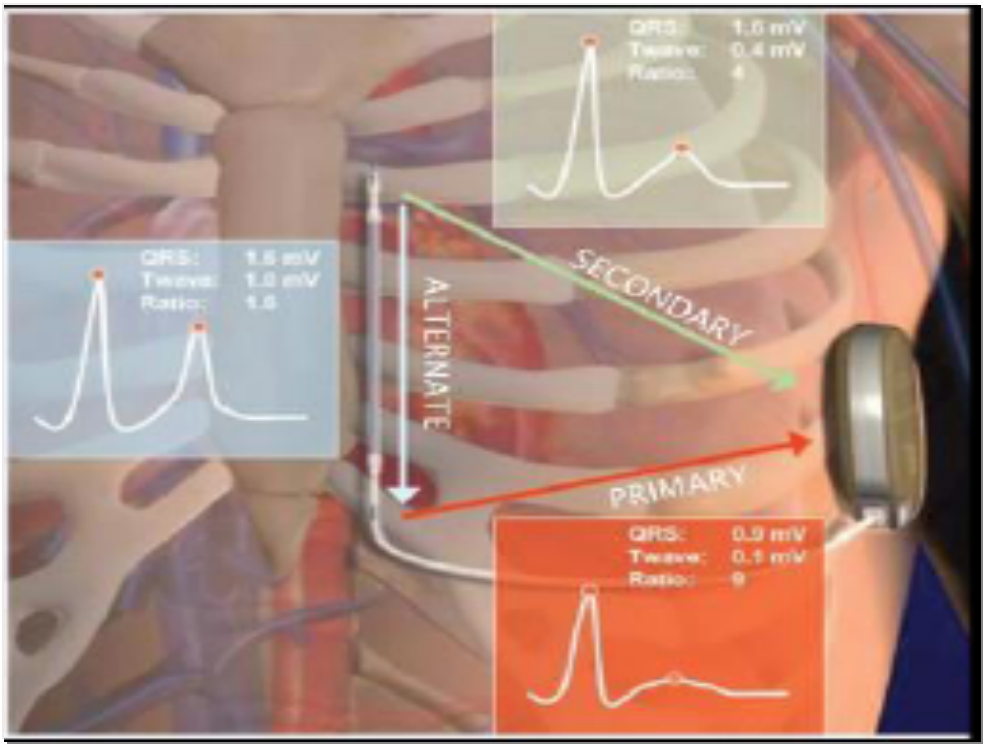


- **Konvansiyonel yöntem: 3 insizyon yöntemi**
  - Sol lateral (jeneratör cebi): 5. İnterkostal boşluk mid ve ant axiller çizgiler arasına
  - iki parasternal insizyon: Xiphoid çıkıntı hemen altına sol parasternal ve distal uç için sternal çentik seviyesine
- **2 insizyon yöntemi**:
  - Sol üst parasternal kesi yapılmaz ve peel-away bir sheath introducer yardımı ve tünel oluşturarak lead yerleştirilir.
- Subkutan yerleştirme yerine son zamanlarda popülarite kazanan kasların arasına yerleştirme (serratus anterior ve latissumus dorsi)
- İmplantasyon anatomik göstergeler kullanılarak floroskopi kullanmadan yapılır/yapılabilir.

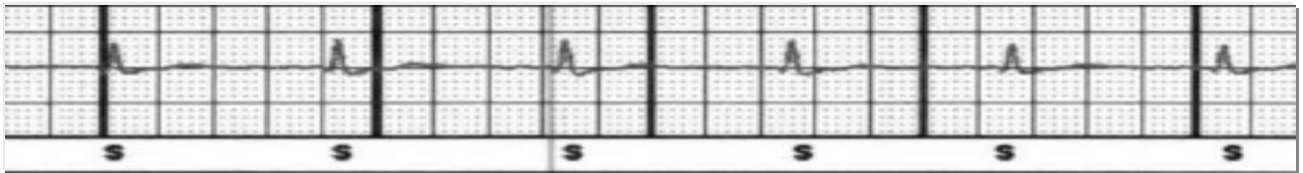




SICD: 3 FARKLI SENSING VEKTÖRÜ

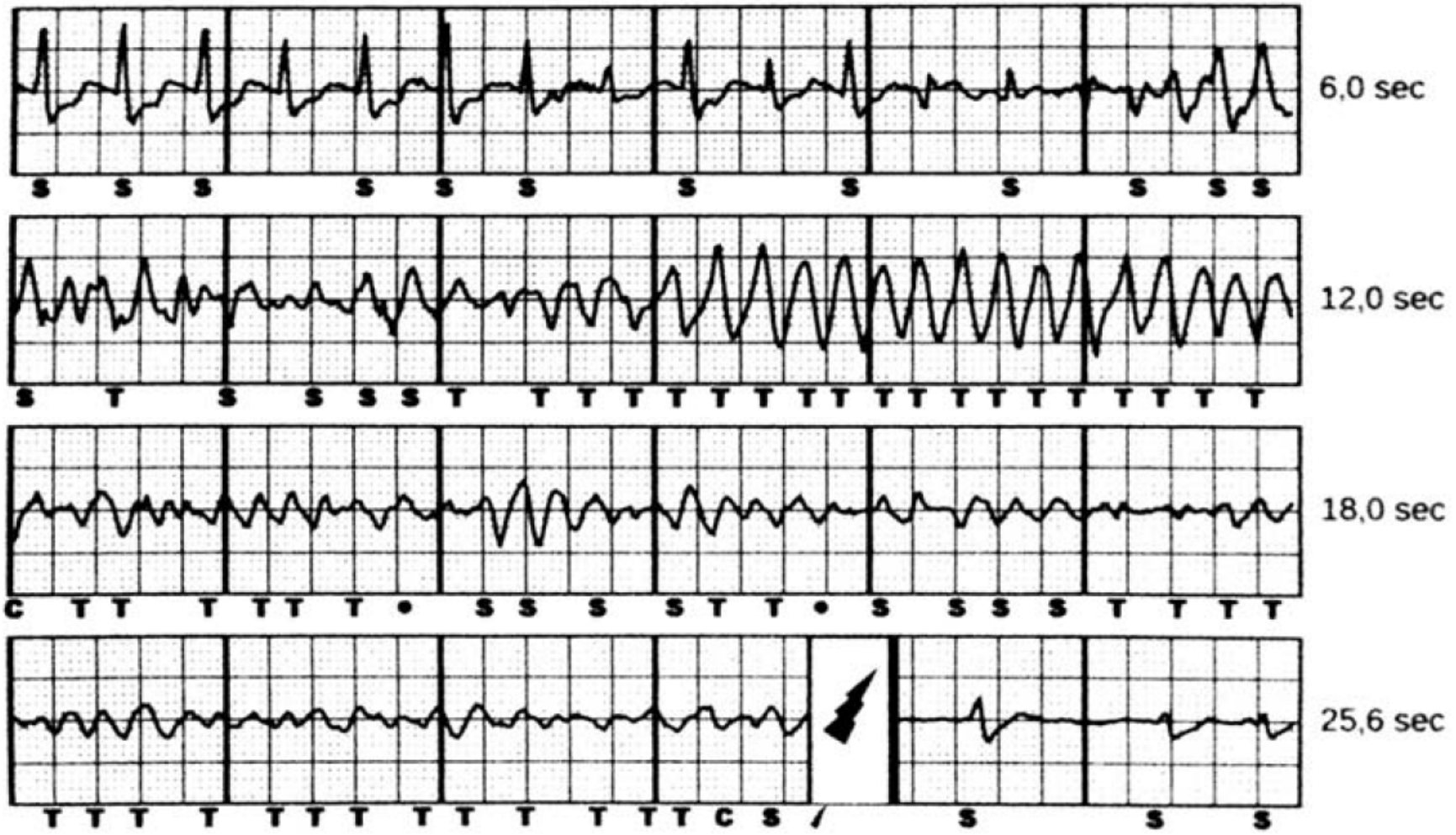


Sinyal/gürültü ve QRS/T oranına göre sistem otomatik olarak en iyi algılama (sensing) vektörünü seçer.

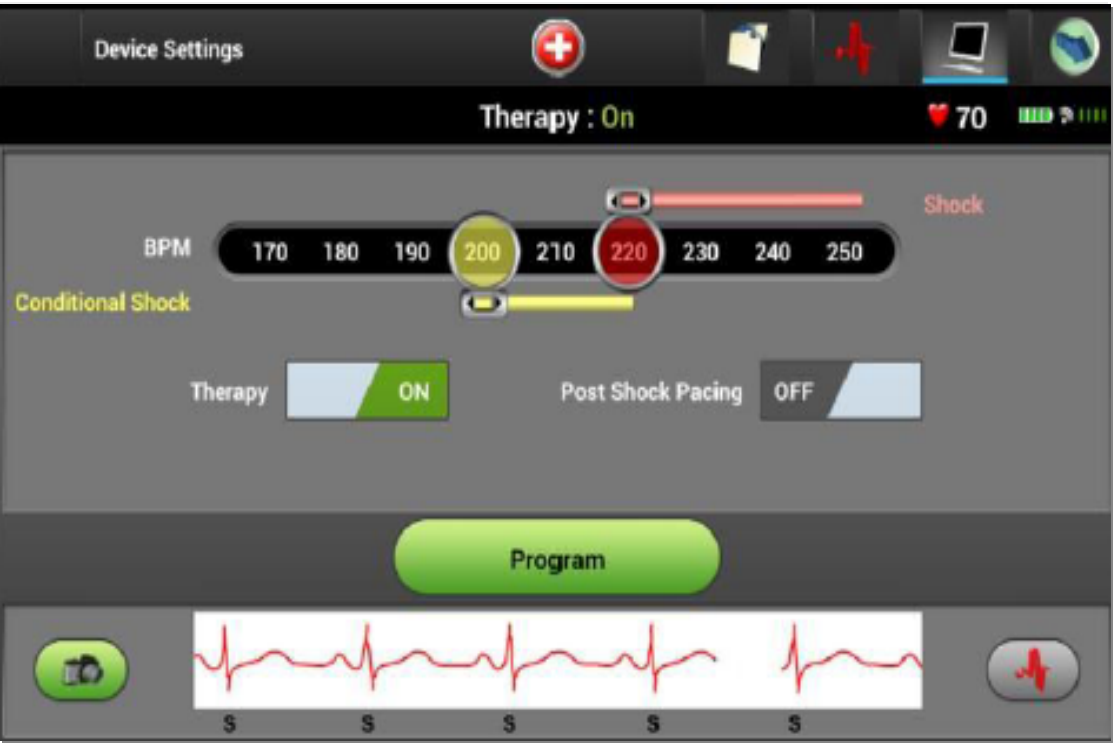


Subkutan ICD

- SICD: Subkutan pulse jeneratörü, subkutan lead (şok koili ile ayrılmış proksimal, distal sensing elektrodları)
- Tablet şeklinde programlayıcı
- **ATP ve bradipacing özelliği yok**
- **Şok sonrası 30 sn *transtorasik pacing*.**
- **İşlem sonrası DFT zorunlu**
- **Programlama :**
  - **Conditional zone**
  - **VF zone**


6,0 sec
12,0 sec
18,0 sec
25,6 sec

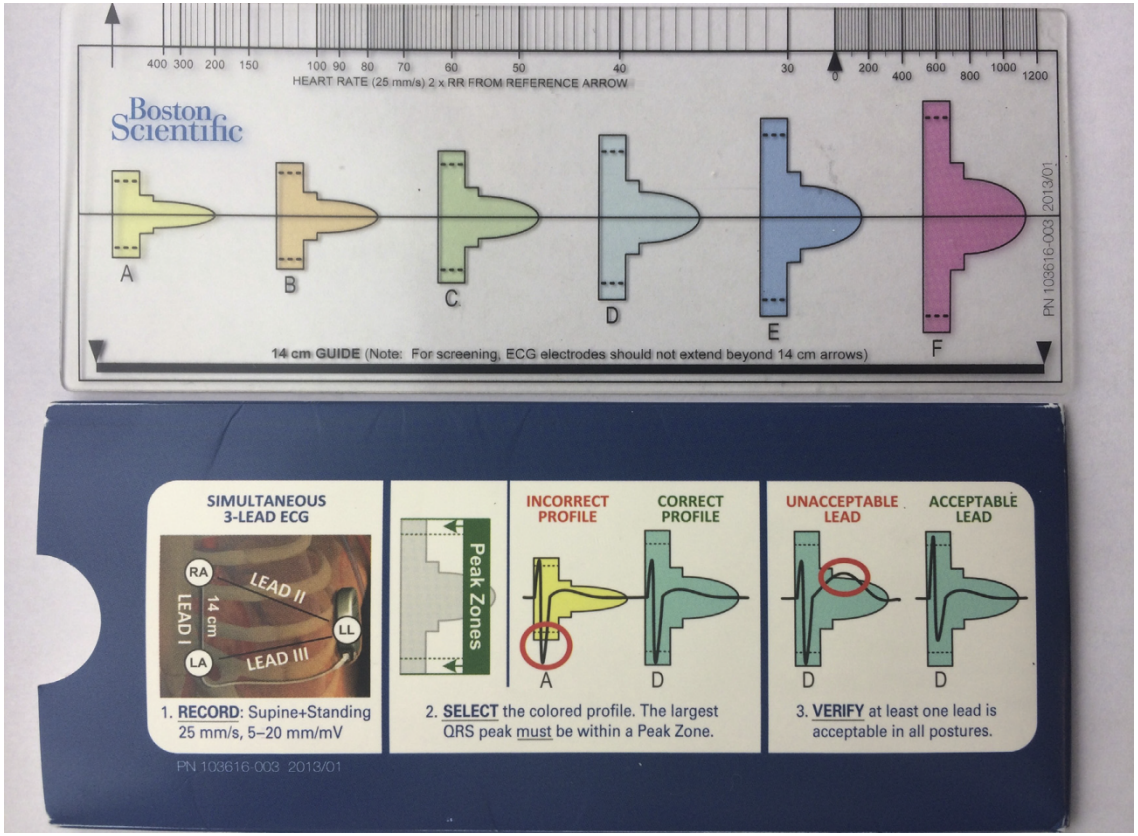
PROGRAMLAMA



- **Şok zonu**
  - 170 – 250/dk arası programlanabilir
  - Hız tek kriterdir
- **Opsiyonel şok zonu** (optional conditional shock zone)
  - 170 – 240/dk arası programlanabilir
  - SVT ayırım özellikleri var
    - 1) **Dalga formu (waveform) analizi :** normal aktivite ile >%50 korelasyon SVT
    - 2) **Atımdan atıma analiz:** considers polymorphic relationship as ventricular tachyarrhythmia, while in the case of monomorphic relationship the algorithm continues to the next analysis step;
    - 3) **QRS genişliği analizi:** QRS genişse VT

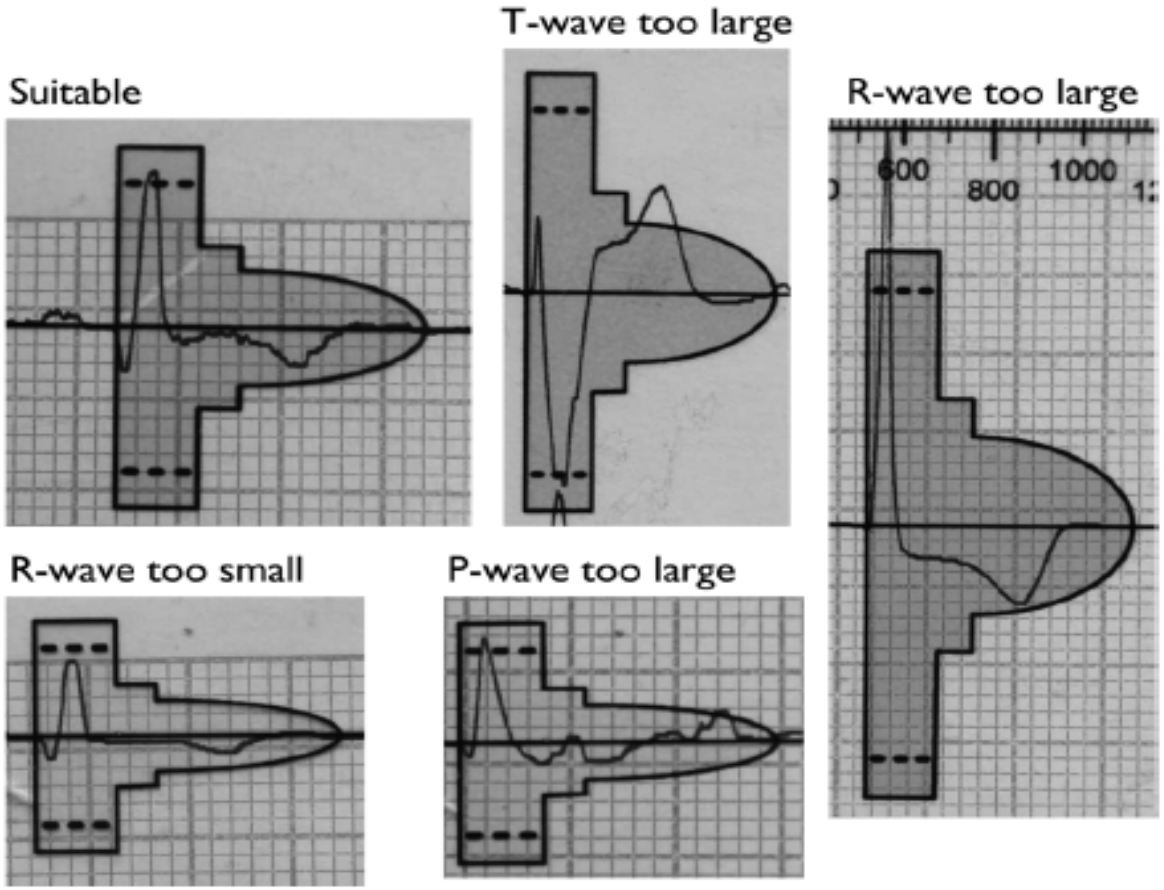
SICD: HASTA SEÇİMİ

- Implant öncesi SICD'ye uygun olmayanlar için standardize edilmiş bir yöntemle hastalar *hem sırtüstü hem de ayakta QRS ve T dalga kompleksinlerine göre tarama* yapılır.
- **Implant öncesi taramalara göre hastaların %8'i SICD için uygun değildir.**
- Implant sonrası yüksek kalp hızlarında şablonu oluşturmak için egzersiz testi önerilir.
- **İskemi veya sol ventrikül hipertrofisine bağlı T dalga negatifliği taramada başarısızlık oranını 23 kat arttırır.**
- **Çok geniş veya dar QRS kompleksleri tarama başarısını azaltır.**



Lewis GF, Gold MR.. J Am Coll Cardiol. 2016 :2;67(445-54)

SICD: HASTA SEÇİMİ

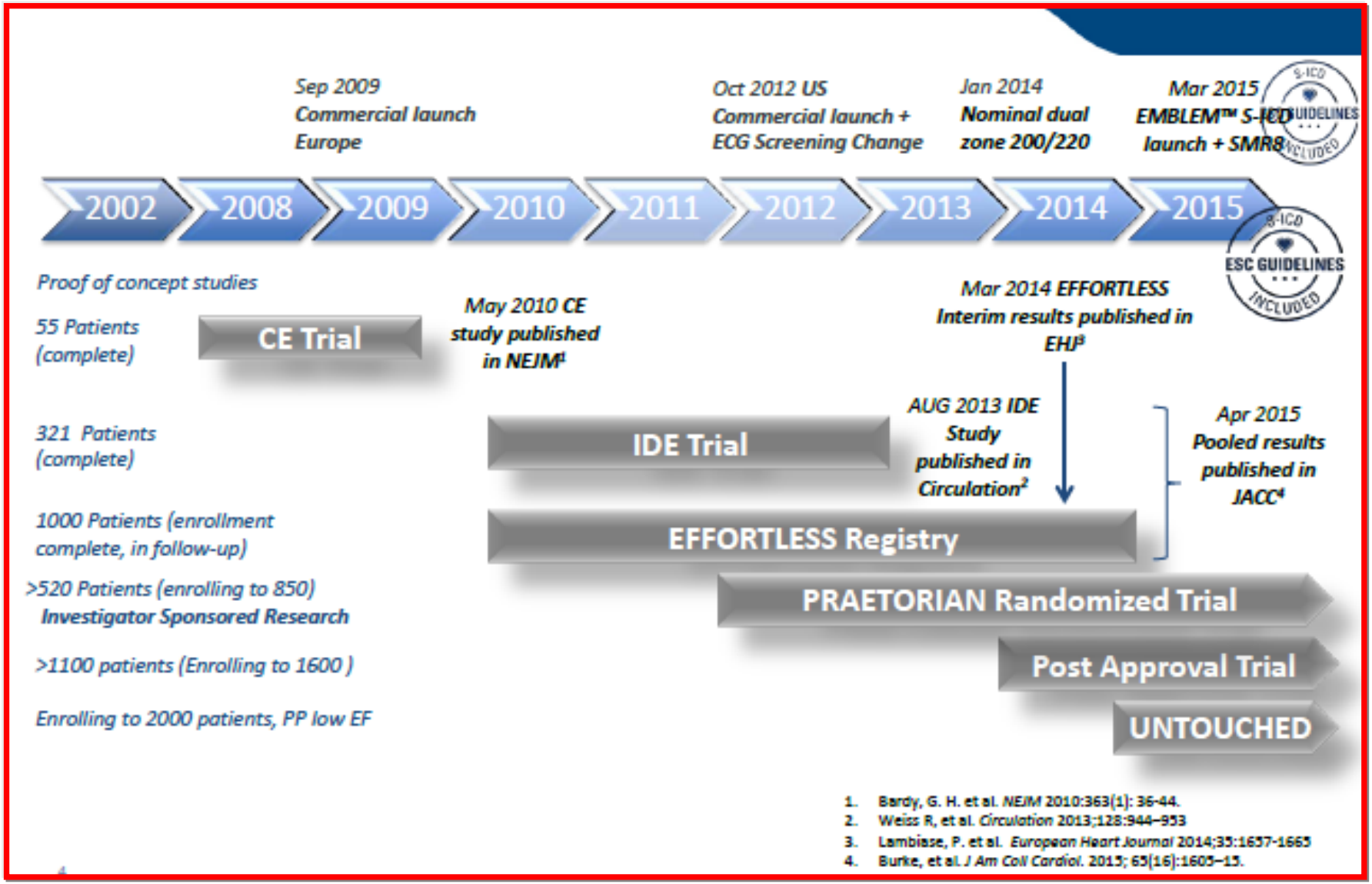


SICD

FIGURE 2 Photograph of Lateral Views of First-Generation S-ICD, Second-Generation (Emblem) S-ICD, and Single-Chamber ICD Pulse Generators Demonstrating Device Thickness

trials reporting any cases of pulse generator erosion, rates ranged from 1.7% to 1.8% (17,19). Nonetheless, the size of the first-generation S-ICD's pulse generator has clearly been an issue. The generator has a volume of 69.9 cc, weighs 165 g, and measures 78.2 × 65.5 × 15.7 mm. Each of these measurements is larger than a comparable transvenous ICD. This large size, particularly the thickness, has been problematic for some patients, primarily those of smaller body habitus. The second-generation S-ICD pulse generator has a smaller volume (59.5 cc), and weight (130 g); it measures 83.1 × 69.1 × 12.7 mm (36) (**Figure 2**). Although the reduced pulse generator size may result in decreased incidence of pulse generator erosion, there is, as yet, no published data on this topic.

S-ICD


Sep 2009
Commercial launch
Europe
Oct 2012 US
Commercial launch +
ECG Screening Change
Jan 2014
Nominal dual
zone 200/220
Mar 2015
EMBLEM™ S-ICD
launch + SMR8
S-ICD ESC GUIDELINES INCLUDED
2002
2008
2009
2010
2011
2012
2013
2014
2015
Proof of concept studies
55 Patients
(complete)
CE Trial
May 2010 CE
study published
in NEJM[1]
Mar 2014 EFFORTLESS
Interim results published in
EHJ[3]
321 Patients
(complete)
IDE Trial
AUG 2013 IDE
Study
published in
Circulation[2]
Apr 2015
Pooled results
published in
JACC[4]
1000 Patients (enrollment
complete, in follow-up)
EFFORTLESS Registry
>520 Patients (enrolling to 850)
Investigator Sponsored Research
PRAETORIAN Randomized Trial
>1100 patients (Enrolling to 1600)
Post Approval Trial
Enrolling to 2000 patients, PP low EF
UNTOUCHED
1. Bardy, G. H. et al. NEJM 2010;363(1): 36-44.
2. Weiss R, et al. Circulation 2013;128:944–953
3. Lambiase, P. et al. European Heart Journal 2014;35:1657-1665
4. Burke, et al. J Am Coll Cardiol. 2015; 65(16):1605–13.

SICD: HASTA PROFİLLERİ

	EFFORTLESS	S-ICD Post Approval Study	US S-ICD Trends
N	985	1637	3717
Males	72%	69%	69%
Age (years)	48 ± 17	53 ± 15	53 ± 15
CAD (previous MI)	29%	33%	40%
EF (mean)	43 ± 18	32 ± 14	32 ± 14
Hypertrophic Cardiomiopathy	11%	NA	5%
Channelopathies	20%	4%	8%
Diabetes	11%	34%	38.5%
Atrial Fibrillation	16%	16%	20%
CKD	8%	26% (dyalisis 13%)	41% (dyalisis 20%)

CAD: Coronary artery disease; MI: myocardial infarction; EF: ejection fraction; CKD: Chronic kidney disease.

Adduci C et al. J Clin Med. 2018 Mar 11;7(3).

U.S. National Library of Medicine

ClinicalTrials.gov

Understanding Outcomes With the EMBLEM™ S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED)

Study Description

Go to

Brief Summary:

This study assesses the 18-month incidence of inappropriate shocks in subjects implanted with the EMBLEM Subcutaneous Implantable Defibrillator (S-ICD) for primary prevention of sudden cardiac death. Devices are to be programmed with zone cutoffs at 200 bpm and 250 bmp in order to mimic the programming settings for transvenous ICDs in the MADIT RIT study. The incidence of inappropriate S-ICD shocks will be compared to the incidence of inappropriate shocks observed in the MADIT RIT study.

Condition or disease	Intervention/treatment	Phase
Ventricular Fibrillation Ventricular Tachycardia Low Cardiac Output	Device: EMBLEM S-ICD System	Not Applicable

Düşük EF (<%35), primer koruma kayıt çalışması

Outcome of Subcutaneous Implantable Cardioverter Defibrillator Implantation in Patients with End-Stage Renal Disease on Dialysis

MIKHAEL F. EL-CHAMI, M.D.,* MATHEW LEVY, B.S.,† HEVAL M. KELLI, M.D.,‡ MARY CASEY, B.S.N.,† MICHAEL H. HOSKINS, M.D.,* ABHINAV GOYAL, M.D.,§ JONATHAN J. LANGBERG, M.D.,* ANSHUL PATEL, M.D.,* DAVID DELURGIO, M.D.,* MICHAEL S. LLOYD, M.D.,* ANGEL R. LEON, M.D.,* and FAISAL M. MERCHANT, M.D.*

From the *Division of Cardiology-Section of Electrophysiology, Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA; †Emory Healthcare, Atlanta, Georgia, USA; ‡Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA; and §Division of Cardiology, Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA

Subcutaneous ICD in Dialysis Patients. ***Background:*** **Although the subcutaneous ICD (S-ICD®) is an attractive alternative in patients with end-stage renal disease (ESRD), data on S-ICD outcomes in dialysis patients are lacking.**

Methods: **Patients with cardiomyopathy undergoing S-ICD implantation in our center were stratified by need for chronic dialysis at the time of implant. The primary endpoint was incidence of death, heart failure hospitalization or appropriate S-ICD shocks, and secondary endpoints were incidence of inappropriate shocks or implant related complications requiring surgical re-intervention. Mean follow-up was longer in the nondialysis cohort (514 ± 495 vs. 227 ± 233 days, P = 0.006), so all endpoints were analyzed using time-dependent comparisons and reported as annual event rates.**

Results: **Out of 79 S-ICD implants included in this analysis, 27 patients were on dialysis. Dialysis patients were older and more likely to be diabetic. Mean ejection fraction across the entire cohort was 26.9% without significant difference between dialysis and nondialysis groups. Although not significant, the incidence of the primary endpoint was higher in the dialysis cohort (23.8%/year vs. 10.9%/year, P = 0.317), driven primarily by a higher rate of appropriate shocks. The rate of inappropriate shocks was similar between groups (dialysis 6.0%/year vs. nondialysis 6.8%/year, P = 0.509). No patients in the dialysis cohort had complications requiring surgical re-intervention versus 6 patients in the nondialysis cohort (P = 0.086).**

Conclusions: **Our data suggest that S-ICD implantation in dialysis patients is not associated with an excess risk of implant related complications or inappropriate shocks.** *(J Cardiovasc Electrophysiol, Vol. 26, pp. 900-904, August 2015)*

dialysis, end-stage renal disease, implantable cardioverter-defibrillator, sudden cardiac death, subcutaneous ICD

SICD: Komplikasyonlar

	Pooled Analysis IDE + EFFORTLESS	EFFORTLESS Midterm	S-ICD Post Approval Study	US S-ICD Trends
Infection requiring removal/revision	1.7%	2.4%	1.2%	0.05%
Erosion	1.2%	1.7%		
Hematoma	0.4%	0.9%	0.4%	0.3%
Discomfort	0.9%	0.8%	0.1%	
Lead dislodgment	0.6%	0.7%		0.1%
Superficial Infection	0.3%	0.5%	0.1%	
Suboptimal PG or/and lead position	1.4%	1.6%	0.5%	
Inappropriate shocks: oversensing	4.6%	5.1%	0.2%	
Inappropriate shocks: SVTs	2.8%	2.3%		
Total complications	9.6%	11.7%		

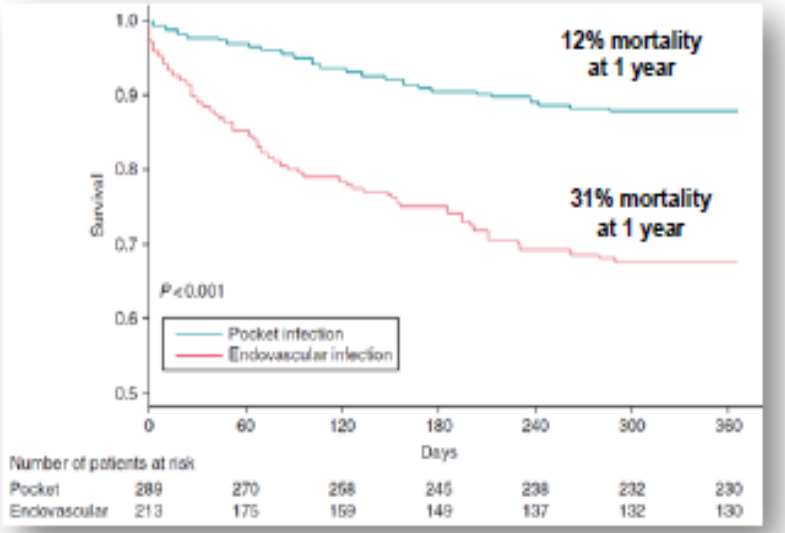
PG: pulse generator, SVT: supraventricular tachycardia.

Complications	SICD	TV-ICD
Infections		
Infection rate (per year)	2%	1.6%
• need for explant	1.7%	>50%
• endocarditis/bacteraemia	0%	22–54%
Implant Site Complications		
Haematoma	4%	0.86–2.4%
Device erosion	1.2–3%	1.5%
Lead or Pulse Generator Complications		
Inappropriate shocks (per year)	1.6%	7–10% (first year) 18% (5 year follow-up)
Electrode dislodgement	0.6%	1.8% (single/dual ICD) 5.9% (CRT)

Adduci C et al. J Clin Med. 2018 Mar 11;7(3).

SICD: Enfeksiyon

- Enfeksiyon oranı TV-ICD ile benzer.
  - %0.13 -% 1.9
- SICD ile bakteriyemi veya endokardit izlenmemiş.
  - TV-ICD: %22- %54 TV-ICD enfeksiyonları
  - IDE ve EFFORTLESS kayıt çalışmalarında endokardit veya bakteriyemi izlenmemiş.



Data from Cleveland Clinic:

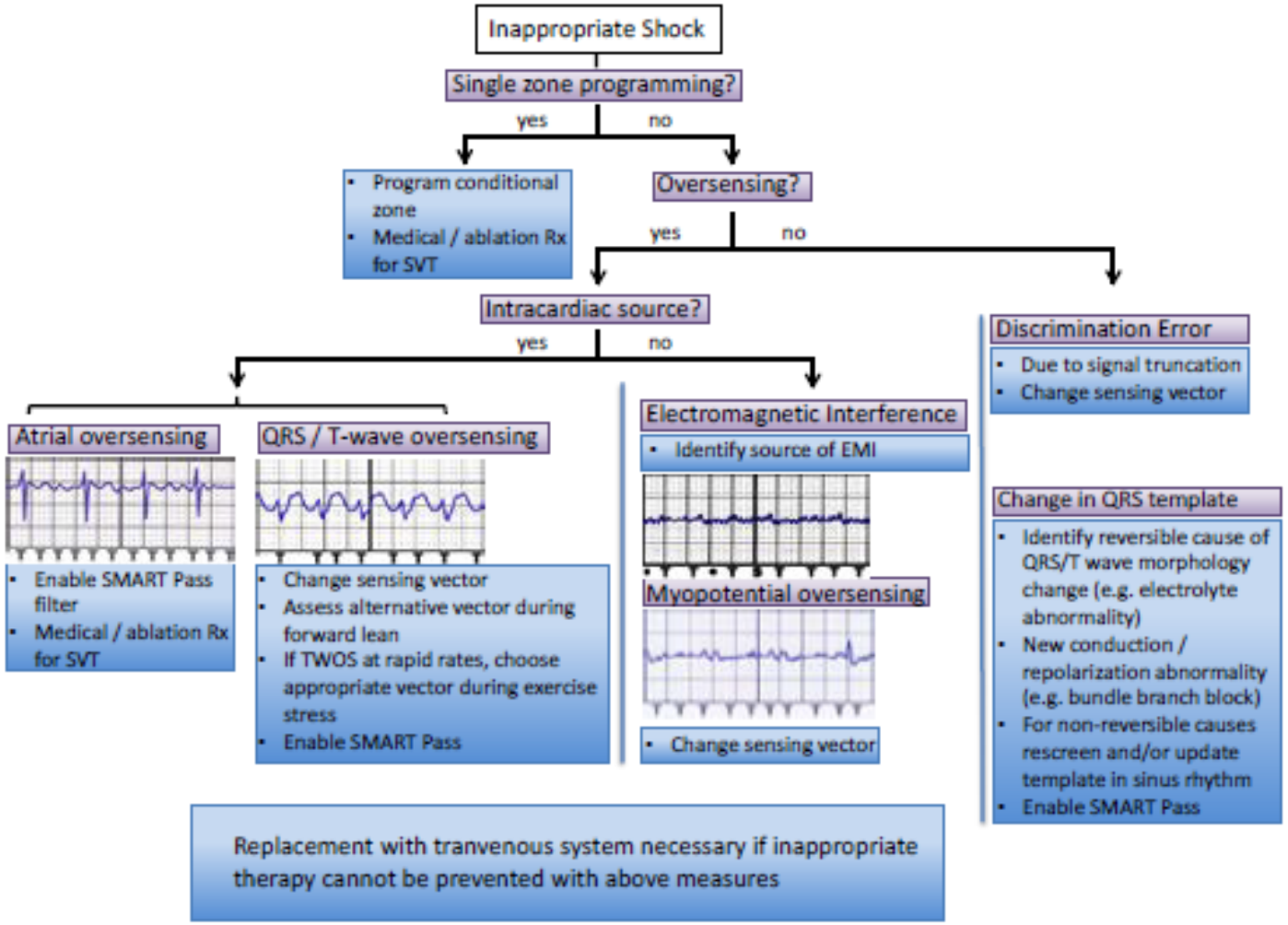
- In patients who had an endovascular infection unadjusted mortality rate approaches 31% within 1 year
- 3-fold higher risk of death in those who had an endovascular infection compared to a pocket infection

1. Priori, SG. et al. *Eur Heart J*. 2015 Aug 29. doi:10.1093/eurheartj/ehv316. Epub ahead of print
2. Tarakji et al; *Europace*, 2014;16:1490-1495

SICD: UYGUNSUZ ŞOK

- **Erken** kayıt çalışmalarında %5-25.
- Sebepler:
  - ***T dalga oversensing***
  - SVT
  - Lead migrasyonu
- Önlemler:
  - Pretest EKG taraması
  - Egzersiz testi: İşlem öncesi ve sonrasında
  - Dual zone programlama (170-220/dk ve SVT ayrımı algoriması) ile SVT tanı spesifitesi %98.
  - Effortless ve IDE kayıt çalışmalarında 3 yılda uygunsuz şok: %11.7 **(%24 SVT, %39 T dalga oversensing)**

SICD: UYGUNSUZ ŞOK



SICD: UYGUNSUZ ŞOK

- Erken kayıt çalışmalarında %5-25.
- Sebepler:
  - ***T dalga oversensing***
  - SVT
  - Lead migrasyonu
- Önlemler:
  - Pretest EKG taraması
  - Egzersiz testi: İşlem öncesi ve sonrasında
  - Dual zone programlama (170-220/dk ve SVT ayrımı algoriması) ile SVT tanı spesifitesi %98.
  - Effortless ve IDE kayıt çalışmalarında 3 yılda uygunsuz şok: %11.7 **(%24 SVT, %39 T dalga oversensing)**

SICD: Etkinlik

- **Defibrilasyon testi:** EFFORTLESS kayıt çalışmasında başarısız defibrilasyon oranı: %0.2.
- S-ICD çalışmasında %0.04.
- %98.7 oranında ilk seferde defibrilasyon başarısı mevcut (%91.2'si ≤65 J, %7.5 70-80 J).
- **Spontan VT/VF:** 994 hastalık EFFORTLESS *midterm* sonuçlarında (3.1±1.5 yıllık takip) yıllık %3.4 spontan VT/VF mevcut. VT fırtınası olmayan grupta ilk şok ile çevirme oranı **%88.5**, ≥2 veya daha çok şok ile **%97.4**. Başarısızlık oranı **%2.6**.
- Transvenöz ICD çalışmalarında benzer başarısızlık oranları bildirilmiş (SIMPLE çalışması % 2.6, NORDIC çalışması %1.6, SCD-HeFT çalışması % 1.6)

Adduci C et al. J Clin Med. 2018 Mar 11;7(3).

SICD: Etkinlik

Table 1: Summary of Available Data from Clinical Trials/Registries Regarding the Performance of the Subcutaneous ICD in Different Patient Cohorts

S-ICD Cohorts/ Trials	Patient Number	Mean Age (Years)	Primary Prevention %	EF %	Ischaemic %	Follow-up (Month)	Successful Termination of Induced VF %	Successful Termination of Clinical VT/VF %	Inappropriate Shocks %	Infection Rate %
CE Trial[21]	55	56	78	34	67	10±1	98	100	9	3.6
UK Cohort[22]	111	33	50	–	14	12	100	100	15	9.9
Dutch Cohort[23]	118	50	60	41	38	18	100	100	13	5.9
German I Cohort[24]	40	42	42.5	47	22.5	7.6	97.5	100	5	–
German II Cohort[25]	69	45	59.4	46	15.9	7.2	95.5	100	7.2	1.4
Pooled data (EFFORTLESS + IDE)[26]	882	50	~70	~40	37.8	21.7±11.5	98.6	98.2	13.1 at 3 years	11.1 at 3 years

When evaluating TV-ICD studies[1-4], S-ICD was as effective as TV-ICD in treating spontaneous arrhythmias

	Spontaneous Shock Efficacy	
	First Shock	Final Shock in episode
S-ICD Pooled Data*	90.1%	98.2%
ALTITUDE First Shock Study[1]	90.3%	99.8%
SCD-HeFT[2]	83%	
PainFree Rx II[2]	87%	
MADIT-CRT[3]	89.8%	
LESS Study[4]		97.3%

* Excluded VT/VT Storm events

S-ICD Pooled Data	Of two "unconverted" episodes
100% Clinical conversion to normal sinus rhythm	• One spontaneously terminated after the 5th shock • In the other episode, the device prematurely declared the episode ended. A new episode was immediately reinitiated and the VF was successfully terminated with one shock

1 Cha YM et al. *Heart Rhythm* 2013;10:702–708. 2 Swerdlow CD et al. *PACE* 2007; 30:675–700. 3 Kutyifa V, et al. *J Cardiovasc Electrophysiol* 2013;24:1246-52. 4 Gold MR et al. *Circulation* 2002;105:2043-2048.

S-ICD had a 2 year mortality rate that compared favorably with mortality rates in studies with TV-ICDs

Study	Mortality (At 2 years)	Average Age	1º Prevention	Ischemic	NYHA	LVEF
S-ICD Pooled*	3.2%	50	70%	38%	37.5% class II-IV	39%
MADIT RIT[1]	5-7% High rate and Delayed Therapy Arms	63	100%	53%	98% class II or III	26%
SIMPLE[2]	11%	64	70%		63% class II or III	32%

*The **1.6% annual mortality rate** with the S-ICD was deemed "**provocative**" by the authors as it is lower than observed in TV-ICD studies.*

*This analysis was not designed or powered to assess mortality and care should be taken as the population in this analysis may differ from the patient population in TV-ICD studies.

1 Burke MC et al. Pooled Analysis of the EFFORTLESS and IDE Registry. *JACC* April 20th 2015 2 Moss AJ et al. MADIT RIT Study *NEJM* 2012;367;2275-2283. 3 Healy JS et al. SIMPLE Study *Heart Rhythm* 2014;LBCT01;LB01-01.

European Heart Journal (2015) 36, 2793–2867
doi:10.1093/eurheartj/ehv316

2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC)

Subcutaneous implantable cardioverter defibrillator

Recommendations	Class[a]	Level[b]	Ref.[c]
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

ICD = implantable cardioverter defibrillator.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

157. Weiss R, et al. Circulation 2013;128:944–953.
158. Lambiase PD, et al. Eur Heart J 2014;35:1657–1665.

S-ICD ESC GUIDELINES INCLUDED

S-ICD not suitable in...

1. Patients who need **CRT**.
2. Patients who **require bradycardia pacing***
3. Patients who suffer from ventricular tachy-arrhythmias that can be **easily terminated by antitachycardia pacing (ATP)**.

* Unless this need is confined to the period immediately following delivery of a shock (transcutaneous pacing can be delivered by the device for 30 seconds after the shock).

ICD hastalarında bradikardi pacing gereksinimi ?

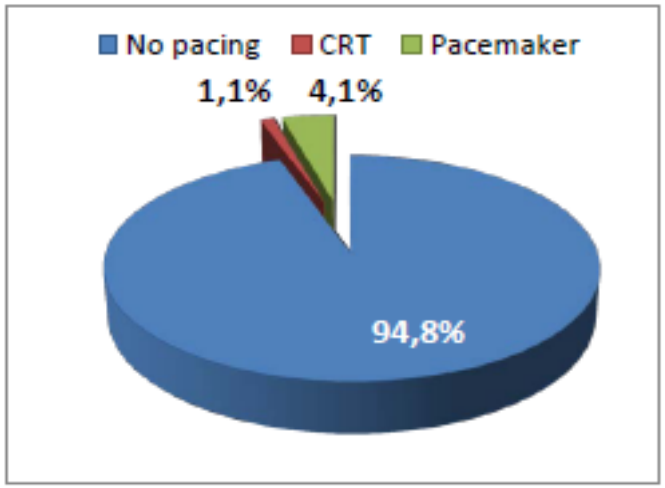
Pacemaker ımplant ın MADIT II control

Prevalence of indication for bradycardia pacing at time of ICD implant ~6%[1]

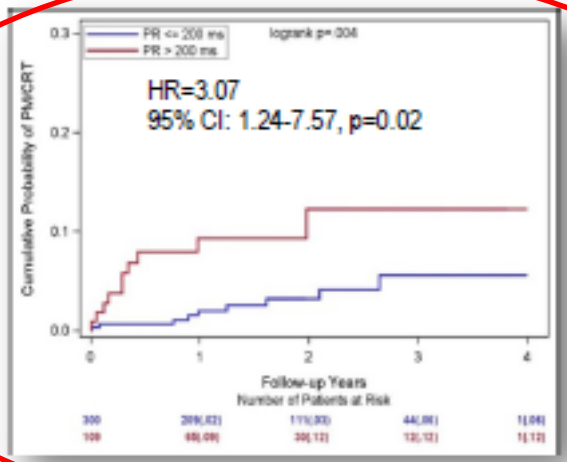
Total Annualized Pacemaker Rate in MADIT II* control ~2% / year[2]

458 pts with over 20 month median follow-up, in the control arm (OPT)

- 4.1% implanted with pacemaker
- 1.1% implanted with CRT



Baseline PR interval >200 ms significantly predicted subsequent PM/CRT implantation



1. de Bie MK et al. Suitability for subcutaneous defibrillator implantation: results based on data from routine clinical practice. Heart. 2013 Jul;99(14):1018-23
2. Kutyifa. et al. The Need for Pacing in patients who qualify for an ICD: Clinical Implications. Presented at ESC 2014; Abstract P4346

CRM-345601-AA OCT

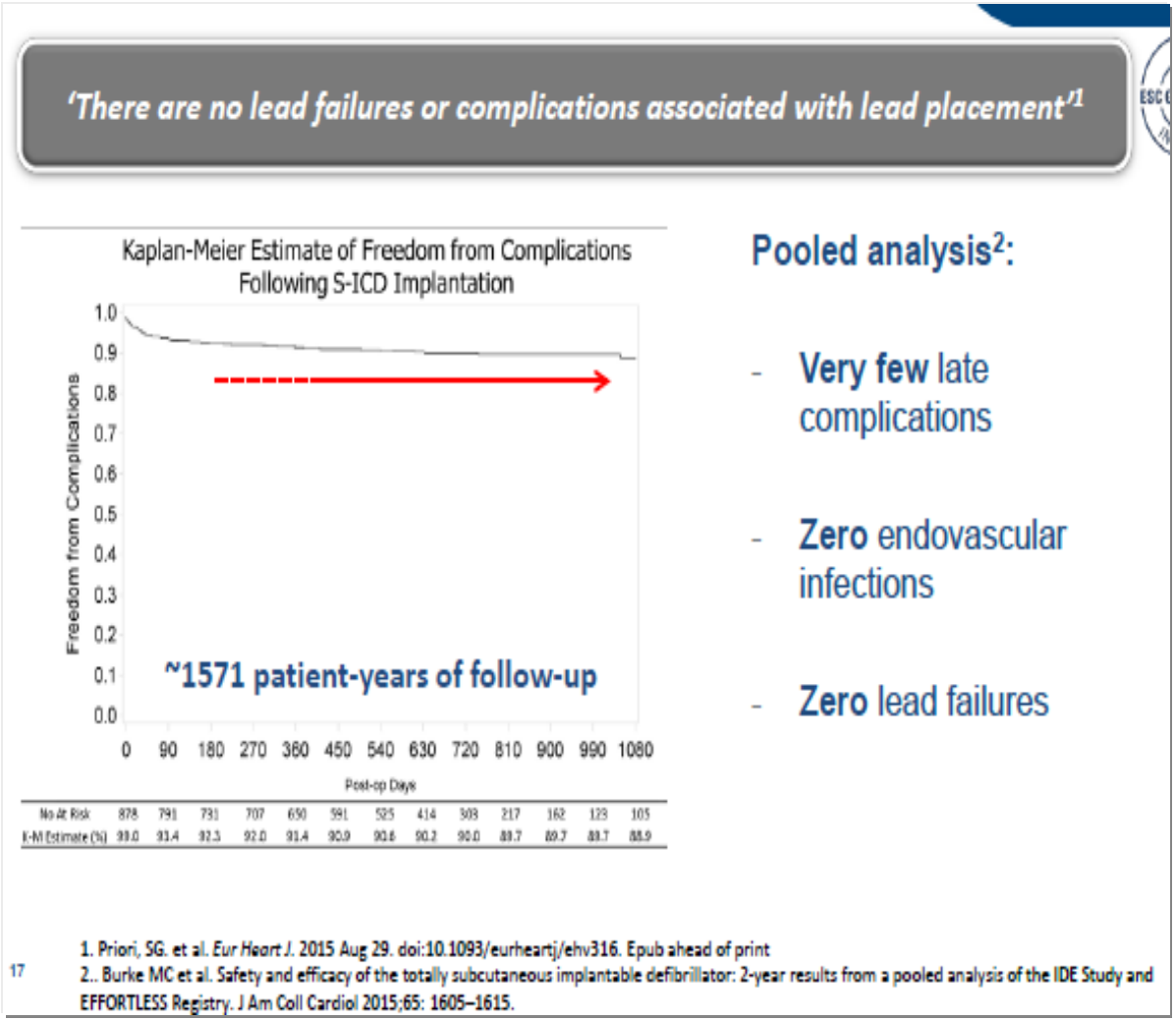
2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator
References that support the recommendations are summarized in Online Data Supplement 55.

COR	LOE	RECOMMENDATIONS
I	B-NR	1. In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (S11.1-1–S11.1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (S11.1-1–S11.1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (S11.1-1–S11.1-4,S11.1-6–S11.1-8).

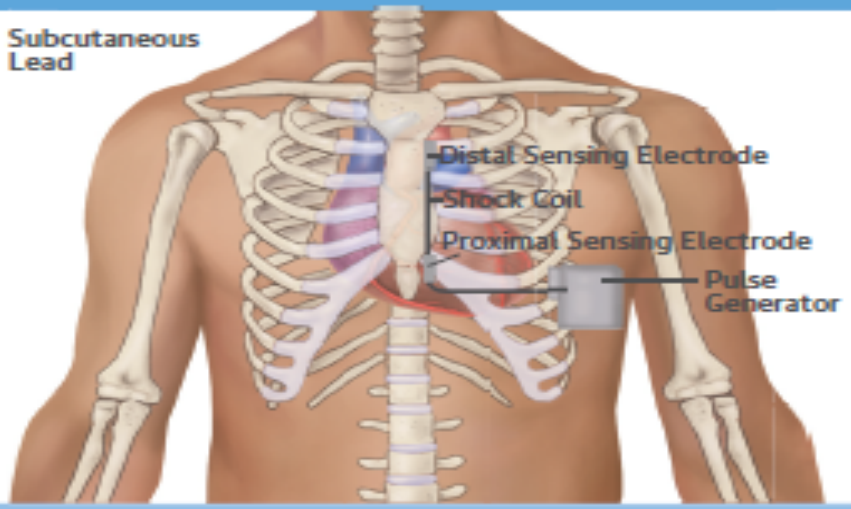
SICD: LEAD



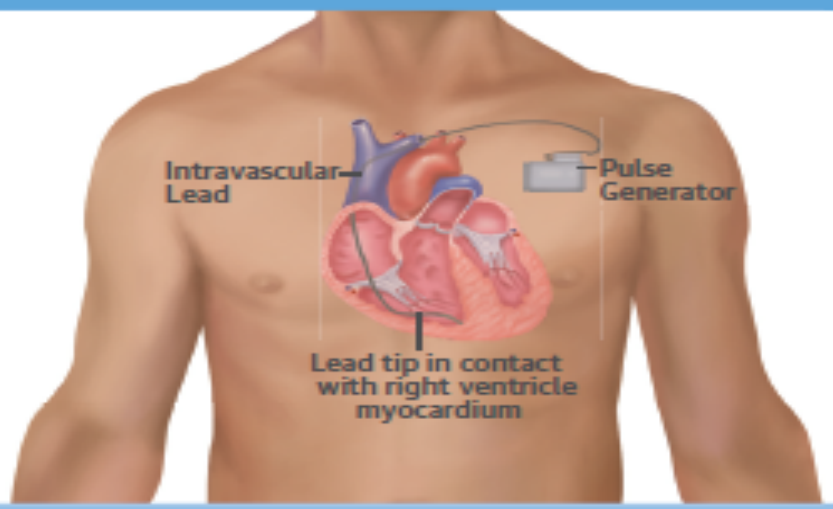
- Lead problemleri transvenöz sistemlerde 10 yolda % 20. SICD leadlerinin içerisinde yerleştirilmeleri için stylet gereken bir boşluk yok ve bu daha iyi bir gerilim (tensile) dayanıklılığı sağlıyor.
- Subkutan yerleşimi sebebi ile kalp hareketlerinden etkilenmiyor.
- Lead problemleri için uzun süreli takip gerekiyor ancak **5.8 yıllık Avrupa takip çalışmasında SICD sistemlerinde lead problemi yok.**

SICD VE TV- ICD KARŞILAŞTIRILMASI: Etkinlik ve Güvenlik

S-ICD



Transvenous ICD



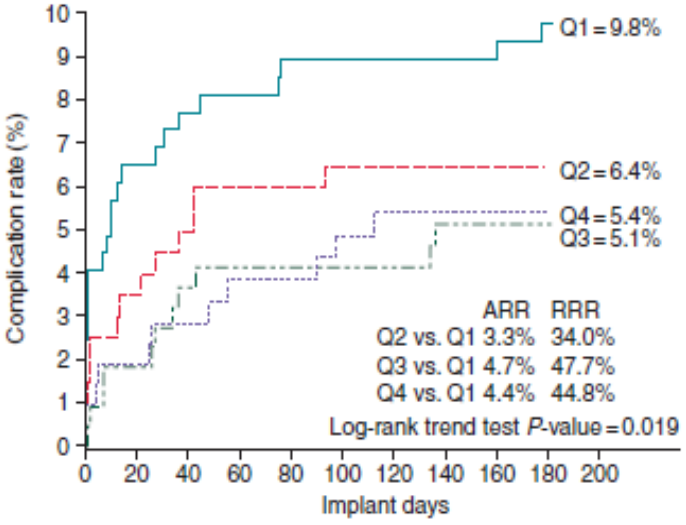
S-ICD Advantages	Transvenous ICD Advantages
• Eliminate need for vascular access	• Pacemaker and ATP functionality
• Possible to implant without fluoroscopy	• Smaller pulse generator
• Reduced mid-term risk of lead malfunction	• Better battery longevity
• Eliminate certain procedural risks (e.g. pneumothorax, tamponade)	• Shorter charge time-faster shock delivery
• Improved arrhythmia discrimination	• Able to deliver CRT
• Relative ease of extraction	• No pre-implant ECG screening required
• Hardware infections not associated with endocarditis	• Long-term follow-up data available

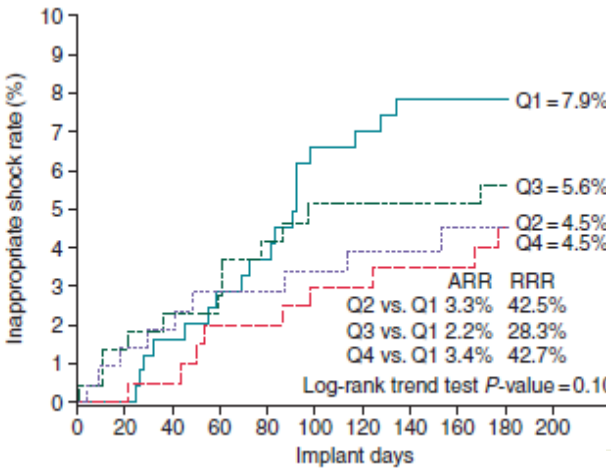
Lewis, G.F. et al. J Am Coll Cardiol. 2016; 67(4):445-54.

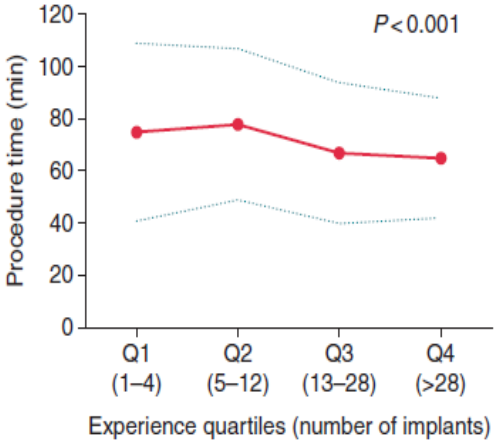
Europace (2016) 18, 1010–1015
doi:10.1093/europace/euv299

The learning curve associated with the introduction of the subcutaneous implantable defibrillator

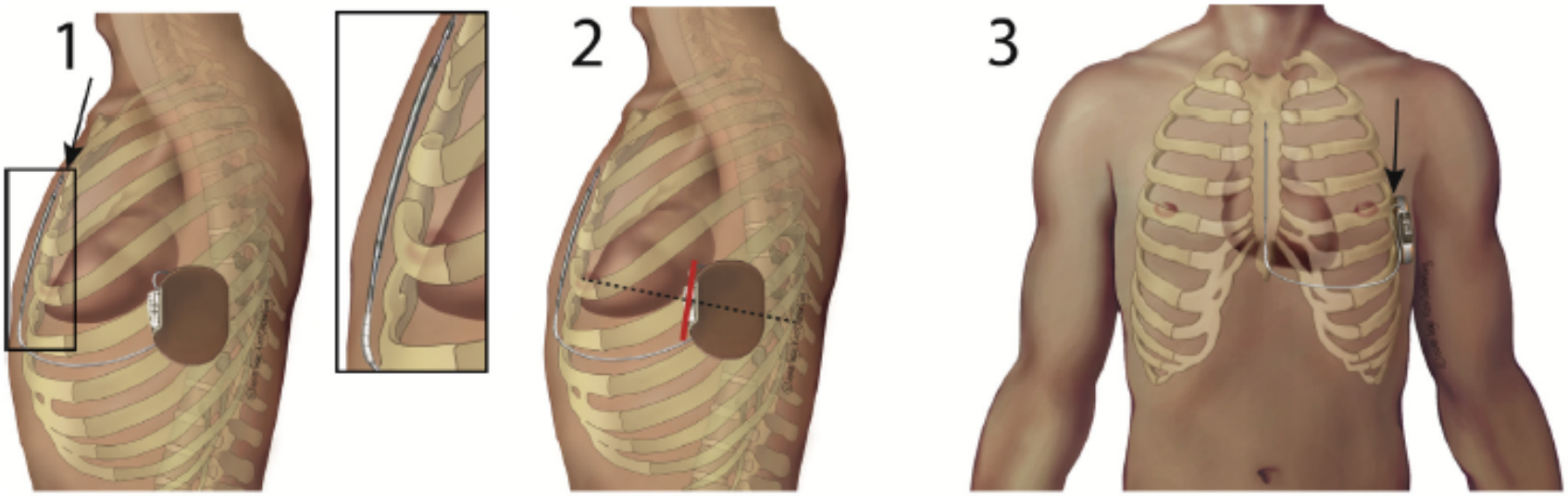
Reinoud E. Knops[1†], Tom F. Brouwer[1*†], Craig S. Barr[2], Dominic A. Theuns[3], Lucas Boersma[4], Raul Weiss[5], Petr Neuzil[6], Marcoen Scholten[7], Pier D. Lambiase[8], Angel R. Leon[9], Margaret Hood[10], Paul W. Jones[11], Nicholas Wold[11], Andrew A. Grace[12], Louise R.A. Olde Nordkamp[1] and Martin C. Burke[13], on behalf of the IDE and EFFORTLESS investigators







A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: The PRAETORIAN score



Step 1)
Determine the number of coil widths of fat tissue between the **nearest** half of the S-ICD coil and the sternum or ribs.

≤ 1	coil-width	**30**
> 1 ≤ 2	coil-widths	**60**
> 2 ≤ 3	coil-widths	**90**
> 3	coil-widths	**150**

Step 2)
Determine the position of the S-ICD generator in relation to the mid-line (**red line**).

Generator is on or posterior of the mid-line	**x 1**
Entire generator is anterior of the mid-line	**x 2**
Entire generator is > 1/2 length anterior	**x 4**

Step 3)
Determine the amount of fat tissue between the **nearest** point of the generator and the thoracic wall.

< 1 generator-width	**x 1**
≥ 1 generator-width	**x 1.5**

Step 4)

PRAETORIAN score ≥ 90:

BMI ≤ 25 kg/m^2	**- 40**
BMI ≥ 25 kg/m^2	**= Final score**

Final PRAETORIAN score

< 90	**Low risk of conversion failure**
90 < 150	**Intermediate risk of conversion failure**
≥ 150	**High risk of conversion failure**

(Heart Rhythm 2018;■:1–8)

A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: The PRAETORIAN score

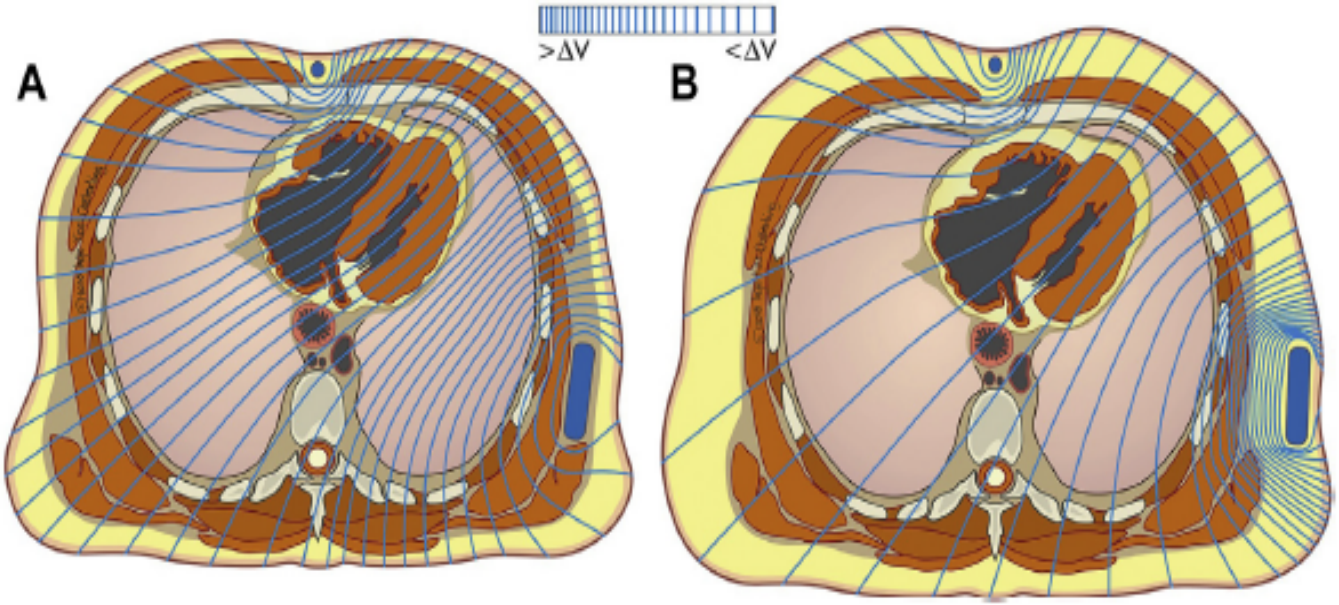
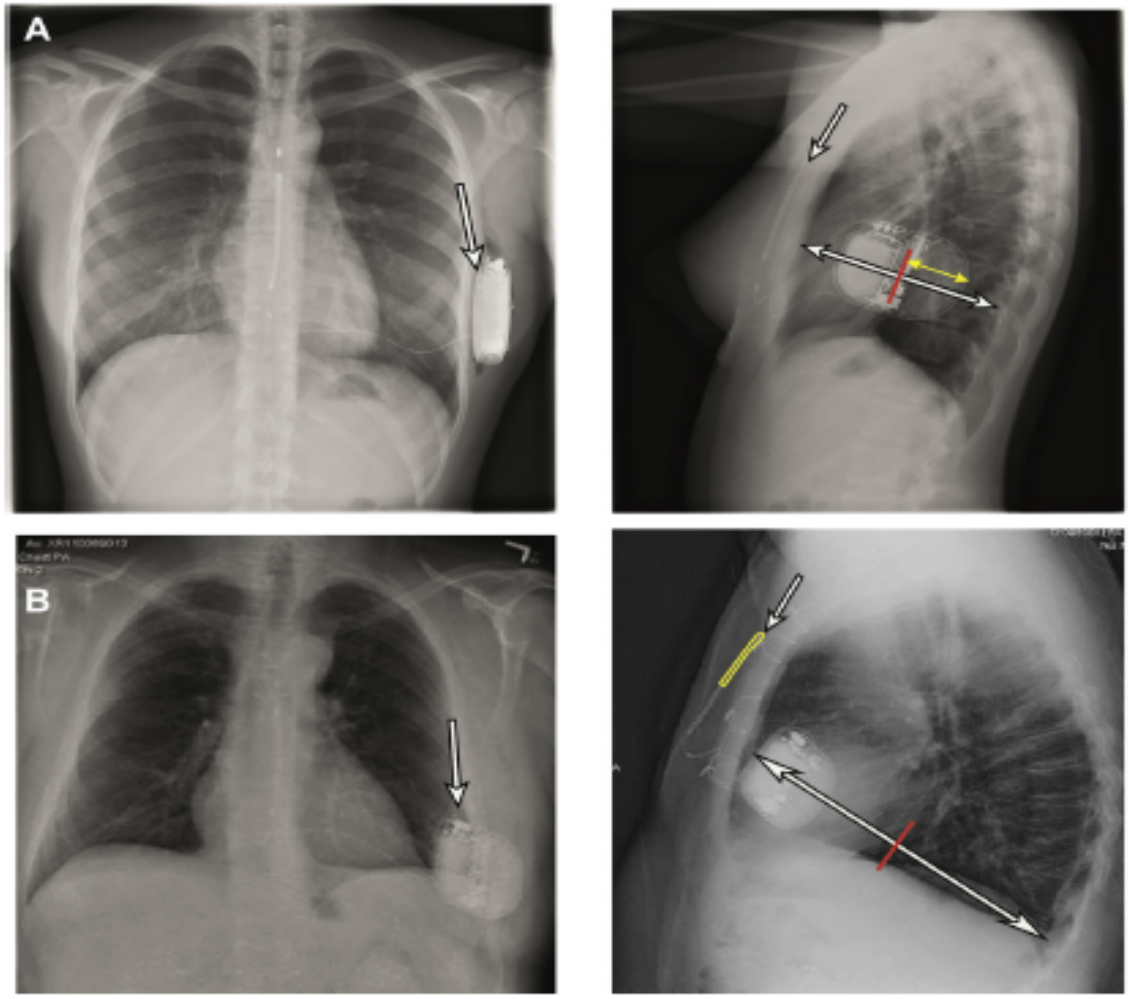


Figure 2 The isolating effect of fat tissue on the effective shock vector. **A:** Normal body mass index. **B:** High body mass index and suboptimal placement of the lead and generator. Fat tissue under the lead and generator has isolating properties causing resistance to the electrical circuit, resulting in a less effective current, illustrated by the less dense electrical field (panel B).

A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: The PRAETORIAN score



Herzschr Elektrophys 2018 - 29:355–361
https://doi.org/10.1007/s00399-018-0602-y
Received: 25 September 2018
Accepted: 9 October 2018
Published online: 31 October 2018

F. V. Y. Tjong[1] · B. E. Koop[2]

[1] AMC Heart Center, Department of Clinical and Experimental Cardiology, Amsterdam University Medical Center, Location Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands
[2] Boston Scientific Corporation, St. Paul, USA

The modular cardiac rhythm management system: the EMPOWER leadless pacemaker and the EMBLEM subcutaneous ICD

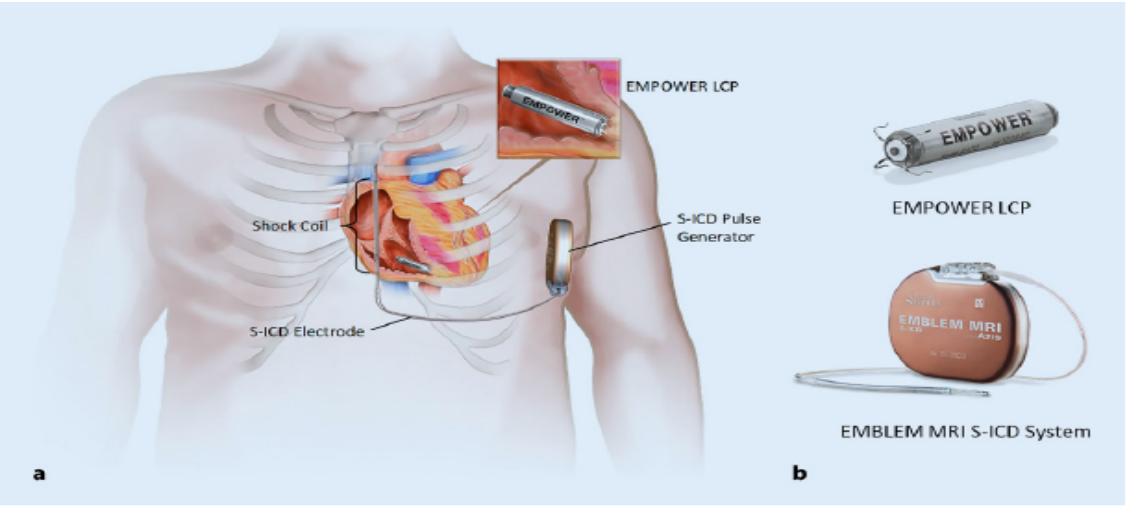


Fig. 1 ◄ The modular cardiac rhythm management (mCRM) system. **a** Depiction of implanted mCRM system. **b** Close-up images of EMPOWER and EMBLEM MRI devices (not to scale). *S-ICD* subcutaneous implantable cardioverter–defibrillator, *LCP* leadless cardiac pacemaker. © 2017 Boston Scientific Corporation or its affiliates. All rights reserved. Used with permission of Boston Scientific Corporation

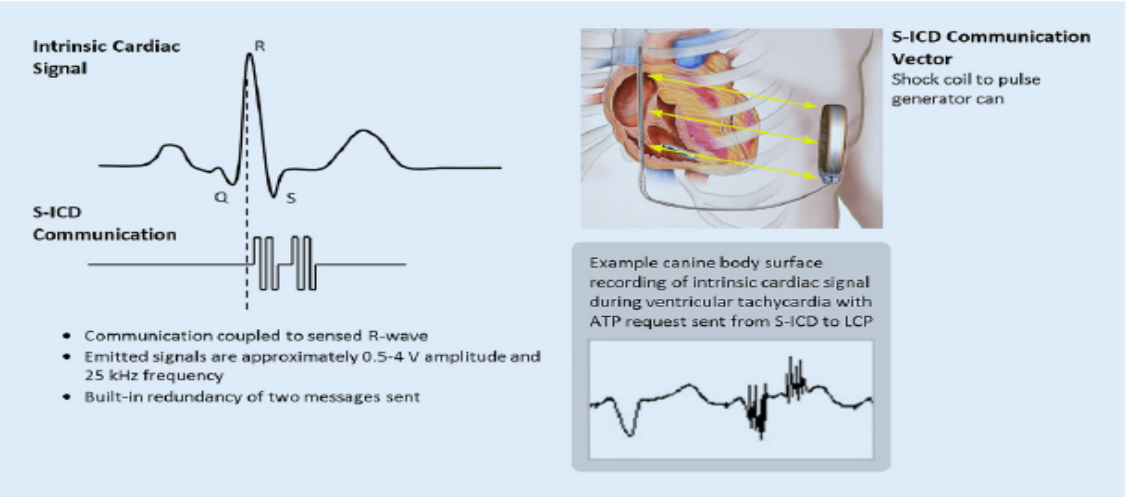
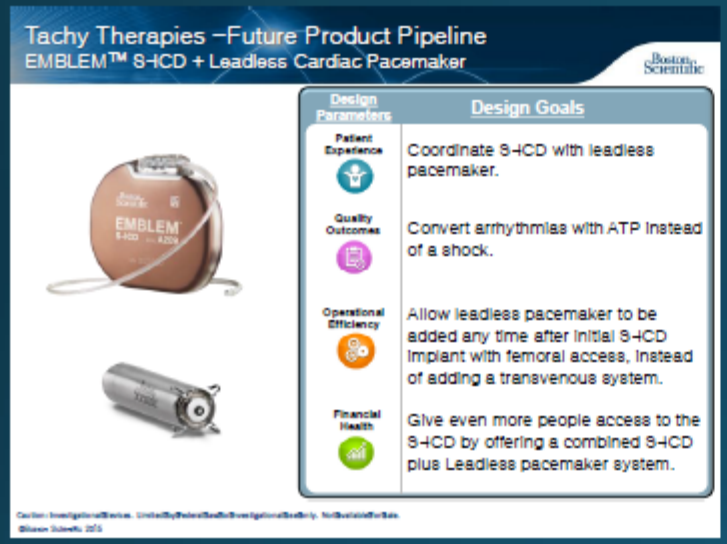


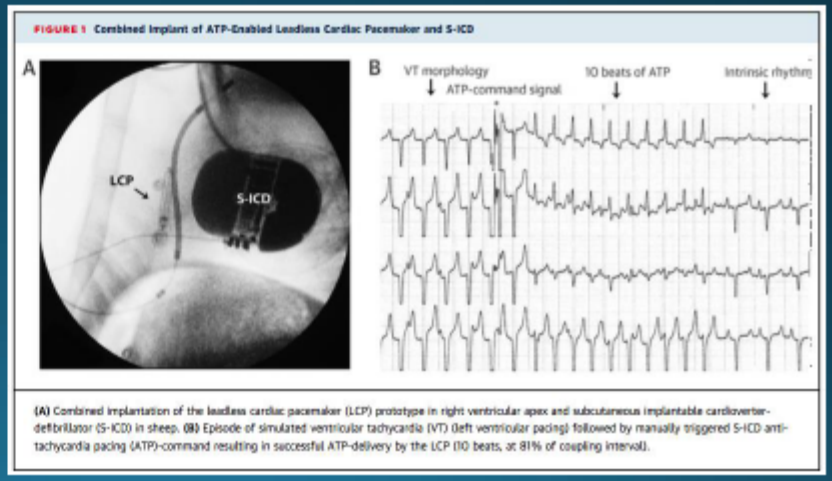
Fig. 2 ◄ Device–device communication of the mCRM system. Depiction of how communication messages are sent from S-ICD to EMPOWER LCP via conducted signals. The EMPOWER LCP senses the conducted signals via its cathode and anode, which are also used for sensing intrinsic cardiac signals. *mCRM* modular cardiac rhythm management, *S-ICD* subcutaneous implantable cardioverter–defibrillator, *LCP* leadless cardiac pacemaker, *ATP* antitachycardia pacing

Future developments: Leadless pacing/ATP



Slide courtesy of Boston Scientific

- First in animal experience with ATP enabled-leadless pacemaker + S-ICD[1]



A Comparison of the Quality of Life of Patients With an Entirely Subcutaneous Implantable Defibrillator System Versus a Transvenous System (from the EFFORTLESS S-ICD Quality of Life Substudy)

Susanne S. Pedersen, PhD[a,b,c,*], Mirjam H. Mastenbroek, PhD[d], Nathan Carter, MSc[e], Craig Barr, MD, PhD[f], Petr Neuzil, MD, PhD[g], Marcoen Scholten, MD, PhD[h], Pier D. Lambiase, PhD[i], Lucas Boersma, MD, PhD[j], Jens B. Johansen, MD, PhD[b], and Dominic A.M.J. Theuns, PhD[c]

The first clinical results from the Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the subcutaneous implantable cardioverter defibrillator (EFFORTLESS S-ICD) Registry on the entirely S-ICD system are promising, but the impact of the S-ICD system on patients' quality of life (QoL) is not known. We evaluated the QoL of patients with an S-ICD against an unrelated cohort with a transvenous (TV)-ICD system during 6 months of follow-up. Consecutively implanted patients with an S-ICD system were matched with patients with a TV-ICD system on a priori selected variables including baseline QoL. QoL was measured with the Short-Form Health Survey at baseline, 3, and 6 months after implant and compared using multivariable modeling with repeated measures. Patients with an S-ICD ($n = 167$) versus a TV-ICD system ($n = 167$) did not differ significantly on physical ($p = 0.8157$) and mental QoL scores ($p = 0.9080$) across baseline, 3, and 6 months after implantation in adjusted analyses. The evolution in physical ($p = 0.0508$) and mental scores ($p = 0.3772$) during follow-up was similar for both cohorts, as indicated by the nonsignificant interaction effect for ICD system by time. Both patients with an S-ICD system and a TV-ICD system experienced significant improvements in physical and mental QoL between time of implant and 3 months (both p's <0.0001) and between time of implant and 6 months (both p's <0.0001) but not between 3 and 6 months (both p's >0.05). In conclusion, these first results show that the QoL of patients with an S-ICD versus TV-ICD system is similar and that patients with either system experience improvements in QoL on the short term. (Am J Cardiol 2016;118:520–526)

A PRospective, rAndomizEd Comparison of subcuTaneOous and tRansvenous ImplANtable Cardioverter Defibrillator Therapy (PRAETORIAN)

Objectives of the study: (1) To compare the subcutaneous ICD to the transvenous ICD for major adverse events (i.e. inappropriate shocks, acute and chronic implant related complications and lead- or device related complications). (2) To determine to which degree the lack of ATP function leads to more appropriate shocks in patients with a subcutaneous ICD.

Study design: Multicenter, prospective, randomized controlled trial with either treatment with the transvenous ICD or subcutaneous ICD (1:1).

Study population: 2x425 patients with class I or IIa indication for ICD therapy without an indication for pacing.

- Patients 18 years and older
- Patients with class I or IIa indication for ICD therapy according to the ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death

SICD

Güçlü endikasyonlar

- Genç yaş
- Primer koruma
- Vasküler giriş yeri problemi
- Daha önce enfeksiyon
- Enfeksiyon riski (mekanik kapak, DM, böbrek yetmezliği)

Rölatif Kontrendikasyon

- ATP'a yanıt veren VT

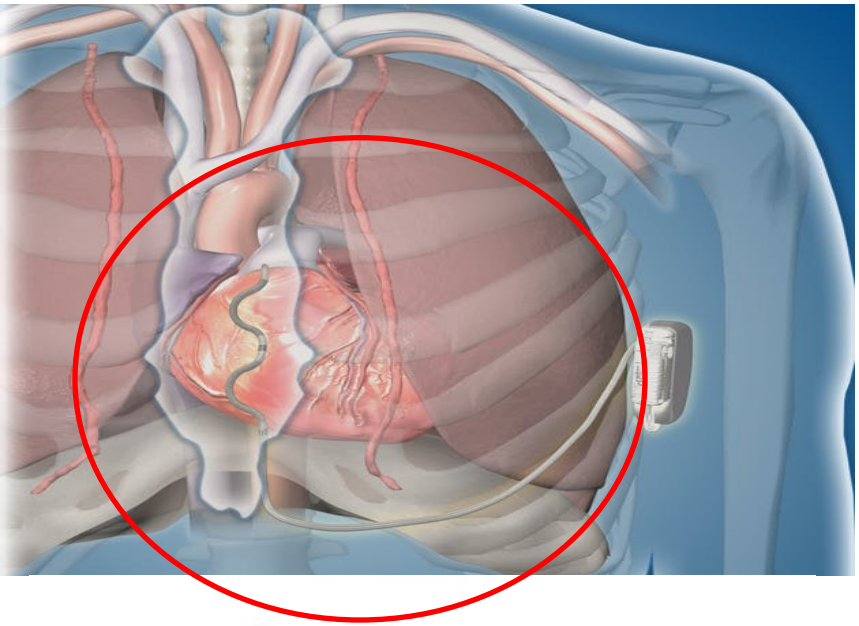
Kontrendike

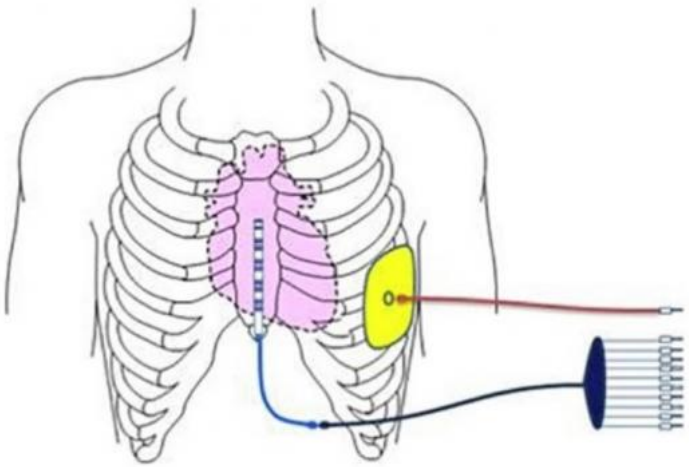
- Pace ihtiyacı (bradikardi, CRT)
- Başarısız tarama

SICD:

- Mevcut SICD ile yüksek şok enerjisi gerekiyor ve düşük output ile ağrısız “pace” mümkün değil.
- Daha büyük batarya ve nispeten kısa batarya ömrü mevcut.
- Özel bir leadle substernal, perikard ön kısmında daha düşük enerji ile defibrilasyon ve pacing mümkün olabilir mi?

Extravasküler ICD





Novel Extravascular Defibrillation Configuration With a Coil in the Substernal Space

The ASD Clinical Study

Joseph Y.S. Chan, MBBS,[a] Jacek Lelakowski, MD, PhD,[b] Francis D. Murgatroyd, MD,[c] Lucas V. Boersma, MD, PhD,[d] Jian Cao, PhD,[e] Vladimir Nikolski, PhD,[e] Griet Wouters, MSc,[f] Mark C.S. Hall, MD[g]

ABSTRACT

OBJECTIVES This study assessed the defibrillation efficacy of the substernal-lateral electrode configuration.

BACKGROUND Subcutaneous implantable cardioverter-defibrillators (ICDs) are regarded as alternatives to transvenous ICDs in certain subjects. However, substantially higher shock energy of up to 80 J may be required. Proposed is a new defibrillation method of placing the shock coil into the substernal space.

METHODS This prospective, nonrandomized, feasibility study was conducted in subjects scheduled for midline sternotomy or implant of ICD. A blunted end tunneling tool was used to insert a defibrillation lead behind the sternum using a percutaneous subxiphoid approach. A skin patch electrode was placed on the left mid-axillary line at the fourth to fifth intercostal space. After ventricular fibrillation induction, a single 35-J shock was delivered between the lead and skin patch.

RESULTS Sixteen subjects (12 males, 4 females; mean age: 61.6 ± 11.8 years) were enrolled. The mean lead placement time was 11.1 ± 6.6 min. Of the 14 subjects with successfully induced ventricular fibrillation episodes, 13 subjects (92.9%) had successful defibrillation. The 1 failure was associated with high and lateral shock coil placement. Mean ventricular fibrillation duration was 18.4 ± 5.6 s with a shock impedance of 98.1 ± 19.3 ohms. Of the 11 subjects with coil-patch electrograms, the average R-wave amplitude during sinus rhythm was 3.0 ± 1.4 mV.

CONCLUSIONS These preliminary data demonstrate that substernal defibrillation is feasible and successful defibrillation can be achieved with the shock energy available in current transvenous ICDs. This may open new alternatives to extra-vascular ICD therapy. (J Am Coll Cardiol EP 2017;3:905-10) © 2017 by the American College of Cardiology Foundation.

References

1. Chan JYS, Lelakowski J, Murgatroyd FD et al. Novel Extravascular Defibrillation Configuration With a Coil in the Substernal Space: The ASD Clinical Study. J Am Coll Cardiol EP 2017;3:905-10.https://doi.org/10.1016/j.jacep.2016.12.026

2. Sholevar DP, Tung S, Kuriachan V, et al. Feasibility of extravascular pacing with a novel substernal electrode configuration: The Substernal Pacing Acute Clinical Evaluation Study. Heart Rhythm. Published online 29Nov2017. DOI: http://dx.doi.org/10.1016/j.hrthm.2017.11.030

3. Boersma, LVA. Feasibility of Extravascular Pacing, Sensing And Defibrillation From A Novel Substernal lead: The Acute Extravascular Defibrillation, Pacing And Electrogram (ASD2) Study. Presented Heart Rhythm Society Scientific Sessions, May 11, 2018.