Bänsch et al., European Heart Journal 2015

NORDIC ICD

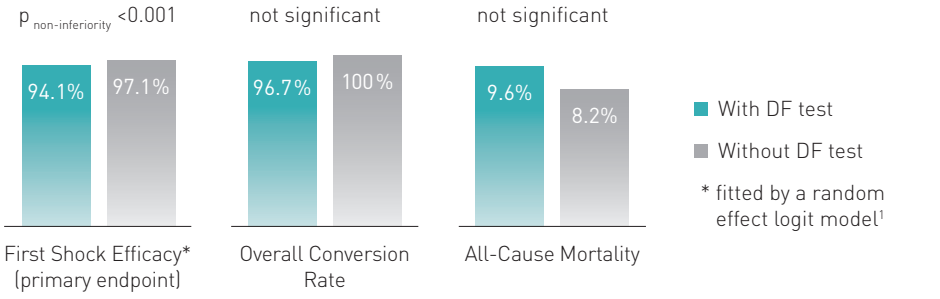
NO Regular **D**efibrillation Testing **I**n **C**ardioverter Defibrillator Implantation (NORDIC ICD) Trial

Study Design

- Prospective, randomized, parallel group, multicenter, non-inferiority study[1]
- To investigate the effect of DF testing at the time of de novo ICD implantation on first shock efficacy during follow-up
- 1,077 (540 with and 537 without DF test) ICD and CRT-D patients at 48 centers in 5 countries

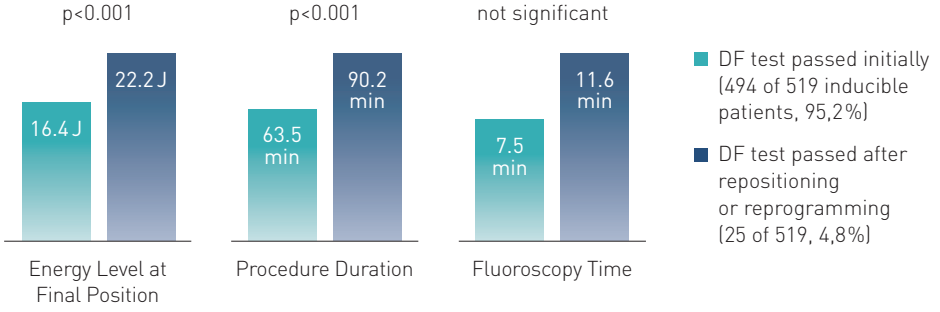
Key Result 1

Defibrillation (DF) testing during implantation does not improve defibrillation efficacy during follow-up nor all-cause mortality (median 22.8 months).[2]



Key Result 2

DF testing or the various measures to improve defibrillation efficacy lengthen the procedure, and may even be harmful.[2]



Clinical Relevance

- Results do not support the routine use of DF testing during left-sided first time ICD implantation.
- Results confirm the safety of omitting the DF test as it is current clinical practice in many implanting centers all over the world.
- Implantation strategy without DF testing should be preferred.

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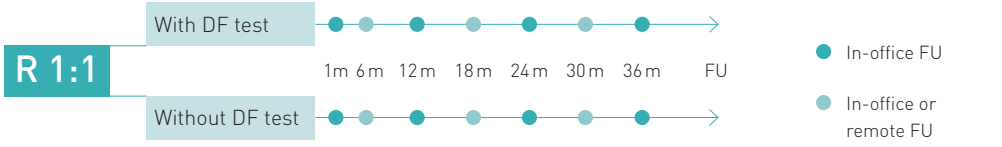
NORDIC ICD Study

1° Endpoint	▪ Average efficacy of the first ICD shock for all true ventricular tachyarrhythmias
2° Endpoint	▪ Serious adverse events associated with the implantation procedure ▪ Frequency of system revisions at implant, such as repositioning of leads, reprogramming the device to reverse polarity ▪ Total fluoroscopy and implantation time ▪ All-cause mortality ▪ Cardiac mortality ▪ Arrhythmic mortality ▪ Ventricular tachyarrhythmia conversion efficacy of the ICD shock therapy
Clinical Sites	▪ 48 centers in five European countries (DEU, SWE, DNK, CZE, LVA)
Sample Size	▪ 1,077 patients (1:1 randomization)
Inclusion Criteria	▪ Indication for implantation of a single chamber ICD, dual chamber ICD and CRT-D therapy according to the ACC/AHA/ESC 2006 guidelines ▪ Primary or secondary prophylaxis ▪ First ICD implantation with no pre/existing or previous ICD therapy or ICD system
Main Exclusion Criteria	▪ Age ⩽ 18 years ▪ ARVC or hypertrophic cardiomyopathy ▪ Anticipated right sided implantation of ICD generator ▪ Terminal renal insufficiency ▪ Persistent AF without pre-operative TEE (Transesophageal echocardiography) ▪ Persistent AF with left atrial thrombus diagnosed by TEE
Devices	▪ All BIOTRONIK Lumax/Ilesto/Iforia ICD (VR-T, VR-T DX, DR-T, and HF-T) with 40J max. shock energy ▪ The choice of the electrode manufacturer was at the discretion of the investigator. Lead type (single/dual coil) had to be defined before randomization.
Study Flowchart	
Follow-Up	▪ At least 12 months through regular on-site visits, and remotely via Home Monitoring
Study Duration	▪ February 2011 – March 2015
Principal Investigators	▪ Dietmar Bänsch, PhD, MD, Rostock University Hospital, Germany ▪ Johan Brandt, PhD, MD, Skane University Hospital, Sweden
Reference No.	▪ NCT01282918 (www.clinicaltrials.gov)

1 Bänsch D, Bonnemeier H, Brandt J, Bode F, Svendsen JH, Felk A, Hauser T, Wegscheider K; The NO Regular Defibrillation testing In Cardioverter Defibrillator Implantation (NORDIC ICD) trial: concept and design of a randomized, controlled trial of intra-operative defibrillation testing during de novo defibrillator implantation, Europace, Jan 2015;17(1):142-7

2 Bänsch D, Bonnemeier H, Brandt J, Bode F, Svendsen JH, Táborský M, Kuster S, Blomström-Lundqvist C, Felk A, Hauser T, Suling A, Wegscheider K; Intra-Operative Defibrillation Testing and Clinical Shock Efficacy in Patients with Implantable Cardioverter-Defibrillators: The NORDIC ICD Randomised Clinical Trial, European Heart Journal Jun 2015, DOI: 10.1093/eurheartj/ehv292

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