



The “Defibrillation Testing, Why Not?” survey. Testing of subcutaneous and transvenous defibrillators in the Italian clinical practice[☆]

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ABSTRACT

Background: Defibrillation testing (DT) can be omitted in patients undergoing transvenous implantable cardioverter-defibrillator (T-ICD) implantation, but it is still recommended for patients at risk for a high defibrillation threshold and for ICD generator changes. Moreover, DT is still recommended on implantation of subcutaneous ICD (S-ICD). The aim of the present survey was to analyze the current practice of DT during T-ICD and S-ICD implantations.

Methods: In March 2021, an ad hoc questionnaire on the current performance of DT and the standard practice adopted during testing was completed at 72 Italian centers implanting S-ICD and T-ICD.

Results: 48 (67%) operators reported never performing DT during de-novo T-ICD implantations, while no operators perform it systematically. The remaining respondents perform it for patients at risk for a high defibrillation threshold. DT is never performed at T-ICD generator change. At the time of de-novo S-ICD implantation, DT is never performed by 9 (13%) operators and performed systematically by 48 (66%). The remaining operators frequently omit DT in patients with more severe systolic dysfunction. DT is not performed at S-ICD generator change by 92% of operators. DT is conducted by delivering a first shock energy of 65 J by 60% of operators, while the remaining 40% test lower energy values.

Conclusions: In current clinical practice, most operators omit DT at T-ICD implantation, even when still recommended in the guidelines. DT is also frequently omitted at S-ICD implantation, and a wide variability exists among operators in the procedures followed during DT.

[☆] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation

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1. Introduction

Defibrillation testing (DT) has traditionally been part of the implantation procedure of implantable cardioverter defibrillator (ICD), in order to confirm adequate defibrillation. Nonetheless, landmark trials [1–3] demonstrated the non-inferiority of DT omission with regard to death and shock efficacy in transvenous ICDs (T-ICDs). According to current guidelines, DT can be omitted in patients undergoing T-ICD implantation, but it is still recommended for patients at risk for a high defibrillation threshold and for ICD generator changes [4].

The subcutaneous ICD (S-ICD) is an effective alternative to the T-ICD, and does not require endovascular lead placement [5,6]. Recent findings from clinical practice in the US and Europe [7–10] showed high rates of successful conversion on DT, and a very high defibrillation safety margin with current S-ICD devices delivering a maximum shock energy of 80 J [11]. However, the results of the above-mentioned trials on DT omission with T-ICDs cannot be extended to the S-ICD, owing to the substantial differences between the two systems, i.e. positioning of the device, energy delivered, cardiac signal detection, and discrimination algorithms. Therefore, DT is still recommended on implantation of S-ICDs [4]. Nonetheless, previous studies have found that adherence to the DT recommendation is declining in clinical practice [8].

The aim of the present survey was to analyze the current practice of DT during T-ICD and S-ICD implantations in Italy, to evaluate its adoption and methods of execution.

2. Methods

In March 2021, all Italian centers with experience in S-ICD implantation, i.e. 102 centers with > 4 implantations [12], were invited to participate in the Survey. Centers were asked to reply to an *ad hoc* questionnaire (one per center) on the current execution of DT and the standard practice adopted during testing of S-ICD and T-ICD. The questionnaire consisted of 16 questions (Table 1 and 2).

A total of 72 S-ICD-implanting centers took part in the Survey. Twenty-eight (39%) of these centers belonged to the fourth quartile of the T-ICD volume distribution (high volume: >50 ICDs per year), according to the ICD Registry of the Italian Association of Arrhythmology and Cardiac Pacing (AIAC) [13]. The volume of S-ICD implantations was high (>13 per year) (12) in 23 (32%) centers.

Table 1 Survey questions and responses on defibrillation testing execution for T-ICD and S-ICD.

Center information	
Participating centers	72
Operators performing	
Electrophysiology / cardiac implantable electronic device procedures	286
T-ICD implantation	278
S-ICD implantation	211
Defibrillation testing execution	N = 72
Defibrillation testing performed during de-novo T-ICD implantations	
Always	0 (0%)
In specific cases *	24 (33%)
Never	48 (67%)
Defibrillation testing performed at T-ICD generator change	
Never	72 (100%)
Defibrillation testing performed during de-novo S-ICD implantations	
Always	48 (66%)
In specific cases #	15 (21%)
Never	9 (13%)
Defibrillation testing performed at S-ICD generator change	
Always	0 (0%)
In specific cases	4 (6%)
Never	47 (65%)
No previous experience in S-ICD generator change	21 (29%)

*: Conditions in Fig. 1.

#: Conditions in Fig. 2.

Table 2 Survey questions and responses on defibrillation testing of S-ICD.

Standard practice during defibrillation testing of S-ICD	N = 63	High-volume (N = 19)	Low-volume (N = 44)
Defibrillation testing:			
performed at implantation	63 (100%)	19 (100%)	44 (100%)
Anesthesiologist support during the procedure	53 (83%)	15 (79%)	38 (86%)
Anesthesia technique:			
General	17 (27%)	5 (26%)	12 (27%)
Local anesthesia or deep sedation	46 (73%)	14 (74%)	32 (73%)
In case of failure in inducing ventricular fibrillation:			
Shock impedance test and DT postponed	3 (5%)	1 (5%)	2 (5%)
DT postponed	9 (14%)	4 (21%)	5 (11%)
Shock impedance test only	20 (32%)	7 (37%)	13 (30%)
No additional attempts or tests	30 (48%)	7 (37%)	23 (52%)
Never occurred	1 (1%)		
First shock energy:			
65 J	38 (60%)	11 (58%)	27 (61%)
<65 J	25 (40%)	8 (42%)	17 (39%)
First shock polarity:			
Standard	63 (100%)	19 (100%)	44 (100%)
Shock failure	N = 63	High-volume (N = 19)	Low-volume (N = 44)
In case of first shock failure:			
Wait until the S-ICD delivers the second 80 J shock	34 (54%)	6 (32%)	28 (64%) #
Immediately deliver external rescue shocks	29 (46%)	13 (68%)	16 (36%) #
Shock energy of the second test:			
≤65 J	39 (62%)	12 (63%)	27 (61%)
>65 J and < 80 J	12 (19%)	2 (11%)	10 (23%)
80 J	11 (18%)	4 (21%)	7 (16%)
Condition for revising the system:			
High shock impedance	23 (36%)	7 (37%)	16 (36%)
Sub-optimal S-ICD placement *	23 (36%)	5 (26%)	18 (41%)
Sub-optimal S-ICD placement * and high shock impedance	10 (16%)	2 (11%)	8 (18%)
Never occurred	7 (11%)		

* : Sub-optimal S-ICD placement assessed through PRAETORIAN score evaluation at 5 centers.

: p < 0.05.

2.1. Statistical analysis

In the present report, categorical data are expressed as percentages. Differences in proportions were compared by means of Chi-square analysis or Fisher’s exact test, as appropriate. A p-value < 0.05 was considered significant for all tests. All statistical analyses were performed by means of R: a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

The list of participating centers is reported in Appendix. At the 72 Survey centers, the operators performing electrophysiology / cardiac implantable electronic device procedures numbered 286. Of these, 278 (97%) perform T-ICD implantation and 211 (74%) S-ICD implantation.

3.1. Defibrillation testing execution

Forty-eight (67%) centers reported never performing DT during de-novo T-ICD implantations, while no centers perform it systematically. The remaining respondents perform it in specific cases: right sided implantations, poor signal sensing, secondary prevention patients, etc. (Fig. 1). DT is never performed at T-ICD generator change. At the time of

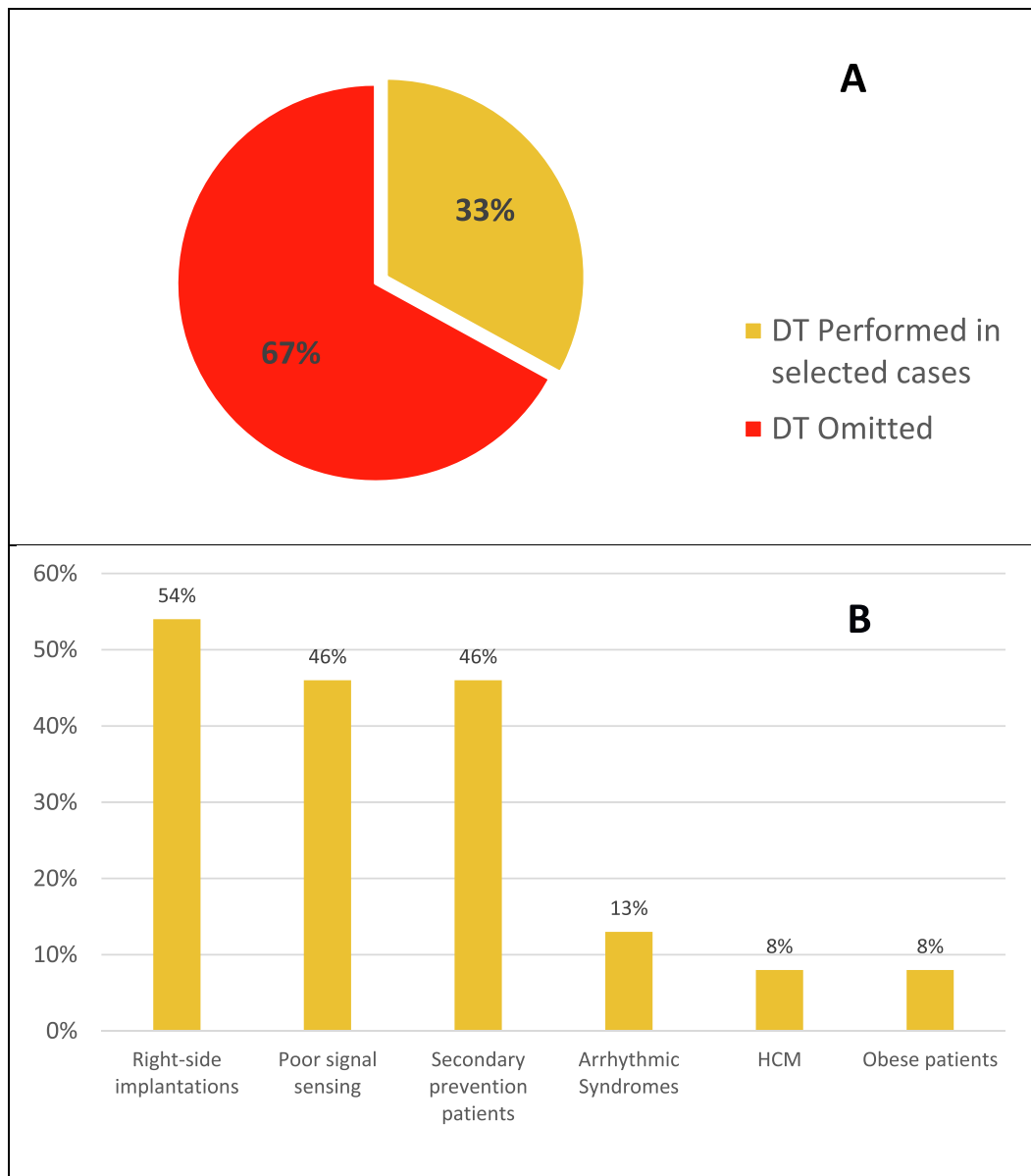


Fig. 1. Defibrillation testing execution during de-novo T-ICD implantations (panel A) and reasons to perform defibrillation testing in selected cases (B).

de-novo S-ICD implantation, DT is never performed at 9 (13%) centers and performed systematically at 48 (66%) centers. The remaining operators perform DT in cases of secondary prevention patients, sub-optimal S-ICD placement, non-compromised ejection fraction, etc. (Fig. 2). At the 51 centers with previous experience in S-ICD generator change, DT is not performed at 47 (92%) centers.

The practice of systematically omitting DT during T-ICD implantation is similar between high volume and low volume centers. While, the DT is less frequently performed systematically at high volume S-ICD centers (52% versus 73% of low volume centers, $p = 0.074$) (Supplemental Fig. 1).

3.2. Standard practice adopted during testing of subcutaneous ICD

At all 63 (100%) centers where DT of S-ICD is performed, the testing is carried out immediately after the implantation, and in 52 (83%) of them an anesthesiologist provides support during the procedure. Only 17 (27%) centers make use of general anesthesia (Table 2).

In case of failure in inducing ventricular fibrillation through the 50 Hz transthoracic pacing, no additional attempts or tests are performed at

30 (48%) centers. The DT is postponed to the next few days in 12 (19%) centers (in 3 of these centers a shock impedance test is immediately performed before rescheduling the DT). In another 20 (32%) centers, shock impedance is assessed without attempting further DT. The DT is conducted by delivering a first shock energy of 65 J at 38 (60%) centers, while lower energy values are tested at the remaining 25 (40%) centers. In all centers the first shock is delivered in standard polarity. In case of shock failure, the operators at 34 (54%) centers wait until the S-ICD delivers the second 80 J shock before delivering external rescue shocks, in order to confirm the efficacy of the system at the maximum output. In case of failure at the first energy tested (at < 65 J or already at 65 J), a second test is performed to ensure the safety margin of at least 15 J at 39 (62%) centers. A test at higher energies (accepting a margin < 15 J) is performed at 12 (19%) centers, while the verification of efficacy at 80 J is considered sufficient at 11 (18%) centers. The condition for revising the system at the end of de-novo implantation procedure is high shock impedance at 23 (36%) centers, sub-optimal S-ICD placement at 23 (36%), and the verification of both conditions at 10 (16%) centers. The sub-optimal positioning is ascertained by measuring a high PRAETORIAN score at 5 of 33 centers (15%). The practice of DT with S-ICD

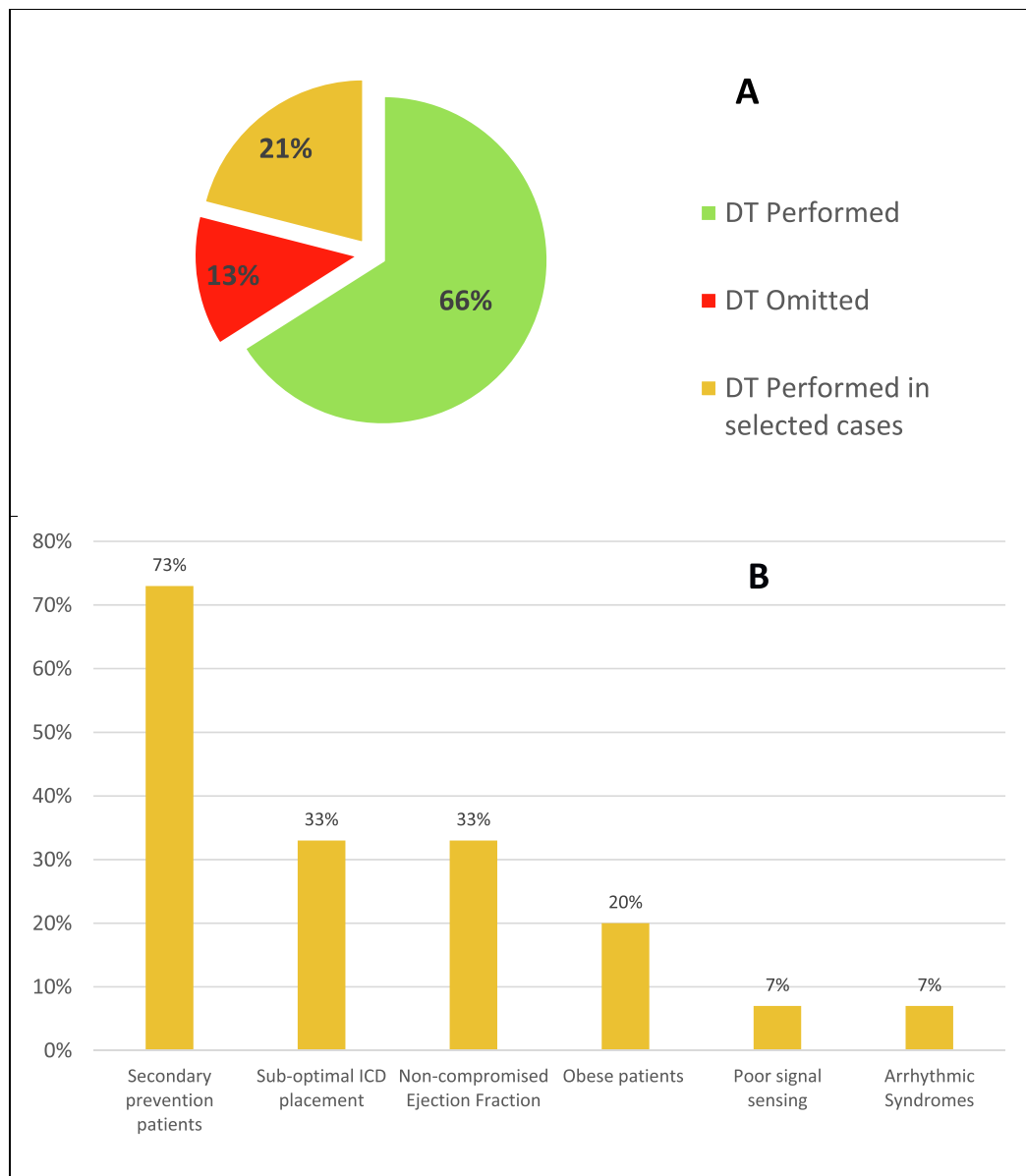


Fig. 2. Defibrillation testing execution during de-novo S-ICD implantations (panel A) and reasons to perform defibrillation testing in selected cases (B).

seems mostly comparable between high and low volume centers (Table 2).

4. Discussion

This Survey reported the current practice of DT during ICD implantations in Italy and revealed that most operators omit DT at T-ICD implantation, even when still recommended in the guidelines. DT is also frequently omitted at S-ICD implantation and, when performed, the procedures followed during DT and in the criteria applied for defining the procedural success are widely variable among operators.

Traditionally, DT has been performed during the ICD implantation procedure in order to ensure reliable detection and termination of ventricular arrhythmias. In the first decade of this century, a debate took place concerning the real need to conduct intraoperative DT at the time of ICD implantation [14,15]. Indeed, advances in defibrillator technology, with higher defibrillation energy being delivered by the devices, improved implantation techniques, and cardiologists' awareness that ventricular defibrillation has a probabilistic nature [16,17] strongly challenged the conventional wisdom of routine DT testing. This

paradigm shift was certainly accelerated by the increased perception of the risks associated with DT [18,19], at a time when ICDs were increasingly being used in more compromised patients with systolic dysfunction. Although DT omission was already very frequent in clinical practice [20], its inclusion in current guidelines with a class IIa recommendation [4] stemmed from the findings of large trials [1,2] that showed the safety of DT omission during transvenous ICD implantation. Nonetheless, according to current guidelines, DT is still recommended for patients at risk for a high defibrillation threshold (e.g. hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, right-sided implantations) and for ICD generator changes [4]. Our findings not only confirm that today the omission of DT represents the standard practice during de-novo T-ICD implantations, but also that DT is rarely performed when still indicated. In particular, at the time of device replacement.

Concerning S-ICD, the current guidelines continue to recommend DT during implantation. Indeed, the substantial differences between the systems do not allow the results regarding conventional ICDs to be extrapolated to S-ICDs. Moreover, all the studies that have demonstrated the efficacy and safety of the S-ICD [5,6], and have determined its

inclusion in current recommendations [21], have required the execution of DT on implantation. The level of clinical evidence and the prevalent perception of S-ICDs today are comparable to those of conventional ICDs more than 10 years ago. Indeed, although DT continues to be routinely performed in most patients, previous studies have found that adherence to the DT recommendation is declining in clinical practice, and that testing is frequently omitted in patients who are at higher risk of complications [8], as happened in the case of transvenous ICDs years ago [20,22]. This trend is moving in parallel with the wider use of S-ICD in patients with heart failure and reduced ejection fraction [10,23]. In the present analysis, we confirmed this finding. Indeed, DT was more frequently omitted in patients with more severe systolic dysfunction. This result is somehow reassuring, since recent data confirmed that the safety margin is very high in these subgroups [11]. Moreover, we showed that also with S-ICD, device replacement is perceived as a safe procedure rarely necessitating DT execution. In addition, stratifying the centers by implantation volume, we noticed no differences in the frequency of testing with T-ICD, while it seems that expert centers are more likely to omit DT with S-ICD, probably for their greater confidence with the procedure.

About the execution of the DT in current clinical practice of S-ICD implantation, we confirmed previous results on the limited use of general anesthesia in Europe and specifically in Italy [10]. In case of failure in inducing ventricular fibrillation, an event that has been shown to occur in about 4% of implantation procedures [10], we reported a wide variability in management. Indeed, the reported approaches range from that of operators who prefer to immediately verify the shock impedance as a surrogate of efficacy and possibly reschedule the test for further verification, to that of centers where no other tests are performed and the patient is discharged with a non-tested device. A wide variability also exists in the procedures for defibrillation and in the criteria applied for defining the procedural success. In line with the manufacturer's recommendation for a safety defibrillation margin of 15 J, the majority of systems are initially tested at 65 J (maximum S-ICD output 80 J). Nonetheless, a fairly high number of operators adopt lower energy shocks in order to initially verify higher safety margins, and to shorten the time to therapy during test [11]. The wide variability also concerns the actions consequent to a shock failure. Indeed, it seems that frequently operators accept margins lower than the usual 15 J value, and that possible revisions of the system are carried out more on the basis of shock impedance measurements (shock impedance greater than 110 Ohm is commonly considered high [24] or on verification of the position of the system rather than on the actual verification of the safety margin. Overall, we have not seen an association between implantation volume and how the DT is carried out, except for a more frequent practice at low volume centers to wait until the S-ICD delivers the second shock, in case of failure of the first one. Perhaps this can be explained by the desire to have further confirmation of the effectiveness of the system, in addition to possible tests conducted later.

In conclusion, we showed that in current clinical practice there is a trend to omit the DT. This is frequently motivated by the frailty of patients and thus it seems justified. Nonetheless, pending the results of the Randomised Trial of S-ICD Implantation With and Without Defibrillation Testing (PRAETORIAN-DFT) [25], a cautious approach and adherence to current recommendations is certainly necessary. In particular, for those patients receiving either T-ICD or S-ICD, that the guidelines consider at increased risk of high defibrillation thresholds (e. g. hypertrophic cardiomyopathy, arrhythmic syndromes, generator changes), the DT should be performed. We also observed wide variability in DT practice among centers performing S-ICD implants. Therefore, more standardization would be desirable, mainly in the management of possible, albeit rare, shock failures and in the criteria applied for defining an adequate device positioning. The ongoing PRAETORIAN-DFT Trial [25] will also validate the PRAETORIAN score, that seems rarely used in practice, as a conventional and non-subjective tool for assessing the quality of the implantation [26].

4.1. Limitations

Although the number of respondents was high, we cannot exclude that some results could have been different if a larger sample of implanting centers and multiple Countries were considered. Moreover, in our survey we have not investigated the clinical reasons for not performing DT, e.g., thrombus, advanced heart failure, disbalance in electrolytes.

5. Conclusion

In current clinical practice, most operators omit DT at T-ICD implantation, even when still recommended in the guidelines. DT is also frequently omitted at S-ICD implantation, and a wide variability exists among operators in the procedures followed during DT and in the criteria applied for defining the procedural success.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcha.2022.100952>.

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