


Key influences of VDD (DX) ICD selection: Results from a prospective, national survey

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Abstract

Background: To preserve the benefit of atrial sensing without the implantation of an additional lead, a single-lead ICD system with a floating atrial dipole (DX ICD) has been developed. The purpose of this nationwide survey was to provide an overview of the current key influences of device selection focusing on DX ICD and to test the applicability of a previously published decision-making flowchart of ICD-type selection.

Methods: An online questionnaire was sent to all implanting centers in Hungary. Eleven centers reported data from 361 DX ICD and 10 CRT-DX systems implantations between February 2021 and May 2023.

Results: The most important influencing clinical factors indicated by the participating doctors were elevated risk of atrial fibrillation (AF)/stroke (56%), risk of sinus/supraventricular tachycardias (SVT) (42%), and a potential need for CRT upgrade in the future (36%). The DX ICD was considered in the majority of cases instead of the VVI system (87%), and only in a small proportion instead of a DDD ICD (13%). 60% of the patients with DX ICDs were also included into remote monitoring-based follow-up. In 83% of the cases, good (>2 mV) or excellent (>5) atrial signal amplitude was recorded within 6 weeks after the implantation.

Conclusion: In the current national survey, the most important influencing factors indicated by the implanters for selecting a DX ICD were the elevated risk of stroke or sinus/SVT and a potential need for CRT upgrade in the future. These findings support the use of a previously published decision-making flowchart.

Abbreviations: AF, atrial fibrillation; AHRE, atrial high-rate episode; AV, atrio-ventricular; CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy defibrillator; DX, Diagnostic eXtension; EP, electrophysiology; EV-ICD, extracardiac implantable cardioverter defibrillator; ICD, implantable cardioverter defibrillator; IEGM, intracardiac electrogram; RM, remote monitoring; S-ICD, subcutaneous implantable cardioverter defibrillator; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

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KEYWORDS

CRT-D, CRT-DX, DX, ICD, implantable cardioverter defibrillator, VDD

1 | BACKGROUND

Different types of implantable cardioverter defibrillators are available (i.e., VVI, VDD, DDD, CRT-D, S-ICD, EV-ICD). Most of them have well-established indications, but certain alternatives are often chosen based on the implanter's discretion in a clinical state-driven fashion, and therefore, their use shows relevant disparities among implanting centers.¹⁻³

To preserve the benefit of atrial sensing without the need for atrial pacing, a single-lead ICD system with a floating atrial dipole (i.e., VDD or as defined by the manufacturing company DX ICD) has been developed.⁴ The DX ICD system offers an additional atrial intracardiac electrogram, with the possibility of early detection of atrial arrhythmias, and improved supraventricular tachycardia (SVT) discrimination to prevent inappropriate shock and AV-sequential pacing in single-lead devices. The "DX" specify the Diagnostic eXtension capability of the system, which consists of a generator and a shock lead equipped with two ring electrodes positioned in the atrium. Due to an optimized atrial dipole spacing, a specifically designed input stage for the atrial sensing, a preamplifier, which progressively increases the atrial gain up to four-fold, and a wider bandpass for the frequency range of the atrial channel, the system provides a stable and reliable atrial sensing. Moreover, the implantational easiness of the VDD shock lead is also an option for beginner implanters. All the currently available DX ICD and CRT-DX systems could be connected to a remote monitoring (RM) follow-up system (Home Monitoring™, Biotronik SE & Co., Berlin, Germany). Due to these advantages, there is a growing interest for DX ICDs.⁵⁻¹²

We have previously developed and published a decision-making flowchart defining the potential indications of DX technology based on the available scientific evidence of the DX ICD and CRT-DX systems, and the current European and American guidelines regarding cardiac pacing, resynchronization therapy, and atrial fibrillation (AF) (Figure 1).⁴ The purpose of this current nationwide survey was to test the applicability of the decision-making flowchart in daily clinical practice and to clarify the key influences of ICD type selection focusing on DX ICD systems.

2 | METHODS

An online questionnaire (The Hungarian DX Survey) comprising nine key clinical questions for DX ICDs and seven for CRT-DX systems related to ICD type selection (and implemented into the previously published decision-making flowchart; Figure 1⁴) was distributed among all implanting centers in Hungary (Supplementary material). The answers were not mutually exclusive. ICDs were implanted based

on standard indications for primary or secondary prophylaxis of sudden cardiac death according to the current European guidelines.¹³⁻¹⁴

Intica 5 VR-T DX DF-1/IS-1, Intica Neo 5 VR-T DX DF-1/IS-1, Rivacor 5 VR-T DX DF-4/IS-1, Intica 7 HF-T DF-1/IS-1, Intica Neo 7 HF-T DF-1/IS-1, Intica 7 HF-T QP DF-4/IS-4, Rivacor 7 HF-T DF-4/IS-1, and Rivacor 7 HF-T QP DF4/IS-4 devices were used (Supplementary Table 1). All systems implanted within the survey manufactured by Biotronik SE & Co. (Berlin, Germany), had ProMRI function with a variable IS1-IS4 and DF1-DF4 connectors.

Results were analyzed by descriptive statistics and presented as numbers and percentages for each answered option.

3 | RESULTS

Out of 18 Hungarian centers 11 (with 27 implanting physicians) reported data from 361 DX ICD and 10 CRT-DX system implantations between February 2021 and May 2023. The response rate was 56.1% for the DX ICDs (644 delivered surveys) and 15.4% for the CRT-DX systems (65 delivered surveys).

The DX ICDs were implanted as a new device in 337 patients (93.3%), and in the remaining 24 cases (6.7%) as generator replacement.

The percentage of the DX ICD systems respect to the global number of the ICDs implanted in the participating centers were 21.8% for new implantations and 12.0% for generator replacements in 2021.

3.1 | Clinical scenarios that influenced device selection

The first question explored *general clinical factors having an impact on device selection*. At the time of the DX system implantation, the following clinical scenarios were indicated by the implanting physicians as influencing factors for device selection: Elevated risk of stroke in 56%, risk of sinus/SVT in 42%, potential need for CRT upgrade in the future in 37%, potential need for AV-sequential pacing in the future in 32%, current need for AV-sequential pacing in 7%, and other factors in 8%, respectively (Figure 2A).

The second question was *about what category of the device would have been implanted if a DX defibrillator had not been available*. If no DX had been available, the implanting physician would have implanted a VVI system in 86.9% of the patients and a DDD ICD in 12.5% of the patients (with a missing answer in two cases). The main reasons for DX ICD implantation instead of a VVI ICD system were the following: the possibility to detect and/or monitor AF in 80%, the availability of

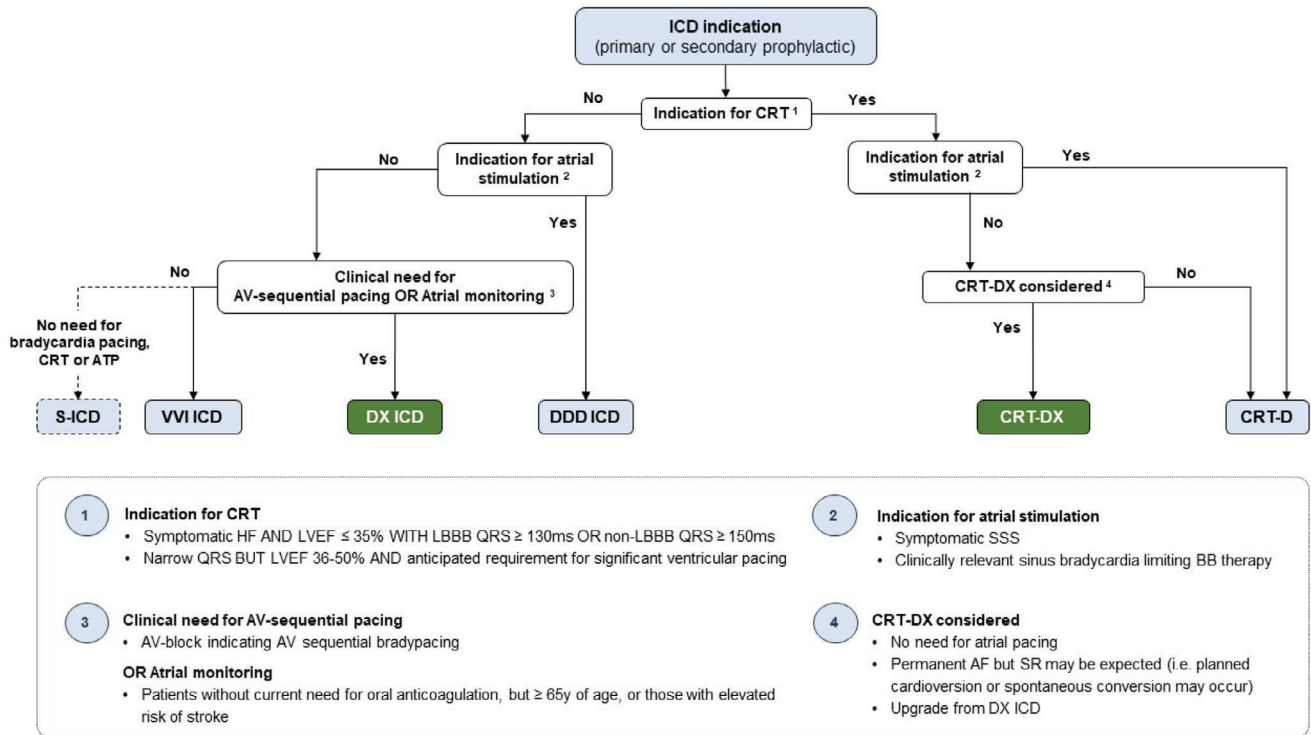


FIGURE 1 Proposed flowchart of device selection for ICD recipients, focusing on the DX technology based on Vamos *et al. Trends Cardiovasc Med.* 2022;32:84-89.⁴ AF, atrial fibrillation; AV, atrioventricular; BB, beta-blocker; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter defibrillator; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; S-ICD, subcutaneous implantable cardioverter defibrillator; SR, sinus rhythm; SSS, sick sinus syndrome.

dual-chamber discrimination algorithms in 66%, the option for two different algorithm types for SVT discrimination in 58%, the 3-channel IEGM supporting troubleshooting in 48%, and the capability of AV-sequential pacing in 16% of the cases (Figure 2B). The following reasons were marked by the implanting physicians why they have chosen a DX ICD instead of a DDD ICD device: dual-chamber discrimination algorithm by one lead in 81%, detection, and monitoring of AF by one lead in 71%, lower implantation associated complication rate in 69%, lower long-term risk due to fewer implanted leads in 67%, and AV-sequential pacing by one lead in 60% (Figure 2C).

3.2 | Data regarding RM

215 out of 361 pts (59.6%) were included into RM (Home Monitoring). The key factors for setting up RM indicated by the implanting physicians were as follows: early detection of arrhythmias (88%), possibility of remote patient management (77%), need for continuous monitoring (74%), concomitant heart failure (67%), elevated risk of stroke (52%), reduction of in-office follow-up visits (51%), frequent ventricular arrhythmias (35%), patient's residency distance is far away from the follow-up clinic (19%), system integrity monitoring is required due to advisory components (15%), or other known arrhythmia requiring continuous monitoring (13%), respectively (Figure 2D). The main reasons

for avoiding involvement into RM (144 out of 361 pts) were a decision of the physician (58%), inadequate patient compliance (38%), or RM was temporarily not available at the institution (4%). For note, there were no patients who were offered RM but refused it.

3.3 | Data regarding atrial sensing parameters in the DX ICD systems

Specially filtered and amplified P-wave amplitude was measured directly after the implantation in most of the cases, but not later than the first follow-up within 6 weeks. In 42 pts (12.5%) with a DX ICD atrial sensing value was $>$ 10 mV, in 24 pts (7.1%) between 7.5 and 10 mV, in 43 pts (12.8%) between 5 and 7.4 mV, in 107 pts (31.8%) between 2 and 4.9 mV, and in 43 (12.8%) under 2 mV, respectively (data not available in 78 cases) (Figure 3).

When just the DX generator was replaced (24 cases), the original device was implanted more than 10 years ago in three cases, between 5 and 10 years in 15 cases, and not more than 5 years ago in six cases. Amplified P-wave amplitude measured via the old DX/A+ leads was \geq 10 mV in 2 pts (8.3%), between 7.5 and 10 mV in 0 pts (0%) between 5 and 7.4 mV in 5 pts (20.8%), between 2 and 4.9 mV in 9 pts (37.5%), and under 2 mV in 6 pts (25%), respectively (data not available in two cases) (Figure 3).

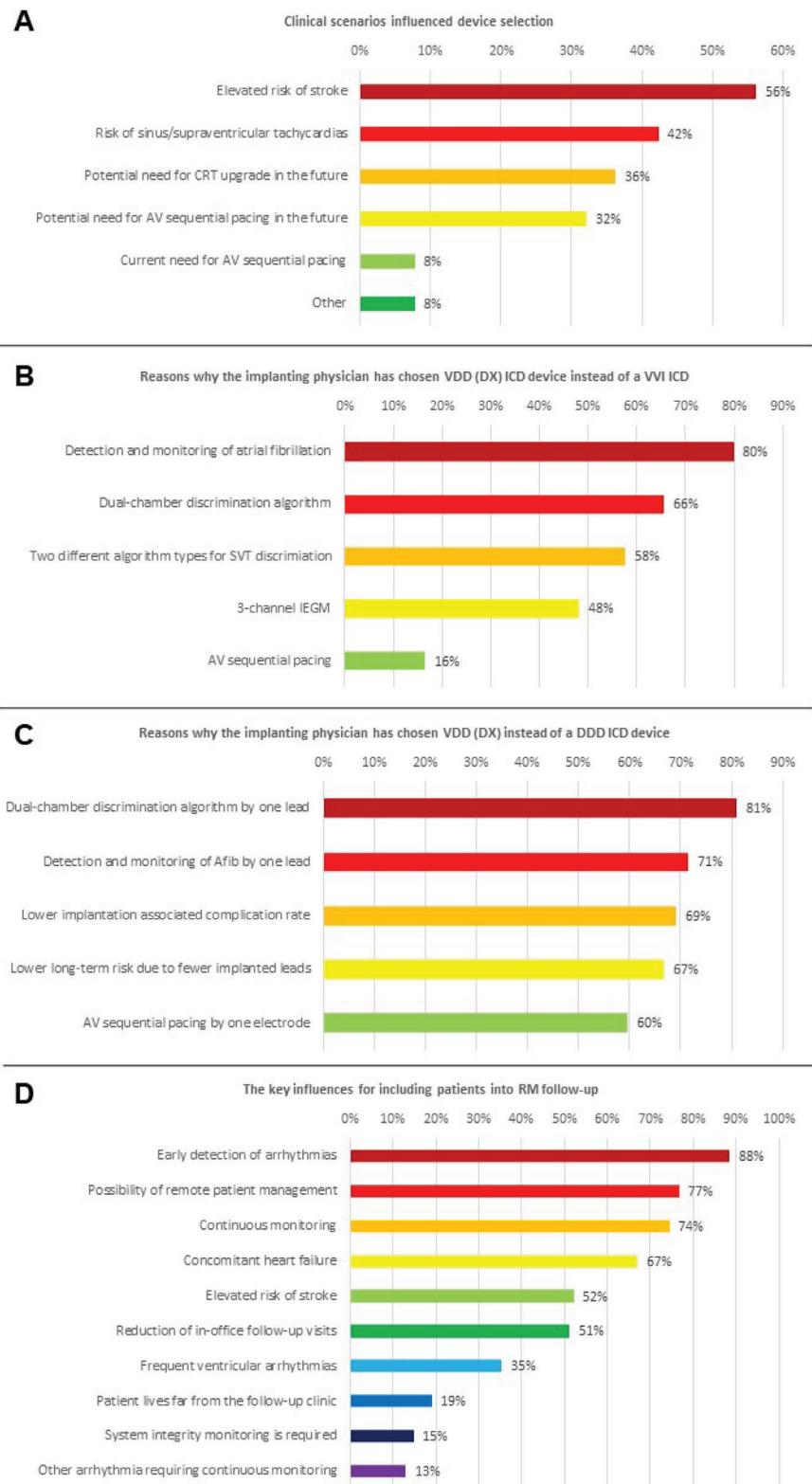


FIGURE 2 The main results of the Hungarian DX survey.

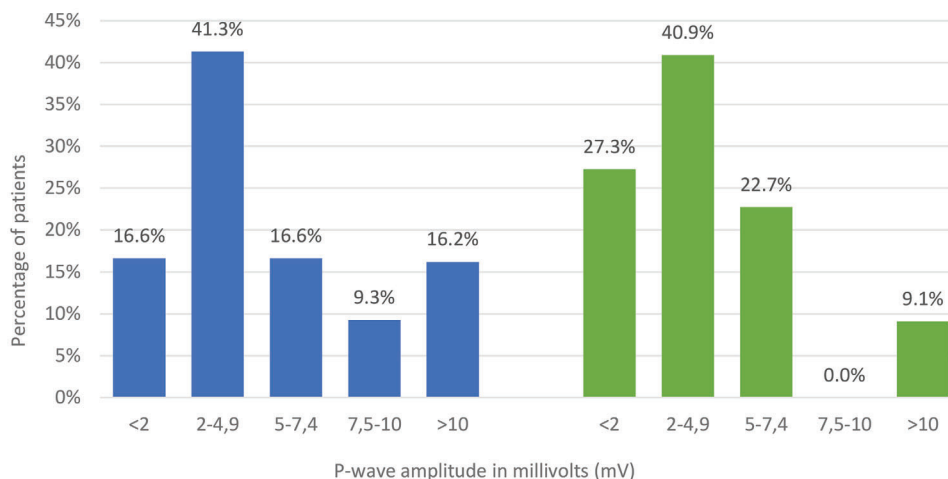


FIGURE 3 Amplified P-wave amplitude measured via DX ICD systems at de novo implantations ($N = 259$) (left/blue) or generator exchange ($N = 22$) (right/green).

3.4 | Cases with CRT-DX systems

Data about 10 cases of new CRT-DX system implantations were also collected in the survey. Indication for CRT was heart failure with reduced ejection fraction ($LVEF \leq 35\%$) and broad left bundle branch block ($QRS > 130$ ms) in nine patients. In the remaining case, a biventricular system was implanted due expected need for a significant proportion of ventricular pacing in a patient with narrow QRS and an $LVEF$ of 36%–50%. Physicians identified two clinical scenarios as contributing factors for selecting a DX device: (I) permanent AF but a high expectancy/chance of spontaneous reversion into sinus rhythm may occur; (II) there was no need for atrial pacing.

Four out of 10 patients were connected to RM system supported by the following reasons: heart failure (100%), possibility of remote patient management (75%), early detection of arrhythmias (75%), reduction of in-office follow-up visits (50%), frequent ventricular arrhythmias (50%), elevated risk of stroke (50%), other known arrhythmia requiring continuous monitoring (50%), continuous monitoring (25%), system integrity monitoring is required due to advisory components (25%). The main reasons to contradict offering RM to the patient were the decision of the physician ($n = 3$), inadequate patient compliance ($n = 2$), or temporary unavailability at the institution ($n = 1$).

Amplified P-wave amplitude was measured between 5 and 7.4 mV in one patient, between 2 and 4.9 mV in 5 pts, and under 2 mV in two cases (missing data in two cases).

4 | DISCUSSION

4.1 | Main results

This nationwide survey aimed to describe the main clinical factors that influenced doctors to choose a DX ICD system instead of a conventional single- or dual-chamber or CRT defibrillator system and to test

the applicability of a previously published decision-making flowchart (Figure 1⁴). The most important influencing clinical factors indicated by the participating doctors were: risk of AF with concomitant risk of stroke, risk of sinus/SVT, and a potential need for CRT upgrade in the future.

The DX ICD was considered in the majority of cases instead of the VVI system, and only in a small proportion instead of a DDD ICD. In more than half of the cases, the advantages of DX ICD were also enhanced by combining it with RM. Notably, in the majority of cases, good or excellent acute and chronic atrial signal amplitude was recorded.

4.2 | The leading influencing factors of DX ICD selection

There is a relevant variability among implanting physicians and institutions regarding ICD system type selection.^{1–3,15} Although the use of dual-chamber devices decreased in the last decade,¹⁵ the implantation of atrial leads in patients without a clear indication for atrial pacing still persists, despite the lack of evidence for clinical benefit.¹⁶ The DX ICD system offers an additional atrial intracardiac electrogram with all the potential benefits but without the risk associated to the implantation of a second lead. The use of DX ICD systems shows an increasing trend in Hungary.^{3,11} More than 1/5 of all implanted ICDs were DX ICD systems during the survey period, also highlighting the increasing interest for this technology.

Based on the available scientific evidence and the current international guidelines a decision-making flowchart was developed and published to define the potential indications of DX technology (Figure 1).⁴ A clinical need for atrial monitoring (based on an elevated risk of stroke) and/or current or future need of AV-sequential ventricular pacing were the leading evidence-based issues to choose a DX ICD instead of a VVI system in that flowchart. Indeed, the responders of the cur-

rent survey indicated the elevated risk of stroke as the key influencing factor for DX device selection (Figure 2A).

The 2nd most frequently indicated clinical factor for DX ICD selection was the risk of sinus/SVT. For note, improved SVT-VT discrimination should not be considered as an indication for a dual- versus single-chamber ICD according to international society guidelines, thus this approach does not decrease the risk of inappropriate shocks if optimal device programming is used.^{2,11,14,17-18} On the other hand, the availability of two different SVT discrimination algorithms and a 3-channel IEGM may support troubleshooting. These advantages seem to be important for the implanting physicians when choosing DX instead of a VVI ICD system (Figure 2B).

Interestingly, a potential need for AV-sequential pacing in the future was just the 4th most important factor, and the DX system has been chosen due to the current need for AV-sequential pacing only in a minority (7%) of the cases. Hence, AV-sequential ventricular pacing without an atrial lead seems to be valuable but rare needed advantage of the DX system. It is, however, important to avoid unnecessary implantation of dual-chamber devices, who still do not fulfill an absolute indication for atrial only or atrioventricular bradypacing but already have a mild AV or ventricular conduction problem (i.e. first-degree heart block, right or left bundle branch block, wider QRS duration), or may develop higher degree conduction abnormalities later. For these patients, a DX ICD lead may be an optimal choice, like in the case of 70 years-old male patient with secondary prophylactic ICD indication and QRS duration of 118 ms due to left anterior hemiblock. Based on a borderline HV interval (74 ms) measured during an EP study before the ICD implantation, a decision was made to implant a DX ICD (Figure 4).

4.3 | Combination of RM and DX technology

Based on the survey, the leading reason for implanting a DX instead of a VVI ICD system was the capability of detection and monitoring of AF. Especially, detection of silent atrial arrhythmias may help to reduce stroke risk through the early initiation of oral anticoagulation. In the THINGS registry, comparing the AT/AF diagnostic capability of standard VVI ICDs to DX, the 2-year incidence of anticoagulation onset was 3.6% for the VVI and 6.3% for DX ICD group (adjusted HR: 1.99, 95% CI: 0.72-5.56, $p = .184$).¹⁰ This advantage seems to be most effective in combination with RM. In a most recent publication from the MATRIX registry, a 99.7% detection accuracy for AHRE ≥ 1 h in patients with DX ICD systems in combination with daily RM was reported facilitating a reliable guideline-recommended screening for subclinical AF and monitoring of AF-duration progression.¹⁹

59.6% of the survey patients with DX ICD were enrolled into an RM-based follow-up. The leading reason for the indication of RM by the implanting physicians was clearly the need for early detection of arrhythmias by continuous monitoring (Figure 2D). Although, for patients with cardiovascular implantable electronic devices RM is recommended to be the standard of care by the most recent 2023 HRS/EHRA/APHS/LAHS Expert Consensus Statement,²⁰ there are

still well-known barriers of uptake of RM, like juristic concerns, workload, lack or shortage of reimbursement, or regional/institutional availability. These barriers may explain the lower number of patients in the survey included into remote care than expected.

For note, further clinical trials are also being conducted to assess the safety and performance aspects of DX ICD/CRT systems with a special interest in combination with RM (DX-AF study: NCT03110627⁵).

4.4 | Reliability of atrial sensing parameters via the floating dipole

In most of the cases (83.4% in the case of primer implantations and 72.7% at the time of box exchange) the P-wave amplitude measured via the DX lead was excellent (>5 mV) or good (>2 mV), however, the proportion of patients with a P-wave < 2 mV increased till the time of device exchange (from 16.6% to 27.3%). The clinical implication of this finding is questionable since we had no detailed information about these cases, and up to 1 mV atrial sensing can be considered acceptable. For note, in a most recent noncomparative meta-analysis of 14 clinical trials and observational studies evaluating DX ICD, the P-wave amplitudes were consistently in a range where they can support clinical decision-making across studies and remained stable over a follow-up of up to two years.²¹ The ongoing prospective, multicenter, open-label SMART-CONTROL trial (NCT03932604) aims to investigate whether the atrial sensing capability of VDD-ICD is useful in AF detection and inappropriate therapy reduction by randomly activating or deactivating the atrial sensing function.²²

4.5 | The use of CRT-DX in the daily clinical practice

Ten patients were implanted with a CRT-DX system during the study period. The two leading factors indicated by the implanting physicians for selecting the CRT-DX device were permanent AF (with expectancy of spontaneous reversion) and the lack of any need for atrial pacing. Beyond the scenario of upgrade from a DX ICD device, these two options were suggested by the decision-making flowchart (Figure 1).⁴

The ratio of RM in the CRT-DX cohort was lower than expected and lower compared to the DX cohort (40% vs. 59.6%), despite the fact that the clinical benefits of RM in heart failure patients are well known.²³⁻²⁸

Notably, the distribution of P-wave amplitudes in different clusters was similar to that observed within the DX ICD group.

Scientific data regarding the feasibility and safety of resynchronization via 2 leads (i.e., CRT-DX system) is still limited. In an early publication by Biffi and colleagues, 12 patients with a CRT-DX system were compared to 25 recipients of conventional CRT-Ds, and no difference in terms of NYHA class improvement, LV reverse remodeling, peak cardiopulmonary performance, or the presence of chronotropic incompetence were observed.⁶ In a larger cohort of patients with CRT-DX ($N = 120$) from the QP ExCELS registry, fewer complications were observed compared to a matched cohort of 120 patients with conven-

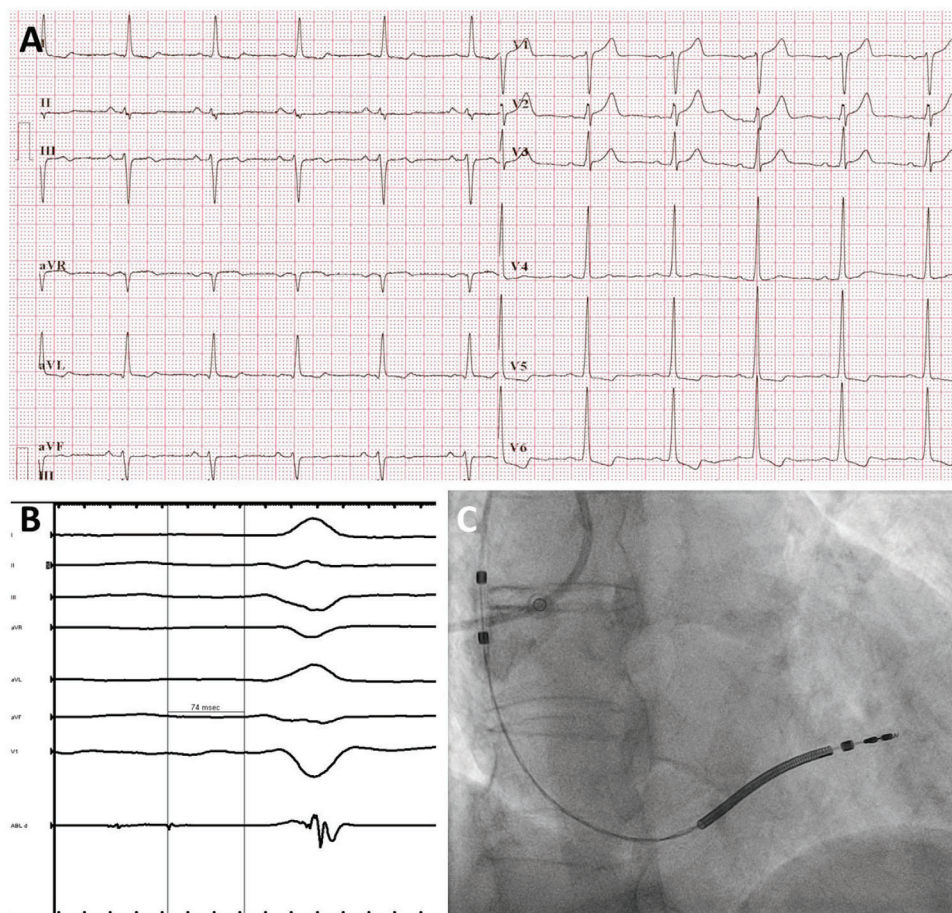


FIGURE 4 An example of a good candidate for the DX ICD system due to mild AV and intraventricular conduction problems. This 70-year-old male patient had a secondary prophylactic ICD indication due to VT. The resting ECG (panel A, 25 mm/sec, 10 mm/mV) showed a normal PR (178 ms) and a QRS duration of 118 ms with left anterior fascicular block. A preimplantation EP study demonstrated an HV interval of 74 ms (panel B) with a suprahisian AV block, accordingly a DX ICD was implanted (panel C).

tional three-lead CRT-D systems, while similar CRT responses were achieved.²⁹ In another report of 50 patients with less favorable venous anatomy, CRT-DX systems represented a safe alternative regarding complication rates and functional parameters.³⁰

Three ongoing studies may provide further insights into the performance and expected outcomes of the CRT-DX technology (CRT-Next: NCT03587064; BIO|REDUCE: NCT03839121; BIO-AffectDX study³¹).

4.6 | Limitations

Our study has all the limitations of such clinical surveys. We had no direct access to patient data, such as detailed clinical information, indications, CHA₂DS₂-VASc score, follow-up data, etc. therefore those could not have been analyzed. Moreover, P-wave parameters were reported in clusters but not as exact numbers making impossible the further evaluate the clinical implications of a sensing value < 2 mV. Prior clinical experience with the DX ICD or CRT-DX was not collected by the survey which may also influenced the device selection.

It should be noted, that the acquisition of pacemakers/ICDs occurs through a centralized tender in Hungary. The allocation of devices to the implanting centers is unrestricted, accordingly, relevant reimbursement bias in the selection of ICD systems was unlikely.

5 | Conclusions

In the current nationwide survey, the most important influencing clinical factors indicated by the responding doctors for selecting a DX ICD were the elevated risk of stroke or sinus/SVT and a potential need for CRT upgrade in the future. These findings support the use of a previously published decision-making flowchart (Figure 1).⁴

Physicians consider DX ICD instead of a VVI system in the majority of cases, and only in a small proportion instead of a DDD ICD, the option of resynchronization via 2 leads (i.e., CRT-DX system) is still rarely used. Some advantages of DX ICD could be clearly enhanced by combining it with RM. Moreover, in the majority of cases, good or excellent atrial signal amplitude could be measured via the floating atrial dipole.

Several ongoing studies are investigating the performance of the DX ICD/CRTs in various clinical scenarios and may provide further guidance in the selection of ICD systems.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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