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Eligibility of patients with temporarily paced rhythm for a subcutaneous implantable cardioverter-defibrillator

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WHAT'S NEW?

The use of a subcutaneous implantable cardioverter-defibrillator in patients with paced ventricular rhythm is associated with a serious risk of inappropriate sensing, due to the different QRS morphology during intrinsic and paced rhythm, and it is particularly high in patients, in whom periods of spontaneous rhythm interchange with periods of ventricular pacing. That risk has been scarcely acknowledged in the available reports, but according to our data it is significant and therefore it should be considered during subcutaneous implantable cardioverter-defibrillator screening.

ABSTRACT

Background: A concomitant use of a pacemaker and a subcutaneous implantable cardioverter-defibrillator (S-ICD) may be required in some patients. The aim of our study was to evaluate the influence of permanent cardiac pacing on the morphology of the QRS complex in the context of S-ICD screening.

Methods: One hundred patients with cardiac electronic implantable devices (CIEDs) were included, in whom S-ICD screening could be performed both during intrinsic and paced rhythm.

Results: The positive result of screening during spontaneous rhythm for at least one vector (the same supine and standing) was obtained in 80%, and for 2 vectors in 59% of patients. Positive screening during paced rhythm for at least one vector was recorded in 36% of patients (78% right ventricular and 22% biventricular pacing), and for 2 vectors in 15% of patients (93% right ventricular and 7% biventricular pacing). At least one vector acceptable during both types of rhythm and in both positions was recorded in 23% of patients, and at least 2 vectors — in 8% of patients.

Conclusions: The use of S-ICD in patients with paced ventricular rhythm is associated with a serious risk of inappropriate sensing, due to the different QRS morphology during intrinsic and paced rhythm, and it is particularly high in patients, in whom periods of spontaneous rhythm interchange with periods of ventricular pacing. That risk has been scarcely acknowledged in the available reports, but according to our data it is significant and therefore it should be considered during S-ICD screening.

Key words: cardiac pacing, implantable cardioverter-defibrillator, subcutaneous implantable cardioverter-defibrillator, sudden cardiac arrest, sudden cardiac death

INTRODUCTION

A subcutaneous implantable cardioverter-defibrillator (S-ICD) has recently become a recognized method of treatment used for prevention of sudden cardiac death [1]. The S-ICD system detects ventricular arrhythmias based on the analysis of one of three available electrocardiogram (ECG) vectors. Those vectors are recorded between either the upper or lower sensing ring on the lead located along the left margin of the sternum and the device can, or between those two rings without involvement of the device can. Sensing signals of appropriate quality are required for the accurate operation of the system. Due to that, a patient being qualified for implantation has to undergo a dedicated ECG test (the so-called ECG screening), that is intended to ensure the correct detection of the cardiac rhythm by the device. Screening is performed with the use of specialized software provided by the manufacturer. It relies on the automated analysis of the ECG signal recorded from the surface of the patient's chest, using the vectors similar to the predicted location of the lead and can of the S-ICD system. At least one of the three available vectors should be acceptable to allow for the implantation of S-ICD, but some authors require at least two acceptable vectors to consider screening positive.

The S-ICD system has become widely used in current clinical practice, although its use is still limited by the inability to perform permanent cardiac pacing and cardiac resynchronization therapy. As a consequence, the need for permanent cardiac pacing is one of contraindications for S-ICD therapy [1]. But the indication for pacing may develop later in time even in if it was not present at the time of S-ICD implantation. In such a situation, the change of QRS morphology during paced rhythm may potentially lead to inappropriate sensing of cardiac activity by the S-ICD system. A similar problem occurs in a patient with an implanted pacemaker, who develops indications for an implantable cardioverter-defibrillator (ICD). If the patient does not give their consent to implantation of a transvenous ICD or there is no possibility to perform such a procedure (that requires transvenous extraction of the existing right ventricular pacing lead with all its risks), S-ICD implantation may become one of the options. But then again the transient changes of the QRS morphology during spontaneous and paced rhythm may lead to inappropriate sensing and inadequate interventions. And - last but not least - infective complications may require extraction of the transvenous ICD system, and implantation of an epicardial pacemaker in pacing-dependent patients, which ceases protection against ventricular arrhythmias. The S-ICD system implanted in addition to the epicardial pacemaker might be a solution in such a complex case. At least one sensing vector acceptable both during intrinsic and paced rhythm should be confirmed before the decision is made to use S-ICD together with a pacemaker. Of note, it has to be the same vector for both types of rhythm, as the S-ICD system cannot adjust the sensing vector automatically to the changing rhythm and QRS morphology, when the intrinsic and paced rhythm are constantly interchanging. The sensing vector can be altered only by a physician during the follow-up procedure. The aim of our study was to evaluate the influence of permanent cardiac pacing on the morphology of the QRS complex in the context of S-ICD screening, and on the possibility of concomitant use of S-ICD and a permanent pacemaker.

METHODS

The study was designed to include 100 consecutive patients hospitalized in the Department of Cardiology and Electrotherapy of the Medical University of Gdansk, Poland, that had just undergone implantation of cardiac electronic implantable devices (CIEDs) due to sick sinus syndrome, atrial fibrillation with bradycardia or heart failure. We collected data regarding demographical parameters, rates of concomitant diseases, left ventricular ejection fraction (based on echocardiography), cardiac rhythm and pacing mode of the implanted device, and registered standard ECG for assesment of cardiac rhythm and measurement of standard

electrocardiographic parameters. Data collection was performed between July and December 2021. We included patients in whom it was possible to record both spontaneous rhythm with intrinsic conduction to the ventricles, and paced ventricular rhythm forced by the implanted device in any mode of ventricular pacing (DDD, VVI or biventricular). Patients with an advanced atrio-ventricular block and ventricular escape rhythm (or no escape rhythm at all) were not qualified for the study. The eligibility screening for S-ICD was performed with the use of a Boston Scientific programmer and EMBLEM™ automated screening tool software within 5 days from implantation of CIED. The ECG signal was recorded for 3 vectors: primary (the proximal pole on the lead [on the left margin of the xyphoid process] to the device can [in the position of the ECG lead V6]), secondary (the distal pole on the lead [14 cm above the proximal pole, on the left margin of the sternomanubrium junction] to the device can) and alternate (the distal pole to the proximal pole on the lead). Only the standard set of vectors and typical positioning were performed in our study. Body surface ECG was recorded for those 3 vectors in supine and standing positions, both during intrinsic rhythm and ventricular pacing. To record the intrinsic rhythm, the implanted device was set to VVI mode with the basic rate of 30 bpm. To force ventricular pacing, the device was set to DDD or VVI mode with the basic rate of 10 bpm more than the intrinsic rhythm, and in case of DDD or cardiac resynchronization therapy (CRT) devices — with the atrioventricular delay time short enough to force ventricular pacing (interventricular delay was set to 0 ms in all CRT devices). Due to the fact that experts differ in terms of the definition of positive screening (one or two passing vectors), both those situations were analyzed, as it is stated and underlined onwards in the manuscript at every occurrence of that issue. We analyzed the percentages of positive screening during intrinsic and paced rhythm, and then by groups divided according to the mode of pacing (right ventricular pacing in comparison with biventricular pacing). And finally, we planned a comparison of patients with positive screening during spontaneous rhythm (at least 2 vectors acceptable, both supine and standing) divided into subgroups with either negative or positive result of screening during paced rhythm. That analysis was intended to include demographical variables (age, sex) and clinical variables (heart rate, electrocardiographic parameters, left ventricular ejection fraction, mode of pacing, rates of concomitant diseases). The study design was approved by the Ethical Board at the Medical University of Gdańsk, Poland.

Statistical analysis

Continuous variables were presented as mean and standard deviation or median and interquartile range in case of non-normal distribution. Categorical parameters were presented

as numbers and percentages. The normality of distribution was tested with the Shapiro–Wilk test. The χ^2 test, and the Student t-test or Mann–Whitney U test (depending on the analysis of distribution and variance) were used to compare the groups, as appropriate for a given variable. A *P* value below 0.05 was considered statistically significant. Data management and statistical analysis were performed with the use of Microsoft Excel and Statistica 13.1 software (TIBCO Software, Palo Alto, CA, US).

RESULTS

One hundred consecutive patients with a pacemaker or ICD were included in the study group. Clinical data of the patients are summarized in [Table 1](#). All the right ventricular leads were in the apical position.

Screening during spontaneous rhythm (implanted device inactive)

Data regarding the number of vectors acceptable for S-ICD implantation are presented in [Figure 1](#) and [2](#). The positive result of screening if at least one acceptable vector was required (the same in supine and standing position) was eventually obtained in 80 patients (80%), and if two positive vectors were required — in 59 patients (59%).

Screening during paced ventricular rhythm forced by the implanted device

Data regarding the number of vectors acceptable for S-ICD implantation are presented in [Figure 1](#) and [2](#). The positive result of screening if at least one acceptable vector was required (the same in supine and standing position) would be eventually obtained in 36 patients (36%). In that subgroup 28 patients (78%) had right ventricular (RV) pacing and 8 (22%) — biventricular (BiV) pacing. But 8 of those 36 patients (22%) had none of the vectors acceptable during spontaneous rhythm. If two positive vectors were required, the positive result of screening would be achieved in 15 patients (15%). In that subgroup RV pacing was present in 14 cases (93%), and BiV pacing in one case (7%).

In the group of 100 patients we obtained at least one sensing vector acceptable during both spontaneous and paced rhythm only in 28 cases (28%). Furthermore, in 5 patients it was not the same vector for those two types of rhythm. Eventually, only in 23 cases out of the initial 100 (23%) we managed to find at least one vector acceptable during both types of rhythm (the same vector in both situations) and in both body positions (5 patients with BiV and 18 with RV pacing). If 2 vectors were required for positive screening (the same 2 vectors for both rhythms

and both body positions), the final positive result of screening would be obtained only in 8 patients (all with RV pacing).

Looking from the perspective of pacing modality, 29 patients (29%) had BiV pacing and 71 (71%) – RV pacing. If one acceptable vector was enough, 5 patients out of 29 with BiV pacing (17.2%) and 18 out of 71 with RV pacing (25.4%) could be considered to have a positive result of screening ($P = 0.38$ for the difference). If two vectors were required, none of the patients with BiV pacing (0%) and 8 with RV pacing (11%) could be considered positive ($p=0.06$). Therefore the type of pacing did not influence the chance of having a positive result of screening with either one or two vectors required.

Analyzing which of the vectors were positive during spontaneous and paced rhythm, we found that it was predominantly the primary vector in both situations (65% and 21%, respectively, see [Figure 2](#)).

Then we analyzed the variance among patients with positive screening according to the criteria used typically in our department (two passing vectors) during spontaneous rhythm, dividing them into subgroups with the negative (group 1) or positive (group 2) result of screening during paced rhythm. Variables in that analysis included age, sex, left ventricular ejection fraction (LVEF), underlying cardiac disease, the history of chronic heart failure and electrocardiographic measurements (the width of paced QRS complex and intrinsic QRS complex, the increment of QRS width with pacing, the QT interval, and the presence of right or left bundle branch block). Only the LVEF was significantly different between those subgroups and it was 40 (25–50)% in group 1 and 55.5 (50–60)% in group 2. The results are presented in [Table 2](#).

DISCUSSION

The inability to provide permanent cardiac pacing is one of the major limitations of the S-ICD system. Predicted rate of the need for pacemaker implantation was found to be between 2% and 6.8% per year of follow-up in numerous studies of patients with transvenous ICDs, and the rate of the need for CRT — between 0.6% and 0.8% per year [2–5], but it should not be directly extrapolated to populations of potential S-ICD recipients. The reported risk of developing indications for permanent cardiac pacing in real-life populations of patients with implanted S-ICD systems is lower. In the analysis of early cumulative results of the EFFORTLESS and IDE studies the need for permanent cardiac pacing occurred only in 2 of 889 patients during 22 months of follow-up [6]. In another report from Germany, the low risk of such a scenario was confirmed. In 28 patients no need for pacemaker implantation was reported during follow up

until S-ICD battery depletion [7]. Finally, in recently published results of the prolonged follow-up of the EFFORTLESS study population (median implant duration 5.1 years), the need for conversion from S-ICD to transvenous ICD due to indications for cardiac pacing occurred only in 13 of 984 patients [8].

Therefore the risk that the necessity to implant a permanent cardiac pacemaker occurs in a patient with pre-existing S-ICD is low, yet not negligible. The opposite scenario seems more probable, when a patient with pre-existing cardiac pacemaker develops heart failure with reduced LVEF, and therefore an indication for ICD in primary prevention of sudden cardiac death. In a study by Khurshid et al., the decrease in mean LVEF from 62.1% to 36.2% over a mean follow-up period of 3.3 years occurred 19.5% of the study population [9].

Two solutions for such a problem are available. One is to upgrade the pacemaker to transvenous ICD or CRT-D, possibly after transvenous extraction of the right ventricular pacing lead. The second solution is to implant S-ICD system as a companion to the existing pacemaker.

Data regarding concomitant use of pacing systems and S-ICDs are limited, although such a solution has been successfully used and reported. Reports are available of S-ICD systems co-existing with both transvenous and epicardial pacemakers [10–13]. Moreover, in single cases the S-ICD system was used together with a leadless pacemaker [14–16]. On the contrary, several cases were reported where the implanted pacemaker changed QRS morphology to such an extent, that continuation of the S-ICD therapy was not possible [17]. Therefore, the concomitant use of pacemakers and S-ICD systems is associated with a significant risk of undesired interactions between those devices. Careful programming may reduce the risk of such interactions. When programming a pacemaker, it is recommended to use low pulse amplitudes with minimal safety margins, as well as to turn off the automatic threshold and automatic switch-of-polarity functions. In DDD and CRT devices, the upper rate limit should be set lower than half of the first therapy zone in S-ICD [18]. But that recommended programming algorithm cannot completely eliminate the problem of unacceptable QRS morphology change due to ventricular pacing, that may preclude appropriate QRS sensing by the S-ICD device.

To evaluate the significance of that phenomenon, we analyzed data acquired from 100 consecutive patients, in whom the ventricular rhythm was forced in the form of RV or BiV pacing. In that group only in 36 patients (36%; 28 RV, 8 BiV) screening was acceptable for at least one vector, and in 15 cases (15%) for at least 2 vectors (14 RV, 1 BiV). The analysis of the results of screening by the mode of pacing revealed that in patients with BiV pacing at least one vector was acceptable in 8 of 29 patients (28%), and with RV pacing — in 28 of 71 patients (39%). Those values are significantly lower than the rates reported by Ip et al. [19]. Those

authors reported positive screening in 80% of patients with biventricular pacing and 46% of patients with RV pacing. That analysis was performed manually using the Boston Scientific screening templates, whereas in our population the automated screening was performed. There are other reports regarding the influence of permanent cardiac pacing on the QRS morphology and the impact of that phenomenon on S-ICD screening. Those reports were based on populations of patients with CRT or His bundle pacing. In those reports S-ICD screening was acceptable in most patients with cardiac pacing, contrary to our results. The rates of positive screening were 82% to 85% for BiV pacing and 90% for His bundle pacing [20–22]. But the authors of those publications analyzed only the results of screening in paced rhythm, and not included the possible temporary change of rhythm for the intrinsic one. Such an event may occur in a setting of transient atrioventricular conduction disturbances, supraventricular tachycardia or ineffective ventricular pacing. In our study group, in 36 of 100 patients (36%) we could find at least one acceptable vector during ventricular pacing, but in 8 patients of those 36 none of the vectors was acceptable during intrinsic activation when ventricular pacing was switched off. Therefore those patients, if equipped with an S-ICD, would be at risk of inappropriate interventions in case of reoccurrence of the intrinsic rhythm. In the subsequent analysis of the remaining 28 patients we noticed that in 5 of them the vectors acceptable during spontaneous activation and ventricular pacing were different. The S-ICD system cannot automatically change the sensing vector depending on the type of ventricular activation (spontaneous versus paced). Therefore those 5 patients would also be at risk of inappropriate interventions. Only 23 patients (23%) could be eventually deemed as having acquired the positive result of screening with minimal requirements, that is at least one vector acceptable both during spontaneous rhythm and ventricular pacing, and in both supine and standing position. Assuming that the reasonable number of acceptable vectors to guarantee long-term safety is 2 (the same vectors in both body positions and both types of cardiac rhythm), the number of patients meeting such restricted criteria was 8 (8%). The phenomenon of the QRS morphology change between spontaneous and paced rhythm, and its influence on S-ICD screening, was reported by Giammaria et al. [23]. In the group of 48 patients with biventricular pacing at least one vector was acceptable in 34 patients (71%). But when pacing was switched off, that number was reduced to 22 (46%) during intrinsic ventricular activation.

Limitations of the study

A limited number of patients included in the study and a relatively low number of CRT recipients (due to the fact that we included consecutive patients undergoing implantation of

CIEDs) resulted in small subgroups, which restricted statistical analysis (especially for comparisons of proportions). We did not analyze the relationship between the position of LV leads and the result of screening, as it would further sub-divide those relatively small groups.

CONCLUSIONS

The use of S-ICD is associated with a serious risk of inappropriate sensing in patients with other cardiac implantable electronic devices, in whom periods of spontaneous rhythm interchange with periods of ventricular pacing. If a pacemaker is implanted first, the analysis of such a risk is possible, and requires repeated screening in both paced and intrinsic rhythms. But if the S-ICD system is implanted first, it is very difficult to predict the possible risk of inappropriate sensing, because screening for the paced rhythm cannot be performed prior to the pacemaker implantation.

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Table 1. Clinical data of patients in the study group

Total number, n (%)	100 (100)
Male, n (%)	65 (65)
Age, mean (SD), range, years	73 (12), 28–94
Coronary artery disease, n (%)	42 (42)
Non-ischemic cardiomyopathy, n	19 (19)
Heart failure, n (%)	62 (62)
LVEF, median (IQR), %	40 (27–55)
Sinus rhythm, n (%)	69 (69)
Atrial fibrillation, n (%)	31 (31)
Type of the implanted device, n (%)	
VVI pacemaker	8 (8)
DDD pacemaker	43 (43)
ICD single-chamber	14 (14)
ICD dual-chamber	6 (6)
CRT pacemaker	5 (5)
CRT defibrillator	24 (24)

Abbreviations: CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction; SD, standard deviation

Table 2. Comparison of patients with positive screening during spontaneous rhythm (at least 2 vectors acceptable, both supine and standing) divided into subgroups with either the negative (group 1) or positive (group 2) result of screening during paced rhythm

Variable	Group 1 (n = 51)	Group 2 (n = 8)	P-value
Age, median (IQR), years	73 (68–82)	74.5 (71.5–80)	0.89
Heart rate, median (IQR), bpm	70 (61–82)	62 (52–70.5)	0.08
Intrinsic QRS, median (IQR), ms	109 (90–160)	128.5 (100–150)	0.63

Paced QRS, median (IQR), ms	160 (150–170)	175 (150.5–189.5)	0.13
Difference between paced and intrinsic QRS width, median (IQR), ms	54 (0–72)	48.5 (31.5–63.5)	0.93
QT, mean (SD), ms	424.39 (56.06)	422.75 (46.19)	0.96
QTc, mean (SD), ms	455.86 (48.61)	424.75 (34.59)	0.06
LVEF, median (IQR), %	40 (25–50)	55.5 (50–60)	0.01
CRT, n (%)	20 (39.22)	0 (0)	0.03
male, n (%)	30 (58.82)	5 (62.5)	0.84
AF, n (%)	17 (33.33)	2 (25)	0.64
RBBB, n (%)	4 (7.84)	2 (25)	0.14
LBBB, n (%)	13 (25.49)	0 (0)	0.11
IVCD, n (%)	5 (9.8)	2 (25)	0.28
ICM, n (%)	23 (45.1)	1 (12)	0.08
HA, n (%)	37 (72.55)	6 (75)	0.89
DCM, n (%)	13 (25.49)	0 (0)	0.11
CHF, n (%)	33 (64.71)	3 (37.5)	0.14

Group 1 — positive screening without pacing, negative during pacing; group 2 — positive screening both without pacing and during pacing

Abbreviations: AF, atrial fibrillation; CHF, chronic heart failure; DCM, dilative cardiomyopathy; HA, hypertension; ICM, ischemic cardiomyopathy; IVCD, intraventricular conduction disturbances; LBBB, left bundle branch block; RBBB, right bundle branch block; other — see [Table 1](#)

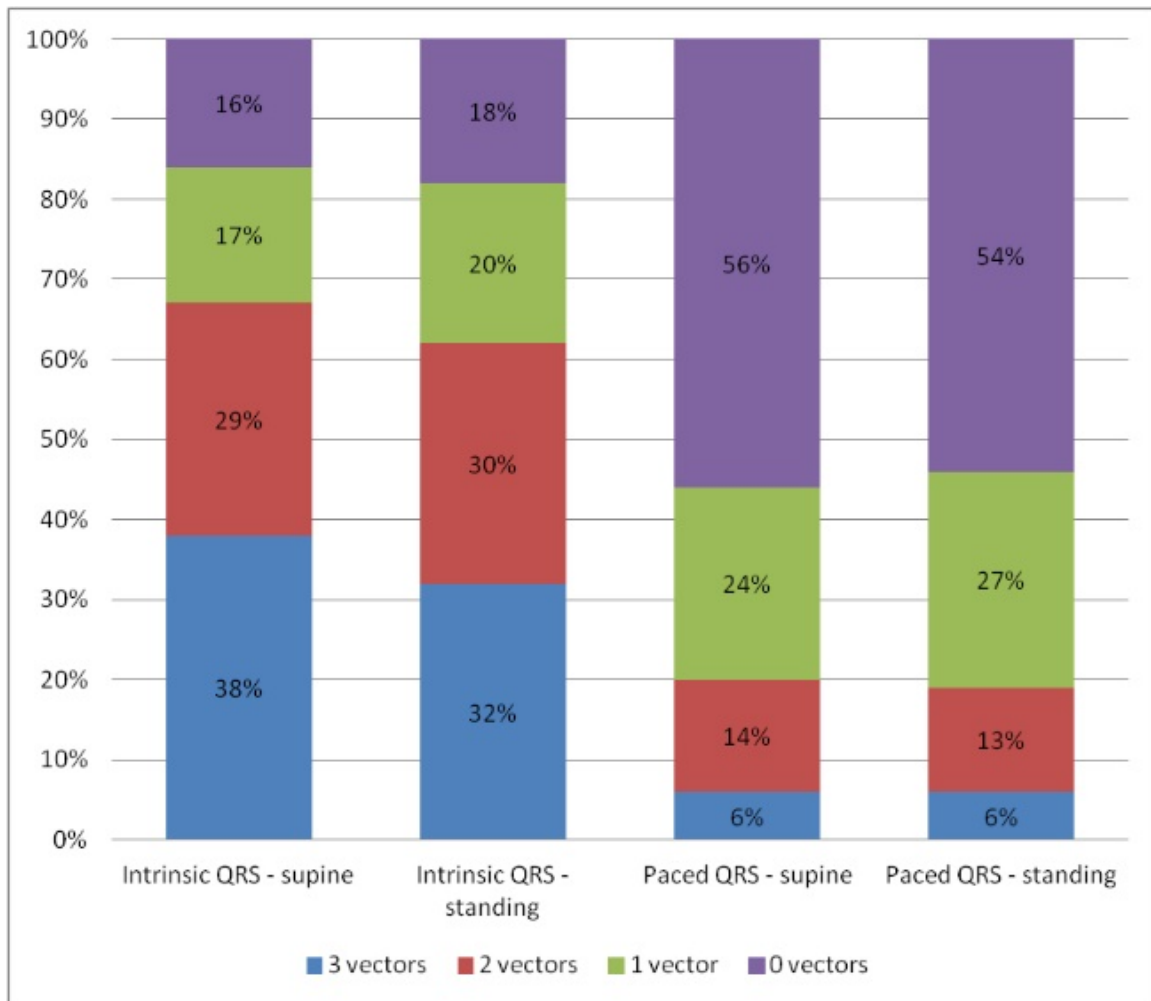


Figure 1. Percentages of patients with different numbers of vectors acceptable in S-ICD screening during spontaneous and paced rhythm

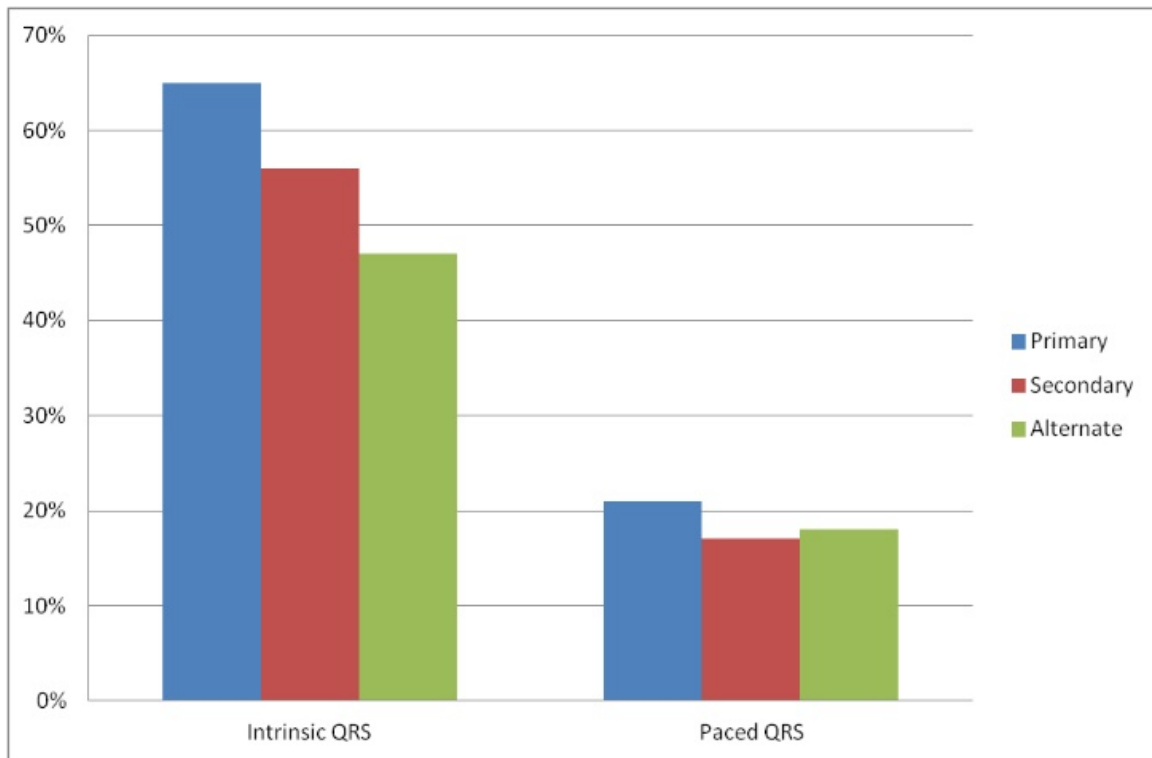


Figure 2. Percentages of vectors acceptable in S-ICD screening during spontaneous and paced rhythm