

S-ICD IS NOW GUIDELINE recommended by ACC/HRS/AHA for patients at high risk for infection, inadequate venous access and any patient without a pacing indication¹

**HIGH RISK
FOR INFECTION**

~75%

**OF ICD
INDICATED
PATIENTS**

have ≥1 comorbidity
associated with device
infection.^{2,3,4}

Class I¹

**ANY PATIENT WITHOUT
A PACING INDICATION**

70%

**OF DR & VR
ICD
PATIENTS**

under 75 have no pacing
indication at implant.^{5,6}

Class IIa¹

**INADEQUATE VENOUS
ACCESS**

AS MANY AS

61%

OF PATIENTS

may have venous
stenosis following
initial device
implantation.⁷

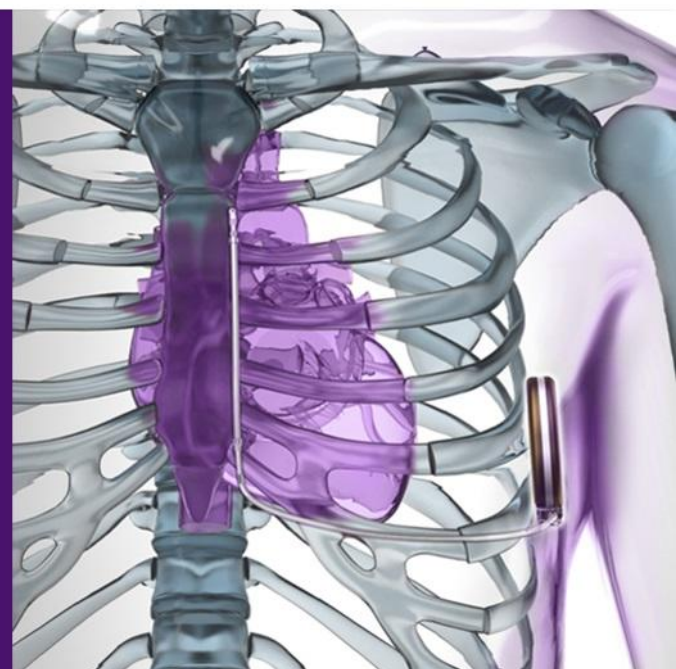
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Eligibility for subcutaneous implantable cardioverter-defibrillators in the adult congenital heart disease population

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Short title: S-ICD in adult CHD

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ABSTRACT

Background: Patients with adult congenital heart disease (ACHD) have an increased risk of arrhythmic, sudden cardiac death. The subcutaneous implantable cardioverter defibrillator (S-ICD) provides a potentially safer alternative to transvenous ICDs in ACHD. Suitability for S-ICD depends on the surface ECG which is often abnormal in ACHD patients. This study investigates the proportion of ACHD patients who meet the screening criteria for S-ICD

Methods A standard screening ECG was performed in 102 patients with complex ACHD (Tetralogy of Fallot, Fontan Circulation, Transposition of the Great Arteries). This process was repeated post-exercise for patients who also had an exercise test.

Results: Three quarters (75.4%) of ACHD patients meet screening criteria for an S-ICD with at least 1 suitable vector. The most common number of acceptable vectors in the eligible group was 2 (35% of total population). In only 12% were all three vectors suitable whilst 28% had only 1. The primary vector (equivalent of ECG lead III) was the most common suitable vector, found in 62% of participants who had appropriate sensing vectors. 25 (24.5%) patients failed to meet the S-ICD screening criteria. Of these, 14 had repaired tetralogy of Fallot. 92% of patients with a Fontan circulation met ECG screening criteria. Of those who had the protocol repeated following their cardiopulmonary exercise test (n=14), only 1 additional patient failed eligibility criteria.

Conclusions: A quarter of ACHD patients do not meet eligibility criteria for the S-ICD. However, more than 90% of patients with a Fontan circulation are suitable for an S-ICD.

Keywords: subcutaneous implantable cardioverter-defibrillator; adult congenital heart disease, Fontan circulation; Tetralogy of Fallot

INTRODUCTION

Patients with adult congenital heart disease (ACHD) have an increased risk of sudden cardiac death due to tachyarrhythmias. Those most at risk are patients with repaired tetralogy of Fallot (TOF)¹ and complete transposition of the great arteries (d-TGA)² and Fontan circulation³. The 2014 HRC/PACES guidelines⁴ recommend implantable cardioverter defibrillator (ICD) implantation in ACHD patients with poor systemic ventricular function, following hemodynamically significant ventricular arrhythmias and in selected higher risk patients with TOF. Unfortunately, transvenous ICD implantation can be challenging in the ACHD population, as a result of their complex anatomy and associated risks of procedural complications⁵. Particular difficulty exists following the Fontan procedure for single ventricle, which often precludes access from the venous system to the heart⁶. Systemic venous pathway obstruction has also been reported in 36% of d-TGA patients⁷. In addition, lead failure, resulting from growth-related lead distortion, is common, with incidence rates as high as 26%⁸.

The most recent development in ICD design is the subcutaneous ICD (S-ICD) system, which comprises of a generator placed in the anterolateral position and a left parasternal coil placement. The absence of transvenous access preserves the vasculature and is thought to minimise procedure-related complications, risk of bleeding, thrombosis and infection⁵. The S-ICD is an attractive option in ACHD patients who are likely to require multiple generator changes in their lifetime and face potential complications with each intervention, particularly when transvenous access to the ventricles is difficult. Their use in this population is recommended by the European Society of Cardiology⁹.

ACHD patients frequently have abnormal ECGs which may interfere with appropriate sensing and is unclear what proportion would be suitable for an S-ICD. Prior to S-ICD implantation ECG screening must be performed to ensure that T waves are not oversensed and shocks are delivered appropriately. This involves assessment of an appropriate R to T (R:T) wave ratio. Screening data for ACHD patients is limited and only small sample studies of around 30 patients have so far been

carried out, with reported ineligibility rates between 13.3%¹⁰ and 48.4%¹¹. Independent predictors of ineligibility include prolonged QRS duration, a R:T_{max} value of less than 3¹² and T wave inversion¹³.

This study investigates what proportion of patients with ACHD meet the ECG screening criteria for an S-ICD.

METHODS

In this prospective study, patients were recruited from the ACHD patient population in a large quaternary specialist ACHD centre (Queen Elizabeth Hospital, Birmingham, United Kingdom). Participants were recruited opportunistically during routine attendance at the ACHD outpatient clinic. Inclusion criteria were: males and females of any race or ethnic origin, age ≥ 16 years and a diagnosis/clinical history of TOF, d-TGA or Fontan palliation. Exclusion criteria were: age < 16 years and a lack of capacity to provide informed consent. Approval was granted by Health Research Authority and an independent review board at the West Midlands, Edgbaston Research Ethics Committee (REC 16/WM/0255).

Study design

The screening ECG was carried out according to the S-ICD manufacturer's protocol¹⁴, which involves using modified electrode positions of 3 ECG electrodes (**Figure 1**). Up to 10 seconds of ECG was recorded (25 mm/s) at a gain of 5, 10 or 20 mm/mV, in the supine, sitting and standing postures. Three vectors were analysed, namely primary, secondary and alternate vectors (**Figure 1**). This process was repeated post-exercise for patients who also had a cardiopulmonary exercise test as part of their routine ACHD investigations. Analysis of the subsequent electrical vectors was undertaken using the patient screening tool (Model 4744, Boston Scientific, St Paul, US)¹⁴ (**Figure 2**). Demographic information and clinical data was recorded for all ACHD participants and ECG data was extracted from their most recent 12-lead ECG. The R:T_{max} was defined as the ratio of the R wave to T wave in the lead with the largest amplitude T wave.

Statistical analysis

For analysis of clinical and electrographic features, categorical data is expressed as percentages and were analysed using the Fisher's exact test. Continuous data was assessed using the Kolmogorov-Smirnov test and expressed, depending on its normality. For normally distributed data, the mean and SD were calculated and an independent t-test was used. For data that was not normally distributed, the median and interquartile range (IQR) was calculated and compared using the Mann-Whitney U-Test. The statistics software package SPSS 22.0 (IBM, Armonk, NY, USA) was used for data collection and analysis.

RESULTS

A total of 107 ACHD patients were recruited. Of these, 5 (4.6%) patients were excluded due to a lack of ECG data in all three postures or at additional gain settings. The complete screening ECG was obtained in 102 participants, 14 (13.7%) of whom also had the protocol repeated post-exercise. As shown in **Table 1**, the mean age was 30.7 (\pm 1.19) years (mean \pm SD) and 54 (53.0%) were female. In addition to their primary diagnosis, 5 (4.9%) patients also had dextrocardia, 61 (59.8%) had a bundle branch block, of which 83.6% were right bundle branch block.

Eligibility. A total of 77 (75.4%) patients were deemed potentially eligible for an S-ICD with at least 1 suitable vector. The primary vector was the most common suitable vector found in 48 (62%) participants who had appropriate sensing vectors. The most common number of acceptable vectors in the eligible group was 2 (n=36, 47%), whereas only 12 (16%) had all 3 acceptable vectors and 29 (38%) had only one suitable vector.

A total of 25 (24.5%) patients failed to meet the S-ICD ECG screening criteria and were deemed ineligible. Of these, 14 (56%) had a diagnosis of TOF. The disease distribution for the ineligible group is summarised in **Figure 3**. In contrast, 26/28 (93%) of patients with a Fontan circulation would be suitable for an S-ICD on the basis of ECG screening. Of those who had the screening ECG repeated following their cardiopulmonary exercise test (n=14), only 1 additional patient (with TOF) failed to maintain their eligibility.

Reasons for ineligibility. Only 1 Fontan patient was deemed ineligible ($p=0.01$). In contrast over a third ($n=14$, 36%) of patients with tetralogy of Fallot were ineligible ($p=0.001$). The measured R:Tmax ratio was significantly smaller in the ineligible group ($p=0.03$), with a mean value of 1.8 for the ineligible group and 2.9 for the eligible group. The QRS duration in the ineligible group was significantly broader ($p=0.01$) with a greater proportion having RBBB rather than LBBB morphology ($p<0.01$). Consequently, the number of patients with a narrow QRS was significantly lower in the ineligible group ($p=0.02$).

A tall T wave was the only reason for no acceptable vectors in all postures ($n=13$), and for the 12 patients who had an acceptable vector in at least 1 posture, the main reason for failure in all three postures was a change in the R:T_{max}. For both groups, the R wave changed significantly with different postures and was lowest in the sitting position (**Figure 4**).

DISCUSSION

This study shows that nearly a quarter of ACHD patients fail to meet the standard ECG screening criteria for the S-ICD. Eligibility was lowest in patients with TOF and highest in patients with a Fontan circulation. **The use of S-ICD in the congenital population is not widely reported in the literature. Moore et al. reported the use of S-ICD in 21 ACHD patients 9 with Fontan circulation, largely for primary prevention. The main indication for a subcutaneous approach was inability to access a non-systemic ventricle percutaneously. Overall the S-ICDs function well but there was a 15% inappropriate shock rate.¹⁵ Ferro et al. showed similar outcomes in 8 patients with S-ICD and adult congenital heart disease in the secondary prevention setting.¹⁶ The main reason for this approach was the inability to implant a standard ICD percutaneously. This group showed a similar inappropriate shock rate (12.5%)**

Effect of disease

Nordkamp et al¹² found an S-ICD ineligibility rate of 7.4% in the general cardiac population based on ECG screening. The significantly higher ineligibility rates in the ACHD population seen in this study may be due to abnormal T wave morphology¹⁷ resulting from structural and functional disturbances that characterises ACHD, including cardiac chamber enlargement, abnormal cardiac position, mechanical strain and augmented repolarisation¹⁸.

Ineligibility was highest in patients with TOF. This is perhaps not unexpected, as patients with TOF may have RV dilatation due to volume overload resulting from pulmonary regurgitation¹⁹.

Moreover, TOF patients also have conduction abnormalities and frequently have prolonged QRS complexes. Indeed QRS duration is one of the major criteria for predicting the risk of SCD and arrhythmia in patients with TOF⁴. Patients with TOF are at particularly high risk of monomorphic ventricular tachycardia, which often responds to anti-tachycardia pacing (ATP). For this reason also transvenous ICD may be preferable to an S-ICD in patients with TOF.

In contrast, we found that up to 93% of patients with a Fontan circulation met ECG eligibility criteria. An S-ICD may be particularly useful in the Fontan population as the surgical repair usually precludes access to the ventricles from the systemic venous circulation. Often the only practical approach to place an ICD would either be a high risk surgical procedure²⁰ or an S-ICD.

It is possible that the number of ACHD patients suitable for S-ICD might be increased by alternative placement of electrodes, in a right parasternal position. This reduces the amplitude of the T waves without reducing the sensitivity of the R wave. *Wilson et al. showed that there was no reduction in the R wave or T wave using the right parasternal position to screen compared to the standard technique in a mixed group of congenital patients (TOF, transposition and single ventricle).*²¹ *There was, however, a significant reduction in these vectors in control patients. Alonzo et al screened 102 patients with TOF and found 34% were ineligible for S-ICD with standard screening but only 25% were ineligible with right sided screening.*²² *The highest rates of ineligibility were found in those patients with the most risk factors for sudden death. In contrast, they found no additional benefit of right*

sided screening in patients with a single ventricle. Okamura et al.²³ showed a much lower rate of ineligibility (21%) using standard screening in a cohort of 100 ACHD patients. This was reduced to 12% by right sided screening. However the vast majority of their patients had simple rather than complex congenital heart disease and only 22 had TOF. In summary right sided placement of an ICD may allow a higher proportion of ACHD patient to be eligible for an S-ICD, particularly those with TOF but may pose difficulties in the patients require further sternotomies. The benefit in other types of congenital heart disease appears limited.

Effect of posture

This study shows that significant proportion of ACHD patients have acceptable vectors in one or two postures, but were ultimately deemed ineligible due to altered R:T upon change in posture, which resulted in the R or T wave falling outside the screening template. This highlights the sensitivity of the subcutaneous sensing electrode to variations in QRS morphology with cardiac orientation. Together with significant changes in R wave amplitude seen across all three postures, this supports screening in multiple positions as a prerequisite for identifying such changes that could affect the function of the S-ICD.

Exercise

Kooiman et al²⁴ suggested that exercise would render a large proportion of patients ineligible, as a result of exercise-induced changes in QRS and T wave morphology. Although only a small proportion of patients underwent exercise testing in this study, it only had a small impact on eligibility in patients with ACHD.

Limitations

This study only included the most common forms of ACHD for whom an ICD may be indicated; others such as atrioventricular septal defects, or Ebstein's anomaly were excluded. Only standard

ECG screening was performed, right parasternal lead positions were not assessed which may have improved eligibility. Only a small proportion of patients underwent exercise testing.

CONCLUSIONS

Patients with ACHD are at increased risk of ventricular arrhythmias and sudden death but the use of transvenous ICDs can be difficult because of the complex venous anatomy and high complication rates. They would appear to be good candidates for S-ICD. This study demonstrates that using standard ECG screening, nearly a quarter of patients with the commonest ACHD indications for ICD are not candidates for the S-ICD, due to a risk of inappropriate sensing. In contrast, the vast majority of patients with a Fontan circulation are suitable. In these patients placing a transvenous ICD lead is usually not possible and S-ICD offers a relatively low risk approach to allow ICD therapy. Whilst improvements to the current screening protocol are expected, they are unlikely to have a significant impact on eligibility without substantial development of the current S-ICD sensing algorithm.

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FIGURE LEGENDS

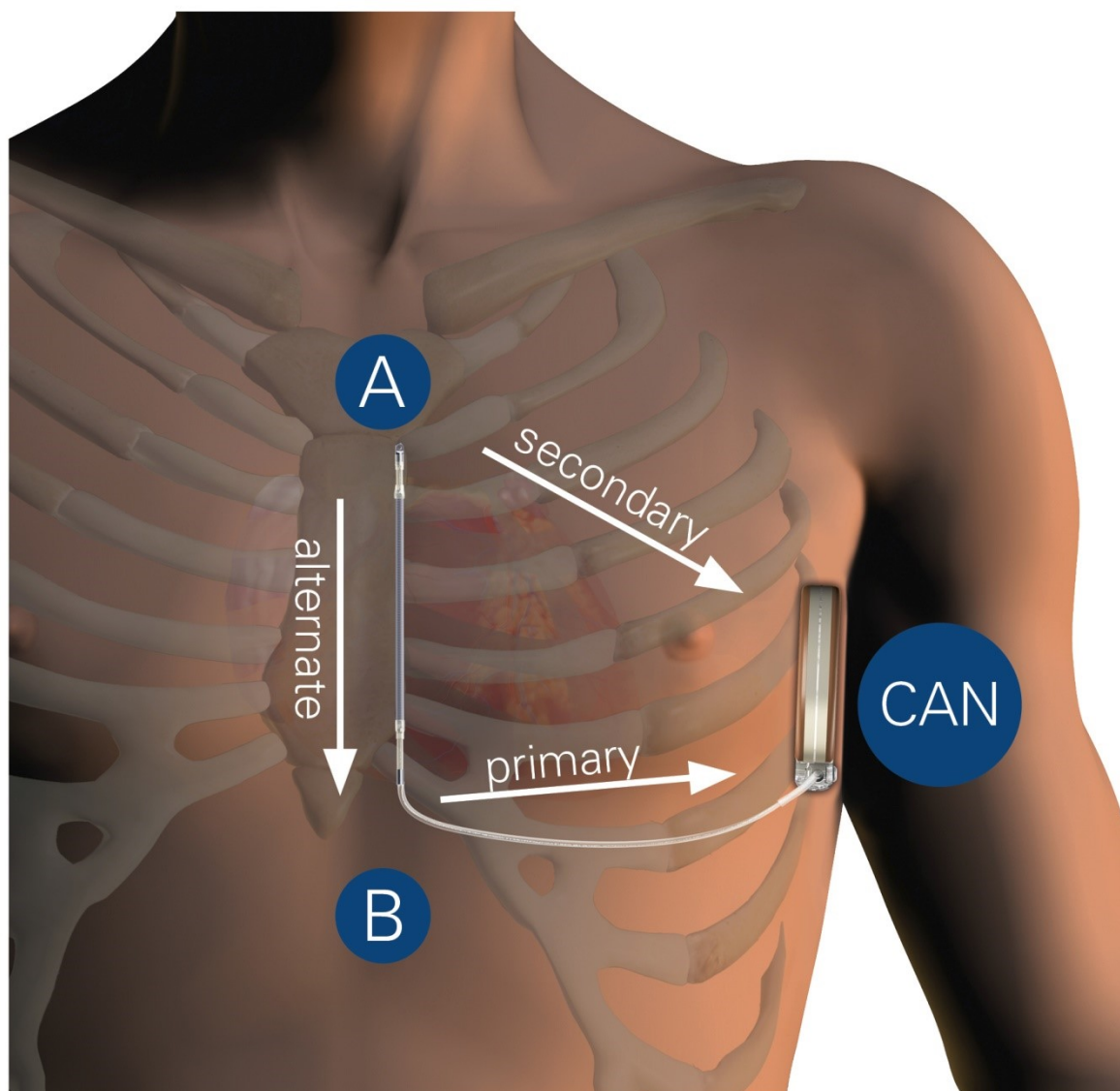


Figure 1. Modified position of the ECG electrodes used for the S-ICD ECG screening protocol. *

*, adapted from Boston Scientific ¹⁴.

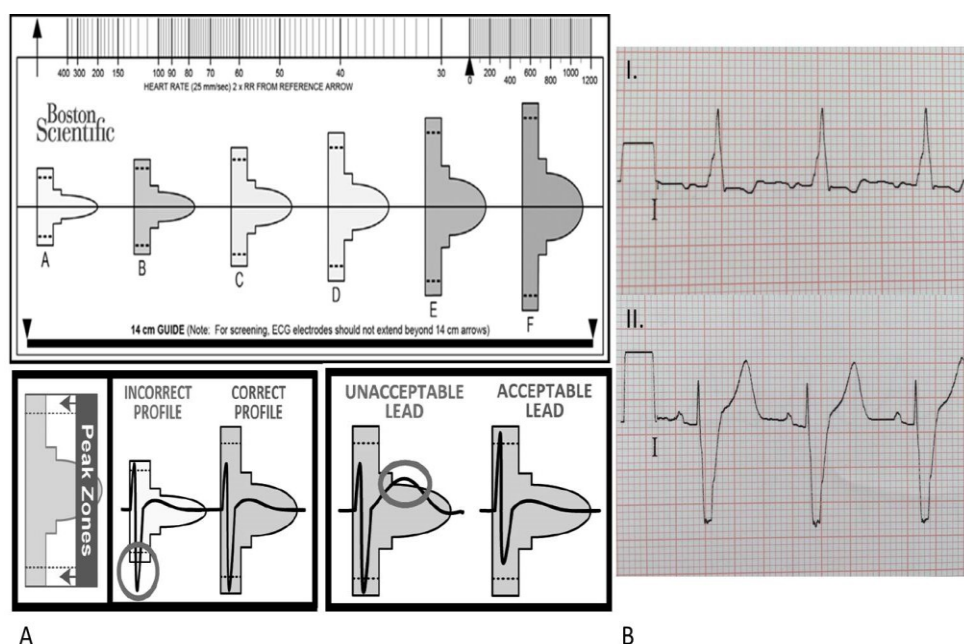


Figure 2a. Patient ECG screening tool. The figure shows the patient ECG screening tool (Model 4744, Boston Scientific, St Paul, US)¹⁴ and the correct alignment of the QRS within a suitable template. According to the required method, the QRS complex and prevailing T wave must fit into any one of the templates shown. In the example shown, the patient was considered suitable for S-ICD as there was a minimum of 1 acceptable sensing vector in all postures.

Figure 2b Example ECGs (I) a screening ECG that fits into one of the screening templates and was deemed eligible. (II) a screening ECG that failed to meet criteria based as a result of the tall T wave and small R:T ratio.

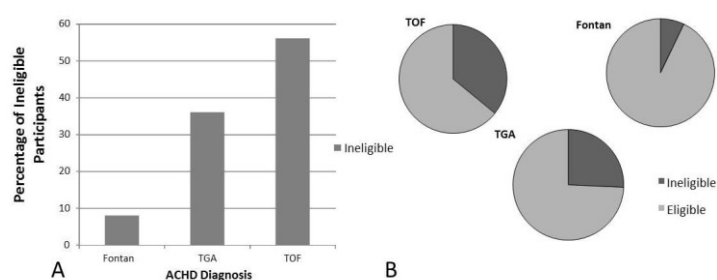


Figure 3a. Disease distribution within the ineligible group.

Figure 3b. Proportion of patients deemed suitable for S-ICD for each of the diagnosis. TOF – repaired tetralogy of Fallot, TGA – transposition of the great arteries, Fontan – Fontan repair for single ventricle.

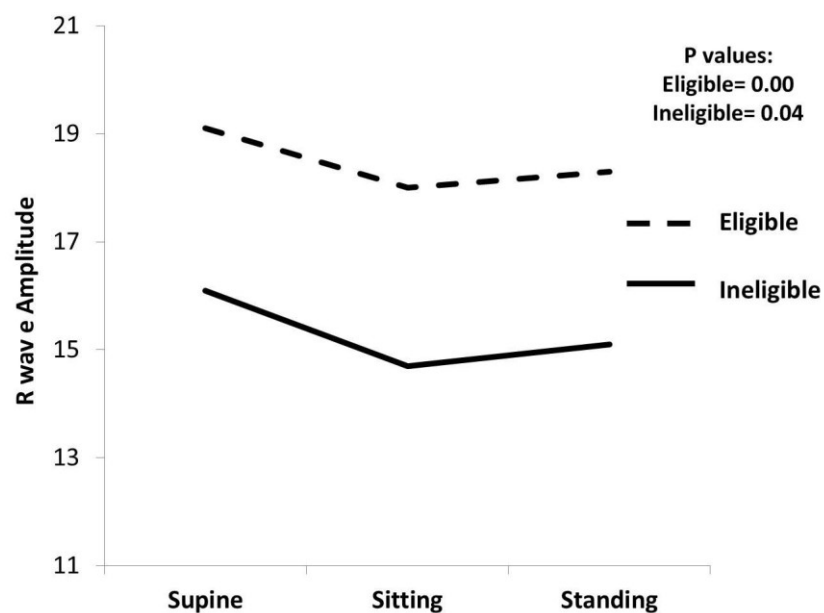


Figure 4. Change in measured R wave amplitude seen across the postures, in both the eligible and ineligible group.

Table 1. Characteristics of the study group.

	All patients (N = 102)	Eligible (N = 77)	Ineligible (N = 25)	P value
Age (years)	30.7 ±1.19	30.1 ± 11.1	32.6 ± 14.6	0.849
Sex (female)	54 (53.0%)	43 (55.8%)	11 (44.0%)	0.360
BMI (kg/m²)	25.2 ±5.85	25.4 ± 6.35	24.6 ± 3.70	0.904
Aetiology				
Fontan	22 (21.6%)	21 (27.3%)	1 (4.0%)	0.016
TGA	35 (34.3%)	26 (33.8%)	9 (36.0%)	0.841
TOF	39 (38.2%)	25 (32.5%)	14 (56.0%)	0.038
Fontan + TGA	5 (4.9%)	5 (6.5%)	0	0.194
TOF + Fontan	1 (1%)	0	1 (4%)	0.081
ECG variables				
PR interval (ms)	162.0 ± (35.2)	161.5 ± 36.1	160.6 ± 32.0	0.993
QRS morphology				
LBBB	10 (9.8%)	7 (9.1%)	3 (12.0%)	0.673
RBBB	51 (50%)	34 (44.2%)	17 (68.0%)	0.041
QRS duration (ms)	130 ± 31.48	121.5 ± 30.8	148.6 ± 32.5	<0.001

Narrow QRS (<120 ms)	41 (40.2%)	36 (46.8%)	5 (20.0%)	0.020
QTc (ms)	455 ± 40.41	450.8 ± 40.5	467.9 ± 38.0	0.065
R wave (mV)				
Supine	18.4 ± 10.08	19.2 ± 9.06	16.1 ± 12.7	0.013
Sitting	17.0 ± 9.83	18.0 ± 8.83	14.1 ± 12.2	0.083
Standing	17.6 ± 9.80	18.3 ± 8.85	15.1 ± 12.2	0.145
R:T_{max}	2.61 ± 2.15	2.87 ± 2.33	1.79 ± 1.11	0.034

Continuous data provided as mean ± SD. p values refer to differences between eligible and ineligible groups. BMI = body mass index, RBBB = right bundle branch block, LBBB = left bundle branch block, R:T_{max} = R:T on the maximum T wave, SVEF = ejection fraction, TGA = transposition of the great arteries, TOF = tetralogy of Fallot