UNMASKING PAEDIATRIC TACHYCARDIAS AT HOME

Applicability of the AliveCor outpatient ECG monitor for clinical management of neonates and infants with tachyarrhythmias

FINAL DEGREE PROJECT

Autor: Anna Balagué Fandos

Tutor: Dra. Georgia Sarquella Brugada

Methodological tutor: Dra. Teresa Puig Miquel

Paediatric Arrhythmias Electrophysiology and Sudden Death Unit Cardiology Department
Hospital Sant Joan de Déu, Barcelona

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1. ABBREVIATIONS

AET	Atrial ectopic tachycardia
AF	Atrial Fibrillation
App	Application
AV node	Auriculo-ventricular node
AVRT	Atrioventricular re-entry tachycardia
AVNRT	Atrioventricular nodal re-entry tachycardia
Bpm	Beats per minute
CHF	Congestive Heart Failure
DC cardioversion	Direct current cardioversion
ECG	Electrocardiogram
EPS	Electrophysiology study
FDA	Food and Drug Administration
FHR	Foetal Heart Rate
HSJD	Hospital Sant Joan de Déu
ILR	Implantable Loop Recorder
iv	intravenous
ms	Millisecond
PJRT	Permanent junctional reciprocating tachycardia
SVT	Supraventricular tachycardia
VT	Ventricular tachycardia
WPW	Wolff-Parkinson-White

2. ABSTRACT

BACKGROUND: Up to 1 in 250 to 1000 children suffer from supraventricular tachycardia, the most common heart rhythm disturbance in the paediatric population. The clinical presentation in infants is non-specific and obtaining the correct diagnosis is further complicated due to most arrhythmias are paroxysmal, making it difficult to capture the abnormal rhythm on an ECG during an outpatient visit. If tachyarrhythmia is correctly identified in a timely manner, most children will lead a healthy live, but if prolonged or misdiagnosed episodes occur, they may develop congestive heart failure. The constant progress of biotechnology is profoundly changing the practice of medicine and the way healthcare decisions are made. The development of a smartphone application to record a high-quality single-lead ECG with the aid of a device such as AliveCor®, makes outpatient monitoring more accessible to these patients. At the same time, it is helpful for timely diagnosis and rapid management of tachyarrhythmia reducing overall morbidity and facilitating parental reassurance.

HYPOTHESIS AND OBJECTIVES: The hypothesis was that remote monitoring by AliveCor® Kardia Mobile single-lead ECG device was a useful tool for outpatient monitoring of paediatric patients under 3 years old at the time of diagnosis of tachyarrhythmia. The aim of this project was to analyse demographic data and clinical characteristics of the patients and describe the electrocardiographic features of single-lead ECG recordings obtained with AliveCor® device. Also, to assess and describe the parental perception of the usefulness of AliveCor® monitoring.

METHODS: A descriptive, cross-sectional, observational and retrospective study was designed with a total sample of 30 anonymized patients with prenatal or postnatal diagnosis of tachyarrhythmia and outpatient monitoring with AliveCor® managed in HSJD. Patient demographics and clinical data were observed to assess the applicability of AliveCor® in paediatric patients with great variability. The tracings obtained with AliveCor® have been thoroughly read and analysed. The parental perception was determined by means of a survey.

RESULTS: A total of 190 tracings obtained with AliveCor® were analysed. 5% of the tracings were considered as non-legible and 13,7%-17,4% had artifacts. 19 tracings with tachyarrhythmia were detected during the follow-up, (6 wide QRS, 13 narrow QRS). During AliveCor® monitoring, 7 patients (23,3%) had to attend the emergency department to manage the tachyarrhythmia detected. In none of these cases the patient became haemodynamically decompensated. Changes in chronic management were made in 50% of patients during the follow-up, of which 40% increased and 60%, reduced treatment. 29 parent surveys were completed. 72,4% of the survey responses indicated that it was easy to obtain tracings and the 100% to transmit them. By having the device, 89,7% reduced the need to visit the emergency department, 89,6% showed added comfort in managing arrhythmia, 86,2% reported reinforcement in medical surveillance and 93,1% in the accessibility to the specialist.

CONCLUSIONS: Our results conclude that AliveCor® monitoring is a useful tool for outpatient monitoring of paediatric patients under 3 years old at the time of tachyarrhythmia diagnosis. AliveCor® recorded the heart rate and rhythm of paediatric patients quickly and reliably. Parents felt that the device provided greater reassurance, promoted rapid and effective assessment by the specialist and enabled early therapeutic decisions, often saving visits to the emergency department.

KEYWORDS: supraventricular tachycardia, tachyarrhythmia, outpatient monitoring, AliveCor®, emergency department visits, parental perception

3. INTRODUCTION

1. PREAMBLE

Neonatal supraventricular tachycardia (SVT) is the most common type of arrhythmia in paediatrics population. Arrhythmias are heart rhythms disturbances, which can prevent the heart pumping efficiently. They can manifest as tachycardia (rapid rhythm) or bradycardia (slow rhythm). SVT causes episodes where the heart beats abnormally fast and it is defined as a sustained tachyarrhythmia originating above the bundle of His. Infants with SVT may be asymptomatic, and they may grow out of the condition. But, rarely, if prolonged episodes occur, infants may develop severe heart failure (1).

Although some mechanisms of SVT are associated with congenital heart disease, most children with SVT have structurally normal hearts. SVT is rarely associated with congenital heart disease and has been reported in the range of 1%–5% of cases (2).

Even though it is rare in the toddlers or adolescents, prolonged and/or untreated SVT episodes can lead to cardiomyopathy with or without congestive heart failure (CHF). It is well known that infants are more likely to present in CHF than older patients and perhaps are at greater risk of an adverse outcome. Mortality resulting from SVT is relatively low, estimated as 4% in patients with associated structural congenital heart disease, and 1% in those without cardiac abnormalities (3).

1.1 SUPRAVENTRICULAR TACHYCARDIA

The most commonly presenting pathological tachycardia in paediatric population is SVT, a narrow QRS complex tachycardia. SVT is characterized by an abrupt onset and termination. AV re-entry tachycardia (AVRT) and AV nodal re-entry tachycardia (AVNRT) are the two most common forms of tachyarrhythmias in children, and both are due to re-entry circuits, either intranodal (AVNRT) or through an accessory pathway (AVRT) (4).

Under normal conditions the atria and the ventricles are only connected through the AV node. The accessory pathways are abnormal bundles of muscle anatomically separated from the normal cardiac conduction system, capable of conduction between the atria and ventricles at a point other than the AV node. These pathways may be overt or concealed. Overt pathways can be demonstrated on 12-lead ECGs for example showing a pre-excitation in front the QRS complex forming a delta wave; whereas concealed pathways cannot be identified on the ECG during sinus rhythm (5).

In AVRT, the most common arrhythmia seen in paediatrics, there is an accessory pathway, bridging between the ventricle and the atrium to form the retrograde limb of the circuit in tachycardia. AVNRT is the second most common arrhythmia in children, with an increasing incidence with age into adolescence, it occurs when the re-entry circuit involves two pathways within tissue associated with the AV node itself. In fact, AVRT and AVNRT are a 'whole heart' tachycardias and not just above the ventricles. The only tachycardias that are truly supraventricular are atrial tachycardias, such as atrial flutter, which do not depend on either the specific conduction tissue or the ventricles for them to be sustained (4).

Although the quintessential tachyarrhythmia in infants is the supraventricular one, and the most frequent SVT mechanism is due to a re-entry circuits, other tachycardias will be discussed, despite being less frequent.

1.1.1 ATRIAL TACHYCARDIAS

Atrial tachycardias often occur in neonates, and they have certain features in common. They are caused by an abnormal electrical impulse that originates from an automatic focus in the atria but outside the sinus node. Atrial ectopic tachycardia (AET), an automatic tachycardia, is rare overall but is one of the most common mechanisms of paediatric incessant SVTs and can result in a dilated cardiomyopathy if it remains undetected. The exact mechanism of AET is unknown, but it appears to be due to abnormal automaticity, perhaps caused by remnant embryonic cells with automatic qualities (6). Another type of atrial tachycardia is atrial flutter, a re-entrant tachycardia that is confined to the atria. Atrial tachycardias can be often associated with variable AV block (1).

1.1.2 AVRT

Accessory pathway-mediated re-entry tachycardia is the cause of approximately 75% of cases of paediatric SVT (1). The presence of accessory pathways facilitates the appearance of tachycardias by re-entry. The re-entry circuit starts in the atrium, travels down either the AV node or the accessory pathway, most of the ventricle and then up back to the atrium through the other, forming a re-entrant circuit. So, there are two ways to produce AVRT (4):

- Orthodromic atrioventricular re-entry tachycardia: is the most common mechanism of SVT in infants. A re-entry short circuit is established, with anterograde conduction by the AV node and retrograde by the accessory pathway, hence producing a narrow QRS complex.

- Antidromic atrioventricular re-entry tachycardia: in this case, the circuit has the opposite direction, so during tachycardia, the stimulus of the atrium passes to the ventricle through the accessory pathway and returns to it through the specific system of conduction. This causes tachycardia with a wide QRS complex.

Wolff-Parkinson-White (WPW) syndrome is a very common type of AVRT, where the accessory pathway is overt (observed in sinus rhythm on the ECG). Pre-excitation is the manifestation on the ECG of the accessory pathway in sinus rhythm, in form of a delta wave in front of the QRS. In WPW syndrome the accessory pathway is known as the Kent bundle. The term WPW Syndrome applies to patients who have pre-excitation identifiable on the ECG and also have episodes of paroxysmal supraventricular tachycardia (usually orthodromic conduction). During that SVT, a conduction loop is formed between the Kent bundle and the AV node. However, there are patients with asymptomatic pre-excitation, who never have tachycardias, and then we only talk about pre-excitation, not WPW syndrome (7). In a small percentage of patients (15-30% (5)) with WPW syndrome, rapid conduction of atrial fibrillation over the accessory pathway to the ventricles may occur and can result in ventricular fibrillation which can lead to syncope and sudden death if the arrhythmia does not spontaneously terminate.

Although the incidence is low, the early diagnosis of pre-excitation in the ECG is essential because of the high risk that involve, and it can be abolished by the elimination of the accessory pathway with an ablation procedure.

AVRT also may be due to concealed accessory pathways that are orthodromic. Permanent junctional reciprocating tachycardia (PJRT) or also known as Coumel type tachycardia, is a specific type of concealed accessory pathway AVRT. It is associated to an accessory pathway most commonly (but not always) located in the postero-septal region of the heart. Coumel type tachycardia is an uncommon but important mechanism of incessant tachycardia that can easily lead to heart failure (8). Unlike other mechanisms, the accessory pathway in Coumel type has slow conduction properties. The slow electrical conduction and the incessant properties of Coumel type tachycardia can result in a dilated cardiomyopathy in patients who remain undiagnosed (8).

1.1.3 AVNRT

Atrioventricular nodal re-entry tachycardia is the second most common mechanism of SVT in children, representing about 15% of cases of paediatric SVT (1). They are much more common in adults and older children. It is due to the existence of two conduction pathways within the AV node, one slow and one fast in general. In sinus rhythm, only the fast pathways conduct electricity anterogradely, but after certain mechanisms like an extrasystole or a prolonged pause, a circuit is produced with both pathways, being able later to return in opposite sense by the other, and so an unconventional conduction loop is organized that perpetuates the tachycardia. During tachycardias, most of the time, the slow pathway leads anterogradely (from atria to ventricles) and the fast way leads retrogradely (from ventricles to atria), so during the tachycardia the circuit usually passes down the slow pathway and up the fast, producing a narrow QRS complex tachycardia (7).

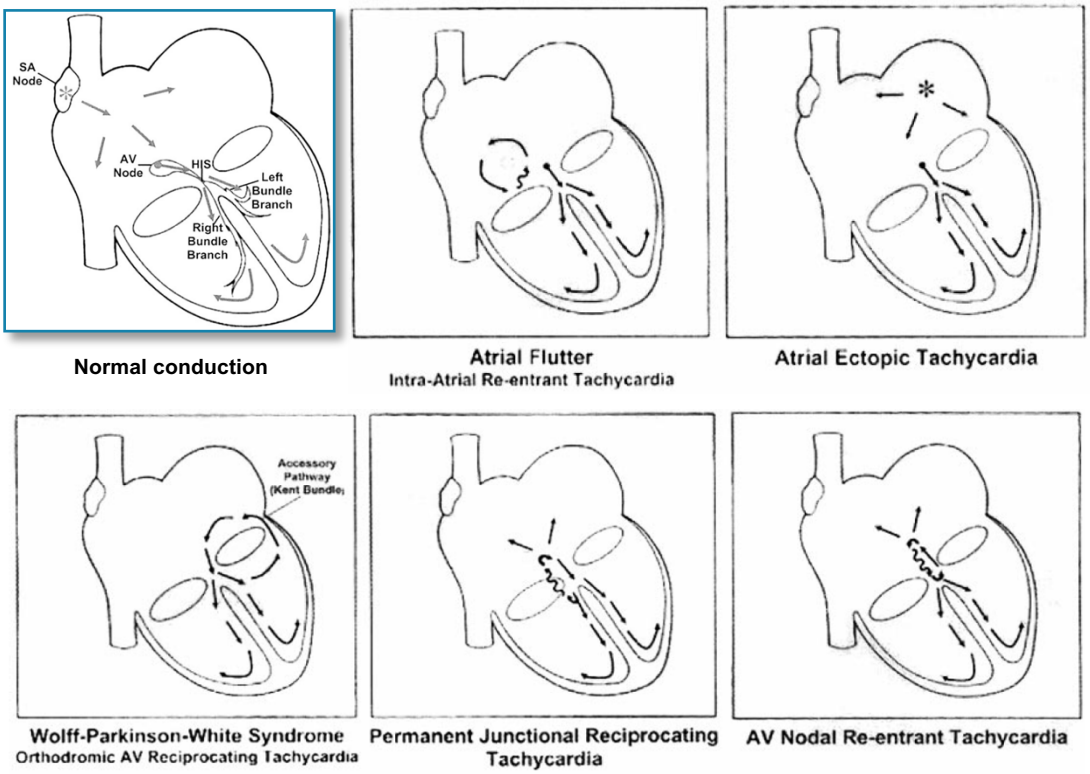


FIGURE 1 : Drawing representation of normal conduction system and common mechanisms of SVT (1).

Key: ✻ = Ectopic focus ⟶ = fast conduction ⇝ = slow conduction

1.2 VENTRICULAR TACHYCARDIA

Ventricular tachycardia (VT) is extraordinarily rare in the neonate, but potentially very lethal. The incidence of VT in paediatric population accounts for about 6% of patients (1). Rapid polymorphic VT or ventricular fibrillation may occur in patients with cardiac channelopathies, such as long QT and Brugada syndromes, and usually present with cardiac arrest and not a sustained tachycardia. However, a sustained and conscious VT can occur in the setting of birth asphyxia, severe electrolyte or metabolic abnormalities, hypothermia, drug toxicity or with a rare ventricular cardiac tumour such as a hamartoma or rhabdomyoma (1). Surgery for congenital heart disease, particularly procedures that involve a ventriculostomy such as Tetralogy of Fallot repair, have been associated with an increased risk of early and late post-surgery VT (9). Mechanisms for VT seems to include re-entry, abnormal automaticity and triggered activity.

1.3 PRENATAL TACHYARRHYTHMIA

Tachyarrhythmias can turn up in foetal period so that's why careful stratification of foetal heart rate (FHR) by gestation is important in all pregnancies. Some can be silent arrhythmias and cannot be detected using ultrasound, but most of them can be suspected due to persistent foetal heart rates (FHR) above 180-200 bpm (10).

The most common foetal tachyarrhythmia is re-entrant SVT with an accessory pathway which accounts for almost two-thirds of foetal tachyarrhythmia. It mainly develops between 24 and 32 weeks of gestation (10). Tachyarrhythmia is generally characterized by sustained FHR above 200 bpm. High FHR may also appear in many other situations as maternal use of stimulants, amnionitis, maternal thyrotoxicosis or other systemic foetal disease that have to be discarded. The diagnosis is made in the majority of cases by M-mode and pulsed Doppler foetal echocardiography (10).

Although foetal arrhythmias represent a small percentage (0.6–2.0% of all pregnancies) certain of these arrhythmias are associated with a high morbidity and mortality. The hemodynamic effects of foetal tachyarrhythmia include low cardiac output, cavities dilation, increased central venous pressure resulting in foetal hydrops (it may occur in 30-40% (11)) and progressive fetoplacental circulatory failure. Undetected foetal arrhythmias may also contribute to a high rate of foetal demise (3–10%), and prematurity. Majority of these arrhythmias will be resolved after birth, but some of them, can remain in postnatal period.

In a retrospective multicentre cohort study of 103 subjects by Hinkle et al. diagnosed with foetal SVT refractory SVT was found in 37% with this group being more likely to be delivered prematurely. Refractory SVT or hydrops did not increase the risk of postnatal SVT. Postnatal SVT was seen in 61% of the cases. A strong correlation was found between postnatal SVT and later gestational age at foetal SVT diagnosis (12).

Choice of antiarrhythmic therapy is influenced by several factors. At present, there is no consensus on first-line treatment of SVT. Even though a wide variety of protocols for the treatment of foetal tachycardias has been proposed, there is a multicentre international trial which is being followed in many important institutions. Flecainide is the preferred fist line drug for the treatment of foetal SVT.

For many years digoxin has been used, but Flecainide has shown shorten time to conversion into sinus rhythm and better rhythm control in foetus with hydrops (13), (14), (15). In case of refractoriness, the combination of Digoxin with Flecainide has shown to be superior to Sotalol in converting SVT to sinus rhythm (13).

2. SVT EPIDEMIOLOGY

SVT is the most common symptomatic tachycardia in children. The incidence was estimated at 1 in every 250 to 1000 paediatric patients (5,16).

Previous studies investigating the age of SVT onset have revealed that the incidence rates are highest during early babyhood, approximately 50% of patients will present their first episode of SVT in the first year of life (3), and decrease after infancy, followed by a gradual increase after the school ages, mostly in childhood (6-9 years), until young adulthood. Patients who develop SVT during infancy have a favourable prognosis characterized by early disappearance and late recurrence after adolescence. In infants there is spontaneous resolution in upwards of 75% by 1 year of age with SVT recurrence in up to one-third at mean age of 8 years (3).

A population-based study in infants from northern England with a resident population of 3.1 million and an annual live birth rate of 33.000 estimated the incidence of clinically significant sustained arrhythmias to occur in 24 per 100.000 live births (1:4.000), of which two-thirds was AVRT with an incidence of 16.3 per 100.000 (WPW syndrome 21%). Data on the cumulative incidence of SVT after infancy are scarce and limited to WPW syndrome, the incidence rate of which ranges from 0.08 to 0.39/1000 in children aged <15 years (5,16).

A research group expanded a population-based study from a national birth cohort database in Taiwan of 2000-2008 from the period 2000 to 2014. From 1.967.911 live births, 2.021 SVT were identified, accounting for an overall incidence of 1.03/1000 (16.2% WPW syndrome). The cumulative incidence was 0.06/1000, 0.25/1000, 0.45/1000, 0.88/1000, and 1.39/1000 for the ages of 1 month, 1 year, 5 years, 10 years, and 15 years, respectively. Major congenital heart disease (5.3%, HR=6.66, 95%CI 2.98-14.87) and cardiomyopathy (0.9%, HR=8.78, 95%CI 3.39-22.78) were associated with mortality. In patients without major congenital heart

disease, the cumulative incidence of SVT was 0.05/1000, 0.22/1000, 0.41/1000, 0.84/1000 and 1.33/1000, for the ages of 1 month, 1 year, 5 years, 10 years, and 15 years, respectively. By age 15 years, the annual risk of death and sudden death were 0.13% and 0.01% per patient-year (5,16).

Ferdman et al. published that the overall incidence of AVRT in paediatric patients with SVT has reported to be 72-80%; but when infants are excluded, the incidence decreases to 56-68%, with the incidence of AVNRT at 20-34% (40).

3. SVT CLINICAL PRESENTATION

The presentation of SVT is related to the age of the patient and the rate, duration, and mechanism of the tachyarrhythmia. The presence of underlying heart disease also may be a factor (8).

SVT is usually paroxysmal and is characterized by an abrupt and unpredictable onset and termination of palpitations, which makes it unlikely that an episode occurs during a visit at the outpatient clinic. That is why many times, SVT can be detected upon evaluation for symptoms or incidentally by paediatricians during routine visits. There are poor data specific to the presentation of SVT in children aged 1 to 6. This could be related, in part, to the natural history of remission in this age group (7,17).

3.1 NEONATES AND INFANTS

The heart rate in neonates with SVT usually ranges from 220 to 280 bpm. In children older than one year generally is slower, ranging from 180 to 240 bpm. The main signs and symptoms that encompass SVT in neonates and infants include diaphoresis, vomiting, poor feeding, increased sleeping/not being as alert as usual and irritability. Infants typically present also with inconsolable bouts of crying and/or tachypnoea. The symptoms of neonatal SVT occur in episodes, which can last for a few seconds to a number of hours (7,17).

These indicators of SVT in neonates and infants are nonspecific and often difficult to recognize, and besides, they can be easily confusing to symptoms of other common childhood disease. Tachycardia may not become evident until infants have

experienced prolonged periods of SVT due to speech limitations. Those infants can end up developing a hemodynamic decompensation as a result from decreased ventricular diastolic filling time, stroke volume, coronary artery perfusion and cardiac output. Congestive heart failure (CHF) can occur if left untreated, after 24-48 hours, and sooner in the presence of concomitant congenital heart disease. Prolonged heart rates above 280 bpm are also associated with the onset of CHF. We should suspect that CHF is occurring when the infant is experiencing pallor, cough, respiratory distress and cyanosis. These signs are directly related to the duration of SVT. Once CHF develops, the infant's condition may deteriorate rapidly (7,17).

3.2 TODDLERS

The presentation of SVT in toddlers is significantly different than in neonates and infants. The difference may reside in the increased ability to report symptoms at that age. The likelihood of CHF complication is near non-existent in rapid tachycardias. Symptoms include palpitations, chest pain, dizziness, or shortness of breath. Incessant forms of slow SVT may present as a gradual decrease in exercise tolerance, and easy fatigability. And also present as congestive heart failure due to left ventricle dilation (7,17).

3.3 ADOLESCENTS

The majority of adolescents are capable of providing very accurate descriptions of their symptoms. Adolescents may experience the same symptoms as toddlers, such as palpitations, chest pain, dizziness, and shortness of breath. They also may exhibit pallor, presyncope, diaphoresis, and clammy skin, which are the same signs of SVT in adults (7,17).

Because the incidence of AVNRT increases in this population, it is perhaps helpful to note that a feeling of palpitations in the neck region is associated with this mechanism of SVT. Heart rates tend to be the same or slightly slower than those in toddlers experiencing SVT, with a range that can drop as low as 150 bpm. Syncope is a rare but potential symptom of SVT and may represent a life-threatening arrhythmia in patients with pre-excitation or underlying congenital heart disease (7,17).

4. DIAGNOSTIC - IDENTIFICATION OF TACHYCARDIAS

Before tagging a patient of SVT, many conditions should be considered in the differential diagnosis, especially in adolescents rather than infants. These conditions include concomitant congenital heart disease, stress, anxiety, panic disorders, hyperthyroidism, electrolyte abnormalities, febrile illness, dehydration, drugs, caffeine consumption and myocarditis (18). The diagnosis of tachycardias is based on thorough clinical history and electrocardiograms.

4.1 ELECTROCARDIOGRAPHY (ECG) FEATURES

A 12-lead ECG should be performed on any patient who presents symptoms or complaints of symptoms similar to previous episodes consistent with SVT. An easy sequence to interpretate the ECG, is: QRS complex rate, regularity and width followed by the relation of the P wave to the QRS complex, and the P wave morphology (4).

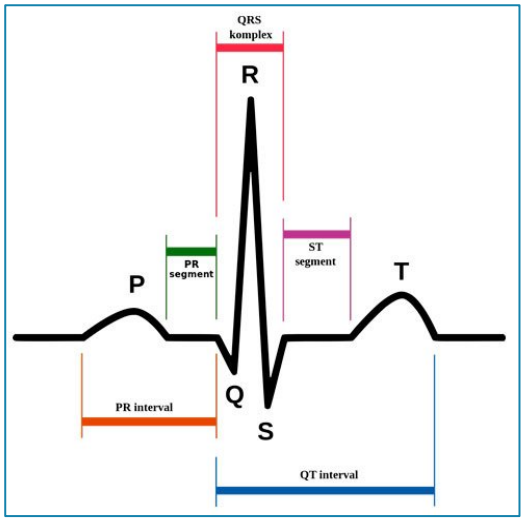


FIGURE 2: Representation of a normal ECG with waves and interval named and pointed

According to Kantoch (2005), Hanash and Crosson (2010) and Uzun (2010), significant ECG findings for SVT are: Heart rate of more than 220 beats per minute in infants and 180 per minute in older children. Narrow QRS complex. Atrioventricular ratio of 1:1. Difficult-to-see or retrograde P waves (19).

4.1.1 AET

As the atrium is depolarised in an abnormal manner, the P wave has a different shape and/or axis from sinus rhythm, easily distinguishable. With all forms, the relation of the P wave to the QRS complex may be variable, depending on AV nodal conduction, and the ventricular rate can be somewhat irregular if there is variable AV block (4).

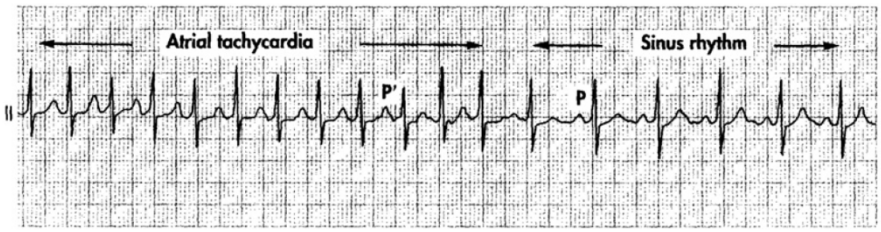


FIGURE 3: Electrocardiogram features of SVT caused by atrial tachycardia and spontaneous conversion to normal sinus rhythm. Note the P wave shape (P') that differs from normal sinus P waves. (Adapted with permission from Goldberger, 2006.) (7)

4.1.2 AVRT

Pre-excitation or WPW syndrome: Typically, on the baseline ECG in normal sinus rhythm we will see short PR interval because ventricular excitation is earlier than under normal conditions, as the accessory pathway conducts the stimulus faster than through the AV node and the beam of His. Pre-excitation of the ventricle through the accessory pathway (Kent bundle) appears as a delta wave, seen as an initial filling of the QRS, the magnitude of which is determined by the amount of ventricular mass that is depolarized by the accessory pathway (7).

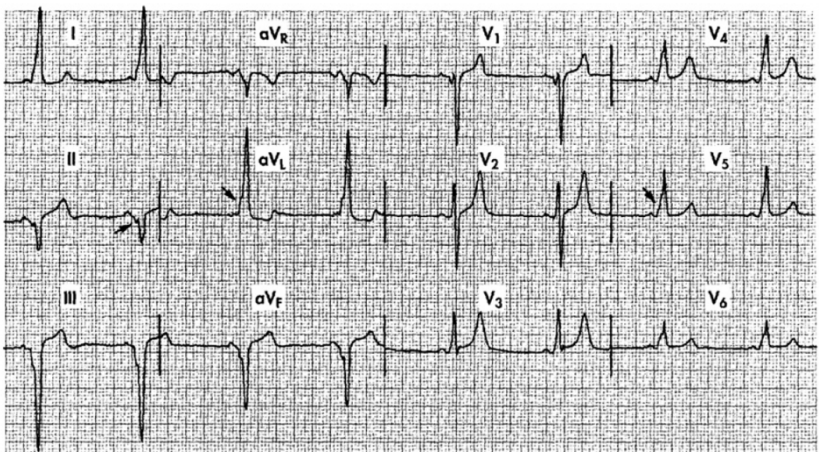


FIGURE 4: Electrocardiogram features of Wolf-Parkinson-White (WPW) syndrome. The triad of a short PR interval (0.08 seconds), wide QRS complex (0.12 seconds) and delta wave (indicated by arrows) are visible. (Adapted with permission from Goldberg, 2006). (7)

The ECG in SVT for patients with a **concealed accessory pathway** is similar to that of orthodromic SVT in a WPW syndrome patient: there is a narrow QRS tachycardia with difficult to discern P waves and the RP interval is shorter than de PR interval (7).

PJRT or Coumel type tachycardia do not have evidence of pre-excitation on the baseline ECG in normal sinus rhythm. It is visualized as a tachycardia of narrow QRS complexes, with a long RP interval (RP>PR), and with deeply negative P waves in the lower wall leads (DII, DIII and aVF), indicating the posterior septal location of this concealed accessory pathway which is the most common location of it (5).

4.1.3 AVNRT

The baseline ECG during normal sinus rhythm is not always useful in identifying patients with AVNRT because it is normal. During tachycardia, it manifests as regular narrow QRS tachycardia on the ECG. Atrial and ventricular depolarizations occur simultaneously, therefore, retrograde P wave is concealed in the QRS complex, hence, it is normally difficult to identify. Sometimes, P wave can appear just at the end of the QRS in of r' in V1 (7).

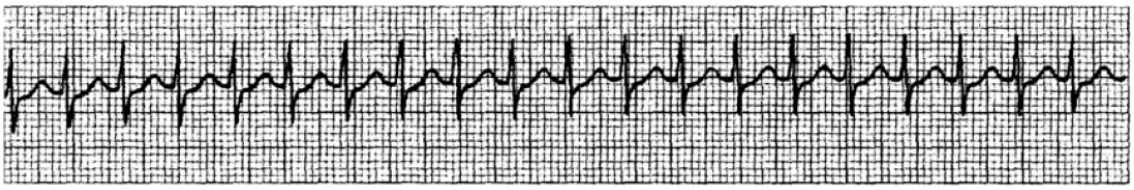


FIGURE 5: Electrocardiogram features of SVT caused by atrioventricular nodal re-entry tachycardia. Note that the P waves are buried in the QRS complex. (Adapted with permission from Goldberg, 2006). (7)

4.1.4 VT

One of the most difficult challenge that exist in electrocardiography is the identification of the mechanism of wide QRS complex tachycardias. Even though in haemodynamically unstable patients this fact should not dilate the implementation of appropriate treatment, in stable patients, accurate diagnostic should be searched.

There are some algorithms that have proven reliability to differentiate ventricular tachycardia versus SVT with aberrancy. The most widely used in the one described by Brugada and cols, where several criteria should be applied to reach the final correct diagnostic when facing a broad QRS complex tachycardia (20) (21).

4.2 HOLTER MONITOR

SVT and VT generally presents as an acute episode, with sudden onset and termination, which may be difficult to record with ECG. When we don't obtain the diagnose through ECG, a Holter monitor should be considered. A Holter monitor is a portable device that records a continuous ECG tracing. It is attached to the patient with ECG wires and electrodes, and typically is worn by the patient for 24 to 48 hours to provide information about symptoms that are likely to occur during that period. A Holter monitor is not the best diagnostic or monitoring option for a patient who experiences infrequent episodes of palpitations. However, it is a useful tool for frequently occurring symptoms and for incessant tachycardias like Coumel type because they are present the majority of the day (7).

It would also have to be considered the possibility of an implantable loop recorders (ILR). ILR are miniaturised Holter monitors that are implanted subcutaneously in the thorax in order to have a prolonged monitoring of the heart rhythm.

4.3 ELECTROPHYSIOLOGY STUDY

Electrophysiology study (EPS) is the most definitive diagnostic procedure for the classification of different mechanisms of SVT. EPS is usually performed under local anaesthesia with mild sedation. An electro catheter is inserted through peripheral vessels, most often the femoral vein, until reaching into the heart. Intracardiac signals are amplified, recorded and analysed to map the electrophysiologic characteristics of the heart and determine the site and mechanism of the arrhythmia (22).

5. SVT TREATMENT

5.1 NON-PHARMACOLOGICAL TREATMENT

Non-pharmacological therapies are immediate, so they are episodic and designed for symptom relief, rather than addressing the actual substrate of SVT. Non-pharmacological treatments include vagal manoeuvres or electrical cardioversion.

Vagal manoeuvres may be successful in terminating the tachyarrhythmia during episodes of SVT by increasing the parasympathetic tone, which can block the AV node. In infants and younger children who cannot be taught specific techniques, the vagal-dive reflex manoeuvre consisting of an ice-cold wet cloth or a bag of ice water placed on the patient's face may be attempted because is often effective (7,19,23).

The most effective technique in older children and adolescents is the Valsalva manoeuvre, which involves bearing down/squatting as if having a bowel movement. Other techniques include the Muller's manoeuvre which is deep inspiration against a closed glottis in which the nose is pinched, and inspiration is attempted with the mouth closed after a forced expiration. We can also end up with SVT stimulating the gag reflex, forceful coughing, pulling of the tongue, doing handstand for 30 seconds or breath holding (24). Historically, carotid sinus massage was performed as an alternative technique of stimulating vagal activity. However, it has been proven ineffective in several studies, is less effective than other vagal manoeuvres overall, and is unsafe if not performed properly by a trained and highly skilled care provider (25). Manoeuvres that enhance vagal activity are effective at terminating episodes of SVT as much as 53% of the time (25).

Electrical cardioversion should be performed when the patient is hemodynamically unstable, such as loss of consciousness, shock or CHF, arise as a result of prolonged and/or especially high rates of SVT (26). We can also use electrical cardioversion when the tachycardia is not responsive to vagal or initial pharmacological agents. Cardioversion is synchronized to avoid delivering the shock during ventricular repolarization when there is a risk of inducing ventricular fibrillation (27).

5.2 PHARMACOLOGICAL TREATMENT

5.2.1 ACUTE DRUG THERAPY

Intravenous adenosine is the first-line pharmacologic measure for termination of SVT in hemodynamically stable infants and children in the emergency setting (28). Adenosine works in AVRT by transiently blocking the AV node limb of the circuit, thus allowing for resumption of the normal cardiac cycle (23).

The second most frequently used drug for acute therapy in SVT patients with heart disfunction is Esmolol. Esmolol is a fast-acting beta blocker and is administered as a continuous intravenous infusion. It allows a slowed conduction and an increase in the AV node refractory period (29).

Flecainide also belongs to acute therapy drugs, it works by blocking sodium channel influx, which increases the effective refractory period of the sinus node, atrial myocytes, and AV node (30).

5.2.2 CHRONIC DRUG THERAPY

Chronic management of SVT should be individualized. In general, the decision to treat a child with SVT depends on the child's age, symptoms and the effect of SVT on the quality of life. The dose of every medication should be increased over time in order to keep up with the child's weight gain (7,19,23).

Chronic drug therapy varies thoroughly, and medication preferences have changed over time. Flecainide and β-blockers, particularly propranolol, are generally considered a first-line treatment for the secondary prevention of SVT in infants. Digoxin was considered the first-line treatment but over time, the use of β-blockers exceeded the Digoxin use. It should be noted that Digoxin and β-blockers are contraindicated in patients with pre-excitation because them enhance conduction properties of the accessory pathway and predispose the patient to rapid conduction of atrial fibrillation and sudden death (27).

Flecainide acetate is a relatively new benzamide-derived drug that has been shown to be more effective than most other drugs in treating SVT and VT in adult patients; every time is being more and successfully used in paediatric patients (32).

The Study of Antiarrhythmic Medications in Infancy (SAMIS), a multicenter study of infants with SVT, excluding WPW, comparing Digoxin with Propranolol, showed no significant difference in SVT recurrence (5).

In the largest series of patients with Coumel type tachycardia by Kang et al., β-blockers were the most common choice (7).

The second line of pharmacologic therapy usually consists of Amiodarone or Sotalol. In a study by Guerrier et al. of SVT hospitalizations from 2003 to 2013 including a total of 851 patients, monotherapy was employed in 534 (86%) patients. 84% of the patients utilized Propranolol, Digoxin, and Amiodarone. The patients who underwent multi-agent therapy, 21% used a combination of Propranolol and Digoxin, followed by 12% with Flecainide and Digoxin (31).

Pharmacologic therapy achieves successful control in approximately 68% of children (9).

5.3 EPS AND ABLATION

In children with refractory SVT, the treatment of choice is catheter ablation. Electrophysiology study (EPS) generally is performed under the assumption that ablation will immediately follow if appropriate. To proceed with the ablation, it means that the mechanism of SVT is isolated, its location and electrophysiologic properties are deemed acceptable for ablation, and the patient is physiologically capable of undergoing the procedure (33). The understanding of ablation and experience level of providers has increased, so ablation is often the first line of therapy for many children with SVT. It has scant morbidity and mortality, and it results are successful in most cases, having a low rate of recurrence of SVT (7,19,23).

Radiofrequency current (RF) ablation is the traditional method, and it uses radiofrequency energy to heat and obliterate the site of origin of the SVT mechanism by making a small scar with the catheter directly to the arrhythmic substrate. The initial success rate of RF ablation exceeds 90%. Infrequently, PSVT may recur if ablation lesions did not damage but only temporarily injured the arrhythmic focus (33).

Cryoablation, a newer technique applied in some indications, depending on the operator preferences. Liquid nitrous oxide is used to cool the catheter to sub-freezing temperatures. This catheter is targeted at the arrhythmic focus and destroys the tissue by freezing producing a small permanent scar. The main advantage of cryoablation is that it allows reversible cooling so that the electrophysiologist can test the area first for accuracy of location and risk of leading to heart block before freezing the tissue to an even cooler level, at which point a permanent lesion will form (9).

Sophisticated three-dimensional mapping systems or cartography allow for successful ablation of complex arrhythmia following heart surgery (34). Su Xinxing et al. studied 4.622 patients who were ablated between 2000 to 2019, with an acute phase success overall rate of 96,4% and of 92,2% in long-term phase. Serious complications occurred in 0,6% of the patients. The recurrence rate of SVT in children with structurally normal hearts having undergone ablation 10 or more years earlier to be 38% (34).

Van Hare et al. in 1994 reported that permanent second-degree or third-degree heart block occurred in approximately 1% to 3% of paediatric patients undergoing ablation. Nowadays, radiofrequency ablation is effective and safe in treating arrhythmias in paediatric patients and has significantly reduced the risk of complications over the years (7).

6. SVT MONITORING

Mobile devices and applications entwine in our daily activities, and recently, thanks to the constant progress of technology, they can also acquire information about our health. The potential of such devices allows the possibility of monitoring and establish health parameters such as heart rate, blood oxygenation, skin temperature, body position, blood pressure, electrocardiogram, respiratory rate, pressure and flow in the airways, through some apps that are already in the market. A proliferation of health or medical apps acquire and analyse that variety of vital signs through embedded sensors, interconnected devices or peripherals (35).

The measurement of vital signs on smartphone platforms and overall, health apps offering health information, have changed the way health care is accessed, monitored and delivered. Currently, with nearly 100.000 mobile health apps in 62 app stores and an increasing number of medical sensors and peripherals, a future of mobile health is unavoidable (36).

6.1 ACQUISITION OF CARDIOVASCULAR SIGNALS ON SMARTPHONES

Several smartphone apps for non-clinical use, such as fitness or lifelogging, are available to measure the heart or pulse rate. Wackel et al. studied 26 paediatric patients undergoing an electrophysiology study, with heart rates measured at baseline and during supraventricular tachycardia using two apps (*Instant Heart Rate* and *Heart Beat Rate*). Both apps function by placing the patients' finger over the video camera while being illuminated by the flash and then recording colour changes in the skin produced by blood flow via photoplethysmography to generate a measurement of heart rate. At baseline, the heart rate was correctly estimated within a 4 ± bpm range. However, during SVT (>200 bpm) the estimation decreased significantly, concluding that the tested apps should not be considered a reliable tool for assessing the heart rate of children during tachycardia, given that paediatric SVT often occurs at rates greater than 200 bpm (37).

6.1.1 ECG MONITORING

The use of smartphones as ECG monitors, with a special smartphone case or smartphone-connected electrodes allows patients to acquire, display and transmit their ECG to medical professionals (35). This technology can be adopted by patients with arrhythmia, palpitations, and recurrent syncope or under specific pharmacological treatment for either diagnostic or monitoring purposes. Most mobile ECG monitors record only single-lead ECG and thus their use is limited mainly to measuring heart rate and rhythm. Their use for the diagnosis of other conditions such as myocardial ischemia or infarction is not recommended. For that conditions a 12-lead ECG should be employed. There are many apps with ECG recording ability like *ECG Check monitor, eMotion* and AliveCor® (35).

The development of smartphone applications to record a high-quality single-lead ECG give the possibility of rapid cardiac monitoring accessible to our patients from virtually anywhere to confirm an arrhythmia for example atrial fibrillation (AF) and take immediate therapeutic actions. Furthermore, there is evidence that cardiac remote monitoring with automatic clinician alerts reduces the time to a clinical decision in response to clinical events (38). This technology has been validated in adults with atrial fibrillation and for its screening (37). Also, the apps to measure heart rates, has been demonstrated the accuracy to detect atrial fibrillation in adults.

AliveCor® (AliveCor Inc., San Francisco, California, USA) created a monitor smartphone case that consists of two metal electrodes on the back of the case that acquires short ECG rhythm strips from 30 seconds up to 10 min. Several validation studies showed that the AliveCor® one-lead system has the same lead I QRS morphology as the standard 12-lead ECG, characterized by higher baseline noise (38).

FIGURE 6: Top panel shows the AliveCor® case on a smartphone with both metal electrodes. The bottom panel shows a rhythm strip recorded by a user (39).

Bruining et al. described that of 204 patients, including 48 with AF, AliveCor® detected AF with 98% sensitivity, 97% specificity and 97% accuracy in comparison with a standard 12-lead ECG (35). In other words, the AliveCor® monitor has been used to successfully differentiate sinus rhythm from atrial fibrillation utilizing the single-lead ECG in adults and it have received FDA approval in 2012 for use in adults with AF diagnosis. It also has been suggested for use in suspected cases of ST elevation myocardial infarction (40).

A new study in 2020 with AliveCor® device on 35 healthy volunteers, aims to validate the in-ear region as a new anatomical site for ECG signal detection (41). First, ECG was detected by standard modality using both hands and then using the left in-ear region instead of the right hand, with no different results observed in both different modalities. The conclusion is that the in-ear region is a reliable novel anatomical site for ECG signal detection in healthy subjects, but further studies are needed to validate that new modality also in case of cardiac arrhythmias (41).

It's also important to mention that nowadays, there are already 6-leads (I, II, III, aVR, aVL and aVF) electrocardiogram devices like Kardia Mobile 6L (42) created by AliveCor®, but the single-lead ECG still remains the most used.

Smart watches have also been studied recently for heart rate assessment and ECG recording of atrial (43) and ventricular (44) arrhythmias.

The conclusive idea in all of this is that smartphones, mobile applications, social media are profoundly changing medicine practice. Thus far for paediatric arrhythmias, only applications to detect heart rate have been evaluated, however, as we have explained, that apps have not been validated for use during SVT. Up to now, there is a paucity of data on the utility of this novel technology for arrhythmia detection and/or monitoring, especially in paediatric population (40).

Ferdman et al. demonstrated that a single-lead ECG obtained with a AliveCor® smartphone case monitor can be used to successfully record SVT in paediatric patients and can predict the SVT at least as well as previously published reports of Holter monitors, along with the added convenience of not requiring patients to carry a dedicated monitor (40). A prior study demonstrated that interpretation of standard event and Holter monitors accurately identifies the tachycardia mechanism in only 45% of recordings (20). They demonstrated the utility of AliveCor® to record SVT and to distinguish atrioventricular re-entrant tachycardia (AVRT), including tracings with visible retrograde P waves, from atrioventricular nodal re-entrant tachycardia (AVNRT), in thirty-seven paediatric patients undergoing an ablation (40).

In this study the AliveCor® device used, records a bipolar chest lead, which is different from the standard unipolar precordial leads on a standard ECG. Tracings were obtained by placing the monitor in three different positions on the chest (PI-horizontal, PII-rotated 60º clockwise, and PIII-rotated 120º clockwise). When they compared tracings obtained by AliveCor® with a standard 12-lead ECG in sinus rhythm, the most frequent similarity was PII to standard leads V3 or V4 in 59% of the tracings (40).

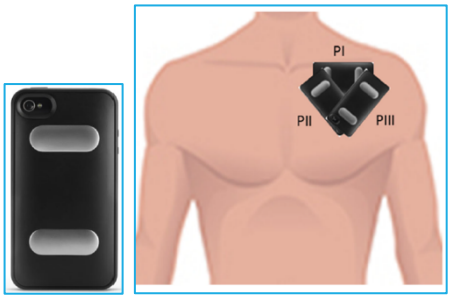


FIGURE 7: AliveCor® smartphone case and lead placement of the monitor

Gropler et al. also did a study with AliveCor® monitoring and in this occasion using Kardia Mobile device and not a smartphone case. They assessed the accuracy of interval measurements on AliveCor® Kardia Mobile tracings by directly comparing to standard 12-lead ECGs in paediatric patients. Measurements studied was heart rate, and intervals as RR, PR, QRS, QT and QTc in both ECG obtained through Kardia device and conventional 12-lead ECG. The results conclude that there is a strong correlation between both measurements obtained with both different ways. Perfect agreement (within 20 msec variance) was seen in 28/30 (93%) for heart rate measurements and 114/150 (76%) of total interval measurements: 21/30 PR, 27/30 QRS, 19/30 QT, and 21/30 QTc measurements (45).

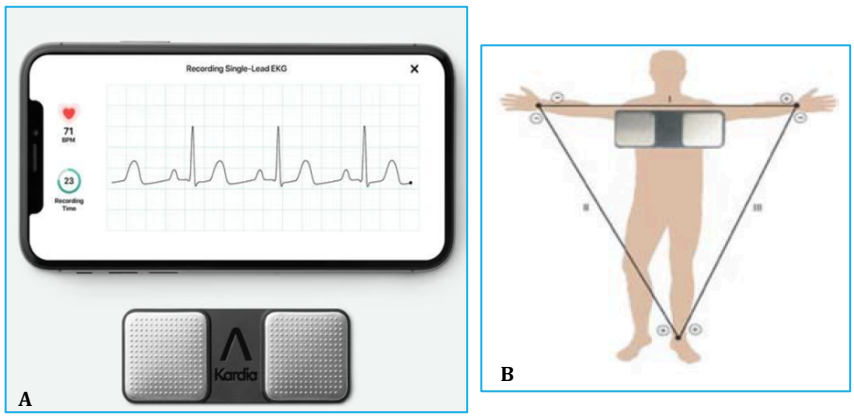


FIGURE 8: A: AliveCor® Kardia ECG device and a single-lead electrocardiogram tracing obtained by it. **B:** Direction of ECG vector using standard lead-I positioning (46).

Arrhythmias in children are often paroxysmal, complicating the ability to capture the abnormal rhythm on routine ECG during an outpatient visit (45). Knowing that, the conclusion is that the use of *Kardia (*AliveCor®*, Inc.)* smartphone application associated with the FDA-cleared Kardia Mobile, Kardia Mobile 6L, or Kardia Band personal ECG devices may be a useful tool for outpatient monitoring of paediatric patients with tachyarrhythmia. Ngunyen et al. used the Kardia Mobile on 35 children. They reported that user satisfaction was high, and of the 238 tracings, 96% were of diagnostic quality (47).

Therefore, AliveCor® Kardia Mobile is a handheld, smartphone based cardiac rhythm monitor that records a thirty-second single-lead electrocardiogram tracing (46), or six-lead tracing, depending on the device used. Recording initiates with placement of two fingers, of the left and the right hands on the respective two electrodes of the monitor. It can also be obtained by placing the monitor directly on the patient's chest, easier on paediatric patients, especially infants. Cardiac electrical activity from the electrodes is transmitted from the monitor to the smartphone wirelessly. The smartphone application converts the signal to a digital ECG-single-lead tracing in case of Kardia Mobile device is used, which can be viewed in real time while being recorded. The tracing is stored locally on the smartphone and also can be emailed directly from the smartphone application to the paediatric cardiologist for review. All recordings were obtained at a paper speed of 25mm/s with a gain of 10 mm/mV, which is the same as standard 12-lead ECG (40).

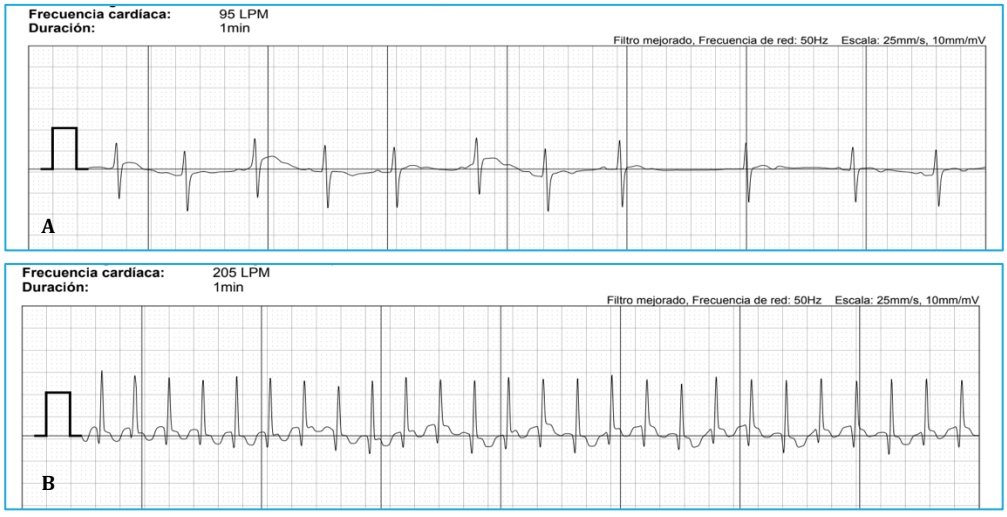


FIGURE 9: Real tracings from the same patient included in our study in different moments, obtained with AliveCor® Kardia Mobile device. **A**: sinus **B**: SVT.

4. JUSTIFICATION OF THE PROJECT

Cardiac arrhythmias are a common cause of morbidity in both the adult and paediatric populations. The Task Force on Children and Youth estimate that annually 30.000 children either develop a cardiac arrhythmia or are born with a conduction abnormality (48). Supraventricular tachycardia (SVT) is the most common heart rhythm disturbance in paediatric population.

As many as 1 in every 250 to 1000 children experience SVT. Approximately 50% of patients will present their first episode of SVT in the first year of life (3), and usually before 2 months of age (49). Therefore, it should be noted that whereas older children and young adults can generally express the symptoms of palpitations indicating tachyarrhythmia recurrence, infants are unable to do so. Besides that, presentation in infants is often ambiguous, and its symptoms could be mistakenly attributed to other common paediatric conditions. Despite this non-specific clinical presentation and apparently well prognosis, prolonged episodes can result in congestive cardiac failure and/or cardiovascular shock. Studies have reported mortality rates up to 4% in infants presenting SVT (49).

Apart from the difficult to recognize symptomatic infants with tachycardia, the problem also lies in the fact that most arrhythmias in children are often paroxysmal, complicating the ability to capture the abnormal rhythm on routine electrocardiogram during an outpatient visit. Current practice utilizes 24-hour ambulatory monitors or implantable loop recorders (ILR) to follow-up children with diagnosed or suspected cardiac arrhythmias. These devices only offer a finite period of use sometimes necessitating repeated uses to record transient arrhythmias. Others disadvantages of these methods include cost, invasiveness (surgical placement of ILR), and inability to provide real-time access to transmitted ECG tracings (45). Also, the interval time period between follow-up routine visits goes unmonitored. The recurrence detection of tachyarrhythmia depends exclusively on the parental ability to guess a fast rhythm or most times subtle non-specific clinical changes in their child appearance. All of these problems lead to potential delay in diagnosis and unattended life-threatening tachyarrhythmia events in the infant population.

This in turn, can cause anxiety and distress for patients but specially in parents. Thus, home event monitoring may facilitate timely diagnosis, reduce overall morbidity, and at the same time, parental concern (49).

Smartphone use has become pervasive in daily life. The development of a smartphone application to record a high-quality single-lead ECG makes portable event monitoring more accessible to our patients. This technology has been validated by the FDA in adults with normal ECG and those with atrial fibrillation but there is a paucity of data about its use in paediatric population with arrhythmia (40), especially in neonates and infants. The smartphone application used in paediatric patients managed in HSJD is *Kardia (*AliveCor®*, Inc.)* and it works with the FDA-cleared Kardia Mobile device. It can detect the most common arrhythmias in just 30 seconds and transmit the tracings directly to their paediatric cardiologist for review. AliveCor® may allow accurately and early diagnose of tachyarrhythmia recurrence in infants with nonspecific symptoms and/or in those who are unable to express them preventing develop of congestive heart failure or shock (47). At the same time, an early diagnosis allows rapid management of the tachyarrhythmia and possibly provides parental reassurance mainly by facilitating intensive outpatient monitoring. AliveCor® follow-up is an effective, simple and cost-efficient monitoring technology. It can be easily incorporated into users' daily life and seems accessible to paediatric population. These characteristics make it ideal for a high-quality individualized care with a decreased cost.

Considering the lack of information in this type of follow-up in paediatric patients with history of tachyarrhythmia, especially infants, a descriptive study on these patients can be extremely useful to improve knowledge about outpatient monitoring with AliveCor®.

5. HYPOTHESIS AND OBJECTIVES

5.1 HYPOTHESIS

Remote monitoring by AliveCor® Kardia Mobile single-lead ECG device is a useful tool for outpatient monitoring of paediatric patients under 3 years old at the time of diagnosis of tachyarrhythmia.

5.2 OBJECTIVES

- To describe demographic data and clinical characteristics of anonymized paediatric patients from Hospital Sant Joan de Déu with history of tachyarrhythmia and outpatient monitoring with AliveCor®.

- Use a descriptive analysis to:
    - Determine the electrocardiographic characteristics obtained with AliveCor® monitoring in paediatric patients with history of tachyarrhythmia and outpatient monitoring with AliveCor®.
    - Determine the percentage rate of not legible tracings registered by AliveCor® of paediatric patients with history of tachyarrhythmia.
    - Determine the number of tachyarrhythmia events during the follow-up detected by AliveCor® device of paediatric patients with history of tachyarrhythmia and outpatient monitoring with AliveCor®.

- To assess the parental perception of the usefulness of AliveCor® monitoring in terms of ease of use, reducing anxiety and the number of visits to emergency department, greater medical surveillance, and accessibility to the specialist.

6. SUBJECTS AND METHODS

6.1 STUDY DESIGN

This study begins with the need for describing and publishing the data collected in an anonymized registry of paediatric patients from HSJD with history of tachyarrhythmia and outpatient monitoring with AliveCor® between the period 2017 to 2021. To describe the collected data, a descriptive and observational cross-sectional and retrospective study has been designed.

6.2 STUDY POPULATION

The study population was based on paediatric patients under 3 years old at the time of tachyarrhythmia diagnosis followed-up in the Paediatric Arrhythmia Unit of Hospital Sant Joan de Déu, in Barcelona with AliveCor® outpatient monitoring.

6.2.1 INCLUSION CRITERIA

- Paediatric patients with prenatal diagnosis of tachyarrhythmia and outpatient monitoring with AliveCor®
- Paediatric patients with postnatal diagnosis of tachyarrhythmia under three years old and outpatient monitoring with AliveCor®
- Paediatric patients with AliveCor® monitoring with at least one tracing obtained during the follow-up period

6.2.2 EXCLUSION CRITERIA

- Paediatric patients without data in the medical history

6.3 SAMPLE

A non-probabilistic consecutive sampling method was performed for our study population resulting in a total of 30 patients managed at the Paediatric Arrhythmia Unit of Hospital Sant Joan de Déu in Barcelona (HSJD), who suited in the inclusion criteria and were included anonymously in our study. We have not estimated the sample size needed due to the limited number of patients, and therefore the entire population was the study sample.

However, we computed the statistical power corresponding to this sample size. In particular, in a two-sided test, with an alpha significance level of 5%, and assuming a moderate effect size, the statistical power was estimated as 59.13%. Computations were carried out with the Prof. Dr. Marc Saez' software based on the package 'pwr' of the free statistical environment R (version 4.0.3).

6.4 DATA ACQUISITION

All the documents, clinical and demographic information of the patients included in the study were obtained from the medical history of paediatric patients with history of tachyarrhythmia and with AliveCor® monitoring managed at the Arrhythmia Unit of HSJD in Barcelona, such as the ECGs from each patient recorded either conventionally or by AliveCor® device.

Clinical histories were carefully revised with HCIS program, the program tool that HSJD doctors use regularly. In order to access to the data, authorization of the Ethical Committee of Sant Joan de Déu Research Foundation (CEIC) was requested. Once authorization was approved, these data registry was created, analysed and exposed in this study in a completely anonymous way and numerically codified.

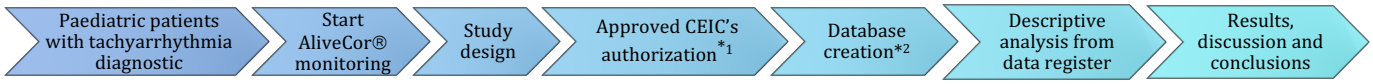


FIGURE 10: study's chronogram and steps followed from the study design and data acquisition process for the registry creation, to its conclusions. *1 This authorization has been included in Annex II *2 The database included the variables described in *section 6.6.*

Abbreviations: CEIC= Comitè Ètic d'Investigació Clínica of HSJD.

6.5 PROCEDURES AND FOLLOW-UP

6.5.1 DEMOGRAPHIC DATA AND CLINICAL CHARACTERISTICS DETERMINATION

To carry out this study, the method to acquire the data was done registering all the information needed for the study described in *section 6.6* obtained from HCIS program. The patient identifications were coded, and the information was organized in an Excel database. This information was from patients who were diagnosed of SVT or VT either in prenatal or neonatal moment and followed-up at the Paediatric Arrhythmia Unit of HSJD. The tachyarrhythmia diagnosis was done at prenatal period by M-mode and pulsed Doppler foetal echocardiography. The postnatal diagnosis was done with a 12-lead baseline ECG recorded at a paper speed of 25 mm/s and amplitude of 10 mm/mV, using a *GE CardioSoft CASE 6.7* ECG machine or by an ECG continue monitoring system during hospitalization, in which the tachyarrhythmia showed up.

Parents of patients who were diagnosed of tachyarrhythmia and who are candidates for remote AliveCor® monitoring were purposed to do that ambulatory monitoring follow-up. Only patients with tachyarrhythmia diagnosis at some point of their life, either supraventricular or ventricular, and with AliveCor® monitoring were included in our study. This encompass symptomatic or asymptomatic patients, those who have received ablation and those who have not, and patients that are currently with or without pharmacological management.

Not all tachyarrhythmia diagnosed in prenatal period remained in the patients once they were born, in fact some disappeared, but even so, remote monitoring was purposed to prevent a recurrence. Thus, our study has included patients with prenatal diagnosis of tachyarrhythmia solved or not in postnatal period.

The presence or absence of underlying structural cardiac abnormalities was also checked in all patients using a *Philips iU22* echocardiography, despite a structurally abnormal heart is not an exclusion criteria.

6.5.2 ALIVECOR® OUTPATIENT MONITORING

The follow-up period with these patients was considered from the start of monitoring with AliveCor®, a single-channel bipolar ECG recorder. Parents were instructed on how to use the AliveCor® Kardia Mobile device once they obtained it. Users downloaded the application *Kardia* on their smartphones and recorded a strip test with the cardiologist help. Parents were instructed to place the AliveCor® monitor on the child's chest and record an ECG trace. The recording by placement two fingers on the electrodes of the device could also be useful but surely less practical due to the age of the patients included in our study, nevertheless, some parents preferred it. It was verified that automatically, the smartphone application converted the signal to a digital ECG tracing, which can be viewed in real time and stored. Then they had to send the transmission to an email of the Paediatric Arrhythmia Unit, were paediatric cardiologist specialized in arrhythmias analysed the traces and answered the parents by email or phone.

Parents were also instructed about identifying clinical signs of tachyarrhythmia and to send an ECG tracing when they suspected that their child was having an event. If in any of these transmissions, symptomatic or not, SVT or VT was seen, families were asked to resubmit a new AliveCor® transmission to assess if the child was really experiencing tachyarrhythmia. If so, they were either sent to the emergency department to manage the episode or recommend by phone modifications in the antiarrhythmic treatment.

Some parents recorded a strip routinely almost every day, while others did it sporadically without an exact pattern, or even others sent almost none. In our study, we had only included patients with at least one tracing during the follow-up, even though they currently do not send any more because the episodes of tachyarrhythmia have resolved.

Alivecor® has a system of self-analysis of the tracings as to whether they are considered to be within normality or not. Parents registered many more tracings than were sent in total, as many of them only sent those where they considered something was wrong or doubted it.

Due to the great variability in the number of traces sent per patient, in order to analyse them, we first calculated the mean number of traces that had been sent, establishing this number as the maximum number of traces per patient that it would be analysed, while the minimum was one.

The tracings were interpreted and analysed during the study, according to evaluation by at least two paediatric cardiologists specialized on arrhythmias of HSJD. They assessed from each record obtained by AliveCor® if it was legible or not, if it has artifacts or not, and if it was in sinus rhythm, or instead, in tachycardia. If tachycardia was found, it was classified according to the QRS into narrow QRS tachycardia (suggests SVT), and wide QRS tachycardia (suggests VT).

To evaluate interobserver concordance, the following values were also taken into account for each tracing: heart rate (bpm) and the measurements in milliseconds (ms) of intervals PR, QRS and QTc.

The QTc (corrected QT) was obtained by Bazzett's formula:

$$QTc = {}^{medium\ QT\ (seconds)}\Big/_{\sqrt{RR}\ (seconds)}$$

Thanks to that, after the study we will be able to determine if AliveCor® monitoring has the ability to distinguish between different types of tachycardia, either sinus, supraventricular or ventricular, also the number of tachyarrhythmia events during the follow-up detected by AliveCor® device and, the percentage rate of not legible tracings registered by AliveCor®.

6.5.3 PARENTAL PERCEPTION OF THE USEFULNESS OF ALIVECOR® MONITORING

To evaluate the parental perception of the usefulness of the AliveCor® monitoring of our patients, a telephone survey has been performed (*ANNEX III*) during the study follow-up. The survey applied has been the same as the one validated one carried out by Nguyen et al. in a study of Washington University in St. Louis School of Medicine with paediatric patients with paroxysmal arrhythmia using AliveCor® device over a yearlong, and whose parents completed a validated survey to assess user's satisfaction (47).

The telephonic survey consisted of 7 questions. Initial question was the preferred placement of the device to obtain a trace. Almost most of the other questions were evaluated using a 5-point Likert scales with questions about the ease of obtaining a tracing, the ease of transmitting the tracings once they have been registered, the level of comfort in managing the arrhythmia with the aid of the device, the level of reinforcement in medical surveillance thanks to the device, and the level of improvement of the accessibility to the specialist. A single option answer (yes/no) was used to assess if they considered that thanks to AliveCor® they had reduced the need to visit the emergency department looking for medical attention for their child.

This survey allowed to assess the parental perception of the usefulness of AliveCor® monitoring.

6.6 STUDY VARIABLES

This is a descriptive and observational cross-sectional and retrospective study, so there are no dependent variables. All the variables included in the created database, are gathered in this table below. They were obtained as explained in the procedures, *section 6.5*.

Name of the variable	Definition	Level of measurement	Operating level
Gender	Phenotypic sexual characteristics of the patient determined by the patient's clinical history	Qualitative nominal	0: Male 1: Female
Age at study	Lifetime in months at the moment of the study	Quantitative continuous	Observed as positive integers without fraction
Geographical origin	City of origin	Qualitative nominal	Municipality codes
Deceased	Mortality data	Qualitative nominal	0: No 1: Yes
Weight	Last weight registered in Kg	Quantitative continuous	Numeric with decimal
Congenital heart disease	Diagnose of congenital heart disease according to clinical history by echocardiography	Qualitative nominal	0: No 1: Yes

Type of congenital heart disease	Type of heart disease recorded in the medical history diagnosed by echocardiography **Simple**: atrial septum defect, patent ductus arteriosus, ventricular septum defect, mild valvular stenosis, aorta coartaction. **Complex**: heterotaxia, atrial-ventricular discordance, ventricular-arterial discordance, anomalous venous drainage, Ebstein abnormally, Fallot, double ventricular inlet, double ventricular outlet, valve atresia, aortic interruption	Qualitative nominal	1: Simple 2: Complex
Prenatal diagnosis of tachyarrhythmia	Tachyarrhythmia detected in the prenatal period, defined by the patient's clinical history	Qualitative nominal	0: No 1: Yes
Maternal treatment	Maternal pharmacological management of foetal arrhythmia.	Qualitative nominal	0: No 1: Yes 2: Unknown
Type of maternal treatment	Pharmacological treatment received by the mother, registered on clinical history	Qualitative nominal	1: Flecainide 2: Digoxin 3: Flecainide + Digoxin
Continuity of tachyarrhythmia after birth	Prenatal tachyarrhythmia remained after birth	Qualitative nominal	0: No 1: Yes
Postnatal diagnosis of tachyarrhythmia	Tachyarrhythmia detected in the postnatal period, or rather after the birth, defined by the patient's clinical history	Qualitative nominal	0: No 1: Yes

Age at diagnosis	Age in days of life at tachyarrhythmia diagnosis	Quantitative continuous	Observed as positive integers without fraction
Time at postnatal diagnosis	Postnatal tachyarrhythmia diagnosed at neonatal period (during the first 28 days of life), or after that (until 3 years old), defined by the patient's clinical history	Qualitative nominal	0: Neonatal 1: Not neonatal
Clinical context at diagnosis	Type of symptoms presented at the time of diagnosis	Qualitative nominal	0: Unknown 1: Foetal context 2: Foetal hydrops 3: Respiratory system infection 4: Poor feeding 5: Casual 6: Irritability 7: Gastroenteritis 8: Myocarditis 9: Choking 10: Breathing difficulty 11: Cardiogenic shock
Type of tachyarrhythmia	Type of tachyarrhythmia registered by foetal echocardiography or 12-lead ECG and described in the patient's clinical history	Qualitative nominal	0: Sinus tachycardia 1: SVT 2: TV

Type of SVT	Type of supraventricular tachycardia registered by 12-lead ECG and described in the patient's clinical history	Qualitative nominal	0: Wolf-Parkinson-White syndrome 1: SVT by concealed accessory pathway 2: Auricular tachycardia 3: Permanent junctional reciprocating tachycardia/Coumel type 4: Flutter
Treatment at discharge	Antiarrhythmic treatment was indicated at discharge	Qualitative nominal	0: No 1: Yes
Type of treatment at discharge	Type of antiarrhythmic drug therapy received at the moment of discharge	Qualitative nominal	0: None 1: Flecainide 2: Flecainide + Propranolol 3: Flecainide + Propranolol + Digoxin 4: Flecainide + Digoxin 5: Amiodarone 6: Amiodarone + Propranolol

Ablation	Cardiac ablation was performed throughout the follow-up period and registered at clinical history	Qualitative nominal	0: No 1: Yes
Events of tachyarrhythmia after ablation	Episodes of tachyarrhythmia persisted after ablation	Qualitative nominal	0: No 1: Yes
Age at the start with AliveCor®	Age in days of life at the start of monitoring with AliveCor®	Quantitative continuous	Observed as positive integers without fraction
Total monitoring time with AliveCor®	Total time of monitoring with AliveCor® in months, defined by start date to present	Quantitative continuous	Observed as positive integers without fraction
Total records sent with AliveCor®	Total number of records per patient that had been sent during the AliveCor® monitoring	Quantitative discrete	Positive integers without fraction
Quality of the tracing	Quality of the tracing sent and obtained with AliveCor®, defined by if it's legible or not	Qualitative nominal	0: Not legible 1: Legible
Sinus rhythm	How is the rhythm in the tracing obtained by AliveCor®, sinus or not. Sinus rhythm was considered if three conditions fulfilled: P-wave was positive during all the trace, every P-wave was before a QRS complex, and every P-wave was after a T-wave.	Qualitative nominal	0: No 1: Yes
Pre-excitation	A delta wave was visible in the tracing obtained with AliveCor®, defined by a slurred initial in the QRS complex	Qualitative nominal	0: No 1: Yes

Tachycardia	If tachycardia was detected, defined by heart rate above the normal limits established for age	Qualitative nominal	0: No 1: Yes
Total events of tachyarrhythmia	Total number of tachyarrhythmia events per patient detected during AliveCor® monitoring	Quantitative discrete	Positive integers without fraction
Narrow QRS tachycardia	Duration of QRS complex in the normal limits established for age	Qualitative nominal	0: No 1: Yes
Type of narrow QRS tachycardia	Type of narrow QRS tachycardia in the tracings obtained with AliveCor®	Qualitative nominal	0: Sinus 1: SVT 2: Others: flutter, fibrillation, auricular tachycardia
Type of SVT tachycardia	Type of SVT tachycardia in the tracings obtained with AliveCor®	Qualitative nominal	1: AVRT 2: AVNRT 3: SVT not specified
Wide QRS tachycardia	Duration of QRS complex greater than the established for age	Qualitative nominal	0: No 1: Yes
Artifacts	Alterations in the tracings obtained with AliveCor® that do not affect the regularity of QRS but affects partially or totally (non-legible) the analysis of the trace	Qualitative nominal	0: No 1: Yes

Visit to the emergency department during the monitoring	During the follow-up with AliveCor®, the patient has required visits to the emergency department to manage a tachyarrhythmia	Qualitative nominal	0: No 1: Yes
Abortive management of tachyarrhythmia	Type of abortive management of tachyarrhythmia received at the emergency department	Qualitative nominal	0: None 1: Vagal manoeuvres 1: Adenosine iv 2: Flecainide iv 3: Electrical cardioversion
Change in chronic treatment	Changes in chronic treatment had been made during the AliveCor® monitoring	Qualitative nominal	0: No 1: Yes
Type of change in chronic treatment	How has been the change in chronic treatment during the AliveCor® monitoring	Qualitative nominal	0: Reduce treatment 1: Increase treatment
Actual treatment	Pharmacological treatment that the patient is currently receiving at the moment of the study	Qualitative nominal	0: None 1: Flecainide 2: Propranolol 3: Flecainide + Propranolol 4: Flecainide + Digoxin 5: Flecainide + Digoxin + Propranolol

6.7 STATISTICAL ANALYSIS

The statistical analysis was carried out using the IBM SPSS® software package (version 27.0.1, SPSS Inc., Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

For univariate analysis, we summarized the qualitative variables in absolute and relative frequencies with its confidence interval (IC 95%). The quantitative continuous variables were described as mean ± standard deviation (those with normal distribution) and with median and interquartile range of 25-75 (those without normal distribution). We performed cross-tables between quantitative variables and sex.

For interobserver concordance in the analysis of AliveCor® registers, categorical variables were evaluated through the kappa coefficient (0,6-0,8 good agreement; 0,8-1 very good agreement), and in the case of quantitative ones through intraclass correlation index (0,75-0,9 adequate concordance; 0,90 excellent concordance).

No bivariate inference has been performed and the model has not been fitted due to the small sample size.

7. ETHICAL AND LEGAL ASPECTS

This study respects the four bioethics principles defined by Beauchamp and Childress in 1979 and has not any commercial interests or bias.

This project obeys with the ethical doctrines of the Declaration of Helsinki determined by the World Medical Association about involving human beings in research. Besides, the correspond protocol was first evaluated by the Clinical Research Ethical Committee (CREE) of HSJD Foundation in Barcelona before starting our study (*ANNEX* II).

In first place, regarding to the Organic Law 3/2018 of December 5 about the Personal Data Protection and Digital Rights Guarantee based on Article 18 of the Spanish Constitution of 1978 that guarantees the familiar and personal right to honour, privacy and secrecy of communications, and protection of personal data processing, public liberties and human rights, data was recorded and studied anonymously and under non-identifying numeric codes. Thus, author did not have access to any confidential information of the patients, which was only applied for the aim of investigation. The Royal Decree 1720/2007 of December 21 which approves the Regulation implementing Organic Law 15/1999 of 13 December, on the protection of personal data was followed.

Secondly, about the Law 41/2002 Of 14 November, regulating patient autonomy and rights and obligations regarding clinical information and documentation was followed. Also, the consent for publication of this data was obtained from all patients/patient's families/legal tutor. Going into legal aspects, as our study is with minors (below 16 years old in medical frame), only from 7 to 16 years old patients' agreement was fundamental since it is considered that they can make reasoned decisions, while were their parents or legal tutors whose had the responsibility in all the patients from 0 to 16 years old.

This study includes medical devices (such as AliveCor® Kardia Mobile), therefore, it will be developed according to the following law of Royal Decree 1090/2015 of clinical investigations with medical devices.

8. RESULTS

8.1 POPULATION CHARACTERISTICS

8.1.1 DEMOGRAPHIC DATA

A total sample of 30 patients younger than 6 years old at the present time (mean age 20,94 ± 17,85 months) born between 2015 and 2020 with history of tachyarrhythmia and outpatient monitoring with AliveCor® were included in our study. 17 were male (56,7%) and 13 were female (43,3%). The mean age of male patients was 19,11 ± 18,1 months, while in females was 28,67 ± 23,29. All patients registered were Spanish. Almost all were from Catalonia (96,7%) and 1 child (3,3%) was from Madrid. The mean weight was 10,54 ± 4,51 kg.

Table 1: Summary of demographic data

DEMOGRAPHIC QUALITATIVE DATA	N=PATIENTS (%)
GENDER	
▪ Males	17 (56,7%)
▪ Females	13 (43,3%)
SPAIN ORIGIN	30 (100%)
▪ Catalonia	29 (96,7%)
▪ Madrid	1 (3,3%)

Values are n (%)

DEMOGRAPHIC QUANTITATIVE DATA	MEAN ± DS	MEDIAN	INTERQUARTILE RANGE
ACTUAL AGE (months)	20,94 ± 17,85	13,50	[8,0 – 34,75]
▪ Age in males (months)	19,11 ± 18,1	11	[6 – 33,5]
▪ Age in females (months)	28,67 ± 23,29	31	[8,5 – 46,5]
WEIGHT (kg)	10,54 ± 4,51	9,30	[8,2 – 14,15]
▪ Weight in males (kg)	9,89 ± 4,30	9,50	[5,66-14,25]
▪ Weight in females (kg)	12,13 ± 5,40	12	[8,60-15,25]

8.1.2 CLINICAL CHARACTERISTICS

Table 2: Summary of clinical characteristics

CLINICAL QUALITATIVE CHARACTERISTICS	N=PATIENTS (%)
DECEASED	1 (3,3%)
CONGENITAL HEART DISEASE	1 (3,3%)
▪ Simple	0
▪ Complex	1 (3,3%)
PRENATAL DIAGNOSIS OF TACHYARRHYTHMIA	**11 (36,7%)**
▪ Received maternal treatment	7 (63,64%)
- Flecainide	3(42,9%)
- Digoxin	2 (28,6%)
- Flecainide + Digoxin	2 (28,6%)
▪ Not received maternal treatment	3 (27,27%)
▪ Unknown	1 (9,09%)
▪ Tachyarrhythmia has remained after birth	8 (72,7%)
▪ Tachyarrhythmia has solved after birth	3 (27,3%)
POSTNATAL DIAGNOSIS OF TACHYARRHYTHMIA	**19 (63,3%)**
▪ In neonatal period	11 (57,9%)
▪ After neonatal period	8 (42,1%)
CLINICAL CONTEXT AT DIAGNOSIS	
▪ Unknown	1 (3,3%)
▪ Foetal	9 (30%)
▪ Hydrops foetal	2 (6,7%)
▪ Respiratory system infection	5 (16,7%)
▪ Poor feeding	1 (3,3%)
▪ Casual	5 (16,7%)
▪ Irritability	1 (3,3%)
▪ Gastroenteritis	1 (3,3%)
▪ Myocarditis	1 (3,3%)
▪ Choking	1 (3,3%)
▪ Breathing difficulty	2 (6,7%)
▪ Cardiogenic shock	1 (3,3%)
TYPE OF TACHYCARRHYTHMIA	
▪ **SVT**	**23 (76,7%)**
- WPW syndrome	8 (34,8%)
- SVT by concealed accessory pathway	12 (52,2%)
- Auricular tachycardia	1 (4,3%)
- Permanent junctional reciprocating/Coumel tachycardia	2 (8,7%)
▪ **VT**	**4 (13,3%)**
▪ **Healed**	**3 (10%)**

RECEIVED TREATMENT AT DISCHARGE	**25 (83,3%)**
▪ Flecainide	12 (48%)
▪ Flecainide + Propranolol	6 (24%)
▪ Flecainide + Propranolol + Digoxin	2 (8%)
▪ Flecainide + Digoxin	2 (8%)
▪ Amiodarone	1 (4%)
▪ Amiodarone + Propranolol	1 (4%)
▪ Propranolol	1 (4%)
NOT RECEIVED TREATMENT AT DISCHARGE	**5 (16,7%)**
ABLATED	**8 (26,7%)**
▪ Tachyarrhythmia episodes persist after ablation	4 (50%)
▪ Tachyarrhythmia episodes do not persist after ablation	4 (50%)
NOT ABLATED	**22 (73,3%)**

Values are n (%)
Abbreviations: SVT= Supraventricular tachycardia, WPW= Wolff-Parkinson-White, VT= Ventricular tachycardia.

CLINICAL QUANTITATIVE DATA	MEAN ± DS	MEDIAN	INTERQUARTILE RANGE
AGE AT POSTNATAL DIAGNOSIS (DAYS OF LIFE)	193,26 ± 318,23	23	[15 – 450]
▪ Age in males (days of life)	66,78 ± 144,08	11	[11 – 30]
▪ Age in females (days of life)	340,67 ± 400,23	31	[16 – 680]

Deceased occurred in 1 patient (3,3%) due to a sepsis, the same one who had diagnosis of complex congenital heart disease.

Eleven of thirty patients (36,7%) were diagnosed of tachyarrhythmia on the prenatal period. Maternal management in these cases, occurred in 7 of 10 patients (63,64%); of these, 3 cases (42,9%) were managed with Flecainide, 2 (28,6%) with Digoxin, and 2 (28,6%) with Flecainide + Digoxin. From those 11 patients with prenatal diagnose of tachyarrhythmia, in 8 cases (72,7%) tachyarrhythmia events remained after birth however, in 3 (27,3%) the tachyarrhythmia was solved.

Nineteen of thirty patients (63,3%) were diagnosed of tachyarrhythmia on the postnatal period, and of these 11 patients (57,9%) were in the neonatal period (during the first 28 days of life), and 8 (42,1%) were after the neonatal period. The

mean age in days of life at the moment of diagnosis was 193,26 ± 318,23; 66,78 ± 144,08 in males, and 340,67 ± 400,23 in females.

Recall that of 30 patients, 11 were diagnosed in prenatal period (36,7%), from these, 2 (6,7%) were diagnosed due to a pregnancy complication, a hydrops fetalis. Focusing on the remaining 19 patients who had a postnatal diagnosis, the most prevalent clinical manifestation at the moment of tachyarrhythmia presentation was an infection of the respiratory system (n=5, 16,7%), but the same number of patients (n=5, 16,7%) were diagnosed incidentally.

The second most frequent clinical manifestation at the moment of diagnosis was breathing difficulty (n=2, 6,7%), followed by the rest of presentations, poor feeding, irritability, myocarditis, choking, gastroenteritis and cardiogenic shock; all with n=1 (3,3%). It should also be noted that in one case (n=1, 3,3%), the clinical context of the patient at the time of diagnostic is unknown.

Concerning the type of tachyarrhythmia, 4 (13,3%) were VT, and 23 (76,7%) were SVT. Of all the SVTs, 8 (34,8%) were WPW syndrome type, 12 (52,2%) were SVT by concealed accessory pathway, 1 (4,3%) atrial tachycardia, 2 (8,7%) permanent junctional reciprocating or Coumel type tachycardia. In 3 patients (10%) the tachyarrhythmia spontaneously resolved, and no recurrences could be observed by the end of this study.

At the time of discharge, 25 patients (83,3%) were under pharmacological treatment while 5 (16,7%) did not. Flecainide alone was the first line treatment in 12 patients (48%), followed by combination of Flecainide + Propranolol in 6 patients (24%). Flecainide + Propranolol + Digoxin was used in 2 patients (8%), the same as Flecainide + Digoxin (n=2, 8%). Finally, Amiodarone (1 patient, 4%), Propranolol (1 patient) and Amiodarone + Propranolol (1 patient) were the least used.

Eight of thirty patients (26,7%) required ablation in order to control the incessant tachycardia. In 4 (50%), the ablation terminated with the tachycardia, and in the other 4, ablation modified the conduction properties of the tachycardias, and pharmacological treatment could help control the tachycardia events.

8.2 ALIVECOR® RESULTS

8.2.1 ALIVECOR® MONITORING DATA

Table 3: Summary of AliveCor® monitoring data

ALIVECOR® QUANTITATIVE DATA	MEAN ± DS	MEDIAN	INTERQUARTILE RANGE
AGE AT THE START WITH ALIVECOR® (DAYS OF LIFE)	**289,17 ± 480,67**	**42,50**	**[27,75 – 394,25]**
▪ Age in males (days of life)	243,67 ± 419,96	37	[22 – 373]
▪ Age in females (days of life)	525,89 ± 726,46	61	[25 – 917,5]
TOTAL MONITORING TIME (months)	**13,07 ± 11,59**	**13,07**	**[6,75 – 14,25]**
▪ Total monitoring time in males (months)	11,33 ± 7,76	11	[5 – 16,5]
▪ Total monitoring time in females (months)	16,22 ± 16,95	8	[6,5 – 29]
TOTAL RECORDS SENT WITH ALIVECOR®	**11,48 ± 11,23**	**6**	**[4 – 19]**
▪ Total records sent with AliveCor® in males	6,33 ± 6,40	4	[2,5 – 8]
▪ Total records sent with AliveCor® in females	13,56 ± 13,73	6	[3,5 – 21,5]

ALIVECOR® QUALITATIVE DATA	N=PATIENTS (%)
VISITS TO THE EMERGENCY DEPARTMENT DURING THE FOLLOW-UP	**7 (23,3%)**
▪ Type of abortive management	
▪ Vagal manoeuvres	1 (14,3%)
▪ Adenosine iv	4 (57,1%)
▪ Flecainide iv	1 (14,3%)
▪ Electrical cardioversion	1 (14,3%)
CHANGES IN CHRONIC TREATMENT DURING THE FOLLOW-UP	**15 (50%)**
▪ Reduce treatment	9 (60%)
▪ Increase treatment	6 (40%)
CURRENTLY WITH PHARMACOLOGICAL TREATMENT[1]	**13 (44,8%)**
▪ Flecainide	6 (20,7%)
▪ Propranolol	1 (3,4%)
▪ Flecainide + Propranolol	5 (17,2%)
▪ Flecainide + Digoxin + Propranolol	1 (3,4%)
CURRENTLY WITHOUT PHARMACOLOGICAL TREATMENT[1]	**16 (55,2%)**

Values are n (%) and mean ± DS. [1] Values calculated over a total of 29 patients.
Abbreviations: iv= intravenous

In the study sample, the mean age of the patients at the start of AliveCor® monitoring, was 289,17 ± 480,67 days of life and the total mean monitoring time with the device of 13,07 ± 11,59 months. As mentioned, there is a large variability in the number of tracings sent per patient. Of the 30 users, the total mean records sent with AliveCor® was of 11,48 ± 11,23.

During the follow-up period with AliveCor®, 7 patients (23,3%) required to visit the emergency department due to an episode of tachyarrhythmia. The episode was reversed only needing vagal manoeuvres in 1 case (14,3%), with intravenous Adenosine in 4 cases (57,1%) and with intravenous Flecainide in 1 case (14,3%). Only 1 patient (14,3%) required electrical cardioversion to reverse tachyarrhythmia to sinus rhythm.

Changes in chronic treatment were made in 50% of patients during the follow-up period with AliveCor®. Of these, in 40% of cases the treatment was increased increasing while in 60% it was reduced.

Of the 30 patients, 16 (55,2%) are currently without pharmacological treatment. Of the remaining 13, 6 (20,7%) are taking Flecainide, 5 (17,2%) Flecainide + Propranolol, 1 (3,4%) monotherapy with Propranolol and the last one (3,4%) triple therapy with Flecainide + Propranolol + Digoxin.

8.2.2 ELECTROCARDIOGRAPHIC CHARACTERISTICS OF ALIVECOR® TRACINGS

Table 4: Summary of AliveCor® electrocardiographic characteristics

CHARACTERSTICS OF THE 190 TRACINGS	N=TRACINGS (%)	
	EP-A	**EP-B**
QUALITY: LEGIBLE	181 (95,3%)	184 (96,8%)
PRESENCE OF ARTIFACTS	26 (13,7%)	33 (17,4%)
SINUS RHYTHM	148 (77,9%)	153 (80,5%)
VISIBLE PRE-EXCITATION	16 (8,4%)	17 (8,9%)
TACHYCARDIA	**20 (10,52%)**	**22 (11,57%)**
▪ WIDE QRS TACHYCARDIA	6 (30%)	6 (27,3%)
▪ NARROW QRS TACHYCARDIA	14 (70%)	16 (72,7%)
- Sinus	1 (7,1%)	3 (18,7%)
- SVT	13 (92,8%)	13 (81,3%)
○ AVRT	10 (76,9%)	8 (61,5%)
○ AVNRT	0	0
○ Non specified SVT	3 (23.1%)	5 (38,5%)
- Others: flutter, fibrillation, auricular tachycardia	0	0

Values are n (%)
Abbreviations: EP-A; EP-B = electrophysiologist A and B. SVT= Supraventricular tachycardia, AVRT= auriculoventricular re-entry tachycardia, AVNRT= auriculoventricular nodal re-entry tachycardia.

Finally, a total of 190 tracings corresponding to the 30 patients were analysed. The inter-observer concordance in the evaluation of the tracings was good to excellent (kappa ≥ 0,67 and ICC ≥ 0,82). *(See table in ANNEX V).*

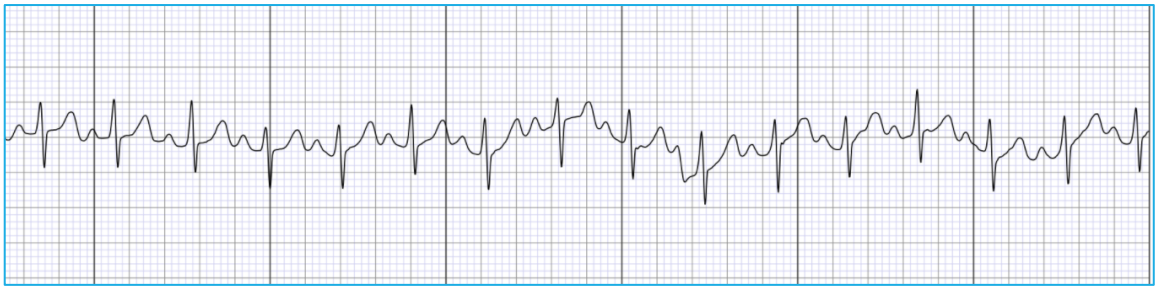
About 5% of the tracings were considered as non-legible. Between 13,7% and 17,4% of the tracings had artifacts, and in 8,4-8,9% of the tracings there is a visible pre-excitation, all according to the observer.

Between 77,9% and 80,5% of tracings were in sinus rhythm. Approximately 11% (10,52% - 11,57%) of tracings were in tachycardia, predominantly those with narrow QRS (70% - 72,7%). Narrow QRS tachycardias were overwhelmingly (81,3% - 92,8%) classified as SVT, and within these the most frequent were AVRT (76,9%).

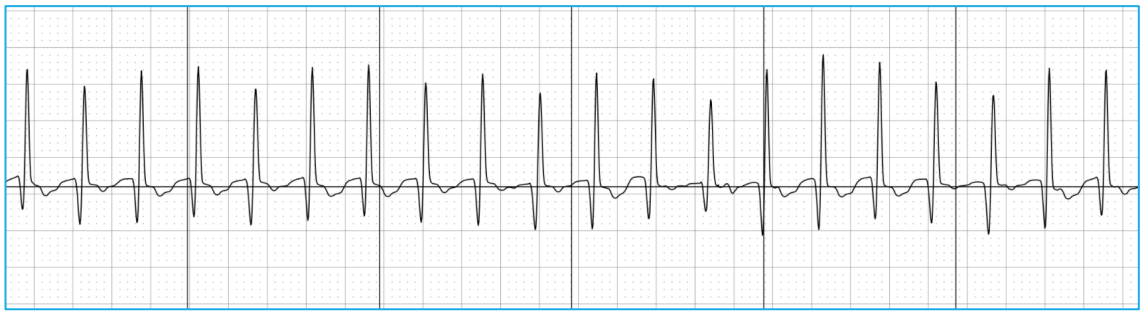
Both examiners diagnosed the same number of tracings with tachyarrhythmia, 19, and the same number for each type. 6 tracings were wide QRS tachycardia and corresponded to 2 patients with ventricular tachycardia. 13 tracings were SVT (AVRT + AVNRT + unspecified SVT) and corresponded to 5 patients.

8.2.3 EXAMPLE OF ALIVECOR® TRACINGS

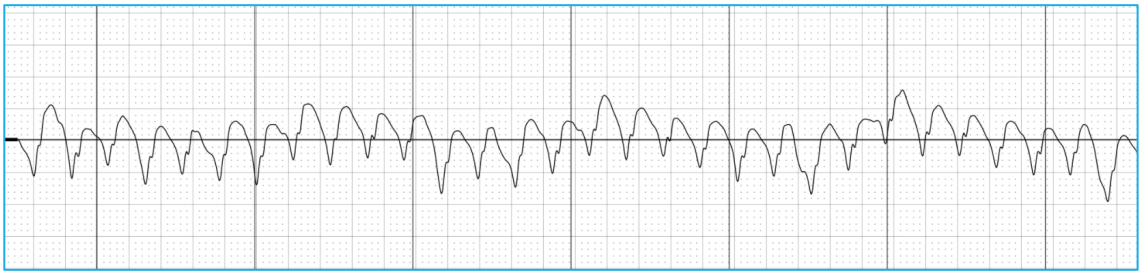
ALIVECOR TRACING 1: Real one-single lead racing from a patient included in this study obtained with AliveCor® Kardia Mobile device. SINUS TACHCARDIA (HR= 150 bpm)



ALIVECOR TRACING 2: Real one-single lead racing from a patient included in this study obtained with AliveCor® Kardia Mobile device. SUPRAVENTRICULAR TACHCARDIA, Atrioventricular re-entry tachycardia type (HR= 214 bpm)



ALIVECOR TRACING 3: Real one-single lead racing from a patient included in this study obtained with AliveCor® Kardia Mobile device. VENTRICULAR TACHCARDIA (HR= 272 bpm)



8.3 SURVEY OF ALIVECOR® EVALUATION

A total of 29 surveys to the parents of paediatric patients with history of tachyarrhythmia and outpatient monitoring with AliveCor® were carried out. There was no population bias as all users of AliveCor® from 2017 until now, have been tested, except for one patient whose parents were not reachable by phone nor mail. Not all the asked users, utilised the device with the same frequency, some used almost it daily while others only occasionally. There were also who had not sent any records for a long time because of the good evolution of the patients.

Answering to the question of the preferred placement of the device, chest placement was used 79,3% of the times while fingers placement was used in 13,8%. The remaining 6,9% used other places, for example the back.

The results obtained from the questions evaluated using a 5-point Likert scales were: 44,8% scored the ease of obtaining a tracing 4/5, 27,6% 5/5, 17,2% 3/5 and 10,3% 2/5. Regarding the question of the ease of transmitting the tracing once obtained, 89,7% valued with 5/5 and the remaining 10,3% 4/5. 72,4% rated the level of comfort in managing the arrhythmia with the aid of the device 5/5, 17,2% 4/5, 6,9% 3/5 and 3,4% 2/5. Questions about the level of reinforcement in medical surveillance and the level of improvement in accessibility to the specialist thanks to the device were rated 5/5 72,4%, 4/5 13,8%, 3/5 6,9%, 2/5 6,9% and 5/5 82,8%, 4/5 10,3%, 3/5 3,4%, 2/5 3,4%, respectively.

Taking into account the functioning and meaning of the 5 Likert scales, we will consider that scores of 1/5 and 2/5 imply dissatisfaction, 3/5 neutral disposition, and 4/5 and 5/5 satisfaction. Knowing that, we can conclude that 72,4% of the users found easy to obtain tracings, and the 100% found it easy to transmit them.

89,6% showed added comfort in managing the arrhythmia by having the device, 86,2% showed improvement of the reinforcement in medical surveillance and 93,1% in accessibility to the specialist thanks to the device.

89,7% of the respondents to the survey indicated that they considered that thanks to AliveCor® they had reduced the need to visit the emergency department looking for medical attention for their child, whereas 10,3% not.

User satisfaction with the device remained high over time, and survey responses from users who transmitted tracings often and users who not, produced similar satisfaction scores.

In addition to completion of the survey, users also provided comments highlighting their experience with the device. Most users found it was difficult to record a tracing on an active infant, because they move a lot and therefore it is difficult for the device to pick up de signal. Most users cited that the device provided them greater relief with the ability to promptly record the rate and rhythm, facilitating rapid and effective assessment by the specialist, and allowing early therapeutic decisions to be made, often avoiding them a visit to the emergency department. *The results are shown in ANNEX IV*.

9. DISCUSSION

The progress and innovation in biotechnology are changing the practice of medicine and the way health decisions are made. The development of a smartphone application to record a high-quality single-lead ECG with the aid of a device such as AliveCor®, makes outpatient monitoring more accessible for patients with history of tachyarrhythmia. At the same time, it is helpful for timely diagnosis and rapid management of tachyarrhythmia reducing overall morbidity and facilitating parental reassurance.

To our knowledge, this is one of the few studies of paediatric patients with history of tachyarrhythmia and outpatient monitoring with AliveCor®. Although there are several studies on wireless devices to record ECG in adult patients with arrhythmias, the data on use in paediatric population is scant. Furthermore, our study focuses only on patients less than three years old at the time of diagnosis, greatly reducing the sample but focusing on the population where there is less published data, so far. In addition, our study is the only one that includes patients with AliveCor® and history of ventricular tachycardia, since so far, the only studies on monitoring with AliveCor® in the paediatric population are exclusively in patients with supraventricular tachycardia.

As mentioned, the clinical presentation of tachyarrhythmia in infants is often ambiguous and non-specific, adding to the fact that infants are unable to express symptoms. The problem also lies in the fact that most arrhythmias in children are often paroxysmal, complicating the ability to capture the abnormal rhythm on routine ECG during an outpatient visit. Furthermore, the interval time period between follow-up routine visits goes unmonitored. The only methods proposed for ambulatory monitoring so far were 24 hour-Holter or implantable loop recorders, with all the advantages but at the same time disadvantages that this entails. All of this leads to a potential delay in diagnosis and potential unattended life-threatening tachyarrhythmia events in the infant population. This, in turn, can cause anxiety and distress for patients but specially in parents. Altogether promoted Hospital Sant Joan de Déu, to start outpatient monitoring with AliveCor® in paediatric patients with history of tachyarrhythmia by 2017.

9.1 CLINICAL CHARACTERISTICS

According to our sample, 11 of 30 patients (36,7%) were diagnosed of tachyarrhythmia in the prenatal period, and in most of these cases (63,64%), maternal treatment was administered in an attempt to reverse the tachyarrhythmia into sinus rhythm. The most commonly used type of therapeutic management was Flecainide (42,9%), agreeing with Karmegeraj, who reported that several studies proposed Flecainide as the first line of treatment (14). As explained, foetal arrhythmias may contribute to a high morbidity and mortality rate, and hydrops fetalis may occur in 30-40% (11) of cases. In our sample, 18,18% of patients with prenatal diagnosis had hydrops fetalis. Of these 11 patients, in 8 cases (72,7%) the tachyarrhythmia events remained after birth, with an incidence similar to that described by Hinkle et al. (12) of 61%. In 3 of our patients (10%), the tachyarrhythmia resolved, with no episodes in the postnatal period to date. As reported by Salerno et al, spontaneous resolution occurs in a high percentage of infants during the first year of age (3).

In this cohort, 19 of the 30 patients (63,3%) were diagnosed with tachyarrhythmia in the postnatal period, at a mean age of 193,26 ±318,23 days of life. Salerno et al. reported that approximately 50% of patients present their first episode of tachyarrhythmia in the first year of life (3), and Yaari et al. reported that this usually occurs before 2 months of age (49). In our study population, 11 of 19 patients (57,9%) were diagnosed in the first 28 days of life, and the remaining 8 (42,1%), after the neonatal period, agreeing with the fact that the first episode of tachyarrhythmia, usually occurs at a very early age.

Taking all data into account, our results are in concordance to all published studies, describing that tachyarrhythmias usually present with a very non-specific clinical presentation and are often diagnosed by chance. 16,7% of the patients in our study were diagnosed with tachyarrhythmia by chance, while another 16,7% were diagnosed when presenting with a respiratory tract infection. Other non-specific clinical manifestations that allowed the diagnosis of tachyarrhythmia were breathing difficulty, poor feeding, irritability, gastroenteritis, myocarditis or choking. If prolonged episodes of tachyarrhythmia occur, these infants may

eventually develop hemodynamic decompensation. Only 1 patient (3,3%) in our sample presented to the emergency department for cardiogenic shock caused by tachyarrhythmia.

As described by Srinivasan et al. (5), SVT is the most common tachyarrhythmia in children. 23 of our patients (76,7%) had SVT diagnosis, while only 4 (13,3%) were VT. Recall that in the remaining 10% of patients, the episodes resolved. As can be seen, supraventricular is notably the most frequent type of tachyarrhythmia, as represented in our sample.

The most prevalent type of SVT tachycardia was SVT by concealed accessory pathway, which occurred in 14 of 23 patients. Of these 14 (60,9%), 2 were of the permanent junctional reciprocating or Coumel type. 8 were of WPW syndrome and 1 was atrial tachycardia. Of the 23 cases, all but one (95,7%) were AVRT, the most common arrhythmia in paediatrics, caused by an accessory pathway between the ventricle and the atrium. The overall incidence of AVRT in paediatric patients with SVT has reported to be 72-80%; but when infants are excluded, the incidence decreases to 56-68%, with the incidence of AVNRT at 20-34% (40). We had no cases of AVNRT, probably because, as mentioned, it is more frequent in adults and older children.

Most patients (83,3%), received treatment at discharge and Flecainide was again the first treatment option in 48% of cases, followed by the combination of Flecainide + Propranolol in 24% of patients. As reported by Ergül et al., Flecainide has been shown to be more effective than most other drugs in treating SVT and VT in adult patients and is increasingly used in paediatric patients (32). We could not demonstrate an association between type of tachycardia and type of treatment used, as in most cases, the choice of treatment was also determined by the characteristics of each patient and so it was individualized. The only thing we can conclude is that none of the patients with pre-excitation had Digoxin or Betablocker in the treatment, as it was described that they may predispose the patient to rapid conduction of atrial fibrillation and sudden death (27). In patients with refractory tachyarrhythmia, ablation was performed. In our sample, 26,7% of the patients were ablated without any complications due to the procedure. Of these, in 50% of cases the tachyarrhythmia episodes resolved, and in the remaining 50%, ablation allowed

better tachycardia control and lower doses of pharmacological treatment. This is in line with the findings of Schlechte et al. that radiofrequency ablation is effective and safe in treating arrhythmias in paediatric patients and has significantly reduced the risk of complications over the years (7).

9.2 ALIVECOR® MONITORING

The number of published studies on the use of AliveCor® in the paediatric population is very limited. To our knowledge, no study has been published that assesses follow-up data, such as whether an emergency department visit has been required due to an episode or whether changes in chronic therapeutic management have been made, such as those reported in our study.

If we focus on the time from which patients started using AliveCor®, the mean age of onset for these patients was 193,26 ± 318,23 days of life. The total mean follow-up time of these patients was 13,07 ± 11,59 months, from the date of onset to present. There was considerable variability in the number of AliveCor® registers sent per patient, as not all parents recorded the same number of tracings, so we estimated the mean to be 11,48 ± 11,23 registries. Thus, to analyse the tracings, the minimum number of tracings analysed per patient was 1 and the maximum was 12, taking this mean obtained from the total number of tracings sent per patient.

The few published studies on the use of AliveCor® in the paediatric population focus on assessing its ability to detect two types of tachyarrhythmia or compare AliveCor® tracings with a 12-lead ECG. Ferdman et al. demonstrated that single-lead ECG obtained with a AliveCor® smartphone case can be used to successfully record SVT in paediatric patients at least as well as previously published reports of Holter monitors. Also, they demonstrated the utility of AliveCor® to record SVT and to distinguish AVRT, from AVNRT, in thirty-seven paediatric patients (40). Gropler et al. demonstrated a strong correlation between electrocardiographic measurements obtained with AliveCor® and with a 12-lead ECG (45).

In this study, it has not been considered to compare the correlation and concordance between the measurements of AliveCor® tracing and 12-lead ECG, as it would only make sense to do so if both are taken at the same time and under the same

conditions. One of the main goals of the AliveCor® device is to reduce the need of attending the emergency department, so it would neither be reasonable or feasible having to obtain both recordings at the same time when the patient has an episode. It is also worth mentioning that the current situation regarding the COVID-19 pandemic has influenced the possible feasibility of doing so.

Referring again to the articles published to date, we did want to assess in this study the electrocardiographic characteristics of tracings obtained with AliveCor® and submitted by the patients. On our cohort of 30 patients, 190 tracings were analysed. We found that inter-observer concordance in the evaluation of tracings was good to excellent with a kappa ≥ 0,67 and ICC ≥ 0,82. We found that only 5% of the tracings were considered non-legible and only 13,7-17,4% of the tracings had artifacts. Therefore, we consider that we can have an adequate performance in the readings of the AliveCor® records.

As mentioned, the most common causes of paediatric SVT are atrioventricular re-entrant tachycardia (AVRT) followed by atrioventricular nodal re-entrant tachycardia (AVNRT). Ferdman et al. described in their prospective study of 37 patients that the AliveCor® monitor is an easy-to-use device and that the SVT recording, can adequately differentiate sinus rhythm and distinguish AVRT from AVNRT. In their study they found that 65% of patients had AVRT and 35% had AVNRT (40).

In our study we found that 77,9% to 80,5% of the tracings analysed were in sinus rhythm. Approximately 11% of the tracings were in tachycardia, predominantly those with narrow QRS (70%-72,7%). Narrow QRS tachycardias were overwhelmingly (81.3% - 92.8%) and classified as SVT. Of these, the most frequent were AVRT, agreeing with Ferdman et al.

Both examiners diagnosed the same number of tracings with tachyarrhythmia, 19, and the same number for each type. 13 tracings were SVT (AVRT + AVNRT + unspecified SVT) and corresponded to 5 patients. Furthermore, in our cohort we were able to diagnose 6 tracings with wide QRS tachycardias corresponding to 2 patients with ventricular tachycardia indicating that we can also obtain a differential diagnosis of VT in the paediatric population using AliveCor monitoring. However, it

is important to highlight that in our study the ages of the patients are younger compared to published studies found in toddlers and adolescents.

During AliveCor® monitoring, those 7 patients (23,3%) had to attend the emergency department to manage the tachyarrhythmia detected with the device. In none of these cases the patient became haemodynamically decompensated. In many of these episodes, the parents already identified from the recording that something was wrong and sent it directly to the paediatric cardiologist, who referred the patient to the emergency department to manage the episode. Thus, we can determine that AliveCor® is a useful tool for detecting episodes of tachyarrhythmia and at the same time making rapid therapeutic decisions about it. However, it should be explained that not in all cases in which a tachyarrhythmia was detected in the AliveCor® record, parents were referred to the emergency department. In some cases, the management was done directly over the phone, where the paediatric cardiologist instructed them to adjust the medication and reverse the episode; avoiding them to attend the emergency department.

Changes in chronic treatment were made in 50% of patients during the follow-up with AliveCor®, of which 40% were to increase and 60%, to reduce treatment. We cannot conclude that this change in treatment was exclusively due to AliveCor® follow-up, as other factors such as age or weight played a role. We know treatment dose is correlated with weight, and also that, as mentioned, episodes of tachyarrhythmia tend to resolve with age. So, the change in chronic management maybe could have occurred anyway even if the patient had not been monitored with AliveCor®.What we can conclude is that this change in patient's chronic treatment has been supported and decided with greater certainty by the clinician, either to increase or to reduce it. That is, if a patient has been monitored for a long period of time and no episodes of tachyarrhythmia have been detected, we have been able to reduce the dose. Conversely, with patients who have had episodes of tachyarrhythmia detected by the device or decompensations that have required emergency department visits, the treatment has had to be increased. In both cases, the change in management has been made with added certainty supported by AliveCor®.

9.3 PARENTAL PERCEPTION OF THE USEFULNESS OF ALIVECOR® MONITORING

To evaluate the parental perception of the usefulness of the AliveCor® monitoring of our patients, 29 telephone survey *(ANNEX III)* were carried out. The survey applied has been the same as that carried out by Nguyen et al. in a study of Washington University in St. Louis School of Medicine with paediatric patients with paroxysmal arrhythmia using AliveCor® device over a yearlong, and whose parents completed a validated survey to assess user satisfaction (47).

The telephonic survey consisted of 7 questions. Initial question was the preferred placement of the device. Chest placement was used 79,3% of the times while fingers placement was used in 13,8%. The remaining 6,9% used other places, for example the back. The survey responses of Nguyen et al. were similar, saying that hand placement was used 78% of the times while chest placement was used in the remaining 22%.

Almost most of the other questions were evaluated using a 5-point Likert scales with questions about the ease of obtaining a tracing, the ease of transmitting the tracings once they have been registered, the level of comfort in managing the arrhythmia with the aid of the device, the level of reinforcement in medical surveillance thanks to the device, and the level of improvement of the accessibility to the specialist. A single option answer (yes/no) was used to assess if they considered that thanks to AliveCor® they had reduced the need to visit the emergency department looking for medical attention for their child.

According to our survey responses 72,4% of the users found easy to obtain tracings, and the 100% found it easy to transmit them. The survey responses of Nguyen et al. were similar, 98% of the users indicated that it was easy to obtain tracings and 93% found it easy to transmit them.

89,6% users of our survey showed added comfort in managing the arrhythmia by having the device, 86,2% showed improvement of the reinforcement in medical surveillance and 93,1% in accessibility to the specialist thanks to the device.

89,7% of the respondents to the survey indicated that they considered that thanks to AliveCor® they had reduced the need to visit the emergency department looking for medical attention for their child, whereas 10,3% not. User satisfaction with the device remained high over time, and survey responses from users who transmitted tracings often and users who not, produced similar satisfaction scores. Respondents to the Nguyen et al. survey agreed with a very similar % for all answers, and users who transmitted tracings often and users who not, produced similar satisfaction scores, as did our survey responses.

It is safe to say that the user satisfaction with the device was very high. Most users rated the ease of use of the device positively, although many reported difficulties in taking a record of an infant when it was active. Most users cited that the device provided them greater relief and consequently, reduced the anxiety that their child's diagnosis could bring. They appreciate the device's facility to promptly record rate and rhythm, promoting rapid and effective assessment by the specialist. At the same time, it allowed early therapeutic decisions to be made, often saving them a visit to the emergency department. It is also worth mentioning that it reduces costs to the healthcare system by avoiding unnecessary emergency department care.

Furthermore, it is important to mention that the patients in our study who use this device are too young, and apart from the concern that a diagnosis of tachyarrhythmia may entail, the parents have added fact that that they have an infant who cannot express what is wrong. So AliveCor® can provide them an added reassurance that they would probably not have without this device.

10. STUDY LIMITATIONS

Due to the cross-sectional descriptive and retrospective nature of this study, some potential limitations should be considered:

1. One of the main limitations of this study was the small number of patients in the sample size. It is due to tachyarrhythmias in paediatric population is a rare event and outpatient management with AliveCor®-type ECG recording devices is not yet widely used in this type of patient, especially in children under three years of age at diagnosis, such as those of our study. Nevertheless, considering the inclusion criteria of our study, getting 30 patients to meet them is quite a lot. Actually, we got involve this number of patients due to Hospital Sant Joan de Déu is the national centre of reference (CSUR) for malignant arrhythmias in paediatric population. In the future, a multicentre study could be envisaged, to be carried out in other hospitals in order to have more external validity.

2. Cross-sectional descriptive studies used to be prevalence studies, but this was not the goal of our project. As national centre of reference in Paediatric arrhythmia, the extraction of a prevalence would be completely biased. Consequently, prevalence was not calculated, and the description of these patients was the main important concept. It was done to avoid the bias of access to Healthcare.

3. Another limitation from our study design was represented by its retrospective design which could have led to some information and recordkeeping biases.

4. We have not proposed a comparative study between two groups of patients, both with history of tachyarrhythmia but one with outpatient AliveCor® monitoring and the other without AliveCor®. The rationale would be that it is such a beneficial tool that we could not consider leaving a group without it.

5. Unlike adults in whom the traces are registered from 2 fingers, in small paediatric patients the position of the device is taken from the chest. Changes in the position of the device around the chest can influence the morphology of the tracing waves (P wave, QRS complex, T wave) and consequently affect the diagnosis. There wasn´t information about the position around the chest for each trace in each patient, so the study couldn´t include that issue. It is also worth mentioning that being such young children, they can't collaborate to stay quiet, so this increases the artifacts on the register.

6. Given the fact that such young patients cannot express the symptoms of tachycardia, there is a possibility that the number of tachyarrhythmia episodes captured by AliveCor® are underestimated, if the parents did not suspect something was wrong. Even though, none of the patients presented with clinical decompensation, therefore, no clinical consequences may have happened after this none-detected tachycardias.

11. IMPLICATION IN CLINICAL PRACTICE

It is important to mention the implications for clinical practice obtained during the analysis of the results of this cross-sectional study involving patients with an uncommon disease and a novel remote monitoring system, as research still has a long way to go and the applicability in paediatric patients could be improved.

AliveCor® is a useful tool for outpatient monitoring of patients with a history of tachyarrhythmia. This technology has been validated by the FDA in adults with normal ECG and those with atrial fibrillation but there is a paucity of data about its use in paediatric population with arrhythmia (40), especially in neonates and infants. In addition, it is worth mentioning that the device is not designed or well-adapted for such small patients, as capturing of rhythm abnormalities is much more difficult in these patients. Moreover, patients cannot register on the AliveCor® *Kardia* app, if they are under the age of eighteen, as all parameters have been standardised for the adult population.

This device is not intended to replace the conventional electrocardiographic system, but rather to complement it. AliveCor® provides single-lead electrocardiographic tracings, so there will always be electrocardiographic differences from a conventional 12-lead ECG. Just as the number of leads is not the same, neither is the sensitivity or the technology used in both methods.

It is true that in this study, AliveCor® was able to distinguish between episodes of sinus tachycardia and non-sinus tachycardia. And, at the same time, it was able to separate them into wide and narrow QRS, thus providing a diagnostic approach. However, the aim of AliveCor® is not to diagnose tachyarrhythmias or to distinguish between different types of tachyarrhythmias, but to improve and strengthen patient clinical follow-up.

Furthermore, AliveCor® has provided a great degree of reassurance to its users, but also, and very importantly, to the specialist physicians, enabling them to make a rapid assessment and clinical decisions to manage the condition.

AliveCor® has enabled early therapeutic decisions to be made to reverse the episode, either by telephone or by referring patients to the emergency department, without any patient becoming hemodynamically decompensated. But it has also allowed such long-term decisions to be made about the chronic management of those same patients.

AliveCor® aims to reduce the number of unnecessary hospital visits and this seems to have been achieved as the participants of this study expressed in the survey. It is also worth mentioning that the current situation regarding the COVID-19 pandemic has been a litmus test for assessing the usefulness of AliveCor® as a tool for outpatient monitoring. Not only have we been able to get continuous, close, safe and effective monitoring, but patients have not had to attend to the hospital. This has been crucial, given the epidemiological situation we live in.

Although this study was not planned as a pilot study, the small number of patients implies that it can be considered as such. In the near future, and based on the results of this study, we plan to test our hypotheses with a much larger sample. Nevertheless, this work will be submitted for publication in a scientific journal in the following three months.

12. CONCLUSIONS

The main aim of this study was to determine if remote monitoring by AliveCor® Kardia Mobile single-lead ECG device was a useful tool for outpatient monitoring of paediatric patients with history of tachyarrhythmia. After a comprehensive analysis, we established the following conclusions stating that:

- AliveCor® has been used in patients with different demographic and clinical characteristics. All patients concurred in having a history of tachyarrhythmia, whether diagnosed prenatally or postnatally (before the age of 3 years). Its use has also been evaluated in patients with both supraventricular and ventricular tachycardia, asymptomatic or not, ablated or not, and currently receiving treatment or not. In all of them, the success rate in its applicability has been very favourable.

- Only 5% of the analysed tracings obtained with AliveCor® were considered non-legible. Therefore, adequate performance can be expected from the readings of the AliveCor® recordings.

- AliveCor® has been able to identify rhythm disturbances in our population. Concretely, it has been able to distinguish between episodes of sinus tachycardia and non-sinus tachycardia (10% of the tracings). And, at the same time, it has been able to separate them into wide (30%) and narrow QRS (70%), thus providing a diagnostic approach.

- The parental perception of the usefulness of AliveCor® monitoring was rated with a high level of satisfaction, improving their child's medical surveillance. Most parents cited that the device provided them greater relief and consequently, reduced the anxiety that their child's diagnosis could bring. They appreciate the device's facility to promptly record rate and rhythm, promoting rapid and effective assessment by the specialist. At the same time, it allowed early therapeutic decisions to be made, often saving them a visit to the emergency department. It is also worth mentioning that it reduces costs to the healthcare system by avoiding unnecessary hospital visits.

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14. ANNEXES

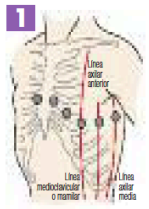
ANNEX I: systematic reading guideline of paediatric ECG

Guía rápida para la lectura sistemática del ECG pediátrico

Abreviaturas

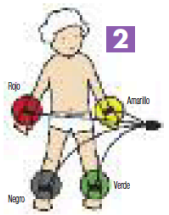
lpm: latidos por minuto. **d:** días. **m:** meses. **a:** años. **s:** semanas. **mm:** milímetros. **seg:** segundos. **LSN:** límite superior de la normalidad. **ACI:** arteria coronaria izquierda. **AP:** arteria pulmonar. **AV:** auriculoventricular. **BAV:** bloqueo auriculoventricular. **BRI:** Bloqueo de rama izquierda. **CAI:** crecimiento aurícula izquierda. **CBA:** crecimiento biauricular. **DAVD:** displasia arritmogénica ventrículo derecho. **HVI:** hipertrofia ventricular izquierda. **HVD:** hipertrofia ventricular derecha. **SQTL:** Síndrome QT largo. **SQTC:** Síndrome QT corto. **TSV:** taquicardia supraventricular. **TV:** taquicardia ventricular. **VD:** ventrículo derecho. **VI:** ventrículo izquierdo.

Colocación de los electrodos



1. Plano horizontal; derivaciones precordiales (V1-V6)
- V1: 4.º espacio intercostal derecho junto al esternón.
- V2: 4.º espacio intercostal izquierdo junto al esternón.
- V3: entre V2 y V4.
- V4: 5.º espacio intercostal izquierdo en línea medio-clavicular.
- V5: 5.º espacio intercostal izquierdo en línea axilar anterior.
- V6: 5.º espacio intercostal izquierdo en línea axilar media.

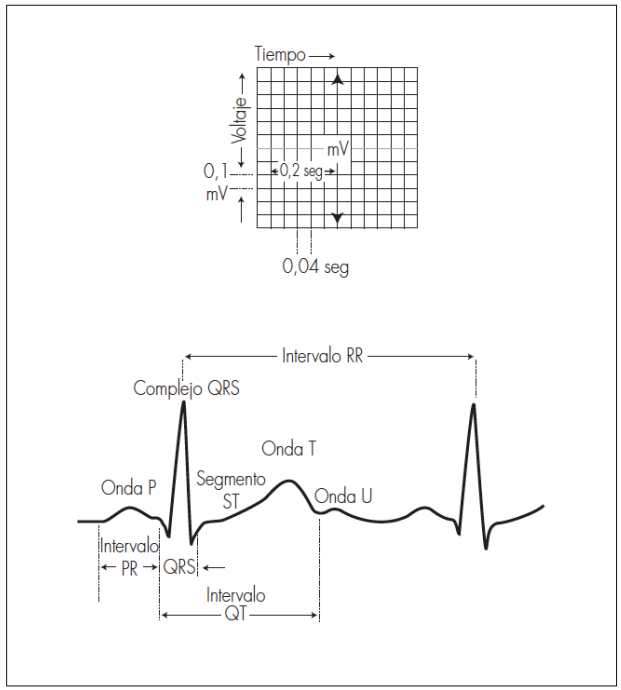
2. Plano frontal; derivaciones de los miembros (I-III, aVR, aVL, aVF)
- Se colocarán proximales a muñecas y tobillos.
- Regla nemotécnica: RANA (siguiendo la secuencia brazo derecho-brazo izquierdo-pierna derecha-pierna izquierda, dispondremos los electrodos de color Rojo-Amarillo-Negro-Verde).
- Así, dejamos situado el electrodo rojo (aVR; *right*, derecha) en la muñeca derecha; el electrodo amarillo (aVL; *left*, izquierda) en la muñeca izquierda, el electrodo negro (toma de tierra) en el tobillo derecho y el electrodo verde (aVF; *foot*, pie) en el tobillo izquierdo.



F. Javier Pérez-Lescure Picarzo
Cardiología Infantil, Hospital Universitario Fundación Alcorcón, Madrid

4ª Edición

1



- Ajustes básicos: Velocidad del papel 25 mm/seg.; Voltaje 10 mm = 1 mV.
- La amplitud de las ondas (altura o profundidad) se mide en milímetros.
- La duración de las ondas y los intervalos se calcula en tiempo (segundos), para ello se mide en milímetros y se multiplica por 0,04.

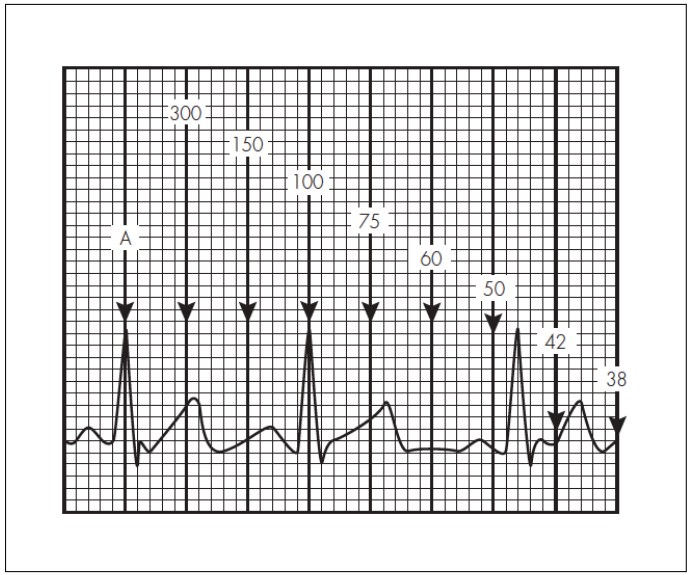
Lectura sistemática

1. Frecuencia.
2. Ritmo y eje de la onda P.
3. Eje del complejo QRS y de la onda T.
4. Onda P.
5. Complejo QRS.
6. Onda T y segmento ST.
7. Intervalos PR y QT.

2

1. Frecuencia cardiaca

Buscar una onda R que coincida con una línea vertical gruesa (A) del papel; localizar el latido siguiente; según donde se sitúe la onda R de éste podemos estimar la FC (100 lpm en el ejemplo).



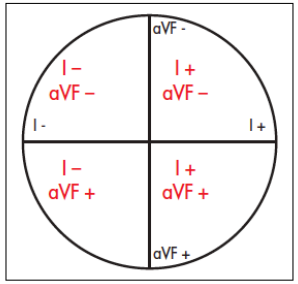
Valores normales Frecuencia cardiaca (lpm)

Edad	Rango (media)
Neonato	95 - 150 (123)
1-2 meses	121 - 179 (149)
3-5 meses	106 - 186 (141)
6-11 meses	109 - 169 (134)
1-2 años	89 - 151 (119)
3-4 años	73 - 137 (108)
5-7 años	65 - 133 (100)
8-11 años	62 - 130 (91)
12-15 años	60 - 119 (85)

2. Ritmo y eje de la onda P

En ritmo sinusal, la onda P es positiva en I y aVF y hay una onda P delante de cada complejo QRS con intervalo PR constante

Si el eje de la onda P ≠ 0-90° y hay una onda P delante de cada complejo QRS con intervalo PR constante: ritmo originado en las aurículas:



- Eje de la onda P: localizar cuadrante con derivaciones I y aVF

Eje onda P	Origen impulso auricular
Entre 0° y 90°	Porción superior AD (nodo sinusal) = normal
Entre 90° y 180°	Porción superior AI
Entre 180° y 270°	Porción inferior AI
Entre 270° y 360°	Porción inferior AD

- Si no hay onda P delante de QRS: ritmo nodal
- Si ondas P presentes pero no se relacionan con QRS: bloqueo AV de 3° grado o disociación AV.

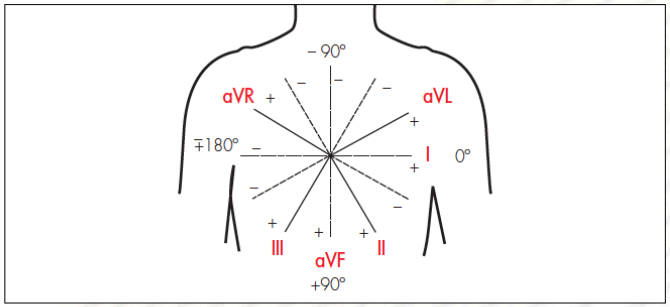
3. Eje del complejo QRS y de la onda T

Eje QRS

1. Localizar un cuadrante utilizando las derivaciones I y aVF.
2. Encontrar una derivación con complejos QRS isodifásicos (altura onda R ≃ profundidad onda S). El eje QRS será perpendicular a esta derivación dentro del cuadrante seleccionado.

Eje QRS valores normales

Edad	Media (rango)
1 semana -1 mes	+110° (de +30 hasta +180)
1 - 3 meses	+70° (de +10 hasta +125)
3 meses - 3 años	+60° (de +10 hasta +110)
> 3 años	+60° (de +20 hasta +120)



Eje de la onda T
- Normal: entre 0 y 90°

4. Onda P

- *Hipertrofia auricular derecha*: Ondas P altas (≥ 3 mm) en cualquier derivación.
- *Hipertrofia auricular izquierda*: Ondas P anchas: < 1 año: > 0,08 seg. 1-3 años: > 0,09 seg. > 3 años: > 0,10 seg.

5. Complejo QRS

Morfología del complejo QRS

Duración QRS (LSN) según edad

Edad (años)	RN -3 a	3-8 a	8-12 a	12-16 a	Adulto
Duración (seg)	0,07	0,08	0,09	0,10	0,10

Complejo QRS prolongado:
- Aparece en: bloqueos de rama, síndrome de preexcitación, bloqueo intraventricular, arritmias ventriculares.

Bloqueo incompleto de rama derecha:
- Patrón RSR'en V1, con duración normal del complejo QRS.
- La imagen RSR' en V1 es normal siempre que:
  - La duración del QRS no esté aumentada.
  - R' < 15 mm en menores de 1 año de edad y < 10 mm en mayores de 1 año.

Bloqueo completo de rama derecha:
- Desviación del eje QRS a la derecha.
- Patrón RSR'en V1, con duración del complejo QRS > LSN.
- S ancha y empastada en I, V5 y V6.
- R' empastada terminal en aVR y V2.

Hemibloqueo anterior izquierdo:
- Desviación izquierda del eje QRS (-30° a -90°) con duración normal.
- Complejo rS en II, III y aVF.
- Complejo qR en I y aVL.

Hemibloqueo posterior izquierdo:
- Desviación derecha del eje QRS (de +120 a +180°)
- Complejo rS en I y aVL.
- Complejo qR en II, III y aVF.

Bloqueo completo de rama izquierda:
- Desviación del eje QRS a la izquierda para la edad del paciente.
- Duración del QRS > LSN para la edad.
- Ondas R empastadas y anchas con ausencia de Q en I, aVL, V5 y V6.
- Ondas S anchas en V1 y V2.

Amplitud del complejo QRS

Voltajes ondas R y S según derivación y edad. Media y (p98)

	Amplitud en V1 (mm)		Amplitud en V6 (mm)	
Edad	R	S	R	S
< 1 d	13,8 (26,1)	8,5 (22,7)	4,2 (11,1)	3,2 (9,6)
1 - 2 d	14,1 (26,9)	9,1 (20,7)	4,5 (12,2)	3,0 (9,4)
3 - 6 d	12,9 (24,2)	6,6 (16,8)	5,2 (12,1)	3,5 (9,8)
1 - 3 s	10,6 (20,8)	4,2 (10,8)	7,6 (16,4)	3,4 (9,8)
1 - 2 m	9,5 (18,4)	5,0 (12,4)	11,6 (21,4)	2,7 (6,4)
3 - 5 m	9,8 (19,8)	5,7 (17,1)	13,1 (22,4)	2,9 (9,9)
6 - 11 m	9,4 (20,3)	6,4 (18,1)	12,6 (22,7)	2,1 (7,2)
1 - 2 a	8,9 (17,7)	8,4 (21,0)	13,1 (22,6)	1,9 (6,6)
3 - 4 a	8,1 (18,2)	10,2 (21,4)	14,8 (24,2)	1,5 (5,2)
5 - 7 a	6,7 (13,9)	12,0 (23,8)	16,3 (26,5)	1,2 (4,0)
8 - 11 a	5,4 (12,1)	11,9 (25,4)	16,3 (25,4)	1,0 (3,9)
12 - 15 a	4,1 (9,9)	10,8 (21,2)	14,3 (23,0)	0,8 (3,7)

Complejos QRS con aumento de la amplitud:
- Hipertrofia ventricular, alteraciones de la conducción intraventricular (bloqueos de rama, síndromes de preexcitación).

Complejos QRS con disminución de la amplitud:
- Pericarditis, miocarditis, hipotiroidismo.

Hipertrofia ventricular derecha:
Uno o más de:
- R en V1 > p98.
- S en V6 > p98.
- T positiva en V1 después del 4º día de vida y antes de los 10 años.
- Complejo qR en V1.
- Complejo RSR´ en V1 con R´>15 mm en menores de 1 año; ó >10 mm en mayores de 1 año.
- Aumento de la relación R/S en V1.
- Desviación del eje a la derecha.

Hipertrofia ventricular izquierda:
Uno o más de:
- R en V6 > p98.
- Onda Q > 4 mm en V5 o V6.
- R en V1 por debajo del percentil 5.
- S en V1 > p98.
- Desviación del eje a la izquierda.

Onda Q
- Puede estar presente en I, II, III, aVL y AVF y casi siempre también en V5 y V6. Se consideran anormales cuando son de duración superior a 0,03 seg, o amplitud por encima del LSN. La amplitud varía con la edad y la derivación. Se considera amplitud normal: < 2 mm en aVL, < 3 mm en I y < 4 mm en II y aVF. En III y V6 varía ampliamente según la edad.
- Ondas Q patológicas: presente en V1 (hipertrofia ventricular derecha), profundas en V6 (hipertrofia ventricular izquierda), ausente en V6 (bloqueo de rama izquierda), anormalmente profundas (hipertrofia ventricular o sobrecarga de volumen), anormalmente profundas y anchas (infarto de miocardio o fibrosis).

Amplitud de la onda Q. Valores p98 (mm) según la edad en III y V6

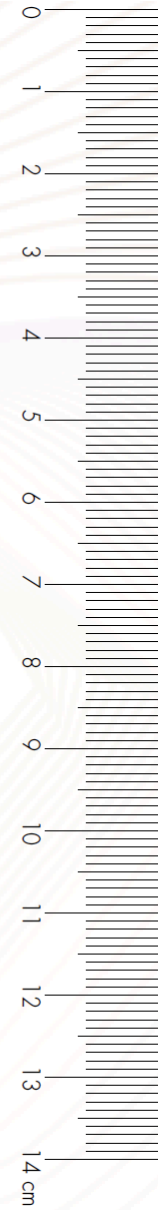
	< 1 día	1-2 d	3-6 d	1-3 s	1-2 m	3-5 m
III	4,5	6,5	5,5	6	7,5	6,5
V6	2	2,5	3	3	3	3

	6-11 m	1-2 a	3-4 a	5-7 a	8-11 a	12-15 a
III	8,5	6	5	4	3	3
V6	3	3	3,5	4,5	3	3

Progresión RS
- En los adultos y en los niños mayores de tres años:
  - R pequeña y S dominante en V1.
  - R y S similares en V2 y V3.
  - R dominantes en V4-V6.
- Neonatos:
  - R dominante en V1 y V2.
  - S dominante en V5 y V6.
- Progresión anormal sugiere: hipertrofia ventricular, alteraciones de la conducción ventricular o infarto de miocardio.

6. Onda T y segmento ST

Onda T
- Positiva en V1 durante los primeros días de vida.
- Negativa de V1-V3 desde los 7 días hasta los 10 años de edad ("patrón infantil"), ocasionalmente persiste durante adolescencia ("persistencia patrón infantil").

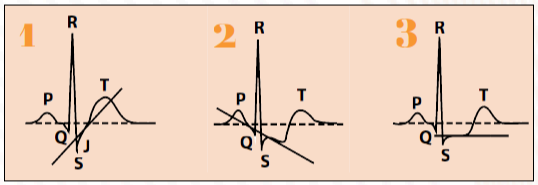


- Siempre positivas en V5-V6 a partir de las 48 horas de vida; si invertidas sugiere: hipertrofia ventricular izquierda grave, miocarditis, pericarditis o isquemia miocárdica.
- **Ondas T altas y picudas:** hiperpotasemia, sobrecarga de volumen ventrículo izquierdo, repolarización precoz.
- **Ondas T aplanadas:** hipotiroidismo, hipopotasemia, digital, pericarditis, miocarditis, isquemia miocárdica.

Segmento ST

- El segmento ST no debe estar elevado más de 1 mm, ni descendido más de 0,5 mm en ninguna derivación, en los niños.
- "Repolarización precoz" (variante normal en adolescentes sanos): elevación del segmento ST < 4 mm en las derivaciones laterales (V4-V6) e inferiores (I, III y AVF) acompañado de ondas T altas.
- Desviaciones segmento ST:

1. Con inclinación del segmento ST "hacia arriba" (habitualmente normal)
2. Con inclinación del segmento ST "hacia abajo" (habitualmente anormal)
3. Con desviación horizontal del segmento ST (habitualmente anormal)

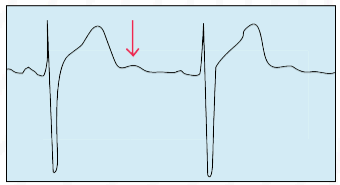


Tomado de: Park MK. How to read pediatric ECGs. 4ª ed. Filadelfia, Mosby, 2006

- Desviaciones anormales del segmento ST, sospechar: pericarditis, isquemia miocárdica, hipertrofia ventricular izquierda o derecha graves, efecto digitálico, miocarditis o alteraciones hidroelectrolíticas.

Onda U

- Deflexión positiva justo después de la onda T, puede ser un hallazgo normal con frecuencia cardiaca baja o aparecer en hipopotasemia.



7. Intervalos PR y QT

Intervalo PR

- PR corto sugiere: preexcitación (síndrome Wolf-Parkinson-White), enfermedades por depósito de glucógeno.
- PR largo: bloqueo AV de primer grado (intervalo PR > LSN), sugiere: miocarditis, alteraciones electrolíticas, hiperpotasemia, intoxicación digital, ingesta de fármacos o personas normales con aumento del tono vagal.
- PR variable: marcapasos auricular migratorio, bloqueo AV de 2º grado Mobitz 1.

Intervalo PR; limites inferior y superior normalidad (seg.)

Límite inferior	Edad	Límite superior
0,08	< 1 día	0,16
	1 día a 3 semanas	0,14
	1 a 2 meses	0,13
	3 a 5 meses	0,15
	6 a 11 meses	0,16
	12 a 35 meses	0,15
0,10	3 a 7 años	0,16
	8 a 11 años	0,17
	12 a 15 años	0,18
0,12	Adulto	0,20

Intervalo QT

- El intervalo QT se mide desde el inicio del complejo QRS hasta el final de la onda T, en derivaciones donde haya onda Q (habitualmente II o V5). El intervalo QT debe corregirse en función de la frecuencia instantánea, mediante la fórmula:
  Intervalo QTc = Intervalo QT (en seg.) / $\sqrt{}$ Intervalo RR previo (en seg.)
  (QTc: QT corregido. QT: QT medido).
  Valor normal intervalo QTc: 0,35-0,45 seg.
  En caso de arritmia sinusal, se deben hacer varias mediciones y calcular el QTc "medio". La onda U claramente separada de la onda T debe excluirse de la medición del intervalo QT. Si no se ve bien el final de la onda T se puede utilizar el método de la tangente donde se considera que la onda T acaba en la intersección de la tangente de la porción más inclinada de la rama descendente de la onda T y la línea de base.
- Intervalo QT prolongado: hipocalcemia, miocarditis, enfermedades miocárdicas difusas, traumatismo craneal y síndrome de QT largo, fármacos (eritromicina, antihistamínicos).
- Intervalo QT corto: hipercalcemia, efecto digitálico, síndrome QT corto.

Depósito Legal: M-8574-2014 ■ ISBN: 978-84-92848-02-7

ANNEX II: CEIC's authorization

Fundació Sant Joan de Déu

CIEC Sant Joan de Déu Foundation

Report of favorable ruling
Biomedical research project

C.I. PIC-169-17

December 20, 2017

Dr. Pablo Ferrer Salvans
Secretary, CIEC, Sant Joan de Déu Foundation

CERTIFIES

1. That the CIEC of the Sant Joan de Déu Foundation, meeting December 18, 2017, has evaluated the following proposed study:

Title: ***"Wolff-Parkinson-White Syndrome in Children"***
Internal code: PIC-169-17
IP: Georgia Sarquella Brugada

2. And has recognized that:

- The proposed project is consistent with the requirements set out in the Law 14/2007, dated July 3, concerning biomedical research, and that it is of relevance.
- The project meets the requirements of the protocol in relation to the aims of the study, and the risks and inconveniences that may be entailed for the subjects in carrying it out are justified.
- The procedure for obtaining informed consent as well as the compensation foreseen for the subjects in the event of damages that may arise from their participation in the study are appropriate.
- The scope of the financial compensation foreseen does not imply any conflict with the applicable ethical guidelines.
- The qualifications of the researchers and the means at their disposal are appropriate for the study to be carried out.

3. In light of the foregoing the CIEC has given a **FAVORABLE RULING**.

4. This CEIC approves of the study's being carried out under the auspices of the following CIEC/research center(s):

CIEC Sant Joan de Déu Foundation	**Dra. Georgia Sarquella Brugada** *Hospital Sant Joan de Déu*

Esplugues de Llobregat, December 20, 2017

Fundació Sant Joan de Déu
Comitè Ètic d'Investigació Clínica

Dr. Pablo Ferrer Salvans
Secretary, CIEC, Sant Joan de Déu Foundation

Edifici Docent Sant Joan de Déu - c. Santa Rosa, 39-57, 3a planta, 08950 Esplugues de Llobregat / Barcelona
Telèfon + 34 93 600 97 51 - Fax + 34 93 600 97 71 e-mail: info@fsjd.org web: www.fsjd.org

ANNEX III: Survey of AliveCor® evaluation

1 NÚMERO DE PACIENT

2 On acostumeu a col·locar el dispositiu d'AliveCor per obtenir un registre?

Instrucciones de pregunta: *Seleccione una respuesta*

○ Pit ○ Mitjançant els dits
○ Altres:

3 Com de fàcil li ha semblat obtenir un traçat amb AliveCor? Valori-ho de l'1 al 5, sent 1 molt poc fàcil i 5 molt fàcil

☆☆☆☆☆ / 5

4 Una vegada obtingut el traçat, com de fàcli li ha semblat enviar-lo? Valori-ho de l'1 al 5, sent 1 molt poc fàcil i 5 molt fàcil

☆☆☆☆☆ / 5

5 Sent vostè que l'ús de la monitorització domiciliària amb AliveCor ha reduït la necessitat de consultes a urgències per atendre al seu fill/a?

Instrucciones de pregunta: *Seleccione una respuesta*

○ SÍ ○ NO

6 De l'1 al 5, com valoraria la tranquilitat que li ha oferit la monitorització domiciliària amb AliveCor? Sent 1 molt poca tranquilitat i 5 molta tranquilitat

☆☆☆☆☆ / 5

7 Sent vostè que la monitorització domiciliària amb AliveCor, reforça el seguiment del seu fill/a? Valori-ho de l'1 al 5, sent 1 la reforça molt poc i 5 la reforça molt

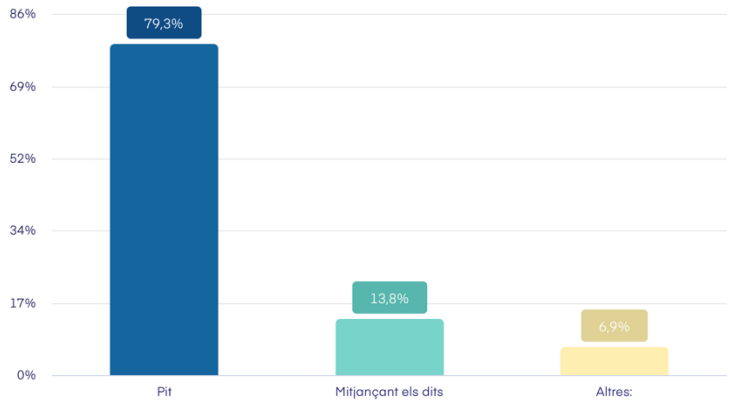
☆☆☆☆☆ / 5

8 Sent vostè que la monitorització domiciliària amb AliveCor, li facilita l'accessibilitat a l'atenció mèdica? Valori-ho de l'1 al 5, sent 1 la facilita molt poc i 5 la facilita molt

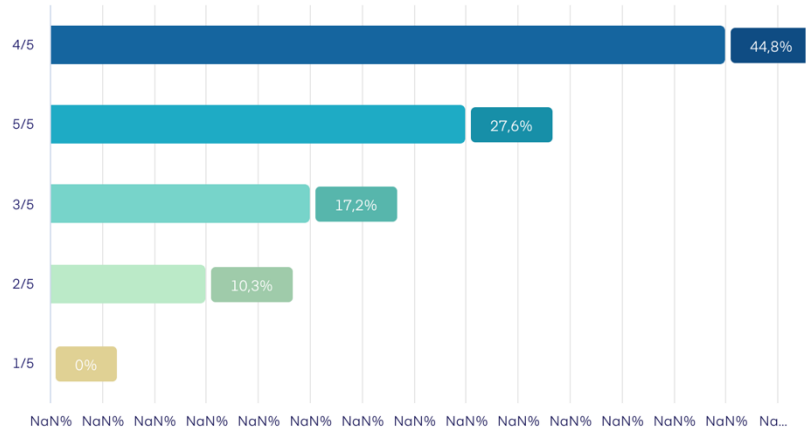
☆☆☆☆☆ / 5

ANNEX IV: Results of the survey about AliveCor®

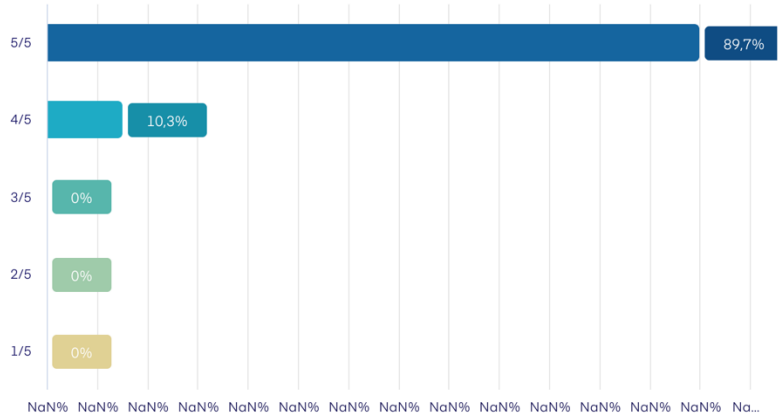
2. On acostumeu a col·locar el dispositiu d'AliveCor per obtenir un registre?



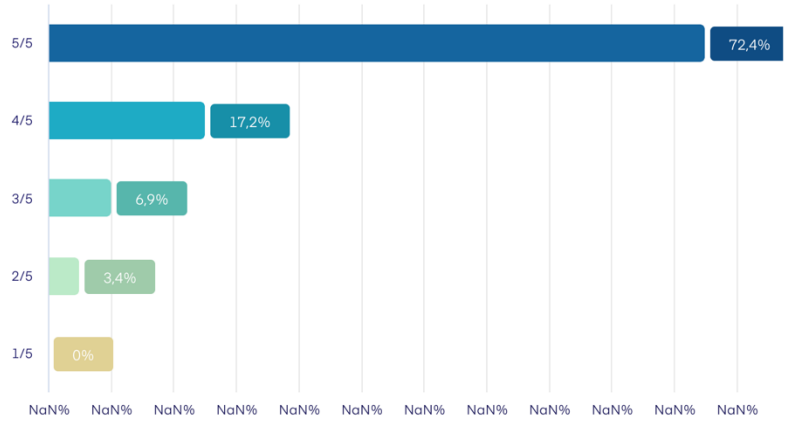
3. Com de fàcil li ha semblat obtenir un traçat amb AliveCor? Valori-ho de l'1 al 5, sent 1 molt poc fàcil i 5 molt fàcil



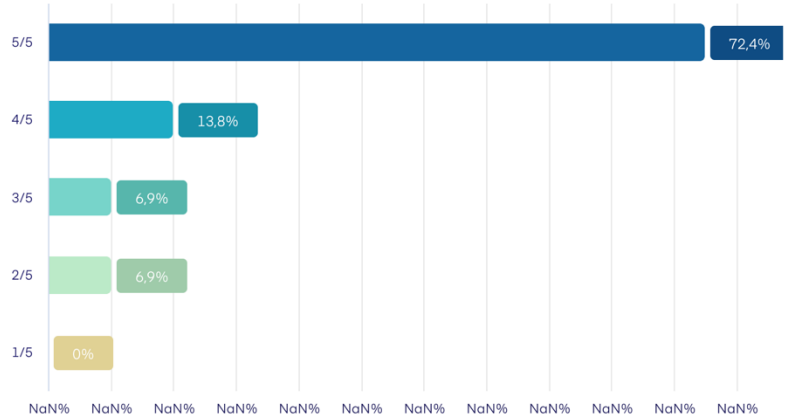
4. Una vegada obtingut el traçat, com de fàcli li ha semblat enviar-lo? Valori-ho de l'1 al 5, sent 1 molt poc fàcil i 5 molt fàcil



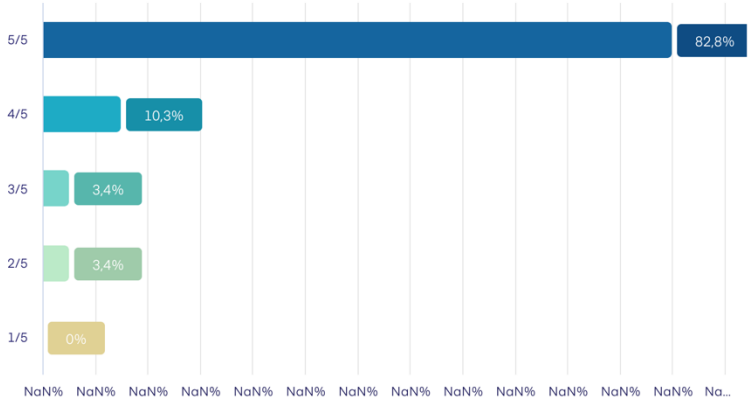
6. De l'1 al 5, com valoraria la tranquilitat que li ha oferit la monitorització domiciliària amb AliveCor? Sent 1 molt poca tranquilitat i 5 molta tranquilitat



7. Sent vostè que la monitorització domiciliària amb AliveCor, reforça el seguiment del seu fill/a? Valori-ho de l'1 al 5, sent 1 la reforça molt poc i 5 la reforça molt



8. Sent vostè que la monitorització domiciliària amb AliveCor, li facilita l'accessibilitat a l'atenció mèdica? Valori-ho de l'1 al 5, sent 1 la facilita molt poc i 5 la facilita molt



ANNEX V INTEROBSERVER CONCORDANCE

Table 5: Summary of interobserver concordance of AliveCor® tracing readings

INTEROBSERVER CONCORDANCE OF ALIVECOR® TRACING READINGS

	Coeficiente (kappa o CCI)	***P***
LEGIBLE	0,983	<0,001
RITMO SINUSAL	0,67	<0,01
TAQUICARDIA	0,963	<0,001
TIPO DE TAQUICARDIA	0.91	< 0.001
FRECUENCIA CARDIACA	0.99	< 0.001
PR	0.82	< 0.001
QRS	0.86	< 0.001
QTC	0.83	< 0.001

ICC: COEFICIENTE DE CORRELACIÓN INTRACLASE;