CHALECO MULTIDETECTOR PARA MAPEO NO INVASIVO DE ARRITMIAS CARDIACAS COMPLEJAS

Título del documento	**Chaleco multidetector para mapeo no invasivo de arritmias cardiacas complejas**
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1. INTRODUCCIÓN

Los sistemas de mapeo no invasivo son una tecnología diagnóstica novedosa. Permiten el estudio detallado de diversas arritmias cardiacas mediante la exploración de la señal electrocardiográfica de superficie. Su carácter no invasivo lo diferencia de los sistemas disponibles en la actualidad en nuestro medio, con los cuales la caracterización de los mecanismos que dan lugar a las arritmias cardiacas y la aplicación de métodos para identificar su origen han de desarrollarse de forma invasiva mediante técnicas de cateterismo cardiaco.

Los procedimientos invasivos mediante cateterismo cardiaco, en ocasiones tienen resultados limitados: según la patología la tasa de recurrencia se sitúa en torno al 50% al año, en ocasiones no son bien tolerados y se recurre frecuentemente al empleo de fármacos anti-arrítmicos con eficacia limitada y toxicidad elevada (por ejemplo, amiodarona). Además la monitorización de los movimientos de los catéteres dentro del sistema cardiovascular es factible gracias al uso de fluoroscopia, que es fuente de efectos nocivos tanto para los pacientes como para los profesionales.

La muerte súbita secundaria a arritmias ventriculares tiene un gran impacto socioeconómico, con una incidencia en Europa de 400.000 muertes anuales, que en un 40% acontecen antes de los 65 años (1). Las taquicardias ventriculares son prevalentes en nuestro medio condicionan el implante de un desfibrilador en aproximadamente a más de ciento cincuenta pacientes al año; con unos costes unitarios muy elevados (aproximadamente unos 15.000euros). Su tratamiento mediante ablación se ve en ocasiones limitado por la intolerabilidad de la arritmia, lo cual impide localizar adecuadamente el sustrato de la arritmia.

La solicitud de esta tecnología es para diagnóstico de pacientes con arritmias cardiacas complejas: taquicardias y fibrilación ventricular, cuyo estudio no es posible por métodos convencionales dada su mala tolerancia hemodinámica y riesgo de complicaciones. Utilizando el chaleco multidetector para mapeo no invasivo en estos pacientes.

El mapeo no invasivo de las arritmias cardiacas se desarrolla con la utilización de un chaleco con electrodos distribuidos sobre la superficie del torso del paciente, junto con un entorno informático necesario hardware y software, que sería cedido por la compartía fabricante Cardioinsight, Medtronic. La información eléctrica del corazón obtenida con ese análisis se cruza con los datos de anatomía del paciente definidos en una tomografía computerizada (TC) realizada con el propio chaleco el mismo día del procedimiento y así mostrar los mapas cardiacos tridimensionales biauriculares y biventriculares, proporcionando información para el diagnostico que permite determinar el origen de la arritmia antes de realizar el estudio electrofisiológico invasivo con catéter.

Este chaleco de un solo uso, se considera material fungible, al tratarse de 250 electrodos que se adhieren directamente a la superficie corporal del paciente distribuidos en tres paneles: delantero izquierdo, delantero derecho y trasero. Los paneles son de licra y están en contacto con la piel por la capa de adhesivo y el gel, conectándose al equipo cardioinsight por unos cables. El chaleco se suministra en cuatro tamaños y el precio de cada uno es de 3000 euros más un 21% de IVA.

Los pacientes candidatos según la solicitud serían aquellos con arritmias cardiacas complejas y con enfermedades arritmogénicas (miocardiopatía hipertrófica, Sd de Brugada, etc) con alto riesgo de muerte súbita y cuyo estudio no es posible por métodos convencionales dada su mala tolerancia hemodinámica. En Asturias, se calcula unos 20-30 pacientes/año según datos aportados por la unidad de arritmias del Hospital Central de Asturias.

A diferencia del método utilizado en la actualidad, la tecnología propuesta no precisa de la utilización de radiaciones ionizantes para el diagnóstico de la localización con el mapeo no invasivo, aunque sí precisa de la realización de un estudio previo con TC.

2. ¿ES UNA PRESTACIÓN DE LA CARTERA DE SERVICIOS DEL SISTEMA NACIONAL DE SALUD?

Esta tecnología podría quedar incluida en el apartado 5.1.7, en este sentido la Cartera de Servicios tiende a ser generalista y no especificar los procedimientos diagnósticos o terapéuticos.

5. Indicación o prescripción, y la realización, en su caso, de procedimientos diagnósticos y terapéuticos

5.1 Técnicas y procedimientos precisos para el diagnóstico y tratamiento médico y quirúrgico de las siguientes patologías clasificadas según la Clasificación Internacional de Enfermedades:

5.1.7. Enfermedades del sistema circulatorio: Fiebre reumática aguda, enfermedad cardiaca reumática crónica, enfermedad hipertensiva, cardiopatía isquémica, enfermedades de la circulación pulmomar, otras formas de enfermedad cardiaca, enfermedad cerebrovascular, enfermedades de las arterias, arteriolas y capilares y enfermedades de venas y linfáticos y otras enfermedades del aparato circulatorio.

3. ¿ESTÁ CONSIDERADA UNA TECNOLOGÍA SANITARIA (TS) EMERGENTE PROPUESTA PARA SU PRIORIZACIÓN Y EVALUACIÓN DENTRO DE LA COMISIÓN DE PRESTACIONES ASEGURAMIENTO Y FINANCIACIÓN (CPAF) DE LA SUBDIRECCIÓN GENERAL DE CALIDAD Y COHESIÓN DEL MSSSI?

No está considerada una tecnología sanitaria emergente propuesta para evaluación en 2018. Ni tampoco se ha priorizado para que la Red de Agencias de Evaluación de Tecnologías Sanitarias realice un informe de evaluación para el año 2019.

4. ¿HAY INFORME DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS REALIZADO POR UNA AGENCIA DE EVALUACIÓN DE TS O REVISIONES SISTEMÁTICAS DE LA LITERATURA?

Se realizaron tres búsquedas en la literatura científica siguiendo la metodología para búsquedas rápidas:

1. NHS Centre for Reviews and Dissemination (CRD) que incluye
    a. -DARE (Database of Abstracts of Reviews of Effects): contiene resúmenes de artículos que valoran y sintetizan RS de efectividad.
    b. -NHS EED: contiene resúmenes de artículos sobre evaluaciones económicas de intervenciones en atención sanitaria.
    c. -HTA (Health Technology Assessment): contiene informes de evaluación de tecnologías sanitarias e información de proyectos en curso realizados por las mismas agencias.
    d. -INAHTA: informes de otras agencias o unidades de Evaluación de Tecnologías Sanitarias. Incluye los informes de la Red Española de Agencias de EvTS.
    e. -EuroScan International Network: informes de tecnologías nuevas y emergentes.
2. Biblioteca Cochrane Plus
3. PubMed (Embase)

Palabras clave: cardioinsight, noninvasive mapping three dimensional.

Fechas: 2013 a enero 2019

No se encontraron informes de evaluación de esta nueva tecnología sanitaria en las bases consultadas.

En la biblioteca Cochrane se encontró un ensayo clínico, que se detalla a continuación.

Damir Erkapic Harald Greiss Dmitri Pajitnev Sergey Zaltsberg Nicolas Deubner Alexander Berkowitsch Susanne Möllman Johannes Sperzel Andreas Rolf Jörn Schmitt. Clinical impact of a novel three-dimensional electrocardiographic imaging for non-invasive mapping of ventricular arrhythmias—a prospective randomized trial. EP Europace, Volume 17, Issue 4, 1 April 2015, Pages 591–597, https://doi.org/10.1093/europace/euu282 (2)

Aims: ECVUE™ technology, a novel, three-dimensional, non-invasive mapping system, offers a unique arrhythmia characterization and localization. We sought to evaluate the clinical impact of this system in routine clinical mapping and ablation of ventricular arrhythmias (VAs).

Methods and results: Patients with monomorphic premature ventricular contractions with or without monomorphic ventricular tachycardia were enrolled prospectively and randomized into two groups: ventricular ectopy localization using either 12-lead electrocardiogram (ECG) algorithms or with ECVUE™, followed by conventional guided ablation. Forty-two patients were enrolled in the study. The ECVUE™ system accurately identified both the chamber and sub-localized the VA origin in 20 of 21 (95.2%) patients. In contrast, using 12-lead ECG algorithms, the chamber was accurately diagnosed in 16 of 21 (76.2%) patients, while the arrhythmia origin in

only 8 of 21 (38.1%), (*P* = 0.001 vs. ECVUE™). Acute success in ablation was achieved in all patients. Regarding the number of radiofrequency-energy applications (in total 2 vs. 4, *P* = 0.005) in the ECVUE™ arm, ablation was more precise than the ECG group which used standard of care activation and pace mapping-guided ablation. Three months success in ablation was 95.2% for the ECVUE™ and 100% for the ECG group (*P* = ns). Time to ablation was 35.3 min in the conventional arm and 24.4 min in ECVUE Group, (*P* = 0.035). The X-ray radiation exposure was 3.21 vs. 0.39 mSv, *P* = 0.001 for the ECVUE™ group and ECG group.

Conclusion: ECVUE™ technology offers a clinically useful tool to map VAs with high accuracy and more targeted ablations superior to the body surface ECG but had significantly higher radiation exposure due to computed tomography scan.

En Embase se recuperaron 11 estudios observacionales, que se exponen a continuación.

Ehrlich MP, Laufer G, Coti I, Peter M, Andreas M, Stix G, Ad N. Noninvasive mapping before surgical ablation for persistent, long-standing atrial fibrillation. J Thorac Cardiovasc Surg. 2019 Jan;157(1):248-256. doi: 10.1016/j.jtcvs.2018.07.104. Epub 2018 Sep 25. (3)

Objective: The study objective was to study the electrophysiologic mechanism of atrial fibrillation using a noninvasive, beat-by-beat, 3-dimensional mapping technique in patients with persistent and long-standing persistent atrial fibrillation undergoing concomitant surgical ablation.

Methods: In this pilot trial, 10 patients (6 male; mean age, 70 ± 10 years) with persistent atrial fibrillation were mapped preoperatively with a noninvasive surface system (ECVUE, CardioInsight, Medtronic Inc, Minneapolis, Minn). Eight patients were candidates for mitral valve surgery, 1 patient was a candidate for aortic valve and ascending aortic replacement, and 1 patient was a candidate for coronary bypass surgery. In 5 patients, tricuspid valve repair was also performed. The Cox-Maze III/IV was performed using combined cryoablation and bipolar radiofrequency, and the left appendage was removed in all cases. The median preprocedural duration of atrial fibrillation was 30 months, and the diameter of the left atrium was 63mm. Atrial regions were divided according to the Bordeaux classification.

Results: Preoperative mapping was successful in all patients with clear identification of the potential mechanism of atrial fibrillation. Biatrial pathology was recognized in all subjects. Rotor and macro re-entry activity were present in all patients, whereas focal activity was demonstrated in only 6 patients. Rotor activity in the right atrium was documented in all patients.

Conclusions: This is the first report on the preoperative use of the ECUVE in surgical candidates for concomitant surgical procedures. The fact that a biatrial mechanism for atrial fibrillation was detected in all patients emphasizes the importance of a Cox-Maze III/IV procedure to treat patients with valvular heart disease and nonparoxysmal atrial fibrillation. Preoperative mapping has the potential to significantly improve our understanding of the pathophysiology in atrial fibrillation and better guide the surgical ablation procedure of choice in a single patient.

Zhang J, Sacher F, Hoffmayer K, O'Hara T, Strom M, Cuculich P, Silva J, Cooper D, Faddis M, Hocini M, Haïssaguerre M, Scheinman M, Rudy Y. Cardiac electrophysiological substrate underlying the ECG phenotype and electrogram abnormalities in Brugada syndrome patients. Circulation. 2015 Jun 2;131(22):1950-9. doi: 10.1161/CIRCULATIONAHA.114.013698. Epub 2015 Mar 25. (4)

Background**:** Brugada syndrome (BrS) is a highly arrhythmogenic cardiac disorder, associated with an increased incidence of sudden death. Its arrhythmogenic substrate in the intact human heart remains ill-defined.

Methods and results**:** Using noninvasive ECG imaging, we studied 25 BrS patients to characterize the electrophysiological substrate and 6 patients with right bundle-branch block for comparison. Seven healthy subjects provided control data. Abnormal substrate was observed exclusively in the right ventricular outflow tract with the following properties (in comparison with healthy controls; P<0.005): (1) ST-segment elevation and inverted T wave of unipolar electrograms (2.21±0.67 versus 0 mV); (2) delayed right ventricular outflow tract activation (82±18 versus 37±11 ms); (3) low-amplitude (0.47±0.16 versus 3.74±1.60 mV) and fractionated electrograms, suggesting slow discontinuous conduction; (4) prolonged recovery time (381±30 versus 311±34 ms) and activation-recovery intervals (318±32 versus 241±27 ms), indicating delayed repolarization; (5) steep repolarization gradients (Δrecovery time/Δx=96±28 versus 7±6 ms/cm, Δactivation-recovery interval/Δx=105±24 versus 7±5 ms/cm) at right ventricular outflow tract borders. With increased heart rate in 6 BrS patients, reduced ST-segment elevation and increased fractionation were observed. Unlike BrS, right bundle-branch block had delayed activation in the entire right ventricle, without ST-segment elevation, fractionation, or repolarization abnormalities on electrograms**.**

Conclusions: The results indicate that both slow discontinuous conduction and steep dispersion of repolarization are present in the right ventricular outflow tract of BrS patients. ECG imaging could differentiate between BrS and right bundle-branch block.

Erkapic D, Neumann T. Ablation of premature ventricular complexes exclusively guided by three-dimensional noninvasive mapping. Card Electrophysiol Clin. 2015 Mar;7(1):109-15. doi: 10.1016/j.ccep.2014.11.010. Epub 2014 Dec 12 (5)

Preprocedural detailed characterization of premature ventricular complexes before ablation, currently limited to the 12-lead electrocardiogram, may aid in planning and improve procedural outcomes. This article summarizes current published data on feasibility, accuracy, and impact on clinical outcomes of a novel, three-dimensional, noninvasive, single-beat mapping system (ECVUE, CardioInsight). ECVUE technology offers premature ventricular complex characterization and localization with clinically relevant accuracy and performance superior to the surface electrocardiogram. With its noninvasive and single beat advantages, ECVUE has the potential to simplify mapping, and reduce ablation and procedural time.

Jamil-Copley S, Bokan R, Kojodjojo P, Qureshi N, Koa-Wing M, Hayat S, Kyriacou A, Sandler B, Sohaib A, Wright I, Davies DW, Whinnett Z, S Peters N, Kanagaratnam P, Lim PB. Noninvasive electrocardiographic mapping to guide ablation of outflow tract ventricular arrhythmias. Heart Rhythm. 2014 Apr;11(4):587-94. doi: 10.1016/j.hrthm.2014.01.013. Epub 2014 Jan 17 (6)

Background: Localizing the origin of outflow tract ventricular tachycardias (OTVT) is hindered by lack of accuracy of electrocardiographic (ECG) algorithms and infrequent spontaneous premature ventricular complexes (PVCs) during electrophysiological studies.

Objectives: To prospectively assess the performance of noninvasive electrocardiographic mapping (ECM) in the pre-/periprocedural localization of OTVT origin to guide ablation and to compare the accuracy of ECM with that of published ECG algorithms.

Methods: Patients with symptomatic OTVT/PVCs undergoing clinically indicated ablation were recruited. The OTVT/PVC origin was mapped preprocedurally by using ECM, and 3 published ECG algorithms were applied to the 12-lead ECG by 3 blinded electrophysiologists. Ablation was guided by using ECM. The OTVT/PVC origin was defined as the site where ablation caused arrhythmia suppression. Acute success was defined as abolition of ectopy after ablation. Medium-term success was defined as the abolition of symptoms and reduction of PVC to less than 1000 per day documented on Holter monitoring within 6 months.

Results: In 24 patients (mean age 50 ± 18 years) recruited ECM successfully identified OTVT/PVC origin in 23/24 (96%) (right ventricular outflow tract, 18; left ventricular outflow tract, 6), sublocalizing correctly in 100% of this cohort. Acute ablation success was achieved in 100% of the cases with medium-term success in 22 of 24 patients. PVC burden reduced from 21,837 ± 23,241 to 1143 ± 4039 ($P < .0001$). ECG algorithms identified the correct chamber of origin in 50%-88% of the patients and sublocalized within the right ventricular outflow tract (septum vs free-wall) in 37%-58%.

Conclusions: ECM can accurately identify OTVT/PVC origin in the left and the right ventricle pre- and periprocedurally to guide catheter ablation with an accuracy superior to that of published ECG algorithms.

Shah AJ, Hocini M, Xhaet O, Pascale P, Roten L, Wilton SB, Linton N, Scherr D, Miyazaki S, Jadidi AS, Liu X, Forclaz A, Nault I, Rivard L, Pedersen ME, Derval N, Sacher F, Knecht S, Jais P, Dubois R, Eliautou S, Bokan R, Strom M, Ramanathan C, Cakulev I, Sahadevan J, Lindsay B, Waldo AL, Haissaguerre M. Validation of novel 3-dimensional electrocardiographic mapping of atrial tachycardias by invasive mapping and ablation: a multicenter study. J Am Coll Cardiol. 2013 Sep 3;62(10):889-97. doi: 10.1016/j.jacc.2013.03.082. Epub 2013 May 30. (7)

Objectives: This study prospectively evaluated the role of a novel 3-dimensional, noninvasive, beat-by-beat mapping system, Electrocardiographic Mapping (ECM), in facilitating the diagnosis of atrial tachycardias (AT).

Background: Conventional 12-lead electrocardiogram, a widely used noninvasive tool in clinical arrhythmia practice, has diagnostic limitations.

Methods: Various AT (de novo and post-atrial fibrillation ablation) were mapped using ECM followed by standard-of-care electrophysiological mapping and ablation in 52 patients. The ECM consisted of recording body surface electrograms from a 252-electrode-vest placed on the torso combined with computed tomography-scan-based biatrial anatomy (CardioInsight Inc., Cleveland, Ohio). We evaluated the feasibility of this system in defining the mechanism of AT-macro-re-entrant (perimitral, cavotricuspid isthmus-dependent, and roof-dependent circuits) versus centrifugal (focal-source) activation-and the location of arrhythmia in centrifugal AT. The accuracy of the noninvasive diagnosis and detection of ablation targets was evaluated vis-à-vis subsequent invasive mapping and successful ablation.

Results: Comparison between ECM and electrophysiological diagnosis could be accomplished in 48 patients (48 AT) but was not possible in 4 patients where the AT mechanism changed to another AT (n = 1), atrial fibrillation (n = 1), or sinus rhythm (n = 2) during the electrophysiological procedure. ECM correctly diagnosed AT mechanisms in 44 of 48 (92%) AT: macro-re-entry in 23 of 27; and focal-onset with centrifugal activation in 21 of 21. The region of interest for focal AT perfectly matched in 21 of 21 (100%) AT. The 2:1 ventricular conduction and low-amplitude P waves challenged the diagnosis of 4 of 27 macro-re-entrant (perimitral) AT that can be overcome by injecting atrioventricular node blockers and signal averaging, respectively.

Conclusions: This prospective multicenter series shows a high success rate of ECM in accurately diagnosing the mechanism of AT and the location of focal arrhythmia. Intraprocedural use of the system and its application to atrial fibrillation mapping is under way.

Hocini M, Shah AJ, Neumann T, Kuniss M, Erkapic D, Chaumeil A, Copley SJ, Lim PB, Kanagaratnam P, Denis A, Derval N, Dubois R, Cochet H, Jais P, Haissaguerre M. Focal Arrhythmia Ablation Determined by High-Resolution Noninvasive Maps: Multicenter Feasibility Study. J Cardiovasc Electrophysiol. 2015 Jul;26(7):754-60. doi: 10.1111/jce.12700. (8)

Introduction: A noninvasive 3D mapping technique (ECVUE™, CardioInsight Inc., Cleveland) maps the origin and mechanisms of various arrhythmias without catheterizing the heart.

Methods: Thirty-three patients (3 centers, mean 45.0 ± 14.6 years,) with symptomatic premature ventricular complexes (24 PVCs), focal atrial tachycardias (2 ATs), and manifest accessory pathways (7 WPW syndromes) were prospectively explored using 3D, noninvasive bedside electrocardiomapping. The location of origin of the focal arrhythmia was first determined using noninvasive mapping. Subsequently, a stimulus artifact was delivered at this site to confirm and evaluate the precise location of the mapped focal origin. The procedural parameters and clinical efficacy were studied.

Results: Ablation was successful in 32/33 (97%) patients (PVCs: 13 right, 10 left, 1 septal; WPW: 3 left, 3 right; ATs: 2 left) without complications. The time from catheterization to permanent arrhythmia elimination/termination, RF duration, skin-to-skin procedural duration, and fluoroscopic exposure were median 16, 3.98, 71, and 11.9 minutes (for n = 29), respectively. At mean 24.7 ± 3.7 months of follow-up, 31 patients remain arrhythmia-free after a single procedure. One patient (right WPW syndrome) required repeat ablation 1 month later. One

patient had recurrence of PVCs and is now deceased. The cumulative radiation (CT scan and fluoroscopy) exposure was median 7.57 mSv.

Conclusion: ECVUE(TM) is a noninvasive tool allowing rapid preprocedural localization of focal arrhythmia and enables the electrophysiologist with highly specific information to direct RF delivery at the source of the arrhythmia with minimal intracardiac mapping.

Weipert K.; Kuniss M.; Neumann T.Noninvasive mapping for catheter ablation of arrhythmias using the CardioInsight™ ECG vest. Herzschrittmachertherapie und Elektrophysiologie (2018) 29:3 (293-299). Date of Publication: 1 Sep 2018 (9)

Background: CardioInsight™ is a noninvasive three-dimensional mapping system technology which offers a unique method for arrhythmia characterization and localization. With a 252-lead ECG vest on the patient's torso and a noncontrast CT scan, epicardial potentials are detected and by means of reconstruction algorithms activation and phase maps are created, offering a deeper understanding of localization and mechanisms of arrhythmias including atrial fibrillation without the need for an endocardial catheter.

Materials and methods: The system has proven to be accurate and applicable in the clinical setting of accessory pathways, premature ventricular contractions (PVC), atrial tachycardias and atrial fibrillation. Beat-to-beat analysis offers detection and thus a therapeutic approach for arrhythmias which occur only paroxysmally such as supraventricular extrasystoles, atrial bursts or PVCs. Another advantage is the simultaneous display of various heart chambers such as the left and right atrium. However, major multicenter prospective randomized data are still lacking.

Conclusion: If in the future noninvasive mapping could be achieved with MRI and if the technology was compatible with invasive mapping systems so that catheter positioning and noninvasive maps can be merged, the authors believe that this would represent a new dimension of mapping technology and ablation strategy of arrhythmias.

Bilchick K.C.; Auger D.; Cai X.; Heckert D.; Phung T.-K.; Ferguson J.D.; Darby A.E.; Dresen W.; Mejia-Lopez E.; Johnson A.; Mehta N.; Malhotra R.; Mason P.K.; Michael Mangrum J.; Holmes J.W.; Epstein F.H.; Ghosh S.; Gillberg J.M. Intraoperative use of cardioinsight noninvasive electrical mapping and magnetic resonance imaging to guide cardiac resynchronization therapy implantation. Heart Rhythm (2018) 15:5 Supplement 1 (S93-S94). Date of Publication: 1 May 2018 (10)

Background: Noninvasive electrical mapping with a multi-electrode vest combined with magnetic resonance imaging (MRI) data on scar and strain can be used to optimize left ventricular (LV) pacing sites and configurations during cardiac resynchronization therapy (CRT). Objective: We assessed the feasibility and effectiveness of the noninvasive electrical mapping with the CardioInsight Cardiac Mapping System (Medtronic, Inc., Minneapolis, MN) combined with MRI to guide CRT LV lead placement.

Methods: A pre-CRT MRI was performed for assessment of scar (late gadolinium enhancement) and strain (Displacement Encoding with Stimulated Echoes [DENSE]) The multi-electrode vest was then ftted to the patient and remained in place for the entire CRT procedure.

Results: The first 10 patients enrolled were 64.4 +/-10.1 years old (50% female). Based on a 17-segment model, the latest activated sites not in scar were distributed across segments 5 (20%), 6 (30%), 11 (20%), 12 (20%), and 16 (10%). Those with latest electrical activation were the same or adjacent segments relative to those with latest mechanical activation by MRI. LV activation time shortened by 48.6 +/-12.3 ms with the optimal pacing configuration versus intrinsic activation (P < 0.0001), and a dependence of LV activation time on pacing site and configuration was noted A typical improvement in activation is shown in the Figure (range of 150 ms; red=early; blue=late; gray=left anterior descending artery).

Conclusion: Noninvasive cardiac electrical mapping can be combined effectively with MRI to assess optimal pacing sites and configurations during the CRT procedure and produce marked reductions in electrical activation timing.

Michael Mangrum J.; Lam A.G.; VanDerveer C.F.; Bilchick K.C.; Mehta N.; Lopez E.M.; Johnson A.; Dresen W.; Mason P.K.; Darby A.E.; Malhotra R.; Ferguson J.D. Clinical experience with cardioinsight™ cardiac mapping system for AF ablation. Heart Rhythm (2018) 15:5 Supplement 1 (S615). Date of Publication: 1 May 2018 (11)

Background: AF termination by ablation has been reported to yield better clinical results. For Non-PAF patients, ablation targets to modify the atrial substrate are debatable. 3-D body surface mapping can identify regions of rotational or focal sources that may be driving the AF.

Objective: We sought to use CardioInsight™ Cardiac Mapping System both prior to the ablation procedure and intra-procedure to help guide ablation in a heterogeneous pt group of both index and repeat AF ablation cases. The goal was AF termination by ablation to sinus rhythm. Methods: Pts were fitted with a multi-electrode mapping vest and pre-procedure mapping was performed. Composite phase maps of at least 15 secs of AF using a 19-segment biatrial model were created. Ablation strategy for Index cases: PVI + driver regions + mapping/ablation of ATs/futters. For repeat cases: Assure PVI and block across any linear lesions + driver regions + mapping/ablation of ATs/futters. Driver regions were prioritized and ablated based upon density of rotations/focals. Additional phase maps were created if AF changed based upon intracardiac EGMs.

Results: A total of 42 pts underwent 44 procedures. AT=6, PAF=7, Persistent=25, Long-Standing Persistent=6. (16 index cases, 28 repeat procedures). 30 pts presented in AT/AF, 14 were induced. Mean procedure time: 355±98min; Mean RF time: 75±45min. Overall acute success was 70.5%. See Figure 1.

Conclusion: Initial clinical experience with PVI + driver domain ablation has resulted in overall high acute success rates. This is seen in both index and repeat cases. This technology may offer the greatest benefit to the persistent group and less for longstanding persistent patients.

Varma N. Variegated left ventricular electrical activation in response to a novel quadripolar electrode: Visualization by non-invasive electrocardiographic imaging. Journal of Electrocardiology (2014) 47:1 (66-74). Date of Publication: January-February 2014 (12)

Improving response to cardiac resynchronization therapy (CRT) remains challenging. Appropriate candidates may be identified by the presence of left ventricular (LV) conduction delay. An additional determinant may be the electrical effect elicited by LV pacing, which may vary among and within individuals. However, this is little explored, reflecting the lack of means for both easily altering lead position in any individual patient and of rapidly assessing its electrical effects. However, the advent of both multipolar LV electrodes and non-invasive single-beat electroanatomic mapping potentially resolves these challenges. These were investigated here. Results confirmed wide variations in electrical responses to LV pacing. In any individual patient, different pacing configurations elicited different electrical effects. Conversely, any one stimulation vector produced different effects in different patients. Thus, the reaction of electrical substrate to LV pacing is inconsistent. This observation introduces an added level of complexity in the understanding CRT electrical action. Attention to this factor may influence response to electrical resynchronization therapy.

Cakulev I.; Sahadevan J.; Arruda M.; Goldstein R.N.; Hong M.; Intini A.; Mackall J.A.; Stambler B.S.; Ramanathan C.; Jia P.; Strom M.; Waldo A.L. Confirmation of novel noninvasive high-density electrocardiographic mapping with electrophysiology study: Implications for therapy. Circulation: Arrhythmia and Electrophysiology (2013) 6:1 (68-75). Date of Publication: February 2013 (13)

Background: Twelve lead ECGs have limited value in precisely identifying atrial and ventricular activation during arrhythmias, including accessory atrioventricular conduction activation. The aim of this study was to report a single center's clinical experience validating a novel, noninvasive, whole heart, beat-by-beat, 3-dimensional mapping technology with invasive electrophysiological studies, including ablation, where applicable.

Methods and Results: Using an electrocardiographic mapping (ECM) system in 27 patients, 3-dimensional epicardial activation maps were generated from >250 body surface ECGs using heart-torso geometry obtained from computed tomographic images. ECM activation maps were compared with clinical diagnoses, and confirmed with standard invasive electrophysiological studies mapping. In 6 cases of Wolff-Parkinson-White syndrome, ECM accurately identified the ventricular insertion site of an accessory atrioventricular connection. In 10 patients with premature ventricular complexes, ECM accurately identified their ventricular site of origin in 8 patients. In 2 of 10 patients transient premature ventricular complex suppression was observed during ablation at the site predicted by ECM as the earliest. In 10 cases of atrial tachycardia/atrial flutter, ECM accurately identified the chamber of origin in all 10, and distinguished isthmus from nonisthmus dependent atrial flutter. In 1 patient with sustained exercise induced ventricular tachycardia, ECM accurately identified the focal origin in the left ventricular outflow tract.

Conclusions: ECM successfully provided valid activation sequence maps obtained noninvasively in a variety of rhythm disorders that correlated well with invasive electrophysiological studies.

5. PRINCIPALES CONCLUSIONES Y RECOMENDACIONES DE LA BIBLIOGRAFÍA SELECCIONADA

Tras la revisión de la documentación podemos concluir que el mapeo no invasivo es una herramienta diagnóstica novedosa y precisa en la localización anatómica del origen de las arritmias auriculares y ventriculares, facilitando el procedimiento de ablación con catéter. Así se podría reducir el tiempo de ablación y el tiempo de procedimiento (5)

Otra ventaja es la visualización simultánea de varias cámaras del corazón latido a latido aportando una mejoría significativa en la compresión de la fisiopatología de la arritmia y guiar mejor el procedimiento de ablación (3).

Al permitir la localización de la arritmia antes de la intervención, el electrofisiólogo dispone de información más específica para planificar el procedimiento de ablación (8), reduciendo así la exposición de radiación al personal sanitario. Al paciente también se le disminuiría la radiación durante el procedimiento al disminuir el tiempo de fluoroscopia, pero no la total dado que el paciente precisa un estudio Cardio TC (tomografía computerizada) previo. (2). Un estudio reciente (10) evaluó la viabilidad y eficacia del mapeo no invasivo Cardioinsight combinado con imágenes de resonancia magnética (RM) para guiar la colocación del electrodo del marcapasos durante la terapia de resincronización cardiacaca, ampliando los usos de la monitorización no invasiva combinada de manera efectiva con la resonancia magnética. En un futuro sería deseable que se pudiera lograr un mapeo no invasivo combinado con imágenes RM, con el objeto de disminuir el tiempo de exposición del paciente a la radiación (9).

Por otro lado, esta nueva tecnología aún no ha sido estudiada de forma extendida y sistemática, faltan datos prospectivos aleatorizados multicéntricos importantes y su utilización en electrofisiología es aún muy baja.

El solicitante aporta un documento (14), donde nos informa sobre recientes avances combinando el mapeo no invasivo de arritmias cardiacas con imágenes electrocardiográficas y la administración no invasiva de radiación ablativa precisa con radioterapia estereotáctica corporal (SBRT). Combinando ambas técnicas para realizar radioablación cardíaca no invasiva guiada por electrofisiología y sin catéter para la taquicardia ventricular. Se trata de una nueva consideración terapeútica, en particular el tratamiento de las arritmias ventriculares cuando el sustrato no es accesible para tratamiento invasivo con catéter. Una nueva herramienta terapéutica de colaboración entre la electrofisiología cardiaca y la oncología radioterápica. Aunque en este informe nos referimos a la solicitud sobre el uso del mapeo no invasivo como técnica diagnóstica.

6. CONSIDERACIONES PARA NUESTRA COMUNIDAD

El mapeo no invasivo para arritmias cardiacas complejas con chaleco multidetector es una nueva tecnología diagnóstica que permite el estudio de arritmias cardiacas mediante la exploración de la señal electrocardiográfica de superficie usando un chaleco multidetector. Las series de casos y estudios hasta la fecha publicados han mostrado ser una herramienta útil para el mapeo de las arritmias ventriculares complejas y ser muy específicos en la localización de las mismas. Sin embargo faltan datos aleatorizados prospectivos multicéntricos importantes con mayor número de pacientes.

La escasa evidencia disponible aún, nos sugiere cautela y reservar dicha técnica a centros de referencia en investigación en arritmias.

Sería muy recomendable que, en caso de utilizarse, se realice bajo un diseño de estudio clínico observacional o registro, en el que se precisen las indicaciones y el seguimiento de los pacientes a quienes se aplicará, de forma que los resultados en la región puedan contribuir a mejorar el conocimiento científico sobre el tema.

Desde la Oetspa podríamos colaborar en el diseño y realización de un estudio coste-efectividad para esta TS en nuestra Comunidad Autónoma.

Esta TS es susceptible de ser tratada en el seno de la Comisión de Evaluación de Tecnologías Sanitarias del Principado de Asturias.

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