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Characterization of patients undergoing cardiac implantable electronic device implantation in a Tertiary Center: emphasis on complications

Caracterización de los pacientes llevados a implante de dispositivos de estimulación cardíaca en un Centro de Tercer Nivel: énfasis en complicaciones

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Bloqueo cardiaco, complicaciones posoperatorias, marcapasos, electrodos.

ABSTRACT

Introduction and objectives: Currently, there are scarce data about follow-up and complications in patients taken to implantation of cardiac implantable electronic devices. We sought to describe the incidence of complications and characteristics of 997 patients, taken to the implant of cardiac implantable electronic devices in a tertiary center in Colombia. **Material and methods:** An observational, descriptive study, with the follow-up of a retrospective cohort, was performed. Based on the systematic revision of medical histories from patients taken to cardiac electronic device implant during 2017 and 2018 in Las Americas clinic, located in Medellin, Colombia. **Results:** 997 patients were included. All of them counted with available medical profiles and histories, with an average age of 74 years old. 55.6% of the patients were males. The most commonly implanted cardiac electronic devices were, dual-chamber pacemakers and the predominant indications for implantation were AV block (47%) and sinus node dysfunction (25.6%). The most frequent complications were the displacement of one of the cardiac electrodes (2.2%), followed by pocket hematoma (1.5%). There were no deaths related to the implantation of the cardiac electronic devices. **Conclusions:** The majority of patients had an advanced age and a high burden of comorbid conditions. However, the procedures related to the implantation of electronic cardiac devices had a low frequency of complications. The population under study had a similar frequency of complications derived from the procedures, to the ones reported through literature. This demonstrates these procedures are also safe and successful in our environment.

RESUMEN

Introducción y objetivos: *En la actualidad, existen escasos datos sobre el seguimiento y las complicaciones en pacientes llevados a la implantación de dispositivos electrónicos cardíacos. Se buscó describir la incidencia de complicaciones y las características de 997 pacientes, llevados al implante de dispositivos electrónicos cardíacos en un centro terciario de Colombia.* ***Material y métodos:*** *Se realizó un estudio observacional, descriptivo, con el seguimiento de una cohorte retrospectiva. Basado en la revisión sistemática de historias clínicas de pacientes llevados a implante de dispostivos electrónicos cardíacos durante 2017 y 2018 en la clínica Las Américas, ubicada en Medellín, Colombia.* ***Resultados:*** *Se incluyeron 997 pacientes. Todos ellos contaban con perfiles e historiales médicos disponibles, con una edad media de 74 años. El 55.6% de los pacientes eran varones. La mayoría de los dispositivos electrónicos cardíacos implantados fueron los marcapasos bicamerales y las indicaciones predominantes para su implantación fueron el bloqueo AV (47%) y la disfunción del nodo sinusal (25.6%). Las complicaciones más frecuentes fueron el desplazamiento de uno de los electrodos cardíacos (2.2%), seguido del hematoma de bolsillo (1.5%). No hubo muertes relacionadas con la implantación de los dispositivos electrónicos cardíacos.* ***Conclusiones:*** *La mayoría de los pacientes tenían una edad avanzada y una alta carga de condiciones comórbidas. Sin embargo, los procedimientos relacionados con la implantación de dispositivos cardíacos electrónicos tuvieron una baja frecuencia de complicaciones. La población estudiada tuvo una frecuencia de complicaciones derivadas de los procedimientos similar a la reportada por la literatura. Esto demuestra que estos procedimientos también son seguros y exitosos en nuestro medio.*

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INTRODUCTION

A considerable increase in the age of general population and the rapid development of technology during the last decades have led to an increase in the detection and management of heart diseases, specifically rhythm disorders, coronary heart disease and heart failure. Different types of cardiac implantable electronic devices (CIEDs) are part of the management of such conditions, whether it be conventional pacemakers for bradycardia, implantable cardioverter-defibrillators (ICDs) for the prevention of sudden cardiac death due to malignant ventricular arrhythmias, or cardiac resynchronization therapy devices (CRT) for the relief of heart failure symptoms, with or without the use of defibrillators.

With the increasing number of implants and procedure complexity, there may be an increment in the incidence of complications directly associated with the intervention. Despite this, its rate is usually low. International literature reports describe a general risk of complications after pacemaker implant of up to 5-6%, with an approximate risk of major complications of 3-4%.[1] In the case of ICDs and CRT, which involve more complex implant procedures, the overall risk of complications is approximately 3-8%,[2] CRT defibrillators (4.1% in-hospital adverse events), and unicameral or bicameral ICDs (2.9% and 1.9%, respectively) with a death incidence of 0.4%.[3]

The most frequent complications are electrode displacement (1%), pocket hematoma (0.9%) and pneumothorax (0.4%); regarding inpatient treatment they are: infection, hematoma, bleeding and mechanical complications, which are directly related to factors such as the center and operator experience, the type of vascular access (puncture or dissection), antibiotic prophylaxis, procedure time, and underlying diseases and comorbidities.[3]

The present study sought to describe the incidence of complications in patients undergoing procedures for CIEDs implants in a tertiary center, as well as the characteristics which could be associated with the development of complications in this population.

MATERIAL AND METHODS

This is an observational, descriptive, follow-up study to a retrospective cohort, based on the review of clinical history records of patients who underwent CIEDs implant during 2017 and 2018 at Las Americas Clinic in Medellin, Colombia. Comparisons were made between the group of patients who underwent complex CIEDs implant (ICDs, CRT or CRT defibrillators) and those who underwent non-complex CIEDs implant (conventional unicameral or bicameral pacemakers and implantable loop recorders (ILR)). The data were collected in an electronic database with all the relevant variables related to implant history and follow-ups.

The confidentiality and anonymity of patients whose records were consulted were guaranteed at all times.

For the analyses, the quantitative variables were presented in the form of averages with their respective dispersion measures according to the distribution. Qualitative variables were summarized by percentages, and mean comparisons were made using the student's t-test for independent samples or Mann-Withney's U test as applied. For the comparison of groups, the chi-square tests and the Fisher test were used for the categorical variables and the ANOVA and Kruskal-Wallis tests to compare continuous variables. Statistical analyses were performed with SSPS software, version 21.

RESULTS

A total of 1,006 CIEDs procedures were performed during the study period, of which 997, with available records of clinical history, were included.

The patient's age was mainly in the eighth decade of life, with a range from 16 to 102 years and an average of 74.4 ± 14 years. There were 554 male patients (55.56%) and 443 female patients (44.44%).

In terms of comorbidities, the most frequently documented were hypertension, followed by dyslipidemia, coronary artery disease, diabetes and hypothyroidism. Other comorbidities recorded that are important from a cardiovascular standpoint, were renal insufficiency, chronic obstructive pulmonary

disease (COPD) and cerebrovascular events, which were found in a percentage equal to or less than 15%. The data on comorbidities in patients who were implanted with complex and non-complex devices are summarized in *Table 1*.

Devices

In terms of implanted devices, the pacemakers were the most common, corresponding to 74% of all devices, followed by ICDs and CRT. For the two initially mentioned, bicameral devices were chosen in most cases, *Table 2*.

Table 1: Clinical characteristics.

Characteristic	Non-complex (N = 794) n (%)	Complex (N = 203) n (%)	p
Age (years)	76.84 ± 13.26	65.31 ± 13.25	0.000*
Gender			0.002
Male	423 (76.4)	131 (23.6)	
Female	371 (83.7)	72 (16.3)	
Comorbidities			
Arterial hypertension	642 (80.5)	156 (19.5)	0.120
Dyslipidemia	370 (76.6)	113 (23.4)	0.013
Diabetes mellitus	199 (79.0)	53 (21.0)	
Hypothyroidism	181 (80.0)	45 (19.9)	0.863
Obesity	131 (84.5)	24 (15.5)	0.129
COPD	108 (78.3)	30 (21.7)	0.709
Stroke	63 (88.7)	8 (11.3)	0.217
TIA			
OSA	21 (80.8)	5 (19.2)	0.559
Medication used			
Beta blockers	343 (65.4)	181 (34.6)	0.000
ACE inhibitors	135 (64.6)	74 (35.4)	0.000
ARBs	379 (81.7)	85 (18.3)	0.112
MRAs	81 (38.8)	128 (61.2)	0.000
Statins	390 (72.2)	149 (27.6)	0.000‡
Furosemide	189 (65.4)	100 (34.6)	0.000
Anticoagulants	323 (72.9)	120 (27.1)	0.000
Antiplatelet agents	44 (56.4)	34 (43.6)	0.000

COPD = chronic obstructive pulmonary disease, TIA = transient ischemic attack, OSA = obstructive sleep apnea, ACE = angiotensin-converting enzyme, ARBs = angiotensin receptor blockers, MRAs = mineralocorticoid receptor antagonists. *Student's t-test. ‡ Fisher's exact test.

In general, 2.70% of patients got a CRT alone, while 5% a CRT defibrillator for the additional prevention of sudden death.

Indications

Conduction disorders such as atrioventricular block and impaired cardiac impulse generation, such as sinus dysfunction, were the most common device implant indications, with unicameral or bicameral pacemakers being the most frequently implanted devices. On the other hand, ICDs and CRT defibrillators were implanted for primary prevention of sudden death in patients with ischemic cardiomyopathy, being almost twice the number of implanted devices for secondary prevention. In the case of nonischemic cardiomyopathy, the number of implanted defibrillation devices was very similar for primary and secondary prevention of sudden death. 2% of indications corresponded to the implant of CRT alone for the management of heart failure symptoms.

A total of 6% ILR were implanted in similar proportions to search for syncope causes of unknown origin and possible atrial fibrillation in embolic events without documented cause *(Table 3)*.

Hospitalization and follow-up

In terms of in-hospital stay, the implant of cardiovascular devices is a procedure that did not require prolonged hospitalization in most cases. Analysis of the data showed that the most frequent number of hospitalization days was zero (less than 24 hours), indicating that after the procedure was performed, the patient was discharged after a short observation period in the recovery room without being hospitalized. 65.3% of procedures required hospitalization for less than 48 hours 9.3% of patients had an in-hospital stay of more than seven days, 7.5% of these cases were due to complications related to device implant; in the remaining cases, prolonged hospital stays were due to associated comorbidities of each patient, unrelated to the procedure. In the latter group of patients, 77.8% were aged 60 or older, being those with longer hospitalizations generally elderly patients.

Table 2: Type of cardiac device implanted.

Devices	n (%)	Relative (%)
Pacemaker	738 (74.0)	
Bicameral	621 (62.2)	84.1
Unicameral	117 (11.7)	15.8
ICD	126 (12.6)	
Bicameral	78 (7.8)	61.9
Unicameral	13 (1.3)	10.3
Not specified	35 (3.5)	27.7
CRT-D	50 (5.0)	–
ILR	56 (5.6)	–
CRT	27 (2.7)	–
Total devices	997	

ICD = implantable cardioverter defibrillator, CRT-D = cardiac resynchronization therapy-defibrillators, ILR = implantable loop recorder, CRT = cardiac resynchronization therapy.

89% of patients had at least one follow-up appointment from the procedure to the end of the investigation, 59% had two follow-ups. The average for follow-up days was 256, with a range between 90 and 738 days from implant day to the end of the research.

Complications

A total of 76 events that were compatible with those previously defined as complications were recorded during follow-up. It was corresponding to 7.7% complications. In two cases, it was impossible to define whether there had been any complication due to the absence of clinical data.

The most frequent complications were the displacement of one of the electrodes and pocket hematoma. During the observation period there were no cases of death associated with the procedure, complications requiring cardiovascular surgery management, or hemothorax presence *(Table 4)*.

Some specific aspects of each type of complication are described below.

Electrode displacement: it was the most frequently found complication with a total of twenty-two cases. In eleven cases the ventricular electrode was displaced, four of them in conventional pacemakers, four were high-energy electrodes, and three were left ventricular electrodes. In the remaining six cases, the displaced electrode was the one in the atrium. No information was obtained regarding the displaced electrode in five cases.

Pocket Hematoma: it was the second most frequent complication and all the cases detected in the first two weeks after the procedure, without any drainage required in any case whatsoever. Out of the fifteen patients who developed a pocket hematoma, eight of them were in direct oral anticoagulants (DOACs) therapy. Of these, four patients were receiving antiplatelet therapy simultaneously with Acetylsalicylic acid (ASA). One patient received dual antiplatelet therapy, and two patients received ASA alone.

Infection: a total of six infection events occurred, two cases corresponded to soft tissues infection circumscribing the implant site, in one case there was a pocket abscess which required drainage, and two events of

Table 3: Indications for device implant.

Indications	n (%)
Atrioventricular block	465 (47.0)
Sinus disfunction	255 (25.6)
Sinus disfunction and atrioventricular block	18 (1.8)
Heart failure	23 (2.3)
Primary prevention for SCD, ischemic cardiomyopathy	74 (7.4)
Secondary prevention for SCD, ischemic cardiomyopathy	38 (3.8)
Primary prevention for SCD, nonischemic cardiomyopathy	38 (3.8)
Secondary prevention for SCD, nonischemic cardiomyopathy	31 (3.1)
Syncope	30 (3.0)
Suspected atrial fibrillation	22 (2.2)
Other	3 (0.3)
Total	997 (100.0)

SCD = sudden cardiac death.

bacterial endocarditis requiring complete device explant were reported, which were diagnosed at 172 and 540 days after the procedure respectively; methicillin-resistant *Staphylococcus aureus* was the responsible bacteria in both cases. The last case corresponded to the development of an early granuloma at the implant site with pocket remodelling because of a previous explant, that subsequently presented infection and the need for device explant.

Extracardiac and diaphragmatic stimulation: two cases were reported, both of them with left endocardial ventricular electrode, explant and re-implant of the left electrode was needed in one of them.

Table 4: Presence of complications according to device type and patient comorbidities.

Characteristic	Complication, n (%)		p
	Yes (n = 78)	No (n = 917)	
Gender			
Male	35 (6.3)	519 (93.7)	0.030
Female	43 (9.8)	398 (90.2)	
Comorbidities			
Arterial hypertension	67 (8.4)	730 (91.3)	0.115*
Diabetes mellitus	22 (8.8)	229 (91.2)	0.307*
Obesity	13 (8.4)	142 (91.6)	0.449*
Device type			
Pacemaker	51 (7.0)	682 (93.0)	
ICD	14 (10.4)	121 (89.6)	
CRT-D	9 (19.1)	38 (80.9)	0.008
ILR	1 (1.8)	54 (98.2)	
CRT	3 (12.0)	22 (88.0)	
Procedure			
Implant	55 (7.7)	660 (92.3)	
Explant/implant	18 (7.2)	232 (92.8)	
Upgrade	2 (20.0)	8 (80.0)	
Electrode repositioning	0 (0.0)	4 (100.0)	0.301
Explant	1 (12.5)	7 (87.5)	
Explant/implant and electrode repositioning	2 (25.0)	6 (75.0)	

ICD = implantable cardioverter defibrillator, CRT-D = cardiac resynchronization therapy-defibrillators, ILR = implantable loop recorder, CRT = cardiac resynchronization therapy.
* Fisher's exact test.

Venous thrombosis: two cases of venous thrombosis of the upper left limb at the subclavian level were detected in follow-up, both cases recognized after 60 days of the implant. They were managed with chronic oral anticoagulation, without any complication reported.

Pneumothorax: a total of seven cases were reported, three of which required thoracotomy. Detection was performed during or immediately after the procedure in all cases, except in one in which the diagnosis was made after 12 hours of the implant.

Pericardial effusion and heart tamponade: there were four cases of pericardial effusion documented after the procedure, all requiring percutaneous drainage by pericardiocentesis. All were associated with manipulation of the right ventricular electrode.

Other complications: during the follow-up period, a pacemaker explant and re-implant were performed on a patient with chronic pocket pain without other documented causes, and another case of intermittent edema of the upper left limb secondary to proximal subclavian slow flow without documented thrombosis, which received conservative management.

There were neither complications that required cardiovascular surgical management nor death cases associated with the device implant during the study period. The three cases of death documented corresponded to heart failure worsening in one patient and to non-cardiovascular causes on the two other cases.

Bivariate analyses did not find a statistically significant difference in any comorbidities, nor in the relationship of the type of procedure with or without the development of complications, or at least with the most frequently presented. It was documented that complications occurred more frequently in females and patients receiving statins, both with statistically significance ($p = 0.03$ and $p = 0.04$, respectively). In respect to the type of devices, CRT-D showed the highest frequency of complications and ILR showed the lowest frequency of them; this difference in complications related to the type of device is considered statistical significance ($p = 0.008$) *(Tables 4 and 5)*.

Table 5: Bivariate and multivariate analysis.

	Bivariate		Multivariate	
Characteristic	OR (CI 95%)	p	OR (CI 95%)	p
Age				
16-45	Ref.			
46-75	0.26 (0.035-1.95)	0.191		
≥ 76	0.40 (0.05-3.02)	0.376		
Female gender	1.03 (1.00-1.07)	0.030	1.71 (1.06-2.74)	0.026
Arterial hypertension	1.56 (0.80-3.01)	0.115		
Diabetes mellitus	1.17 (0.70-1.97)	0.307		
Hypothyroidism	1.37 (0.81-2.30)	0.144		
Device type				
Pacemaker	Ref.		Ref.	
ICD	0.65 (0.35-1.21)	0.179	0.58 (0.31-1.10)	0.10
ILR	0.34 (0.15-0.77)	0.012	0.35 (0.15-0.79)	0.012
CRT-D	0.43 (0.14-1.30)	0.180	4.0 (0.54-29.78)	0.172
CRT	0.434 (0.14-1.30)	0.137	0.40 (0.13-1.22)	0.109
Statins	1,56 (1.0-2.53)	0.041		
Beta blockers	1,26 (0.79-2.01)	0.194		

ICD = implantable cardioverter defibrillator, ILR = implantable loop rec order, CRT-D = cardiac resynchronization therapy-defibrillators, CRT = cardiac resynchronization therapy.

In the multivariate analyses, the statistical significance was preserved for the difference in female patient's complications and those who were taken to ILR implant.

The patient's age was not significantly associated with the presentation of complications. p = 0.334 (Mann-Whitney U test).

DISCUSSION

CIEDs implant is an increasingly common procedure in high-complexity centers. The current work was carried out in a center with a high implant volume (> 400/year). This high volume could be explained by the high complexity of the center in which the study was performed, which receives a large population of patients from multiple insurers, health care providers and electrophysiology service with multiple specialists (six electrophysiologists plus training specialists). We analyzed 997 clinical history records, finding a predominance of men in the group analyzed, who had a more significant burden of cardiovascular diseases and comorbidities. In general, the patients evaluated had a significant burden of comorbidities. The population's age could explain this; also, the attention took place in a fourth-level complexity center where complex cases that cannot be solved in other hospitals are referred. We also found a high burden of cardiovascular risk factors, with a higher prevalence of arterial hypertension, dyslipidemia and diabetes mellitus, which predispose to ischemic and nonischemic cardiovascular disease, therefore, eventually relating directly and indirectly to cardiac electrical problems and the need for CIEDs implant. Almost a third part of the patients had coronary artery disease, most of which had been actively managed, especially percutaneously.

The use of cardiovascular medication was also frequently found, highlighting statins, beta-blockers and ASA, which are typically used to manage coronary artery disease, thus supporting the common finding of this

condition and/or its associated risk factors like dyslipidemia.

These data suggest an elderly and comorbid population in general, with active management of its comorbidities, especially coronary artery disease.

Another striking fact was the high prevalence of anticoagulated patients corresponding to 26% of the total. All patients with mechanical valve prostheses were anticoagulated with Warfarin. In most cases, the predominant anticoagulants used were DOACs, principally factor X inhibitors; this allows us to infer that the pharmacological management of patients was adjusted to guidelines and recommendations of optimal pharmacological therapy.

17% of patients had flutter or atrial fibrillation, and all of them were considered a high embolic risk with a CHA2DS2VASC score of 4 in most cases. This information is closely related to anticoagulation data. It suggests an adequate frequency of anticoagulation in patients with high embolic risk atrial fibrillation, because the percentage of anticoagulated patients is higher than that of patients with atrial fibrillation.

The most commonly implanted devices were bicameral pacemakers, being atrioventricular block and sinus dysfunction its more frequent indications. The available literature also shows a higher proportion of bicameral pacemaker implants than unicameral pacemakers for the management of these disorders, which ensures a more synchronous type of pacing and lowers the incidence of atrial arrhythmias and pacemaker syndrome.[4] In the population studied, despite the high average of age, bicameral pacemakers were frequently implanted, demonstrating that priority is given to physiological heart stimulation and that the implant of a second electrode in the right cavities does not generally represent a step that makes this procedure more complex or that increases complications significantly.

ICDs were the second most implanted type of device, also predominantly bicameral. There are no data on the need for bradycardia stimulation in these patients, which would have allowed us to infer if its indication was the aim of atrioventricular synchrony during stimulation or the improvement in discrimination of cardiac arrhythmias.

Regarding cardiac resynchronization therapy devices, the CRT-D was the most commonly implanted, highlighting the importance of the prevention of sudden cardiac death in patients with symptomatic heart failure who were candidates for resynchronization therapy.

Regarding the general short in-hospital stay, it can be inferred that although these are high complexity technological devices, the implant procedure usually requires short periods of hospitalization. In the cases of prolonged in-hospital stays, the cause of the hospitalization was not directly related to the device implant.

The events referred to as «complications» occurred in 7.7% of all implanted electronic devices. In general, the literature describes the presence of complications in a 3-5% after device implants, being a little higher (5-8%) for complex devices such as ICDs, CRT or CRT-D.

There is no homogeneous definition of «complication», and this introduces a wide variability in the frequency and type of complications reported, making comparisons difficult. Despite this, some universally reported complications such as infection, hematoma, electrode displacement and surgery requirement (by perforation, hemothorax or pneumothorax).[5,6]

The ideal time for discharge has been a matter of discussion considering the safety and the presentation time of complications. The Emotion trial showed no difference in terms of complications, including electrode displacement, in patients taken to CIEDs implant who were early mobilized compared to those mobilized up to 24 hours after the procedure.[7] Similarly, a recent German study mentions that most of the potentially fatal complications occur between the initial 24-72 hours after device implant and that a safe discharge implies to discard them.[8]

In our study, severe pneumothorax and pericardial effusion complications were detected immediately, and only in one case during the first 6-12 hours post-procedure. On the other hand, none of the patients discharged within the first 24 hours presented any severe complications that would have been detected after discharge.

Potentially fatal complications such as hemothorax, pneumothorax, and cardiac tamponade are related to vascular access. The standard vascular approach in our group was cephalic vein dissection, which may reduce some risks, especially for pneumothorax or hemothorax.

In the population studied, most of the complications reported were not severe complications. The most common of these was electrode displacement followed by pocket hematomas, device threshold increase, and infections.

When discriminating between complications of conventional pacemakers and «complex» devices (ICDs, CRT and CRT-D), 4.8% of the complications were found in pacemakers and 2.8% in complex devices, being the most common complications after pacemaker implant pocket hematoma followed by electrode displacement, and after complex device implant the contrary: displacement of the electrodes (usually high energy or left ventricular), followed by pocket hematomas. These discriminated data are compatible with what is reported in the international literature, even with a lower percentage of complications.[3,9]

Surgical management was not required in any case, nor deaths directly associated with the procedure presented. No hematoma required drainage. Although electrode displacement is not the most frequently reported complication, in the case of our population, several circumstances can contribute to this finding, first of all, patients have multiple comorbidities. They are treated in a teaching center by a group with training specialists, in which, despite adequate supervision, the skill acquisition curve in the implant process may play an important role in this regard.[10] Besides, with respect to comorbidities, the fact of being more ill can also mean greater structural heart disease, which in turn increases the technical difficulty of the implant and the possibility of electrodes displacement. The largest number of displaced electrodes were ventricular electrodes, and a significant percentage were high-energy defibrillator electrodes.

It is also a center in which multiple commercial house devices are implanted, thus introducing certain variability related to the elements and the implant for each specific brand. Despite being the same type of devices, the different materials between commercial houses may contribute to this finding.

Finally, it exists the possibility that more frequent events like hematomas have been mild enough in several cases to not to be reported in the history after implant or in follow-ups, thus, making electrode displacement the most frequent event in our study, without necessarily being so.

Women presented more complications in a statistically significant way. This difference was mainly explained by infection events, since other frequent complications such as hematomas and electrodes displacement were presented in a similar pattern for both genders. A large cohort of patients from Australia and New Zealand who were taken for CIEDs implants also found a higher risk of complications in women, which could be explained by anatomical differences.[11]

Concerning the more severe complications found in the study, pericardial effusion and cardiac tamponade occurred in a deficient number of cases. All of them could be managed percutaneously, being a less morbid treatment in relation to the need for open surgical management.[12]

A recently published study carried out in another center in the country, analyzed the rate of complications in a slightly smaller number of patients who underwent the CIEDs implant during the years 2012 to 2015.[13] In general, their population characteristics in terms of the average age of implant, gender distribution, and percentage of pacemakers implanted are similar to our findings. Similarly, the most frequent complications were electrode displacement and pocket hematoma.

It should be noted that in our population, approximately 0.9% of the implants corresponded to cardiac resynchronization left electrodes, being this procedure usually technically more laborious and bound to anatomical variations of the venous tree. On the other hand, in the previous work, the frequency of pocket hematoma, infection and other significant complications were higher than those found in the present investigation.

Some factors could influence this difference; first, these implants were performed between 2012 and 2015, that is up to six years before our study, and some tools and elements for the implants may have been optimized in this period; second, by the time this work was done, bridge therapy with low molecular weight heparins in anticoagulated patients was still common, which is now known to increase the risk of bleeding and implant associated hematoma possibly. Therefore, it is not generally used nowadays and was not used in the implants reported in our work.[14]

Finally, in the present study, the percentage of patients under antiplatelet therapy was between 43 and 56%, and under anticoagulants of 21 and 72%, for patients with complex and non-complex devices, respectively.

It has been observed that the presence of antiplatelet therapy and the basal count of platelets in patients with CIEDs implants are independent risk factors for the development of hematomas.[15] In our case, the presence of antiplatelet therapy or anticoagulation in patients taken to implant more complex devices was not so high, which may also influence the fact that hematoma was not the most frequent complication found.

CONCLUSIONS

The implant of cardiac electronic stimulation devices is a frequent procedure which is part of the active management of the patients' different diseases and comorbidities included in our study. Despite the advanced age and significant disease burden, these patients had low complication rate procedures, similar to the ones reported on the national and international literature, thus suggesting that these procedures, even in the case of high complexity devices, are successful and safe in our environment.

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