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Steps to Reduce Incidence of Atrial Lead Dislodgment

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Abstract

Background: Cardiac implantable devices are now an established effective treatment for patients with heart block and advanced heart failure. The most common complications related to pacemaker insertion are lead displacement and device related infection. An optimal technique for placement of the RA lead could improve outcome of device implantation and reduce complications.

Objective: To test the impact of applying certain steps during pacemaker implantation on reducing of the percent of atrial lead dislodgment. 166 patients who were candidate for cardiac device implantation underwent complete general and local examination; conventional 2D echo and 12 leads ECG. They were followed up in the pacemaker clinic for at six months for pacemaker lead complication with emphasis on atrial lead dislodgment. The patients were classified into two groups randomly, the first group underwent conventional pacemaker implantation with the standard traditional technique for the atrial lead insertion and the other group underwent the same procedure with the addition of certain technical steps during atrial lead implantation. These steps include applying minimal traction of the atrial lead before screwing, inserting a straight stylet to the middle of the lead after its fixation, visualization of the atrial lead stability while the patient takes deep breath and cough and providing the patient with arm sling to wear for 2 weeks.

Results: No statistically significant difference in the demographic, clinical or ECG characteristics between group A with traditional technique of RA lead insertion and group B with applying the previously described additional steps during atrial lead implantation. Early atrial lead dislodgment occurred in 3 cases (3.9%) in the traditional group while no cases (0%) occurred in the other group (p=0.057).

Conclusion: Applying certain simple maneuvers during pacemaker insertion could help in reducing the pacemaker related complications by reducing the percent of atrial lead dislodgment.

Keywords: Pacemaker; Device; Complications; Atrial lead dislodgment

Abbreviations: CHB: Complete Heart Block; CIED: Cardiac Implantable Electronic Devices; CRT: Cardiac Resynchronization Therapy; CRT-D: Cardiac Resynchronization Therapy with Defibrillator; DDD: Dual Chamber Pacemaker; DICD: Dual Chamber Implantable Cardioverter Defibrillator; HB: Heart Block; LAO: Left Anterior Oblique; LBBB: Left Bundle Branch Block; PA: Posterior-Anterior; RA: Right Atrium; RAA: Right Atrial Appendage; SSS: Sick Sinus Syndrome

Introduction

The number of cardiac rhythm device implantations including DDD, ICD and CRT has been growing fast due to expanding indications and ageing of the population. Several prospective and retrospective studies reported both short- and long-term complications of device implantation [1-3]. The majority of device re-interventions are due to lead dislodgements, particularly with right atrial and ICD leads [2]. The incidence of overall lead dislodgement in published studies is low (1.5-3.3%) [2-4], with higher values in old reports due to leads with passive fixation (4.0-8.4%) [1].

Lead dislodgement is commonly classified into macro dislodgment and micro-dislodgment, With the macro dislodgment is diagnosed when there is documentation of a change in the lead tip position on chest X-ray and changes in electrical lead parameters (rise in impedance, loss of sensing and pacing) [4]. The risk of any lead dislodgement or malfunctioning was higher in dual-chamber devises as compared with single-chamber pacemaker in a large observational study about lead related re-intervention [4] raising the importance of applying certain technique for atrial lead implantation.

In a large study tested cardiac devices complications, Lead-related re-intervention was necessary in 4.4% of patients with the most common cause was lead dislodgement (66%), then malfunctioning (20%) or perforation (18%) [5]. Right atrial lead dislodgement was the most common at this study registry followed by ICD lead [5]. At this large registry, they proposed the possible causes of dislodgment are inadequate fixation of the lead sleeve in one third of the study cases and in two thirds of the cases the cause of dislodgement was unclear [5].

Several precautions were tested to avoid lead dislodgment [6]. With Adequate operator experience and adequate lead sleeve fixation and possible greater lead diameter, about 1/3 of the cases a lead dislocation could be prevented [5].

Research Methodology

The current study was conducted on 166 patients who were candidate for cardiac device implantation in the period from 2017 to 2019 according to ESC guidelines. All patients underwent complete general and local examination; conventional 2D echo and 12 leads ECG. They were followed up in the pacemaker clinic for one year for detection of pacemaker lead complication with emphasis on atrial lead dislodgment. The patients were classified into two groups randomly, group A underwent conventional pacemaker implantation with the standard traditional technique for the atrial lead insertion and the other group (Group B) underwent the same procedure with the addition of certain steps during atrial lead implantation:

1. First step is applying minimal traction of the atrial lead before screwing to emphasis proper attachment of the screw.

2. Second step is inserting a straight stylet to the middle of the lead after its fixation to test its stability.

3. Third step is visualization of the atrial lead position and its stability during while the patient takes deep breath and cough.

4. Last step is to provide the patient with arm sling to wear for 2 weeks to avoid excessive limb mobility after pacemaker insertion.

The atrial leads themselves are very floppy with little stiffness with a central lumen which allows passage of a stiffer thin stylet. These stylets are pre-shaped and can be reshaped easily to allow the tip of the lead to be further steered in a specific direction [6].

Traditionally in our study the RA lead was placed in the RA appendage (RAA) in all patients with a good pacing and sensing parameters through the detailed following steps. The distal tip of the atrial lead was placed in the middle of the right atrium through the subclavian vein access. Then the straight stylet was exchanged with the pre-shaped J-stylet gently with a minimal advancement of the lead to allow the tip of the lead to enter RAA by fine rotation. Position of the atrial lead was confirmed by the anterior projection of the atrial appendage in the standard fluoroscopic posterior-anterior (PA) and left anterior-oblique (LAO) fluoroscopic projections and the pendulous movement of the lead tip.

All leads were an active fixation leads with the screw at lead tip pointing traditionally perpendicular to the wall. The ventricular and atrial leads were then connected to a pulse generator, and device function was evaluated.

Statistical Analysis

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

1. Independent-samples t-test of significance was used when comparing between two means.

2. Chi-square (χ^2) test of significance was used in order to compare proportions between two qualitative parameters.

3. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the with a p-value<0.05 was considered significant.

Results

The clinical characteristics of our study patients are summarized in Table 1, 83 patients (50%) underwent DDD pacemaker insertion, and 78 patients (47%) underwent CRT insertion. RA lead dislodgment occurred in 3 cases (1.8%) of all study patients. Other detected device related complications that occurred during patients follow up included the following, one case of controlled pocket hematoma, one case had CS lead dislodged within one month of insertion, and one case had RV lead dislodgment with subsequent diaphragmatic stimulation. Coronary Sinus dissection occurred also in one case which resolved spontaneously after one month.

Our findings demonstrated no demographic or clinical differences between both study groups; group A of patients who underwent implantation of atrial lead with the traditional steps and group B of patients who had atrial lead inserted with applying the previously described additional steps during atrial lead implantation (Tables 2 and 3).

Parameters	Total (N=166)
Gender	
Female	55 (33.1%)
Male	111 (66.9%)
Range [Mean ± SD]	20-79 [59.98 ± 11.31]
ECG (indication)	
CHB	56 (33.7%)
LBBB	81 (48.8%)
Normal	2 (1.2%)
Second degree HB	14 (8.4%)
SSS	13 (7.8%)
Type of PPM	
CRT	78 (47.0%)
CRTD	1 (0.6%)
DDD	83 (50.0%)
DDDR	1 (0.6%)
DICD	3 (1.8%)
RA lead technique	
Traditional	76 (45.8%)
Certain extra steps of insertion	90 (54.2%)
Atrial Lead dislodgment	
No	163 (98.2%)
Yes	3 (1.8%)

Note: Data represented as number, percentage and Mean ± SD
DICD: Dual Chamber ICD; CHB: Complete Heart Block; LBBB: Left Bundle Branch Block; HB: Heart Block; SSS: Sick Sinus Syndrome

Table 1: Clinical characteristics of the all study patients.

Demographic Data	RA lead implantation technique		t/ $\chi^{2\#}$	p-value
	Traditional (N=76)	Fine traction before screwing (N=90)		
Gender				
Female	25 (32.9%)	30 (33.3%)	0.004#	0.952
Male	51 (67.1%)	60 (66.7%)		
Age (years)				
Mean ± SD	59.79 ± 12.10	60.14 ± 10.66	0.04	0.841
Range	23-79	20-78		

Table 2: Comparison between the group A and group B according to demographic data.

This table shows no statistically significant difference in demographic data between group A with traditional technique of RA lead insertion and group B with certain extra steps of insertion.

ECG (indication)	RA lead technique		χ2	p-value
	Traditional (N=76)	Fine traction before screwing (N=90)		
CHB	25 (32.9%)	31 (34.4%)	3.177	0.529
LBBB	36 (47.4%)	45 (50.0%)		
Normal	0 (0.0%)	2 (2.2%)		
Second degree HB	7 (9.2%)	7 (7.8%)		
SSS	8 (10.5%)	5 (5.6%)		

Table 3: Comparison between the group A and group B according to ECG.

This table shows no statistically significant difference in ECG characteristics between group A with traditional technique of RA lead insertion and group B with applying the previously described additional steps during atrial lead implantation. No statistical differences between both groups of our study as regards type of cardiac device inserted (Table 4).

Type of PPM	RA lead technique		χ2	p-value
	Traditional (N=76)	Certain steps of insertion (N=90)		
CRT	36 (47.4%)	42 (46.7%)	4.421	0.491
CRTD	0 (0.0%)	1 (1.1%)		
DDD	40 (52.6%)	43 (47.8%)		
DDDR	0 (0.0%)	1 (1.1%)		
DICD	0 (0.0%)	3 (3.3%)		

Table 4: Comparison between group with traditional lead insertion and group with certain steps of insertion according to type of PPM.

This table shows no statistically significant difference between both study groups according to type of PPM. RA lead dislodgment occurred in 3 cases of our study patients, one case occurred within 2 days of hospital stay and the other two cases within the first month after device insertion. All these patients were in the group who underwent traditional technique of atrial lead insertion 3.9%, with no detected dislodgment of the atrial lead within the first year of insertion in the other group 0% (Table 5). Although this difference did not reach the statistically significant value, it showed a trend towards significance (0.057).

Atrial Lead dislodgment	RA lead technique		Fisher's exact test
	Traditional (N=76)	Certain steps of insertion (N=90)	
No	73 (96.1%)	90 (100.0%)	0.057
Yes	3 (3.9%)	0 (0.0%)	

Table 5: Comparison between the two groups according to atrial lead dislodgment.

This table showed the difference between the two groups as regards atrial lead dislodgment (p=0.057). There were 3 cases (3.9%) of atrial lead dislodgment in traditional group and no cases (0%) in the other group who underwent certain steps of atrial lead insertion.

Discussion

The number of cardiac implantable electronic devices (CIED) has been significantly increased over the past several years due to expanding indications [7]. CIED implantation is a minimal surgical procedure, however, implantation procedure and follow-up of such patients require certain skills, which are cumulative learned techniques and expedites that performed at experienced centers [8]. Certain steps and protocols should be followed meticulously to improve results of these procedures and minimize risk of complications.

Lead dislodgement is still considered a troublesome complication of device implantation [2,6], that would necessitate re-intervention and increase risk of device related infection. In a prospective registry tested cardiac devices complications in 1929 patients, Lead-related re-intervention was necessary in 4.4% of patients within the first year of implantation with the most common cause was lead dislodgement. At

their registry RA leads had a higher risk of dislodgement (1.9%) compared with the RV lead [5].

In our study we aimed to test addition of certain steps in pacemaker implantation technique to reduce such incidence. There were only three cases in our study patients (166 patients) who had an atrial lead dislodgment for one year follow up after pacemaker insertion, with an overall incidence of 1.8%. This percent was comparable to the other published studies [9-14].

All of cases with lead dislodgment in our study occurred in the group of patients who underwent traditional technique of atrial lead implantation, early within one month of insertion. These results were comparable to more than one study that showed higher incidence of lead dislodgement, malfunction and perforation during the six months following device implantation [2,5] with the majority of lead dislodgements occurred before discharge [5].

In the other group who had the addition of the previously described certain steps during atrial lead implantation, there was no detected any dislodgment (0%) during the same follow up period. Although this difference did not reach the statistically significant value, it showed a trend towards significance p-value (0.057) and could be attributed to small number of patients in this study population.

Over the last years, numerous procedural techniques have been added or modified in pacemaker implantation aiming to improve outcomes and reduce risk of complications and lead dislodgments. Active fixation leads, large lead sizes and certain procedural steps could help in reducing percent of dislodgment [6].

This study is encouraging applying the previously described simple maneuvers during atrial lead insertion as a technical step that could be helpful to reduce the risk of dislodgment that is in addition to tested important step of adequate lead sleeve fixation.

Conclusion

Applying certain simple maneuvers during pacemaker insertion could help in reducing the pacemaker related complications by reducing the percent of atrial lead dislodgment. We concluded that applying certain technical steps in atrial lead implantation had reduced the percentage of detected lead dislodgment compared to the traditional steps of implantation.

Ethics Approval and Consent to Participate

The study was approved by the research Ethics Committee (REC) of Cardiovascular Medicine Department at Ain Shams University and written consent was taken from the patients.

Availability of Data and Materials

All data and materials of our work are available (not online) and can be sent to the journal upon request (only after acceptance for publication).

Conflicts of Interest

There are no conflicts of interest for the present study.

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