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infection.<sup>2,3,4</sup>

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ICD  
PATIENTS**

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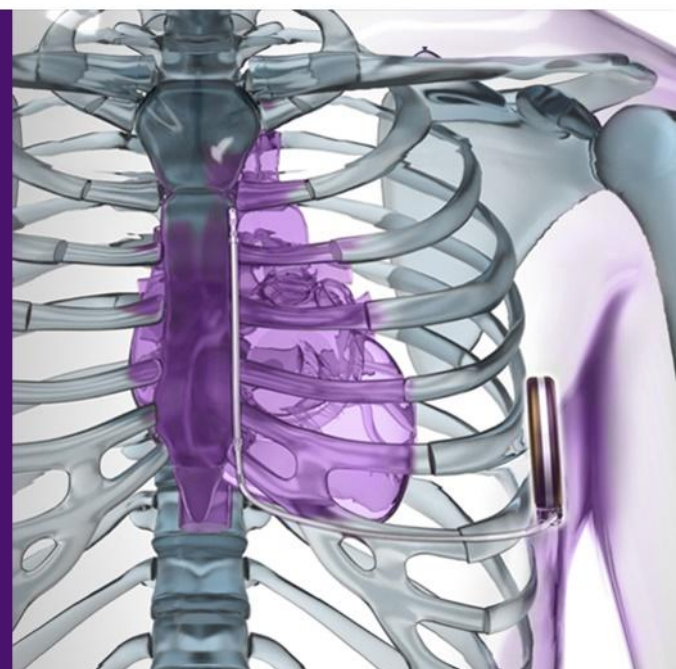
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# Meta-analysis of the Incidence of Lead Dislodgement with Conventional and Leadless Pacemaker Systems

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Running title: the Incidence of Lead Dislodgement

**Abstract:** *Introduction:* Leadless cardiac pacemaker (LCP) implantation using a transcatheter was recently developed to avoid pocket- and lead-related complications. Although a LCP has an active fixation mechanism using tines or a helix, LCP and lead dislodgement issues remain a major safety concern for patients. This article reviews the literature to determine the incidence of lead and LCP dislodgement.

*Methods and Results:* A total of 18 studies which included 17,321 patients undergoing conventional single or dual chamber pacemaker implantation and 3 studies which included 2,116 patients undergoing LCP device implantation were reviewed. The incidence of lead dislodgement ranged from 1%–2.69% in individual studies with a mean of 1.63%, weighted mean of 1.71%, and median of 1.60%. There was a relatively higher lead dislodgement rate

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<sup>1</sup> “†” represents the first author ; “††” represents corresponding author.

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between atrial and ventricular electrodes (OR, 3.56; 95% CI, 1.9–6.70;  $P = 0.6$ ;  $I^2 = 0\%$ ), and between MRI conditional and conventional leads (OR, 2.79; 95% CI, 1.30–5.99;  $P = 0.16$ ;  $I^2 = 46\%$ ). The use of active fixation leads (OR, 1.06; 95% CI, 0.66–1.70;  $P = 0.29$ ;  $I^2 = 20\%$ ) showed no significant difference in dislodgement risk compared to passive fixation leads. The incidence of LCP device dislodgement was 0%, 0.13% and 1.1% in three leadless pacemaker studies.

*Conclusions:* The incidence rates of conventional pacemaker lead dislodgement vary in individual studies with an overall high incidence. Use of the currently available LCP systems appears to result in a lower rate of device dislodgement. This may reflect the effectiveness of this novel technology and the fixation design of LCP devices.

**Keywords:** Leadless cardiac pacemaker; lead dislodgement; incidence; risk; cardiac pacemaker

## Introduction

Since their introduction in the late 1950s, cardiac pacemaker (PM) and lead technology have markedly improved, and include a reduction in generator size and lead diameter, increased battery longevity, electrode quality and durability<sup>[1]</sup>. The implantation of transvenous endocardial leads is a safe and relatively simple procedure, although effective lead placement is still a critical part of the procedure. Nearly one million patients worldwide receive transvenous cardiac PMs to treat bradycardia and heart block each year<sup>[2]</sup>. However, despite the technological advancements in PMs, lead dislodgement is still one of the most common complications.

It is known that traditional PM and lead systems are subject to infection and lead failure. To avoid pocket- and lead-related complications, two LCP systems have been developed to meet this clinical requirement<sup>[3]</sup>. As the LCP is implanted with a relatively large delivery trans-catheter through the femoral vein using active fixation, the device and/or electrode dislodgement remains a major safety concern with this new technique.

This study aimed to provide a detailed analysis of the available literature on the incidence of lead electrode dislodgement with conventional PMs compared with the incidence observed in recently published LCP trials. Additionally, reasons for lead and device dislodgement were analyzed.

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## Methods

### Study retrieval strategy

A systematic search of the PubMed, Cochrane Library, and Google Scholar databases was performed from 1990–2018. Only full-sized papers in English, published in peer-reviewed journals reporting detailed data on the most common PM lead-related complications were considered. Studies eligible for inclusion were identified using the following search strategy: 1st run: “pacemaker,” 2<sup>nd</sup> run: (dislodgement or dislocation) and “pacemaker.” According to the inclusion criteria and exclusion criteria the flow chart of literature selection was as follows:

### Inclusion criteria

The eligibility criteria for this meta-analysis were as follows. (1) Inclusion of patients undergoing conventional PM system implantation for standard indications. (2) Pacemaker implantation type included: implantation position (atrium and ventricle), fixation type (passive vs. active), and lead type (MRI conditional vs. conventional leads). (3) Detailed data on the rate of lead dislodgement was reported, defined as inadequate capture and/or sensing, or phrenic nerve stimulation with (macro-dislocation) or without (micro-dislocation) a visible change in the lead position on chest X-ray.

### Exclusion criteria

(1) Studies reporting only pooled data for PM, coronary sinus or ICD leads associated complications were not considered. (2) Studies using repeated clinical data were not considered. (3) Studies or reviews with no direct data were not considered.

### Data extracted

The total number of patients, the number of patients with dislodgement, patient characteristics, frequency and timing of lead dislodgement, utilized lead and system types and rate of dislodgement were extracted from the selected studies. The methodological quality of non-controlled studies was assessed using the Methodological Index for Nonrandomized Studies (MINORS)<sup>[4]</sup>. Studies were defined to be of low, moderate, or high quality based on their MINORS scores of  $\leq 8$ , 9–16, and  $\geq 17$  points, respectively.

The methodological quality of randomized controlled studies was assessed using the Cochrane risk bias assessment tool. The risk of bias was evaluated mainly from six areas of the project team, and judgment was carried out on each indicator using “low bias risk,” “moderate bias risk,” and “high bias risk.”

### Statistical analysis

Statistical analyses were conducted using R 3.3 (Biostat, Inc., Englewood, NJ, USA) and Microsoft Excel 2016 MSO (Microsoft Corp., Redmond, WA, USA). Event rates were synthesized using descriptive statistics; minimum and maximum, mean, weighted mean, and median incidences were calculated. OR and its 95% confidence intervals (CI) were calculated from events and sample sizes for a head-to-head comparison of different systems and lead types or lead positions. Heterogeneity between individual trial estimates was assessed using the Q statistic and I<sup>2</sup> statistic. In the case of I<sup>2</sup> index values >50% indicating significant heterogeneity, the random-effect model was used, otherwise the fixed-effect model was used.

## Results

### Study characteristics

A total of 18 studies fulfilled the predefined selection criteria for leads and three studies fulfilled the criteria for LCP devices. These studies included 17,321 patients undergoing conventional single or dual chamber PM implantation (Fig. 1; Table 1) and 2,046 patients for a LCP device (Table 2). Of the identified studies, only one<sup>[7]</sup> was a randomized controlled clinical trial, whereas the remainder were post-hoc analyses of randomized trials,<sup>[17,24]</sup> or observational retrospective<sup>[5,8,16,18,22-23]</sup> or observational prospective studies<sup>[9-13,14-15,19-21,25]</sup>. The vast majority were multicenter studies<sup>[5,12-13,15,17,20-22,24-25]</sup>, with seven single-center studies<sup>[9,11,13,16,18-19,23]</sup>. Individual studies used different definitions of lead dislodgement or dislocation including signs of elevated pacing thresholds or a decrease in sensing or failure to capture, or a visible change in lead position on chest X ray (Tables 1 and 2).

### *Lead Dislodgement with Conventional PM Systems*

The incidence of lead dislodgement ranged from 1%–2.69% in individual studies with a mean of 1.63%, weighted mean of 1.71%, and median of 1.60% (Fig. 2). In the present review, lead dislodgement was the most common complication of conventional PM systems .

There was a relatively higher lead dislodgement rate with atrial as compared to ventricular electrodes (OR, 3.56; 95% CI, 1.9–6.70; P = 0.6; I<sup>2</sup> = 0%) and between MRI

conditional and conventional leads (OR, 2.79; 95% CI, 1.30–5.99;  $P = 0.16$ ;  $I^2 = 46\%$ ). The use of active fixation leads (OR, 1.06; 95% CI, 0.66–1.70;  $P = 0.29$ ;  $I^2 = 20\%$ ) had no significant difference in dislodgement risk compared to that of passive fixation leads.

Armaganijan's study<sup>[17]</sup> demonstrated that elderly patients were at increased risk of peri-implant complications, particularly lead dislodgement and pneumothorax. The development of perioperative complications was more common in patients aged 75 years or over (5.1% vs. 3.4%;  $P = 0.006$ ).

### ***Device Dislodgement with LCP Systems***

The incidence of LCP device dislodgement was 0%, 0.13% and 1.1% in three leadless pacemaker studies (Fig. 2)<sup>[12,13,25]</sup>. In the second MICRA study, one local device dislodgement (without embolization) was noted 2 days post-implant, and in this case, two tines were observed to not be embedded in tissues and two tines were positioned between the wall and papillary muscle. Fortunately at 50 days post-implant, the same device was successfully repositioned, with normal pacing thresholds and no further issues noted at the time of repositioning<sup>[12]</sup>. In the Nanostim study, device migration to the pulmonary artery or right femoral vein occurred in four and two patients, respectively. There was no significant difference in the dislodgement rate between devices positioned in the right ventricular apex and those in non-apical positions ( $P = 0.42$ ) in the total cohort of 526 patients<sup>[13]</sup>.

## **Discussion**

### ***Main Findings***

Eighteen studies which included 17,321 patients undergoing conventional single or dual chamber PM implantation showed an overall high incidence of lead dislodgement (on average >1.5%). In the LCP studies, the dislodgement incidence of MICRA was 0% and 0.13%, respectively, and the dislodgement incidence of Nanostim was 1.1%. These values were all lower than the traditional PM lead dislodgement risk, reflecting the significant potential of this new technology.

### ***Incidence of Lead Dislodgement with Conventional PM Systems***

As shown in Figure 3A, Ghani et al. (2014) reported an atrial electrode dislodgement rate that is 7 fold higher than that of ventricular dislodgement. Most studies showed that the dislodgement rate of atrial electrodes was slightly higher than that of ventricular electrodes.

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This may be due to the thin wall and the anatomical location of the right atrial appendage the most targeted site for RA lead placement.

The results in Figure 3B show that the type of lead fixation design also had some influence on electrode dislodgement. The rate of lead dislodgement in the active fixation design was lower. The active fixation leads, with a screw-in mechanism, conceptually were purported to provide more consistent contact with myocardial tissue and prevent dislodgement, thus leading to a lower incidence of high pacing threshold or loss of capture events. One year follow-up data from Witt et al.<sup>[8]</sup> showed that lead dislodgement in the active fixation method was similar to that in passive fixation. However, after a 5-year follow-up period, the rate of lead dislodgement in active fixation was significantly lower than that in passive fixation.

As shown in Figure 3C, the results from Elmouchi et al. demonstrated that the rate of MRI conditional lead dislodgement was 13.54 times higher than that of non-MRI-conditional lead dislodgement. This may be attributed to the different skill level of the implanter, which can result in instability of the electrode implanted. For example, a study reported that two implanting physicians both had two lead dislodgements, whereas the remaining three electrophysiologists had no dislodgements<sup>[23]</sup>. The higher rate of dislodgement between the 5086 MRI conditional lead and the 5076 lead may be due to the reduced filar design, the slightly increased lead weight and physician learning curve during implantation of this active fixation lead<sup>[24]</sup>.

### ***Device Dislodgement with LCP Systems***

This study showed that dislodgment of LCP occurs at a lower magnitude compared to transvenous leads dislodgment. While there is no head to head randomized comparison, it appears that dislodgment rate of Micra is lower than Nanostim. Conceivably, the active nitinol tines allow a more stable position as compared to the nanostim helix active fixation. Targeting at least 2/4 tines for engagement within the myocardium gives the implanting physician a visible landmark that helps ensure stability of the pacemaker.

## **Limitations**

We did not have access to individual patient data from all the studies reviewed but relied on published information. Furthermore, there were large variations in the follow-up periods,



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and no long-term follow-up data were available in some of the studies. LCP systems represent single-chamber devices only and patient populations were limited; therefore, the comparison of complications with dual-chamber systems could be biased.

## Conclusions

Dislodgement rates of conventional PM leads vary in individual studies with an overall high incidence. Use of the currently available LCP systems, appears to result in a lower rate of lead dislodgement. This may reflect the effectiveness of this novel technology and the design of these devices. A better classification scheme of device dislodgement would be advantageous for future research. Despite the lack of long-term data, results from these studies showed that leadless pacing therapy is an efficacious and safe alternative to conventional pacemakers.

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Fig.1 Flow chart of the literature search and study selection.

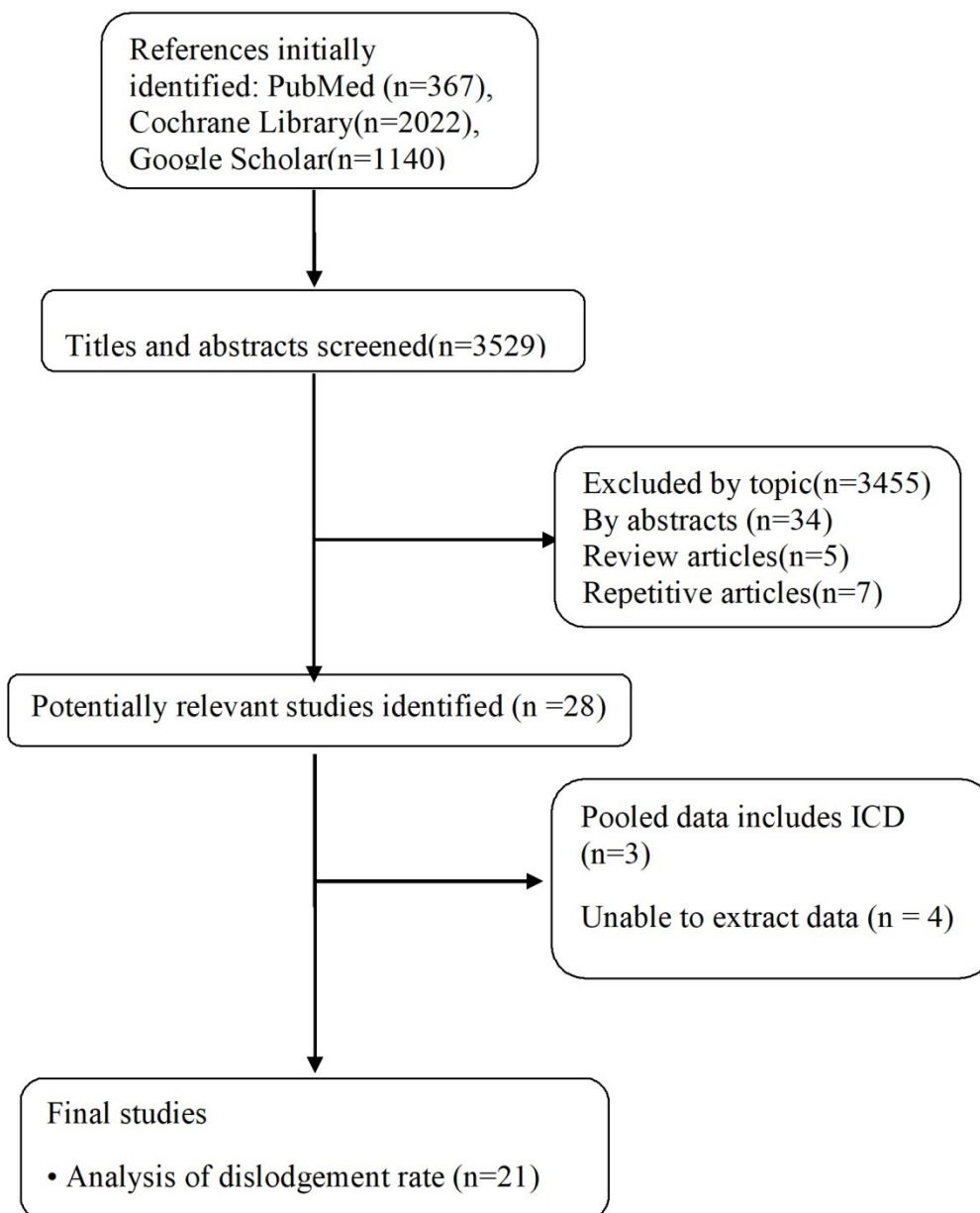


Fig 2. Incidence of pacemaker lead dislodgement in different studies.

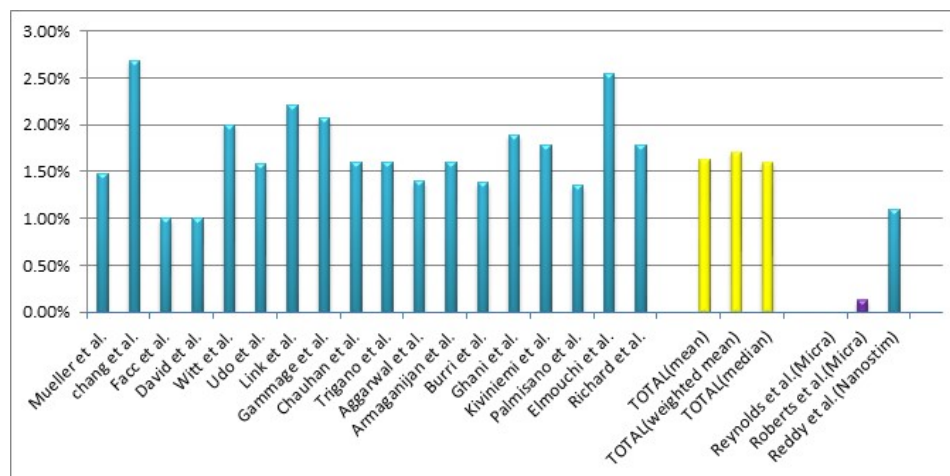


Fig3.(A) Risk of pacemaker lead dislodgement by lead type (RA vs. RV).(B) Risk of pacemaker lead dislodgement by fixation type (passive vs. active).(C) Risk of pacemaker lead dislodgement by lead type (MRI conditional vs. conventional leads).

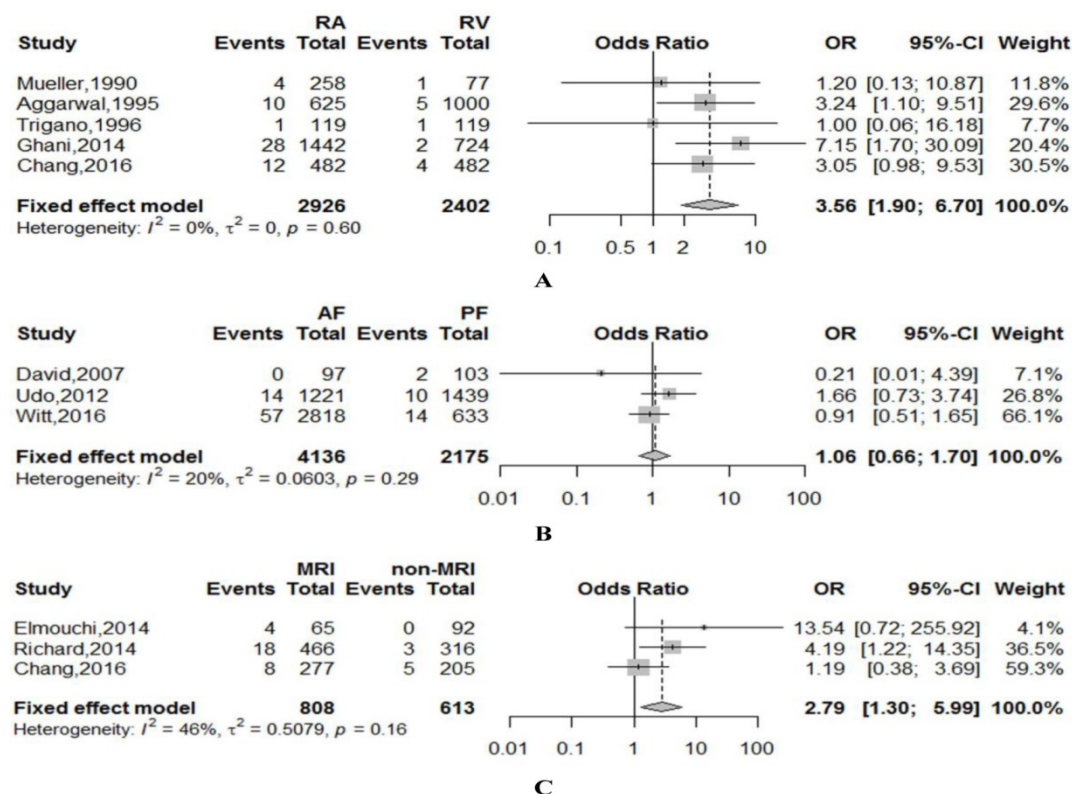


TABLE 1

## Characteristics of Conventional Pacemaker Systems in the Included Studies

Study	Subjects		Incidence	Age (Years)	Sex (Female)	Follow-Up	Devices Implanted	Rate of Dislodgement	Dislodgement Defined as	Quality
	Total	Dislodgement								
Mueller <i>et al.</i> <sup>14</sup>	337	5	1.48%	67~75	43%	16 months	VVI 77%; DDD 23%	4/258 ventricular; 1/77 atrial lead displacement	n.a.	moderate
Chang <i>et al.</i> <sup>5</sup>	482	13	2.69%	66.6±12.8	56.3%	30 days	n.a.	RA lead dislodgement 2.48%; RV lead dislodgement 0.83%;	the movement of the pacing lead from its originally implanted position resulting in elevated pacing thresholds or a decrease in sensing.	high
Facc <i>et al.</i> <sup>6</sup>	486	4	1%	71.4±13.5	45%	33 months	DDD 100%	n.a.	lead dislodgement Exit block with a rise in pacing threshold above the safety margin without evidence of macro-	low
David <i>et al.</i> <sup>7</sup>	200	2	1%	75±10	49.5%	one year	DDD 100%	AF Lead dislodgement (0/97); PF Lead dislodgement (2/103)	lead dislodgement Exit block with a rise in pacing threshold above the safety margin without evidence of macro-	Low Risk

													dislodgement
Witt <i>et al.</i> <sup>8</sup>	34 51	68	2%	73.9	46.6%	1 year	dual-chamber pacemaker	Active fixation dislodgement 2%; Passive fixation dislodgement 2.1%	lead dislodgement	high			
Udo <i>et al.</i> <sup>15</sup>	15 17	24	1.58%	73.7±10.8	44%	long-term follow-up	AAI 1.5%; VVI 25.1%; DDD 73.3%	14 atrial leads and 10 right ventricular leads	Dislocation	moderate			
Link <i>et al.</i> <sup>20</sup>	40 7	9	2.21%	76±8	31%	18 months	DDD 100%	7 with a ventricular lead and 2 with an atrial lead dislodgement	n.a.	moderate			
Gammage <i>et al.</i> <sup>21</sup>	33 8	7	2.07%	70.6±11.6	40%	3 months	DDD 100%		Lead dislodgement a rise in pacing threshold resulting in failure to capture or a visible change of lead position on the chest X ray.	moderate			
Chauhan <i>et al.</i> <sup>9</sup>	20 19	33	1.6%	n.a.	40~45%	6 weeks	VVI 85.8%; DDD 14.2%	18(1%) VVI patients and 15 (5.2%) DDD patients		low			
Trigano <i>et al.</i> <sup>10</sup>	11 9	2	1.6%	69±8	40%	4 weeks	DDD 100%	lead dislodgement of one atrial and one	lead dislodgement	moderate			

									ventricular lead		
Aggarwal <i>et al.</i> <sup>11</sup>	1059	15	1.4%	74.8±12.2	49%	Up to 2 months	AAI 5.2%; VVI 40.7%; VDD 54.1%; DDD 100%	Atrial lead displacement (n = 10, 1.6%)>> ventricular lead displacement (n = 5, 0.5%)	electrode displacement	low	
Armaganijan <i>et al.</i> <sup>17</sup>	4818	80	1.6%	76	43%	5.1 years	AAI/VVI, DDD	n.a.	Lead dislodgment/ Loss of capture	Moderate risk	
Burri <i>et al.</i> <sup>18</sup>	362	5	1.38%	78±10	39%	24 months	VVI 37%, DDD 63%	n.a.	n.a.	moderate	
Ghani <i>et al.</i> <sup>19</sup>	685	13	1.89%	74~78	45%	1 year	AAI/VVI 38%; DDD 62%	Right atrial dislodgment (1.9%); right ventricular dislodgment (0.3 %)	A change in the lead tip position on chest X-ray and changes in electrical lead parameters	high	
Kiviniemi <i>et al.</i> <sup>16</sup>	446	8	1.79%	72±13	59%	27+-20 months	AAI 19%; VVI 55%; VDD 3%; DDD 23%	Dislodgment of atrial lead 6(3.3%); ventricular lead 2(0.6%)		moderate	
Palmisano <i>et al.</i> <sup>22</sup>	959	13	1.35%	n.a.	n.a.	27 months	AAI/VVI 21%; DDD 79%	n.a.	n.a.	moderate	
Elmouchi <i>et al.</i> <sup>23</sup>	157	4	2.55%	68.9~74.8	45%~47%	30 days	DDD 100%	Three of the lead dislodgments were atrial and one was	n.a.	high	



ventricular.

Richard <i>et al.</i> <sup>24</sup>	78 2	14	1.79 %	65.3~7 0.3	55~62 %	9.6~ 30.8 months	DDD,C RT	n.a.	n.a.	Low risk
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TABLE 2

## Characteristics of Leadless Pacemaker Systems in the Included Studies

Study	Subjects(N)		Incidence	Age(Years)	Sex(Female)	Follow-Up	Devices Implanted	Dislodgement Defined as	Quality
	Total	Dislodgement							
Reynolds <i>et al.</i> <sup>25</sup>	725	0	0	75.9±10.9	41.2%	1 year	Micra TPS	No dislodgement 2 times were observed to not be embedded in tissue and 2 times were positioned between the wall and papillary muscle Device migration to the pulmonary artery or right femoral vein occurred in 4 and 2 patients, respectively.	high
Roberts <i>et al.</i> <sup>12</sup>	795	1	0.13%	75.2±14.2	62.3%	1 months	Micra TPS		high
Reddy <i>et al.</i> <sup>13</sup>	526	6	1.1%	75.8±12.1	385	6.9±4.2 months	Nanostim-LCP		high