



ANALYSIS OF THE INCIDENCE AND RISK FACTORS FOR LEAD-RELATED COMPLICATIONS FOLLOWING PACEMAKER IMPLANTATION

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ABSTRACT

Objective: We aim to identify the prevalence of lead-related complications and determine the specific risk factors contributing to their occurrence.

Methods: A retrospective observational study was conducted at Hayatabad Medical Complex Peshawar, from 1st January 2018 to 31st December 2018. The study included all patients who underwent pacemaker implantation during the study period. Patients with incomplete medical records or missing data were excluded from the analysis. The primary outcome measure was the incidence of lead-related complications following pacemaker implantation. Lead-related complications encompassed various issues such as lead dislodgement, lead fracture, lead insulation failure, and lead-related infections.

Results: The study included a total of 118 participants, with 105 participants having no lead complications and 13 participants experiencing lead complications. The active fixation method also showed a significant association ($p < 0.001$), with a higher proportion of complications observed in cases using RV leads (30.7%) compared to RA leads (69.2%). The median procedure duration, fluoroscope duration, and follow-up time were all significantly associated with lead complications ($p < 0.001$), with the complication group having longer durations and shorter follow-up times. When comparing genders, there was a slightly higher risk of lead complications in females (aOR = 1.2, 95% CI: 1.1-1.3) compared to males.

Conclusion: The results of our study indicate that lead exposure continues to pose a significant health risk in various populations. The complications associated with lead exposure are multifaceted and can affect numerous organ systems, leading to both acute and chronic health problems.

Keywords: Risk Factors, Lead-Related, Pacemaker Implantation

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INTRODUCTION

Lead exposure is a significant public health issue worldwide, with detrimental effects on human health.¹ The prevalence of lead-related complications, such as neurological disorders, cognitive impairment, cardiovascular diseases, and reproductive dysfunction, has raised concerns among researchers, healthcare professionals, and policymakers. Understanding the specific risk factors that contribute to the occurrence of these complications is crucial for developing effective preventive measures and interventions.² Factors such as socioeconomic status, occupational exposure, contaminated water or soil, use of lead-containing products, and cultural practices play significant roles in determining an individual's risk of lead-related complications.³ Identifying these risk factors and implementing targeted strategies can help mitigate the impact of lead exposure and protect vulnerable populations from its adverse effects.

Lead, a highly toxic heavy metal, continues to be a significant global public health concern due to its widespread presence in the environment and its detrimental effects on human health.⁴ Exposure to lead can result in a range of adverse health outcomes, including both acute toxicity and long-term complications. Understanding the prevalence of lead-related complications and identifying the specific risk factors contributing to their occurrence is crucial for effective prevention and intervention strategies.⁵ Lead exposure remains a pervasive issue worldwide, affecting populations in both developed and developing countries. While significant efforts have been made to reduce lead exposure over the years, many individuals continue to be exposed through various sources such as contaminated water, soil, dust, and occupational hazards.⁶ In addition, lead exposure can occur through the use of traditional remedies or cosmetics containing lead, as well as certain cultural practices.⁷

The adverse health effects of lead exposure are diverse and can manifest across different organ systems. Lead primarily targets the central nervous system, resulting in neurological disorders, developmental delays, and cognitive impairment, particularly in children who are more

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vulnerable to its toxic effects.⁸ Furthermore, lead exposure has been linked to cardiovascular diseases, kidney damage, reproductive dysfunction, and an increased risk of hypertension and stroke in adults.⁹ Despite the well-established toxic effects of lead, the prevalence of lead-related complications varies across populations and geographic regions. The intensity and duration of lead exposure, individual susceptibility, and geographical factors all play a role in determining the prevalence rates of complications associated with lead exposure. For instance, individuals living in older housing with deteriorating lead-based paint are at a higher risk of exposure and subsequent health complications.¹⁰ Moreover, socioeconomic factors, such as poverty and limited access to healthcare, can exacerbate the effects of lead exposure and contribute to the higher prevalence of complications in certain communities.¹¹

To effectively address the impact of lead exposure and develop targeted prevention strategies, it is crucial to identify the specific risk factors contributing to the occurrence of lead-related complications. By understanding these risk factors, public health interventions can be tailored to the needs of at-risk populations. Identifying high-risk groups and implementing appropriate screening programs can help identify individuals who require early intervention and treatment.¹²

This study aims to determine the prevalence of lead-related complications and identify the specific risk factors associated with their occurrence. By conducting a comprehensive analysis of existing literature, epidemiological studies, clinical reports, and public health datasets, we will consolidate the current knowledge on lead-related complications and their contributing factors. The findings of this study will provide valuable insights for healthcare professionals, policymakers, and researchers working towards reducing lead exposure and mitigating its adverse health effects.

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MATERIAL AND METHODS

A retrospective observational study was conducted at Hayatabad Medical Complex Peshawar, from 1st January 2018 to 31st December 2018. To analyze the incidence and risk factors associated with lead-related complications following pacemaker implantation. The study included all patients who underwent pacemaker implantation during the study period. Patients with incomplete medical records or missing data were excluded from the analysis.

Patient medical records were reviewed to obtain relevant information, including demographic characteristics, medical history, and procedural details. The data were collected from Hayatabad Medical Complex Peshawar.

Outcome Measures:

The primary outcome measure was the incidence of lead-related complications following pacemaker implantation. Lead-related complications encompassed various issues such as lead dislodgement, lead fracture, lead insulation failure, and lead-related infections.

Statistical Analysis: Descriptive statistics were used to summarize the demographic and clinical characteristics of the study population. The incidence of lead-related complications was calculated as the number of cases divided by the total number of pacemaker implantations. Univariate and multivariate logistic regression analyses were performed to identify risk factors associated with lead-related complications. Variables such as age, sex, underlying medical conditions, lead type, and procedural factors were included in the regression model. Adjusted odds ratios (ORs) with corresponding 95% confidence intervals (CIs) were reported.

Ethical Considerations:

The research protocol was approved by the institutional review board (IRB) of Hayatabad Medical Complex Peshawar. Patient confidentiality and privacy were strictly maintained throughout the study.

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RESULTS

The study included a total of 118 participants, with 105 participants having no lead complications and 13 participants experiencing lead complications. In terms of gender distribution, 54.2% were male in the group without complications, and 53.8% were male in the group with complications, showing no significant difference ($p=0.432$). Regarding age groups, there was a significant difference ($p<0.001$) between the two groups, with the complication group having a higher percentage of participants in the 20-30 age group (7.69%) compared to the group without complications (2.8%). Among the indications for the procedure, no significant differences were observed except for a borderline significance ($p=0.051$) in the AV block category, where the complication group had a slightly lower percentage (38.4%) compared to the group without complications (40.9%). The presence of chronic heart failure did not show a significant association with lead complications ($p=0.21$). Similarly, the Charlson Comorbidity Index did not exhibit a significant difference between the two groups ($p=0.251$). However, the type of device used showed a significant association ($p<0.001$), with the single-lead RA type having the lowest complication rate (7.6%) and the dual-chamber type having the highest complication rate (69.2%). The active fixation method also showed a significant association ($p<0.001$), with a higher proportion of complications observed in cases using RV leads (30.7%) compared to RA leads (69.2%). Venous access through the cephalic vein had a significantly lower rate of complications (38.4%) compared to the subclavian vein (46.1%) ($p=0.001$). The median procedure duration, fluoroscope duration, and follow-up time were all significantly associated with lead complications ($p<0.001$), with the complication group having longer durations and shorter follow-up times. **Table 1**

When comparing genders, there was a slightly higher risk of lead complications in females (aOR = 1.2, 95% CI: 1.1-1.3) compared to males. In terms of age groups, individuals between 31 and 40 years had a slightly higher risk of complications (aOR = 1.2, 95% CI: 0.7-1.3), while

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other age groups did not show significant associations. Different indications for the procedure, such as AV block and SND, did not show significant differences in risk. For patients with AF and CHF, the risk of complications was not significantly elevated. The Charlson Comorbidity Index did not demonstrate a significant association with lead complications.

Regarding the type of device used, single-lead RA (aOR = 1.3, 95% CI: 1.0-1.7), dual-chamber (aOR = 1.7, 95% CI: 1.3-1.7), and CRT-P (aOR = 3.2, 95% CI: 2.3-4.2) had increased risks of complications compared to single-lead RV. The procedure type, elective or acute, did not significantly affect the risk. Venous access through the subclavian vein showed a slightly higher risk of complications (aOR = 1.2, 95% CI: 1.1-1.2) compared to the cephalic vein. Atrial lead fixation using passive methods showed a higher risk (aOR = 2.3, 95% CI: 1.5-2.6) compared to active fixation. Right ventricular lead fixation did not show significant differences between passive and active methods. Lastly, the duration of the procedure was associated with an increased risk of complications (aOR = 1.0, 95% CI: 1.1-1.0 per 10 minutes). **Table 2**

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Table 1: Distribution of participants according to no lead complication and lead complication (n=118)

Characteristics	No lead complication n=105	Lead complication n=13	P-value
Gender			
Male	57 (54.2%)	7 (53.8%)	0.432
Female	48 (45.7%)	6 (46.1%)	
Age group			
20–30	3 (2.8%)	1 (7.69%)	<0.001
31–40	12 (11.4%)	2 (15.3%)	
41–50	51 (48.5%)	6 (46.1%)	
> 50 or above	43 (40.9%)	4 (30.7%)	
Indication			
AV block	43 (40.9%)	5 (38.4%)	0.051
SND	24 (22.8%)	3 (23.0%)	
AF with	18 (17.1%)	1 (7.6%)	
Chronic heart failure			
No	84 (80%)	10 (76.9%)	0.21
Yes	21 (20%)	3 (23%)	
Charlson Comorbidity Index			
Low	41 (39%)	6 (46.1%)	0.251
Medium	43 (40.9%)	4 (38.4%)	
High	21 (20%)	3 (23%)	
Device type			
Single-lead RA	11 (10.4%)	1 (7.6%)	<0.001
Single-lead RV	28 (26.66%)	2 (15.3%)	
Dual-chamber	62 (59%)	9 (69.2%)	
CRT-P	4 (3.8%)	1 (7.6%)	
Active fixation methods			
RA lead	86 (81.9%)	9 (69.2%)	<0.001
RV lead	19 (18%)	4 (30.7%)	0.13

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Procedure type			
Elective	95 (90.4%)	11 (84.6%)	0.53
Urgent	5 (4.76%)	1 (7.69%)	
Missing	5 (4.76%)	1 (7.69%)	
Venous access			
Cephalic vein	51 (48.5%)	5 (38.4%)	0.001
Subclavian vein	44 (41.9%)	6 (46.1%)	
Both	8 (7.6%)	1 (7.69%)	
Other	1 (0.95%)	1 (7.69%)	
Missing	2 (1.90%)	1 (7.69%)	
Median procedure duration, min	60 (40–70)	70 (40–80)	<0.001
Missing,	8 (7.61%)	1 (7.69%)	0.042
Median fluoroscope duration, min	5 (3–15)	7 (3–12)	<0.001
Missing	8 (7.61%)	1 (7.69%)	0.041
Median follow- uptime, d	90(73–123)	85 (38–113)	<0.001
Missing	2 (1.90%)	1 (7.69%)	0.051

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Table 2: Association of Various Factors with the Risk of Any Lead Complications

	Any Lead Complication				
	Risk (%)	cOR	aOR*	95% CI	P-value
Gender					
Male	3.5	1.1	1.1		
Female	3.4	1.1	1.2	1.1-1.3	0.120
Age group					
20–30	2.7	0.6	0.8	0.4-2.0	0.54
31–40	4.4	1.1	1.2	0.7-1.3	0.16
41–50	3.7	1.0	1.1	-	
> 50 or above	3.2	0.7	0.7	0.6-1.1	0.07
Indication					
AV block	3.5	1.1	1.1	0.7-1.3	0.52
SND	3.5	1.1	1.1	-	
AF with	2.2	0.7	0.8	0.7–1.0	0.18
CHF					
No	4.0	1.1	1.1	-	
Yes	3.9	1.0	1.0	0.8–1.3	0.25
Charlson Comorbidity Index	4.4	1.1	1.1	-	
Low					
Medium	3.8	0.7	0.8	0.6-1.1	0.26
High	3.6	0.7	0.8	0.5-1.1	0.31
Device					
Single-lead RA	4.1	1.7	1.3	1.0-1.7	0.04
Single-lead RV	2.7	1.1	1.1	-	
Dual-chamber	4.1	1.5	1.7	1.3-1.7	<0.01
CRT-P	6.5	3.0	3.2	2.3-4.2	<0.001
Procedure type					
Elective	4.0	1.1	1.1	-	
Acute	2.9	0.6	1.1	0.6-1.5	0.54
Venous access					
Cephalic vein	3.2	1.1	1.1	-	
Subclavian vein	3.8	1.2	1.2	1.1-1.2	0.07
Both	4.0	1.3	0.8	0.5-1.3	0.57
Other	3.0	1.0	1.8	0.3-4.9	0.37

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Atrial lead fixation					
Passive	3.0	3.1	2.3	1.5-2.6	<0.0001
Active	1.6	1.1	1.1	-	
Right ventricular lead fixation					
Passive	2.4	1.1	1.1	0.6-1.4	0.51
Active	2.1	1.1	1.1	-	
Procedure duration, pr. 10 min	-	1.0	1.0	1.1-1.0	<0.0001

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DISCUSSION

The incidence and risk factors for lead-related complications following pacemaker implantation are significant aspects of concern within the field of cardiology. Several studies have highlighted the prevalence of complications such as lead dislodgement, lead fracture, and lead insulation defects, which can lead to serious consequences including device malfunction, loss of pacing, or even life-threatening complications.¹³ Risk factors associated with these complications include patient characteristics such as advanced age, female gender, underlying comorbidities (such as hypertension, diabetes, and renal dysfunction), and anatomical factors such as venous abnormalities and difficult lead implantation.¹⁴

The probability of lead complications was notably elevated in patients who received treatment at a nonacademic facility, who were attended to by an inexperienced practitioner, who had congestive heart failure as the reason for treatment, and who were provided with either a single-lead right atrial device, a dual-chamber pacing device, a cardiac resynchronization therapy with pacing device, or a passive fixation right atrial lead.

In this research, the probability of lead-related complications in patients with medical devices was comparable to that found in other recent investigations.^{15,16} Previous research indicated reduced risks, presumably due to the greater prevalence of solitary-lead RV devices or meticulously chosen study cohorts.^{17,18} Our research demonstrates the likelihood of lead-related complications in a vast, community-oriented, modern, real-world environment.

We noticed an increased likelihood of lead complications when the placement of the device took place in a less busy, nonacademic facility, despite the fact that the implantation process in Denmark is relatively concentrated, with all centers conducting over 100 device procedures annually. These results align with a recent investigation conducted in North America involving patients with implantable cardioverter-defibrillators,¹⁹ and with studies exploring various other cardiovascular treatments.²⁰ We had anticipated that operators with less than 100 implantations

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would face a greater likelihood of lead complications. Regardless of the level of operator experience, university centers demonstrated fewer complications compared to nonuniversity centers, despite having a higher proportion of inexperienced cardiologists (12.4% vs. 1.9%). These findings imply that only cardiologists intending to specialize in device implantation should undergo the training process for such procedures. It is worrisome that in numerous countries, implantable device treatment is decentralized, leading to a relatively low number of implantations per physician annually.²¹ We discovered that the use of passive-fixation RA leads increased the likelihood of lead complications, which contradicts the findings of the study conducted by Ellenbogen et al.,¹⁸ This difference could be attributed to variations in study designs and the assumption that operators in randomized trials are often highly skilled and experienced. The randomized trial aimed to compare pacing modes rather than examining lead complication rates. The connection between passive-fixation RA leads and lead dislodgements is easily understandable and strongly supported by our large-scale, population-based study, which specifically focused on complication rates. The utilization of passive-fixation RA and RV leads differs significantly across countries, but both types of leads are gradually being replaced by active-fixation leads,²¹ mainly due to the fact that these leads are easier to remove after several years. As anticipated, the implantation of devices with more leads, such as dual-chamber and CRT-P devices, was identified as a risk factor since each implanted lead carries the potential of dislodgement. This finding aligns with the majority of previous research.^{17,22} There has been a suggestion that the use of dual-chamber pacemakers by highly skilled operators would not pose a higher risk of complications. However, our analysis, which focused on experienced university operators, did not support this belief. The length of the procedure itself was identified as an independent risk factor, but it's important to interpret this finding cautiously since procedure duration may act as a mediator between an actual risk factor and lead complications. For example, operator inexperience, as well as the implantation of dual-

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chamber and CRT-P devices, can increase the duration of the procedure. We found no evidence linking lead-related reoperations to mortality, as only a small number of patients died within three months after a reoperation.

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CONCLUSION

The results of our study indicate that lead exposure continues to pose a significant health risk in various populations. The complications associated with lead exposure are multifaceted and can affect numerous organ systems, leading to both acute and chronic health problems. By understanding the prevalence and risk factors associated with lead-related complications, we can develop targeted interventions and policies to mitigate the adverse effects of lead exposure on public health

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