Original Article

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Asymptomatic Complete Heart Block: How Soon Should a Pacemaker be Implanted?

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Abstract:

Objective: This study aimed to determine the onset of adverse events after the diagnosis of asymptomatic complete heart block in order to guide the appropriate timing of pacemaker implantation.

Material and Methods: A retrospective analysis of data from the electronic medical records from 2002 to 2020 was conducted at a university hospital in Southern Thailand. The study focused on patients diagnosed with asymptomatic complete heart block using standard 12-lead electrocardiograms. Kaplan-Meier survival analysis was used to examine the time from diagnosis to any adverse events before pacemaker implantation.

Results: Among 95 asymptomatic complete heart block patients with incidental detection of bradycardia (mean age 70.4±15.0 years old) during hospital visits, the mean heart rate was 40.5±7.2 beats per minute and the median QRS duration was 110 milliseconds (ms) (interquartile range (IQR) 92, 145.8 ms). All patients eventually underwent pacemaker implantation. The median waiting time for the implant was 61 days (IQR 14, 223 days). During the waiting period, 34 patients (35.8%) experienced adverse events. Syncope was the first major adverse event that occurred 27 days after the diagnosis. According to survival analysis, the 30-day and 90-day event-free survivals were 94.2% and 83.7%, respectively.

Conclusion: The waiting period for pacemaker implantation in patients with asymptomatic complete heart block poses certain risks. To mitigate the chance of developing major adverse events, it is better to implant a pacemaker sooner rather than later.

Keywords: adverse events, asymptomatic, complete heart block, pacemaker implantation, prevalence, waiting time

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Introduction

Complete heart block requires prompt evaluation and management. The prevalence of complete heart block in the general population is reported to be 40 per 100,000[1]. Factors associated with all degrees of atrioventricular (AV) block include older age, male sex, history of myocardial infarction, history of congestive heart failure, high systolic blood pressure, and high fasting blood glucose level[2].

The clinical presentation of complete heart block varies among individual patients. While some may present with pre-syncope, syncope, or heart failure symptoms, others may be asymptomatic at the time of diagnosis[1]. The survival rate among symptomatic patients is reported to be lower than that of asymptomatic individuals[3].

Although both US and European guidelines clearly state that permanent pacemaker implantation is recommended for patients diagnosed with complete heart block regardless of symptoms[4,5], the timing of the implant, especially for asymptomatic patients, was not included in the recommendation.

A previous study demonstrated that delayed pacemaker implantation for patients admitted to hospitals because of bradycardia resulted in an increased number of adverse events[6]. There is still limited evidence regarding when asymptomatic complete heart block patients will experience adverse events and how soon a pacemaker should be implanted.

Material and Methods

Study design, study setting, and study population

This retrospective study was conducted at Songklanagarind Hospital, a university hospital in Southern Thailand. Using the International Classification of Diseases-Tenth Revision (ICD-10) code for complete heart block, code I44.2, electronic medical records (EMR) from 2002 to 2020 were reviewed to identify a potential study population.

Patients aged 18 years or older were included if they had complete heart block documented on 12-lead electrocardiograms (ECGs), had no reversible causes (e.g., serum electrolyte abnormalities or currently taking atrioventricular nodal blocking medications), and did not have specific diseases that required urgent management, such as myocardial infarction, infective endocarditis, or complications from cardiac procedures. At the time of diagnosis, all study patients must not have had symptoms related to complete heart block, such as dyspnea, lightheadedness, syncope, or cardiac arrest. Patients with indeterminate symptom status or insufficient data were excluded.

Measurement

Clinical and ECG data were collected from EMR. The clinical data consisted of age, gender, comorbidities, and waiting time for pacemaker implantation. The ECG data included reasons for obtaining ECGs, ventricular rate, QRS duration, and presence of atrial fibrillation or atrial flutter. All ECGs were reviewed and confirmed by attending cardiologists.

Outcomes of interest were all adverse events that occurred after the diagnosis and prior to pacemaker implantation. Major adverse events were defined by syncope, congestive heart failure, ventricular arrhythmias, cardiac arrest, or death. The time to develop adverse events was collected.

Statistical analysis

Descriptive statistics and tables were used to describe demographic data, clinical manifestations, laboratory results, and any adverse events that occurred while awaiting permanent pacemaker implantation in the patients diagnosed with asymptomatic complete heart block. If data were normally distributed, continuous

variables were presented as means±standard deviation (S.D.) and compared using a t-test. When data were not normally distributed, continuous variables were presented as medians and interquartile range (IQR) and compared using the Wilcoxon rank-sum test. Categorical variables were presented as numbers and percentages and compared using the chi-square test or Fisher's exact test. The study employed Kaplan-Meier survival analysis to assess the time from diagnosis to the occurrence of adverse events preceding pacemaker implantation. The results were considered statistically significant if p-value<0.05. All analyses were performed using R-Program 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria, 2018) with survival package.

Ethical considerations

The research protocol for this study received formal approval from the Ethics Committee of the Human Research Ethics Unit (HREU), Faculty of Medicine, Prince of Songkla University, under reference number REC. 64-426-14-1. In light of the retrospective data collection, informed consent was waived, adhering to the established ethical guidelines. Privacy and data protection measures were meticulously upheld to preserve participants' confidentiality.

Results

An electronic medical records search using ICD-10 code I44.2 identified 1,442 patients. One hundred and fourteen patients were excluded due to incorrect diagnoses, e.g., sinus node dysfunction or second-degree AV block. One hundred and eighty-seven patients were excluded due to insufficient clinical or ECG data. The patients with insufficient data consisted of, for example, receiving pacemaker implantation from outside hospitals or no recorded ECGs. The remaining 1,141 patients were confirmed to have complete heart block. One thousand and forty-six patients were excluded because they were symptomatic or had an urgent condition at the time of diagnosis. A total of 95 patients were included in the study (Figure 1).

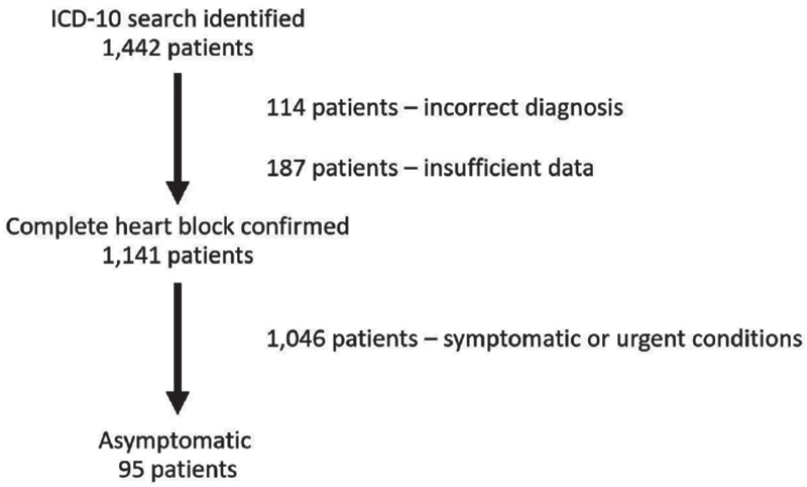
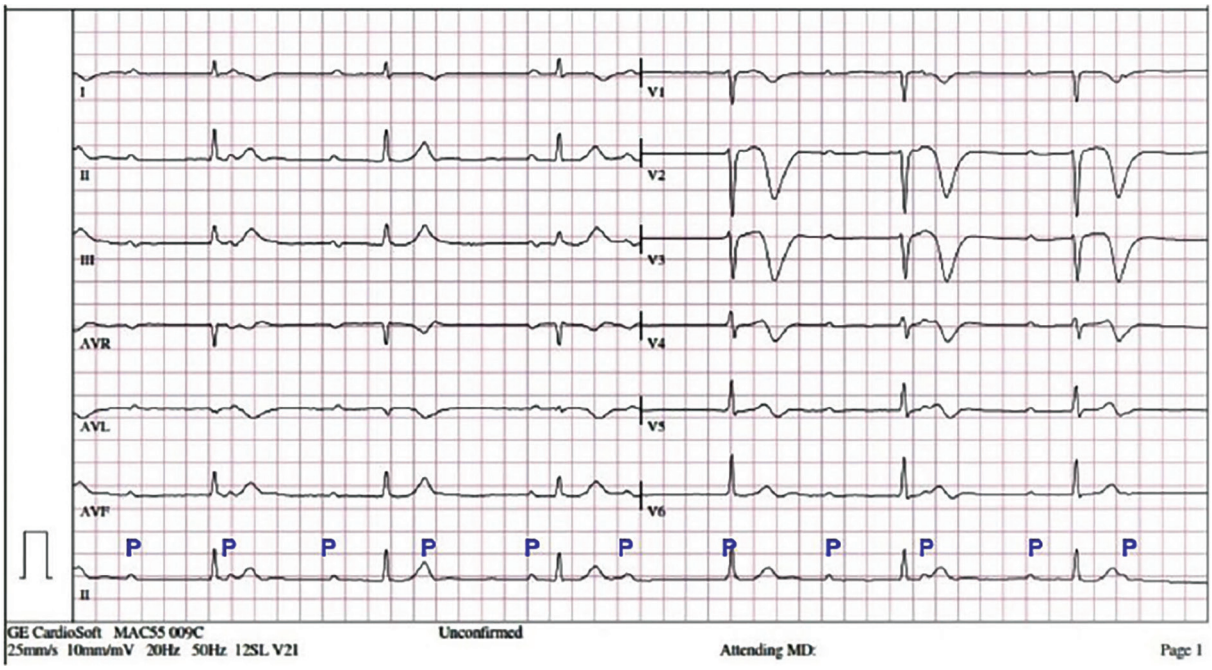


Figure 1 Flow chart of patients recruited to the study.

All patients, with an average age of 70.4±15.0 years and 57.9% being male, were incidentally detected to have asymptomatic bradycardia during hospital visits for annual physical checkup, pre-operative evaluation for non-cardiac surgeries, visits for other non-related illnesses (e.g., respiratory tract infection), or routine follow-up for treatment of hypertension. All of them had 12-lead ECGs that confirmed the presence of complete heart block with junctional or ventricular escape rhythms (escape rate 40.5± 7.2 beats per minute; median QRS duration 110.0 milliseconds (ms) (IQR 92.0, 145.8 ms)). Atrial rhythms in almost all the patients were sinus rhythms (96.8%). Figure 2.1 and Figure 2.2 display ECG samples from patients in this study cohort.

All patients finally received pacemaker implantation. The median waiting time for the implant was 61 days (IQR 14, 223 days). Thirty-four patients (35.8%) experienced adverse events during the waiting period. Age, gender, and comorbidities were not different between patients with and without adverse events.



*P indicates sinus P-waves

Figure 2.1 An ECG from one of the patients who had adverse events during the waiting period. "A 73-year-old woman was incidentally detected to have asymptomatic bradycardia during routine follow-up for treatment of hypertension. ECG revealed sinus rhythm with complete heart block with narrow QRS escape, suggesting AV nodal block (QRS duration 94 ms) at a ventricular rate of 39 beats per minute. The patient reported having dizziness 41 days after the diagnosis of complete heart block and underwent pacemaker implantation 64 days after the diagnosis. Coronary angiogram prior to the implant showed insignificant stenosis of the coronary artery."

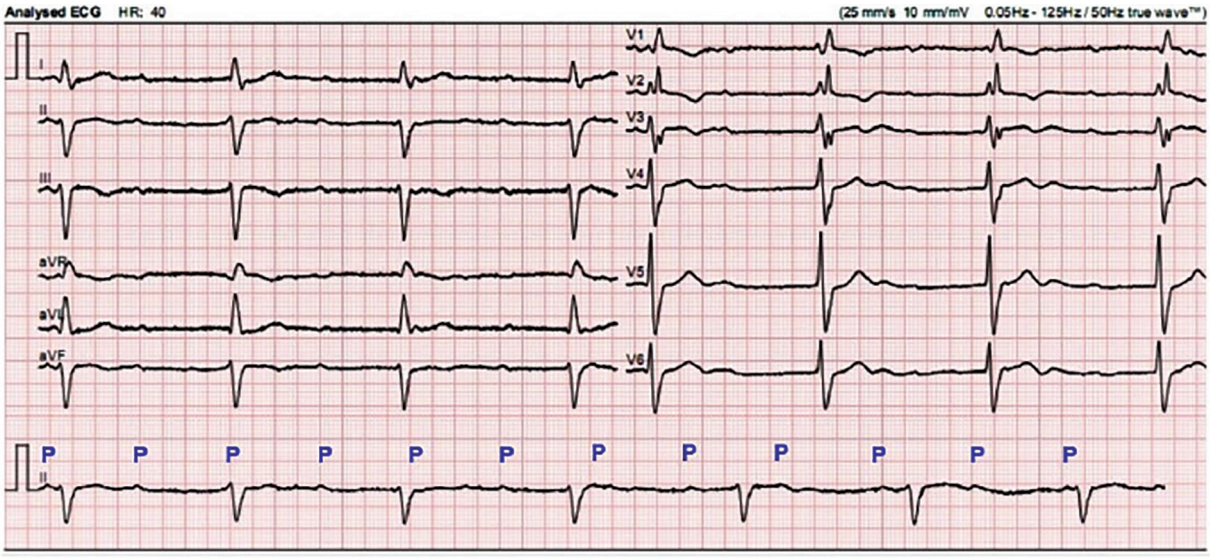


Figure 2.2 An ECG from one of the patients who did not have adverse events during the waiting period. "A 93-year-old man was detected to have a slow heart rate by his caregiver without having bradycardia-related symptoms. ECG revealed sinus rhythm with complete heart block with wide QRS escape (QRS duration 158 ms) at a ventricular rate of 40 beats per minute. The QRS morphology was consistent with right bundle branch and left anterior fascicular block, which suggested infra-nodal AV block. He underwent pacemaker implantation 15 days after the diagnosis. There was no adverse event reported during the waiting period."

Patients experiencing adverse events had a markedly longer waiting period for pacemaker implantation compared to those without adverse events (542 days, IQR 78.8-1314.8 vs. 33 days, IQR 9-73, p-value<0.001) (Table 1). In terms of ECG findings, while heart rates were not different between the two groups, QRS duration was longer in the group without adverse events (123 ms (95.8, 148.5 ms) vs 95.5 ms (82.0, 121.5 ms), p-value=0.007) (Table 2).

The most frequent adverse event documented in the record was dyspnea on exertion, which accounted for 15.8% of the patients (Table 3). Syncope was the first major adverse event that occurred in 4.2% of the patients. The first syncopal event occurred 27 days after diagnosis. The most serious adverse event in this cohort was survived cardiac arrest, which occurred in two patients (2.1%). The first cardiac arrest event occurred 36 days after the diagnosis. Both cardiac arrest events were attributed to prolonged ventricular asystole, which necessitated a few minutes of chest compression followed by temporary pacemaker pacing. Notably, there was no cardioversion or defibrillation documented during these two events. Some adverse events, such as cerebrovascular accidents or ventricular arrhythmias, occurred years after the diagnosis. These events were still considered relevant since they could be related to episodes of very slow heart rate or intermittent ventricular asystole. No deaths were reported during this waiting period.

The Kaplan-Meier curve demonstrates a 94.2% probability of surviving without adverse events at 30 days, slightly decreasing to 83.7% at 90 days (Figure 3).

Table 1 Clinical characteristics of patients with and without adverse events.

Clinical characteristics	Patients with adverse events (n=34)	Patients without adverse events (n=61)	p-value
Age-years (IQR)	74.0 (59.8, 80.0)	73.0 (66, 80.0)	0.524
Male-n (%)	17 (50)	38 (62.3)	0.410
Comorbidities			
Diabetes-n (%)	9 (26.5)	14 (23.0)	0.893
Hypertension-n (%)	21 (61.8)	38 (62.3)	1.000
Dyslipidemia-n (%)	11 (32.4)	18 (29.5)	0.995
Coronary artery disease-n (%)	8 (23.5)	11 (18.0)	0.708
Cerebrovascular accident-n (%)	3 (8.8)	4 (6.6)	0.703
Chronic kidney disease-n (%)	2 (5.9)	4 (6.6)	1.000
Connective tissue disease-n (%)	0 (0.0)	4 (6.6)	0.293
Smoking-n (%)	10 (29.4)	28 (45.9)	0.190
Alcohol drinking-n (%)	10 (29.4)	15 (24.6)	0.418
Waiting time for pacemaker implant-days (IQR)	542.0 (78.8, 1314.8)	33.0 (9, 73.0)	<0.001*

*p-value significant, IQR=interquartile range

Table 2 ECG characteristics of patients with and without adverse events.

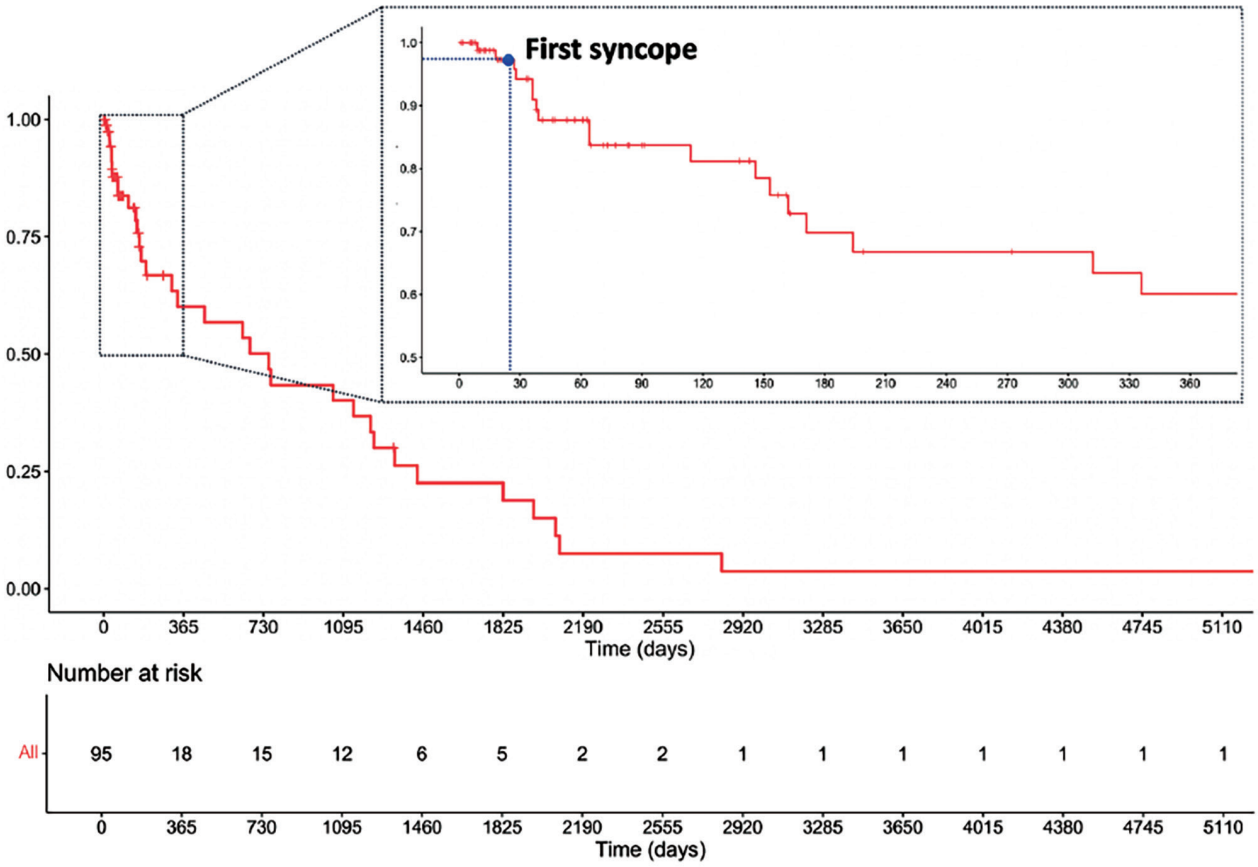
ECG Characteristics	Patients with adverse events (n=34)	Patients without adverse events (n=61)	p-value
Heart rate-bpm (IQR)	40.0 (36.0, 46.5)	40.0 (35.0, 44.0)	0.607
QRS duration-ms (IQR)	95.5 (82.0, 121.5)	123.0 (95.8, 148.5)	0.007
Atrial fibrillation-n (%)	1 (3.3)	1 (1.8)	
Atrial flutter-n (%)	0 (0.0)	1 (1.8)	
Reasons for obtaining ECGs			0.562
Hospital visits for non-related illnesses-n (%)	26 (76.5)	50 (82.0)	
Preoperative evaluation-n (%)	6 (17.6)	5 (8.2)	
Checkup-n (%)	2 (5.9)	6 (9.8)	

ECG=electrocardiograms, bpm=beats per minute, IQR=interquartile range, ms=milliseconds

Table 3 Frequency and timing of adverse events after the diagnosis of asymptomatic complete heart block.

Adverse events	Number of patients (%)*	Distribution of timing of adverse events (days after diagnosis)
Dyspnea on exertion	15 (15.8)	9, 18, 38, 64, 114, 171, 336, 461, 754, 1,048, 1,141, 1,432, 2,064, 2,083, 2,822
Syncope	4 (4.2)	27, 312, 634, 1,218
Dizziness	5 (5.3)	28, 36, 162, 194, 669
Survived cardiac arrest	2 (2.1)	36, 64
Chest discomfort	2 (2.1)	39, 146
Congestive heart failure	4 (4.2)	153, 1,234, 1,329, 1,824
Cerebrovascular accident	1 (1.1)	764
Ventricular arrhythmia	1 (1.1)	1,964

*Percentage calculated from total number of patients in the cohort (95 cases)



*First syncope indicates the first reported syncopal event that happened 27 days after the diagnosis of asymptomatic complete heart block

Figure 3 Kaplan Meier analysis for freedom from developing adverse events while awaiting pacemaker implantation.

Discussion

Patients with complete heart block are sometimes incidentally detected by the presence of a slow heart rate and diagnosed by an ECG without having symptoms. In this study, 95 out of 1,141 patients (8.3%) were asymptomatic at the time of complete heart block diagnosis. They came to the hospital for various reasons without previous recognition of bradycardia episodes or related symptoms.

In this patient cohort, the majority of the patients were older adults with a mean age in their 70s, and more than half had underlying hypertension. This may suggest that most of the complete heart block in this cohort was caused by a degenerative disease of the conduction system. The degenerative change possibly developed gradually; hence, all patients tolerated the slow heart rate well and did not have any symptoms at the time of diagnosis. Another possible explanation for an asymptomatic nature could also be the physical inactivity of some elderly patients.

The waiting time for pacemaker implant for the entire cohort was longer than one would expect. Since they were asymptomatic and the appropriate timing of pacemaker implant is not clearly stated in guidelines, the procedures were scheduled based on the availability of the patients and the hospital. Some patients initially refused the procedure but later consented months or even years after the diagnosis. Consequently, the waiting duration varied widely from patient to patient.

Around a third of the patients in this cohort experienced adverse events during the waiting period, while the remaining patients were free from events. Except for the waiting time, other baseline characteristics were not different between patients with and without adverse events. This could mean that if their wait is too long, adverse events will occur, even when they were asymptomatic at the time of diagnosis. This interpretation is also supported by the survival analysis for freedom from developing adverse events. The analysis demonstrated that the longer the waiting time, the lower the chance of being event-free.

Among patients with and without adverse events, almost all ECG findings were similar, except for the QRS width. In patients without adverse events, the QRS width was wider. However, the majority of the patients in the cohort still had narrow QRS complexes. Specifically, the median QRS duration was 95.5 ms (82.0, 121.5) in the group with adverse events and 123.0 ms (95.8, 148.5) in the group without an event. Additionally, the median heart rates were 40 beats per minute in both groups. These findings suggest that the site of the block was mainly AV nodal block (Figure 2.1). However, it is worth noting that a few patients might have infra-nodal AV block, which could be suspected by a wide QRS with specific bundle branch or fascicular block pattern (Figure 2.2).

Our findings, once again, demonstrate that even though the escape rhythm has a narrow QRS, if the waiting time for pacemaker implant is long enough, adverse events can also occur. This information also aligns with a previous study by Lane and Kennelly, which demonstrated that neither heart rate nor QRS width could predict the incidence of syncope in complete heart block patients[7].

A nationwide community study reported that the prevalence of any degree of AV block increases with age[8]. With the growth of elderly populations globally and the higher accessibility to ECG testing, the number of asymptomatic complete heart block patients, as well as the need for pacemaker implantation, tends to increase progressively. Hence, the findings from this study would be beneficial for physicians and patients conducting shared decision-making regarding when to implant a pacemaker in this condition.

To our knowledge, this is the first study to collect such a large number of patients with asymptomatic complete heart block at the time of diagnosis and report the adverse events while awaiting pacemaker implantation.

Still, there are some limitations to be aware of. First, this is a single-center study conducted at a university-based referral hospital that might not represent complete

heart block patients in different healthcare facilities or communities. Second, in order to confirm the accuracy of the diagnosis and symptom status, a number of patients were excluded from the study due to insufficient clinical or ECG data. Additionally, the retrospective design is unavoidably subject to some degree of bias.

Conclusion

The waiting period for pacemaker implantation in patients with asymptomatic complete heart block poses certain risks, including the possibility of cardiac arrest. To mitigate the chance of developing major adverse events, the findings from this patient cohort suggest that it is better to implant a pacemaker sooner rather than later, ideally within 27 days of diagnosis.

Ethics and integrity statements

This manuscript has never been published elsewhere.

All co-authors meet the criteria for authorship and have made the appropriate acknowledgements in the manuscript.

Data availability statement

Research data are not shared.

Ethics approval statement

This research received formal approval from the Ethics Committee of the Human Research Ethics Unit (HREU), Faculty of Medicine, Prince of Songkla University, under reference number REC. 64-426-14-1.

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Conflict of interest

The authors declare that there is no conflict of interest.

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