Received: 30 October 2024 | Revised: 20 February 2025 | Accepted: 4 March 2025

DOI: 10.1002/joa3.70043

Journal of Arrhythmia Open Access WILEY

ORIGINAL ARTICLE

Cost-effectiveness analyses to assess the value of reactive atrial-based anti-tachycardia pacing for patients with pacemakers and defibrillators: An Australian private healthcare system perspective

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Funding information
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Abstract

Background: Cardiac implantable electronic devices (CIED) with reactive atrial-based anti-tachycardia pacing (rATP) have been developed to stop the progression of atrial fibrillation (AF), a frequently occurring arrhythmia. This study assessed the value of rATP from the Australian private healthcare payer perspective.

Methods: A Markov state-transition model, including bradycardia, stroke, heart failure (HF), and death, was used to evaluate the value of rATP in conjunction with either pacemakers (PM), implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy pacemakers (CRT-P), or CRT defibrillators (CRT-D). It was assumed that PM patients have bradycardia with no AF, and other patients have mild HF at insertion. Efficacy inputs, battery life, and device costs varied between devices. Conservatively, outpatient/follow-up costs of stroke and HF were excluded. All analyses were conducted using a cost-effectiveness threshold of 50 000 Australian dollars (A$) per quality-adjusted life year (QALY) gained, and deterministic sensitivity analysis was performed on key inputs.

Results: Using a 30-year horizon and a 5% discount rate, rATP was cost-effective up to a value of A$5609 (PM), A$11 628 (CRT-D), A$14 142 (CRT-P), and A$17 858 (ICD). In sensitivity analysis, varying patient age, rATP efficacy, HF and stroke mortality, stroke recurrence risk, utility values, time horizon, battery life, and the discount rate, the value of rATP ranged from A$3122 to A$11 375 (PM), A$1455 to A$26 409 (ICD), A$1171 to A$20 674 (CRT-P), and A$973 to A$16 907 (CRT-D).

Conclusion: Reactive ATP provides clinical benefits to patients who require a CIED. These benefits justify a value premium for devices with rATP functionality.

KEYWORDS
cardiac, cost, economics, ICD, pacemaker

This author (M.H.) takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

1 | INTRODUCTION

Atrial fibrillation (AF) is a type of tachycardia that causes an irregular heart rhythm. It is one of the most frequently occurring arrhythmias and is most prevalent in people aged 65 years and older.[1] The estimated prevalence of AF in Australia in 2020–2021 was 2.2%.[2] The symptoms of AF include chest pain, shortness of breath, dizziness, and palpitations, and both asymptomatic and symptomatic AF increase the risks of stroke, death, and heart failure (HF).[3] An estimated A$1.30 billion was spent on the management of AF in Australia between July 2019 and June 2020.[4]

AF is a progressive condition that, over time, generally increases in duration from paroxysmal AF (characterized by spontaneously terminating episodes) to persistent and permanent forms (which continue for longer and do not self-terminate). Among patients with a cardiac implantable electronic device (CIED), the risks of stroke and HF are raised alongside an increasing duration of AF.[5,6]

CIEDs with a reactive atrial-based anti-tachycardia pacing (rATP) algorithm have been developed to stop the progression of paroxysmal AF to persistent and permanent forms. This is achieved by rATP devices delivering atrial anti-tachycardia pacing to terminate AF episodes after a programmed interval or when the rhythm stabilizes.[7] An international, randomized controlled trial (MINERVA) comparing dual-chamber pacemakers (PM) with or without rATP found that patients with rATP devices experience slower progression of their AF, which is expected to reduce the risks of potentially fatal complications such as stroke and HF.[8–10] Further, a retrospective study conducted in Japan among HF patients with a cardiac resynchronization therapy defibrillator (CRT-D) found the risk of deterioration and hospitalization for HF is significantly lower if the device has rATP functionality.[11] Dual-chamber PMs with rATP have also been shown to substantially reduce AF-related healthcare costs compared to those without.[12]

Australia has a mixed public and private healthcare system, and approximately 45% of the population has private hospital treatment cover.[13] The Prescribed List (PL) is a schedule of medical devices that outlines the minimum amount ('benefit') that private health insurers (PHIs) are required to pay hospitals that utilize these devices in the provision of care to privately insured individuals. The PL forms part of the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, which is a legislative instrument developed under the Private Health Insurance Rules (No. 1) 2023 (previously Private Health Insurance Act 2007). As in many other countries with centrally managed health systems, various types of healthcare products and services are valued and reimbursed based on their cost-effectiveness. That is, the prices paid by the Federal Government or PHIs reflect socially acceptable costs per unit of additional benefit relative to current best clinical practice. It is therefore hypothesized that, since rATP provides greater clinical benefits over CIEDs without this capability, there is a value premium for rATP up to which rATP would be considered cost-effective. The aim of this study was to determine the value of rATP with reference to the available clinical data and when viewed from the Australian private healthcare payer perspective.

2 | METHODS

2.1 | Model structure

This study utilizes a Markov state-transition model that has been previously reported in detail elsewhere[14] and was adapted to the Australian population and healthcare system for the current analysis (Figure 1).

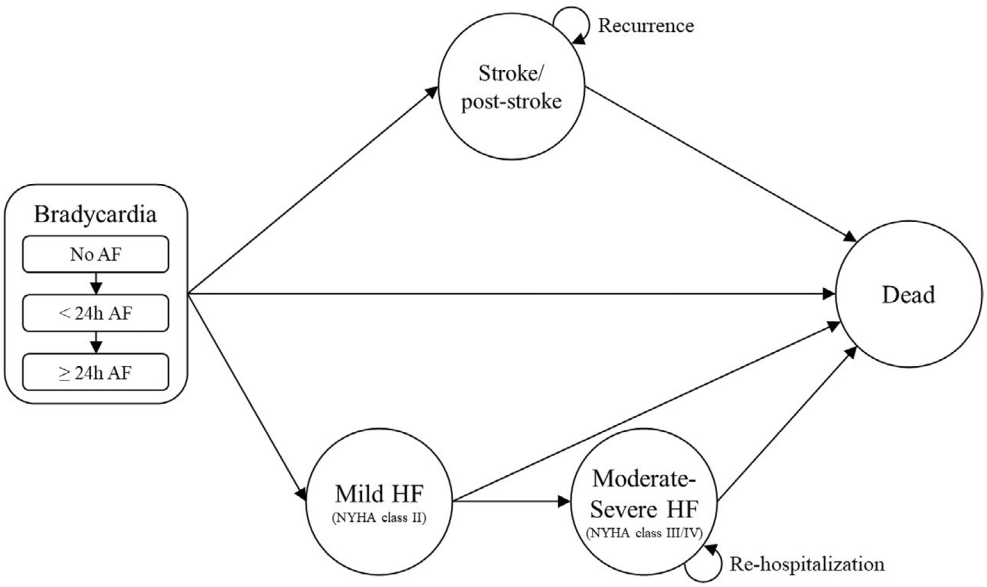

FIGURE 1 Markov model diagram. For the PM analysis, all patients were entered into the model in the bradycardia no AF health state, and no replacement with another type of device was performed in case of transition to HF. For all other analyses, all patients were entered into the model in the mild HF state. AF, atrial fibrillation; HF, heart failure; NYHA, New York Heart Association; PM, pacemaker.

This model represents pathological changes in patients who require the insertion of a CIED for bradycardia or HF and comprises five health states: bradycardia, stroke/poststroke, mild HF [New York Heart Association (NYHA) Class II], moderate-to-severe HF (NYHA Class III/IV), and death. The bradycardia state is further subdivided into: no AF; AF lasting <24 h; AF lasting ≥24 h. During each monthly cycle, patients may progress through the AF stages, experience a stroke or HF, die, or remain in the same health state. The onset of stroke and HF are assumed to be irreversible and to not occur simultaneously; therefore, patients in the stroke/poststroke and moderate-to-severe HF states can only progress to death, and patients with mild HF can progress to either moderate-to-severe HF or death. The model does not include adverse events, which are assumed to be similar for either rATP or control devices.

This model was used to evaluate four CIED types: PM, implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P) and CRT-D. However, the initial health state distribution of patients, efficacy inputs, and device costs varied by CIED type. For the PM analysis, all patients were assumed to have bradycardia with no AF at insertion. For the other three devices, patients were assumed to have mild HF at insertion. It was further assumed that patients do not have their PM replaced with a different type of device if they develop HF.

In each cycle, patients accrue costs and quality-adjusted life years (QALYs), which are calculated as the utility value (a quality-of-life weight between zero and one) for their health state multiplied by 1/12 (to reflect the 1-month cycle). Costs and QALYs are summed across health states to calculate totals per cycle and are discounted at an annual rate of 5% in line with published recommendations for Australia.[15] The time horizon for the analysis was set to 30 years, with a maximum patient age of 100 years. The parameters and input values used in the model are summarized in Table 1.

2.2 | Modelled population

The mean ages of patients at the start of the model were derived from an observational cohort study of adults undergoing a new CIED implant in New South Wales and Queensland private hospitals between 2010 and 2015.[16] The sex distributions were derived from an expanded dataset covering 99% of the Australian and New Zealand population.[17]

2.3 | Transition probabilities

Event and incidence rates reported in clinical studies were converted to monthly probabilities for the model. For patients in any bradycardia state, the monthly transition probabilities for AF progression, mild HF, and stroke were obtained from a multi-center cohort study (ASSERT) of patients with a recently implanted PM or ICD.[5,6,18] The monthly probability of transition from mild HF to moderate-to-severe HF was derived from the incidence of HF hospitalization (a proxy for worsening HF) reported in a randomized study (RAFT) of CRT-D versus ICD comparing morbidity and mortality in patients with mild-to-moderate HF.[19] The relative risks of AF progression and HF deterioration with rATP were derived from the MINERVA trial[8] and the single-center retrospective study in Japan.[11]

The monthly mortality risk for patients with no AF was derived from a retrospective study of patients with no history of AF who underwent dual-chamber PM implantation at a single center in the US.[20] The monthly mortality risk for patients with AF (any duration) differed according to whether they had or did not have a rATP device. These risks were derived from patients who had rATP and managed ventricular pacing activated (rATP group) or deactivated (non-rATP group).[8]

Consistent with the available clinical data,[10] the mortality risks for patients with HF were assumed to differ by CIED type but not by whether the device had or did not have rATP. For patients with mild HF, mortality was derived from the RAFT study of CRT-D versus ICD[19] and for patients with moderate-to-severe HF, mortality was derived from the COMPANION trial of CRT-P versus CRT-D in patients with NYHA class III/IV HF.[21]

The model accounts for recurrent strokes, recurrent HF hospitalizations, and acute mortality following a stroke or HF. The monthly risk of recurrent stroke for patients in the stroke/poststroke state was derived from the 10-year cumulative incidence reported in a study of over 400 000 hospitalizations for HF in Australia and New Zealand between 2008 and 2017.[22] The monthly risk of re-hospitalization for moderate-to-severe HF was obtained from the RAFT study, with a risk reduction applied to rATP patients.[11,19]

The proportions of patients who die in the first 30 days following a stroke or HF were derived from a meta-analysis of Australian observational studies of HF hospitalization[23] and a cohort study linking Australian Stroke Clinical Registry data for over 16 000 episodes of stroke care with registered deaths during 2009–2014.[24] These acute mortality rates are applied in the same model cycle that the stroke or HF event occurs. Natural mortality by age was derived from Australian general population life tables for 2019–2021[25] and weighted by the initial gender distribution in the model.

2.4 | Costs

All analyses were conducted using private sector healthcare costs. The costs of the devices, insertion procedures, and value premiums for rATP are applied in the first model cycle and the time when battery exchange is assumed to be required. Average battery life was derived from product brochures (which was based on data from the Carelink network, a remote monitoring network) and was assumed to be the same regardless of rATP.[26–28] Device costs were derived from the July 2023 PL[29] based on clinical expert advice regarding the current standard of care for devices and their corresponding leads in Australia.

For each CIED type, the procedure costs (i.e., time and complexity) were assumed to be identical regardless of whether the device

TABLE 1 Model parameter values.

Parameter	Value	Source
Baseline characteristics		
Age, years	78.1 (PM), 67.9 (ICD), 74.2 (CRT-P, CRT-D)	Ganesan et al.[16]
Male	58.2% (PM), 79.0% (ICD), 67.5% (CRT-P, CRT-D)	Moore et al.[17]
Initial distribution		
No AF	100% (PM), 0% (other)	Assumption
Mild HF	0% (PM), 100% (other)	Assumption
Monthly transition rates from no AF		
To <24 h AF	1.65%	ASSERT[18]
To ≥24 h AF	0.46%	ASSERT[18]
To stroke	0.05%	ASSERT[5]
To mild HF	0.19%	ASSERT[6]
To death	0.43%	Gonzalez et al.[20]
Monthly transition rates from <24 h AF		
To ≥24 h AF, rATP	0.30%	ASSERT,[18] MINERVA[8]
To ≥24 h AF, no rATP	0.77%	ASSERT[18]
To stroke	0.08%	ASSERT[5]
To mild HF	0.21%	ASSERT[18]
To death, rATP	0.18%	MINERVA[8]
To death, no rATP	0.22%	MINERVA[8]
Monthly transition rates from ≥24 h AF		
To stroke	0.26%	ASSERT[5]
To mild HF	0.78%	ASSERT[18]
To death, rATP	0.18%	MINERVA[8]
To death, no rATP	0.22%	MINERVA[8]
Monthly transition rates from stroke		
To death, rATP	0.18%	MINERVA[8]
To death, no rATP	0.22%	MINERVA[8]
Monthly transition rates from mild HF		
To severe HF, rATP	0.19% (CRT-D), 0.26% (other)	RAFT,[19] Ueda et al.[11]
To severe HF, no rATP	0.44% (CRT-D), 0.61% (other)	RAFT[19]
To death	0.42% (CRT-D), 0.59% (other)	RAFT[19]
Monthly transition rate from severe HF to death	1.08% (CRT-D), 1.30% (other)	COMPANION[21]
Recurrent/re-hospitalization rates (month)		
Stroke	0.26%	Peng et al.[22]
Severe HF, rATP	0.41% (CRT-D), 0.62% (other)	RAFT,[19] Ueda et al.[11]
Severe HF, no rATP	0.95% (CRT-D), 1.45% (other)	RAFT[19]
Acute death risk		
Stroke	12%	Cadilhac et al.[24]
HF	8%	Al-Omary et al.[23]
Costs (private sector), AUD		
Initial implantation/battery exchange	8536 (PM), 37033 (ICD), 13360 (CRT-P), 42047 (CRT-D)	Prostheses List[29]
Stroke	4485	PHDB[30]
HF	8219	PHDB[30]
Utilities		

TABLE 1 (Continued)

Parameter	Value	Source
No AF/ <24 h AF/≥ 24 h AF, age ≥ 75 years	0.8	Clemens et al.[31]
No AF/<24 h AF/≥ 24 h AF, age 65–74 years	0.82	Clemens et al.[31]
Stroke	0.65	Joundi et al.[32]
Mild HF	0.751	Kularatna et al.[33]
Moderate-to-severe HF	0.701	Kularatna et al.[33]
Time to device replacement, years	13.7 (PM), 11.9 (ICD), 9.9 (CRT-P), 10.1 (CRT-D)	Medtronic[25–27]
Discount rate	5%	National guidelines[15]

Abbreviations: AF, atrial fibrillation; AUD, Australian dollars; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; h, hours; HF, heart failure; ICD, implantable cardioverter defibrillator; PHDB, Private Hospital Data Bureau; PM, pacemaker; rATP, reactive atrial-based anti-tachycardia pacing.

has rATP or not. Procedure costs were calculated as the total average admission costs for relevant Australian Refined Diagnosis Related Groups (AR-DRG, version 10) in the private sector minus the prostheses cost component.[30]

Average total inpatient costs for patients admitted to hospital with either a stroke or HF are applied in the cycle in which an event occurs. Using a private hospital dataset, the average costs per admission were obtained for admissions coded under the AR-DRGs (version 10) B70A, B70B, and B70C for stroke and F62A and F62B for HF. These average costs were weighted by the number of patient separations for each AR-DRG.[30] Conservatively, outpatient and other follow-up costs of stroke and HF (beyond the model cycle in which the event occurs) were excluded from this analysis.

2.5 | Utility values

For the PM cohort, age-based utility norms were applied to all bradycardia states; that is, patients who do not have HF or have not experienced a stroke.[31] For the base case analysis, the utility norm for Australians aged ≥75 years was used to align with the baseline age of 78.1 years.[16]

The utility value for patients in the stroke/poststroke state is the mean pooled EQ-5D-3L index value at ≥3 months poststroke reported in a meta-analysis of 73 studies and over 50 000 patients.[32] The utility values for patients with HF were derived from mean EQ-5D-3L values reported in a sample of 280 patients in Australia.[33] The mean value for patients with NYHA class II was applied to the mild HF state, and the unweighted mean value for patients with NYHA class III or IV was applied to the moderate-to-severe HF state. Conservatively, no additional disutility was applied in the acute phase following a stroke or HF event.

2.6 | Analysis

To determine the value premium up to which rATP is cost-effective, the base case analysis uses a conventional willingness-to-pay (WTP) threshold of 50 000 Australian dollars (A$) per QALY gained.[34] A value premium is considered to be the additional cost for a device with rATP over the same device without rATP at which the incremental cost-effectiveness ratio (ICER) comparing the two devices meets the WTP threshold. For each device type, deterministic sensitivity analysis (DSA) was performed to assess the robustness of the value premium to uncertainty in the model inputs. The cost-effectiveness of rATP is driven by its relative efficacy in preventing stroke or HF and the costs and the disutilities associated with those events. Therefore, the relative risks with rATP, the risk of stroke recurrence, acute mortality risks with HF, and utility values were varied within their 95% confidence intervals (CI). For the acute mortality risk with stroke, the lower and upper 95% CI limits were not reported, and the range across hospitals with at least 200 episodes of care was used instead.[24] Patient age was also varied within the reported 95% CIs for each device type.[16] Alternative discount rates of 3.5% and 0% were also tested in the DSA.[15]

The published tariffs and hospital datasets used to derive device, procedure, and hospitalization costs did not report statistical (or any other) variability. Therefore, the impacts of variations in costs were not explored. Average battery life is inherently uncertain and varies according to device user settings and was therefore varied by 20% in either direction in the DSA. Probabilistic sensitivity analysis was not conducted due to a lack of information on the statistical variation in many of the key model inputs.

3 | RESULTS

The modeling demonstrates that for an Australian private patient population, the additional QALYs gained with rATP are 0.117 for PM, 0.397 for ICD, 0.306 for CRT-P, and 0.282 for CRT-D. The reduction in the cost of severe HF with rATP (from preventing HF deterioration and recurrent events) is A$358 for PM, A$2822 for ICD, A$2564 for CRT-P, and A$1959 for CRT-D. In addition, for patients with a PM, the combined reduction in the cost of stroke and mild HF is A$147.

Using a cost-effectiveness threshold of A$50 000 per QALY gained, the rATP is estimated to be cost-effective up to a value

of A$5609 for PM, A$11 628 for CRT-D, A$14 142 for CRT-P, and A$17 858 for ICD (Table 2).

The results of the DSA (Table 3) show that the cost-effective value of rATP is most sensitive to its efficacy, the modelled time horizon, and (for all devices except PM) the utility values for HF. In the DSA, the cost-effective value premium ranged from A$3122 to A$11 375 for PM, A$1455 to A$26 409 for ICD, A$1171 to A$20 674 for CRT-P, and A$973 to A$16 907 for CRT-D. These results are also reflected in the tornado diagrams for rATP value premiums for PM (Figure 2), ICD (Figure 3), CRT-P (Figure 4) and CRT-D (Figure 5).

4 | DISCUSSION

To our knowledge, this is the first study to assess the cost-effectiveness and economic value of rATP as a feature of CIEDs in Australia and as a feature of ICD and CRT-P globally. The results of this study suggest that not only do rATP devices provide additional clinical benefits in terms of slower AF progression, fewer stroke and HF events, improved quality of life, and increased survival, but devices with rATP are cost-effective compared to devices without rATP even at a substantially higher theoretical price.

The process of health technology assessment in Australia generally requires interventions and services to be cost-effective—that is, priced to achieve an acceptable incremental cost for additional benefit—rather than to be cost-saving overall. Nevertheless, the current models suggest that rATP is cost-saving when its value is set to A$325 for PM, A$1017 for ICD, A$1533 for CRT-P, and A$355 for CRT-D.

The model used in this study was adapted from a previous Japanese cost-effectiveness assessment of rATP.[14] The Japanese study reported ICERs of 763 729 Japanese yen (JPY, A$8126) per QALY gained for PM and 1 393 280 JPY (A$14 825) per QALY gained for CRT-D, at an incremental price of 158 000 JPY (A$1681) for rATP and a 2% annual discount rate (JPY/AUD exchange rate on 12 July 2023). The authors reported that rATP devices are therefore cost-effective at this price using a WTP threshold of five million JPY (A$53 200) per QALY gained in Japan. The current study uses Australian data for health care costs, event recurrence, and natural mortality, a 5% annual discount rate, and updated non-country-specific probabilities where relevant. Further, the study perspective is slightly different in demonstrating the cost-effective value of rATP for an assumed WTP threshold, rather than the cost-effectiveness for a specific price. Nonetheless, the Australian analysis is consistent with the Japanese study findings with respect to there being a significant, justifiable value for rATP functionality in cardiac devices.

The progression of AF and stroke and the effectiveness for ATP in reducing the rate of AF progression and mortality for stroke patients is only considered for patients with a PM within the model. It should therefore be noted that the cost-effectiveness of rATP for patients with an ICD, CRT-P, or CRT-D is primarily determined by the rate of re-hospitalization for HF[11] which is applied to both the progression from mild-to-severe HF and re-hospitalization with severe HF. Moreover, the modelled analyses are likely to be conservative since the risk of re-hospitalization with severe HF is derived from patients with moderate HF (NYHA Class III)[11] and may therefore be underestimated.

4.1 | Limitations

There are several limitations to the modelled analysis, which primarily relate to a lack of available data for either Australian patients or the specific device, event, or patient group. First, the

TABLE 2 Base case results.

Device	Total costs	Total QALYs	Inc. costs (AUD)	Inc. QALYs	rATP value premium (AUD)
PM					
rATP	27 101	5.137	5825	0.117	5609
Control	21 275	5.021	-	-	-
ICD					
rATP	79 073	4.926	19 848	0.397	17 858
Control	59 225	4.529	-	-	-
CRT-P					
rATP	45 501	4.461	15 294	0.306	14 142
Control	30 207	4.155	-	-	-
CRT-D					
rATP	81 822	5.056	14 122	0.282	11 628
Control	67 700	4.774	-	-	-

Abbreviations: AUD, Australian dollars; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter defibrillator; PM, pacemaker; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing.

TABLE 3 Deterministic sensitivity analysis on the value premium (AUD) for rATP.

Parameter	PM	ICD	CRT-P	CRT-D
Base case	5609	17858	14142	11628
Patient age				
77.9 (PM), 67.4 (ICD), 73.7 (CRT-P/CRT-D)	5731	18074	14421	11886
78.3 (PM), 68.4 (ICD), 74.7 (CRT-P/CRT-D)	5529	17635	13865	11364
rATP efficacy (RR) for HF deterioration or re-hospitalization				
0.19	6514	26339	20674	16907
0.95	4259	1455	1171	973
rATP efficacy (RR) for AF progression from <24 h to ≥24 h				
0.21	6137	-	-	-
0.75	4699	-	-	-
rATP efficacy (RR) for bradycardia to death				
0.42	11375	-	-	-
1[a]	3122	-	-	-
Recurrent stroke risk				
0.255%	5609	-	-	-
0.264%	5609	-	-	-
HF mortality (acute)				
7%	5568	17510	13853	11404
10%	5687	18535	14707	12069
Stroke mortality (acute)				
7%	5581	-	-	-
23%	5670	-	-	-
Utility with mild HF				
0.709	5522	15913	12578	10176
0.793	5695	19802	15706	13080
Utility with moderate-to-severe HF				
0.649	5735	18898	15033	12480
0.742	5442	16479	12960	10498
Utility with stroke				
0.63	5621	-	-	-
0.67	5596	-	-	-
Utility with bradycardia, ≥75 years				
0.78	5451	-	-	-
0.81	5688	-	-	-
Time horizon				
10 years	3194	12133	8857	9056
20 years	5515	16928	13812	11576
Battery life, years				
11.0 (PM), 9.5 (ICD), 7.9 (CRT-P), 8.1 (CRT-D)	5129	15864	12575	10093
16.4 (PM), 14.3 (ICD), 11.9 (CRT-P), 12.1 (CRT-D)	5967	19442	15285	12791
Discount rate				
0%	8498	26409	19615	16176
3.5%	6336	19973	15538	12800

Abbreviations: AF, atrial fibrillation; AUD, Australian dollars; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; HF, heart failure; ICD, implantable cardioverter defibrillator; PM, pacemaker; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing; RR, relative risk.

[a]Upper 95% confidence interval is 1.58, therefore an assumption of no difference in efficacy was tested.

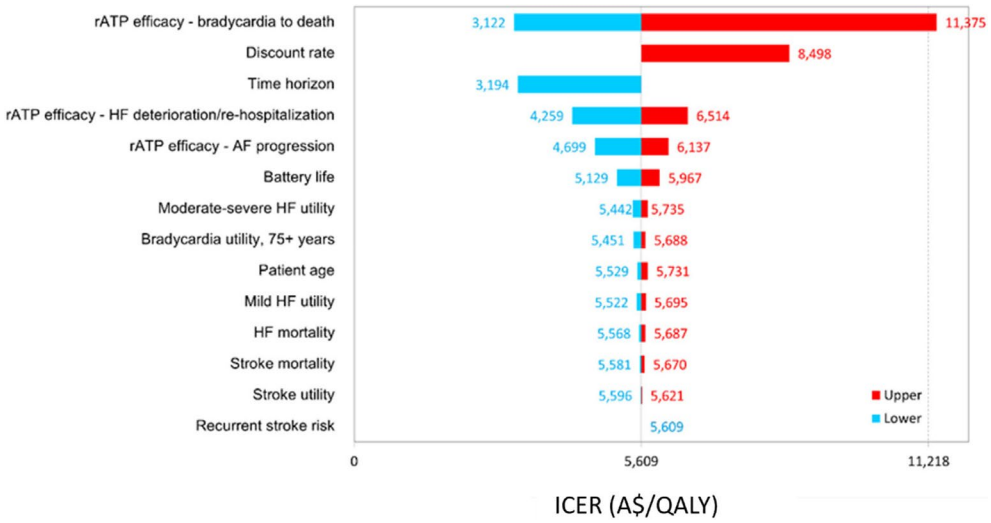

FIGURE 2 Tornado diagram for rATP value premium (pacemaker, cost-effectiveness threshold A$50 000/QALY). AF, atrial fibrillation; HF, heart failure; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing.

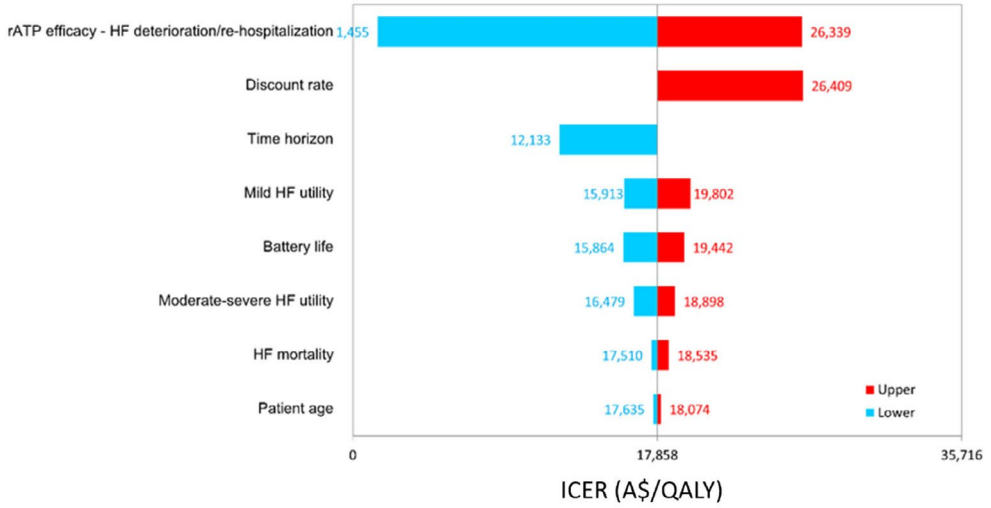

FIGURE 3 Tornado diagram for rATP value premium (ICD, cost-effectiveness threshold A$50 000/QALY). AF, atrial fibrillation; HF, heart failure; ICD, implantable cardioverter defibrillator; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing.

rates of AF progression, stroke, HF, and the efficacy of rATP were derived from clinical trials conducted in North America, Europe, Hong Kong, Japan, and the United States.[5,6,8,11,18,20,21] Only the RAFT study, which was used to model HF progression, included Australian treatment centers.[19] However, as clinical practice and treatment of AF and other cardiovascular conditions across these countries are similar, it is assumed that clinical outcomes and the efficacy of rATP are not expected to differ substantially between countries.

Second, for the transitions from mild-to-severe HF, mild HF to death, and re-hospitalization for severe HF, ICD data (rather than CRT-D data) were applied to the PM and CRT-P models,[19] and for the transition from severe HF to death, CRT-P data (rather than CRT-D data) were applied to the PM and ICD models.[21] These allocations were considered reasonable based on device functionality. Allocating CRT-P data to PM patients may underestimate mortality—however, this would lead to an underestimation of the survival benefits from rATP and is therefore a conservative approach.

Third, due to a lack of data, the longer-term mortality risk following a stroke is assumed to equal the mortality risk with bradycardia (pre-stroke), and no disutility is applied to AF progression. Again, these

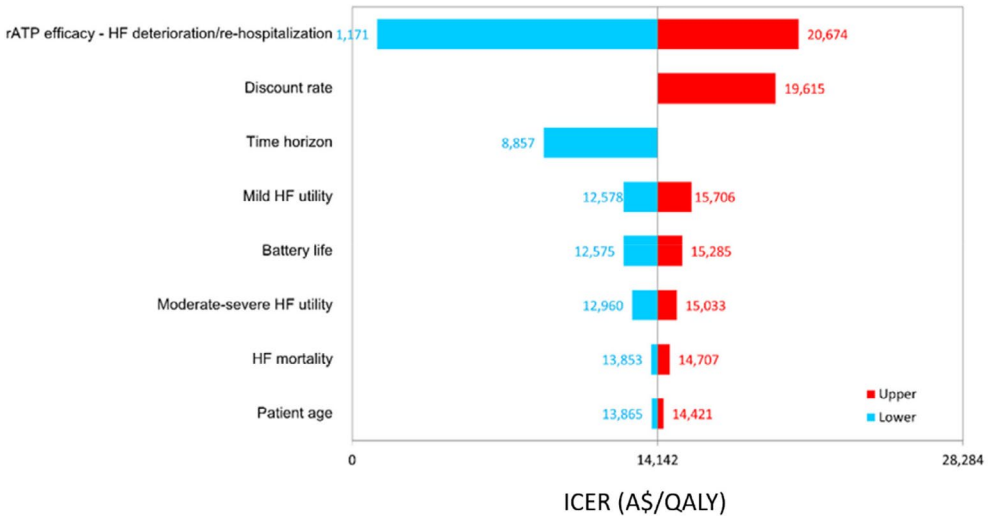

FIGURE 4 Tornado diagram for rATP value premium (CRT-P, cost-effectiveness threshold A$50 000/QALY). AF, atrial fibrillation; CRT-P, cardiac resynchronization therapy with pacemaker; HF, heart failure; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing.

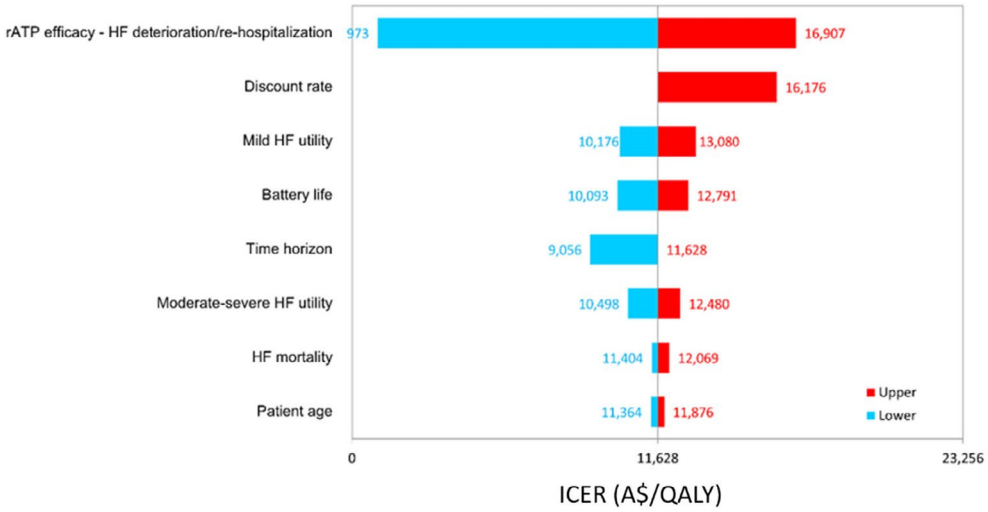

FIGURE 5 Tornado diagram for rATP value premium (CRT-D, cost-effectiveness threshold A$50 000/QALY). AF, atrial fibrillation; CRT-D, cardiac resynchronization therapy with defibrillator; HF, heart failure; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; rATP, reactive atrial-based anti-tachycardia pacing.

assumptions will underestimate the impact of AF progression and stroke on survival and quality of life and therefore the value of rATP.

Fourth, as reported above, the risk of re-hospitalization with severe HF is derived from patients with moderate HF[11] and may therefore be underestimated. This likely leads to conservative estimates for the absolute risk reduction of HF re-hospitalization with rATP and, hence, the value of rATP across all device types.

Finally, outpatient costs were excluded from the model to simplify the analyses and to avoid making assumptions regarding the timing of outpatient visits following a stroke or HF. Again, this is a conservative approach that underestimates the value of rATP in reducing the risk of HF progression.

5 | CONCLUSION

Reactive anti-tachycardia pacing has been shown to provide clinical benefits to patients with AF and HF who require CIEDs. The economic analysis presented here suggests that rATP has value such that devices with rATP are cost-effective compared to standard CIEDs without rATP up to a substantial price premium within the Australian private healthcare sector.

FUNDING INFORMATION

This cost-effectiveness analysis and consulting fees for preparing the publication were funded by Medtronic.

CONFLICT OF INTEREST STATEMENT

Michelle Hill and Yuji Tanaka are employees of Medtronic. The other authors are employees of third-party consulting companies who were contracted to perform the economic modeling or write the manuscript.

DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article.

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How to cite this article: Gordois A, Tanaka Y, Uenishi T, Yamaguchi H, Shoji A, Hill M. Cost-effectiveness analyses to assess the value of reactive atrial-based anti-tachycardia pacing for patients with pacemakers and defibrillators: An Australian private healthcare system perspective. J Arrhythmia. 2025;41:1–11. https://doi.org/10.1002/joa3.70043