Original Article

A Cost-Utility Analysis of the Syncope: Pacing or Recording in The Later Years (SPRITELY) Trial

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ABSTRACT

Background: The **S**yncope: **P**acing or **R**ecording **i**n the **L**ater **Y**ears (SPRITELY) trial reported that a strategy of empiric permanent pacing in patients with syncope and bifascicular block reduces major adverse events more effectively than acting on the results of an implantable cardiac monitor (ICM). Our objective was to determine the

RÉSUMÉ

Contexte : L'essai SPRITELY (*Syncope: Pacing or Recording in the Later Years*) a été mené auprès de patients ayant subi une syncope et un bloc bifasciculaire. Elle a montré qu'une méthode de stimulation électrique permanente et empirique du cœur permet de réduire les événements indésirables majeurs plus efficacement qu'une méthode

Bifascicular heart block predisposes patients to syncope due to intermittent complete heart block,[1,2] but competing potential causes exist.[3,4] Whether the best treatment is that based on direct demonstration of the etiology during a syncopal spell or simply implantation of a pacemaker is unknown. This uncertainty has led to both empiric treatments that may be inaccurate and investigations that may be costly and unnecessary while placing patients at risk based on a strategy of awaiting a recurrence. The diagnostic problem faced in this

aging population is that historical features are often absent or of limited diagnostic accuracy.[5]

The **S**yncope: **P**acing or **R**ecording **i**n the **L**ater **Y**ears (SPRITELY) pragmatic randomized trial sought to determine whether implantable cardiac monitor (ICM) insertion or pacemaker (PM) insertion[3-6] is more effective and cost-effective for participants with bifascicular block, syncope, preserved left ventricular function, and age > 50 years.[6] Trial participants were randomized 1:1 to ICM and empiric PM insertion arms, and followed for a median of 33 months.[6] The primary outcome was a composite of death, syncope, symptomatic and asymptomatic bradycardia resulting in PM insertion, and acute and chronic device complications analyzed over 2 years of follow-up.[6] Collected resource-utilization data included hospital admissions, emergency department visits, diagnostic tests, and procedures. An economic evaluation was planned *a priori* and was incorporated into the overall trial design, outcomes, and protocol.

The objective of this analysis was to assess the cost-effectiveness of ICM vs PM insertion in the management of

cost-effectiveness of using the ICM, compared with a pacemaker (PM), in the management of older adults (age > 50 years) with bifascicular block and syncope enrolled in the SPRITELY trial.

Methods: SPRITELY was a pragmatic, open-label randomized controlled trial with a median follow-up of 33 months. The primary outcome of this analysis is the cost per additional quality-adjusted life-year (QALY). Resource utilization and utility data were collected prospectively, and outcomes at 2 years were compared between the 2 arms. A decision analytic model simulated a 3-year time horizon.

Results: The mean cost incurred by participants randomized to the PM arm was $9918, compared to $15,416 (both in Canadian dollars) for participants randomized to the ICM arm. The ICM strategy resulted in 0.167 QALYs fewer than the PM strategy. Cost and QALY outcomes are sensitive to the proportion of participants randomized to the ICM arm who subsequently required PM insertion. In 40,000 iterations of probabilistic sensitivity analysis, the PM strategy resulted in cost-savings in 99.7% of iterations, compared with the ICM strategy.

Conclusions: The PM strategy was dominant—that is, less costly and estimated to result in a greater number of QALYs. For patients with unexplained syncope, bifascicular block, and age > 50 years, a PM is more likely to be cost-effective than an ICM.

reposant sur les résultats d'un moniteur cardiaque implantable. Notre objectif était de déterminer le rapport coût-efficacité de l'utilisation du moniteur cardiaque implantable par rapport à un stimulateur cardiaque dans la prise en charge de personnes âgées de plus de 50 ans présentant un bloc bifasciculaire et une syncope, inscrits à l'essai SPRITELY.

Méthodologie : SPRITELY était un essai contrôlé ouvert et pragmatique à répartition aléatoire, dont le suivi médian était de 33 mois. Le paramètre d'évaluation principal de cette analyse était le coût supplémentaire par année de vie ajustée en fonction de la qualité (AVAQ). Les données sur l'utilisation des ressources et l'utilité ont été recueillies de manière prospective, et les résultats à deux ans ont été comparés entre les deux groupes. Un modèle décisionnel analytique a été utilisé pour simuler un horizon temporel de trois ans.

Résultats : Le coût moyen pour les participants répartis aléatoirement dans le groupe utilisant un stimulateur cardiaque était de 9 918 $ CAN comparativement à 15 416 $ CAN pour ceux utilisant un moniteur cardiaque implantable. La stratégie du moniteur cardiaque implantable s'est traduite par une réduction de 0,167 du nombre d'AVAQ par rapport à la stratégie reposant sur le stimulateur cardiaque. Les résultats relatifs aux coûts et aux AVAQ sont sensibles à la proportion de participants répartis aléatoirement dans le groupe du moniteur cardiaque implantable qui ont par la suite dû recevoir un stimulateur cardiaque. Sur 40 000 itérations de l'analyse de sensibilité probabiliste, la stratégie du stimulateur cardiaque a occasionné des économies dans 99,7 % des itérations comparativement à la stratégie du moniteur cardiaque implantable.

Conclusions : La stratégie du stimulateur cardiaque était dominante, autrement dit moins coûteuse et, selon les estimations, entraînerait un plus grand nombre d'AVAQ. Pour les patients de plus de 50 ans présentant une syncope idiopathique et un bloc bifasciculaire, un stimulateur cardiaque est plus susceptible d'être moins coûteux qu'un moniteur cardiaque implantable.

unexplained syncope and bifascicular block in older adults (age > 50 years) in the context of a publicly funded healthcare system.

Methods

A prospective economic evaluation was conducted within the SPRITELY trial. Authors M.H., R.S.S., D.R., S.S., and C.M. had full access to all the data in the study and take responsibility for data integrity and analysis. This economic evaluation was conducted from the perspective of a publicly funded healthcare system, with patient outcomes measured in quality-adjusted life-years (QALYs). The trial evaluation was conducted with resource-use and utility measurements collected over 2 years during the SPRITELY trial. Utility was measured with the EuroQOL - 5 Dimension - 3 Level (EQ-5D-3L) at baseline and annually for 2 years, and calculated with the time tradeoff Canadian scoring algorithm.[7,8] A decision analytic model was used to extrapolate the findings for one additional year.

Trial design

The SPRITELY trial[6] was a multicenter, open-label, parallel group, pragmatic trial, conducted between August 2011 and November 2017,[9] at sites in Canada, the US, Italy, and Japan. Inclusion criteria were age > 50 years,

bifascicular block on a 12-lead electrocardiogram, and at least one syncopal episode in the preceding year. Participants were randomized 1:1 to the ICM or PM arm. Both of these alternatives are used in Canada and globally for the management of bifascicular block and syncope.[6] Ethics review committees in each center approved the SPRITELY trial.

Secondary measures of resource use collected in the trial include number of emergency department visits, hospital days, chest X rays, echocardiograms, PM lead revisions, PM lead removals, electrocardiograms, and magnetic resonance imaging/computed tomography scans. For magnetic resonance imaging/computed tomography, the assumption was made that the head was imaged-based. Health-related quality of life was also collected as a secondary outcome, with the EQ-5D-3L instrument.[7] Device type and settings were left to the discretion of the investigators. SPRITELY was a pragmatic trial, and outcomes reflect effectiveness rather than efficacy. A 2-year time horizon was selected for the trial evaluation, to be consistent with the prespecified analysis of the primary clinical composite outcome.[6]

Costs

Costs were analyzed from the perspective of a Canadian publicly funded healthcare system. Unit costs were obtained

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Table 1. Unit costs and observed resource use

Event	Empiric PM insertion resource use (n = 56)	ICM resource use (n = 57)	Unit cost (2017 Canadian dollars)
ICM insertion, n (%)	0	57 (100)	$4498.26[10,13]
PM insertion	56 (100)	38 (66.7)	$8390.04[10,14,15]
• Including ICM removal, n (%)			$8610.17[10,14,15]
Day(s) in hospital	0.76 (3.66)	2.2 (3.5)	$1088.93[15,16]
Admissions	0.18 (0.61)	0.60 (0.60)	NA
ICM removal	0	0.72 (0.45)	$248.26[10,13]
Emergency department visit(s)	0.26 (0.58)	0.32 (0.54)	$267.98[17]
Chest X ray	0.55 (2.58)	0.40 (0.56)	$121.91[10,18]
Echocardiogram	0.11 (0.37)	0.09 (0.34)	$278.75[10,15]
Lead adjustment	0.06 (0.23)	0.02 (0.13)	$1468.90[15,19]
Lead removal	0.02 (0.13)	0	$1785.80[10,20,21]
Electrocardiogram	0.74 (2.43)	1.26 (1.87)	$64.11[10,22]
Magnetic resonance imaging/computed tomography, head	0.13 (0.69)	0.11 (0.31)	$486.29[10,14,15]
Implantable cardioverter-defibrillator	0	0.02 (0.13)	$23,240.32[10,14,15]

Values are mean (standard deviation), unless otherwise indicated.

ICM, implantable cardiac monitor; NA, not available; PM, pacemaker.

from published literature, gross-costing estimates, and the Alberta Medical Schedule of Benefits, in conjunction with expert opinion; they reflect the cost incurred by the government for the provision of care.[10] Unit costs were linked to patient-level resource use collected in the SPRITELY trial (Table 1). When applicable, costs were converted to Canadian dollars (CADs–$) using purchasing-power parity.[11] The Canadian Consumer Price Index was used to calculate inflation, which is congruent with Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines.[12] All costs are presented in 2017 CADs. Device-insertion costs and follow-up schedule were assumed.

The average cost of PM insertion in Alberta inflated to 2017 CADs was $7455.97.[14,15] This case-mix grouper cost for PM insertion is the average cost of all PMs inserted in Alberta and does not include physician billing fees. Physician billing fees, calculated as the weighted average of 45 double-chamber PM and 11 single-chamber PM implantations, at $934.07, was added to the case-mix grouper cost estimate to give a total cost of $8390.04 for PM implantation.[10,14,15]

The device cost for an ICM was estimated to be between $4000 and $4500, depending on the manufacturer, and reflected the price paid by the Foothills Medical Centre for each device; the mean of this range ($4250) was used. The physician billing fees and half an hour of time for a registered nurse assisting in the procedure were added to the device cost, giving a total cost of $4498.26 for ICM insertion.[10,13] For healthcare providers that are paid hourly, such as registered nurses, 11% was added to account for fringe benefits (holidays, health benefits, etc.), congruent with CADTH guidelines.[23] Regardless of management strategy, follow-up was assumed to occur every 6 months after insertion, at a cost of $45.63 per visit, which includes the physician billing fee and 30 minutes of a registered nurse's time.[10,13]

Health outcomes

QALYs are used as the measure of health effect in this analysis. Both the CADTH and the International Society for Pharmacoeconomic Outcomes Research (ISPOR) recommend the QALY as the primary outcome of economic evaluation.[23,24] Utility, or health-related quality of life, was assessed at baseline and annually for 2 years, with the EQ-5D-3L instrument and a Canadian scoring algorithm.[7,8] The 5 assessed dimensions of health-related quality of life are mobility, self-care, ability to carry out usual activities, pain/discomfort, and anxiety/depression.[25] QALYs gained are calculated as the product of the change in utility using the method described by Sassi,[26] or health-related quality of life, and the length of time spent in that health state.

Costs and QALY outcomes are combined in the incremental cost-effectiveness ratio, which is interpreted as the cost per additional QALY. In Canada, a commonly cited cost-effectiveness threshold is $50,000 per additional QALY.[27] Choosing to fund technologies for which this ratio is greater than the cost-effectiveness threshold, or $50,000 per QALY in this case, acknowledges the opportunity cost, or the greater health gains that might have been achieved had those dollars been spent elsewhere.

Analysis

The methods of last observation carried forward imputation, and imputation of the mean, were used for values missing in participants that were lost to follow-up. These methods assume no improvement or deterioration in condition and avoid the loss of power associated with complete case analysis. Cost, effectiveness, and cost-effectiveness uncertainty were explored through nonparametric bootstrapping in the trial-based economic evaluation. One thousand sampling replicates were generated to inform sampling distributions.

Decision analytic model

A decision tree was used for the first year of follow-up, and a Markov process was used for the following 2 years, with a cycle length of 1 year. The 3-year time horizon was selected based on the usual lifetime of the ICM device. After the ICM battery expires, uncertainty increases because physicians may remove or replace the device, or leave it in place. The model diagram is included in Figure 1. Initial health states in the Markov process were determined by the health state of participants at the end of the first year. Costs and QALYs for health states were used from the second year of observation in
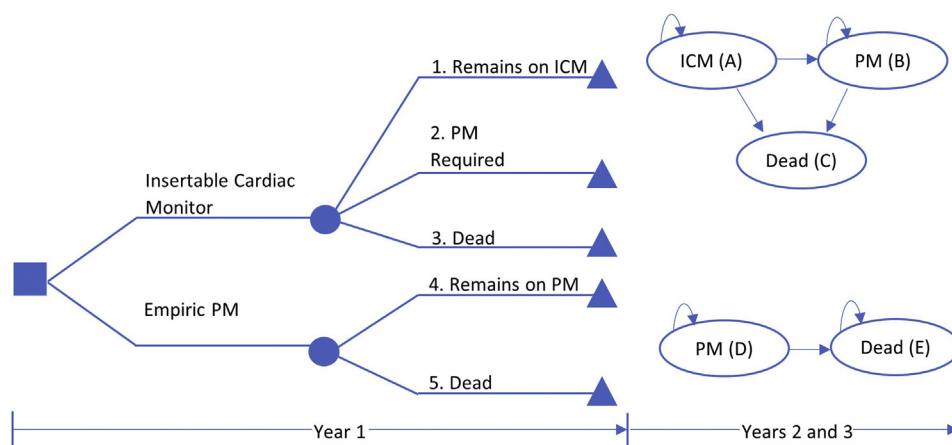
Figure 1. Model diagram. ICM, implantable cardiac monitor; PM, pacemaker.

the trial evaluation. Transition probabilities were computed from those who participated in extended follow-up beyond 2 years. The response of the model to all variables was assessed with 1-way sensitivity analysis, in which all variables were increased and decreased by 25%. In scenario analysis, the PM follow-up costs were increased to include a more involved assessment by a cardiologist. A total of 40,000 iterations of probabilistic sensitivity analysis were conducted, with distributions for all inputs defined in Supplemental Table S1. Values in the table reflect the mean value per participant in the indicated health states.

Results

Trial-based economic evaluation

This economic analysis included 113 participants. Four participants were lost to follow-up before baseline economic

Table 2. Syncope: Pacing or Recording in the Later Years (SPRITELY) trial participant characteristics at baseline in economic evaluation

Characteristics	Empiric PM insertion (n = 56)	ICM (n = 57)
Age, y (mean [SD])	74.5 (9.3)	77.4 (8.5)
Sex, female	19 (33.9)	14 (24.6)
Comorbidities		
Diabetes	12 (21.4)	18 (31.6)
Atrial fibrillation	1 (1.8)	3 (5.3)
Supraventricular tachycardia	1 (1.8)	1 (1.8)
Ventricular tachycardia	1 (1.8)	0 (0)
Medications		
Calcium-channel blockers	16 (28.6)	20 (35.1)
Beta-blockers	17 (30.4)	17 (29.8)
Alpha 1 antagonists	1 (1.8)	7 (12.3)
Angiotensin receptor blockers	18 (32.1)	9 (15.8)
Angiotensin-converting enzyme inhibitors	16 (28.6)	20 (35.1)
Diuretics	20 (35.7)	16 (28.1)
Nitrates	5 (8.9)	5 (8.8)
LVEF, mean (SD)	59.9 (7.7)	58.1 (8.0)
Lifetime syncopal spells, mean (SD)	4.5 (5.3)	4.3 (7.3)

Values are n (%), unless otherwise indicated.

ICM, implantable cardiac monitor; LVEF, left ventricular ejection fraction; PM, pacemaker; SD, standard deviation.

data could be collected, and were excluded from this analysis. Participants randomized to the PM vs ICM arms were similar in age (74.5 vs 77.4 years), sex (19 vs 14 female), and left ventricular ejection fractions (59.9% vs 58.1%; Table 2).

The PM strategy resulted in significantly fewer clinical composite outcomes than the ICM strategy ($P < 0.0001$).[28] Differences in clinical composite outcome event rates between arms were driven by those participants randomized to the ICM arm who went on to receive a PM due to documented bradycardias. At the end of 2 years, 38 of 57 participants (66.7%) randomized to the ICM arm had received a PM. By the end of 3 years, 39 participants randomized to the ICM arm had a PM implanted. These instances were associated with a cost of $8610.17[10,29] per event.

In the PM group, the device insertion cost per participant was $8390.04.[10,29] In the ICM group, the device insertion cost was $4498.26.[10,13] At 2 years of follow-up, the mean total cost per participant randomized to the PM arm was $9806 (95% confidence interval [CI]: $8494 to $11,118), and the mean total cost per participant randomized to the ICM arm was $13,483 (95% CI: $11,359 to $15,607). The mean QALYs gained per participant randomized to the PM arm was -0.021 (95% CI: -0.081 to 0.042), and the mean QALYs gained per participant randomized to the ICM arm was -0.046 (95% CI: -0.115 to 0.023). No evidence was seen of a difference in QALYs gained between the 2 strategies (t (111) = 0.570, $P = 0.570$). One participant randomized to the ICM arm received an implantable cardioverter defibrillator. If this participant is excluded, the mean cost per participant randomized to the ICM arm decreases to $12,854 (95% CI: $11,113 to $14,594).

In 1000 bootstrapped replicates of incremental cost and incremental effectiveness at 2 years of follow-up, the PM strategy was less costly than the ICM strategy (Fig. 2). In 70.2% of bootstrapped replicates, the PM strategy resulted in a greater number of QALYs (Fig. 2).

Decision analytic modelling

In the PM group, the mean total cost per patient over 3 years was $9934 in 2017 CADs. In the ICM group, the mean total cost per patient over 2 years was $15,500. The mean QALYs per patient in the PM and ICM groups were -0.031

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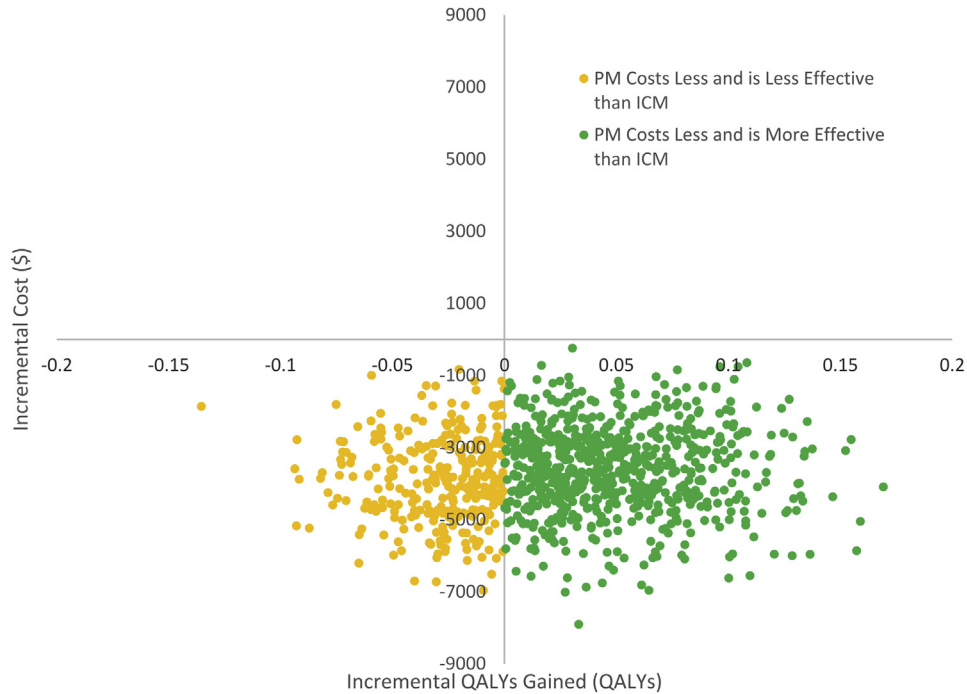
Figure 2. One thousand bootstrapped replicates of incremental cost and incremental quality-adjusted life-years (QALYs) gained. Incremental outcomes were calculated as pacemaker (PM) outcome minus implantable cardiac monitor (ICM) outcome.

and -0.134, respectively. The PM strategy is dominant in that it resulted in greater QALYs and was less costly than the ICM strategy.

Uncertainty analysis

Model inputs, values tested in 1-way sensitivity analysis, and distributions for probabilistic sensitivity analysis are included in Supplemental Table S1. Figure 3 depicts the top 5 variables affecting the incremental cost-effectiveness ratio. Four of the top 5 variables affecting this ratio were related to the transition from ICM to PM (Fig. 3). In a scenario analysis in which follow-up for a PM includes a more involved assessment by a cardiologist, the cost per PM follow-up visit was increased to $157.35.[10] This cost increased the mean cost of the ICM strategy to $15,856 per participant, and the mean cost of the PM strategy to $10,565 per participant.
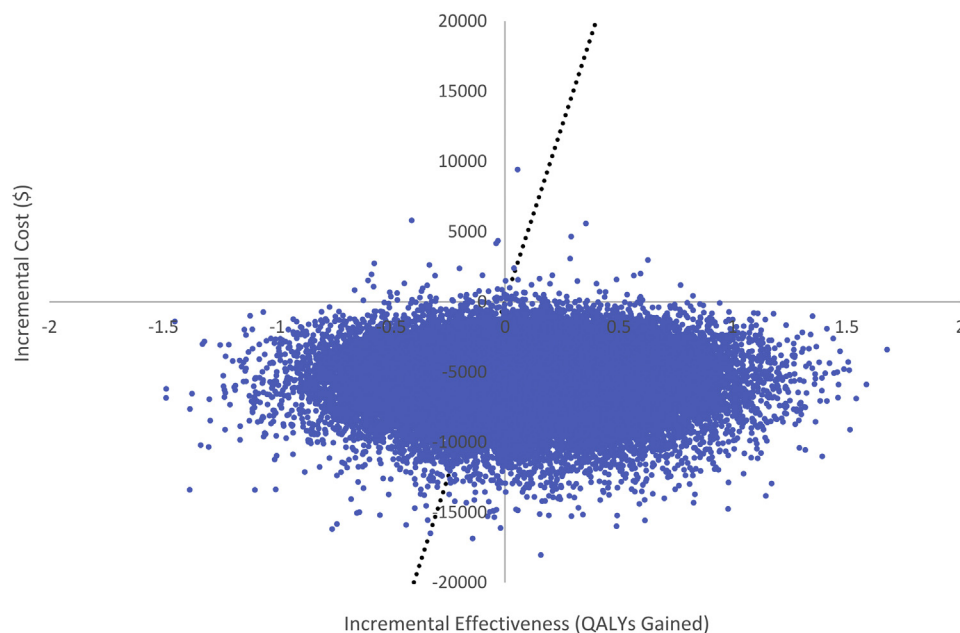
In probabilistic sensitivity analysis of 40,000 iterations, uncertainty was seen in both cost and effectiveness outcomes (Fig. 4). Compared to the ICM strategy, the PM strategy resulted in cost-savings and greater effectiveness in 60.9% of iterations. In a further 38.8% of iterations, the PM strategy resulted in lower costs and reduced effectiveness. In the remaining 0.3% of iterations, the ICM strategy was cost-saving compared to the PM strategy. In 89.7% of iterations, the PM strategy was cost-effective at the threshold of $50,000 per QALY.

Discussion

At the end of the 2-year follow-up period, the cost of the ICM strategy was greater than that of the empiric PM insertion strategy. This trend continues when the follow-up period is extended to 3 years with a model. However, no
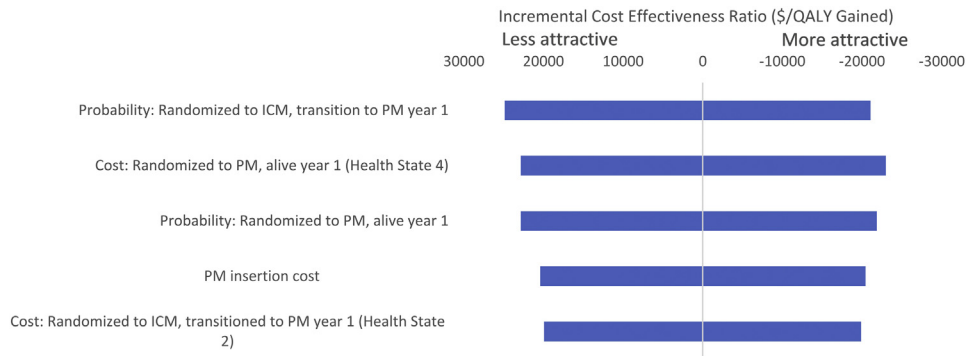
Figure 3. Tornado diagram of top 5 model variables affecting the incremental cost-effectiveness ratio, when increased and decreased by 25%. ICM, implantable cardiac monitor; PM, pacemaker; QALY, quality-adjusted life-year.

Figure 4. Probabilistic sensitivity analysis, 40,000 iterations. Incremental outcomes calculated as pacemaker outcome minus implantable cardiac monitor outcome. QALY, quality-adjusted life-year.

evidence was seen of any difference in effectiveness or QALYs gained at the 2-year time horizon or the 3-year time horizon (Table 3). Modelling demonstrates that the cost is highly sensitive to the cost and probability of transition to a PM for those randomized to the ICM arm. In nearly all iterations of nonparametric bootstrapping and probabilistic sensitivity analysis, the PM strategy was less costly than the ICM strategy, and it was more effective in most iterations.

The increased cost of the ICM was sensitive to the number of patients that required subsequent PM insertion. Krahn et al.[30] suggest that in the setting of unexplained syncope, the ICM has a high diagnostic yield, which leads to appropriate management and a subsequent reduction in resource use. The study by Krahn et al.[30] focused on all patients with unexplained syncope, whereas the current analysis focused on the subset who also have bifascicular block. Although the ICM may provide additional diagnostic information, if a patient still requires a subsequent PM, then the ICM was of low value.

A previous model demonstrated that pacemaker insertion was cost-effective compared to electrophysiologic testing when the probability of bradyarrhythmia exceeded 72% in patients with bifascicular block and syncope.[31] The ICM was not part of this model, and model inputs were heavily based on assumptions.[31] In another Markov model by Providência et al.,[32] the ICM appeared to result in fewer syncope admissions and cost reductions for patients with unexplained syncope, compared with a conventional diagnostic pathway. Our work extends this finding, by comparing the ICM to PM insertion, and analyzes a subset of the patients with unexplained syncope included in the model by Providência et al.[32]

For patients similar to those enrolled in the SPRITELY trial, current guidelines and recommendations support 2 strategies for management: the ICM and PM insertion.[3-6] In the SPRITELY trial, empiric PM insertion was superior to the ICM in prevention of a clinical composite outcome of death, syncope, symptomatic bradycardia, asymptomatic actionable bradycardia, and device complications (PM: 65% event-free; ICM: 24% event-free) over 2 years.[28] Forty of 58 patients received a PM after randomization to the ICM arm, owing to syncope (n = 16) or asymptomatic (n = 7) or moderately symptomatic (n = 17) bradycardias.[28] Agreement between clinical and economic outcomes in the SPRITELY trial clarifies uncertainty introduced by conflicting guidelines.

Limitations

The SPRITELY trial evaluation and model are heavily based on trial results, and model overfit is a possibility. Transition probabilities between years 2 and 3 were from

Table 3. Summary of outcomes

Analysis	Cost: PM	Cost: ICM	QALYs: PM	QALYs: ICM	ICER
Trial evaluation (2-y time horizon)	$9806	$13,483	−0.021	−0.046	PM dominates
Decision analytic model (3-y time horizon)	$9934	$15,500	−0.031	−0.134	PM dominates

Costs are given in Canadian dollars.

ICER, incremental cost-effectiveness ratio; ICM, implantable cardiac monitor; PM, pacemaker; QALY, quality-adjusted life-year.

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observations in the SPRITELY trial, but by the end of the third year of follow-up, only 54 participants remained in the trial. Power was reduced for this final year. However, we are aware of no other study that has collected similar data in the same population over the third year without loss to follow-up. Remote monitoring costs for the ICM were not included in this analysis, as practices for ICM monitoring and associated costs are likely to vary. If ICM remote monitoring costs were included, this would further increase the cost of the ICM strategy—making the PM strategy appear less costly by comparison. Additionally, this trial was not powered for economic outcomes. Whether a difference in QALYs gained between the 2 management strategies exists or was undetected cannot be determined.

Advances in PM technology have reduced the cost of the device. Given that the cost used for PM insertion is from 2015 and was inflated to 2017 CADs, this cost does not incorporate the recent downward trend in PM device costs. In cases in which the cost for PM insertion is lower than the value of $8390 used in this study, the empiric PM insertion strategy would appear to be even more favourable.

Selection of a 3-year time horizon assumes that by the end of the time horizon, the accumulation of cost and QALY outcomes will not differ between strategies. Given the lack of long-term data available for these patients, we believe this assumption is reasonable.

Conclusions

The ICM strategy resulted in a greater mean cost per participant than the PM strategy, with no evidence of a difference in QALYs gained. In the subset of patients with unexplained syncope who also have bifascicular block and age greater than 50 years, empiric PM insertion is likely to be cost-effective at the threshold of $50,000 per additional QALY in Canada. Agreement between economic and clinical outcomes resolves uncertainty in the guidelines. For these patients, a strategy of empiric PM insertion is likely to result in reduced cost and improved outcomes, compared with the ICM strategy.

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Disclosures

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2022.03.009.