Title
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Journal
American Heart Journal, 144(4)

ISSN
0002-8703

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Publication Date
2002-10-01

DOI
10.1067/mhj.2002.124835

Peer reviewed

Electrophysiology

Health values before and after pacemaker implantation

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Background Health value or utility is the abstracted magnitude of a person's preference for quality and quantity of life. It reflects how much lifetime with the patient's current health condition a patient is willing to exchange for a life in excellent health. Health values are used in cost-effectiveness analysis as a means of calculating quality-adjusted years of life.

Objective This study assessed the health values of elderly patients before and after pacemaker implantation.

Methods We prospectively examined 398 patients from the Pacemaker Selection in the Elderly study, in which patients were randomized to either VVIR or DDDR mode. Health values were estimated with the time tradeoff method before implantation and at 3, 9, and 18 months after implantation.

Results The mean age of patients was 76 ± 6 years; 234 patients (59%) were male. At baseline, patients were, on average, willing to exchange 5 years of current health for approximately 4 years in perfect health (value 0.76 ± 0.06). There was no difference in baseline health values with implant diagnosis (sinus node dysfunction n = 172, 0.72, atrioventricular block n = 227, 0.75, other diagnoses n = 39, 0.78, *P* = not significant). The overall improvement in health values at 3 months after pacemaker implantation was 0.165 ± 0.4 (*P* = .0001). The improvement in health values was independent of pacing mode (*P* = .6). The time tradeoff score was modestly correlated with other measurements of health-related quality of life. The change in time tradeoff score with time was not influenced by demographic characteristics such as age and sex, diagnoses, pacing mode, employment status, or history of angina. Patients with a lower functional class at enrollment (III or IV on the Specific Activity Scale) demonstrated an absolute improvement of 23% in their health values, whereas patients in class I or II improved only by 12%, (*P* = .03).

Conclusions Permanent pacemaker implantation for standard indications improves health values and descriptive health status measures. The values reported here may be used as a means of calculating the cost-effectiveness of different pacing modalities. (Am Heart J 2002;144:687-92.)

More than 200,000 pacemakers were implanted in the United States in 2000, at a cost of nearly $2 billion for pacemakers and leads alone. Pacemakers are implanted in a generally elderly population as a means of preventing or treating bradycardia and preserving a normal heart rate response to effort. To be considered effective, medical interventions must demonstrate improved survival rate or quality of life. Because treatments are likely to differ in their effects on the length and the quality of life, evaluating the cost-effectiveness of different interventions requires a common unit of measured benefit that properly reflects the tradeoff between longevity and the quality of life.[1]

Earlier reports of the Pacemaker Selection in the Elderly trial reported health status in a pacemaker population. In contrast, we report the measurement of utility, or health value, in a pacemaker population. Health values quantify a person's preference for quality and quantity of life simultaneously. They ascertain the magnitude of a person's preference for a shorter but healthier life by asking how much of the expected survival the patient would be willing to give up for a

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Supported by a grant from Intermedics, Inc.
Submitted March 23, 2001; accepted March 13, 2002.
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0002-8703/2002/$35.00 + 0 ***4/1/124835***
doi:10.1067/mhj.2002.124835

shorter life in good health.[2] Health values are useful not only in assessing health-related quality of life, but also in providing the necessary metric to perform cost-effectiveness analyses.[3] This utility value is the correction factor that allows quality-adjusted life years (QALYs) to be calculated from years of life saved. QALYs are commonly used as the denominator in estimating cost-effectiveness. Although cardiac pacing is an expensive and frequently used modality in an elderly population, little prospective data have been reported on the utilities of pacemaker recipients. However, the data presented here are of particular importance in assessing the effect of pacemaker implantation on health values, describing the clinical correlates of improvement in health utilities, assessing whether health values change with time in this population, and determining the correlation between health values and several generic or disease-specific health status measurements.

Methods

Study participants

The Pacemaker Selection in the Elderly (PASE)[4] trial was a single-blind, randomized, 29-center controlled trial of ventricular pacing versus dual chamber pacing in 407 patients aged ≥65 years. The primary end point was health-related quality of life. To participate, patients had to be in sinus rhythm at the time of implantation and had to have bradycardia as the indication for a permanent pacemaker. All participants provided written informed consent before participation. Patients were excluded from the study when they could not participate or complete the health utility or health status assessment, when they had a low score in the telephone interview of cognitive status, when they had clinically overt congestive heart failure or a life-threatening noncardiac illness at the time of the implantation, or when they had inadequate atrial capture or sensing thresholds at the time of the implantation. All patients received an Intermedics dual chamber (DDDR) pacemaker (Intermedics, Inc, Freeport, Tex) that was noninvasively programmed after randomization and before implantation. Of the 407 patients enrolled in the study, 204 were randomly assigned to ventricular rate-modulated pacing (VVIR), and 203 were programmed to dual-chamber rate-modulated pacing (DDDR). Reprogramming to dual-chamber pacing for patients assigned to VVIR patients was considered to be a secondary clinical end point of the study and was strongly discouraged except in cases of severe intolerance to ventricular pacing or pacemaker syndrome.

Interviews and instruments

Follow-up visits and health value and descriptive health status assessments took place 3, 9, and 18 months after enrollment and at the end of the study. The local clinical site performed the prerandomization health value and descriptive health status assessments before mode assignment. Subsequent assessments were performed by means of telephone from the coordinating center by 2 experienced telephone interviewers. Both telephone interviewers and patients were blinded to the pacing modality. Utilities or health values were assessed by use of the time-tradeoff score.[5,6] Participant were asked in a systematic fashion whether they would prefer living 5 years in their current state of health or less time in excellent health, until an indifference point was ascertained. To avoid a possible anchoring effect, questions increasing the period of excellent health were alternated with questions shortening the period of excellent health. The time-tradeoff score was then calculated as the fraction of time in excellent health that was equivalent to 5 years in current health. For example, if a patient considered it equivalent to live 5 years in the current health status or 3 years in perfect health, then the patient's health value is 0.6.

Multidimensional descriptive health status assessment was performed by use of the 36-item Medical Outcomes Study Short-form General Health Survey (SF-36),[7] which includes 1 multi-item scale measuring each of 8 health concepts: physical function, social function, physical role, emotional role, mental health, energy and fatigue, pain, and general health perception. The score of each of the 8 health domains is expressed as a unitless number ranging from 0 (worst) to 100 (best). The Karnofsky Performance Status scale[8] was used as a means of assessing the overall ability of patients to perform daily activities and thus to estimate their needs for medical care. Although originally used on patients with cancer, it has been validated in many other patient populations as a measurement of performance and independence. The score is expressed as a percentage, and the higher the number, the more able a patient is to perform daily activities. The Charlson Comorbidity Index[9] was determined for each patient at the time of enrollment. This index provides a global measurement of common comorbid conditions; the higher the number, the higher the number and severity of comorbidities. Disease-specific cardiovascular functional status was measured with the Specific Activity Scale (SAS),[10] which classifies patients on the basis of different activities, each of which is graded according to its required metabolic expenditure.[11]

Statistical analysis

Continuous variables were compared by use of the Wilcoxon rank-sum test. Within-patient changes with time were evaluated with the Wilcoxon signed-rank test. Associations between the time tradeoff and other continuous health-related quality-of-life scales were assessed by use of Spearman correlation coefficients. Ordinal logistic regression analysis was used as a means of identifying independent correlates of change in time-tradeoff scores.

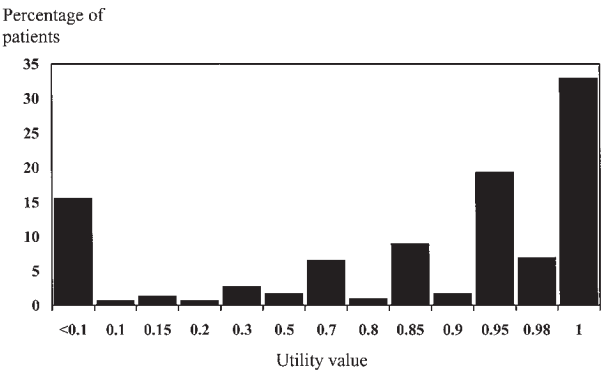
Results

PASE enrolled 407 patients who were observed for an average of 550 days. The time-tradeoff questionnaire was completed by 398 patients at baseline, by 284 patients at 3 months, by 291 patients at 9 months, and by 250 patients at 18 months of follow-up.

Baseline characteristics

The mean patient age was 76 ± 6 years; 41% of patients were female, and 43% of patients underwent

Figure 1



Distribution of patient time-tradeoff scores at the initial interview.

Table I. Characteristics of patients at baseline

	No. (%)
Age (y) (mean ± SD)	76 ± 6.3
Male sex	234 (59)
Race white	342 (86)
Symptoms	
Syncope	151 (41)
Dizziness	236 (63)
New York Heart Association	
Class III or IV	109 (28)
Overweight (BMI >27)	142 (36)
History of congestive heart failure	108 (27)
Retired or unemployed	353 (89)
Charlson comorbidity index ≤1	300 (75)
Indication for pacemaker implant	
AV block	227 (57)
Sinus-node dysfunction	172 (43)
Carotid hypersensitivity	39 (10)
Assigned to dual-chamber pacing	196 (49)

BMI, Body mass index; *AN*, aterioventricular.

pacemaker implantation because of sinus node dysfunction (Table I). Only 25% of patients had ≥2 concurrent chronic medical conditions included in the Charlson Comorbidity Index.

Baseline utilities

At baseline, patients on average would be willing to exchange 5 years of current health for about 4 years in perfect health (utility 0.76 ± 0.06). Eighty-three patients (21%) would trade 5 years in current health for ≤18 months in perfect health (utility <0.3), and 122 patients (31%) would not exchange any time (utility 1) (Figure 1). There was no difference in health values with implantation diagnosis (sinus node dysfunction n = 172, 0.72, atrioventricular block n = 227, 0.75, other diagnoses n = 39, 0.78, P = not significant).

Validation of the time-tradeoff score

As a means of assessing the validity of the responses to the time-tradeoff questions, a series of known-group validity tests were performed. We compared the mean score of patients with a history of congestive heart failure with the mean score in patients without failure; we also compared the score of patients with and without stable angina. Our expectation was that participants with congestive heart failure and angina would have lower health utilities than patients without these conditions. Study patients with a baseline history of congestive heart failure had significantly lower time-tradeoff scores than patients without a history of heart failure (0.64 vs 0.78, $P < .001$), and patients with a New York Heart Association functional class of III or IV had a much lower time-tradeoff score than patients with a functional class of I or II (0.62 vs 0.80, P = .0001). For comparison, the difference in time-tradeoff scores in patients with a baseline history of angina compared with patients without angina was more modest (0.69 vs 0.77, $P = .03$).

Relationship of health values with other measurements

The time tradeoff had a modest correlation with the different domains of the SF-36 questionnaire, the 0-to-100 single question scale, and the Karnofsky performance status (Table II). In the multivariate analyses, only the 0-to-100 single question value, the energy domain score of the SF-36, female sex, and white race were independently associated with a higher baseline time-tradeoff score.

Change in utilities after pacemaker implantation

The overall improvement in health values at 3 months after pacemaker implantation was 0.165 ± 0.4 ($P = .0001$) (Table III). The improvement in health values was independent of pacing mode ($P = .6$).

Stability of the time tradeoff score during follow-up

The main change in the utility values was seen in the comparison between baseline and 3 months after pacemaker implantation. After that, the mean time tradeoff scores remained relatively stable for the study period (Table III).

Pacemaker syndrome

Intolerance to ventricular pacing (pacemaker syndrome) developed in 47 patients, requiring crossover from ventricular pacing to a dual-chamber pacing mode. These patients had not improved their time-tradeoff scores between baseline and the time before crossover to dual-chamber pacing (0.75 at baseline vs

Table II. Correlation between time tradeoff values and health status scores measured with SF-36, Karnofsky performance status, and the 0–100 question

	Time tradeoff score		Karnofsky performance status		0–100 Question	
	r	*P* value	*r*	*P* value	*r*	*P* value
Karnofsky performance status	0.18	.003	–	–	–	–
0–100 Question	0.28	.0001	0.25	.0001	–	–
SF-36						
Physical function	0.26	.0001	0.50	.0001	0.38	.0001
Social function	0.17	.004	0.40	.0001	0.32	.0001
Physical role	0.21	.0005	0.43	.0001	0.36	.0001
Emotional role	0.15	.01	0.23	.0001	0.23	.0001
Mental health	0.20	.0006	0.27	.0001	0.31	.0001
Energy	0.31	.0001	0.42	.0001	0.42	.0001
Pain	0.15	.01	0.16	.006	0.25	.0001
Health perception	0.30	.0001	0.33	.0001	0.50	.0001

Time tradeoff values showed a modest but statistically significant correlation with other measurements of quality of life. *SF-36*, 36-Item Medical Outocmes Study Short-Form General Health Surgery; *r*, Spearman correlation coefficient.

Table III. Time tradeoff scores, functional status and health status scores at baseline, and 3 and 9 months later

Scale	Mean at baseline	Mean at 3 months	Mean at 9 months	Mean at 18 months
Time tradeoff	0.74	0.91*	0.87	0.87
SAS	2.0	1.89	1.7†	
0–100 question	64.1	71.0*	68.8†	
SF-36				
Physical function	53.9	57.5	57.0	
Social function	63.0	76.7*	70.2†	
Physical role	34.7	62.4*	57.0†	
Emotional role	68.6	89.5*	82.3†	
Mental health	72.7	78.2*	78.3	
Energy	43.3	55.3*	52.2†	
Pain	66.7	70.2	71.3	
Health perception	60.5	62.6	59.9†	

The improvement in mean health values occurred mainly after the intervention and then remained similar during follow-up. This pattern of improvement–stabilization was not seen with other measurements of quality of life. *SAS*, Specific Activity Scale.
*$P < .05$ between baseline and 3 months.
†$P < .05$ between 3 and 9 months.

0.76 before crossover, $P = .8$). However, after changing pacing mode at the time of the crossover, the time tradeoff scores improved (0.73 before crossover vs 0.91 after crossover, $P < .01$) and became similar to those scores of patients who had not crossed over at 9 months (0.89 vs 0.91, respectively, $P = .6$).

Subgroup analysis

The improvement in health values after pacemaker implantation was consistent across demographics and diagnoses, such as implantation diagnosis, pacing mode, sex, age, employment status, and history of angina. Patients with a lower functional class (III or IV) as measured by means of either the New York Heart Association class or the SAS demonstrated a greater improvement in the time-tradeoff score at 3 months follow-up. For example, patients in SAS class III or IV had an absolute improvement of 23% in their utility value, whereas that of patients in class I or II improved only by 12% ($P = .03$).

Discussion

This study demonstrated that health values improve after pacemaker implantation and that that improvement is only partially explained with the improvement in other measurements of quality of life. The 2 main approaches to assessing health-related quality of life are descriptive health status and health utility measurement.[12,13] The health status evaluation describes the individual's well being and functioning in 1 or several domains such as health perception, physical functioning, mental health, or vitality. This approach has been tested extensively. Currently, many instruments allow healthcare workers to measure health status with acceptable validity and reliability.[14] Utilities or health values are means of measuring patient preferences between a morbid condition and an ideal healthy status. In the assessment of utilities, patients give a proportional value or weight to a state of sickness that they would trade for a healthy condition. Health status, however, measures quality of life from a more utilitarian perspective by using functionality and social role as some of the major domains to assess. Although both measurements may correlate, they do not measure exactly the same characteristics. For example, a patient may have a high tolerance to pain and therefore will have utilities measured similar to a healthy state, despite a low score in the health status assessment. Utili-

ties integrate not only deterioration in well-being, but also personal preferences for health versus disease and how these are affected by beliefs and cultural factors. The time-tradeoff instrument has been used in different clinical scenarios as a means of assessing patient preferences for quality instead of quantity of life. Table IV shows utilities in other medical conditions for comparison.

Measurement of health-related quality of life in pacemaker patients has been reported.[10] In the original PASE report, we showed that elderly patients undergoing pacemaker implantation had a poor baseline quality of life. We also demonstrated that measurements of quality of life in that specific population were valid and reliable. However, despite intensive interest in utility assessment in recent years,[15] there is little published information on utilities in pacemaker recipients. The measurement of utilities is particularly significant when evaluating an expensive intervention such as pacemaker implantation. Utilities are useful not only in assessing health-related quality of life, but also effectiveness because they provide the necessary metric to perform cost-effectiveness analyses.[3] The utility value is the correction factor that allows QALYs to be calculated from years of life saved. QALYs are commonly used as the denominator in estimating cost-effectiveness.

Utilities have been used in quite a few clinical scenarios, such as myocardial infarction and breast cancer, and in seriously ill patients.[16,17] However, data about health values in patients with sinus node dysfunction, atrioventricular block, or other bradyarrhythmias are needed to analyze the effect of pacemaker implantation. In this study, patients at entry would trade 24% of their time in the next 5 years in their baseline condition in exchange for perfect health (mean 0.76). Compared with earlier studies that have measured health utilities, this study had a mean time-tradeoff score that was lower (worse) than that of hospitalized patients ≥80 years (mean 0.81) and patients who had sustained acute myocardial infarction (mean 0.87),[18] but not much different from that of patients who were seriously ill (mean 0.73).[6] The heterogeneity of the responses among different patients demonstrates substantial variability, which has also been reported in the health utility assessment of several other diseases.[19]

This study also confirms that permanent pacemakers improve health-related quality of life of patients with standard indication for pacemaker implantation[20] when measured with the utility approach. The clinical benefit of pacemaker implantation as expressed by means of health values was impressive, and the resultant utility value after pacemaker implantation (0.92) was quite good. This improvement was not influenced by demographic characteristics such as age, sex, or implant diagnosis. Although this finding may look counterintuitive, it suggests that patient preference for quality instead of quantity of life is independent of demographic features and implant diagnosis. Patients with lower functional capacity showed the highest improvement in health values, which supports the hypothesis that pacemakers improve functional capacity and also increase the validity of the time-tradeoff measurement, because the sicker the patient, the higher absolute improvement in utilities would be expected with an effective intervention.

Table IV. Utilities or health values in other medical conditions

Condition	Utility
Asthma	0.89
Postmyocardial infarction	0.87
Before knee replacement	0.78
Sinus node dysfunction or AV block	0.76
AIDS	0.75
Seriously ill (patients in intensive care unit)	0.73
IDDM on dialysis	0.40

AV, Atrioventricular; *AIDS,* aquired immune deficiency syndrome; *IDDM,* insulin-dependent diabetes mellitus.

The improvement in health values, however, should not be completely attributed to the pacemaker, because other interventions, regression toward the mean, and the placebo effect may have influenced the favorable response.[21] This is the first-ever report of utilities in patients with pacemaker syndrome and the first study proving that utilities in these patients may improve after initiation of atrial-based, or physiologic, pacing. It has been shown, however, that patients intolerant to VVIR mode have an improvement in other aspects of quality of life after reprogramming to the dual-chamber mode.[22] Nevertheless, it was noteworthy that patients who developed pacemaker syndrome did not, on average, report improvement in their own baseline utility values until after they crossed over to the DDDR pacing mode; these findings suggest that most of the improvement in utility can be attributed to a physiologically beneficial cardiac pacemaker. Furthermore, the improvement in utility was consistent among different subgroups of patients.

Another important finding of this study is the limited correlation (r values 0.15-0.30) between health values and other measurements of quality of life, such as the SF-36 instrument, the Karnofsky Performance Status, and the SAS scale. This result should not be interpreted as a poor validity of any of the instruments, but rather as evidence that utilities measure health from a different perspective than the health status approach. The time tradeoff value was not fully explained with the change in other outcomes measurements, indicat-

ing that health values actually measure complementary domains of health. This discrepancy also reinforces the need to consider patient preferences as expressed by means of time tradeoffs when assessing outcomes. Paradoxically, we would not expect these instruments to be fully independent because it would be hard to explain that significant changes on health status would not impact health values at all.

In summary, pacemaker implantation improves health values to a mean level close to the equivalent of normal health.

We thank Elaine Abrams, the telephone interviewer, without whose determined and careful efforts, these analyses would not have been possible, the PASE coordinators and investigators, and Mrs Lori Saint-Thomas, for her careful secretarial assistance.

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