Case Study

Choosing an electronic cardiac pacemaker: A decision analysis

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Abstract: Cardiac pacemaker malfunctions are of continuous concern to the medical profession as well as to the electronics industry. Several dozen pacemaker models are on the market and cardiologists often find it difficult to choose amongst them. The main concern is for the distribution of the various failure modes due to premature battery exhaustion or malfunctions in the electronic circuit, and the criticality of the failure. This paper employs a decision analytic framework to help cardiologists choose among several pacemaker models. Failure data were obtained from the literature and a utility function over failure outcomes was elicited from a cardiologist. The paper presents a 'Batch Reliability Comparison' method for utility assessment which might also be attractive in other reliability settings. Three specific pacemaker models used at the Chaim Sheba Medical Center were evaluated. The expected utility approach yielded a different ranking than the conventional expected life approach. The results have already been implemented even though they implied choosing a different model than was originally preferred.

Keywords: Decision theory, medicine, reliability

Introduction

An electronic cardiac pacemaker is a device that artificially controls the pulse rate of the heart when the intrinsic pacemaker of the heart can no longer provide adequate spontaneous rhythm. Such a pacemaker is surgically implanted under the skin in the chest, and provides electronic stimulation through a special electrode that connects the pacemaker to the heart. There are dozens of pacemaker manufacturers and models on the market, differing mainly in the distribution of possible failure modes, technology, battery type, and function. There are cost differences but pressures from highly competitive markets have kept

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prices roughly similar. This paper illustrates how decision analysis can be employed by the cardiologist in choosing amongst several alternative contending pacemakers.

Cardiac pacemakers are vulnerable to malfunctions in the electrode, batteries, and electronic circuit, and pacemaker failures can also occur due to ineffective sensing and infection. Some failures, as with routine battery exhaustion, necessitate the replacement of the pacemaker, while other failures can be overcome through external manipulation. Replacement of a pacemaker requires minor surgery under local anaesthesia but involves some hospitalization, inconvenience and cost.

Cardiac pacemaker malfunctions are, therefore, of continuous concern to the medical profession as well as to the electronic industries. Certain failures in pacemaker performance are critical and can result in patient deaths. This has resulted in strict governmental standards (in the U.S.) to preserve appropriate reliability on the part of pacemaker manufacturers. The highly sophisticated nature of today's pacemakers provides a strong incentive to constantly evaluate their performance and failures. All pacemakers must be periodically checked to ensure appropriate pulse generating frequency. Checking the pacing rate is also a commonly used method for checking the end-of-life characteristics of batteries and lead integrity.

In today's practice there are no systematic methods to compare and evaluate pacemaker performance. Available are detailed data on failure modes and survival time, but, as presented, these do not enable a systematic comparison (Bilitch et al., 1982).

Failure modes

In general, cardiac pacemakers are vulnerable to malfunctions in (a) the electronic circuit, (b) the batteries, (c) the electrode, and (d) other causes. Only the first two are intrinsic to the pacemaker itself so only these will be considered in this paper.

Failures in the electronic circuit usually result in the need to replace the defective pacemaker. Electronic circuit malfunctions include loss of capture and sensing, which may be critical; rate decrease which can usually be detected in time; intermittent, no output; and loss of capture.

Table 1
Ranking of possible failure modes (decreasing order of severity)

Rank	Failure mode
1	Loss of capture and sensing malfunction
2	Battery exhaustion – 1 year
3	Intermittent, no output
4	Battery exhaustion – 18 months
5	Battery exhaustion – 2 years
6	Rate decrease
7	Battery exhaustion – 3 years
8	Battery exhaustion – 4 years
9	Battery exhaustion – 5 years
10	Loss of capture
11	Battery exhaustion – 6 years
12	Battery exhaustion – 7 years
13	'OK'

The predominant pacemaker malfunctions are due to premature battery exhaustion. It can be sub-divided according to elapsed time from initial implantation. We considered several time periods until failure ranging from 1 year to 7 years.

The failure modes considered in our analysis are presented in Table 1. They are ranked from the one with the most serious implications (loss of capture and sensing malfunction) to the least severe (longer than expected battery life—7 years).

When considering electronic circuit failures, the timing of failures should also play a role. That is, a loss of capture after 5 years is considered a better outcome than loss of capture after 1 year. The cardiologist involved in this study (S.F.), as well as other cardiologists we had interviewed found it difficult to attach a time point to the occurrence of an electronic failure. Therefore, we decided to assume an average battery life of about 3 years for the timing of electronic circuit failures. The ranking in Table 1 reflects this assumption. There is usually sufficient warning about battery exhaustion and there is no rush for immediate pacemaker replacement. As long as there is no such warning, pacemakers will not be replaced even if they are functioning well beyond the manufacturer's claimed life span.

The decision problem

Of several available cardiac pacemakers, which should the cardiologist (in consultation with the patient) prefer? Should he prefer one with a high failure rate but with mild outcomes, or should he choose a pacemaker with a low failure rate but with severe outcome implications? Should be prefer a pacemaker with non-serious failures but with longer battery life? The decision problem can be represented by the decision tree of Figure 1. The branching following the choice of any pacemaker is basically the same as the one described for Pacemaker A although some failure modes may be specific to one pacemaker but not the other. The square node reflects a decision point at which the decision maker has control over which branch to choose. The circular nodes represent chance events over which the decision maker cannot exercise control. These chance nodes represent the uncertainty inherent in the problem. The difference between two pacemakers lies in the distribution of the various malfunctions. Some malfunctions are more frequent with one pacemaker model than with an alternative model, while others are less frequent. In order to decide among the various models we must consider both the likelihoods of the various outcomes as well as their implications. We must, therefore, quantify the uncertainties in the chance nodes by assigning (or assessing) appropriate probabilities for the various outcomes, and then quantify the preferences for outcomes by assigning 'values' (or utilities) to each of the outcomes.

It may be possible, in the general case, that some malfunctions are specific to certain pacemakers, and cannot occur with others, hence the chance nodes for various alternatives may have different branching. Or, we could list all possible failures for each of the alternatives and simply assign a probability of zero when a certain malfunction cannot occur.

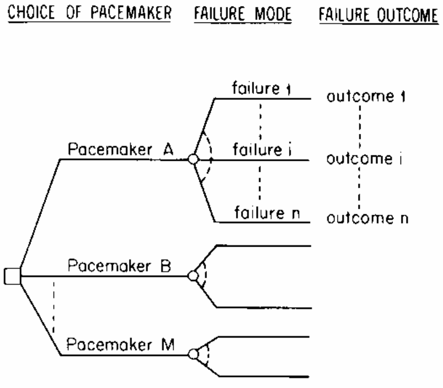

Figure 1. Decision tree for pacemaker choice

Our analysis evaluated three different pacemaker models used at the Chaim Sheba Medical Center in Israel. World experience with over 7000 pacemakers was used in our analysis (Bilitch et al., 1982).

Utility assessments

Before assessing utilities for the various outcomes we must clarify whose preferences we are incorporating. There has been a constant debate about whose preferences to incorporate in clinical decision problems (Pliskin et al., 1980). We want to avoid this issue here and feel quite comfortable using the cardiologist's utility function. His vast experience with hundreds of pacemaker implants and replacemens established a good 'feel' for the implications of the various malfunctions.

The malfunctions of Table 1 were rank-ordered according to a decreasing degree of severity. The cardiologist incorporated the following attributes in his ranking: (1) criticality of failure as it relates to risk of death; (2) suddenness of the failure; (3) degree of patient dependence on the pacemaker; and (4) whether the failure is permanent or appears intermittently. Since the cardiologist found it difficult to separate the various attributes from each other and was always incorporating them collectively we decided to proceed by assessing a one-dimensional utility function over the possible failure modes.

Initially, the cardiologist found it difficult to compare battery exhaustion failures with electronic circuit failures. He even found it difficult to provide the ordinal ranking of Table 1. In addition, he had no previous experience with utility assessment procedures. To make things easier for him and more meaningful for the analysis, we decided to elicit two separate utility functions: one for battery exhaustion failures, and the other for circuit failures (nos. 1, 3, 6, 10 of Table 1). Only after gaining experience through the elicitation of the two functions did we feel comfortable enough (vis-a-vis the cardiologist) to mix 'apples' and 'oranges' and come up with a single utility scale. Also, having a utility function span a continuous scale (i.e., time) proved beneficial in the final analysis of comparing different pacemaker types.

A utility function for time until battery exhaustion

Battery life of more than 7 years (the 'OK' mode) was assigned a utility of 100 and the shortest assumed battery life of 1 year was assigned a utility of 0. These two values, that could be assigned arbitrarily, determine the origin and unit of measurement. The two most common approaches for assessing a utility function over the range of 1 to 7 years are: (1) the direct certainty equivalent (CE) determination method by which the assessor is asked to determine the CE for a given gamble on battery survival; and (2) the probability assessment method for determining indifference between a given certainty and a gamble (Hershey et al., 1982). The former approach is most suitable for continuous attributes while the latter is more appropriate for discrete attributes or for attributes not measured by the same units. Since data on battery function are given only for individual years we looked at 9 discrete points on the battery survival scale and used the probability assessment method. Another reason for using this approach was that this was the only viable approach to assess a utility function over electronic circuit failures and for combining both utility curves.

Using the probability assessment method, the following type of question was posed to the decision maker: "You can use a pacemaker which you know for sure that the batteries will be exhausted at the end of 2 years, or you could use a pacemaker which has a probability p of exceeding the manufacturer's claimed life of 7 years ('OK') and a complimentary probability $1-p$ of battery exhaustion at 1 year. For which value of p would you be indifferent between the two alternative pacemakers?" This choice problem is represented graphically in Figure 2.

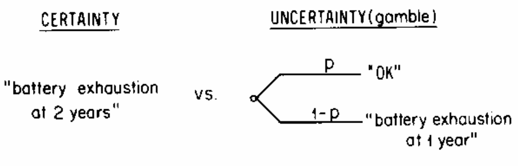

Figure 2. The probability method choice problem

The indifference probability, p_0, to the above question can then be used to calculate the utility value of the intermediate outcome 'battery exhaustion at 2 years' by calculating the expected utility of the gamble.

However, our cardiologist experienced difficulties in approaching the assessment problem by questions of the above nature. We revised our assessment technique to be more realistic to the context of the specific decision problem at hand. This method could also be helpful in other reliability contexts and we shall refer to it as "Batch Reliability Comparison" (BRC). This method involves the comparisons of (hypothetical) batches of pacemakers. The cardiologist was presented with a choice problem as follows: "You are presented with two batches of 1000 pacemakers each. Batch A contains 999 pacemakers that will function at least 7 years and one pacemaker whose batteries will 'give' after 2 years. Batch B contains one pacemaker with a battery life of only 1 year and the rest (999) will last at least 7 years. Which batch would you rather work with?" This choice problem is presented in Figure 3. It was in this pictorial form that the problem was posed to the cardiologist. His obvious preference was for batch A. But what if this batch contained not one 'battery exhaustion at 2 years' but two such pacemakers, or 10, or 20? The choice was no longer obvious. We varied the proportions until indifference between the two batches was observed.

In general, if the decision maker is indifferent between batch A containing a proportion p_A of '2 year battery exhaustion' pacemakers (and the rest 'OK') and batch B containing a proportion p_B of '1 year battery exhaustion' pacemakers, then the utility u of '1 year battery exhaustion' can be calculated from

$$p_A U(\text{'2 years'}) + (1-p_A)U(\text{'OK'}) = p_B U(\text{'1 year'}) + (1-p_B)U(\text{'OK'}).$$

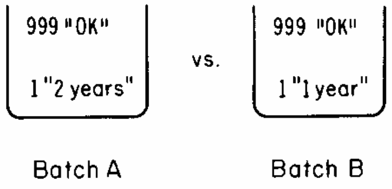

Figure 3. The realistic choice problem

Table 2
Utility values for battery exhaustion failures

Failure mode (years to exhaustion)	Utility
1 year	0
$1\frac{1}{2}$ years	80
2 years	90
3 years	98
4 years	99
5 years	99.6
6 years	99.8
7 years	99.9
> 7 years ('OK')	100

With $U(\text{'OK'}) = 100$ and $U(\text{'1 year'}) = 0$, this reduces to

$$U(\text{'2 years'}) = 100(p_A - p_B)/p_A.$$

In the above example, $p_A = 0.01$, $p_B = 0.001$, implying $U(\text{'2 years'}) = 90$. Utility values for all intermediate time periods for battery exhaustion were similarly determined by the BRC method and are depicted in Table 2. The values for exhaustion between 3 and 7 years seem very close but that is a matter of the scale chosen. The values for $1\frac{1}{2}$ years and 2 years are a bit remote. The reason for this distribution is the rather uncomplicated nature of the battery exhaustion failure. There is usually sufficient warning with barely any problem for the patient. However, pacemaker replacement within the first two years after implantation is a relatively bad outcome because of the possible psychological effects on the patient and his subsequent anxiety.

After the cardiologist became familiar and rather comfortable with the BRC method we tried again the probability assessment method and experienced less aversion to it and more acceptance. We used this method for some consistency checks, mainly because we realized that the BRC method implied some constraints on some of the probabilities.

A utility function for electronic circuit failures

The Batch Reliability Comparison method was especially suitable for the electronic circuit failures where attributes were described qualitatively and not on a single numerical scale. We took the 'OK' mode as representing no electronic failures and assigned it a utility value of 100. The worst failure category was 'loss of capture and sensing malfunction' and it was assigned a utility of 0. Intermediate values were obtained using the BRC method, and are presented in Table 3. Again, the 'rate decrease' and 'loss of capture' failures do not have any serious implications for the patient. Therefore, their utility values are relatively closely bunched with that of the 'OK' mode.

Table 3
Utility values for electronic circuit failures

Failure mode	Utility
'OK'	100
Loss of capture	99.96
Rate decrease	99.6
Intermittent, no output	90
Loss of capture and sensing malfunction	0

It should be noted that the electronic circuit failures somehow ignored the timing of these failures. Failure after 2 years is less desirable than the same failure mode after 5 years of operation. Both the literature and our cardiologist found it difficult to explicitly consider the timing of electronic circuit failures. We therefore assumed that these failures would occur at about 3 years of operation to reflect an average duration. These 3 years were implicitly considered in establishing the utility scale of Table 3.

Combining both utility functions

The 'OK' modes in both of the preceding utility functions indicate defect free pacemakers and hence reflect the same preference for them. Let us therefore keep $U(\text{'OK'}) = 100$ on the combined scale. Also, a malfunction of 'rate decrease' is similar in nature to battery exhaustion. Since we implicitly assumed the rate decrease to occur at about 3 years we will consider 'rate decrease' and 'battery exhaustion at 3 years' to reflect the same outcome. If we want $U(\text{'rate decrease'})$ to equal 0.98 as it does on the utility curve for battery life, we have now determined both the new origin and new unit of measurement for the utility function over electronic failures so that it corresponds to the scale for battery exhaustion. The required linear transformation for the utility function over

Table 4
Utility values for all failure modes

Failure mode	Utility
Loss of capture and sensing malfunction	−400
Battery exhaustion − 1 year	0
Intermittent, no output	50
Battery exhaustion − 18 months	80
Battery exhaustion − 2 years	90
Rate decrease	98
Battery exhaustion − 3 years	98
Battery exhaustion − 4 years	99
Battery exhaustion − 5 years	99.6
Loss of capture	99.8
Battery exhaustion − 6 years	99.8
Battery exhaustion − 7 years	99.95
'OK'	100

electronic failures is:

$$U(\text{new scale}) = 500U(\text{old scale}) - 400.$$

The final utility scale for all possible failure modes (as ranked in Table 1) is presented in Table 4.

The entire assessment procedure, although frustrating at first, proved to be a very positive experience for the cardiologist. It went far beyond just being an 'academic exercise'. He stated that it provided new insights into his entire approach to pacemaker implantation and he began to think more explicitly about issues he had swept aside in the past.

Assessing failure probabilities

Estimates for failure probabilities for each of the three pacemakers compared in our analysis were obtained from reported experience with over 7000 pacemakers (Bilitch et al., 1982). Performance of cardiac pacemakers is tabulated by survival as a function of the specific battery chemistry and type, by individual models even if they have the same battery technology, and according to failures in the electronic circuit. The above source provides direct model actuarial survival.

Given the electronic circuit design, a component failure mode analysis can help determine the probabilities of overall failure (Ronen et al., 1984). However, in the current analysis we used only actual frequencies of observed malfunctions.

The presentation of data on pacemaker performance enables simple calculations for the expected survival of each pacemaker model and the expected utility of each model.

Results

We compared performance of three pacemaker models routinely used by our cardiologist at the Chaim Sheba Medical Center in Israel. They are all manufactured by Cardiac Pacemakers and the model numbers are CPI501, CPI502 and CPI505. The CPI501 has a lithium chromate ($LiAgCrO_4$) chemistry as the power source while the others have lithium iodine (LiI).

Two criteria were used to compare the three pacemakers: life expectancy and expected utility as expressed by certainty equivalents of length of life. The certainty equivalent months were obtained from the utility curve on battery survival by reading off the calculated expected utility values. Table 5 presents the results. As can be seen, the conventional approach of considering life expectancy ranks the three pacemakers rather closely with CPI505 being best and CPI502 worst. The expected utility analysis ranks the CPI501 a distant third, only because of an observed 'loss of capture' failure which has a very low utility value. The CPI502 came out ahead of CPI505 because the latter have more failures during the first year, a rather undesirable outcome.

If we use the expected utility approach on survival only (ignoring electronic circuit failures), the CPI501 comes out way ahead of the others (75 equivalent months of survival as opposed to 46 and 41 of CPI502 and CPI505, respectively). This is due to the fact that the CPI501 models experienced no failures during the first three years. However, from ranking first on survival (using the expected utility approach) the CPI501 drops to a distant third when the critical electronic circuit failure is considered. We believe the expected util-

Table 5
Ranking of cardiac pacemakers using two criteria

Pacemaker model	Expected utility (equivalent months of survival)	Expected survival (months)
CPI501	34	85.25
CPI502	46	83.12
CPI505	41	87.28

ity approach is the one to be utilized because the conventional life-expectancy approach fails to accomodate the relative criticality of the various failure modes.

There is a third criterion which has sometimes been used to compare pacemakers. It considers the percentage of pacemakers surviving longer than some specified period. If, for example, we look at 5 years as that time period, then 77.5% of CPI501 function beyond that period, 84.6% of CPI502 and more than 90% of CPI505. This method yields yet a different ranking where CPI505 is best and CPI501 worst. We presented this criterion separately because of its infrequent use and the arbitrariness of the choice of time period.

The decision analysis indicated CPI502 to be the pacemaker of choice among the three compared. Up to the time of the analysis it was much less preferred than CPI505. The CPI501 continued to be the least preferred. Not only did the analysis lead to different decisions but the cardiologist had a great deal of confidence in his decisions regarding choices of pacemakers.

Summary

The paper presented an analysis that proved to be a valuable decision aid to the cardiologist. It provided an approach to comparison of cardiac pacemakers which was not used in the past and which yields choices different from ones generated by common approaches. These new choices reflect the criticality of the various failure modes and the preference of the decision making team. Other cardiologists may exhibit different preference patterns and a similar analysis can be easily performed for them. The present analysis addressed the specific choice problem of a given cardiac pacing center and provided a systematic and consistent approach to their decisions in selecting pacemakers for their patients.

In the process of assessing preferences over possible failure modes, a new approach of eliciting preferences was introduced, Batch Reliability Comparison, which may be helpful in other reliability analyses.

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