

Cost-Effectiveness of Implantable Cardioverter Defibrillators in Brazil in the Public and Private Sectors

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Abstract

Background: Many randomized clinical trials have demonstrated the effectiveness of the implantable cardioverter-defibrillator (ICDs) in death reduction of chronic heart failure (CHF) patients. Some developed countries studies have evaluated its cost-effectiveness, but these data are not applicable to Brazil.

Objective: To evaluate the cost-effectiveness of ICD in CHF patients under two perspectives in Brazil: public and supplementary health systems.

Methods: A Markov model was developed to analyze the incremental cost-effectiveness ratio (ICER) of ICD compared to conventional therapy in patients with CHF. Effectiveness was measured in quality-adjusted life years (QALYs). We searched the literature for data regarding effectiveness and complications. Costs were retrieved from public and health insurances reimbursement codebooks and from mean cost of admissions from a public and a private hospital. One-way sensitivity analysis was performed in all variables of the model.

Results: ICER was R\$ 68,318/QALY in the public and R\$ 90,942/QALY in the private perspective. These values are much higher than the one suggested by the World Health Organization of 3 times the gross domestic product per head (R\$ 40,545 in Brazil). The results were sensitive to the cost of the device, battery replacement interval and ICD effectiveness. In a simulation resembling MADIT-I population survival and ICD benefit, ICER was R\$ R\$ 23,739/QALY in the public and R\$ 33,592/QALY in the private perspective.

Conclusion: The ICER of ICD is elevated in the general ICC population, in either the public or private perspective. A more favorable result occurs in patients with a high sudden death risk. (Arq Bras Cardiol 2010; 95(5): 577-586)

Keywords: Defibrillators, implantable; cost-benefit analysis; Brazil.

Introduction

Congestive heart failure (CHF) is currently a public health problem, with increasing incidence and mortality in the last years¹⁻⁴, currently being among the main causes of hospital admission at the Brazilian Public Health System (*Sistema Único de Saúde* - SUS)⁵. The implantable cardioverter defibrillator (ICD) has been broadly studied in this group of patients, as this device has the potential to interrupt life-threatening arrhythmias, which account for up to 50% of the mortality in this pathology⁶.

The first important clinical trial in this area, the MADIT (Multicenter Automatic Defibrillator Implantation Trial) study, which evaluated patients with CHF and acute myocardial infarction (AMI), in addition to inducible tachyarrhythmia in an electrophysiological study, found a decrease in total mortality of 54%⁷. After this clinical trial, other large studies,

such as MADIT-II and SCD-HeFT, which evaluated almost 4,000 patients, expanded the ICD indication for patients with heart failure with both ischemic and non-ischemic etiology, with no history of severe arrhythmia in the past^{8,9}.

In total, ten clinical trials evaluated the use of ICD in the primary prevention of events in CHF and two meta-analyses that reviewed these studies found a decrease in total mortality of around 25%^{10,11}.

However, considering the increasing costs in healthcare currently observed worldwide, it is crucial to assess not only the effectiveness but also the costs before approving new inputs in health systems, especially in high-cost technology such as the ICD. Although some cost-effectiveness studies on this therapy have been carried out in international settings¹²⁻¹⁶, the obtained results are scarcely applicable to our reality, especially considering the large difference in costs in healthcare sectors among different countries. To date, there had been no description in the literature on the cost-effectiveness of this device using Brazilian data.

Therefore, the aim of this study was to estimate the incremental cost-effectiveness ratio (ICER) of the implantable cardioverter defibrillator (ICD), when compared to the

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conventional therapy in the primary prevention of events, considering two perspectives in Brazil: the public health system (SUS) and the supplementary health systems. Secondly, the aim of the present was also to perform sensitivity analyses in order to estimate the most influent parameters in the cost-effectiveness ratio.

Methods

A more detailed description of the methodology has been published elsewhere¹⁷. The main points are discussed next.

Description of the economic assessment

A Markov model was constructed, considering a population of patients with left ventricular dysfunction and left ventricular ejection fraction (LVEF) < 35%. This model was built to analyze the cost-effectiveness ratio of the ICD in a population with general heart failure and in a subgroup of patients at higher risk for arrhythmias. When constructing both models, the methodological patterns recommended by the Panel on Cost-Effectiveness in Health and Medicine¹⁸⁻²⁰ were employed. Model assumptions and included costs were based on the the third-party payer perspective, assessed through the viewpoint of the public and the private healthcare system. The time horizon was 20 years and the adopted discount rate was 3% in the base-case.

Population model

The hypothetical target population consisted of individuals with heart failure and clinical characteristics similar to those studied in the clinical trials: systolic dysfunction (LVEF < 35%), of both ischemic and non-ischemic etiology; initial age of 60 years; NYHA functional class (NYHA-FC) II and III and clinical and surgical conditions for the ICD implantation. The patients

had no history of malignant arrhythmias and the model was established as a primary event prevention one.

Description of the clinical-decision model

The decision tree, created using the Data Treeage software (release 5.0), was divided in two strategies: defibrillator + conventional therapy versus conventional therapy only. A schematic representation of the tree is depicted in Figure 1.

The clinical model followed the following assumptions: after the implant, procedure-related complications can occur, including mild complications (such as brachial thrombosis, deep venous thrombosis and pneumothorax), as well as severe ones, with the latter capable of causing perioperative death. The patients that survived the implant entered a transition state model, the Markov model. At each annual cycle, the patients could remain stable, die or present complications, such as lead break or systemic infection, in addition to lead displacement (this complication only occurred during the first year post-implantation or lead replacement). The patients undergoing conventional therapy could remain stable or die at each cycle, as well as those who were initially in the defibrillator group and present implantation failure or had to have the device removed during the follow-up.

The defibrillator analyzed in the model was the single-chamber type, due to the lower rate of complications of this kind of device, as well as the lower cost and similar effectiveness. The defibrillator generator replacement occurred every five years in the base-case.

Clinical outcome measurements

The clinical outcomes considered in the assessment were life-years saved (LYS) and quality-adjusted life years (QALY).

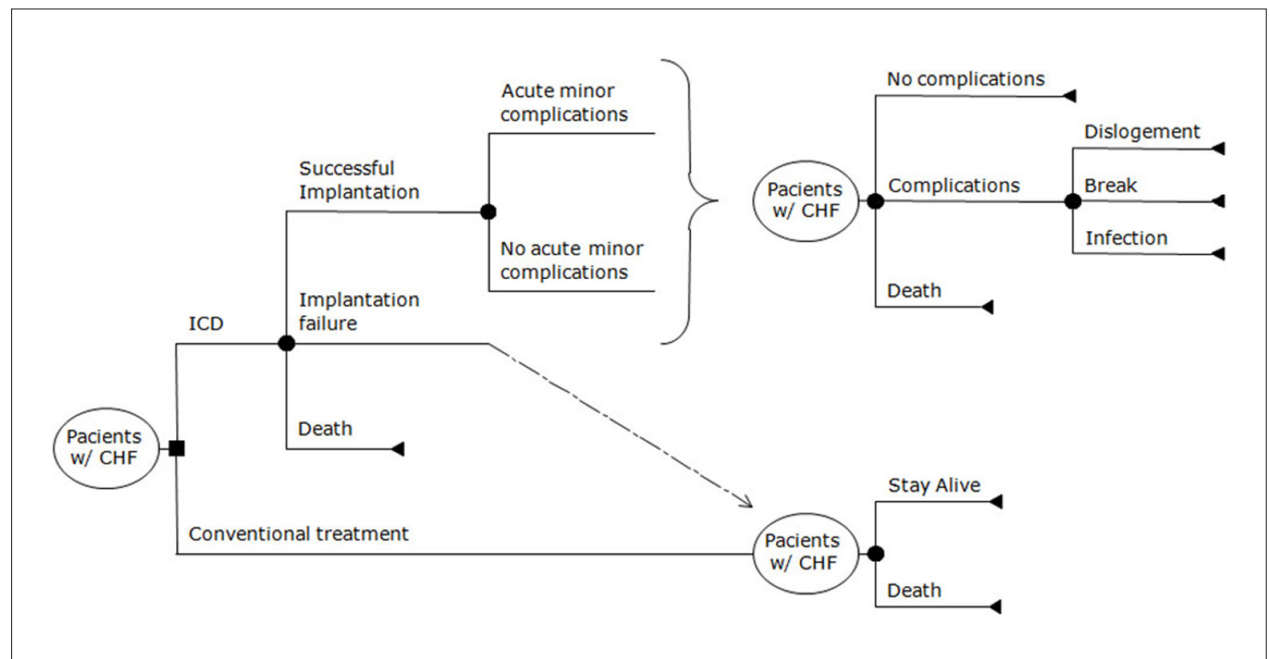


Figure 1 - Schematic representation of the decision tree.

The main model used the quality-adjusted outcome, according to the recommendation of the Panel on Cost-effectiveness²⁰.

Data from a cohort of 386 patients with CHF from a specialized outpatient clinic, from Hospital de Clínicas de Porto Alegre, were used for the survival projection in an usual population of CHF aged 60 years in the baseline, incorporating data from life tables of the Brazilian Institute of Geography and Statistics (IBGE). This cohort consisted of 63% men, with a mean age of 59 years, with an interquartile range (IQR) of 49 to 68 and a mean follow-up of 35 months (IQR = 18-60). These patients presented hypertension (53% of the sample), diabetes (33%) and current smoking status (13%); 89% used ACE inhibitors and 73%, beta-blockers^{21,22}.

Analysis of effectiveness

A search in the Medline database was carried out for clinical trials and meta-analyses that had evaluated the use of ICD in CHF, in order to obtain data on effectiveness. The effectiveness data of the meta-analysis performed by Nanthakumar and cols.¹¹ was used, which showed a decrease in the risk of death associated with the ICD of 26% (95%CI: 17%-33%, $I^2 = 5.2\%$), based on the compilation of seven clinical trials. Considering the lack of data on long-term effectiveness of the ICD, it was considered to be constant throughout time, in accordance with other cost-effectiveness studies that evaluated this device.

Complication data

Regarding data on ICD-related complications, the search was carried out in both clinical trials and observational studies, especially international cohort and registry studies. A meta-analysis carried out by Ezekowitz et al²³ provided rates of systemic infection (total number of patients = 12,436), perioperative mortality (N = 39,858) and ICD implantation failure (N = 11,129). The values adopted in the base-case for lead displacement and mortality due to infection were the result of a meta-analysis of incidences of values that were found in the clinical trials and cohorts, using the method of random effects by DerSimonian and Laird. In order for the study to be eligible for inclusion in the meta-analysis, the ICD leads should have been implanted via the transvenous route and the generator had to be located in the chest. Studies with less than 10% of abdominal implants were also included. Moreover, the devices used in the studies had to be, in the majority, the single-chamber type. In total, four studies that reported lead displacement²⁴⁻²⁷ and four that reported mortality due to infection^{24,25,28,29} were included.

Regarding the data on lead complications that required lead replacement (such as break or isolation defect), we used data from a single article, which was considered the most reliable among the identified ones, as it was the only one that performed a long-term follow-up of the studied cohort (ten years)³⁰.

The values used in the model were the following: up to the 7th year, in which there were 168 patients under follow-up³⁰, we used the values supplied by the study for each year. After the 7th year, in which the lead replacement rate was around 6.7%, we chose to maintain the rate constant at this value, as

the number of patients in the study decreased significantly, reducing the reliability of estimates.

Utility data

Due to the lack of Brazilian data on the utility of patients with heart failure, international data were used. The estimate of utility for the base-case was 0.88, with no difference between the defibrillator group and the conventional therapy group, in accordance with several previously published studies^{13,14,16,31}. At the sensitivity analysis, the values that ranged between the findings in other literature studies³²⁻³⁵ were used.

Cost analysis

Regarding the costs of the procedures related to the ICD implantation and the associated complications, values from the reimbursement table of the Hospital Admission Authorization (AIH - *Autorização para Internação Hospitalar*) of SUS were used in the public perspective. From the perspective of the health insurance companies, the mean values of hospital admissions for these procedures (n=17) in a private hospital in the city of Porto Alegre, state of Rio Grande do Sul, Brazil, in the year 2007, were used.

Regarding the annual costs of heart failure, the study by Araújo et al carried out in 2002, of 70 patients being followed due to this pathology in the city of Niteroi, state of Rio de Janeiro, Brazil, was used as the basis³⁶. This study computed all direct costs in the annual management of patients with this disease. As this study provides tables with details on all inputs used by the patients (days of hospitalization, exams, used medications, number of consultations), we recalculated some cost portions:

- For the public perspective, we extracted the costs of exams from the SUS table and for the health insurance companies, we used the costs included in the study, from the List of Medical Procedures in the year 1999.
- For the public perspective, we computed only the costs of medications that are available in the public healthcare system. For the health insurance companies, we did not use the cost of medications, as there is no reimbursement for them in most healthcare plans.
- We used the costs of hospitalizations by SUS in a public hospital and a private hospital in the city of Porto Alegre, state of Rio Grande do Sul, Brazil, in the year 2007. The values used were R\$ 1,596.00 for the public perspective and R\$ 6,593.00 for the health insurance companies.

After these calculations, we arrived at a mean annual cost per patient of R\$ 3,160.00 for the public perspective and R\$ 7,045.00 for that of the health insurance companies.

Finally, the following costs were also computed:

- In cases of death, an additional cost was computed, related to hospital admission due to heart failure.
- The annual cost of ICD maintenance was calculated as three extra consultations per year, at an estimated value of R\$ 22.50 for SUS and R\$ 129.00 for health insurance companies.

Sensitivity analyses

Univariate sensitivity analyses were carried out in all parameters of the model. The parameters of effectiveness and complications oscillated within the confidence intervals of their estimates. Costs ranged 50% higher and lower than their values in the base-case. The interval for generator replacement ranged between 3 and 7 years. The discount rate, for both cost and effectiveness, ranged from 0 to 7%. The basal values and their variations at the sensitivity analyses are shown in Table 1 (measures of clinical effectiveness, occurrence of complications) and in Table 2 (costs).

With the objective of simulating the model in a population with a more severe disease, such as that in the MADIT study - in which all patients presented ventricular fibrillation or sustained ventricular tachycardia non-suppressed by procainamide in a electrophysiological study - a survival curve similar to the one in that clinical trial was designed, using the ICD effectiveness attained in the same study.

Results

The analysis of the base-case found a mean survival projection of 6.99 years for the treatment with the ICD and 5.95 years for the conventional treatment. When adjusted for quality, these values were 6.15 and 5.23, respectively (Figure 2). The absolute cost difference between the treatments was higher in the health insurance company scenario (R\$ 83,894) than in public perspective (R\$ 62,723), generating a higher incremental cost-effectiveness ratio in the first case: R\$ 90,942 per QALY in the perspective of the health insurance companies versus R\$ 68,318 per QALY in public perspective (Table 3).

In the univariate sensitivity analysis, the parameters with the highest impact on results - in both perspectives - were the decrease in mortality with the ICD, the frequency of generator replacement and the cost of ICD implantation. The discount rate and the utility of a patient with CHF also presented significant influence; the other parameters had minimal impact on the results (Table 4).

Table 1 - Parameters of effectiveness of the base-case and variations used in the sensitivity analysis

Parameter*	Base-case	Sensitivity analysis variations	Source
Operative death	1.3	1.2-1.4	23
Frequency of generator replacement (years)	5	3-7	
Decrease in relative risk in relation to conventional treatment	26	17-33	11
Annual probability of systemic infection	0.6	0.5-0.8	23
Annual probability of lead replacement			30
1 st year	2.36	2.36-2.93	
2 nd year	1.62	1.62-2.01	
3 rd year	2.09	2.09-2.59	
4 th year	2.19	2.19-2.71	
5 th year	3.16	3.16-3.92	
6 th year	5.44	5.44-6.75	
From 7 th to 20 th year	6.72	6.72-8.33	
Lead displacement	3.48 [‡]	1.92-5.23	24-27
Mortality due to infection	21	0-50	24, 25, 28, 29
Implantation failure	1,1	0.9-1.3	23
Minor perioperative complications [†]	0	0-4	24
Discount rate (cost and effectiveness)	3	0 - 7	
Heart failure utility	0.88	0.71-0.88	13, 14, 16, 31, 35

*Expressed in % unless otherwise stated. [‡]This value is considered only after the first year of lead implantation, either on the first year post ICD-implantation or the 1st year after lead replacement. [†]Minor complications include pneumothorax, brachial thrombosis and deep venous thrombosis.

Table 2 - Parameters of costs of the base-case, in SUS and supplementary health costs, with their variations used in the sensitivity analysis. All monetary values are expressed in Brazilian Reals (R\$)

Parameters of costs	Base-case - public healthcare service	Variation in the sensitivity analysis	Base-case - health insurance companies	Variation at sensitivity analysis
ICD implantation	30,460	15,230 - 45,690	41,428	20,714-62,142
Generator replacement	29,408	14,704 - 44,112	39,997	19,998-59,995
Hospitalization for lead replacement	7,594	3,797 - 11,391	10,328	5,164-15,492
Hospitalization for lead repositioning	393	196 - 589	534	267-801
Hospitalization due to systemic infection (additional) [†]	1,500	0 - 3,000	2,040	1,020-3,060
Annual cost of ICD treatment	3,160	1,580 - 4,741	7,045	3,522-10,567
Annual cost of ICD follow-up	22	15 - 30	129	64-193

[†]Additional cost per infection, considering that the patient admitted due to such complication will have, at least, the cost of the implantation of a new ICD device. The monetary value expressed here is additional for the infection treatment.

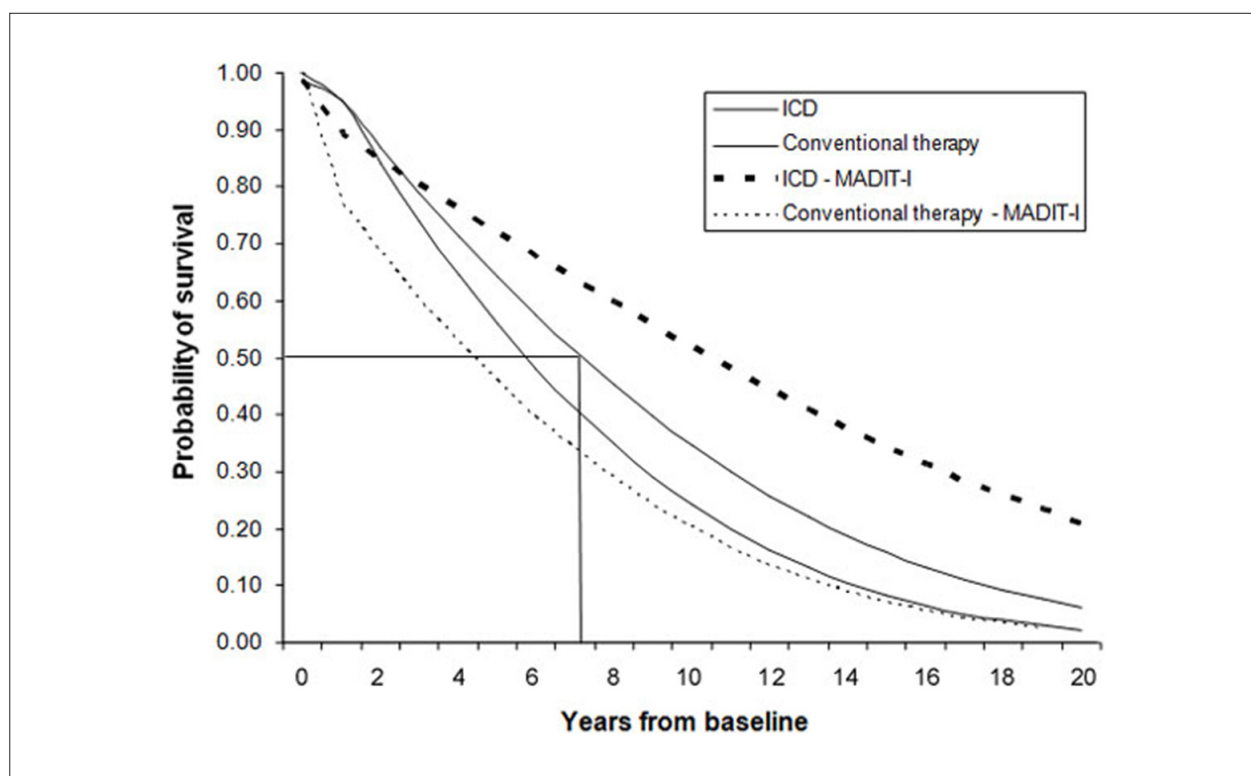


Figure 2 - Survival predicted by the model for the ICD strategies and conventional treatment in the base-case and in the model based on the population of the MADIT-I study.

Table 3 - Cost, effectiveness and incremental cost-effectiveness of the assessed strategies

	Total Cost:		Effectiveness		Incremental cost-effectiveness:		Incremental cost-effectiveness:	
	Public healthcare services	Health insurance companies	Mean LYS	Mean QALY	public healthcare service	R\$/QALY	health insurance companies	R\$/QALY
	R\$	R\$			R\$/LYS	R\$/QALY	R\$/LYS	R\$/QALY
Conventional treatment	33,408	101,330	5.95	5.23	-	-	-	-
ICD treatment	96,131	184,824	6.99	6.15	60,121	68,318	80,029	90,942

ICD - implantable cardioverter defibrillator; LYS - Life Years Saved; QALY - quality-adjusted life year.

In the bivariate sensitivity analysis, it was possible to observe that the more effective the ICD was in reducing mortality in patients with CHF and the less costly the device, the higher the cost-effectiveness of this strategy. For instance, in the public perspective, if the cost of ICD was 25% lower and the device granted a decrease in mortality > 30%, the ICD use could be an attractive strategy from this point of view (Figure 3A). It is interesting to observe that, when comparing with the data from the health insurance companies, the interrelation between the variables is similar, although the absolute values are higher (Figure 3B). In both scenarios, the longer the time period between generator replacement, the lower the additional cost-effectiveness ratio (Figure 4).

At the analysis of the scenario projected to depict the reality of the MADIT-I study, in which the patients were more severe and presented higher arrhythmic mortality (and consequently, higher benefit of the ICD), the incremental

cost-effectiveness ratio was R\$ 23,739 per QALY in SUS and R\$ 33,592 per QALY in health insurance companies. At the analysis per life-years saved, these values were R\$ 20,890 and R\$ 29,561, respectively.

Discussion

Heart failure is a very prevalent condition in Brazil and it presents high morbidity and mortality. Among recent therapies aiming at decreasing the disease-associated death rate, the implantable cardioverter defibrillator (ICD) is a remarkably important strategy, with a mean decrease in general mortality of around 25%. The costs, however, constitute an impediment to its large-scale use, especially at the Brazilian Public Health System (SUS).

The present study performed a formal economic analysis of the ICD use, when compared to the conventional therapy,

Table 4 - Univariate sensitivity analysis of all parameters included in the model

Variables	Public healthcare service (R\$/QALY)		Health insurance companies (R\$/QALY)	
	Lower limit	Upper limit	Lower limit	Upper limit
Mortality decrease with ICD	51,973	113,551	68,793	152,239
Probability of systemic infection	67,512	69,968	89,848	93,181
Probability of death due to infection	65,468	72,694	87,080	96,872
Probability of operative death	67,915	68,726	90,466	91,424
Probability of implantation failure	68,238	68,398	90,835	91,049
Probability of minor complications	68,307	68,329	90,928	90,956
Probability of lead displacement	68,308	68,327	90,929	90,955
Probability of lead replacement	68,318	69,004	90,942	91,878
Utility of a patient with CHF	68,318	84,675	90,942	112,717
Discount rate	56,985	86,428	75,461	115,671
Frequency of generator replacement	56,447	97,819	74,839	131,068
Cost of ICD implantation and generator replacement [†]	36,409	100,223	47,545	134,339
Annual cost of ICD treatment	66,521	70,113	86,939	94,945
Cost of lead replacement	66,886	69,749	88,995	92,889
Cost of systemic infection	68,236	68,399	90,832	91,052
Cost of ICD maintenance	68,261	68,375	90,456	91,428
Cost of lead repositioning	68,308	68,327	90,928	90,956
Cost of minor complications	68,312	68,323	90,935	90,949

ICD - implantable cardioverter defibrillator; CHF - congestive heart failure.

under two different perspectives: the Brazilian public health system and health insurance companies. The incremental cost-effectiveness ratios were R\$ 68,318 and R\$ 90,942 per QALY in the two scenarios, respectively. Although some countries - such as the United States and England - have already adopted limits to establish cost-effectiveness ratios considered either attractive or unfavorable, there is no consensus about this value in Brazil.

Whereas studies performed in the USA mention a limit of US\$ 50,000 per QALY, in Canada, between Can\$ 20,000 and Can\$ 40,000, and in England, £ 30,000, these values are not applicable to our reality. According to the World Health Organization (WHO), for countries with a level of economic development such as the one in Brazil, values of up to three times the *per capita* gross domestic product, approximately R\$ 40,545 in 2007, would be considered attractive. The cost-effectiveness ratios for the ICD found in these studies are above this value. However, it is important to remember that these limits (suggested by the WHO as well as those adopted by some developed countries) have been developed for the societal perspective or, possibly, for the public perspective, with the comparison of values under the perspective of a third-party payer, such as health insurance companies, being a more delicate issue. In our second scenario, which evaluated a hypothetical cohort of more severe patients and that presented higher arrhythmic mortality, the values were significantly more favorable, being below the limit suggested by the WHO in both perspectives.

The cost-effectiveness studies in Brazil are scarce and most of them focus only on one perspective, normally the public one. This is the second study by our group that performed a cost-effectiveness analysis of a technology from the perspective of SUS and health insurance companies. In our previous study, an economic assessment that compared the rapamycin-coated stent with the conventional stent, the ICER was more attractive in the private healthcare scenario, differently from the present study, which showed more favorable values in the public health system. The reason for this phenomenon is that the ICD, differently from the coated stent, does not decrease costs of disease management (re-stenosis, in that case), when compared to the conventional treatment. In the developed CHF model, the technology being studied has a global effect on mortality, but no reduction in disease morbidity is expected; on the contrary, the device-related complications potentially add hospitalization and secondary costs. Considering that the parameter with the highest impact on the univariate sensitivity analysis was the ICD cost and that the device costs approximately 35% more for health insurance companies than for SUS, it is possible to observe that this isolated parameter accounts for almost all the difference between the ICER of the two perspectives.

Some articles published in the international literature that evaluated the cost-effectiveness of the ICD are noteworthy. In the study by Sanders et al¹⁶, carried out with data from the North-American population, the assessment was performed

Figure 3A

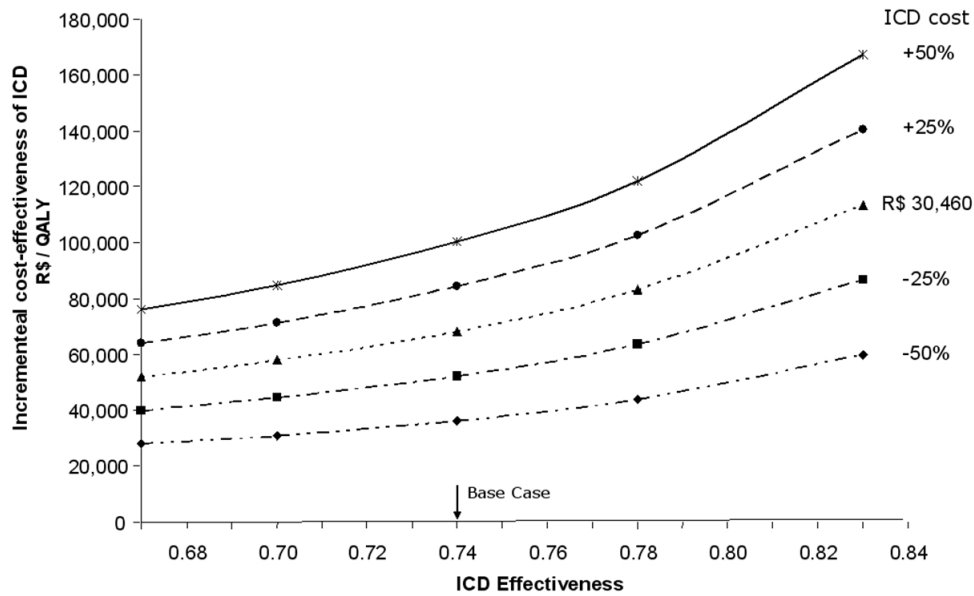


Figure 3B

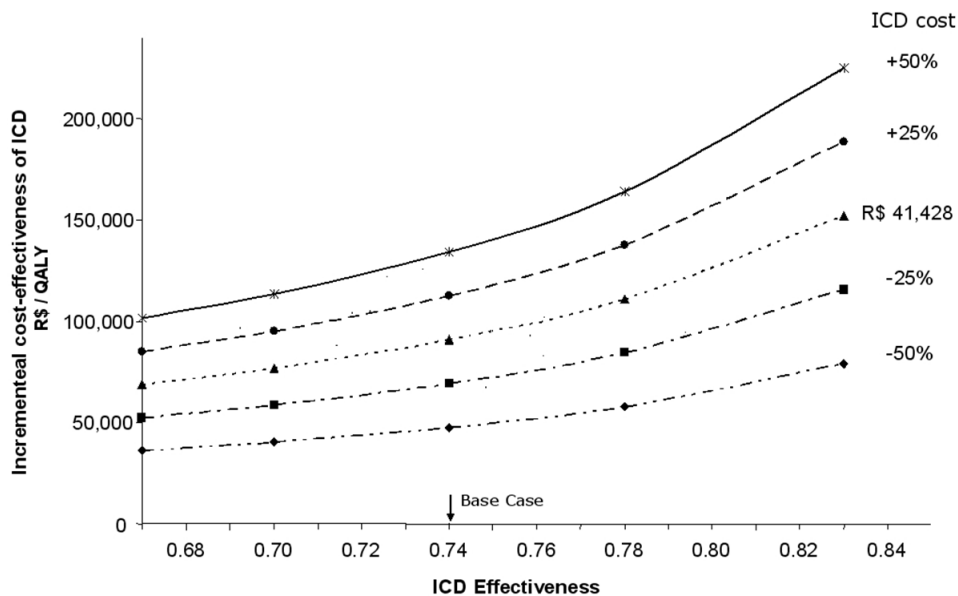


Figure 3 - Bivariate sensitivity analysis, simultaneously assessing the impact of different costs of the ICD (lines) and the variation of effectiveness (abscissae) on the incremental cost-effectiveness ratio (ordinate), from the perspective of the Brazilian Public Health System - SUS - (3A) and health insurance companies (3B).

individually for each one of the published clinical trials. The ratios ranged between US\$ 34,000 and US\$ 70,200, and the MADIT-I scenario (US\$ 34,900) was below the cutoff more often accepted in the USA, that is, US\$ 50,000, whereas the

MADIT-II (US\$ 54,100) and the SCD-HeFT (US\$ 70,200) were a little higher than this limit. These differences represent the varied populations assessed in the studies, which was also explored in the present study, in which the base-case had

Figure 4A

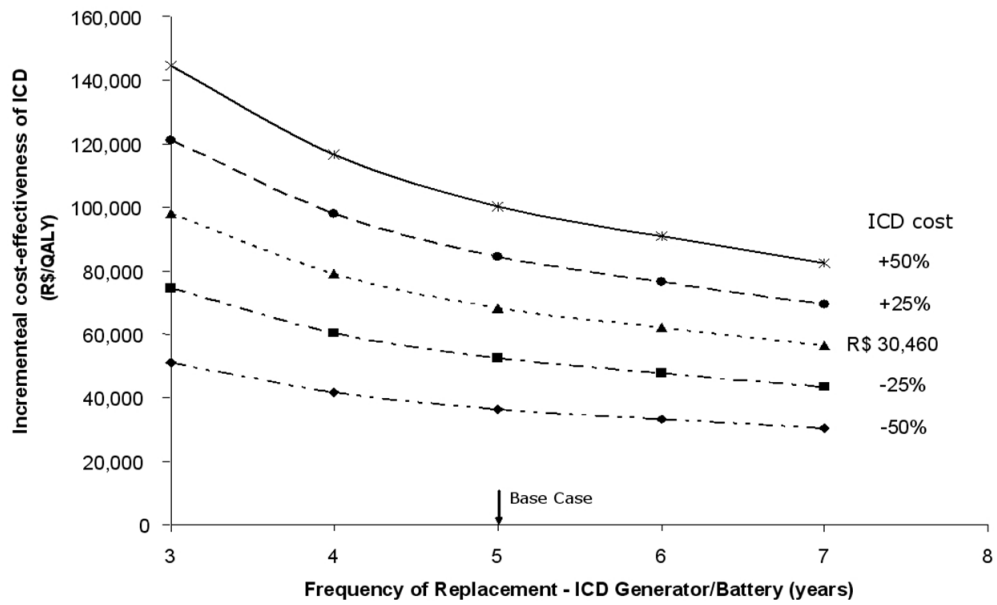


Figure 4B

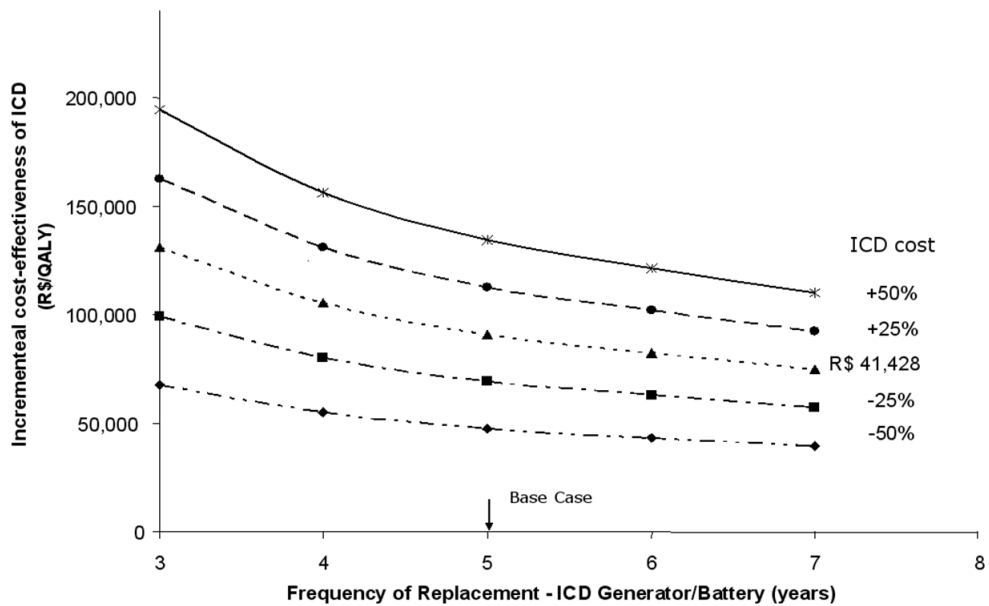


Figure 4 - Bivariate sensitivity analysis, assessing simultaneously the impact of different ICD costs (lines) and the frequency of generator replacement (abscissae) on the incremental cost-effectiveness ratio (ordinate), from the perspective of the Brazilian Public Health System - SUS - (4A) and health insurance companies (4B).

a hypothetical population similar to the two last studies and the alternative model, to the MADIT-I study. Our results are in agreement with this study, if one considers the cutoff suggested by the WHO as the reference.

In Europe, the English studies published to date have not clearly individualized primary and secondary prevention^{34,37} and have not incorporated recent data, such as the SCD-HeFT⁹, using only five of the ten studies on primary prevention

concluded to date. The most interesting European study available to date was carried out in Belgium, of which model used clinical and effectiveness parameters from the SCD-HeFT³⁸. The gain in QALY, of 1.03, was quite similar to that found in our study (0.92), with an ICER of around € 70,000, which probably reflects, as expected, higher direct medical costs in that country, when compared to Brazil. It is noteworthy that the sensitivity analysis of the present study showed a decrease in the cost-effectiveness ratio of 20% when the generator replacement interval increased from 5 to 7 years, a figure similar to that found in our study. This fact suggests that, although the costs are higher in that country, their proportionality does not differ from the one observed in the Brazilian scenario.

Some limitations of the present study must be mentioned. Firstly, the benefit of the ICD was considered to be constant throughout time, in agreement with other cost-effectiveness studies in the area, although the clinical trials did not follow the patients for more than 5 years, in their majority. If the benefit decreased throughout time, which is reasonable if we imagine an increase in other causes of death that are non-preventable by the ICD, the cost-effectiveness ratios would be even higher. Secondly, the utility data of patients with CHF that were used in the present study were obtained from the international literature, due to the lack of Brazilian data. Additionally, not even the international literature showed a definitive conclusion on the impact of the ICD on the quality of life, with opinions on the worsening due to inappropriate shocks, as well as improvement in the quality of life, as the patient can feel safer due to the protection provided by the device.

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Conclusion

The data of the present study show that, from the public as well as the private perspective in Brazil, the cost of the implantable cardioverter defibrillator in the primary prevention of death is high in proportion to its benefit. Strategies to improve this ratio must be pursued, especially the decrease in the cost of the ICD and the increase of its effectiveness.

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Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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