Non-Invasive Imaging Procedures in Cardiology: Are They Really Cost-Intensive?

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Keywords

• Cost-efficiency • magnetic resonance imaging
• coronary heart disease • myocardial infarction
• patient management

Introduction

Cost pressures on national healthcare systems are rapidly increasing in many parts of the world. In response, the trend has been to search for ways to utilize the limited available resources as efficiently as possible. The demand for scientific proof of this efficiency, e. g. in the form of outcome analyses, is gaining in importance as a result. These analyses possess special health-economic importance in the evaluation of pervasive, cost-intensive diseases such as coronary heart disease and myocardial infarction.

In the USA alone, cardiovascular diseases result in annual costs of over 100 billion dollars [1], a significant deal of which can be attributed to the relatively large number of invasive procedures such as coronary angiography, PTCA, and bypass surgery. New developments in the area of cardiac MRI, as well as other imaging procedures, are making it increasingly possible to obtain more diagnostic information about the heart and coronary arteries, even without invasive diagnosis [2, 3]. In many cases, this enables treatment that is easier on the patient, since an accurate diagnosis can be reached prior to invasive steps. For some patients, invasive procedures can be avoided entirely; the non-invasive examination serves as a kind of filter process. Since these examinations result in additional costs at the outset, however, the future spread of these methods depends on an assessment of the entire diagnostic and treatment process to see if cost reductions can be obtained by including such filter examinations.

In the following sections, we will investigate this potential for reducing costs while simultaneously minimizing patient stress and optimizing the quality of patient management based on two examples. We will first discuss the possibilities of utilizing cardiac MRI and Nuclear Medicine in the diagnosis of coronary heart disease for patients that cannot be effectively examined with echocardiography. After having presented a diagnostic scheme enhanced by a non-invasive diagnostic step, we will illustrate the resulting medical and financial consequences. Next, we will examine the applicability of viability studies for myocardial infarction patients prior to revascularization (PTCA or bypass). For this step as well, we will consider the medical aspects and the financial impact. In conclusion we will discuss the results.

The Diagnosis of Coronary Heart Disease

Coronary heart disease is the no. 1 cause of death in the Western world, accounting for nearly 20% of all deaths [1, 4]. In 1998, more than 12 million people suffered from coronary heart disease in the USA; nearly half a million people died as a result [1]. The number of diagnostic cardiac catheterizations alone amounted to almost 2 million [1], but only approx. 40% of these examinations were followed by PTCA or an operative revascularization. This means that 60% of the patients had to assume the risk of the invasive procedure without directly benefiting from the cardiac catheterization. These numbers clearly demonstrate the importance of efficiently managing patients with coronary heart disease. Fig. 1 provides a simplified outline of a widespread diagnosis process used in Germany and around the world for patients suspected of having coronary heart disease[1]. After anamnesis the diagnostic process begins with an (exercise) ECG. This examination usually does not provide clear diagnostic results. In connection with case history and other patient data such as cardiovascular risk factors, however, it enables an estimation of the probability of significant coronary heart disease p, which is important for our further calculations. In the continuing course of this diagnostic process, a stress echocardiography (and/or Nuclear Medicine examination) is frequently added for unclear cases. This scheme high-

[1] In the USA and Great Britain, the direct use of nuclear medicine is customary as well.

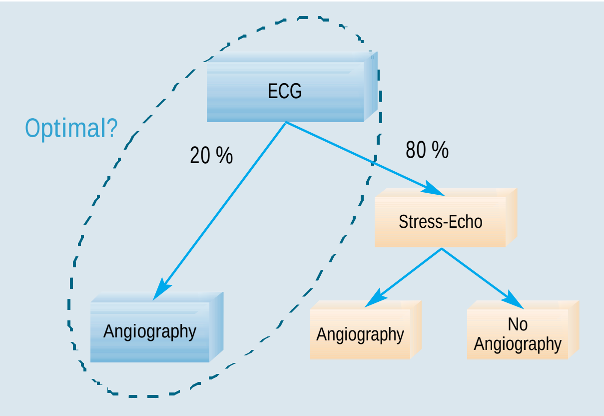


Fig. 1
Simplified illustration of a widely used diagnostic scheme for CHD. If a clear diagnosis cannot be obtained following ECG and/or stress ECG (usually on account of low sensitivity (68%) and specificity (77%) [5]), then a stress echo is performed on 80% of these patients.

Having a higher sensitivity (88%) and specificity (81%) [6], this stress echo provides a more accurate diagnosis which can be used to determine whether coronary angiography is necessary.

However, for 20% of the patients, the stress echo does not provide diagnostically useful information. In such cases, the next step is normally to proceed directly to a coronary angiography.

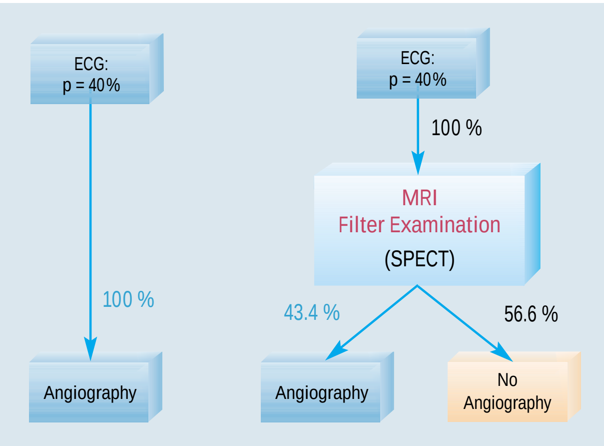


Fig. 2
A comparison of the diagnosis scheme without and with a filter examination for patients who cannot be effectively examined via ultrasound.

Whereas all of these patients normally undergo coronary angiography (as shown on the left), the cardiac MRI or SPECT filter exam can help a portion of these patients to avoid the invasive procedure.

In the example selected (with a probability of disease of $p = 40\%$), only 43.4% of patients without diagnostically useful stress echo examination receive angiography.

lights the serious diagnostic problems of 20% of the patients. For them, a stress echo does not deliver diagnostically useful information, e.g. due to too much fatty tissue in the chest area, lung emphysema or thorax deformities.

Currently, in the case of patients with difficult to interprete stress echo results, the next diagnostic step is often coronary angiography, an invasive procedure involving risks of complications as well as radiation exposure and the side effects of X-ray contrast media[2]. As a result, many patients, who do not have significant CHD, undergo angiography. The current question is whether the diagnostic process can be optimized for patients who cannot be effectively diagnosed via stress echo examinations. In Fig. 2 the diagnostic process was complemented by a filter examination. With the filter exam, a portion of patients was spared from having to undergo the invasive coronary angiography procedure. The exact percentage of these patients depends on two factors: first, the probability p of the presence of significant CHD, and second, the diagnostic quality of the filter exam.

The quality of the filter exam used is determined by its sensitivity and specificity. For cardiac MRI [7], the sensitivity and specificity are both 83%; cine images were used here for functional diagnostics[3] (stress MRI) (Fig. 3). SPECT has a sensitivity of 89% and a specificity of 76% [11].

Based on this data, e.g., the percentage of patients with a probability of disease of $p = 40\%$ who undergo angiography despite an absence of significant CHD could be reduced from 35.2% (without a filter exam) to 18.5% (with cardiac MRI) – this corresponds to approx. one half the amount. Conversely, the amount of patients with significant CHD who erroneously did not undergo angiography only increased to 13% with cardiac MRI as opposed to 9.5% without filter examination.

Consequently, for many patients non-invasive filter examinations enable the diagnosis of coronary heart disease with less associated risks and stress. However, it is also evident that these additional examinations represent extra costs as well. In the following section, we will examine how the modified diagnostic scheme financially affects healthcare systems in the USA and Germany.

[2] Additionally or alternatively, nuclear medical diagnostics may be performed.

[3] As an alternative to functional diagnostics, MRI perfusion diagnostics [8-10] could also be used. In this case, the sensitivity and specificity are approx. 85% and 80% respectively.

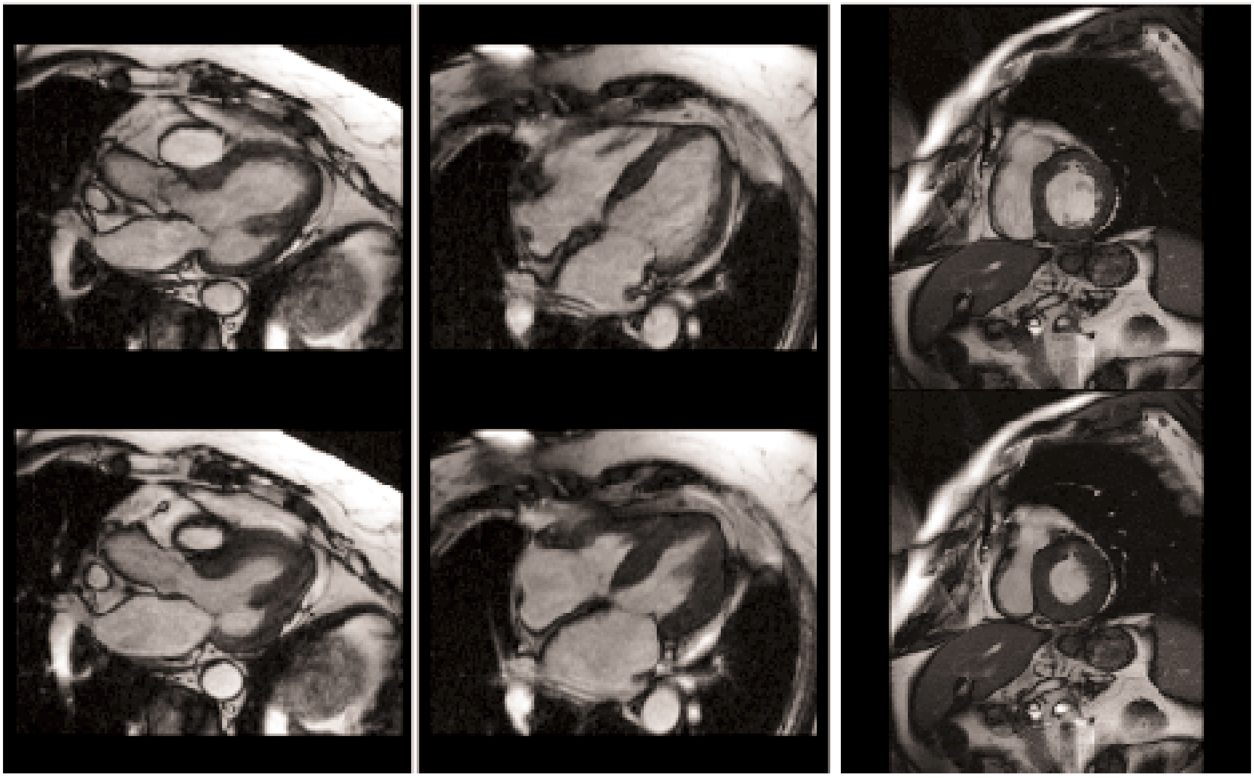


Fig. 3
Exemplary cine images for the diagnosis of CHD. Two images from TrueFISP cine sequences (MAGNETOM Sonata 1.5T, Robert Bosch Hospital, Stuttgart) taken during the diastole (above) and the systole (below). Displayed from left to right: a 3-chamber view, a 4-chamber view, and a short-axis image.

Costs Associated with Diagnosing Coronary Heart Disease

The structure of health insurance carriers is very heterogeneous in the USA. Federal programs such as Medicare and Medicaid exist together with organizations such as Managed Care and private insurance companies. Furthermore, reimbursement rates differ regionally and depending on whether treatment is performed in a private practice or a hospital. Medicare has taken a leading role in establishing reimbursement rates. For this reason, we borrowed Medicare's reimbursement rates as the basis of the following calculations. For the US, we decided to concentrate on a typical example: healthcare treatment provided within a private practice in Ohio in 2001.

In Germany, approximately 90% of the population is insured by Statutory Health Insurance funds and substitute statutory health insurance funds. For this reason, our following observations are based on the reimbursement rates of the Statutory Health Insurance funds established in the EBM (Uniform Evaluation Standard = doctor's fee scale) for private practitioners. As a basis for calculating reimbursement rates, we applied the average point values from the Association of SHI-Accredited Physicians in the State of Hessia for the year 2000.

The resulting total costs in both healthcare systems are listed in Table 1 based on a probability of disease of $p = 40\%$. In addition to the direct examination costs (not including costs for ECG), the total costs also take account

Diagnostic costs / Diagnostic process	USA: Medicare patient in a physician's practice in US $	Germany: Legally insured patient in a physician's practice in €
Without filter examination	1828	773
With SPECT	1717	711
With MRI	1621	672
Maximum savings	**207**	**101**

Table 1
Total costs of diagnosis of CHD for a patient with a 40% probability of disease.

of additional costs resulting from serious catheter-related complications such as e. g. local complications, reactions to contrast media, degraded kidney function, or death during coronary angiographies. In the USA [5], these costs amount to approx. US $ 40,000 per complication as compared to approx. € 20,000 in Germany[4]. Since serious complications occur in about 2 % of all coronary angiographies, additional costs amount to approx. US $ 800 or € 400 for each coronary angiography performed. The cost benefits of implementing imaging filter examinations, cardiac MRI in particular, are clear. Despite the costs associated with an additional filter examination, savings of around US $ 200 or € 100 per patient can be achieved.

As discussed in the previous section, the number of invasive procedures (and as a result, the total cost per patient) depends on the probability of disease factor *p*. For this reason, we have plotted the total costs per patient and the associated savings potential versus this probability factor *p*. In all cases, cardiac MRI represents the most cost-effective filter method as compared to SPECT. The greatest savings potential can be achieved with low and medium probability of disease factors, since such cases offer the greatest possibility of reducing invasive procedures. On the other hand, in cases with high probability of disease, cardiac MRI offers little or no cost savings, since nearly all patients require coronary angiography investigation.

Thus, in the area of CHD, cardiac MRI enables the symbiosis of improved quality in patient management together with simultaneous financial savings.

Viability Studies Following an Acute Myocardial Infarction

According to estimates from the American Heart Association [1], each year more than one million people suffer from a heart attack in the USA. Following primary survival from a heart attack, revascularization procedures such as PTCA or a bypass surgery are performed if the patient's condition allows (Fig. 5). However, with such an approach, the viability of the myocardial area to be revascularized is still unclarified at this point. As a result, in extreme cases, functional recovery of the myocardium affected by the heart attack cannot be achieved, and the patient's condition and prognosis are not improved. In such cases, the already weak patient is forced to undergo an ineffective invasive procedure.

In order to prevent this, an increasing amount of research has recently investigated methods of determining the viability of myocardial tissue. Such viability studies, performed via PET, SPECT, stress echo or cardiac MRI methods such as Late Enhancement (Fig. 6)

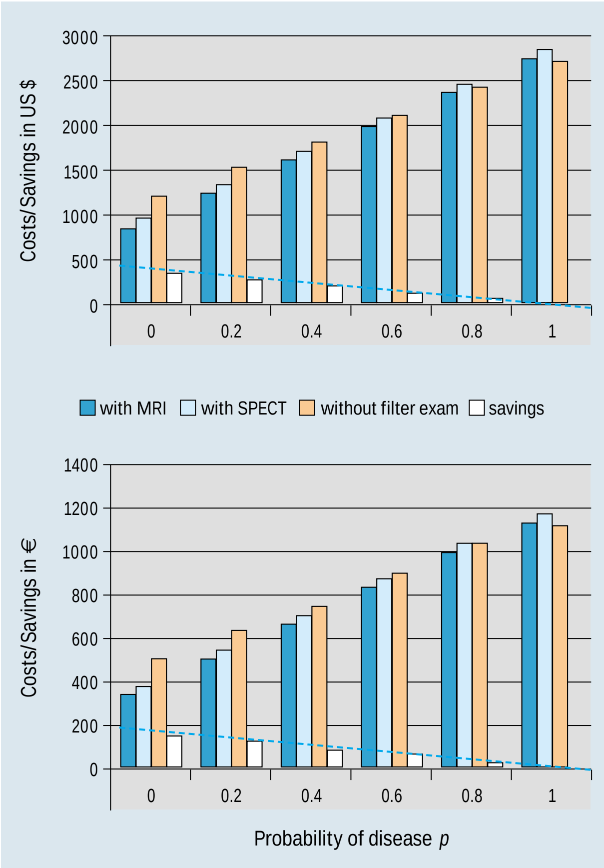


Fig. 4
Diagnostic costs and savings potential in CHD diagnostics. The average diagnostic costs and the maximum savings are listed for different diagnostic schemes, according to the probability *p* of a significant CHD.

The upper diagram shows the respective data for the case of an examination in an American physician's practice. The lower diagram shows the circumstances of patients insured by a statutory healthcare fund receiving treatment in a German practice.

The dashed lines depict the dependence of the savings potential on *p*.

[4] Unfortunately, we did not have access to data regarding complication costs in Germany. Our cost estimation is based on the assumption that treatment costs of US $ 1 correspond to roughly € 0.5 in Germany.

[12] and First-Pass Perfusion [13], permit the effectiveness of revascularization to be estimated prior to the procedure. The results of the Late Enhancement Method are particularly interesting. Not only can a binary decision be obtained with respect to viability, but rather the transmural extent of the irreversible damaged tissue can be determined as well [12], which correlates with the probability of functional recovery of the myocardium. The characteristic data of the individual viability studies are summarized in Table 2.

When viability studies are included for patients with myocardial tissue of uncertain viability, who could be revascularized in principle, the treatment process shown in Fig. 7 is obtained. As with the diagnosis of CHD, this non-invasive imaging procedure serves as a filter exam to avoid ineffective invasive procedures.

Thanks to the filter examination, a considerable number of patients, for whom revascularization would not result in improved heart function, are spared from having to undergo further invasive procedures. From a medical perspective, such viability studies are therefore desirable because they provide additional information and, more importantly, because they can have a decisive effect on the continuing optimal treatment of the patient.

Cost Reduction Through Viability Studies

In effect, to what extent do these viability studies affect costs for the healthcare system? Initially, additional costs have to be ascribed to viability studies. However, savings are achieved through a reduction in the number of revascularization procedures performed. Taking the 5-year costs for heart attack patients from the year 1995 (provided in the BARI study [14]) and adjusting this figure for the year 2001 (based on an annual inflation rate of 2%) results in total 5-year patient costs of US $ 63,315 for PTCA and US $ 66,319 for bypass surgeries. In calculating the cost of viability studies, we applied the Medicare reimbursement rates for non-facility settings in Ohio in the year 2001. For PET, we already used the lower reimbursement rate of US $ 1,400 valid from April 2002.

Furthermore, we still need to determine the costs of diagnostic coronary angiography as well as drug therapy. We assume US $ 4,000 as reimbursement for the diagnostic catheter examination and US $ 15,000 for the proper 5-year drug therapy including additional physician visits.

These estimates are also based on data from the BARI study. Viability studies, which provide a false-negative result for the presence of sufficient viable tissue, unnecessarily restrict patients' quality of life and prognosis as a result. This may be manifested as a diminished ability to work or an increased susceptibility to other diseases. Therefore, we estimate the average 5-year costs for these erroneously non-revascularized patients at US $ 100,000.

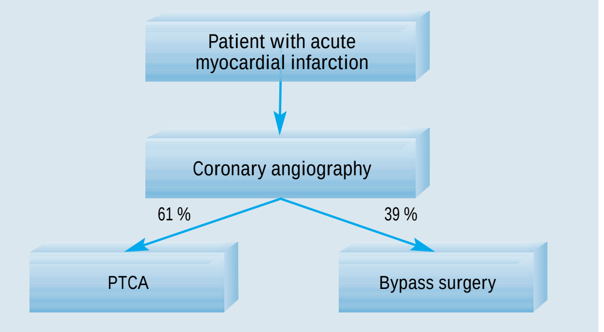


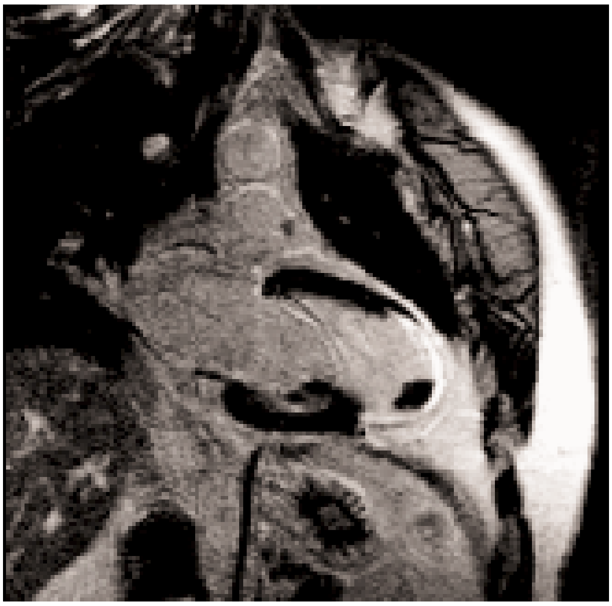
Fig. 5
Simplified treatment process for heart attack patients without viability studies. If a patient is brought in with symptoms indicating acute myocardial infarction, and revascularization is a feasible option, a coronary angiography is performed first in addition to other tests.

Based on the results of this examination, either a PTCA or a bypass operation is performed.

The percentage distribution of revascularization measures is 61% for PTCA and 39% for bypass surgery [1].

	Sensitivity	Specificity	Remarks
MRI (I)	97%	96%	Combined First Pass Perfusion + Cine Diagnostics [13]
MRI (II)	90%	81%	Calculated from Late Enhancement Data in [12]
SPECT	91%	88%	Study with Tc-99m sestamibi-NTG from [6]
PET (I)	88%	73%	Study with F-18 FDG [6]
PET (II)	81%	86%	Control check of MRI (I) [13]
Stress Echo	84%	81%	Pharmacological Stress Echo [6]

Table 2
Characteristic data of the viability studies reviewed.



These parameters show the following picture (Fig. 8) of the financial aspects of this treatment scenario: without viability studies, the average 5-year costs for each revascularized patient amount to US $ 64,488. Since the viability of the myocardium is not tested, these costs are dependent on the probability *p* of sufficient viable tissue.

With viability studies, on the other hand, the average costs increase in proportion to the probability of sufficient viable tissue, since the higher the probability *p*, the more revascularizations are performed. Especially with low and medium probability factors, the costs are significantly less with viability studies as opposed to direct revascularization. Among all viability studies, the combined Cine- and First-Pass perfusion analysis [13] provides the best results. Late Enhancement viability studies [12] are easier and quicker to perform than these examinations; however, their total costs are somewhat higher and comparable to SPECT. Stress echo and PET viability studies result in the highest average costs

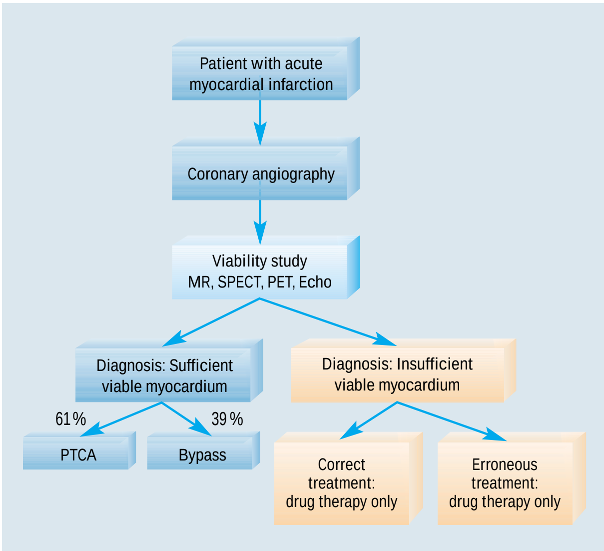


Fig. 6
Apicoseptal infarction with apical aneurysm and thrombus.
The scar formation in the region of the septum and the apex of the heart (TruFISP, MAGNETOM Sonata 1.5T, Cleveland Clinic Foundation, Ohio, USA) is clearly visible.

The 2-chamber view (above) and the short-axis image (below) provide a signal-intensive display of these scarred regions using the Late Enhancement technique.

Fig. 7
Course of treatment for heart attack patients, incorporating viability studies. When viability studies (using MR, SPECT, stress echo or PET) are integrated in the course of treatment shown in Fig. 5, patients without sufficient viable tissue in myocardial areas affected by an infarction do not undergo revascularization treatment.

A large proportion of patients are justifiably spared revascularization procedures if the selected viability study has sufficiently high sensitivity and specificity values.

However, a small amount of patients will improperly receive no revascularization treatment due to a false-negative viability diagnosis.

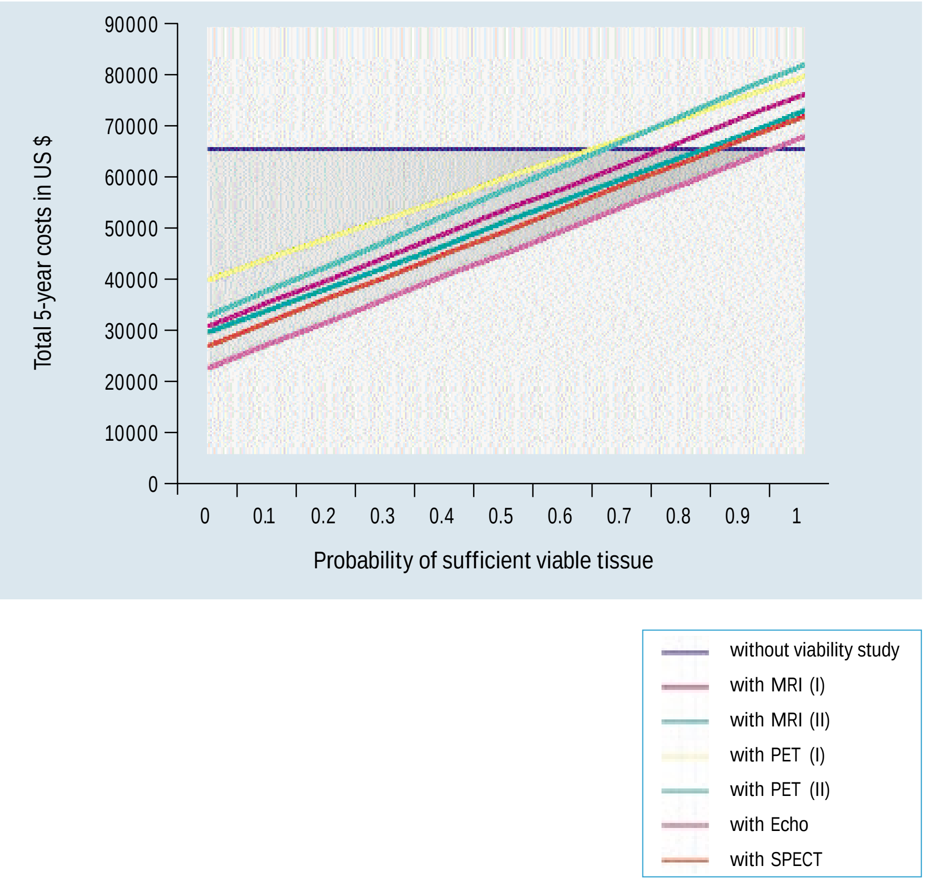


Fig. 8
Five-year total costs for the treatment of heart attack patients. The total costs of treatment for a patient within five years following a heart attack are listed here above the probability of sufficient viable myocardial tissue.

Without a viability study, the average costs per patient are independent of the viability of the myocardium, approx. US $ 64,500.

With viability studies, however, costs increase linearly with the probability of viable tissue, since the higher the probability, the more revascularizations are performed.

MRI and SPECT viability studies prove to be the most cost-effective procedures for patients with low and medium probabilities of sufficient viable tissue.

among all viability studies. With stress echo, this is primarily due to the relatively low sensitivity and specificity values; with PET, the high reimbursement rates add to the considerable average costs.

Discussion

By focusing on two very prevalent clinical pictures, namely chronic CHD and acute myocardial infarction, we have demonstrated how cardiac MRI and other imaging modalities can be used to simultaneously provide patient-friendlier and qualitatively improved treatment in addition to cost reductions. These non-invasive examinations are integrated into the respective diagnostic and treatment process prior to invasive procedures: cardiac MRI proved to be especially efficient in this respect. The number of coronary angiographies, PTCA's, and bypass operations can be reduced as a result. Consequently, patients and cardiologists are exposed to less radiation, less X-ray contrast media is required, and patients experience fewer complications overall. Moreover, the number and length of hospital stays is reduced, leading to even more cost reductions which were not treated in this study. The ideal objective of providing increased quality medical care through new methods coupled with cost reductions for the healthcare system can become a reality, if cardiac MRI is consistently utilized within the scope of the diagnostic paths described here.

Why, then, isn't cardiac MRI used comprehensively despite all these benefits? One reason is the current lack of medical personnel with proper cardiac MRI training and experience. This can be attributed to the fact that cardiac MRI has developed rapidly in a relatively short time. In addition, the problems in invoicing cardiac MRI examinations are a serious drawback. Cardiologists are usually not able to receive reimbursement for MRI examinations from the health insurance companies. And for the radiologists and cardiologists who could be reimbursed, the complexity and time involved with cardiac MRI exams do not make these especially attractive considering the current reimbursement rates.

In the long run, fascinating possibilities will become available in the management of cardiovascular diseases, as soon as these problems associated with cardiac MRI are solved. As a kind of "one-stop shopping", cardiac MRI could enable the acquisition of all relevant data in one examination. Moreover, because of the absence of ionizing radiation and invasivity, cardiac MRI meets all the requirements necessary for preventive screening programs in the cardiology sector.

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Abbreviations

Cardiac-MRI	= Cardiovascular Magnetic Resonance Imaging
CHD	= Coronary Heart Disease
EBM	= Uniform Evaluation Standard (physician's fee scale)
PET	= Positron Emission Tomography
PTCA	= Percutaneous Transluminal Coronary Angioplasty
SPECT	= Single Photon Emission Computed Tomography