In business and legal transactions, a warranty is an assurance by one party to the other party that certain facts or conditions are true or will happen; the other party is permitted to rely on that assurance and seek some type of remedy if it is not true or followed.


Warranty Period: What Do We Expect From SPECT?
As single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) has reached scientific and clinical maturity, we have grown to expect that the results of this test when negative, reliably predicts an excellent patient outcome. Typically, less than 1% of patients with a normal study will have a “hard” cardiac event, defined as myocardial infarction or cardiac death, but that 1% can be shortened or lengthened based on the presence of coronary artery disease (CAD), cardiac symptoms, age, sex, the need for pharmacological stress, and coronary risk factors such as diabetes mellitus. The time variability was assessed by Hachamovitch et al,1 and termed the “warranty period” for a normal SPECT MPI, defined the time to 1% risk of a cardiac event per year.

Imaging Too Soon and Too Late?
The study published in this issue of Circulation: Cardiovascular Imaging by Carryer et al2 sought to explore the timing of follow-up SPECT study after a normal initial study and its prediction of cardiac events during a 5-year follow-up. They identified 3010 patients with a normal SPECT study in the year 2002 and examined 708 patients who had follow-up studies at a median of 2 years. They were stratified by the presence or absence of known CAD at the time of the first test and then by the clinical indications for follow-up scan: “routine versus nonroutine,” indicating “surveillance” imaging despite clinical stability versus symptom- or event-driven imaging. The frequency of follow-up testing leading to coronary angiography or revascularization or predicting death was noted. The interval between images was then compared with the published “warranty period” tables.1

The authors found that 13% of patients without any prior CAD had “routine” follow-up scans compared with 26% of those with known CAD. Only 6% of patients with any prior CAD had “nonroutine” follow-up scans compared with 13% of those with known CAD. However, there was a low frequency of coronary angiography and an extremely low rate of subsequent revascularization being driven by abnormalities in the follow-up SPECT imaging after a normal study 2 years early.

When compared with the data of Hachamovitch et al,1 Carryer et al found that patients without CAD were generally imaged a second time too short (45%) of the calculated warranty period, whereas those with CAD were imaged on average beyond their warranty period (164%). Of all the routine follow-up scans, a high-risk summed stress score was observed in only 2% and 3% of patients without and with a history of CAD, respectively.

The authors identify the number of patients in each category needed to test to find 1 case that was subsequently referred for coronary angiography or revascularization. However, a more clinically relevant measure would have been the number needed to treat to warrant a change in management, such as intensification of medical therapy.

How Relevant Is the SPECT Warranty Period?
The authors quote some older data on the economic burden of the growing use of cardiac imaging, which was admittedly a concern before 2006. However, use of SPECT MPI has declined over the past 4 years, probably because of the cumulative effects of the Deficit Reduction Act of 2005, the publication of the 2005 SPECT MPI appropriate use criteria,3 the technetium-99m shortage, the rise of CT angiography and other perfusion imaging techniques, and the incursion of radiology benefit managers.

The idea that undertaking the time, expense, and resource utilization to repeat studies in patients with prior normal SPECT studies should be driven by an estimate of increased risk, such as a “warranty period” is a sound one provided that data can be found that apply to a given clinical risk pattern and the patient has no intercurrent symptoms. However, as confirmed by this study, the development of symptoms (“nonroutine”) or the presence of CAD at baseline increase

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the likelihood of conversion of a normal SPECT to abnormal over a 2-year period.

**Is Using the “Warranty Period” Ever Warranted?**

An inherent weakness of this approach is that the data from which the “warranty period” was derived was actually from 1991 to 1997,¹ a time during which HMG-CoA-reductase inhibitors (“statins”) had far less clinical penetration than they do today in the treatment of patients with CAD. SPECT MPI is now expected to improve over time in the era of statins⁴ and therapeutic lifestyle changes, including dietary intervention and daily exercise, as shown in the COURAGE trial.⁵ Also, newly symptomatic patients should be evaluated in short order because the majority of acute coronary syndromes occur by plaque rupture on a previously insignificant coronary lesion that was unlikely to cause myocardial ischemia on a previous SPECT.⁶

Thus, it would seem both prudent and logical to confine the use of the “warranty period” to those patients who (1) have no known CAD, (2) were not treated with statins, (3) were unsuccessful at risk-lowering lifestyle changes, and (4) have no new symptoms.

Last, it is a significant limitation that the “warranty period” describes the time to a certain risk of an untoward outcome, that is, 1% risk of cardiac death or myocardial infarction. This is not the end point that either clinicians or patients would want. The use of the “warranty period” implies that an annualized risk of sustaining a hard cardiac event of 1% is somehow an acceptable level. However, in the busy nuclear imaging laboratory, for example, that is performing 5000 normal studies annually, this would mean about 50 bad outcomes, with the attendant human loss and medical-legal implications. What is needed, therefore, is a measure of the time to develop an abnormal SPECT study that would allow an intervention to prevent myocardial infarction or death. Unfortunately, no large-scale data describing serial deterioration of myocardial perfusion is available or would be forthcoming, as this would require repetitive imaging in an era of high scrutiny of imaging volume and appropriateness.

In summary, Carryer et al has demonstrated that in a single large academic facility, the timing of follow-up SPECT imaging after an initial scan varied from their expectation, based on published literature. However, the use of the “warranty period” developed from older outcomes data that are likely no longer clinically relevant, and reflecting the time to a hard cardiac event rather than the development of ischemia, that is, an opportunity for intervention before that hard cardiac event, should be challenged and reconsidered.

**Disclosures**

None.

**References**


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