Cost Utility Analysis of Radiographic Screening for an Orbital Foreign Body before MR Imaging

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BACKGROUND AND PURPOSE: Our purpose was to evaluate the cost-effectiveness of clinical versus radiographic screening for an orbital foreign body before MR imaging.

METHODS: Costs of screening were determined on the basis of published reports, disability rating guides, and a practice survey. Base case estimates were derived from published guidelines. A single-state change model was constructed using social cost as the unit of analysis. Sensitivity analysis was performed for each variable. The benefit of screening was avoidance of immediate, permanent, nonameliorable, unilateral blindness.

RESULTS: Using base case estimates and a discount rate of zero, we calculated the cost of the current guideline as \$328,580 per quality-adjusted life-year saved. Sensitivity analysis identified screening cost as a critical variable. Discount rates and effectiveness of foreign body removal also were found to be important factors. Probability of injury and prevalence of foreign body may impact the analysis.

CONCLUSION: Clinical screening before radiography increases the cost-effectiveness of foreign body screening by an order of magnitude, assuming base case ocular foreign body removal rates. Asking the patient "Did a doctor get it all out?" serves this purpose. Occupational history by itself is not sufficient to mandate radiographic orbital screening. Current practice guidelines for foreign body screening should be altered.

A single case report early in the clinical application of MR imaging has led to great controversy regarding the need to screen patients before MR imaging. The patient was reported to have sustained an ocular injury from a retained ferromagnetic foreign body. No other adverse reactions to MR imaging due to an orbital foreign body have been documented in the literature. Despite case reports of human subjects unharmed by MR imaging in the presence of metallic orbital foreign bodies, recent investigators have concluded that "a history of occupational exposure to potential metallic ocular injury" necessitates radiographic orbital screening before MR imaging (1–6).

An increasing concern in health care delivery at present is cost. The cost of pre-imaging screening for a metallic foreign body may represent a significant portion of the overall cost of an MR imaging program at rates for orbital screening reported in the literature. The costs of overscreening can be clinical as well as financial; for example, MR resources in the community are used less effectively as a result of inefficient scheduling, canceled examinations, and delays, denying the benefit of MR imaging to some individuals who might require it. Similarly, the costs of underscreening might be financial as well as clinical; for instance, if an individual becomes partially disabled as a result of an ocular injury (7–11).

Cost-effectiveness analysis is a method whereby financial and clinical risks can be quantified and compared. By using explicit assumptions, the magnitude and direction of risks and benefits can be discussed rationally, and choices regarding radiographic screening for an orbital foreign body before MR imaging can be compared with other, less emotion-laden choices made daily in our society. Critical variables in the analysis can be identified when the results of the analysis change materially over a plausible range of the variable in question (12–24).

Methods

Literature Review

A MEDLINE literature search was undertaken in which various permutations of the terms MR imaging, safety, injury, screening, and related expressions were used to seek systematically collected data on this topic. Relevant references from articles found in this manner were also retrieved.

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Assessment of Disability

The extent and nature of disability caused by injury from an orbital foreign body were gleaned from the medical literature. Disability rating guides were used to assess the relationship between the type and extent of disability versus the economic value of a healthy person. We used the Disability Rating Guide of the American Medical Association (AMA) and the Worker's Compensation Form developed by the state of California. Because these two documents were in close accord, the calculations from the AMA guide were used because of their national scope (7, 25).

Life Expectancy

Life tables published in a standard medical decision-making textbook were used for an estimate of longevity at age 45. We selected age 45 as the base case because this is the approximate median age of patients in our MR imaging practice (26).

Discount Rate Analysis

Discount rates varied from 0% to 10%. These values were obtained from medical and economic literature. The 0% discount rate, sometimes called the social discount rate, is considered by some to be most appropriate for assessment of medical and social projects, since they assume the value of human suffering to have no temporal component. Others consider rates of 3% or 5% to be most valid, since 3% is similar to historical rates of inflation and 5% is close to historical Treasury bond rates. A discount rate of 10% approximates the historical rate of stock market returns (10, 23, 24, 27–34).

Probability of Injury

We used the medical literature to derive 1) the sensitivity of clinical and radiologic examinations for detection of a foreign body, 2) the probability that injury would result when a metallic foreign body was present within the orbit, and 3) the sensitivity of radiography for detection of a metallic foreign body (2, 5-7, 35-44).

Clinical Model

A single-state change model was used. Because MR imaging is a discrete event that occurs at a particular point in time, and because we assumed that blindness occurring immediately at the same point in time would be complete, permanent, and nonameliorable, this represented a single-state change and therefore did not require a Markov process analysis or complex decision tree. Each of the nodes of the trivial case decision tree is represented, if one were to have been constructed, as a discrete variable in a single equation (26).

Economic Model

Our economic model was based on the assumption that a perfectly functioning labor market exists. "Where perfectly functioning labor markets are assumed to exist economists can comfortably argue that workers' earnings perfectly reflect their productivity." "The cost is evaluated based on overall earnings defined as a proxy for the lost output to society. This conceptualization stems from the economists' traditional framework that considers full or near to full employment as equilibrium" (45).

At risk of double-counting in our sensitivity analysis, we added to the lost wages the cost of futile treatment and rehabilitation. We used the figures of \$100, \$1000, and \$10,000 as the cost of initial medical care for each injury, and the figures of \$100, \$1000, and \$10,000 per year as costs of rehabilitation. We assume that no benefit whatsoever was derived from the expenditure. Because we double-count these costs in our sen-

 TABLE 1: Incremental cost per quality-adjusted life-year for radiographic versus clinical screening

OALY	= Oualit	y-adjusted	life-year

- C = Cost of radiologic screening for intraocular foreign body
- R = Probability that a foreign body remains after eye examination
- Fe = Probability that a metallic foreign body is ferromagnetic
- Pr = Prevalence of metallic foreign body in screening population
- S = True-positive rate (sensitivity) of radiologic screening for foreign body
- I = Probability of injury if patient with foreign body is examined by MR imaging
- is examined by wirk imaging
- D = Degree of disability associated with ocular injury
- L = Average life expectancy of screened population
- $\Sigma d = \text{Discount factor of life expectancy after disabling} \\ injury by rate and duration$
- A = Annual cost of rehabilitation and medical care per blinded patient
- M = Cost of medical care at the time of injury per blinded patient

C

Cost per

$$QALY = \frac{C}{(R) (Fe) (Pr) (S) (I) (D) (L) (\Sigma d)}$$

$$\frac{[(L) (\Sigma d) (A) + M] [(Fe) (Pr) (S) (I) (R)]}{D}$$

TABLE 2	2: Base	case	values
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Variable*	Magnitude	Reference
С	\$ 173	Murphy (5)
R	.1	Bartley (35) and Bryden et al (36)
Fe	.5	Newell (38) and Bray (58)
Pr	0.65%	Gushee (34)
S	90%	Otto (39) and Shingleton (40)
Ι	.25	Boutin (1), Elmquist (2), Kelly (4), and
		Shellock and Kanal (6)
D	.24	Sox (26)
L	30 yr	Gushee (34)
Σd	0%	Gushee (34)
А	\$ 0	Barth (45)
М	\$ 0	Barth (45)

* See table 1 for explanation of variables.

sitivity analysis and assume there is no benefit to the expenditure, our analysis is quite conservative.

Frame of Reference.—The cost to society as a whole was taken as our frame of reference.

Cost Utility Equation.—The derived cost utility equation is illustrated in Table 1.

Base Case Values.-These are summarized in Table 2.

Clinical Screening Protocol

At the time of scheduling for an MR examination, patients are asked whether they have a high-risk occupation and whether they have had an ocular injury. If they have sustained an ocular injury from a metallic object, they are asked whether they had a medical examination at the time of the injury, and whether they were told by a doctor, "It's all out." If they did not have an injury, if they were told their ophthalmologic examination was normal, and/or if the foreign body was removed at the time of injury, then they proceed to MR imaging as scheduled. The incremental cost of asking these questions has been ignored in our analysis.

Radiographic Screening Protocol

Patients are screened radiographically if they sustained an ocular injury related to a metallic foreign object and they were not told their post-injury eye examination was normal. In these cases, the MR examination is postponed and the patient is scheduled for screening radiography. The results of screening are then communicated to the MR imaging department and the examination is rescheduled. The incremental costs of these steps, other than the cost of the radiographic examination itself, have been ignored in our analysis.

Costs of Radiographic Screening

The cost of radiographic screening is considered to represent only the charge for the examination itself. We have ignored the cost of lost time to the patient, transportation, child care, wages, or other costs that might accrue as a result of an additional medical appointment. We have also ignored the costs of the delay of the MR imaging examination and the loss of efficient use of the capital invested in the MR imaging equipment, as manifest by incomplete utilization or other costs. We have ignored these costs because they are extremely difficult to calculate, and in any case would favor clinical over radiographic screening. The costs of screening were culled from the medical literature on screening for an orbital foreign body, the Medicare fee schedules for various examinations, and the usual, customary, and reasonable fee schedules for various examinations (5, 45, 46).

Cost Utility Threshold

We allow the reader to establish the cost utility threshold from the data we present from a large number of medical and nonmedical interventions. The precise level selected may not be relevant, since orders of magnitude separate the cost utility values for the interventions given.

Results

Using base case values for the variables in our analysis, we estimated a cost per quality-adjusted life-year (QALY) of \$328,580. In other words, if the cost of radiographic screening is \$173, if the probability of a metallic orbital foreign body being ferromagnetic is .5, if the probability of its being of sufficient size and precise position so as to induce complete blindness in the affected eye is .25, if the sensitivity of radiographic screening for this type of foreign body is 90%, if an ophthalmologic examination would miss 10% of ocular foreign bodies, if the patient has a life expectancy of 30 years, and if the value of a dollar today is identical to the value of a dollar 30 years hence, then we must be willing to spend \$328,580 per year of life adjusted to reflect the value of perfect health in order to justify current screening recommendations. Put another way, we must be willing to pay \$2,464,350 today to avoid a blind eye event.

The analysis is sensitive to screening cost. The results in Table 3 show that a screening cost of about \$25 would result in cost per QALY below \$50,000. When a 5% discount rate is applied, this

TABLE 3: Sensitivity to screening cost

Cost per	Cost per Quality-Adj	usted Life-Year (\$)
Screening (\$)	30 Years at 0%	30 Years at 5%
25.16	47,778	93,175
50.32	95,556	186,351
100.64	191,112	372,702
173.00	328,580	641,240
212.30	403,220	786,260
638.40	1,212,520	2,364,400

 TABLE 4: Sensitivity to discount rate and expected longevity cost

 per quality-adjusted life-year

Expected	Discount Rate			
Longevity (yr)	0%	3%	5%	10%
20	\$ 492,860	\$ 662,600	\$ 791,000	\$ 1,157,940
30	\$ 328,580	\$ 502,920	\$ 614,240	\$ 1,045,780
40	\$ 246,420	\$ 426,460	\$ 574,480	\$ 1,008,020

TABLE 5: Sensitivity to prevalence of foreign body

Prevalence of Foreign Body	Cost per Quality-Adjusted Life-Year (\$)
2.5	85,430
0.65	328,580
0.27	791,026

TABLE 6: Sensitivity to screening efficacy

True-Positive Screening Rate (%)	Cost per Quality-Adjusted Life-Year (\$)
100	295,722
90	328,580
69	428,580

is no longer the case. Sensitivity analysis shows that the expected life span of the patient impacts the analysis significantly; the shorter the life span, the greater the cost of screening (Table 4). However, even with a life expectancy of 40 years, the cost per QALY is very high. As time preference for money increases, the radiographic screening program becomes less cost-effective. The prevalence of an ocular foreign body among the screened population is also an important variable (Table 5).

The efficacy of radiographic screening is not a critical variable (Table 6), and the probability of injury is most likely not a critical variable (Table 7). At an extremely radical assumption of 100% injury rate, the cost per QALY is over \$70,000. The probability of a false-negative ophthalmologic examination is probably not critical (Table 8). Severity of injury does not appear to be an important variable (Table 9), nor is the probability of having a ferromagnetic foreign body in the eye (Table 10). The incremental cost of radiographic screening is

 TABLE 7: Sensitivity to probability of injury

Probability of Injury	Cost per Quality-Adjusted Life-Year (\$)
1.0	73,930
0.25	328,580
0.10	739,305
0.01	7,393,050
0.001	73,930,500

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TABLE X:	Sensifivity	to talse	-negative ev	e examination	rate
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Probability	Cost per Quality-Adjusted Life-Year (\$)
1.0	32,858
0.1	328,580
0.01	3,285,800
0.001	32,858,000

TABLE 9: Sensitivity to severity of injury

Percentage of Monocular Vision Loss (%)	Cost per Quality-Adjusted Life-Year (\$)
100	328,580
50	1,314,320
25	5,257,280

TABLE 10: Sensitivity to probability that metallic foreign body is ferromagnetic

Probability	Cost per Quality-Adjusted Life-Year (\$)
1.0	164,290
0.5	328,580
0.25	657,160
0.10	1,642,900
0.05	3,285,800

TABLE 11: Sensitivity to cost of rehabilitation and medical care

Acute Medical Care (\$)	Ongoing Annual Rehabilitation (\$)	Cost per Quality- Adjusted Life-Year (\$)
0	0	328,580
1,000	1,000	328,576
10,000	10,000	328,536

not sensitive to medical or rehabilitation expenses (Table 11).

Discussion

Physicians operate under uncertainty every day. In our society, the frequency and severity of rare events with dramatic adverse outcomes are systematically overestimated and overemphasized. The social and clinical consequences of these errors have been explored, and means to avoid them have been discussed. Consider that the risk of reaction to MR contrast agents are at least an order of magnitude lower than those associated with iodinated contrast material. Despite this, a recent article states that "the indexes of suspicion . . . must be as rigorous for reactions associated with MR contrast agents as they are for reactions associated with iodinated contrast material." (47) It is in this milieu that some current screening recommendations have developed (8, 47–57).

Methodological complexities abound in an analysis of this sort. Fortunately, the problem at hand is relatively straightforward. Only one event needs to be considered, the MR imaging examination, and all the costs, except lifelong monocular blindness, are incurred immediately. The incremental costs of clinical screening are de minimus, only one or two questions need to be asked, and this incremental cost is less than the incremental costs of arranging the radiographic screening examination, losing MR imaging availability, substituting less efficacious or more invasive diagnostic procedures, and rescheduling the MR imaging examination.

Decision tree analysis has been suggested as the ideal method for analyzing cost utility problems in medicine. This may be true for situations in which complex sequential chains of events are analyzed, in which succeeding decisions depend on those that have come before. However, here we have a single, discrete event, so a decision tree is not appropriate. Furthermore, the complexity of decision tree depictions may mask analytic deficiencies and distract even educated observers (26, 48).

Our base case estimates for the frequency and magnitude of risks associated with performing MR imaging in patients possibly harboring metallic foreign bodies were constructed in such a manner as to favor the hypothesis that radiographic screening is justified. For example, we chose a probability rate of possible injury associated with MR imaging in a patient with an orbital foreign body as 0.25. This rate was based on the two cases reported by Williamson et al in which patients had MR imaging and subsequent foreign body injury revealed at radiography, on another similar recent case in which no injury occurred, as well as on one case reported by Kelly et al in which an injury did occur. The rate of probability is most likely a great deal lower, since the sensitivity of orbital screening for detecting radiopaque foreign bodies is between 69% and 90%, and because patients' memories of remote occupational exposure must be faulty in many cases. Furthermore, in one survey, 5% of the MR imaging facilities polled had no orbital screening protocol. There has almost certainly been MR exposure in thousands of patients harboring metallic foreign bodies in whom no injuries resulted. The probability of injury is likely to be one per several thousand. Using a different analytical approach, Williamson et al estimated one in 2000 (1-4, 39, 42-44, 46, 58).

We assumed a base case discount rate of zero, which clearly favors the radiographic screening project. Since the costs are borne in year zero, when MR imaging is performed, and the costs of monocular blindness are borne in the future, this selection strongly biases our conclusion in favor of radiographic screening. The sensitivity analysis here is interesting. For example, recent studies of the medical care cost impacts of cigarette smoking used a variety of discount rates, and the discount rate of zero was abandoned in favor of nonzero rates. A recent comparison of multiple cost-effectiveness analyses normalized results to a 5% discount rate (27).

Furthermore, we ignore the radiation effects on the lens of the eye, on calvarial and spine bone marrow, and on the thyroid gland and brain. These effects would be seen only in a radiographically screened population and not in a clinically screened population. We concluded that the rates of these potential complications would be so low as to be negligible.

We assumed that complete loss of vision would result in the affected eye and that this would be immediate and permanent. We also assumed that all medical care to ameliorate blindness would be futile. Ratings of disability due to monocular blindness were based on complex formulas in which central and peripheral vision losses are taken into account and partial disabilities may be graded from 0% to 100%. Lesser degrees of ocular injury result in smaller fractions of disability (25, 59).

Complete monocular blindness is considered to result in 25% impairment of the visual system and 24% impairment of the whole person; 50% impairment of the worse eye is considered to represent 12% impairment of the visual system and 11% impairment of the whole person; and 25% impairment of the worse eye causes 6% impairment of the visual system and 6% impairment of the whole person (25).

We have assumed that medical care would be provided acutely to the injured individual and annually thereafter. We performed sensitivity analysis over a range of values, and the impact on the cost of radiographic screening was negligible. Our base case value of zero expenditure in medical and rehabilitation costs was based on the standard economic assumption that lost productivity represents the economic loss to society. After all, workers ultimately must, on average, produce the resources expended to care for themselves and others. The net impact on society as a whole must eventually be accounted for as the lost output to society manifest as lost productivity by the injured person. If labor markets are at all efficient, this ought to be accounted for in compensation to workers, on average. As we ran these medical costs to very high levels, the analysis was only minimally changed. This is because many individuals must be screened and only a very few are even potentially injured. Our assumptions with respect to medical care are extremely conservative, because we assume that no beneficial impact ever accrues to the patient. The disability is permanent, nonameliorable, and immediate (45).

Our base case estimates of an age of 45 years and a life expectancy of 30 years were derived from our clinical experience and from life tables. We used male life tables for this analysis because industrial exposure to metallic foreign bodies is vastly more common in men than in women. As social transformation in workforce composition continues, it is possible that these calculations would need to be reassessed, since greater longevity in females would result in longer life expectancy. Potential confounding variables that we ignored in this analysis are the near absence of significant exposure in pediatric populations and differential rates of eye protection use in contemporary versus remote occupational exposure (26).

Cost of screening is a critical value in our analysis. Our assessment of the cost of screening as the dollar charges for the examination therefore bears further scrutiny. We used a figure quoted from a recent paper strongly advocating screening based on occupational history alone (5). If the cost can be reduced to about one seventh of this level, the screening enterprise may be cost-effective. The level of \$25 approximates the allowable Medicare fee for a single-view screening examination (46). It is highly probable that the costs of performing the examination are not fully reimbursed at this level of payment (personal communication). The figures for CT are included because a pre-MR imaging CT study had been available in the index case of ocular injury (4), and because the allowable Medicare fee for CT is close to the plain film charge reported (5, 46; and Personal communication, Unanimous declaration of California Managed Imaging Board of Directors, 1999).

The probability of injury is potentially a critical value as well. If 100% of patients with ocular foreign body injuries are blinded completely in the affected eye, the cost per QALY approaches the median household income, or the annual cost of dialysis. However, we know of only one case of injury and at least three documented cases in which persons with an orbital metallic foreign body were examined by MR imaging without injury. Furthermore, patients forget exposure, radiographic examination is not 100% sensitive, and some sites have no screening protocol. The probability of injury must be very much lower than the .25 we used in our base case. The true value for this variable is probably less than .0005 (1, 43).

The prevalence of a foreign body in the screened population is potentially a critical variable. We used the most recent published data in our base case, but if this is increased to 2.5%, the cost per QALY approaches the median income, or annual cost of dialysis (5, 43).

The concept of QALY is somewhat controversial. Some regard the valuation of human life by a continuously variable function as anathema. We adopt a neutral position. However, if there is no difference between a year of life in perfect health and a year of life disabled, then the entire discussion would be moot, and radiographic screening for MR imaging would be abandoned outright. The precise function for the assessment of disability is necessarily complex. It also changes over the course of one's life. For example, disabled patients consistently rate the quality of life with a given degree of disability higher than do those who are not disabled. We adopted the disability scales developed by the AMA and by California Workmen's Compensation, since these are widely used and have been vetted in a wide social milieu. Sensitivity analysis for this variable was not performed, since the discussion of plausible ranges may be theological as well as scientific. We did analyze the sensitivity of our conclusions to partial blindness injuries and found no critical impact (7, 25, 60-67).

The critical dollar value of the cost utility ratio, which changes the conclusion of the analysis, is necessarily arbitrary. We can compare the ratio calculated here with other published figures and draw conclusions based on the relative magnitude of the cost utility ratio. The median cost utility ratio for medical interventions is \$19,000 per life-year saved. Another standard commonly used is the annual cost of renal dialysis, which is \$35,000 to \$45,000 in 1997 dollars (6, 10, 30–32, 67).

Cost-effectiveness analysis has been applied to many medical and nonmedical interventions designed to save lives and preserve health (68). As can readily be seen, the intervention under discussion here, radiographic screening for an orbital foreign body before MR imaging, based on recent recommendations, is very expensive relative to other interventions. Note also that the price of low-osmolality contrast media has declined markedly since the publication of the highest figure shown other than that for pre-MR imaging orbital screening. Therefore, the discrepancy between that figure and the cost of orbital screening is even more pronounced at present costs (Table 12).

Critical variables in cost-effectiveness analysis are those whose values, when varied over a plausible range, alter the cost per QALY sufficiently to alter the conclusion of the analysis. We identified several critical variables. If ophthalmologic evaluation for a metallic foreign body had a false-negative rate near 100%, the conclusion of our analysis would be altered. This seems unlikely, since the toxic effects of iron and steel in the eye are well known to ophthalmologists and the magnetic properties of these foreign objects actually facilitate their removal from the eye. The cost of screening is potentially a critical variable, but the level at which it becomes critical is probably below the cost of providing the service (personal communication). In populations in which the rate of ocular foreign body exposure exceeds that published in the literature, screening radiography may be cost-effective ORBITAL SCREENING BEFORE MR

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.	Cost per Quality- Adjusted Life-	D. (
Intervention	Year (\$)	Reference
Automobile seat belt Antismoking education	Cost savings	Graham et al (62)
program Breast cancer screening every 2 yr, ages 50–70	1,915	Cromwell et al (30)
yr Neonatal intensive care,	4,836	Danese et al (30)
1.0–1.5 kg Breast cancer screening every 2 yr, ages 40–70	5,100	Detsky and Naglie (14)
yr Breast cancer screening every 2 yr, ages 35–75	6,943	Danese et al (31)
yr Mild thyroid failure	9,223	Danese et al (31)
screening, women Exercise to prevent myo-	10,426	Danese et al (31)
cardial infarction	13,508	Danese et al (31)
Hypertension screening, men Low-osmolality contrast media for high-risk	18,323	Danese et al (31)
patients	22,600	Detsky and Naglie (14)
Driver's air bag Hypertension screening,	24,000	Graham et al (61)
women Neonatal intensive care,	26,130	Danese et al (31)
0.5–1.0 kg Bone marrow transplant	30,900	Detsky and Naglie (14)
for acute leukemia	59,300	Detsky and Naglie (14)
Passenger's air bag Low-osmolality contrast media for low-risk	61,000	Graham et al (30)
patients Orbital screening based on occupational exposure	220,000 328,580	Detsky and Naglie (14) Present article

under some circumstances (35, 38, 40; and Personal communication, Unanimous declaration of California Managed Imaging Board of Directors, 1999).

Taking many years of clinical experience into account, we have adopted the following criteria in our practice. Occupational history by itself is not sufficient to mandate radiographic orbital screening. If a patient reports injury from an ocular metallic foreign body that was subsequently removed by a doctor or that resulted in negative findings on an eye examination, we perform MR imaging. To date, we have encountered no adverse clinical impact. Those persons with a history of injury and no subsequent negative eye examination are screened radiographically. We have performed approximately 100,000 MR imaging examinations under this protocol, so the upper bound of the 95% confidence limits for the rate of injury to the eye due to a ferromagnetic foreign body is less than three per 100,000, or 0.003% (69).

Conclusion

Radiographic screening before MR imaging on the basis of occupational exposure alone is not cost-effective. It is also probably not clinically necessary. The critical variables we identified that may affect the validity of this conclusion are cost of screening, effectiveness of ophthalmologic evaluation, probability of injury, and frequency of foreign body invasion of the orbit. To date, our approach has been clinically successful.

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