EVALUATION OF RISK-BENEFIT IN DIAGNOSTIC IMAGING

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INTRODUCTION

Medical radiation exposure of patients undergoing diagnostic imaging procedures accounts for around 95% of man-made radiation exposure of the population. Application of the ALARA principle to this group is therefore extremely important, and in this context some sort of quantitative evaluation of risk-benefit may prove to be useful in determining whether the benefit of a diagnostic examination (for a given group of patients) outweighs the iatrogenic effects produced by radiation: This, in fact, is a primary requisite for proceeding with the examination, as explicitly stated in I.C.R.P. Reports Nos. 26 and 34.

DECISION TREE ANALYSIS OF LIFE EXPECTANCY

The use of life expectancy in risk-benefit calculations facilitates the comparison of risk-benefit in terms of net years lost or gained. This sort of analysis can also be used to advantage in cost-benefit comparisons. In order to quantitate the net life loss or gain, the diagnostic test being evaluated must be looked at in the context of the diagnostic/therapeutic chain which both precedes and follows it. Figure 1 illustrates the type of decision tree which would typically be associated with a diagnostic imaging procedure. The consequences of each decision (1 to 4) can be computed and compared in terms of years of life expectancy (YLE) lost or gained.

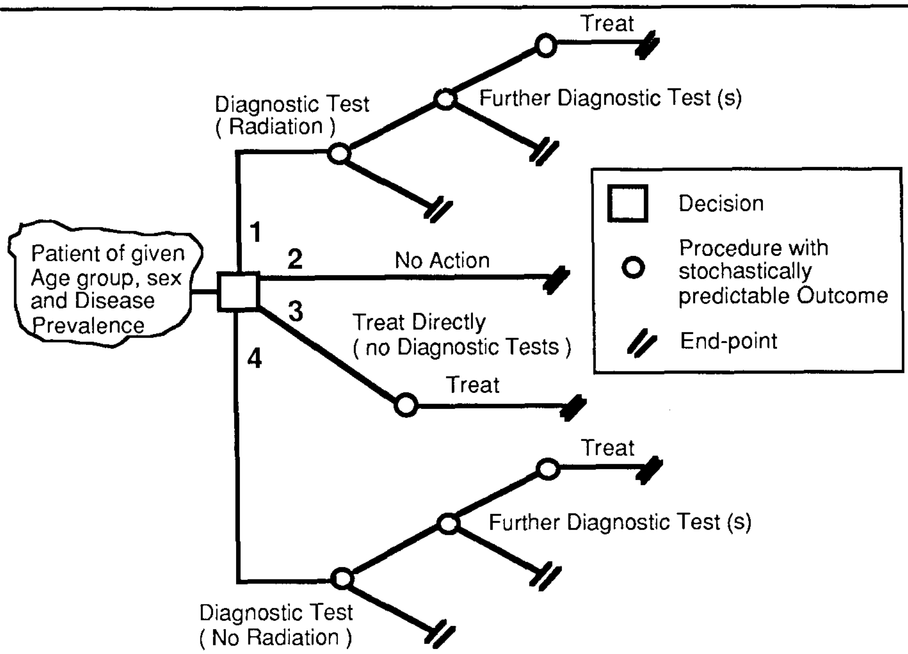

Figure 1. Simple Decision Tree relating to Patients being considered for a Diagnostic Imaging Procedure.

IMPLEMENTATION

The mathematical formulation required to compute the outcomes of the various decision tree branches is relatively straightforward, but is too lengthy to expound in detail in this short paper. Basic input data required includes the following:

* Survival tables for males and females (Australian Bureau of Statistics Life Tables, 1980-82).
* Radiation risk data (BEIR Report 3, 1980).
* Prevalence of disease being investigated.
* Survival data for diseased patients who are untreated.
* Treatment details (risk and survival data)
* Diagnostic test details (sensitivity, specificity and radiation dose).

RESULTS

Obviously, in terms of YLE lost, the effect of radiation risk will be much greater for younger patients than for older patients. Figure 2 shows the radiation risk for males and females as a function of age.

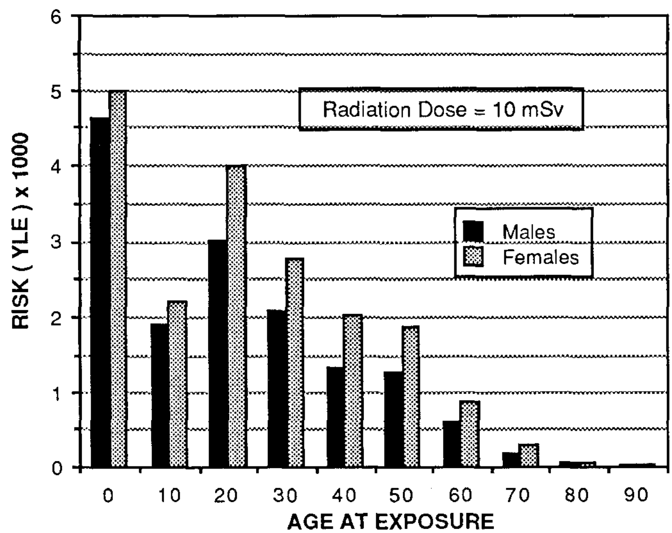

Figure 2. Radiation Risk in Terms of Years of Life Expectancy (YLE) Lost as a Function of Patient Age and Sex

Using this sort of technique, it is also possible to obtain quantitative answers to questions such as the following:

"Diagnostic imaging procedure A has a sensitivity of 89% and a specificity of 84% and for the detection of a given disease, and does NOT involve ionizing radiation. Diagnostic imaging procedure B has a slightly improved sensitivity of 91% and a specificity of 86%, but delivers an effective dose equivalent of 10 millisieverts . Which is the best test to use (ignoring cost considerations)?"

Some further information is required before an answer can be given, this being as follows:-

- Male patient, aged 50
- Disease prevalence: 15%
- Survival for diseased patients (untreated): 50% at 5 years.
- Survival for diseased patients (treated): 100% at 5 years.

Although the above data is for a hypothetical diagnostic examination and treatment, the parameters chosen are not at all unrealistic or atypical.

The answer to this question, perhaps surprisingly, is that imaging procedure B is best (2% improvement in YLE is obtained) despite the relatively high radiation dose. Even if the sensitivity and specificity of procedure A were increased to 90% and 85% respectively, the effective dose equivalent of procedure B would have to exceed 50 millisieverts in order to annul the benefit of procedure B's 1% increase in sensitivity and specificity .

The effect of radiation dose on the net benefit of a diagnostic procedure is illustrated inFigure 3. The radiation detriment is, relatively speaking, much more significant for examinations with poor diagnostic efficiency. At 10 millisieverts, for example, radiation detriment has reduced the potential net gain of the better imaging procedures by around 6%, whereas, for the less efficient procedures this figure is nearer 13%. Since most diagnostic procedures entail effective dose equivalents of a few millisieverts or so, it is evident from Figure 3 that the diagnostic utility of an examination would have to be very poor in order to exclude it because of radiation dose to the patient.

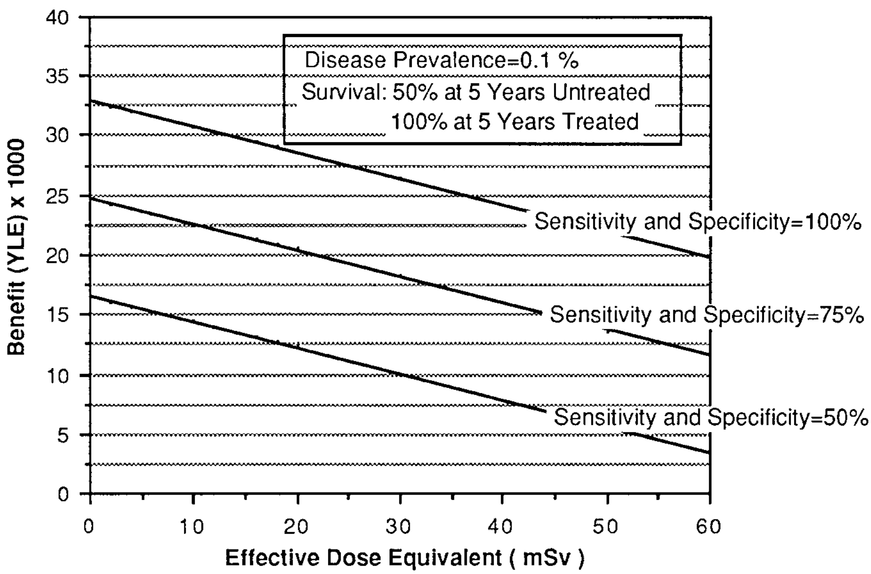

Figure 3. Effect of radiation dose on net benefit

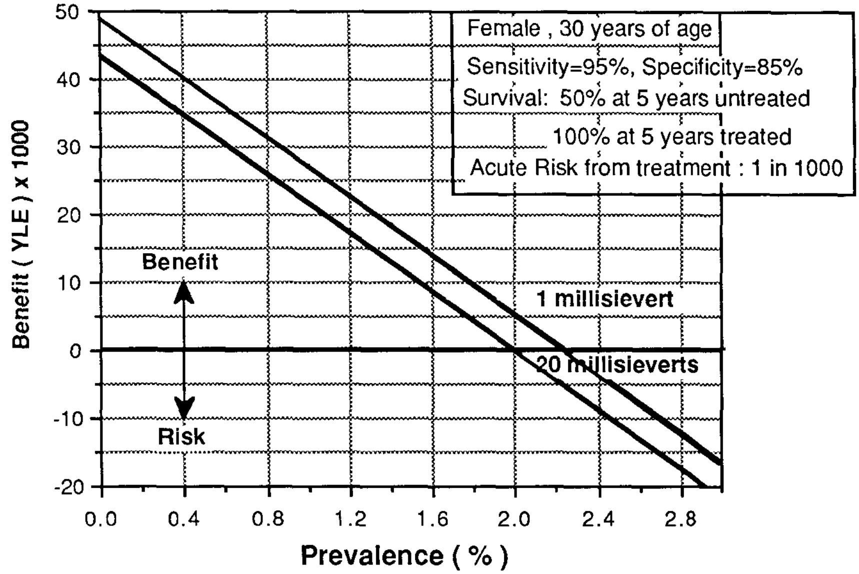

Figure 4. Effect of disease prevalence on risk-benefit

Figure 4 shows the effect of disease prevalence on the risk-benefit of a typical diagnostic procedure. Details of the diagnostic procedure and test procedure are shown on the Figure. It is quite evident that the question as to whether or not there is a net benefit to the patient is highly dependent on disease prevalence. Note also that there may be a relatively narrow "band" of disease prevalence for which the diagnostic examination is useful, and that this band narrows as the radiation detriment increases.

Finally, this type of technique can be used to evaluate screening procedures such as mammography. The input data used for this calculation (drawn from various sources) was as follows:-

Sensitivity of Mammography = 91%

Specificity of Mammography = 100%

Prevalence of Breast Cancer = 0.18%

Survival: 60% at 5 years if untreated

90% at 10 years if treated

Radiation Dose Equivalent = 10 mSv to female breast

Effective Dose Equivalent = 3 mSv.

Using the above data a Benefit : Risk ratio of 85 : 1 and a net benefit of 0.039 years per patient was computed. This sounds small, but it should be remembered this figure will, as with most screening procedures, be comprised of a large benefit to a small number of diseased patients and a very small risk to a large number of non-diseased patients. Put differently, this means that if 10,000 patients are screened, 390 person-years will be saved. Whether or not this is worthwhile may also be a matter of cost-benefit.