Cost-effectiveness analysis for determining optimal cut-off of immunochemical faecal occult blood test for population-based colorectal cancer screening (KCIS 16)


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The study examined the optimal cut-off of the immunochemical faecal occult blood test (iFOBT) in population-based colorectal cancer screening using both a receiver operating characteristics curve analysis and a cost-effectiveness analysis. The authors concluded that screening dominated no screening regardless of the cut-off value of iFOBT and the most cost-effective cut-off was at 110ng/mL. The analysis appears to have been satisfactorily carried out, although an investigation of uncertain areas of the study would have further strengthened the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the optimal cut-off point, considering the trade-off between sensitivity and specificity, of the immunochemical faecal occult blood test (iFOBT) in population-based colorectal cancer (CRC) screening, using both a receiver operating characteristics (ROC) curve analysis and a cost-effectiveness analysis. The patient population was aged between 50 and 80 years.

Interventions
This study compared several cut-offs of iFOBT ranging from 30 to 200 ng/mL, which were also compared against a no screening strategy. Subjects with positive iFOBT results underwent colonoscopy.

Location/setting
Taiwan/primary and secondary care.

Methods
Analytical approach:
In the economic evaluation, a Markov model was developed to simulate the natural history of the disease and the impact of the alternative strategies. A lifetime horizon was considered. The authors stated that a societal perspective was adopted.

Effectiveness data:
The clinical data came from two selected sources: the Taiwan cancer registry system, and the implementation of the Keelung Community-based Integrated Screening (KCIS) experience, which enrolled 22,672 individuals until the end of 2003. Both of these sources were country-specific. The first source was used to obtain CRC incidence and transition probabilities among cancer states. The second source was used to obtain the screening accuracy, risk of death for CRC, and compliance with colonoscopy. The key clinical inputs were the sensitivity and specificity of iFOBT.

Monetary benefit and utility valuations:
None.

Measure of benefit:
Life-years (LYs) were used as the summary benefit measure, and were discounted at an annual rate of 5%.

Cost data:
The economic analysis included both the direct costs (iFOBT, colonoscopy for iFOBT positive patients, polypectomy, biopsy, surgery, hospitalisation, continued oncological care, and terminal care) and the indirect costs (productivity losses due to screening, colonoscopy, biopsy, and treatment). The health care costs came from prices reimbursed by the Bureau of National Health Insurance. The indirect costs were calculated using data from the Accounting and Statistics issued by the Directorate General of Budget in Taiwan. The data on resource consumption were not presented for all items. All costs were in US dollars ($). The price year was not explicitly reported, although the conversion from New Taiwan dollars to $ used year 2000 exchange rates. A 5% annual discount rate was applied to future costs.

Analysis of uncertainty:
Not carried out.

Results
The optimal cut-off using the ROC curve was 100ng/mL at which the corresponding sensitivity was 81.5% (95% confidence interval, CI: 70.2, 89.2), false positives were 5.7% (95% CI: 5.4, 6.0) and the odds of being affected given a positive result (true positive odds) were 1:24 (95% CI: 1:19, 1:32) for the detection of CRC. At this cut-off point the ROC analysis showed that the area under the curve was 0.87 (95% CI: 0.81, 0.93).

In the economic evaluation, the no screening strategy led to 13.7797 LYs and cost $2,005.40. All screening strategies, irrespective of the cut-off, were more effective and less expensive than the no screening strategy, which was therefore dominated. The optimal incremental cost-effectiveness ratio was achieved at 110ng/mL, which yielded 0.054 LYs gained and saved $905.30 over the no screening strategy.

Authors’ conclusions
The authors concluded that screening dominated no screening regardless of the cut-off value of iFOBT and the most cost-effective cut-off was at 110ng/mL.

CRD commentary
Interventions:
The selection of the comparators was appropriate and was consistent with the objective of the study.

Effectiveness/benefits:
The clinical data used in the analysis were derived from local sources such as a cancer registry and the experience of a national screening programme. Thus, caution should be exercised if extrapolating these data to other populations, given the peculiarities of the epidemiological characteristics of cancer, especially in Eastern populations. The cancer registry has the typical strengths and limitations of an administrative database, which on the one hand covers a large number of individuals, but on the other does not collect all the information which might be required in a clinical study. The longitudinal study source, reflected the real-world implementation of the screening experience and followed a large number of patients until a diagnosis was made. The authors pointed out that a strong feature of their analysis was the good study design used to identify interval CRC cases missed at initial screening. The use of a sensitivity analysis as a means to investigate uncertain areas of the clinical evaluation would have been useful.

Costs:
The selection of a broad perspective represents a strong aspect of the analysis, because all the costs were included regardless of the payer. A breakdown of costs borne by the health care system was not provided. The unit costs and quantities of resources were presented separately only for indirect costs, with direct costs being reported as macro-categories. This was presumably due to the accounting system of reimbursement rates, which considers the average consumption of resources. The sources of costs were reported, but the price year was not given, which could limit the possibility of making reflation exercises for other time periods. Variations in economic data were not considered and no sensitivity analyses for the costs were carried out.

Analysis and results:
A synthesis of costs and benefits was not required given the dominance of the screening strategies over no screening. The results of the economic evaluation were presented only graphically, while an extensive description was provided for the ROC analysis, the findings of which were presented for all cut-off values. The issue of uncertainty was not
addressed and this might limit the validity of the analysis. For example, the attendance rate was set at 100%, but the authors acknowledged that a realistic reduction of this rate (to 70%) would have changed the optimal cut-off value (to 100ng/mL).

**Concluding remarks:**
On the whole, the analysis appears to have been satisfactorily carried out, although an investigation of uncertain areas of the study would have further strengthened the authors’ conclusions.

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