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Original Article

Cost-effectiveness and budget impact analysis of a population-based screening program for colorectal cancer

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ABSTRACT

Background: Colorectal cancer (CRC) is one of the leading causes of cancer mortality in Belgium. In Flanders (Belgium), a population-based screening program with a biennial immunochemical faecal occult blood test (iFOBT) in women and men aged 56–74 has been organised since 2013. This study assessed the cost-effectiveness and budget impact of the colorectal population-based screening program in Flanders (Belgium).
Methods: A health economic model was conducted, consisting of a decision tree simulating the screening process and a Markov model, with a time horizon of 20 years, simulating natural progression. Predicted mortality and incidence, total costs, and quality-adjusted life-years (QALYs) with and without the screening program were calculated in order to determine the incremental cost-effectiveness ratio of CRC screening. Deterministic and probabilistic sensitivity analyses were conducted, taking into account uncertainty of the model parameters.
Results: Mortality and incidence were predicted to decrease over 20 years. The colorectal screening program in Flanders is found to be cost-effective with an ICER of 1681/QALY (95% CI −1317 to 6601) in males and €4,484/QALY (95% CI −3254 to 18,163). The probability of being cost-effective given a threshold of €35,000/QALY was 100% and 97.3%, respectively. The budget impact analysis showed the extra cost for the health care payer to be limited.
Conclusion: This health economic analysis has shown that despite the possible adverse effects of screening and the extra costs for the health care payer and the patient, the population-based screening program for CRC in Flanders is cost-effective and should therefore be maintained.

1. Introduction

Colorectal cancer (CRC) is the fifth leading cause of death in Europe. From a national perspective, it is the third most prevalent cancer in Belgian men and the second most prevalent cancer in Belgian women [1]. Annually, 8500 people in Belgium are diagnosed with CRC [2] and about 1800 persons die from the disease. In light of this burden, program-based cancer screening has been recommended by various international organisations [3–5]. However, in times of limited budgets, policymakers require clinical and health-economic evidence in order to spend the available resources in the most optimal way. Several studies have illustrated that detection of pre-cancerous lesions (adenomas) and early-stage cancers results in significant health benefits, although observational studies provide inconsistent results on the magnitude of these benefits [6–10]. The CRC screening policy recommended by the European Commission is the Faecal Occult Blood test for men and women aged 50–74 with a screening interval of maximum 2 years [3]. Since 2013, a biennial CRC population-based screening program has been organised in Flanders, the northern region of Belgium, inviting men and women between 56 and 74 years old to be screened by means of the Immunochemical Faecal Occult Blood test (FIT). The FIT seems to be a cost-effective alternative to the older and low-sensitivity Gaiac Faecal Occult Blood test [11,12]. However, up to now, the value for money of the recent Flemish CRC screening program has not yet been evaluated. Therefore, the purpose of this study was to analyze the cost-effectiveness as well as the budget impact of the population-based CRC screening program in Flanders. The result of this analysis is an important source of information for policy decision makers in order to make evidence-based choices concerning the screening policy for CRC.

2. Methods

2.1. Screening strategy

The health economic model assessed the costs and effects of the Flemish CRC screening program and compared these costs and effects to those expected in the absence of an organized screening program.

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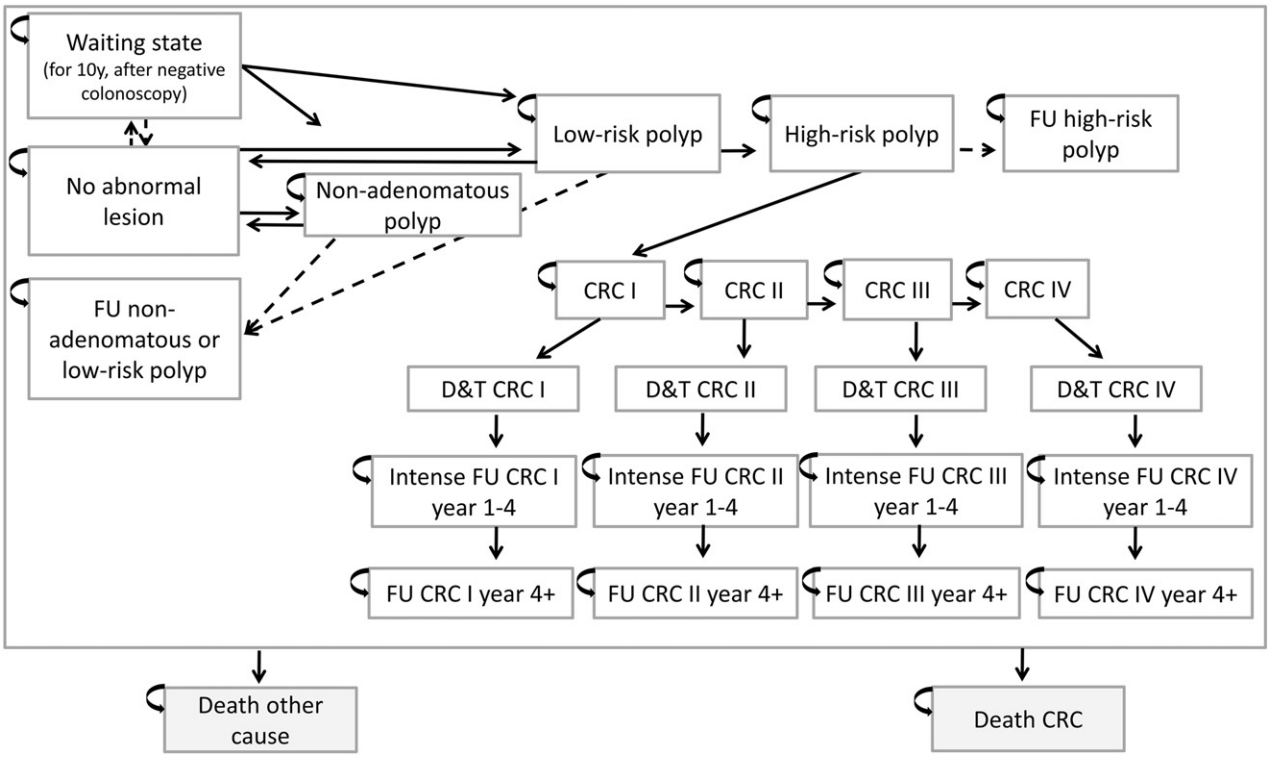

Fig. 1. Markov model depicting the natural progression of CRC and the possible transitions. CRC = colorectal cancer; D&T = diagnosis and treatment; FU = Follow-up. From the state of treatment or follow-up regional metastasis (stage III) or distant metastasis (stage IV) can occur, after which one transitions to the treatment phase of this stage. Death from CRC is only possible for a person with CRC stage III or stage IV. Dotted lines correspond to transitions which are only possible in case of systematic or opportunistic screening.

In the Flemish CRC screening program an FIT is mailed to the target population as a self-test with simple instructions. The stool needs to be pierced with a small included stick and mailed back for testing. The stool is then analyzed by means of the one-sample OC-sensor test, using a hemoglobine cut-off value of 75 nanogram/milliliter. At each FIT-screening round, men and women attending the screening may have either a (false) negative result or a (false) positive result which will lead to further examination with colonoscopy. After a negative colonoscopy, one will not be invited to the screening program for the next 10 years. After a positive colonoscopy, the patient will be treated accordingly.

2.2. General model description

The health economic model consisted of a decision tree, simulating the screening process, and a state-transitional Markov model simulating the natural progression of the disease, over a period of 20 years for the Flemish population aged 50 and older. The population was distributed in age-categories of five years and simulated until they reached the age of 100 or until death. Several disease states were comprised in the model, categorized as unidentified lesions (i.e. not yet detected and diagnosed by a physician) and identified lesions (i.e. detected and diagnosed) (Fig. 1). At the start of the model, according to observed 2011 prevalence figures, the total population was distributed over the state of 'free of any abnormal lesion', 'unidentified polyp' (defined as non-adenomatous polyp, low-risk adenomatous polyp[1] or high-risk adenomatous polyp), or 'unidentified invasive CRC', assuming that all existing lesions were unidentified by start. Furthermore, the model presumed all cancers to arise from pre-existing adenomas. Adenomas could only be detected by means of organised or spontaneous screening since it was assumed that these lesions are not associated with symptoms. Non-adenomatous and low-risk adenomatous polyps could naturally regress every year. However, all polyps detected by screening were removed by polypectomy (resection). CRC stages were determined according to the 7th edition of the tumour-nodes-metastases-classification for malignant tumours [13]. The population transitioned through the states on an annual basis, based on age- and gender-specific transition probabilities estimated from national epidemiologic data and published literature. From the stages treatment or follow-up, one could develop regional metastases (stage III) or distant metastases (stage IV) and go back into treatment. From stage III and stage IV, one could die from CRC and from all stages one could die from other causes than CRC. CRC could be detected by means of the screening program, spontaneous opportunistic screening in case one was not invited or did not participate in the screening program, or it could be clinically detected (based on symptoms). In case of detection, in either way, it was assumed that the tumour was treated in the same year of detection. In the year following treatment, the patient progressed to the follow-up state which was separated into a temporary intense follow-up state (first 4 years) and a long-term follow-up state (next years), because of more intense follow-up and higher risk of recurrence and death in the first years after treatment.

2.3. Epidemiological and clinical inputs

Epidemiologic input data were collected from the Belgian Cancer Registry. The prevalence of unidentified CRC at start of the model was defined as the total prevalence of CRC, namely, the prevalence of registered CRC diagnoses (most recent available data, but before the screening program was implemented) [14] supplemented with the yield of the screening program (2014). Since at the moment of the analysis, test characteristics of the screening were not yet systematically measured, we relied on published literature to estimate the sensitivity and specificity of the FIT and colonoscopy. The incidence of polyps was derived from the study of Brenner et al. [15], as diagnosis of polyps is not registered in

[1] 1 or 2 small tubular adenomatous polyps with low-grade dysplasia; serrated polyps < 10mm or without dysplasia