

Assessment of Cancer Screenings and Impact of Computer Simulation

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The effectiveness of cancer screening for colorectal, breast and cervical cancer has been established by intervention studies and observational studies. In particular, randomized controlled trials (RCTs), case-control studies and cohort studies are designs that are frequently applied. Optimally designed RCTs can minimize various biases and present more reliable results compared with observational studies [1-3]. However, RCTs require observations taken over an extended period to obtain final results. For instance, RCTs for colorectal cancer screenings using fecal occult blood testing (FOBT) conducted in the USA, the UK or Denmark showed a decrease in mortality from colorectal cancer [4-9], but it took more than ten years to obtain the final results [10].

The development of semiconductor chips has contributed to the progress of diagnostic modalities in the medical field. Moore's law predicts the exponential development of performance in semiconductor chips over time [11]. Furthermore, the law of accelerating return indicates that innovations in technology that have an impact on conventional technologies and concepts could contribute to a further accelerated development of technologies and concepts [12]. These laws suggest that advances in the performance of semiconductor chips will accelerate the further progress of diagnostic technology in the medical field.

Under such circumstances, traditional assessments for cancer screenings based on RCTs might not keep pace with the development of diagnostic applications. Furthermore, the evidence presented by an RCT is valid only under certain assumptions; therefore, extrapolating data for different conditions is difficult and is likely to be inaccurate.

The evidence that colorectal cancer screening using FOBT and sigmoidoscopy reduces the mortality from colorectal cancer has been established primarily by RCTs [4-10,13-15]. On the other hand, several RCTs are now being conducted worldwide to assess the effectiveness of colonoscopy as a screening modality [16-22], but we do not have any confirmed evidence of mortality reduction. However, the US Preventive Services Task Force (USPSTF) recommends colonoscopy every ten years for colorectal cancer screening. Some observational studies of good quality show that screening with a colonoscopy can decrease mortality from colorectal cancer [23-26], but the results do not seem sufficient to recommend colonoscopy as a modality for screening. Skepticism may arise about whether the USPSTF is actually recommending colonoscopy without any evidence. Practically speaking, the USPSTF conducted a technology assessment of the colonoscopy using microsimulation models for the recommendation, and the simulation results indicated a decrease in mortality through colonoscopy screening as well as through FOBT [27].

Microsimulation has been developed as computer power has progressed. Different from traditional computer simulations, it can simulate virtual people with different attributes (gender, age, socioeconomic status and so on) and other risk factors contributing to the morbidity or mortality of cancer. Through this process, we can observe the incidence and death from cancer and can more

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flexibly compare the change of morbidity in an intervention group (cancer screening) with that of a group without any intervention. The microsimulation model can also estimate data more accurately if risk factors that have optimally been extracted by clinical and epidemiological studies can be added to the model [28].

Microsimulation could close gaps between instances of evidence as well. For example, a screenee with a positive FOBT should undergo a diagnostic examination. If the diagnostic test does not detect any lesion, the screenee will participate in an FOBT again in the following year. However, if the following FOBT is positive again, should he or she undergo a diagnostic examination once more? How long can the person postpone the next FOBT after the negative diagnostic examination? In another example, the decrease in the incidence of colorectal cancer after colonoscopic polypectomy is considered evidence [29], though we do not have any accurate knowledge about the impact of polypectomy for a reduction in mortality from colorectal cancer. If we wish to know the answer, we will need to conduct a comparative study and follow people who undergo a polypectomy as well as those who do not undergo a polypectomy despite having polyps detected. However, such a study could not be conducted because of the unethical study design. In such a case, a microsimulation model could produce an answer close to the evidence [30].

However, microsimulation has a weak point as well. A simulation should be carried out based on real evidence. In other words, if we request accurate simulations, we should obtain the evidence from RCTs of good quality. An accurate simulation model should also be based on unbiased evidence reported by multiple optimally designed studies. Under such circumstances, a microsimulation model could estimate data for which we do not have any confirmed evidence. On the other hand, a simulation result based on biased data could deliver confusion in the decision-making process of health policy. As another problem, a simulation model is likely to become a so-called "black box." The algorithm applied in the simulation model is difficult for researchers to understand without specific knowledge.

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The significance of microsimulation in studies of cancer screenings or other clinical settings is not yet fully assessed. Nor have study methods involving a simulation model along with traditional methods been established. However, as described above, the progress of diagnostic technologies in the medical field has been exponentially accelerated and will also be accelerated with advances in the performance of semiconductor chips. In the near future, we will not be able to evaluate a cancer screening using a traditional study design. Before then, we should establish the study method by which to use computer simulations in medical research, because a diagnostic test that is superior to the conventional one should be introduced to a screening program without any delay.

Competing Interests

The authors have no competing interests with the work presented in this manuscript.

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