

**Studies underestimate the benefit of lower gastrointestinal endoscopy**

**Precancerous lesions of colorectal cancer can be detected and safely removed through a procedure called lower gastrointestinal (GI) endoscopy, making this measure very effective in cancer prevention. Researchers are currently trying to determine how many colorectal cancer cases and deaths are actually being prevented by endoscopic screening. Scientists from the German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) have calculated that its benefit is much higher than study results have suggested so far.**

Randomized controlled trials are considered to be the gold standard for evaluating new therapies as well as proving the effectiveness of screening exams. In this type of study, participants are randomly assigned to an experimental group or a control group. The evaluation includes all participants.

However, when the purpose is to discover the value of screening exams such as lower GI endoscopy, a problem arises: participants in an experimental group frequently do not undergo the procedure. On the other hand, participants from the control group may do so outside the study protocol – if for example, they have a health concern.

“This means that the difference between experimental and control groups is diluted, making the protective effect of endoscopic gastrointestinal screening appear smaller than it actually is,” says Professor Hermann Brenner from the German Cancer Research Center. Brenner’s team at DKFZ has now carried out calculations to quantify the amount by which this effect is likely underestimated. The team based their calculations on data from four completed randomized trials on the effectiveness of an endoscopic examination called flexible sigmoidoscopy.

The actual participation rates in from members of the experimental groups were generally 70 percent or even lower. On the other hand, during the relevant period, up to 50 percent of participants from the control groups underwent lower gastrointestinal endoscopy outside the screening programs.

Under these conditions, if lower gastrointestinal endoscopy were 70 percent effective in coping with the incidence and mortality of colorectal cancer, the usual study evaluation method would reduce that figure to approximately 38 percent. If the procedure prevented the incidence of cancer cases by 50 percent, the result in the standard evaluation would be a much less convincing 23 percent.

“Randomized controlled trials do provide information about the effect that screening programs have on the colorectal cancer incidence in the whole population that is offered the examination,” Hermann Brenner says. “However, when considering the protective effect of examinations that have actually been conducted, the rate is much higher and should be correctly communicated in colorectal cancer screening consultations.”

Brenner expects even greater discrepancies to emerge during ongoing studies with a focus on full colonoscopies, because participation rates in the experimental groups are yet lower and, at the same time, the proportion of people in the relevant age group who receive lower gastrointestinal endoscopy outside screening programs continues to rise.

Hermann Brenner, Christian Stock, Michael Hoffmeister: In the era of widespread endoscopy use, randomized trials may strongly underestimate the effects of colorectal cancer screening. *Journal of Clinical Epidemiology* 2013, DOI: 10.1016/j.jclinepi.2013.05.008

The German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) with its more than 2,500 employees is the largest biomedical research institute in Germany. At DKFZ, more than 1,000 scientists investigate how cancer develops, identify cancer risk factors and endeavor to find new strategies to prevent people from getting cancer. They develop novel approaches to make tumor diagnosis more precise and treatment of cancer patients more successful. The staff of the Cancer Information Service (KID) offers information about the widespread disease of cancer for patients, their families, and the general public. Jointly with Heidelberg University Hospital, DKFZ has established the National Center for Tumor Diseases (NCT) Heidelberg, where promising approaches from cancer research are translated into the clinic. In the German Consortium for Translational Cancer Research (DKTK), one of six German Centers for Health Research, DKFZ maintains translational centers at seven university partnering sites. Combining excellent university hospitals with high-profile research at a Helmholtz Center is an important contribution to improving the chances of cancer patients. DKFZ is a member of the Helmholtz Association of National Research Centers, with ninety percent of its funding coming from the German Federal Ministry of Education and Research and the remaining ten percent from the State of Baden-Württemberg.

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