

## **The First Randomized Controlled Trial Re Colonoscopy**

**Pamela A. Popper, President  
Wellness Forum Health**

For many years, I have been providing people with objective information about colonoscopy so that they could make informed decisions about it. Until very recently, there were no randomized controlled trials evaluating the efficacy of population screening with colonoscopy for reducing the risk of colorectal cancer, death from colorectal cancer, or all-cause mortality. It's hard to fathom how an invasive and risky procedure could become a standard recommendation for all adults ages 45 and older without any evidence showing that it was beneficial. Some public health organizations recognized this and responded accordingly. The Canadian Task Force on Preventive Healthcare updated its recommendations for colon cancer screening in 2016, advising against colonoscopy as a primary screening test due to lack of evidence.<sup>1</sup>

The reason most people agree to regular cancer screenings is because they have been told that doing so "saves lives." But most people are not given accurate information BEFORE screening that addresses what is most important to them – reducing the risk of death; not just for the type of cancer that the screening test is designed to detect, but also all-cause mortality. There are risks associated with cancer screening, which range from turning healthy people into sick patients, to diminished quality of life or even death due to aggressive treatment. These risks should be considered when making a decision about screening. A 2016 paper that looked at the results of the most commonly recommended cancer screenings showed that none of them resulted in a reduction in all-cause mortality.<sup>2</sup>

During the last 15 years, the US Preventive Services Task Force has increased the recommended options for colorectal screening to include fecal immunochemical tests (FITs) and blood-based cancer screening for methylated DNA.<sup>3</sup> The USPSTF has also expanded the recommended ages for colorectal cancer screening to 45-70 years; previously it was ages 50-70 years.<sup>4</sup>

In 2016 a USPSTF evidence report stated that there were no colorectal cancer screening methods that reduce all-cause mortality. However, a reanalysis showed that flexible sigmoidoscopy slightly reduced all-cause mortality by three deaths per 1000 persons screened.<sup>5</sup>

Another 2016 article concluded that while blood-based screening might result in more people being screened (adherence to both invasive and noninvasive tests is low), these tests have little utility. The manufacturer of one of the tests proposed including a warning with the test stating that a negative result "does not guarantee absence of cancer" and that patients should still pursue other screening methods.<sup>6</sup> Translation: this test is useless and should never have been approved.

Finally, there is good news for patients who are concerned about colorectal cancer screening and struggling to figure out what to do as they try to reconcile the information included in this article with the pressure they receive from health professionals who insist that screening is necessary. The results of the first randomized controlled trial investigating colonoscopy are now available. This study included over 84,000 subjects, ages 55-64. The primary end point was risk of colorectal cancer and related death. The secondary endpoint was all-cause mortality. The study design was excellent and resulted in significantly greater long-term follow-up due to the use of unique personal identification numbers which were linked to cancer registries and cause of death registries for all participants in each country.

The conclusions:

Point #1: Risk of colorectal cancer:

In order to prevent just one case of colorectal cancer, 455 people have to be screened.

Point #2: Risk of death from colorectal cancer:

Risk of death was 0.28% in the colonoscopy arm and 0.31% in the non-colonoscopy arm.

Point #3: Risk of all-cause mortality (death from any cause)

Risk in the colonoscopy arm was 11.03%; in the non-colonoscopy arm it was 11.04%

In other words, colonoscopy made no real difference in outcomes.<sup>7</sup>

An intention-to-screen analysis concluded that the risk of colorectal cancer for screened patients would be 0.98% as compared to 1.20% in the usual care group, a risk reduction of 0.22%. But even this miniscule risk reduction is not realistic since the assumption is that 100% of patients instructed to get a colonoscopy would comply. This is not currently the case in the U.S. – the compliance rate is only 70%.

Now we have data – from a well-designed trial. Colonoscopy does not reduce the risk of developing colorectal cancer, dying from colorectal cancer, or all-cause mortality. There are risks associated with the procedure that include perforation of the colon. Add in the fact that almost everyone agrees that it is an unpleasant experience that involves drinking awful fluids to clean out the colon, taking time off from work or other activities for the procedure and recovery from it, and most people would just say “no.”

There are a few take home points:

- Well-designed Randomized Controlled Trials should be performed BEFORE screening programs are instituted.
- Screening often turns healthy people into patients who do not benefit from medical intervention.

- Billions of dollars is spent on cancer screening tests every year. This money would be better spent on teaching people how to prevent cancer and other common degenerative diseases with diet and lifestyle change.

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<sup>1</sup> <https://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/>

<sup>2</sup> Prasad V, Lenzer J, Newman DH. "Why cancer screening has never been shown to "save lives" – and what we can do about it." *BMJ* 2016;352:h6080

<sup>3</sup> Powell K, Prasad V. "Colorectal cancer screening at a younger age: pitfalls in the model-based recommendation of the USPSTF." *BMJ Evid Based Med* 2022 Aug;27(4):206-208

<sup>4</sup> <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#:~:text=The%20USPSTF%20expanded%20the%20recommended,was%2050%20to%2075%20years>)

<sup>5</sup> Swartz AW, Eberth JM, Josey MJ, Strayer SM. "Reanalysis of All-cause Mortality in the U.S. Preventive Services Task Force 2016 Evidence Report on Colorectal Cancer Screening." *Ann Intern Med* 2017 Oct;167(8):602-603

<sup>6</sup> Parikh RB, Prasad V. "Blood-Based Screening for Colon Cancer. A Disruptive Innovation or Simply a Disruption?" *JAMA* 2016 Jun;315(23):2519-2520

<sup>7</sup> Bretthauer M, Loberg M, Wieszcrzy P et al. "Effect of Colonoscopy Screening on Risks of Colorectal Cancer and Related Death." *NEJM* <https://www.nejm.org/doi/full/10.1056/NEJMoa2208375>