

## Colonoscopy to Prevent Colon Cancer: It Works but There Seems to be a Quality Issue

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My particular field of research is breast cancer and with colleagues, we have proposed what may be a simple inexpensive and non-toxic method to prevent early relapse [1]. It is based on clinical data plus extensive analysis and includes a retrospective study. It could potentially reduce breast cancer deaths by 25 to 50% and perhaps more in certain settings. It needs to be confirmed in a randomized controlled clinical trial. A problem that occurs because it is quite inexpensive is that there seems to be no financial justification to pursue an expensive clinical trial to confirm it [2]. Despite this impediment, according to clinicaltrials.gov a small trial is underway in Belgium, another is planned for South Korea and my colleagues and I are pursuing trials in Africa where it would be most useful. Hopefully, trials will be underway in the near future.

However what I wish to discuss here is colon cancer - a disease of which I am a 20 year survivor from stage IIIc. I am a founder and on the board of directors of the Colon Cancer Alliance (www.ccalliance.org) - the main patient support and advocacy organization in the world. The Colon Cancer Alliance is well supported and is doing excellent work. The really good news regarding colon cancer is that ordinary screening of the colon to find and remove polyps works well to reduce incidence of colon cancer and mortality from the disease. In contrast, based on our research in other cancers where there has not been such clear advantage of early detection such as breast, non-small cell lung, pancreatic, osteosarcoma, and prostate, one consideration is that surgery to remove primary tumors may initiate growth of metastatic disease so the advantages of early detection are offset to various extents by surgery-induced metastatic activity. This detracts from the seductively obvious benefit of "catching it early". This does not seem to occur in colon cancer since the result of colonoscopy is simply to remove suspicious polyps without major surgery. One note of caution is that the previous optimistic statements about colon cancer refer to mortality from colon cancer not mortality from any cause. For example the colon cleansing process prior to colonoscopy is unpleasant and might cause distress or perhaps heart attack in elderly or less healthy persons. Or perhaps the colonoscopy process would cause a puncture and resulting fecal matter leakage and serious internal infection. These would not be recorded as events due to colon cancer and being very small effects are difficult to measure with sufficient accuracy. Clinical trials to measure death from colon cancer with and without early detection are not sufficiently powered to find mortality from all causes.

The clear reason why colon cancer responds well to early detection is that colon cancers begin as polyps in the colon that can be identified and removed without extensive intervention. Colonoscopy is able to detect such polyps and at the same time remove them very effectively, preventing any further development to life threatening extent. The other cancers mentioned above need to have much more extensive surgical intervention that as we have reported can sometimes accelerate metastatic activity. Compared to these other cancers, early detection is the Achilles heel of colon cancer and indeed there has been significant reduction in incidence of colon cancer and death from colon cancer in recent years. It may indeed be possible in a decade or two to claim significant victory over that disease at least in some countries. Colonoscopy is not the only tool for early detection of colon cancer but is considered the gold standard. Other means of early detection of colon cancer include fecal occult blood test, virtual colonoscopy, sigmoidoscopy, barium enema, and molecular detection of cancer cells in stool. That is all excellent news but one cloud over this issue is that based on recent reports, there seems to be a quality problem in the practice of colonoscopy. I think that the public should be made aware of this.

In 2014 a paper appeared in New England Journal of Medicine that investigated and reported how effective colonoscopy is conducted in Kaiser Permanente, a well respected health provider organization in the west coast of US that is large and provides uniform good quality access to medical care [3]. The paper examined the records of 136 gastroenterologists (GIs) who performed 330,000 colonoscopies for patients over age 50 in the preceding 10 years. The GIs were grouped into 5 levels or quintiles according to how frequently they find and remove adenomas or polyps that have potential to become colon cancers if left undisturbed. The metric used was adenoma detection rate or ADR. The ADR reported ranged from 10% to over 50%. The investigators also examined the records of the patients who were under care of these GI doctors. The paper reported that there was a strong almost linear inverse relationship between the GI's ADR and whether his or her patients were later diagnosed with interval colon cancer and also whether the patients died from colon cancer. There was a 1/0.52 or almost 2-fold difference between the best and worst quintile in presentation of interval colon cancer and 1/0.38 or almost 3-fold advantage in death from colon cancer between the best and worst quintile.

There was another later paper that discussed this effect with similar conclusions [4]. I contacted corresponding authors of both papers. ADR is described as a surrogate metric for quality of colonoscopy performed by individual GIs. I was convinced that persons who are screened for early detection would benefit from this knowledge. It could potentially help them identify where to get a high quality colonoscopy. It cost the same and has the same unpleasant preparation whether or not the person uses a GI who has a high ADR or one who

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has a low ADR. Being on the board of directors of the Colon Cancer Alliance I have ability to recommend to the board that the CCA take some initiative in passing this information on to the public. Each of the corresponding authors were asked what could or should advocacy groups do to help. They each volunteered to participate in a webinar hosted by CCA. The public should probably be made aware of this but in a proper thoughtful scientific presentation and definitely not in high dudgeon. This would not be sensationalized or overly dramatized but this information should be made freely and openly available, at least in my opinion.

To illustrate how this could and should work, I had a routine colonoscopy scheduled a few months ago. I contacted my GI's office and inquired what his ADR was. It took a few weeks before a nurse director got back to me and related that the GI's ADR was about 50%. That according to Dr. Corley puts my GI in the top quintile. I was very satisfied. If the GI was in one of the lower quintiles, I would have looked for another GI.

The level of benefit difference from the worst quintile to the best quintile is large compared to any medical intervention I have ever seen in following cancer research for over 30 years. It is free and nontoxic. What could be any possible reason for not publicizing this? I am not suggesting it should be headlined in major newspapers and TV news reports as a major breakthrough but some proper notification to the public should be done.

For some unknown reason such as not taking enough time, not being careful enough, not sufficiently skilled, inferior equipment or support facilities, a fair number of GIs are not doing a proper job and we should not be overly concerned about bruised egos or pocketbook issues. This is life and death and the public needs to be made aware.

I relayed this information to the CCA board at a regular board meeting in June 2015. After listening to my report they decided against such a webinar. The board decided that this information would

confuse some of the millions of persons who visit our website. The board instead decided to contact the professional GI organizations to request that they take some action. I initially was skeptical that professional medical organizations were going to take steps to reduce this problem by applying some internal pressure to improve quality or police their membership and bring negative attention to GIs with low ADR. However I am pleased to report that this is indeed happening. I understand now that GIs will be given financial reasons to publish their ADR and other metrics that would allow consumers to make proper decisions on who should be their GI. I am going to watch developments carefully but as of now I am guardedly optimistic that this quality problem is being properly addressed. We will see what happens in the next months. My personal goal would have this problem cut in half in two years.

What are the best and worst outcomes that could result from presenting the above information in a scientific cancer journal? Perhaps some lives will be saved and perhaps some persons could be misled in judging their GI. I think both are possible and the former easily outweighs the latter.

Conflicts of Interest: Michael Retsky has a patent pending for treatment of early stage cancer and is on the Board of Directors of the Colon Cancer Alliance.

## References

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