Health Risk Analysis:

Validity of the Health Risk Assessment in Predicting Colorectal Cancer and Colonoscopy as a Preemptive Intervention in Colon Cancer

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Description of the Disease Category

Colorectal cancer is a disease in which cells in the colon or rectum become abnormal, divide without control, forming a mass called a tumor in a form of a polyp, adenoma (precancer) or neoplasm (cancer). The danger of colorectal cancer is that the abnormal reproducing cells may invade and destroy the tissue around them or break away from the tumor and spread to form new tumors in other parts of the body, such as, liver, lungs, brain, bone or ovaries.

Colorectal cancer (CRC) is the third most common type of non-skin cancer in men and women. It is the second leading cause of cancer death in the United States after lung cancer. An estimated 146,000 new cases of colorectal cancer and 56,000 deaths from this disease are expected to occur each year. The most common cause of CRC is colorectal polyp. Colorectal polyps are abnormal growths that protrude from the inner wall into the lumen of the colon or rectum. Experts believe that the majority of colorectal cancers develop in polyps known as adenomas. A colorectal polyp the size of 1 cm or larger, when left unattended, will most likely develop into CRC over a period of 3 to10 years, depending on the size and stage of the adenomatous polyp.[i] Early detection and removal of colorectal polyps helps to prevent colorectal cancer. The procedure to remove polyps, called a polypectomy, is performed with colonoscopy. The effectiveness of colonoscopy as a screening tool in early intervention depends on the ability to detect high risk for polyps in asymptomatic individuals who have a negative fecal occult blood test.[ii] This study intends to demonstrate the advantage of determining the population with a significant CRC risk by using a highly sophisticated Health Risk Assessment or Analysis tool (HRA) prior to colonoscopy, and compare it to the same age non-tested group of individuals with an undetermined risk for colorectal cancer.

Presently, the attempted curative treatment of colorectal cancer in non-tested and non-screened individuals is in the hands of the surgeon. Most recent studies support that colonoscopic polypectomy should be strongly considered as a method of preventive intervention, since almost one-third of screened individuals may already have a well-developed, neoplastic lesion in the colon.[iii] There is mounting evidence that the detection and treatment of early-stage colorectal polyps reduces mortality rate[iv]; Medicare and some other payors recently authorized reimbursement for colorectal cancer screening as a cost deterrent in persons at risk for this malignancy.[v] A highly intelligent health risk analysis (HRA) identifying high risk individuals leading to a specific, targeted secondary screening, such as, a colonoscopy in asymptomatic population is not only warranted but absolutely necessary as a cost-effective method of preventing CRC. The rationale behind the study is to evaluate and validate that applying colonoscopy as an early intervention to an HRA prequalified high CRC risk population is a cost-effective method to lower the need for surgical procedure (chemotherapy and radiation), thus lowering the overall cost of colorectal cancer treatment.[vi]

Background

Screening for colorectal cancer is desirable and has been endorsed by the American College of Gastroenterology, the American Gastroenterological Association, the American Cancer Society, and the U.S. Preventive Services Task Force. In the past, fecal occult blood, rectal exam, double contrast barium x-ray and sigmoidoscopy were frequently used as the method of choice in screening for CRC. In spite of the effectiveness as a diagnostic and prevention tool for CRC, the question of colonoscopy as a screening procedure remained one of cost vs. outcomes (US Preventive Service Taskforce.) The problem still remains with the colonoscopy screening for polyps using age and gender as sole criteria. According to University of Michigan Hospital System Study, a population should be prescreened by a health risk assessment (HRA) for high-risk individuals for CRC prior to recommending a colonoscopy procedure. It recommended a colorectal colonoscopy screening to be performed every three years in high-risk individuals and every 10 years in low-risk individuals (3/10 strategy) as the optimal strategy under the vast majority of clinical circumstances.[vii] Other studies have shown that screening for colorectal cancer could save 188,000 lives per year.[viii]

By using US HealthCenter's (USHC) health risk assessment (HRA) in prequalifying a population for colonoscopy screening, the study will demonstrate that colonoscopy is the most effective and cost-justified screening method in lowering the incidence of colorectal cancer.

Objectives

1. To prove how relative is an intelligent health risk assessment (HRA) is an indicator for a colonoscopy.
2. To demonstrate the accuracy of USHC HRA algorithms, as an effective tool in predicting high risk individuals for CRC in a three-year period of time.
3. To validate the relevance of using colonoscopy as an effective deterrent of colorectal cancer.

Design

This is a population-based case study. It is based on the HRA using USHC segmented predisease predictive algorithms and clinical findings from the results of the colonoscopy to verify accuracy of the USHC HRA's predictive analytical algorithms.

For the control group in evaluating the accuracy of USHC segmented predisease predictive model, the study used National Center for Health Statistics, Centers for Disease Control and Prevention and NIH National Cancer Institute - Surveillance, Epidemiology, and End Results Program, published statistics in a non-tested population, which report the prevalence of polyps in 50 to 59 year old men and women at 3%; 30% of adenomatous polyps larger than 1 cm. may convert into cancerous lesions[ix].

As the second control group, the colonoscopy results for the tested population were also compared to the non HRA tested results from Screening Colonoscopy Study, a Cohort study of 44,350 participants in a national screening colonoscopy program over a 4-year period (2007 to 2010) in Austria,[x] that reviewed colonoscopies in the age group of 50 years and older, (Screening Colonoscopy Study[xi], which showed 40% of individuals (25% men and 15% women) were identified with polyps and 60% without polyps.

For economic evaluations (control group) of colorectal cancer screening in an average-risk population, we used the study published in 1999 by American Family Physician, which reviewed 180 potential articles of which 7 studies were retained in the final cost analysis1. The Study used the cost ratios when screening with any of the commonly considered methods including colonoscopy, to be generally between $10,000 and $25,000 (average of $17,500) per life-year saved as published in Annals of Internal Medicine.[xii]

Setting

This study was based on a cohort of government employees in the City of Green Bay, Wisconsin. The colonoscopy was arranged with the local St. Vincent's and St. Mary's clinical gastroenterologists. Participants were encouraged to engage with the highest rated providers in their health plan network at a negotiated discount of 25% or $600 per colonoscopy which resulted in a reduction of the cost of the screening from $2,400 to $1,800 per colonoscopy. The study used only high risk-level participants as determined by USHC HRA algorithms, as elevated, high and serious, (referred to as "significant" risk population) for determining eligibility for the colonoscopy screening procedure. The study did not include participants with a risk of inherited predisposition to the disease, such as familial polyposis, where the incidence of colorectal cancer may occur before age of 50 years. The evidence on predictive accuracy of the HRA was drawn from the results of physicians' findings from colonoscopic procedures and pathological reports.

Participants

754 HRA participants at an average age of 47 years old were reviewed for health risk factors. 60 participants (32 men and 28 women with mean age of 60.8 years) were identified as having significant risk for CRC and were recommended for secondary colonoscopy screening.

Measurements

A detailed health risk assessment (HRA), including a self-administered, intelligent questionnaire, developed by USHC, biostatic measurements and metabolic chemistry panel for determining CRC risk factors were used to obtain the data after adjustment for sex, age, and gender. The risk variables included family history, smoking, body mass index, genetics, exercise, diet and comorbidities, such as, inflammatory bowel diseases and colonoscopy history.

The odds ratio of CRC was determined from the colonoscopy results of the HRA tested population compared to colorectal polyp prevalence in a non-HRA tested population of 3% in the population of 50 years and older. The colonoscopy results for the tested population was also compared to the non-HRA tested results from a study that reviewed 40,000 colonoscopies in the age group of 50 years and older (Austrian Screening Colonoscopy Study), which showed 40% of individuals (25% men and 15% women) were identified with polyps and 60% without polyps.

Colonoscopy Results

60 participants in the "significant" risk group' for CRC were found to be eligible for the secondary colonoscopic screening procedure. 38 participants or 63% were identified having suspicious precancerous polyps, which were removed; 22 other or 37% examined participants had no evidence of precancerous polyps. The USHC HRA which predicted significant risk for a three year period showed a high level of predictive accuracy with an RR of 19*, when compared to the general population. When compared to the Austrian Screening Colonoscopy Study, the RR was 1.6* the Statistics show that in the general, non-tested HRA

population, the average prevalence of precancerous adenomatous polyps was 3% in the same age group. Using the general population as a test group, the USHC HRA tested colonoscopy odds ratio was 50. When compared to the Screening Colonoscopy Study, USHC HRA tested colonoscopy group odds ratio was 2.6.

The cost comparison of the preemptive colonoscopy vs. surgery of colon cancer shows that in 38 detected adenomatous polyps in this study, if the colonoscopy was not performed, 10% of polyps develop into CRC within 3 to 10 years, depending on their size and neoplastic nature at an average cost of $55,000 per CRC case[xiii].

Participants were encouraged to engage with the highest rated providers in their health plan network at a negotiated discount of 25% or $1,800 per colonoscopy, which resulted in a reduction of the cost burden of the screening for colorectal cancer from $144,000 to $108,000.

The study evidenced a 100% reduction of colorectal polyps and their potential for developing into CRC for a period of 10 years in the HRA-tested, screened population. The potential cost exposure of $55,000 per colon cancer (including surgery and chemotherapy treatment) is $209,000** if the colonoscopy was not performed in the same population representing potential savings of $108,000, or an ROI of 2:1.

Due to the relatively slow and predictable progression of polyps in CRC (Winawer, 1997), even the high-risk population, providing modifiable lifestyle risks are reduced, will remain cancer-free for a period of 10 years[xiii]. Using the estimate per life-year saved as published in Annals of Internal Medicine, the savings, based on cost per life year saved over a three-year period, are $1,995,000 with an ROI 4.4 : 1 per year.

Limitations

The study was observational, with potential for residual confounding and selection bias. While we have first-hand evidence of the colonoscopy tests and its cost, for the HRA tested group, the control group, CRC prevalence and the cost of surgery, were obtained from studies and national statistics.

Conclusion

The study showed through empirical evidence using colonoscopy reports the significance and accuracy associated with the USHC health risk assessment for CRC. The empirical verification of 63% positive cases for precancerous polyps in the 1st year of the health risk assessment in a cohort of 60 individuals identified with a high risk for CRC in a three-year predictive model, proves the accuracy of the USHC segmented predisease predictive model. It demonstrates a high level of accuracy of the USHC predictive analytical faculty, as well as, its potential in indicating the need for secondary screening and preemptive intervention and a strong potential for reduction of all stages of colorectal cancer in individuals 50 years and older. It also demonstrates that colonoscopy with polypectomy is associated with a significant cost reduction in the health risk tested population setting.

Thus, aside from strong risk reduction with respect to CRC, we have demonstrated the accuracy and significance of a highly intelligent health risk assessment in determining the eligibility for colonoscopy screening in asymptomatic individuals, thus increasing the cost-effectiveness in early detection and preemptive intervention in treatment of colorectal cancer.

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* Relative risk is a ratio of the probability of the event occurring in the tested (experimental) group versus a non-tested (control) group. RR of > 1 means the event is more likely to occur in the experimental group than in the control group. An RR of 63 is a strong indicator of the accuracy of predictive analysis to identify high risk individuals for CRC, and an effective method to determine the need for colonoscopy as means to prevent occurrence of CRC.

** 10% of adenomas larger than 1 cm develop into neoplasms in 10 years. - BMJ-February 7, 2012(gut.bmj.com)

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