A Prospective Study Evaluating Cologuard® Ordering in the Community Setting

Eesha Sachdeva, BA[1]; Monica Arora, DO[2]; Vibhuti Khatri, MBBS[2]; Justin Crocker, MD, FACG[3]; Sanjay Jagannath, MD[2]
[1]Boston University School of Medicine, Boston MA, [2]Wake Endoscopy Center, Raleigh NC, [3]Duke University, Durham NC

Objective

To determine if referring primary care providers (PCPs) are ordering the Cologuard® test in compliance with approved screening criteria.

Introduction

Colonoscopy remains the gold standard screening test for colorectal cancer[1]. Cologuard®, a non-invasive mtsDNA-FIT test, is indicated for use in asymptomatic patients without risk factors[2]. Our previous studies suggested inappropriate use of Cologuard® in the community setting. This prospective follow-up study was conducted to evaluate the true rate of adherence to approved criteria for Cologuard® testing.

Methods

This prospective study enrolled all referred patients to Wake Endoscopy Center (Raleigh, NC) with a positive Cologuard® test from May 2021 to May 2022. All records were reviewed. Patients were asked if they had seen blood in their stool, were hemoccult positive, had a personal history of polyps or a family history of colon cancer. Data was collected from patients at the time of procedure. Colonoscopy results and patient demographics were analyzed. Follow-up discussions with referring PCPs were conducted after data collection.

Results

123 patients (58 male, 65 female) with a positive Cologuard® test were enrolled. Mean age was 63.5 years (97.6% patients >50 years). 17% were diabetic. 83.7% identified as White, 11.4% as Black, 1.6% as Hispanic, 0.8% as Asian and 2.4% with >2 races.

Prior to Cologuard® prescription, 23.6% of patients reported visible bleeding. 2.4% reported a positive hemoccult test. 13.0% reported both visible bleeding and a positive hemoccult test **(Table 1, Figure 1).**

8.9% of patients indicated a family history of colon cancer. 14.6% of patients reported a personal history of polyps. 4.1% of patients reported both personal and family history **(Table 2, Figure 2).**

In total, 47.1% of patients presented with one or more contraindications (visible or occult bleeding and/or personal or family history) to Cologuard® prescription. 27.6% presented with 1 contraindication and 19.5% presented with more than 1 contraindication **(Figure 3).**

Of these patients, 35.8% had a negative colonoscopy or a non-adenomatous polyp. 29.3% had a non-advanced adenoma while 31.7% had an advanced adenoma. 3.25% had an invasive adenocarcinoma **(Figure 4).**

Table 1. Number of patients with a bleeding contraindication to Cologuard® prescription.

Visible Bleeding	Fecal Occult Blood	Both	Total
29	3	16	48
			123

Table 2. Number of patients with a history contraindication to Cologuard® prescription.

Family History of Colon Cancer	Personal History of Polyps	Both	Total
11	18	5	34
			123

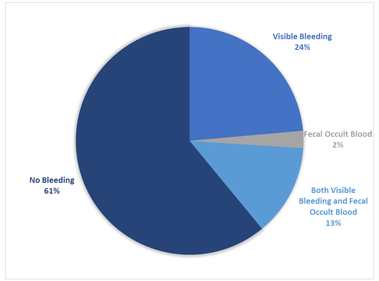

Figure 1. Percentages of patients presenting with a bleeding contraindication to Cologuard® prescription, including visible bleeding in stool and fecal occult blood.

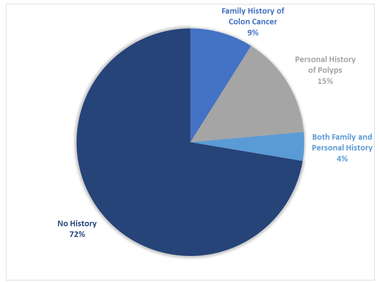

Figure 2. Percentages of patients presenting with a personal and/or family history contraindication to Cologuard® prescription.

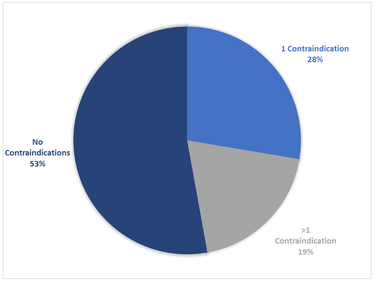

Figure 3. Breakdown of patients by number of contraindications to Cologuard® prescription.

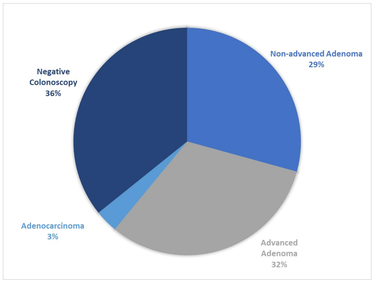

Figure 4. Colonoscopy results of 123 Cologuard®-positive patients. Negative colonoscopy (36%) includes patients with no polyp or a non-adenomatous polyp.

Conclusions

This prospective study reveals, in our large community practice, 47.1% (58/123) of Cologuard®-positive patients were tested incorrectly. Widespread erroneous testing leads to increased cost to the system and patient. Even though colonoscopy is readily accessible in our community, conversations with referring PCPs reveal that PCPs often order Cologuard® when patients are resistant to bowel prepping for colonoscopy despite being aware of contraindications.

Contact

Eesha Sachdeva, BA
Boston University School of Medicine, Boston MA
Email: eeshars@bu.edu
Phone: (919)-802-2318

References

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