Fecal Immunohistochemistry Testing for Early Colorectal Cancer Diagnosis in South Africa

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Research Question: Can point-of-care fecal immunohistochemistry tests (FIT) be used to triage symptomatic patients for urgent colonoscopy and facilitate early diagnosis of colorectal cancer (CRC) in South African public hospitals?

BACKGROUND

- Colorectal cancer (CRC) is the third most diagnosed cancer globally and its incidence is increasing across sub-Saharan Africa.[1]
- In South Africa, screening for CRC is not offered in public hospitals. Advanced stage at CRC diagnosis is common and associated with poor outcomes.[2]
- Endoscopic capacity is limited and not equitably distributed in South Africa, contributing to excessive diagnostic delays among patients with symptoms suggestive of CRC.[3]
- An accessible and affordable strategy for accurate early CRC diagnosis among symptomatic patients is needed.

METHODS

- 300 adults (≥18 years) will be recruited from two public hospitals in Durban, South Africa: Inkosi Albert Luthuli Central Hospital and Dr Pixley Ka Isaka Seme Memorial Hospital.
- Patients referred for colonoscopy with ≥1 "red flag" symptom (abdominal mass, anemia, change in bowel habits, rectal bleeding, and/or weight loss) are eligible. Patients with known inflammatory bowel disease (IBD), history of CRC, or an incomplete colonoscopy are excluded.
- All participants submit a stool sample prior to or during the colonoscopy for a point-of-care FIT (InSure™ FIT™).
- The primary outcome is the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of FIT for CRC. **Preliminary results for a composite endpoint of CRC or high-risk polyps are presented for the first 72 patients.**

RESULTS

Table 1: Cohort Demographics

Age *median (range)*	52 (17-83)
Gender	
Female	45.8%
Male	54.2%
Race	
African	47.2%
Colored	1.4%
Indian	50.0%
White	1.4%
Site	
Albert Luthuli	52.8%
Pixley	47.2%
Family History of CRC	
Yes	8.3%
No	86.1%
Don't Know	5.6%
Indications for Colonoscopy (% yes)	
Abdominal Mass	7.6%
Anemia % yes *(% unknown)*	41.7% *(31.9%)*
Change in Bowel Habits	55.6%
Rectal Bleeding	38.8%
Weight Loss	50%
Time Between Symptoms and Presentation	
< 1 month	42.9%
1-3 months	31.7%
> 3 months	25.4%

Figure 1: Breakdown of Colonoscopy Patients

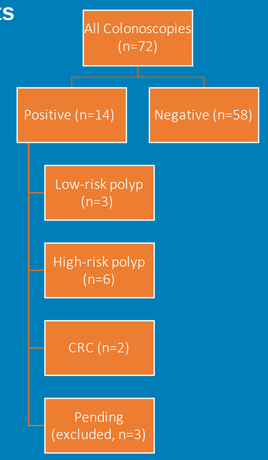

Table 2: FIT results versus colonoscopy (gold standard) for composite endpoint of colonic polyps or CRC (n=69)

	Positive Colonoscopy	Negative Colonoscopy
Positive FIT	5	27
Negative FIT	6	31

Table 3: FIT Performance Statistics for composite endpoint of colonic polyps or CRC (n=69)

Sensitivity	**45%**
Specificity	**53%**
Positive Predictive Value	**16%**
Negative Predictive Value	**84%**

RESULTS

- Figure 1 shows the total number of colonoscopies (n=72) and the breakdown of positive colonoscopies between low-risk polyps (n=3), high-risk polyps (n=6), CRC (n=2), and those with pending histology (n=3). Patients with pending histology are excluded from the FIT performance analysis.
- Baseline demographic and clinical data for included patients is presented in Table 1. The median age was 52 years, the majority of patients were male (54.2%), and the most common indication for colonoscopy was change in bowel habits (55.6%). More than half the patients reported having symptoms for >1 month.

Out of the 69 patients with complete data, 11 (15.9%) had a positive colonoscopy (9 polyps and 2 malignant lesions), while 32 (46.4%) had positive FIT.
FIT had 45% sensitivity, 53% specificity, 16% PPV and 84% NPV for the composite endpoint of polyp or CRC.

DISCUSSION AND FUTURE DIRECTIONS

- Preliminary results suggest that in symptomatic South African patients referred for colonoscopy, FIT has a moderate NPV for colonic polyps or CRC, but a weak PPV.
- Patient recruitment is ongoing (goal n=300). Final data analysis is needed to draw conclusions about the predictive value of FIT and its use in South Africa.
- After completion of recruitment, a clinical prediction model for CRC will be developed, incorporating patient demographics, clinical characteristics, and FIT results.

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