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Research Article

Risk Prediction Models for Colorectal Cancer in Middle Income Countries: A Scoping Review Used to Develop a Risk Assessment Tool for South Africa and Brazil

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Abstract

Background: There is evidence that screening for colorectal cancer (CRC) contributes towards early treatment and survival. CRC risk predictive models have been developed to assist with segmenting population by risk category for targeted screening. The models also assist to inform prevention interventions to lower incidence of CRC.

Aim: We conducted a scoping review to map and analyse published CRC risk predictive models for colorectal cancer (CRC) with the purpose to inform the development of a risk assessment tool, for potential use in South Africa (SA) and Brazil (BR), using the risk factors with high discrimination values from these published models.

Methods: We used scoping review technique, to identify and map the scientific publications on CRC risk predictive models related to SA and BR and middle-income countries. We identified the systematic reviews completed and published on the CRC risk predictive models. We reviewed each publication to identify year, countries, authors, gender, risk factors added on the model, data sources, statistical methods used and results and also allocated TRIPOD level based on the analysis of the study. We analysed publications from January 2000 to November 2021 as indexed in the Web of Science Core Collection, PubMed and Cochrane Centre. We documented and analysed each model based on Arksey and O'Malley (2005) framework for scoping reviews.

Findings: One systematic review and one scoping review publications were identified. The reviews included 59 peer-reviewed original research articles on CRC risk predictive models from both high and middle-income countries. Of these, 12 models were included with 10 models published from middle income countries and two models used global data. None of the models were developed from SA or BR. Questionnaires and medical records were used as data sources. Eight models focus on CRC and four models focused on advanced colorectal neoplasia (ACN). All models focused on CRC asymptomatic men and women as part of their study population. The risk factors assessed included demographics, medical, familiar, genetics, biomarkers, environmental and lifestyle/behavioural practices. All models were regarded to have good discrimination for CRC risks.

Conclusions: Scoping the CRC risk predictive models highlighted potential benefits of developing an evidence-based risk assessment tool and identified research gaps due to lack of existing CRC risk predictive models that can be developed to better understand the risk factors in both countries. Having validated risk factors could inform policy and planning; clinical practice particularly, health promotion as well as future research needs for increased CRC research outputs in this area particularly, as all countries strive to implement cost efficiency screening programmes through stratify the general population by risk categories to help prevent and control the CRC burden in both countries.

Keywords: Colorectal Cancer; Risk Prediction Model; Scoping Review; Developing Countries; Assessment Tool

Introduction

CRC epidemiology globally, South Africa and Brazil

Based on Globocan 2020, the new cases of colorectal cancer (CRC) were more than 1.9 million and there were 935 000 deaths due to CRC. It is anticipated that more people will suffer from CRC due to global increase of the increasing human development index. One of the critical component of the global public health response will be intensifying risk stratified screening approaches and behavioural prevention measures to reduce the incidence and ensure early detection for treatment and survival [1,2].

Colorectal cancer is ranked third among the top five most frequent cancers in both women and men in South Africa. South Africa (SA) has the highest incidence of Colorectal cancer (CRC) in sub-Saharan Africa, with the age-standardised incidence (ASRi) rate of 17.6 per 100,000 and 1.5 per 100 000 in men and women respectively in 2020. The age standardised world mortality rate (ASRm) is 7.5 per 100 000 populations [3-5].

According to the Globocan 2020, colorectal cancer is ranked third most common cancer in Brazil (BR). The ASRm is 9 per 100 000 populations while the ASRi for men is 21.7 and 17.6 per 100 000 populations for women respectively [4,5]. de Oliveira (2018) reported an increase in colorectal cancer mortality among men located in seven country states and in nine States among women [6]. An increase in both incidence and delayed access to diagnosis and treatment are factors that have contributed to an upward trajectory in mortality rate with 34.92 per 100 000 five-year prevalence cases [5-7].

Predictive models to inform risk assessment and screening

Researchers have developed risk predictive models to assist clinical practices by identifying specific populations at high risk for CRC. Considering high cost of screening and potential harms of using colonoscopy and flexible sigmoidoscopy, and low lifetime risk there is evidence to suggest targeted screening over routine and the risk predictive models play a critical role to stratify individuals by risk for CRC screening. Moreover, the risk models inform the development of risks assessment tools and health promotion and CRC prevention programmes that can be implemented in the primary health care settings [8-10].

Given access to primary health care setting for acute and chronic care, this platform has potential to screen the majority of people accessing care within the catchment geographical areas, as part of health promotion and assessment. In addition, at this level, the tool can be easily acceptable for integration by all health care workers since with other risk assessment tools already implemented including for HIV, breast and cervical cancer and TB screening in both countries [11].

Hence, predictive risk models provide adequate information and the scoping review provided a solid landscape in terms of volume of existing models and systematic reviews provides model discrimination and give direction towards their effectiveness.

Current CRC surveillance and screening practices

Currently, a pathological based registry is used to estimate CRC incidence and mortality rate in South Africa. To compensate for the lack of population-based cancer registry in South Africa, a prospective CRC study of 716 patients was launched in 2016, to describe the clinical presentation, demographics, risk factors, treatment, and outcomes recruited from both private and state health–care facilities located in Johannesburg metropolitan city of South Africa [12]. Efforts to establish a National CRC surveillance, in South Africa, are underway, learning from the Ekurhuleni National population-based cancer registry, as reported by the National Health Laboratory Services annual report of 2017.This will go a long way to assist in the development of a responsive national control strategy and accurate risk assessment tool [12].

Currently, South Africa does not have a national CRC screening policy and programme, although targeted screening occurs in targeted high risk-population in selected cities across the country. The screening modality vary by target population, including static and mobile services. The data is also used for surveillance as it is linked to the pathology-based registry managed by the country's National Health Laboratory Services. However, efforts to establish hospital-based surveillance in KwaZulu-Natal province [13].

Unlike, South Africa, Brazil has both the population national cancer registry and a national CRC screening programme, however, is reported to be opportunistic programme and only available in the Southern regions [14,15].

Lambert (2009) did not recommend mass screening for colorectal cancer in most developing countries, as the incidence is very low and may not be cost-effective noting competing demands and limited resources [16]. Kamaraju, 2020, reported that the LMICs contributed 75% of the global annual incidence and mortality from gastrointestinal cancers [17,18].

Nonetheless, it is anticipated that there will be upwards trajectory for CRC cases in lower and middle-income countries as changes in lifestyle and behaviours continue, in addition to an increase in life expectancy, improved screening, diagnosis of CRC, registration and reporting processes, as well as improved provider competencies in screening [19].

To date, studies on screening and treatment from South Africa have identified that the patients diagnosed with CRC are often di-

agnosed in late stages of cancer, particularly those accessing state-own facilities [20,21]. This impedes early treatment, increases re-occurrence and lowers survival [19]. Similarly, this observation has been reported by studies in Brazil. In addition, access; unequal availability of screening services with limited allocation in the Northern and Central Western regions, adherence to guidelines, competing demands on universal health coverage insurance were some of the factors affecting the demand for and supply of CRC screening reported from Brazil [14,15,22].

This calls for targeted and risk-based screening to improve the uptake [23]. Hence, a CRC risk assessment tool is proposed to enhance targeting for CRC screening.

Purpose, Aim and Objectives

- **Purpose:** to conduct a scoping review is to map and assess the volume of publications on CRC risk predictive models related to both countries and any other developing country similar to the two countries.
- **Aim:** to conduct a scoping review in order to develop a CRC risk assessment tool for potential use in primary health care settings as means to stratify population at risk for referral to CRC screening services in South Africa and Brazil.

The objective was to

- Identify and tabulate the CRC risk predictive models that have been developed and or validated and published on the scoping and systematic reviews or meta-analysis from middle income countries.
- Outline risk factors tested and found to have good discrimination in the model with relevant TRIPOD levels
- Propose the draft risk assessment tool for consideration in SA and BR based on significant factors identified from the models.

Methods and Materials

We identified the systematic reviews completed and published on the CRC risk predictive models. We reviewed each publication to identify year, countries, authors, gender, risk factors added on the model, data sources, statistical methods used and results and also allocated TRIPOD level based on the analysis of the study. We documented and analysed each model based on Arksey and O'Malley (2005) framework for scoping reviews PubMed/Medline, Google Search, Academia, Research gate, Web of Science and Cochrane database were included as part of the search, focusing on peer reviewed journal from January 2000 to November 2021 [24].

The search was limited to articles published in English or with abstracts translated in English. The research terms used were" Colorectal, colon cancer; colon neoplasm, risk predictive models/score, risk assessment, worldwide, South Africa, Brazil, developing country, meta-analysis, systematic, scoping review". Only scoping reviews, systematic reviews and meta-analysis articles were included with models highlighted in these reviews. Further search of each article was done only if included in the analysis to gain better understanding of the study design, population and key findings.

Inclusion Criteria	1	Systematic, meta-analysis or scoping reviews
	2	Published articles or abstracts written in English
	3	Published from the developing countries specifically middle-income countries (upper or lower) based on World Bank* criteria with English translation of an abstract or article
	4	Risks for CRC cases on adult asymptomatic population 18 years and over
		CRC, colon, rectal cancer, advanced colon cancer
	5	All Study designs and all settings identified by articles as stated in point 1 above.
Exclusion	1	Risk models developed and calibrated in developed countries
	2	Risks models developed for symptomatic, metastasis or coping mechanism, reoccurrence or survival

Table 1: Eligibility criteria for selecting studies.

*World Bank (2021) = gross national income per capita between (USD 4,096 -12,695) [18].

Since South Africa and Brazil are both members of the BRICS partnership with Indian, Russia and China and are regarded as high middle-income countries, we therefore, identified other predictive models, from the recent systematic review completed, from China, Asian region or globally.

Each study was tabulated to highlight basic characteristic of the study, according to Author, year of publication, study location,

study design, gender of target population, outcome of the model, risk factors analysed, analysis method and results, data sources, and TRIPOD level.

Results

Two systematic reviews and one scoping review publications were identified by Usher_Smith (2016) and Samarakoon, (2017); reviewed and reported with the TRIPOD levels of each model as indicated in Table 2 [25-42]. The reviews included 59 peer-reviewed original research articles on CRC risk predictive models from both high and middle-income countries. The majority of these models have been developed in high income countries mostly with high CRC burden such as United States, United Kingdom, Japan and Netherlands, hence were excluded [18,25,26]. The main finding from this scoping review is that none of the risk predictive models have been developed or validated or calibrated in South Africa and Brazil [25-43].

Of these, 12 models were included in this scoping review with 10 models were published from middle income countries similar to SA and BR. The models were published between the year 2009 and 2021. There were also two risk predictive models, that were included, developed or validated using global population. One model used case control study design and the one used a meta-analysis approach [27,32]. Three models were excluded as they met the exclusion criteria as stated in Table 1 above, including one from South Africa [19]. This model from South Africa, published in 2021 focused on recurrence of CRC and survival, hence it was also excluded [19]. The only risk predictive model developed in Africa, was published and tested in Tunisia, which was a prospective study and only used three factors (age, meat and milk consumption) [43].

In terms of data sources, ten models used questionnaires while 2 used questionnaires with medical records with or without a blood test as the main data source. Eight models focused on CRC and four models focused on advanced colorectal neoplasia (ACN). All models focused on CRC asymptomatic men and women as part of their study population. The risk factors assessed a combination of risk factors including demographics, medical, familiar, genetics, biomarkers, environmental and lifestyle or behavioural practices. All models were reported to have good discrimination of the factors [25,32].

In terms of study design, only one model, was an epidemiologic prospective study published from Tunisia in North Africa [43]; seven models published of which five were from China, used case-control design; two models used cross-sectional study published from Asia region [41] and China [28]; one used faecal immunochemical test with a scorecard published from Taiwan [29], and one reviewed random effects models of the logarithms of risks across published global studies [24]. In terms of statistical analysis methods, seven models used multiple logistic or logistic regression statistical analysis method for analysis; one model used the meta-analysis; one model used the Cox proportional hazards regression model; and two models used beta-coefficients values for analysis to determine risk factor discrimination.

Seven models were in the development stage only (TRIPOD 1a); two models were in development and validation using resampling (TRIPOD 1b); one model was in development and validation using non-random resampling and was also used for validation only (TRIPOD2a, 4); and two models were in development and validation using separate data (TRIPOD 3).

Discussion

This mini scoping review included published systematic and scoping reviews articles published between 2000 and 2021. A total of twelve existing models that meet the inclusion criteria were included. The strengths of the models are that: 1) all used and analysed a combination of factors, including medical, family history, demographics, genetics, phenotypical and lifestyle factors, the sample sizes were large for generalisability; and that 2) the study designs and statistical methods employed produced results showing good discrimination as measured by (AUROC, 95% CI) and enabled findings to be generalisable. The main weakness is that the majority of these models have not been validated in diverse countries and populations and that a meta-analysis has not been inclusive of the majority of those recently published after the year 2013 [29].

Comprehensive search was conducted using different databases and screening abstracts of the articles as a first step to identify relevant articles for inclusion. The time frame also improved the volume of models that were identified and ensured that the analysis was up to date, noting that all models up to November 2021 were included.

As none of the predictive models were tested or developed in South Africa or Brazil. Kruger (2020) reported on symptoms experienced by patients that had colonoscopy and found to have CRC [44]. The symptoms included weight loss; rectal bleeding; diarrhoea or constipation; asymptomatic anaemia; alteration in bowel habit and abdominal pain. Two of the symptoms were included

Author Year	Out come	Study Design	Factors included in a score	Score C Statistic or Relative Risk (RR) with confidence interval (CI)	Calibr ation	TRIPOD Level	Data source	Statistical Methods used	Population
Global/ Worldwide									
Dunlop_ 2013	CRC	Case Control Study	Age, gender, first degree relative with CRC	0.59	PPV=0.71 NPV=0.51	3	Question-naire and blood test for genet-ics	Multiple logistics regression	Develop-ment and Cross validation/ bootstrap
Johnson_ 2013	CRC	Literature review using random ef-fects models of the loga-rithms of risks across studies	Body mass index (BMI), smoking, first degree relative with CRC, physical activ-ity, alcohol, Irritable bowel diseases (IBD), hormone therapy (current/ former), aspirin, NSAIDs	Significant risk factors include inflammatory bowel disease (RR = 2.93, 95% CI: 1.79-4.81); CRC history in first-degree relative (RR = 1.79, 95% CI: 1.60-2.02); body mass index (BMI) to overall population (RR = 1.10 per 8 kg/m^2 increase, 95% CI: 1.08-1.12); physical activity (RR = 0.88, 95% CI: 0.86-0.91 for 2 standard devia-tions increased physical activity score); cigarette smoking (RR = 1.06, 95% CI: 1.03-1.08 for 5 pack-years), and consumption of red meat (RR = 1.13, 95% CI: 1.09-1.16 for 5 servings/week), fruit (RR = 0.85, 95% CI: 0.75-0.96 for 3 servings/day), and vegetables (RR = 0.86, 95% CI: 0.78-0.94 for 5 servings/day).	None	1a	Question-naire	Meta-Analysis	N/A
Asia Region									
Yeoh-2011_ Asia	ACN	Hospital based cross sectional study	Age, gender, smok-ing, first degree relative with CRC,	0.66 (0.62-0.70)	p.0.29	3	Question-naire	Risk points allocated based on Beta-coeffi-cient	Develop-ment population only
Samara-koon_2019 _Sri Lanka	CRC	Case control study	Older age, frequent deep fried food, frequent red meat consumption, first degree relative with CTRC or other cancers at 60 years or under; history of hypertension for 10 years, IBD before 10 years and polyps before 10 years	0.849 (0.8 to 0.9)	95% CI: 0.8 to 0.9, P<0.001). It has a sensitiv-ity of 76.9%, specific-ity of 83.1%, positive predictive value (PPV) of 82.0%, negative predictive value (NPV) of 79.3%	1a.	Question-naire and medical records	logistic regression model	Develop-ment population and cross population validation

China									
Wei_2009	CC	Hospital based case control study	BMI, smoking, first or second degree relative with CRC, alcohol	0.61(0.59-0.63)	None	1a.	Questionnaire	Logistic regression	Development population ross_Validationn and sub-set population
Cai_2012	ACN	Hospital based cross sectional study	Age. gender, smoking, diabetes mellitus, green vegetables, pickled food, spiced food, white meat	0.74(0.72-0.77)	P=0.77	2a. 4	Questionnaire	Risk points allocated based on beta-coefficients values	Bootstrap/ Cross Validation
Chen_2013	ACN	Hospital based Case control study	Age, smoking, alcohol	0.66 (0.62-0.68)	None	1b.	Medical Records	Multiple logistics regression	Bootstraps/ cross validation
Chen_2014	ACN	Hospital based Case control study	Age, gender, history of coronary heart disease, egg intake, defecation frequency	0.75(0.70-0.82)	None	1b.	Questionnaire	Risk points allocated based on Beta-coefficient	Bootstraps/ cross validation
Xin_2019	CRC	Hospital based case control study	Genetic and phenotypic factors	0.61(0.58-0.63)	None	1a.	Medical Records and blood tests	Multivariate logistic regression	Development population
Chen, 2021_Taiwan	CRC	FIT test, a user-friendly CRC scorecard	Family history, body mass index (BMI), smoking, drinking, inactivity, hypertension, diabetes, carcinoembryonic antigen, and C-reactive protein.	C statistic =0.81	None	1a.	Questionnaire/ medical screening and quantitative FIT.	Cox proportional hazards regression model	Development population
Africa Region									
Guesmi_2010_ Tunisia	CRC	Epidemiologic prospective study	Age, meat and milk consumption	age 40/60 years (OR: 5.15), processed meat consumption; frequent/ rare (OR: 5.1), milk consumption rare/frequent (OR: 7.07)	None	1a	Questionnaire	Multivariate logistic regression	Development population

Table 2: Risk predictive models from Middle Income Countries.

Data sources: Usher_Smith (2016) and Samarakoon (2017).

Notes

CRC: Colorectal Cancer; CAN: Advanced Colorectal Neoplasia; PPV: Positive Predictive Value; NPV: Negative Predictive Value; OR: Odds Ratio; NSAIDS: Non-Steroid Anti-Inflammatory Drugs

TRIPOD guidelines

1a: DEVELOPMENT only; 1b: Development and validation using resampling; 1c: Random; 2a: Non_random; 2b: Split sample development and validation; 3: Development and validation using separate data; 4: Validation only

in the CRC risk predictive models (alteration of bowel habits and weight in the form of BMI). The increasing prevalence of obesity, lack of physical activity among people living in urban areas; excessive, alcohol and tobacco use as well as environmental and genetics based on family history have been reported to have adequate evidence for identifying high CRC risk groups [15,21,31]. Hence, the introduction of a risk assessment tool, could promote behaviour change and assist to reduce other non-communicable diseases [4,11,45]. Because of patient stratification by risk, the tool assists health care providers to limit the number of patients referred for CRC screening. This approach could reduce screening costs and reduce any other complications associated with the tests.

The algorithm of the tool can be structured similar to the one developed in the United States by National Health Institute and the one from the United Kingdom developed by Hippisley-Cox (2011), using primary risk factors to identify clients at high risk for CRC in primary health care settings [46]. The primary risk factors that can be considered include (demographic; lifestyle; medical and family history, including age, sex, prior screening history, lifestyle and/or genetic information, family history and GIT symptoms) [11,46], as tabulated in Table 3 below.

Components	Risk Factors
Demographical Information	Age 45+ years Gender Male Female BMI>27 Weight Height
Medical History	Prior CRC screening Other cancers Change in bowel action or discomfort (constipation, pain, cramps, gas, diarrhoea, stool inconsistency) Medication: aspirin, non-aspirin, contraceptive pills or replacement therapy (women)
Lifestyle Patterns	Smoking (14+ cigarette/day) Alcohol (>1 drink /day)
Family History	First degree relative diagnosed Family member with Lynch Syndrome

Table 3: Proposed CRC Risk Assessment tool for South Africa and Brazil.

Note: If a patient answers "YES" to all or 3 tool components (1-4 or 3 making up of a combination of 1-4), refer for gFBOT screening cleared by the resident medical doctor or manager at the facility.

This risk assessment tool can also be used as a self-assessment by individuals in the privacy of their homes to assist with decision making for CRC screening and linkage to services. Further work can be done to allocate scores and weights using the South African CRC surveillance data. The tool can also be piloted and validated to ensure that it has potential to increase efficiency for screening uptake as recommended based on data that only those at moderate and high risks will be preferred [6,47]. The tool can also complement the current hospital cancer surveillance systems located in 3 tertiary public sector hospitals located in KwaZulu-Natal province, SA, as most common cancers are from eThekwini metropolitan and uMgungundlovu the two most populated cities in this province [13]. In addition, from the hospital surveillance system, CRC was top three of five most common cancers diagnosed from the three hospitals.

Besides improving efficiency in screening by grouping patients accessing PHC into risk categories; the data collected could also improve effectiveness by identifying the eligible age for screening; scores that better categorise patients by risk, guide the integration of the assessment with other screening tools; identify uptake; patient and health care provider views on the use of the tool. Moreover, the tool could be evaluated for robustness to distinguish better those most at risk [48].

To increase access and use of the tool, other conducive platforms can be identified where the risk assessment tool can be marketed for use, especially in social media platforms, to widen coverage, expand motivation and mobilisation to increase screening uptake by first-time users and young people, especially males that have higher ASRi in South Africa and in women and men in Brazil [2-4].

The systematic review of risk assessment tools in primary health care settings, the authors identified benefits of using the tool to boost clinician confidence and better facilitate appropriate referral patterns between PHC and tertiary levels where actual CRC screening will take place. However, the tools were most successful when used by patients concerned about their health based on family history of cancer; used by a dedicated clinician; used with health promotion messages and when supported by decision support for next steps. Likewise, Kamaraju (2020) recommended tobacco and alcohol control as part of health promotion as this was found to be cost-effective prevention measures for low and middle -income countries [17].

Hence, these recommendations points to interconnectedness and link of tools to referral guidelines; screening guidelines and other information, educational and communication materials necessary for the interpretation of findings and in mapping next steps for the patient. The tools that link decision options helps to streamline the next steps for both clinicians and patients [46]. Equally, cost-effectiveness study recommended that screening be started earlier for men than women to attain cost and health benefits [49].

Reducing barriers to screening has potential to strengthen referral pathways and continuum of care as some studies had reported low screening uptake among high-risk population [50,51]. Sociodemographics, patients' attitudes, beliefs, health literacy, cultural influences, together with inadequate number of facilities equipped with cancer screening tools, and lack of access to health care have been cited as factors preventing timely screening [52,54]. Elimination of patients, providers, and health systems related barriers to CRC screening uptake, was recommended by Kaminski (2020) and Levin (2018) as well as patient education promoting benefits and importance of screening has shown to improve the uptake of screening [54,55], as reported by other studies [42,57,58].

Limitations

The weakness, firstly, is that the most models identified and included from developing countries were from China. Secondly the risks factors identified cannot be extended to those with familiar syndromes or already diagnosed with CRC. Despite that, the literature of multiple electronic databases and the broad inclusion criteria as well as good discrimination found from these models tested with asymptomatic population were key strengths of the review. Furthermore, most of the models used a combination of clinical indicators to lifestyle, family history and genetic factors. Lastly, none of the models were calibrated and scoping review does not evaluate their discriminative power [36]. The limitations identified points to potential capacity for development and calibration of CRC risk models in SA and BR using large-scale, population-based data to identify risk by category.

Conclusion

In conclusion, this study highlights for the first time the importance of conducting scoping reviews to outline the landscape of risk predictive models in Africa and South America in order to identify critical gaps and potential options for consideration. The existing models outlined by published scoping and systematic reviews can be calibrated in both South Africa and Brazil, as means to build a body of evidence in each country. Doing so, will assist to further finalise the development of CRC assessment tools that could help with the segmentation of the general populations by risk category. Cost-effectiveness studies and testing the implementation of the existing models in clinical practice to document lessons and assess feasibility of application in different primary health care settings could be considered at this stage in the absence of SA and BR current models. There is also a need to invest in research to advance innovation efforts for CRC prevention and control in both countries. Developing robust surveillance systems, risks assessment tools and diverse non-invasive screening modalities can enhance understanding of CRC burden and inform appropriate differentiated prevention, screening and care approaches feasible for the primary health care settings. Development of basic risk assessment algorithms is critical for early detection for those with unknown susceptibility. However, the tools need to be user-friendly, quick and easy to interpret the findings and can direct both clinicians and patients towards appropriate next steps on the CRC screening continuum of care in both countries.

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