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An Assessment, with NICE Guidelines as a Benchmark, of Delay to Care in a Cohort of Colorectal Cancer Patients Seen in the Witwatersrand University Academic Complex

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Abstract

Background: Colorectal cancer (CRC) in South Africa (S.A) is the second most common in women and the third in men. Worldwide it is the second most deadly cancer. As a subset, colon cancer is the fifth most deadly with an estimated 551,000 deaths in 2018. CRC makes up 5.8% of all cancer-related deaths globally. Despite this, there are no screening programmes in S.A, with a diagnosis being largely dependent on symptomatology. Additionally, there is no clear understanding of the significance of the outcome imposed by delay in referral and treatment. Unlike countries in Europe, South Africa has no guidelines defining cut-offs for acceptable delays in this context. **Methods:** A retrospective study was done on the delay in referral, diagnosis, and treatment of CRC patients. A cohort of patients in which surgery was the primary treatment that was presented to Witwatersrand Academic Hospitals was studied. Delays were benchmarked against fourteen days from primary contact to consultation with a specialist and consultation to treatment delay of more than 31 days. Definitive treatment delay was defined as the time from referral to the treatment centre and tumour resection of more than 62 days. Outcomes were evaluated by defining the 90-day mortality. **Results:** The median referral delay was 78 days, for treatment delay was 54 days and for definitive treatment delay was 175 days. Of the 587 patients analysed, 341 had therapeutic surgery, 17 demised within 90 days post-surgery. Longer delays and higher mortality rates were seen in the public sector and a lower socio-economic group of patients. **Conclusion:** The time parameters set out by the NHS and Europe were not met. There were greater delays seen in patients with lower socio-

economic backgrounds and in those attending the public sector. The effect of delays on 90-day mortality is doubtful. Delays to care both outside of hospitals and in hospitals may be a point of investigation in future studies.

Keywords

Treatment Delay, Colorectal Cancer, 90 Day Mortality, Pathways to Care

1. Introduction

The incidence of colorectal cancer (CRC) in the developing world has been shown to increase each year. Demographic trends have reflected an expected increase in incidence by 80% within the next two decades. Most of this increase has been expected to occur in less developed regions (62%). This has been accompanied by a proportional increase in the yearly reported mortality rates reflecting the inability of health services to deal with the demand of the burgeoning incidence in the circumstance of poverty [1]. In 2018 alone, over 1.8 million new cases were identified and 881,000 deaths occurred worldwide. This ranks CRC globally as the third most common cancer in terms of incidence and the second most common cause of cancer-related death globally [2].

In South Africa, we have no convincing data on the yearly change in the incidence of colorectal cancer or the change in the associated mortality rate [3]. The national cancer registry (NCR), which provides statistical updates, has not up to date. However, in the last updated registry, NCR pined this malignancy as the third most common in women and the second most common in men [4]. At present, the population-based data regarding colorectal cancer in South Africa has been scanty. In the absence of national data, it has been the clinician's responsibility to use hospital-based data to determine current statistics and to monitor outcomes within their institution.

With this in mind, we were interested in identifying possible management deficiencies in the pathways to care in CRC. Using United Kingdom (UK) and European guidelines for treatment quality. We have subjected our cohort of patients to an evaluation of various delays in management to see if this has had a bearing on the outcome.

The direct comparison of these patients with those in the UK and Europe was not feasible, but we attempted to see how the delays in our pathways to care in CRC compare with the stipulated requirements of best quality of management defined by the National Health Service (NHS) and services in the European Union.

In South African Health care facilities, there have been no attempts made to determine indices of best practice in CRC treatment pathways. Interruptions incurred both in getting into the health system as well as delays within the system may be worth exploring in this context. Internationally, the effect of delays to referral and treatment on outcomes has shown mixed results [5]. Most re-

search on this topic from Europe has shown that diagnostic and treatment delay has not been shown to decrease survival [6]. In the United States, some components of delay were examined with similar findings [7]. However, in developing countries, where CRC treatment pathways are new or poorly developed, lengthy delays has been commonplace. From Taiwanese data, treatment within 30 days of confirmed diagnosis questionably decreased the risk of death while delays beyond 90 days unfavorably impact outcomes [8].

Despite these discrepancies, the Cancer Research Society UK has produced three broad time periods. If we followed the recommendations of Cancer Research UK, patients with suspected cancer were to be seen within 2 weeks of referral/presentation by a specialist. This time interval supports early diagnosis and improved survival of patients. Once the decision to treat cancer is made, the first cancer treatment is to be started within the first 31 days of this decision. The First definitive treatment of cancer was to occur within 2 months/62days from the initial GP referral/presentation of the patient. [9] These time frames have been used as targets in the UK and European Union. They are not official targets at local hospitals. We have hoped to compare the local data in our cohort of patients used in this study to these.

The primary aim of this study is to determine if time delays in caring in our population compared to that in the UK as benchmarked against the stipulated NHS standards. The secondary aim of this study is to determine 90-day mortality of colorectal cancer post-major resection. This may provide some insight into the circumstances of a cohort of South African CRC patients as they pass through care and whether delays as describe having any bearing on these outcomes.

2. Methods

2.1. Data Sources and Study Population

Ethics approval was obtained from the University of Witwatersrand, Johannesburg, South Africa, and the Human Research Ethics Committee (Certificate number M1811110). Subjects used were enrolled on the REDCap database: MRC Prospective Colorectal Cancer Database. Data obtained was on 587 adult patients (≥18 y at enrolment) with histologically confirmed colorectal cancer (CRC). Only patients with adenocarcinoma were selected. Enrolment for the study was over the period 1 Jan 2016-31 Dec 2019 (last follow-up on 31 Mar 2020). The following study centres were included: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Chris Hani Baragwanath Academic Hospital (CHBAH), Wits Donald Gordon Medical Centre (WDGMC) and Edenvale Hospital, which are part of the major centres in the circuit that treat colorectal cancer. CMJAH and CHBAH are tertiary institutions within public service, whereas WDGMC is a tertiary university hospital within private practice. Edenvale Hospital is a public-based secondary treatment hospital that refers to CMJAH. Patients with recurrent cancer, patients with synchronous lesions, patients with anal carcinoma, patients who had received treatment before being seen at the

specialist centre, patients diagnosed more than 1 year before presentation at the specialist centre were excluded from the study. In order to define the population and for reasons of analysis, the independent variables analysed were derived from demographic domains, socioeconomic status, treatment intent and tumour/patient specific data. Demographic data analysed from the database included: age at the first visit, gender and ethnicity. Instruments pertinent to socioeconomic status (SES) that were used include centre at which treatment was received, healthcare sector (public/private), the number of people per household, employment status, highest level of education (HLOE) and SES assets score (range 0-11). Tumour specific data included was defined by location/sidedness of malignancy, AJCC staging of the CRC. The patient's clinical makeup was determined by: ECOG status and initial definitive treatment received (therapeutic surgery/radiation/chemotherapy).

The dependant variables measured in this study are specific timelines which included: date of primary consult (with GP/at primary care centre), date of first visit to specialist centre, date of first definitive treatment (if any), date of first therapeutic surgery (if applicable), date of death/date last seen. The timelines used are illustrated in the diagram below (Figure 1).

2.2. Data Analysis

Patients recruited at Edenvale hospital were grouped with the CMJAH patients. An overall SES score was derived from employment status, HLOE, the number of people in household, and the 11 assets (for data collected from Nov 2016 onwards) using Principal Component Analysis (PCA) (ref: Vyas, 2006). The first component was used as the SES score, which was then categorised as the lowest 40% of households as "poor", the highest 20% as "rich" and the rest as the "middle" group (Filmer and Pritchett, 2001).

Initial treatment (date and type) was derived from treatment after the first specialist centre visit: Therapeutic surgery was taken as surgery done to resect tumour in its entirety for cure. Palliative procedures were not considered as therapeutic surgery. The earliest treatment (of surgery/chemo/radiation) was taken

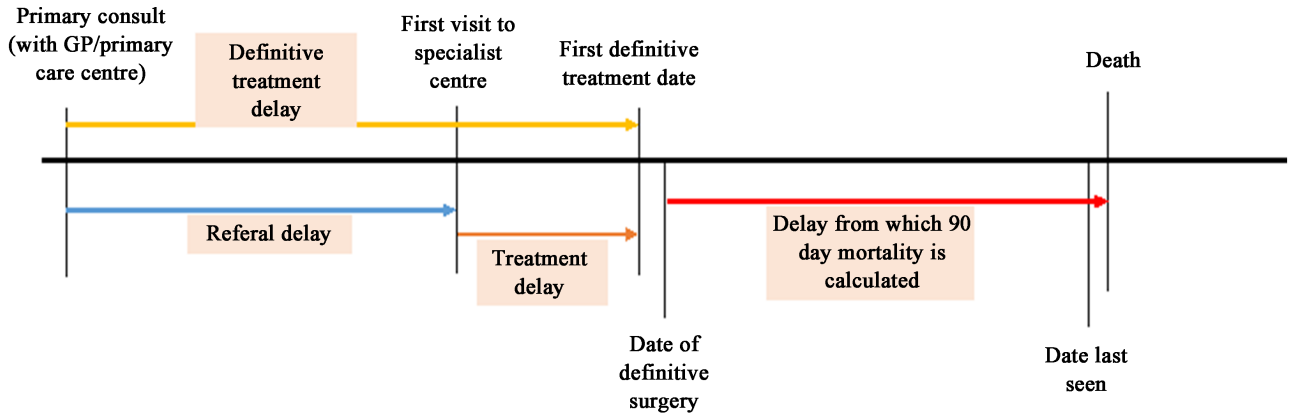

Figure 1. Timeline ti treatment.

as the initial treatment. Some patients, therefore, had no treatment, and this study only considers those patients managed with curative intent.

90-day mortality was determined for all therapeutic surgeries (as defined above) carried out prior to 31 Dec 2019. Where a patient had more than one therapeutic surgery, the first surgery was considered. The p-values provided in the tables are the p-values for the overall analysis of the different groups. If the p-value is ≥0.05, nothing further was done. If the p-value was <0.05, then the significant differences where determined. If the overall test was significant, then the following was done.

Referral delay (percentage exceeding 14 days), as well as 90-day mortality after definitive surgery, was compared between groups (age, gender, ethnicity, centre, healthcare sector) using the X^2 test (Fisher's exact test was used for 2 × 2 tables or where the requirements for the X^2 test could not be met). Treatment delay and Definitive treatment delay were compared between groups using competing-risks Cox Proportional Hazards regression analysis, with death as competing event and censoring for those who had neither had definitive treatment nor died.

Data analysis was carried out using SAS version 9.4 for Windows. A 5% significance level was used.

3. Sample Size

As a starting point, we assumed a definitive treatment delay of 75% within 62 days. Based on a prevalence of a risk factor (e.g., age > 50 y) of 50%, the detection of a hazard ratio of at least 1.3 with 80% power at the 5% significance level required minimum sample size of 608 patients. (Or HR 1.35 requires 465 patients).

Inclusion/Exclusion Criteria

716 patients were enrolled onto the MRC Prospective Colorectal Cancer Database between 1 Jan 2016 and 31 Dec 2019. All patients had histologically confirmed primary adenocarcinoma of the colon or rectum. All patients were aged 18y or older. The following patients were excluded from our analysis of the MRC database; we excluded: 1 from a non-qualifying centre, 1 with unknown date of the first visit to the specialist centre, 81 who had received treatment before being seen at the specialist centre, 36 with recurrent cancer, 8 with synchronous lesions, 2 with missing referral date.

A total of 129 patients were excluded, leaving 587 patients included in the study.

4. Results

4.1. Study Sample

Of all the 587 patients analysed, 264 were diagnosed with either left or right sided colon cancer and 323 had rectal cancer. Of the greater than fifty age group 73.8% of the population were analysed. There was an almost even distribution

between male and female patients.

Characteristics of the study samples and cancer location are provided in Table 1.

Table 1. Selected characteristics of colorectal cancer patients.

		Overall	
n		**587**	
Variable	**Category**	**n**	**%**
Age at first visit (y)	≤50 y	154	26.2
	>50y	433	73.8
Gender	Male	301	51.3
	Female	286	48.7
Ethnicity	Black	307	52.3
	White	206	35.1
	Indian	38	6.5
	Coloured/ mixed race	33	5.6
	East Asian (e.g., Chinese)	2	0.3
	Other	1	0.2
Study site (recruitment)	CHBAH	216	36.8
	WDGMC	190	32.4
	CMJAH	181	30.8
Study site (recruitment) (grouped)	State	397	67.6
	Private	190	32.4
SES class (from PCA) (recruitment 1 Nov 2016 onwards; n = 481)	Wealthy	95	20.0
	Intermediate	191	40.1
	Poor	190	39.9
	Unknown	5	
SES class—STATE	Wealthy	18	5.6
	Intermediate	121	37.9
	Poor	180	56.4
	Unknown	4	
SES class—PRIVATE	Wealthy	77	49.0
	Intermediate	70	44.6
	Poor	10	6.4
	Unknown	1	
Location of malignancy	Colon: right	112	19.1
	Colon: left	152	25.9
	Rectum	323	55.0

Continued

AJCC staging	Stage 1	40	7.6
	Stage 2a	73	13.9
	Stage 2b	14	2.7
	Stage 2c	13	2.5
	Stage 3a	7	1.3
	Stage 3b	82	15.6
	Stage 3c	122	23.1
	Stage 4a	112	21.3
	Stage 4b	64	12.1
	Unable to stage	60	
AJCC staging (grouped)	Stage 1 or 2	140	26.6
	Stage 3 or 4	387	73.4
	Unable to stage	60	
ECOG status	Grade 0: Fully active, able to carry on all pre-disease performance without restriction.	128	26.7
	Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	208	43.4
	Grade 2: Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.	98	20.5
	Grade 3: Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.	42	8.8
	Grade 4: Completely disabled; cannot carry on any self-care; totally confined to bed or chair.	3	0.6
	Test not done/not recorded	108	
ECOG status (grouped)	Grade 0 - 2	434	90.6
	Grade 3 - 4	45	9.4
	Not done/not recorded	108	
Initial Treatment	Surgery	229	39.0
	Radiation	171	29.1
	Chemotherapy	99	16.9
	None	88	15.0

*Age of first visit is tabulated in years(y) as either less than or equal to fifty (≤50) or more than fifty (>50). *The standard deviation of age of first visit was 13.5 and the range was 18 - 91.

4.2. Referral Delay

The median referral delay was 78 days (IQR 23 - 201 days) (range 0 - 1319 days). The distribution of the data is shown below (Figure 2).

The data below shows the following in Table 2:

Overall, 83.3% of the patients in the study had a referral delay in excess of 14 days. This percentage was significantly higher for:

- Black compared to white patients.

*there was no significant difference found between the other ethnicities.

- CHBAH patients compared to WDGMC patients.
- State patients compared to private patients.
- Intermediate/Poor SES patients compared to Wealthy SES patients.

There were no significant differences with regard to age and gender.

4.3. Treatment Delay

88 patients had no treatment; of these 68 died (competing risk which is an event which precluded the occurrence of the primary event of interest) and 20 are still awaiting treatment (or had refused treatment) (censored time to treatment). All these patients and both of these factors are taken into account in the subsequent analysis and were excluded from the analysis.

The median treatment delay was 56 days (IQR 20 - 125 days). The cumulative incidence function for treatment is shown below (Figure 3).

4.4. Treatment Delay

Overall, 64.5% of patients had a treatment delay in excess of 31 days. This percentage was significantly higher for:

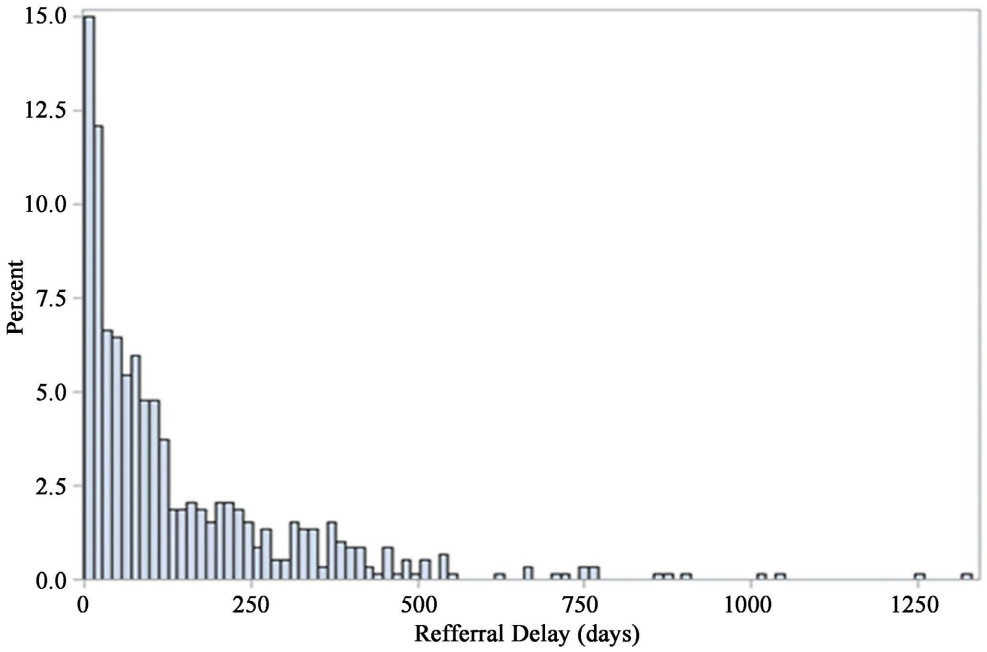

Figure 2. Percentage of patients delayed to referral.

Table 2. Referral delay.

Variable	Category	n	Referral delay > 14 days	
			% Of patients	p-value for between-group test
Overall		587	83.3	
Age at first visit (y)	≤50 y	154	81.2	0.45
	>50 y	433	84.1	
Gender	Male	301	85.4	0.18
	Female	286	81.1	
Ethnicity	Black	307	87.0	
	White	206	77.2	0.022
	Indian	38	89.5	
	Coloured/mixed race	33	81.8	
	East Asian (e.g., Chinese)	2		>0.05
	Other	1		
Study site (recruitment)	CHBAH	216	93.5	
	WDGMC	190	73.2	<0.0001
	CMJAH	181	81.8	
Study site (recruitment) (grouped)	State	397	88.2	<0.0001
	Private	190	73.2	
SES class (from PCA) (recruitment 1 Nov 2016 onwards; n = 481)	Wealthy	95	73.7	
	Intermediate	191	90.6	0.0004
	Poor	190	87.4	
	Unknown	5		

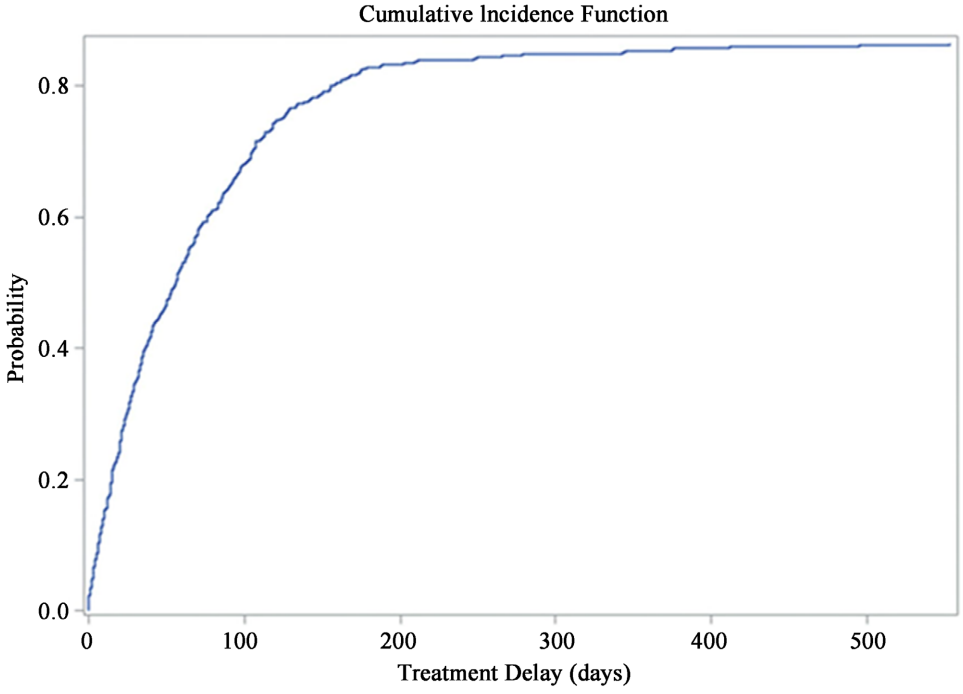

Figure 3. Cumulative incidence of treatment delay.

- Black compared to white and Indian patients.

  *there were no significant differences found between the other ethnicities.
- Patients from different hospitals in the order CHBAH > CMJAH > WDGMC.
- State patients compared to private patients.
- SES in the order Wealthy > Intermediate > Poor.

There were no significant differences with respect to age and gender (Table 3).

4.5. Definitive Treatment Delay

Definitive treatment delay was calculated by adding, referral delay to the Treatment delay and applying a cut off of 62 days.

88 patients had no treatment; of these 68 died (competing risk) and 20 were still waiting for treatment (or had refused treatment) (censored time to treatment). All these patients and both of these factors are taken into account in the

Table 3. Treatment delay.

Variable	Category	n	Treatment delay > 31 days	
			% Of patients	p-value for between-group test
Overall		587	64.5	
Age at first visit (y)	≤50 y	154	62.6	0,37
	>50 y	433	65.1	
Gender	Male	301	63.7	0,52
	Female	286	65.3	
Ethnicity	Black	307	71.1	<0.0001
	White	206	55.7	
	Indian	38	59.0	
	Coloured/mixed race	33	66.7	
	East Asian (e.g., Chinese)	2		>0.05
	Other	1		
Study site (recruitment)	CHBAH	216	78.9	<0.0001
	WDGMC	190	44.6	
	CMJAH	181	68.1	
Study site (recruitment) (grouped)	State	397	74.4	<0.0001
	Private	190	44.6	
SES class (from PCA) (recruitment 1 Nov 2016 onwards; n = 481)	Wealthy	95	49.6	<0.0001
	Intermediate	191	63.1	
	Poor	190	72.6	
	Unknown	5		

subsequent analysis.

The median definitive treatment delay was 172 days (IQR 78-406 days). The cumulative incidence function for definitive treatment is shown below in Figure 4.

Overall, 79.0% of patients had a treatment delay in excess of 62 days. This percentage was significantly higher for:

- Black compared to white and Indian patients; Mixed race compared to white patients.

*no significant differences were found between East Asia and other ethnicities.

- Patients from different hospitals in the order CHBAH > CMJAH > WDGMC.
- State patients compared to private patients.
- SES in the order Wealthy > Intermediate > Poor.

There were no significant differences with respect to age and gender (Table 4).

4.6. 90-Day Mortality after Therapeutic Surgery

There were 341 therapeutic surgeries in the study period which had at least a 90-day follow-up period.

The overall 90-day mortality was 17/341 = 5.0%. This percentage was significantly higher for:

- Patients from CHBAH and CMJAH compared to WDGMC.
- State patients compared to private patients.

There were no significant differences with respect to age, gender, ethnicity or SES.

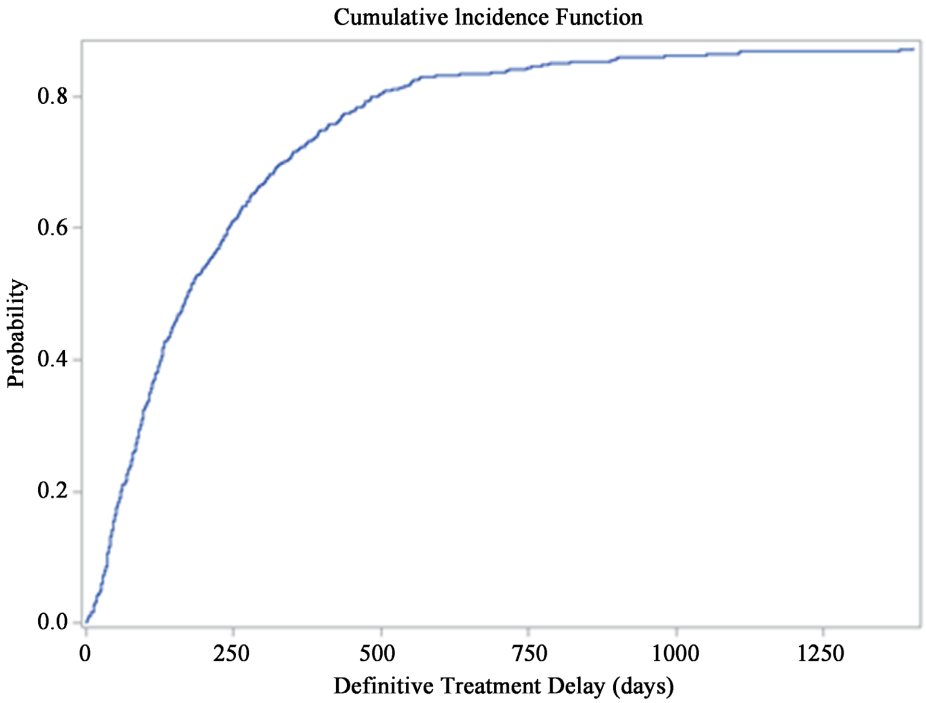

Figure 4. Cumulative incidence of definitive treatment delay.

Table 4. Definitive treatment delay.

Variable	Category	n	Definitive Treatment delay > 62 days	
			% Of patients	p-value for between-group test
Overall		587	79.0	
Age at first visit (y)	≤50 y	154	78.3	0.64
	>50 y	433	79.2	
Gender	Male	301	78.4	0.52
	Female	286	79.5	
Ethnicity	Black	307	84.8	<0.0001
	White	206	70.7	
	Indian	38	74.1	
	Coloured/mixed race	33	79.2	<0.0001
	East Asian (e.g., Chinese)	2		>0.05
	Other	1		
Study site (recruitment)	CHBAH	216	89.1	<0.0001
	WDGMC	190	61.8	
	CMJAH	181	83.6	
Study site (recruitment) (grouped)	State	397	86.8	<0.0001
	Private	190	61.8	
SES class (from PCA) (recruitment 1 Nov 2016 onwards; n = 481)	Wealthy	95	66.8	<0.0001
	Intermediate	191	82.3	
	Poor	190	87.0	
	Unknown	5		

The selected characteristics of patients that underwent surgery are in the Table 5.

5. Discussion

The delay in the diagnosis and treatment of colorectal cancer in the South African population is largely unexplored. Most studies from developed countries suggest that prognosis is not worsened by delay in diagnosis and treatment. However, newer international studies from less developed countries showed that delay does, in fact, increase the risk of mortality. The study described above done in Taiwan showed that the risk of death increased 1.5 times if treatment was delayed by 31 - 150 days post-diagnosis and was 1.6 times higher if the delay was more than 150 days. This study, however, did not clearly differentiate patients managed with curative intent and those managed with a view to cure which will fundamentally effect

Table 5. 90-day mortality.

Variable	Category	n (surgeries)	90-day mortality	
			Mortality (%)	p-value for between-group test
Overall		341	5.0	
Age at first visit (y)	≤50 y	85	2.4	0.26
	>50 y	256	5.9	
Gender	Male	171	6.4	0.32
	Female	170	3.5	
Ethnicity	Black	134	7.5	
	White	157	3.8	0.27
	Indian	27	0.0	
	Coloured/mixed race	20	0.0	
	East Asian (e.g., Chinese)	1		
	Other	2		
Study site (recruitment)	CHBAH	76	13.2	
	WDGMC	170	0.6	<0.0001
	CMJAH	95	6.3	
Study site (recruitment) (grouped)	State	171	9.4	<0.0001
	Private	170	0.6	
SES class (from PCA) (recruitment 1 Nov 2016 onwards; n = 279)	Wealthy	78	1.3	
	Intermediate	112	6.3	0.18
	Poor	87	6.9	
	Unknown	2		

outcomes defined by mortality. They did point out; timely treatment is found to decrease patient anxiety and improve quality of life, but this was not substantiated in the data [8].

Against this background of uncertainty, there have been no international or South African guidelines for acceptable delays in referral and treatment in this setting.

Our study clearly showed substantive higher referral delays and treatment delays when compared with the NHS and European equivalent. However, this poor outcome is driven by poverty and low SES scores. Prehospital delays are probably playing a much greater role in unfavorable outcomes. Prehospital delays can be patient related or physician related. In the context of developed nations, it would appear patient related delays are significant. Patients do not recognise symptoms of concern in the unfolding natural history of CRC. They tend to self-

medicate and out of fear of possible tests and interventions that might be required avoid medical attention. Physician related factors included a lack of recognition of symptoms, inadequate investigations and avoidance of digital rectal examination [10]. All of these prehospital events were unexplored in this study but certainly need to be evaluated in future research.

Importantly, approximately 85% of the South African population is dependent on public health care. Understanding and exploring the differences in access to care between private and public health sectors have been pertinent. In this study, it has been found that patients from state sector and of lesser socio-economic status (SES) backgrounds had longer delays to referral and treatment. This has buried deeper issues in access to care. In other studies, unfavorable access to care was dependent on socio-economic status, insurance status and geographic location. ethnicity, the poor, the uninsured and rural residence [11]. Poor access immediately has its roots in long travel distances and high travel costs, high out-of-pocket payments for care, long queues, and patient disempowerment [12]. In our setting, the cause of preadmission delays in the care of the poorer patient desperately needs exploration.

As noted by the NHS "where patients wait longer, this should be because of the diagnostic process or their personal choice, not because of built-in delays in the system of care". Delays in referral and treatment were clearly demonstrated in our study. If this in itself was considered a reason for action, there is much that could be done. In a study from Minnesota, Canada, overall delay in treatment was found to be the consequence of delays in diagnosis. Simplification of steps in well-structured diagnostic pathways was seen as the solution to this issue. This is a course we could well imitate [13].

Finally, 30-day mortality has conventionally been used to reflect the peri-operative outcome. By extending mortality reporting to 90-days, this study set out maximise the number of patients with an unfavorable outcome and a greater number of mortality outliers [11]. Internationally, 90-day mortality was also used as a surrogate of surgeon's outcome and is a quality metric system by which hospitals are benchmarked [14]. Within this study group 5% of patients demised within a 90-day period post-therapeutic resection. Using this as a quality metric system in South Africa has not been explored. However, with significant differences found between the three study sites, it can be assumed that implementing such a system could benefit the future care of colorectal patients. Better service may be driven by implementing ongoing quality assessments, forcing us to reflect on management techniques and identifying areas of need.

6. Limitations

The data collected for the study was done retrospectively. Therefore data was collected with convenience sampling and are thus not representative of the general population. Additionally, only information about the patients presented to the four Witwatersrand Hospitals, used in the study was utilised. Patients seen

outside of these hospitals were not included in the study. Therefore, the sample of patients used does not represent Gauteng as a whole. Secondly, there are no reliable registries to utilise for patient recruitment. Recruitment was only possible through the activity of a research nurse, which introduced bias to the sample. Thirdly the sample size used in the study was small; when sub categorising the patients for the subgroup analysis the power of prediction was further decreased. Finally, extended delays may contribute to other patient outcomes other than death. Future research could explore the effect of delays on outcomes such as postoperative complications, hospital stay, hospital readmission, cost, quality of life, and psychosocial outcomes such as anxiety.

7. Conclusion

This study is one of the first studies in South Africa to look at delays in treatment pathways and 90-day mortality in colorectal cancer. We found that most patients did not meet the time parameters recommended by the NHS guidelines. With greater delay times seen in lower socio-economic subgroups and within the public sector. The effects of this on prognosis and mortality were not directly explored in this study. However, when looking at 90-day mortality post-surgery, it was found that a similar distribution of results was seen within the subcategories. With such discrepancies found within the subgroups, it can be assumed that developing a treatment pathway guideline would be of benefit in this setting in an attempt to improve and equalise the standard of care. In addition, monitoring 90-day mortality post-major resection could also help us reflect on institutional-based outcomes and ultimately improve the overall management of colorectal cancer patients in South Africa

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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