TYPE: ORIGINAL ARTICLE

NOTE: *OAs should not exceed 3000 words and the main text should be arranged under the headings of: Abstract, Introduction, Methods, Results, Discussion, Conclusion and References.*

TITLE:

Direct Access Colonoscopy: impact of intervention on time to colorectal cancer diagnosis and treatment in North West Tasmania

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ABSTRACT: *(Should be structured for Original Articles, as per below; no more than 250 words.)*

Background: Direct access colonoscopy (DAC) allows general practitioners to refer directly for colonoscopy, without specialist review. Research suggests DAC reduces times to diagnosis and treatment of colorectal cancer. However, there is no information about outcomes of DAC in Australia.

Aims: To determine if Direct Access Colonoscopy (DAC) in North-West Tasmania expedited colorectal diagnosis and treatment.

Methods: Pre-post intervention study evaluating time from referral to diagnosis and definitive treatment. Patient demographic characteristics, referral, colonoscopy and treatment information was retrieved from hospital records. Timelines were investigated in standard referrals (SR), Emergency Department (ED)/Inpatient referrals and DAC using survival analysis.

Results: 206 colorectal cancer cases were identified (115 SR, 26 DAC, 47 ED/inpatient and 15 unknown pathways). Median time to colonoscopy/diagnosis (DAC 6 weeks vs. SR 7 weeks, $p=0.55$) or definitive treatment (surgery/chemoradiation) (DAC 8 weeks vs. SR 9 weeks, $p=0.81$) was not significantly improved with DAC. Among SR only, time to diagnosis was 9 weeks pre-intervention vs. 5 weeks post-intervention ($p=0.13$), and time to treatment was 11 weeks pre-intervention vs. 6 weeks post-intervention ($p=0.07$).

Conclusion: There was no statistically significant improvement in time to colorectal cancer diagnosis or treatment among patients referred via DAC compared to standard referrals. There was a trend towards improved waiting times for standard referrals concurrent with the introduction of the DAC pathway, indicating improvement of all referral processes. DAC may not be effective at expediting colorectal cancer diagnosis if it is not accompanied by strict referral guidelines. Larger evaluations of DAC are required in the Australian context.

KEYWORDS: *(Five key words in order of importance for indexing purposes should be supplied below the abstract and should be taken from those recommended by the US National Library of Medicine's Medical Subject Headings (MeSH) browser list at <http://www.nlm.nih.gov/>)*

Cancer diagnosis, colorectal cancer, direct access colonoscopy, time to diagnosis

TITLE:

Direct Access Colonoscopy: impact of intervention on time to colorectal cancer diagnosis and treatment in North West Tasmania

BACKGROUND:

Tasmania has the second highest rate of cancer diagnosis and cancer-related death in Australia.¹ Colorectal cancer is one of the most common cancers in the region¹ and accounts for 12.6% of all new cancer diagnoses in Australia.² Whilst survival rates are improving,³ it remains the second leading cause of cancer-related mortality.⁴

Reduced access to diagnostic services, specialist care and treatment have a negative impact on stage at diagnosis and survival among rural cancer patients. Research has found that, compared to patients living in urban areas, rural patients are more likely to be diagnosed with non-localised cancers.^{5,6} Additionally, cancer patients who live in areas classified as moderately accessible or remote (under the now superseded Accessibility/Remoteness Index of Australia) have been found to have an increased risk of death within five years compared to patients living in regions classified as highly accessible.⁷ Patients with rectal cancer have a 6% increase in mortality for each 100 km increment in distance from a radiotherapy facility.⁸

One approach for diagnosing colorectal cancer at an earlier stage, and therefore better prognosis, is the implementation of rapid access systems for colonoscopy. Rapid access or direct referral colonoscopy services allow primary care providers to refer directly for colonoscopy in suspected colon cancer, without review in a specialist clinic. Internationally, these systems have demonstrated patient satisfaction⁹ and safety,^{10,11} and have been shown to significantly reduce times to diagnosis and treatment.^{9,10} While some research has found direct access colonoscopy has colorectal cancer detection rates equivalent to, or worse than, standard referral pathways,^{11,12} evidence from Spain indicates improved diagnostic yields.¹³

A direct access colonoscopy (DAC) referral system was introduced in North West Regional Tasmania in July 2010, but its use has not been evaluated to-date.

AIMS:

To determine if DAC improved diagnostic and treatment timelines compared to standard referral (SR). The secondary aim was to investigate overall survival of patients diagnosed with colorectal cancer before and after DAC implementation.

METHODS:

Ethical approval

The University of Tasmania Human Research Ethics Committee provided ethical approval for the research (HREC reference number: H12562).

Study design

Retrospective pre-post intervention study assessing time to diagnosis, time to definitive treatment (chemoradiation or surgery) and overall survival.

Study population

All patients diagnosed with colorectal cancer (CRC) in North West Tasmania, Australia.

Data collection

All pathological diagnoses of CRC in North West Tasmania from 1 January 2009 to 30 June 2012 were obtained from the sole pathology service provider in the region. The pre-intervention period was 1 January 2009 to 30 June 2010 and the post-intervention period was 1 January 2011 to 30 June 2012. Data was collected from electronic and paper patient medical records by means of a unique patient record number. Data points were gender, date of birth, date of referral, referral source (e.g. GP referral [standard referral, SR], DAC, Emergency Department [ED] or inpatient wards), symptoms recorded in notes, faecal occult blood screening test result, date of colonoscopy, result of colonoscopy, other investigations, diagnostic information (histology), date of surgery, type of surgery, date of treatment initiation, treatment details, recurrence of CRC, date of recurrence, date of last hospital appointment and date of death (if applicable). There were a small number of specialist referrals from inpatient wards (categorised as ED/inpatient referrals) but no other specialist referrals. Information on patient deaths and recurrences of CRC was updated annually, and a final update was conducted at the end of the study period (30 September 2015).

Data analysis

The study data were imported into Stata 14 (StataCorp, College Station, Texas) for analysis. Time from referral to diagnosis, and from referral to definitive colorectal cancer treatment (chemoradiation or surgery), was compared between standard referrals (SR), Emergency Department (ED)/Inpatient referrals and DACs. Overall survival was measured from date of diagnosis to death and compared between the three groups. Additionally, time to key events was investigated among standard referrals pre-intervention, standard referrals post-intervention and DACs. Kaplan-Meier survival graphs were produced and survivor functions were investigated using the Tarone-Ware test. Differences were accepted as significant at $p < 0.05$ level.

Patients with missing referral dates in hospital notes ($n=20$) were excluded from all time to event analyses. Patients with intentionally delayed colonoscopy were excluded from time to treatment/surgery analyses. For rectal cancer patients who had neoadjuvant chemoradiation, the date of definitive treatment was the date of initiation of chemoradiation.

RESULTS: *(Statistically significant results and relevant negative data cited.)*

There were 206 CRCs diagnosed in North West Tasmania from 1 January 2009 to 30 June 2012. For 15 (7.3%) patients there was no referrer information recorded in their hospital notes. There were 117 (56.8%) patients referred for colonoscopy by their primary care provider (SR, standard referral), 48 (23.3%) ED or inpatient referrals and 26 (12.6%) DAC (Direct Access Colonoscopy) referrals. Three patients (1 SR pre-intervention, 1 SR post-intervention and 1 inpatient) had intentionally delayed

colonoscopy (due to illness or patient decision). A further five patients from the SR group (3 pre and 2 post) had missing referral dates.

Baseline characteristics

Mean age at diagnosis was 69 years (SD 11.7, range 37-93 years) and 115 (55.8%) were males (Table 1). Sixty (29.1%) patients had a positive FOBT result. There were 196 patients who had one or more pre-diagnosis symptoms recorded, with the most common symptom being per rectal (PR) bleeding (22.8%). There were 4.9% of patients with no pre-diagnosis symptoms recorded in their hospital notes (n=10).

Colonoscopy was conducted in 179 (86.9%) patients and 166 patients had more than one diagnostic investigation (Table 1). Adenocarcinoma was confirmed by histology in all 206 patients. The most common grade was grade II (71.4%), while stage III was the most common tumour stage (38.3%). There were 70 (34.0%) patients diagnosed with rectal cancer. There were 37 patients for whom polypectomy was sufficient, surgery was not indicated, or were too frail for surgery or died prior to treatment. There was no significant difference between the three referral pathways (SR, DAC, ED) with respect to gender ($\chi^2(2) = 3.8$, $p = 0.15$), mean age at first visit ($p = 0.54$) and the number of symptoms ($p = 0.74$).

Time to diagnosis and treatment and patient survival in standard referrals, direct access referrals and ED/inpatients

After excluding patients with missing referrer information, intentional delay or missing referral date, there were 183 patients included in the time to event analyses (110 SR, 26 DAC and 47 ED/inpatient). Overall, there was a median of 3 weeks (IQR 1, 5) between the date of referral and first hospital appointment, 5 (1, 10) weeks between referral and diagnosis, and 7 (2, 12) weeks between referral and definitive treatment. Thirty-two of the 70 patients with rectal cancer received neoadjuvant chemoradiation.

There were significant differences between the SR, DAC and ED/inpatient groups for time to diagnosis ($p < 0.001$) and time to treatment ($p < 0.001$) (Table 2). The ED/inpatient group had a median of 1 week between referral and diagnosis. After excluding the ED/inpatient group and comparing time to events in the SR and DAC groups only, there were no significant differences in time to diagnosis ($p = 0.55$) or time to treatment ($p = 0.81$).

Five patients were lost to follow-up after diagnosis/surgery. Two patients died within one week of diagnosis and a further 5 patients died within one month of diagnosis. During the total study period, 84 (40.8%) patients died. Median patient survival for ED/inpatients was 52 weeks (Table 2). Median survivals could not be calculated for the SR and DAC groups as fewer than 50% of patients had died by the end of study period (median of 37 months follow-up).

Time to diagnosis and treatment and patient survival in standard referrals pre-intervention, standard referrals post-intervention and direct access referrals

Time from referral to diagnosis, (Table 3) referral to definitive treatment and referral to death was investigated in the pre-intervention SR group (n=76), post-intervention SR group (n=39) and the post-intervention DAC group (n=26). Amongst the three groups, there was no significant difference in the median number of weeks to diagnosis ($p = 0.28$) or treatment/surgery ($p = 0.15$). After excluding the DAC group, there was also no significant difference between the median number of weeks to diagnosis ($p =$

0.13) and time to treatment or definitive surgery ($p=0.07$) (Table 3 and Figure 1). Median survivals could not be calculated for the groups as fewer than 50% of patients had died by the end of study period.

Time to diagnosis and time to treatment, pre-intervention and post-intervention (standard referrals plus direct access referrals)

Time from referral to diagnosis, referral to definitive treatment and referral to death was investigated in the pre-intervention SR group ($n=73$) and post-intervention SR group plus DAC ($n=63$). Median time from referral to diagnosis in the pre-intervention SR group was 9 weeks (IQR 4, 13) and 6 weeks (IQR 4, 10) in the post-intervention SR+DAC group ($p=0.12$). Median time from referral to treatment/surgery was 11 weeks (IQR 6, 14) in the pre-intervention and 7 weeks (IQR 5, 11) in the post-intervention SR+DAC group ($p=0.07$). Too few patients died to calculate median survival between the two groups.

DISCUSSION:

Following introduction of a Direct Access Colonoscopy program in North West Tasmania, there was no statistically significant difference in time from referral to diagnosis of CRC for patients referred via the DAC pathway compared to standard referrals. There was also no statistically significant difference in time from referral to definitive treatment for CRC. However, an important incidental finding was the trend towards improvement in time from referral to diagnosis, and referral to treatment, for all patients diagnosed with CRC, regardless of referral pathway.

During the pre-intervention period, there was widespread community concern regarding a perceived higher incidence of cancer in the region, and delays in cancer diagnosis. However, annual cancer incidence and mortality reports produced by the Tasmanian Cancer Registry has shown that community fears of higher cancer incidence are unfounded.¹⁴ In response to community concerns regarding delays in diagnosis, the regional health service established the DAC program in mid-2010. Since this time, primary care providers have been able to directly refer patients with suspected CRC for elective colonoscopy. In parallel with the DAC, there was a review of internal business process for management of GP to specialist referrals at the health service. This included consolidating referral points and ensuring the triaging, specialist review of referrals, and booking of patients was conducted in a way that enabled patients to access the care they required in a timely way. Additionally, in 2011, an electronic template for all endoscopy referrals was introduced for primary care providers to increase the quality of information contained in the referrals. This avoids referrals being returned to the GP for additional information, and maximized the accuracy of urgency-related triage.

Patients who presented to the ED or were already inpatients had the shortest waiting times. This is often due to significant symptoms and emergency presentations, such as bowel obstruction. In this study, over 80% of ED or inpatient referrals were diagnosed with Stage III or IV tumours. They subsequently had the shortest median overall survival.

In the United Kingdom, patients referred to Direct Access Colonoscopy clinics via the two-week referral rule had a median of 9 days from referral to diagnosis, compared to 55 days via standard outpatient appointments.⁹ In Madrid, patients referred for colonoscopy via a rapid referral system had a mean waiting time of 14 days compared to 34 days among patients referred via the standard pathway.¹³

However, in this study, there was no statistically significant difference in time to diagnosis among all standard referrals (both pre and post-intervention) compared to DAC referrals.

A number of other unexpected confounding factors may explain the the absence of a significant difference in time to diagnosis between DAC and the post-intervention SR pathway. It is likely that electronic referrals and business restructuring that occurred concurrently to the introduction of DAC reduced referral congestion and led to improvements in referral and triaging processes for all patients, irrespective of referral pathway. Another possible explanation may be an influx of patients to the new DAC pathway, flooding the system and resulting in no improvement in timelines. The lack of improvement in waiting time to treatment/surgery may be a result of the two pathways (DAC and SR) joining post-colonoscopy, to form a single waiting list for surgery/treatment. Additionally, the DAC pathway is streamlined, resulting in, theoretically, a higher turnover of referrals. Therefore the whole system benefits from DAC. Changes in hospital staffing, regional GP numbers, improvements in public awareness of CRC symptoms and patient adherence to appointments may have also have played a role in improved waiting times post-intervention, regardless of referral pathway. We also expect that lack of familiarity with the DAC system shortly after its introduction resulted in no difference in waiting times, although we expect this improved over time as clinicians became more familiar with the system and its utility. However, exploration of these varied factors were outside the scope of this study.

Additionally, our research found that the duration of time from referral to treatment was not shorter among DAC patients. This is supported by Flashman et al.,¹⁵ and a Madrid study,¹³ who also did not find a reduced time to treatment amongst patients referred via the 'two-week wait' pathway or rapid referral, respectively. In contrast to this, Maruthachalam et al.⁹ found DAC patients had a median time from referral to definitive treatment almost 3 weeks shorter compared to standard referrals (55 days vs. 75 days). Despite this, our research indicated that median time from referral to treatment among patients referred via the standard pathway nearly halved from 11 weeks pre-intervention to 6 weeks post-intervention. While this was not statistically significant, it is a clinically important finding.

It remains unclear whether the introduction of a direct access improves time to diagnosis or treatment for patients. Overseas research indicates that despite improved times to diagnosis, direct access or rapid referral does not improve survival among CRC patients.^{16,17,18} Due to the small number of patients in the DAC group, and the low incidence of death during the study period, we were unable to measure median overall survival in the standard referral and DAC groups.

Given the low population detection rate of colorectal cancer, inappropriate referrals can overburden the health system and result in longer delays for symptomatic patients.¹⁹ In the United Kingdom, the government directive that all patients with suspected colorectal cancer be seen by a specialist within two weeks of referral was accompanied by National Institute for Health and Care Excellence (NICE) guidelines.²⁰ This lists criteria to identify patients with suspected cancer suitable for an urgent referral pathway. The latest iteration of the criteria list comprises of: unexplained weight loss or abdominal pain in patients aged 40 or older; unexplained rectal bleeding in patients 50 years or older; iron-deficiency anaemia or a change in bowel habit in patients aged 60 years or older; or any patient with a positive faecal occult blood test.²⁰ These guidelines have been revised since their introduction, in order to identify patients most appropriate for the two-week referral pathway. However, research suggests less than half of referrals comply with these specified guidelines.¹⁹ The DAC referral pathway in NW Tasmania does not have a list of criteria to guide triage, raising other possible reasons for no improvement in corresponding waiting

times. Incorporation of the NICE guidelines to identify patients likely to benefit most from rapid referral for colonoscopy may reduce the number of inappropriate referrals for DAC and assist with triage.

The failure to detect statistically significant improvements in diagnostic and treatment timelines, despite time to diagnosis and treatment nearly halving in standard referrals pre to post-intervention, is due to the small sample size, which resulted in the study being underpowered to detect statistically significant differences in times to events in each group. However, it is not possible to increase the study sample size due to all known CRC cases in the region, within the study period, already being included. This is a limitation of conducting research in rural/regional centres. A post-hoc power calculation indicated that a sample of more than 1,000 CRC patients would need to be included to achieve study power ≥ 0.80 given the hazard rates observed in this study.

The research was not a prospective study, but rather a retrospective audit of an existing intervention. However, despite the retrospective design, this study provided valuable information about colorectal cancer diagnoses in the region as well as waiting time between referral and diagnosis, and definitive treatment. Other limitations include the possibility that some patients may have been referred to a specialist colorectal surgeon in another locality (either Launceston, located more than 100 kilometres away, Hobart, located approximately 300 kilometres away, or Melbourne, requiring a domestic flight). Such patients were not included in our research. Secondly, only patients with an ultimate diagnosis of CRC were identified. This did not account for the total number of patients referred via the DAC and as such, we cannot comment on the sensitivity of DAC in detecting CRC. Thirdly, we were unable to investigate the total number of patients referred to the DAC, and the diagnostic yield, as we did not have access to the program's records. However, we were able to identify a total of 65 CRC cases diagnosed in North West Tasmania during the post-intervention study period. Of these, 26 (40%) were DAC referrals and 39 were standard referrals. Lastly, due to small numbers of patient deaths, overall survival could not be estimated. Accurate comparisons of survival benefits cannot be commented on.

CONCLUSION:

Following introduction of direct access colonoscopy, there was no improvement in time to colorectal cancer diagnosis and definitive treatment among patients referred via direct access colonoscopy compared to standard referrals. However there was an overall trend towards improvement in timelines regardless of the referral pathway. Further research is needed to reduce time to diagnosis and treatment within the DAC framework, possibly by incorporation of NICE guidelines to identify patients most likely to benefit from rapid referral for colonoscopy.

REFERENCES: *(Supply a maximum of 60 references. Style and punctuation should conform to the Vancouver format. List all authors when six or fewer; when seven or more list the first six and add et al. The issue number should not be quoted. Website references – treat as other reference. In the text, references should be cited using superscript Arabic numerals in the order in which they appear. If cited only in tables or figure legends number them according to the first identifications of the table or figure in the text. In the reference list, the references should be numbered and listed in order of appearance in the text.)*

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TABLES: (Should be self-contained and complement but not duplicate information contained in the main text.)

Table 1 Demographics, referral pathway and diagnosis (n=206)

	n (%)
Age at diagnosis [mean, (SD)]	69 (11.7)
Sex	
Female	91 (44.2)
Male	115 (55.8)
FOBT positive	60 (29.1)
Referrer	
GP referral	115 (55.8)
ED presentation	41 (19.9)
DAC referral	26 (12.6)
Inpatient referral	6 (2.9)
Specialist referral	1 (0.5)
Not recorded in notes	15 (7.3)
Number of symptoms	
None	9 (4.4)
One	122 (59.2)
Two	58 (28.2)
Three	7 (3.4)
Not recorded in notes	10 (4.9)
Investigations	
Colonoscopy	179 (86.9)
CT	21 (10.2)
Colonography	1 (0.5)
Barium enema	2 (1.0)
MRI	1 (0.5)
Histology	
Adenocarcinoma	206 (100.0)
Grade†	

I	12 (5.8)
II	147 (71.4)
III	45 (21.8)
Not available	2 (1.0)
<i>Tumour Stage‡</i>	
I	27 (13.1)
II	24 (11.7)
III	79 (38.3)
IV	45 (21.8)
In-situ	10 (4.9)
Not available	20 (9.7)

†Highest grade and stage reported for multiple lesions. Grade refers to degree of differentiation of the primary tumour from I well-differentiated to III poorly-differentiated. ‡Stage is according to the American Joint Committee on Cancer TNM staging system for colorectal cancer, 7th edition (2010).

Table 2 Time to event analysis for 3 referral groups in weeks - referral to diagnosis, referral to treatment and diagnosis to death

	Standard Referral n=110		Direct Access Colonoscopy n=26		ED attendance or Inpatient n=47		3 groups p-value	2 groups p-value
	Median (IQR)	Incidence rate	Median (IQR)	Incidence rate	Median (IQR)	Incidence rate	p-value	p-value
Referral to diagnosis (weeks)	7 (4, 12)	0.11	6 (4, 10)	0.12	1 (1,2)	0.50	< 0.001	0.55
Referral to surgery/treatment (weeks)	9 (6, 13)	0.09	8 (7, 11)	0.09	4 (2, 7)	0.22	< 0.001	0.81
Survival - diagnosis to death (months)	* (37, *)	0.007	* (52, *)	0.005	29 (10, 56)	0.03	n/a	n/a

Note: patients with missing referral dates, intentional delayed scope excluded from this table. 2 group p-value reported for standard referral vs. direct access. *Unable to estimate median and 75th percentile for probability of dying as 50% of patients in group had not yet died, as a result no p-values are reported.

Table 3 Time to event analysis - standard referrals pre-intervention, standard referrals post-intervention and direct access for time from referral to diagnosis, referral to treatment and diagnosis to death

	Standard Referral Pre-Intervention n=73		Standard Referral Post-Intervention n=37		Direct Access Colonoscopy n=26		3 groups p-value	2 groups p-value
	Median (IQR)	Incidence rate	Median (IQR)	Incidence rate	Median (IQR)	Incidence rate	p-value	p-value
Referral to diagnosis (weeks)	9 (4, 13)	0.11	5 (4, 10)	0.52	6 (4, 10)	0.12	0.28	0.13
Referral to surgery/treatment (weeks)	11 (6, 14)	0.09	6 (5, 10)	0.10	8 (7, 11)	0.09	0.15	0.07
Survival - diagnosis to death (months)	* (37, *)	0.007	* (32, *)	0.008	* (52, *)	0.005	n/a	n/a

Note: patients with missing referral dates, intentional delayed scope excluded from this table. 2 group p-value reported for standard referral pre-intervention vs. post-intervention. *Unable to estimate median and 75th percentile for probability of dying as 50% of patients in group had not yet died, therefore no p-values are reported.

FIGURES: *(The legend should be self-explanatory. Number consecutively in Arabic numerals; cite in consecutive order in the main text. Please position on a separate page; incorporate legends and definitions of any symbols used; explain all abbreviations and units of measurement.*

Figure 1 Kaplan-Meier Survival Estimates Weeks to Diagnosis, standard referrals pre-intervention, Direct Access Colonoscopy referrals and standard referrals post-intervention

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