International Surgery Journal
Watter HK et al. Int Surg J. 2025 Dec;12(12):2084-2088
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20253830

Original Research Article

Organ preservation in rectal adenocarcinoma: safety in the regional setting

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Received: 01 September 2025
Revised: 13 October 2025
Accepted: 01 November 2025

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ABSTRACT

Background: The 'watch and wait' (W&W) approach to rectal cancer patients with a complete clinico-radiological response to neoadjuvant treatment is safe when implemented appropriately. However, patients that are not enrolled and surveilled appropriately, have increased risks of local recurrence, metastases and mortality. Regional colorectal units have additional barriers to surveillance, compared to metropolitan equivalents including increased distances to services and poorer health literacy.
Methods: This retrospective cohort study assessed enrolment and surveillance of W&W rectal cancer patients by a regional colorectal multidisciplinary team (MDT) and surgical department. Patients enrolled in a W&W protocol via this regional MDT between 2020 and 2024, were included. Adherence to accepted enrolment criteria and the established surveillance protocol was assessed, with particular focus on flexible sigmoidoscopy, MRI and CT/PET.
Results: Seven patients achieved complete response and were assigned to the W&W protocol. All were enrolled with endoscopic and radiologic evidence of complete or near complete response. Surveillance flexible sigmoidoscopies were delayed in 63% (n=15/24) of cases. Delays to CT/PET and MRI surveillance were seen in 33% (n=6/18) and 34% (n=11/32) of scans respectively.
Conclusions: In this regional setting, enrolments in the W&W approach were appropriate, but delays to surveillance investigations (especially flexible sigmoidoscopy) were common. Specialist colorectal cancer nurses may assist in protocolised surveillance, to overcome both hospital and patient related delays.

Keywords: Colorectal, Rectal cancer, Surgery, Surveillance, Watch and wait

INTRODUCTION

Total neoadjuvant treatment (TNT) is now standard of care for locally advanced rectal cancer.[1] Approximately three quarters of patients achieve complete or near complete clinical response, with half of these patients remaining disease free after five years.[2,3]

The W&W approach for patients with complete clinical response to neoadjuvant treatment has been demonstrated to be safe when enrolment is appropriate and the surveillance regime is adhered to.[2,3] Patients follow a strict surveillance regime including regular MRI rectum, flexible sigmoidoscopy, digital rectal examination, CEA estimation and CT/PET imaging, for at least 5 years.[3] Strict adherence is critical as almost one quarter of patients with complete clinical response experience local recurrence, needing salvage resection.[2]

The W&W approach avoids total mesorectal excision (TME) for a significant proportion of rectal cancer patients, avoiding associated morbidity and the possibility of a permanent stoma.[4] Literature also suggests that despite the increased burden of surveillance investigations, the W&W approach is more cost-effective than routine TME.[5] However, if patients are not enrolled

and surveilled appropriately, there is an increased risk of local recurrence, metastases and mortality.[6] Enrolment in W&W requires complete clinical response to neoadjuvant treatment, with no residual disease on digital rectal examination, endoscopy and rectal MRI.[4,7] Patients with near complete response on initial restaging may also be eligible for W&W, however this is a nuanced assessment and requires multidisciplinary team input to avoid inappropriate enrolment.[2,3,7]

The W&W protocol places a significant burden on patients to attend; and on radiology/endoscopy departments to provide surveillance investigations. Regional colorectal units may have additional barriers to surveillance, compared to metropolitan equivalents. These may include longer wait times, increased distances to services, less colorectal nursing support and poorer health literacy.[8,9]

Central Queensland Hospital and Health Service (CQHHS) covers 117,813 km^2, with a population of 228,246 in 2021.[10,11] Rockhampton hospital is the largest hospital in the region, with a Colorectal service comprising of three colorectal surgeons, but no specialist colorectal nursing support.

The tertiary referral centre is Royal Brisbane and Women's Hospital (RBWH), 627 km by road from Rockhampton hospital. Central Queensland HHS (CQHHS) has an independent colorectal MDT. Using the RBWH W&W protocol, CQHHS has been enrolling selected rectal cancer patients since 2020.

No previous studies have considered the safety of the W&W approach in the regional setting. This study aims to assess adherence to accepted enrolment criteria and surveillance protocol for the W&W approach, in this regional setting. Ultimately, the study aims to determine if a W&W approach is safe in this regional Australian context, with the current services available.

METHODS

This retrospective cohort study included patients diagnosed with rectal adenocarcinoma and discussed in the Central Queensland Hospital and Health Service (CQHHS) colorectal MDT, between 01/01/2020 and 11/11/2024. Patients planned for palliative management from the initial MDT discussion were excluded. Initial endoscopy, rectal MRI, systemic staging imaging (CT, PET) and MDT notes were used to determine clinical details, tumour characteristics and treatment plan.

Re-staging investigations (digital rectal exam, endoscopy and rectal MRI) and MDT notes for patients enrolled in W&W post neoadjuvant treatment, were used to assess if they had documented complete response.

The Royal Brisbane and Women's Hospital W&W surveillance protocol includes frequent clinical review, CEA estimation, MRI and PET/CT imaging (Figure 1). Details of surveillance investigations and MDT discussions were collected from patient records. Dates of clinic appointments were accessed from HBSCIS. Delays were defined as intervals >1month longer than protocol.

Data analysis was completed in Microsoft Excel. Chi-squared test was used to assess for statistical significance when comparing delays in surveillance investigations between patients living inside Rockhampton versus outside.

RESULTS

The study cohort included 74 patients treated with curative intent for rectal adenocarcinoma. Most of these (64%) were palpable at index colonoscopy and 92% were traversable endoscopically. Evidence of oligometastatic disease was seen in 16% (n=12) of patients on initial staging. 11 patients had liver metastases on diagnosis, whilst 1 had a lung metastasis.

Of the 74 patients; 43 underwent neoadjuvant treatment, 16 underwent local excision and 15 proceeded to upfront TME. Of those that underwent neoadjuvant treatment, 7 patients achieved complete clinico-radiological response and were assigned to a W&W protocol via the CQHHS colorectal MDT. Table 1 shows the demographics and clinical characteristics of the W&W cohort and those not assigned to W&W.

"Watch & Wait" Protocol for Rectal Cancer - Royal Brisbane & Women's Hospital

Year:	CEA	Scope	Imaging	Clinical review
Year 1	Every 3 months	Flexi Sig / EUA +/- biopsy every 3 months (surgical list) + Colonoscopy @ 1 year (surgical list)	- MRI every 3 months - PET/ CT CAP every 6 months	OPD every 3 months (same day as FS if possible)
Year 2	Every 3 months	Flexi Sig / EUA +/- biopsy every 3 months (surgical list)	- MRI every 3 months - PET/CT CAP every 6 months	OPD every 3 months (same day as FS if possible)
Year 3	Every 6 months	Flexi Sig / EUA +/- biopsy every 6 months (surgical list)	- Annual CT CAP - MRI every 6 months	OPD every 6 months (same day as FS if possible)
Year 4	Every 6 months	Flexi Sig / EUA +/- biopsy every 6 months (surgical list) + Colonoscopy 3yrs post previous (surgical list)	- Annual CT CAP - MRI every 6 months	OPD every 6 months (same day as FS if possible)
Year 5	Every 6 months	Flexi Sig / EUA +/- biopsy every 6 months (surgical list)	- Annual CT CAP - MRI every 6 months	OPD every 6 months (same day as FS if possible)

- General Surgery Unit at patient's closest QHealth facility to coordinate surveillance (where appropriate)
- Imaging to be requested at patient's closest QHealth facility
- Pathology forms given / sent to patient (& ideally performed at patient's closest QHealth facility)
- Rectal examination +/- rigid sigmoidoscopy at each clinic appointment
- Any imaging abnormality or significant rise in CEA → phone call to RBWH Colorectal Registrar (ph. 3646 8111) +/- refer back to RBWH
- End of Year 3 - Consider discharge to GP (if appropriate & patient can continue regular follow-up)
- End of Year 5 - Discharge to GP with regular follow-up

Figure 1: Royal Brisbane and women's hospital 'watch and wait' surveillance protocol.

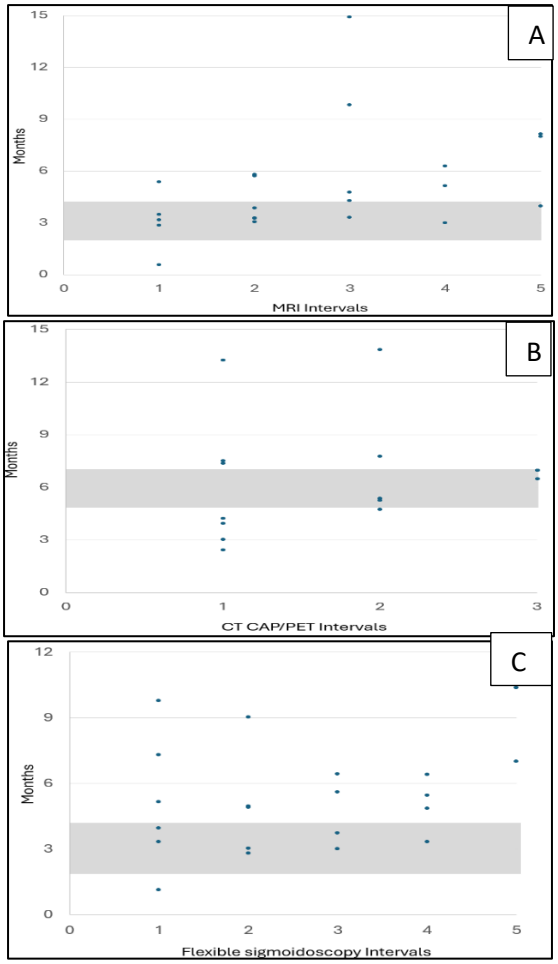

Figure 2: Actual time between consecutive surveillance investigations for 'Watch and Wait' (W&W) rectal cancer patients; (A) MRI, (B) CT CAP and/or PET, (C) Flexible sigmoidoscopy. Shaded areas represent recommended intervals as per RBWH W&W protocol±1 month.

All patients assigned to W&W had endoscopic evidence of complete response (flat-white scar). Digital rectal examination completed at time of flexible sigmoidoscopy showed complete response in all patients who had palpable tumours.

Four patients had MRI rectum's showing complete or near complete response with tumour regression grades (TRG) of 1 (n=1) or 2 (n=3). Two patients showed moderate response and the MRI was repeated after 3 months, which showed complete response (TRG 1) in one patient and near complete response (TRG 2) in another patient. The last patient was unable to have MRI's due to an incompatible pacemaker; thus PET/CT was used to show complete radiological response. This patient was also a borderline surgical candidate with significant medical comorbidities.

Within this W&W cohort, surveillance flexible sigmoidoscopies were delayed 63% (n=15/24) of the time. Delays to CT/PET and MRI surveillance were seen with 33% (n=6/18) and 34% (n=11/32) of scans respectively, some delayed over 12 months (Figure 2).

The effect of patient's residential address being inside Rockhampton (the major regional centre within the health service) or outside, is shown in table 2. Although all differences were non-significant, the increased delay to flexible sigmoidoscopy when patients lived outside Rockhampton, was approaching statistical significance (p=0.07).

Of these 7 patients on a W&W protocol, 5 remain disease free (after median follow up of 35 months). One experienced local recurrence after 9 months and underwent a salvage ultralow Hartmann's procedure. The remaining patient experienced local recurrence with a metachronous lung metastasis after 12 months.

Table 1: Demographics and clinical characteristics of study groups.

		Not W & W		W & W	
N		67		7	
Median age (IQR)		63 (57-71)		71 (54-72)	
Year of diagnosis	2020	5	7%	1	14%
	2021	17	25%	3	43%
	2022	14	21%	0	0%
	2023	18	27%	3	43%
	2024	13	19%	0	0%
Palpable	Yes	43	64%	4	57%
	No	9	13%	0	0%
	x	15	22%	3	43%
Traversed	Yes	61	91%	7	100%
	No	4	6%	0	0%
	x	2	3%	0	0%
MMR deficient		3	4%	0	0%
T stage (radiological)	T1	2	3%	0	0%
	T2	15	22%	0	0%

Continued.

		Not W & W		W & W	
	T3	31	46%	5	71%
	T4	9	13%	1	14%
	x	10	15%	1	14%
N stage (radiological)	N0	37	55%	1	14%
	N1	14	21%	4	57%
	N2	11	16%	1	14%
	x	5	7%	1	14%
Mesorectal fascia involvement	Positive	14	21%	2	29%
	Threatened	6	9%	2	29%
	Negative	41	61%	0	0%
	x	6	9%	3	43%
Extramural venous invasion	Yes	17	25%	6	86%
	No	45	67%	0	0%
	x	6	9%	1	14%
Distant metastases		12	18%	0	0%
Neoadjuvant treatment		36	54%	7	100%
Upfront local excision (e.g., TAMIS, TART, EMR)		16	24%	0	0%
Upfront TME		15	22%	0	0%

Abbreviations: W&W=Watch and Wait; IQR=interquartile range; x=not documented/established in medical record; TAMIS=Transanal minimally invasive surgery; TART=Transanal resection of tumor; EMR=endoscopic mucosal resection; TME=total mesorectal excision. Note percentages may not add to 100%, due to rounding.

Table 2: Delays to surveillance investigations according to proximity to major hospital.

Patient address	MRI delayed >1 m	CT/PET delayed >1 m	Flexi sig delayed >1 m
Rockhampton	4/8 (50%)	2/5 (40%)	3/8 (38%)
Outside Rockhampton	7/24 (29%)	4/13 (31%)	12/16 (75%)

DISCUSSION

Patients were appropriately enrolled in the W&W protocol, over the study period. All patients had endoscopic evidence of complete response. This was prioritized over MRI, where a complete response (TRG 1) and near complete response (TRG 2) was accepted. This is in line with accepted enrolment criteria from the literature, especially the OPRA trial where complete or near complete clinical response was eligible for W&W enrolment.[2-4] As is possible through an MDT, the radiological surveillance protocol was modified for a comorbid patient who was unable to have MRI surveillance due to an incompatible pacemaker.

The W&W cohort here contained all T3 and T4 cancers, predominantly node positive. Most had extramural venous invasion and either threatened or positive mesorectal fascia. This is comparable to the study population of the OPRA trial.[2]

Delays to surveillance investigations were common, with flexible sigmoidoscopy most often delayed. The reasons for this may be hospital or patient related. Hospital related explanations may include breaches of endoscopy waitlist recommended timeframes and unfamiliarity of junior doctors with the W&W protocol, leading to delays in bookings. Patient related factors may include distance from services and poor health literacy.[8,9] Although not statistically significant (p=0.07), patients living outside the major regional centre within the health service had longer delays to flexible sigmoidoscopy. Larger sample size may demonstrate a significant difference.

No previous studies have examined adherence to W&W protocols in the regional setting. However, a metropolitan American retrospective cohort study of 107 patients demonstrated poor adherence to a W&W protocol, with 50.5% of patients being fully adherent in the first year and only 34% in the second year.[12] Their surveillance protocol was somewhat less intensive than the RBWH protocol discussed here (to which none of our patients were completely adherent) but still suffered from very poor adherence. Like our study, flexible sigmoidoscopy was most commonly delayed. Clearly, poor adherence to W&W protocols is a problem for both metropolitan and regional colorectal departments.

Clinical nurse specialist support has been shown to streamline access to services, improve patient health literacy and reduce costs of surveillance in various oncology settings.[12,13] Regional hospitals have a relative sparsity of specialist nursing support compared to metropolitan equivalents.[14] Strikingly, in data collection

for this study, no single staff member could provide a list of the W&W rectal cancer patients currently under surveillance. The presence of specialized colorectal cancer nursing support may fill this gap to help overcome both hospital and patient related delays to surveillance investigations.

The major limitation of this study was its small sample size from a single institution. Reasons for delays to surveillance investigations could be the focus of follow up studies. Future studies could also compare delays to those experienced in metropolitan centres and investigate impacts of specialist nursing support on these delays.

In this regional setting, enrolments in the W&W approach were appropriate, however delays to surveillance investigations were common, especially with flexible sigmoidoscopies. Specialized colorectal cancer nursing support may assist in reducing delays to surveillance investigations and is recommended in the application of a W&W protocol.

CONCLUSION

Enrolment in the W&W protocol for rectal adenocarcinoma was appropriate, however significant delays to surveillance investigations were seen, in this regional setting. The literature indicates that these delays are also experienced in metropolitan centres. Further studies are needed to directly compare to metropolitan centres and assess if these delays negatively impact patient outcomes.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Watter HK, Simpson F, Lamparelli M, Bhorat N. Organ preservation in rectal adenocarcinoma: safety in the regional setting. Int Surg J 2025;12:2084-8.