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RESEARCH ARTICLE

Local excision for T1 rectal cancer: A population-based study of practice patterns and oncological outcomes

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Abstract

Aim: Local excision (LE) for T1 rectal cancer may be recommended in those with low-risk disease, while resection is typically recommended in those with a high risk of luminal recurrence or lymph node metastasis. The aim of this work was to compare survival between resection and LE.

Method: This was a population-based retrospective cohort study set in the Canadian province of Ontario. Patients were individuals with T1Nx rectal cancer between 2010 and 2014 and demographics, disease characteristics, treatments and outcomes were determined using linked administrative databases. This study does not include clinical information regarding individual patient treatment decisions. The main outcome measure was overall survival (OS).

Results: A total of 719 patients were identified, including 359 with upfront resection, 113 with LE and immediate resection (<90 days) and 247 with LE with definitive intent. The majority of LEs were performed via colonoscopy. Piecemeal excision (42% vs. 49%, $p = 0.28$) and positive margin (50% vs. 77%, $p < 0.01$) rates were high in both LE groups, with the highest rate in those with immediate resection. The prevalence of poor differentiation (<5%, $p = 0.70$) and lymphovascular invasion (LVI) (14%, $p = 0.80$) was similar across groups. In those with LE with definitive intent, 21% ultimately underwent resection (median 150 days, interquartile range 114–181 days) and 4% received radiation. There was no difference in 5-year OS between groups (resection 83.2% vs. LE and immediate resection 82.3% vs. definitive LE 83.3%; $p = 0.33$). Adjusted analyses demonstrated no association between approach and survival [definitive intent LE hazard ratio (HR) 0.97 (95% CI 0.70–1.35), LE and immediate resection HR 0.97 (95% CI 0.60–1.45), upfront resection HR 1 (Ref); $p = 0.98$]. Differentiation, piecemeal excisions and LVI were not associated with OS in the LE groups.

Preliminary results and parts of this work were presented at the Canadian Association of General Surgeons Annual Meeting on 20–23 September 2023 in Vancouver, BC, Canada as a podium presentation.

This work was also submitted and has been accepted by the American Society of Colon and Rectal Surgeons 2024 Annual Meeting as a poster presentation to be presented on 2 June 2024 in Baltimore, Maryland, USA (Can J Surg. 2023;66(6 Suppl 1):S98. doi: 10.1503/cjs.014223).

Conclusion: There were no observed differences in survival between those who underwent resection, LE and immediate resection and definitive intent LE. Although, these are observational data, they call into question the reflexive decision to offer radical resection for those with suspected T1 rectal cancer.

KEYWORDS
local excision, rectal cancer, T1

INTRODUCTION

Colorectal cancer represents a significant global health burden, with a steadily increasing incidence, particularly in the case of rectal cancer [1]. In Canada in 2023, colorectal cancer was the third most commonly diagnosed malignancy [2]. Rectal cancer comprises approximately 30% of all newly diagnosed cases of colorectal cancer [1]. With the rising prevalence of rectal cancer, treatment paradigms have become increasingly sophisticated and nuanced. For example, the advent and implementation of total neoadjuvant therapy for locally advanced rectal cancer has been increasingly studied over the past decade and its use in the current management of rectal cancer is becoming more common [3]. With advances in colorectal screening modalities, however, we are now seeing a decrease in colorectal cancer-related mortality and a concomitant increase in the detection of early stage disease (i.e. T1N0) [4, 5]. This has necessitated further study and understanding of the optimal treatment pathways for these patients.

The management of T1 rectal cancer poses a clinical challenge, necessitating a judicious consideration of therapeutic options [6]. Favourable prognosis in this group must be balanced with the morbidity of a major surgical resection. Thus, two predominant approaches have emerged in current oncological practice: local excision (LE) and radical oncological resection. LE, encompassing techniques such as traditional endoscopic polypectomy, endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS), has gained prominence as a less invasive alternative to radical resection [7]. While LE is associated with reduced morbidity and a shorter recovery period, concerns persist regarding the potential for inadequate oncological clearance and the risk of local recurrence [8]. In contrast, radical oncological resection, typically in the form of total mesorectal excision (TME), ensures comprehensive removal of the tumour and its associated lymphatic drainage. The choice between these strategies hinges on factors such as tumour pathological risk factors [i.e. margin status, lymphovascular invasion (LVI), perineural invasion, tumour budding, differentiation], patient comorbidities and patient quality of life.

Currently, when to treat with LE versus radical oncological resection is based on relatively poor-quality evidence. Large retrospective studies and data synthesis studies have identified risk factors such as LVI, perineural invasion, high-grade tumour budding, poor differentiation, piecemeal excision and positive endoscopic resection margins as being associated with a heightened risk of lymph node metastases [9–11]. As such, patients with these factors are often recommended to undergo radical oncological resection. However, the likelihood of residual malignancy in these cases is often low [12]. This raises the concern of over-treatment and a potential for consideration of less invasive management, even in the context of high-risk pathological features. While there are some data suggesting that LE for T1 disease is safe in terms of long-term oncological outcomes, further investigation is required [13–15]. Thus, the purpose of this population-level retrospective cohort study was to assess practice patterns for those with T1 rectal cancer in Ontario, Canada, and to compare the long-term oncological outcomes of patients undergoing LE and radical oncological resection.

What does this paper add to the literature?

Local excision (LE) and radical resection for T1Nx rectal Cancer has similar overall survival. Approximately 20% of those undergoing inital definitive LE required a radical resection at a median of 150 days.

METHOD

Study design and population

This is a population-based, retrospective cohort study of patients undergoing either LE or major resection for stage T1Nx rectal cancer in the Canadian province of Ontario between 2010 and 2014. Individuals with available histopathology reports were included. We excluded those who had preoperative radiation to ensure accurate staging information.

Ontario has a population of approximately 14.6 million people and a single-payer universal health insurance programme. Individuals who were diagnosed with rectal cancer between 2010 and 2014 were identified through the Ontario Rectal Cancer Cohort (OntaReCC). The methodology has been explained in full elsewhere [16]. The OntaReCC includes those identified in the Ontario Cancer Registry, which captures incident cancer cases through mandatory reporting, and is estimated to include >95% of newly diagnosed cancer cases, in which >94% of colorectal cancers were microscopically confirmed [17]. The study was approved by the Research Ethics Board of Queen's University, Kingston, Canada. This study was designed, analysed and reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [18].

Data sources and linkage

The OntaReCC combines data from several provincially maintained administrative data sets with data from histopathology reports that are made available through the Ontario Cancer Registry (OCR). Histopathology reports were Ontario Cancer Registry (OCR) for individuals who were diagnosed with rectal cancer during the study period. The validation and accuracy of the abstraction processes at Cancer Care and Epidemiology at the Queen's Cancer Research Institute has been previously reported [16]. The administrative data sets include health administrative data that are generated whenever a healthcare service is delivered to an individual, and are utilized for billing, registration, transactions or record keeping by healthcare providers. The health administrative data sets are linked to other provincially maintained data sets that provide vital statistics, census information and other demographic data. These data sets provide comprehensive data on individual characteristics (i.e. demographics, comorbidities and socioeconomic status), diagnostic details (i.e. date of diagnosis, histological variants and cancer sites) and treatment details. In addition, healthcare provider details and institution details are captured. After linkage of these data sets important factors or characteristics are derived, including: the completeness of preoperative investigations; the type, extent and completeness of treatments (including surgery, radiation and chemotherapy); treating clinician characteristics (volumes and practice setting) and institution characteristics (volumes, the level of care and the presence of a multidisciplinary cancer centre); and cancer-related outcomes (overall and cancer-specific survival, the treatment of metastatic disease, the use of palliative treatments, symptom burden).

Variables

Three treatment groups were defined for comparison of surgical management patterns and outcomes: immediate radical resection, LE with definitive intent and LE followed by resection within 90 days. LE included both endoscopic excision and surgical transanal techniques.

Pathological variables available for study from the histopathology reports during the study period included piecemeal excision (yes/no), positive margin status (yes/no) and degree of tumour differentiation (high, moderate or low). Lymphovascular and perineural invasion were also included if reported. Nodal stage was determined if the patient underwent radical resection.

Outcomes

Overall (OS) was determined from the date of primary tumour resection. Complete information about vital status in the OCR was available up to 31 December 2022 including cause of death.

Statistical analysis

The primary objective was to compare disease characteristics, management and outcomes of patients across the three study groups; immediate radical resection, definitive LE and LE followed by resection within 90 days. Comparisons of proportions between study groups were made using the chi-square test. Associations between patient-, disease- and treatment-related factors with completeness of staging, treatment and surveillance were analysed with multivariable logistic regression. Survival was determined from the date of initial surgery using the Kaplan–Meier technique. The association between patient-, disease- and treatment-related factors with overall and cancer-specific survival was evaluated using Cox proportional hazards regression models. Results were considered statistically significant at $p < 0.05$. As per institutional policy, data that relate to fewer than six patients are not reported due to small size. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Between 2010 and 2014, a total of 719 individuals with a T1Nx rectal cancer were identified (Figure 1). Patient characteristics can be found in

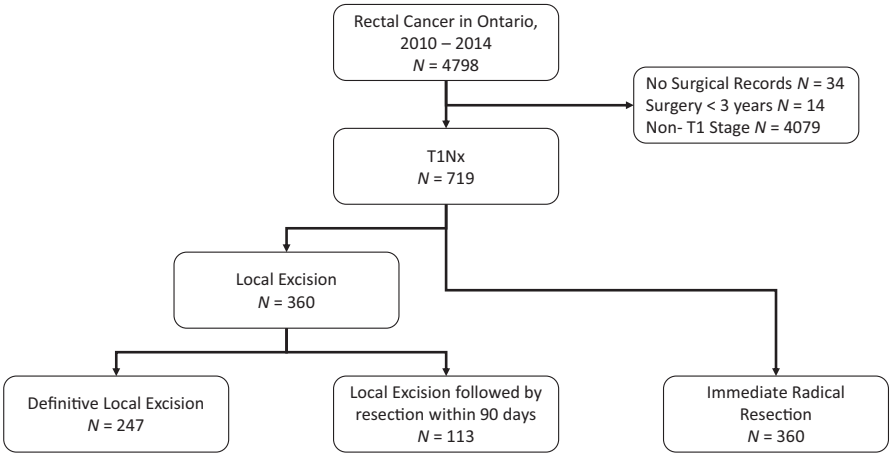

FIGURE 1 Identification of study population.

TABLE 1 Patient characteristics.

	LE alone		LE + immediate resection		Radical resection		Total	
	n = 247	34.4%	*n* = 113	15.7%	*n* = 359	49.9%	*n* = 719	*p*
Age group (years), *n* %								
18–29	≤5	≤100.0%	≤5	≤100.0%	≤5	≤100.0%	≤5 (≤1.0%)	0.20
30–39	≤5	35.7%	≤5	21.4%	5–10	42.9%	≤15 (≤2.1%)	
40–49	24	48.0%	10	20.0%	16	32.0%	50 (7.0%)	
50–59	58	34.7%	31	18.6%	78	46.7%	167 (23.2%)	
60–69	57	30.3%	33	17.6%	98	52.1%	188 (26.1%)	
70–79	65	33.5%	26	13.4%	103	53.1%	194 (27.0%)	
80+	37	35.2%	10	9.5%	58	55.2%	105 (14.6%)	
Median age (years) (IQR)	66.0 (55.0–75.0)		64.0 (55.0–71.0)		67.0 (58.0–76.0)		67.0 (56.0–75.0)	0.01
Sex, *n* %								
Female	106	34.6%	49	16.0%	151	49.3%	306 (42.6%)	0.96
Male	141	34.1%	64	15.5%	208	50.4%	413 (57.4%)	
Income quintile, *n* %								
1 (lowest)	34	31.5%	17	15.7%	57	52.8%	108 (15.0%)	0.41
2–4	171	36.0%	78	16.4%	226	47.6%	475 (66.1%)	
5 (highest)	42	32.1%	18	13.7%	71	54.2%	131 (18.2%)	
Residential region, *n* %								
Rural	48	60.9%	21	15.4%	67	49.3%	136 (18.9%)	0.28
Urban	199	34.4%	92	15.9%	287	49.7%	578 (80.4%)	
Charlson comorbidity score, *n* %								
Low (0–2)	217	34.8%	103	16.5%	303	48.6%	623 (86.6%)	0.42
Mid (3)	18	26.9%	8	11.9%	41	61.2%	67 (9.3%)	
High (>3)	≤10	44.4%	≤5	5.6%	≤10	50.0%	≤20 (≤2.8%)	
Unknown	≤5	36.4%	≤5	9.1%	≤10	54.5%	≤15 (≤2.1%)	
Cancer centre level designation of surgical treatment (if applicable), *n* %								
Level 1–2 (highest)	94	31.5%	42	14.1%	162	54.4%	298 (41.4%)	<0.01
Level 3	86	32.8%	36	13.7%	140	53.4%	262 (36.4%)	
Level 4–5	67	42.1%	35	22.0%	57	35.8%	159 (22.1%)	

Note: *n*, number of patients.

Abbreviations: IQR, interquartile range; LE, local excision.

Table 1. Of those included, 247 (34%) underwent 'definitive' LE (i.e. no major resection within 90 days), 113 (16%) underwent LE with immediate resection and 359 (50%) underwent oncological resection only. The groups were similar in the proportion of men ($p = 0.96$), residential location type (rural versus urban) ($p = 0.28$), income quintile ($p = 0.41$) and Charlson comorbidity score ($p = 0.42$). Those undergoing major resection had a higher mean age (67.1 years) than those with definitive LE (65.2 years) or those with LE and immediate surgery (63.2 years) ($p = 0.01$). Notably, the type of hospital where the procedure took place differed. The location of those undergoing a definitive local excision compared with those undergoing local excision followed by immediate surgery was similar: Definitve LE - Regioncal Cancer Centre 38% vs. Affiliated Cancer Centre 35% vs. Satellite/Non-Designated Cancer Centre 27%; LE followed by Immediate Resection - Regioncal Cancer Centre 37% vs. Affiliated Cancer Centre 32% vs. Satellite/Non-Designated Cancer Centre 31%. The primary observed difference was that a higher proportion of those undergoing a radical resection only occured at a regional cancer centre (45% vs. 39% at an affiliated cancer centre vs. 16% at a satellite or non-designated centre).

The tumour characteristics can be found in Table 2. Few tumours were poorly differentiated (≤3.5%) and the proportion was similar in each treatment group. Perineural invasion was also infrequently reported (≤3% for the cohort), but it should be noted that this variable was not reported in the majority of patients who underwent LE. LVI was reported more commonly at 15% for the entire cohort, with a higher risk in the major resection group: definitive LE 28/247 (11%); LE with immediate resection 12/113 (11%); major resection only 66/359 (18%) ($p < 0.01$).

TABLE 2 Disease characteristics and completeness of excision.

	LE alone		LE + immediate resection		Radical resection		Total	
	n = 247	34.4%	*n* = 113	15.7%	*n* = 359	49.9%	*n* = 719	*p*
Grade, *n* %								
High (poorly differentiated)	9	39.1%	≤5	21.7%	≤10	39.1%	20–25 (2.8–3.5%)	<0.01
Low (moderate or well differentiated)	207	32.1%	93	14.4%	344	53.4%	644 (89.6%)	
Unknown	31	59.6%	10–15	28.8%	5–10	11.5%	50–55 (7.0–7.6%)	
Perineural invasion, *n* %								
Yes	≤5	16.7%	≤5	≤27.8%	15	83.3%	15–20 (2.1–2.8%)	<0.01
No	30–35	9.9%	≤5	1.5%	305	88.7%	340–345 (47.3–48.0%)	
Unknown	210	59.0%	108	30.3%	39	10.9%	357 (49.6%)	
Lymphovascular invasion, *n* %								
Yes	28	26.4%	12	11.3%	66	62.3%	106 (14.7%)	<0.01
No	172	33.3%	71	13.8%	273	52.9%	516 (71.8%)	
Unknown	47	48.5%	30	30.9%	20	20.6%	97 (13.5%)	
Piecemeal excision, *n* %								
Yes	93	62.0%	50–55	35.3%	≤5	2.7%	148–153 (20.6–21.3%)	<0.01
No	127	65.1%	56	28.7%	12	6.2%	195 (27.1%)	
Unknown	27	7.2%	≤5	1.1%	340–345	91.7%	370–375 (51.5–52.2%)	
Positive LE, *n* %								
Deep margin	45–50	46.5%	45–50	46.5%	≤10	6.9%	100–105 (13.9–14.6%)	<0.01
Peripheral margin	≤5	50.0%	≤5	10.0%	≤5	40.0%	8–13 (1.1–1.8%)	
None	52	53.6%	14	14.4%	31	32.0%	97 (13.5%)	
Unknown	143	28.0%	51	10.0%	317	62.0%	511 (71.1%)	

Note: *n*, number of patients.

Abbreviation: LE, local excision.

The completeness of LE for those who had either definitive LE or LE with immediate surgery can also be found in Table 2. A high rate of piecemeal excision was seen in both groups (definitive LE 93/247, 38%; LE with immediate resection 53/113, 47%, $p = 0.10$). A positive margin (deep or peripheral) was also commonly reported in these two groups (definitive LE 52/104, 50%; LE with immediate surgery 48/62, 77%; $p < 0.01$). It should be noted that in both groups a very large number of the pathology reports did not state or report the margin status (definitive LE 143/247, 58%; LE with immediate surgery 51/113, 45%). Of those within these two groups, the following had a clear indication for definitive resection (i.e. at least one of positive margin, piecemeal excision, LVI, poorly differentiated tumour): definitive LE 133/247, 54%; LE with immediate surgery 81/113, 72% ($p = 0.002$).

The subsequent treatment summary can be found in Table 3. Of those in the initial definitive LE group, 21% (54/247) ultimately underwent a major resection. The median time from LE to resection was 150 days (IQR 114–181 days). A resection-free survival curve is included as Figure 2.

In those ultimately undergoing major resection, the type of resection did not differ between the groups, with LAR being the most common in each (failed definitive LE 47/54, 87%; LE with immediate resection 100/113, 88%; major resection only 319/359, 89%; $p = 0.95$).

In the patients who failed definitive LE, 15% (8/54) went on to receive radiation and 13% (7/54) received chemotherapy. Radiation was given at a median of 211 days (IQR 174–242 days) after LE. Chemotherapy was given at a median of 182 days (IQR 155–227 days) after excision. Radiation was given more frequently to those with LE and immediate resection (21/113, 19%) and those with major resection only (34/359, 9.5%) (Table 3).

Estimates of 3- and 5-year OS can be found in Table 4. Overall 5-year survival (from date of first surgery) for the three groups was: definitive LE 83.3%; LE with immediate surgery 82.3%; major resection only 82.4% (Figure 3). Adjusted survival analysis demonstrated no association between surgical treatment and OS [definitive LE hazard ratio (HR) 0.95 (95% CI 0.69–1.32); LE with immediate surgery HR 0.95 (95% CI 0.59–1.53); major resection only 1 (ref);

TABLE 3 Treatment characteristics.

	LE alone		LE + immediate resection		Radical resection		Total	
	n = 247	34.4%	*n* = 113	15.7%	*n* = 359	49.9%	*n* = 719	*p*
Type of resection, *n* %								
APR	7	11.9%	13	22.0%	39	66.1%	59 (8.2%)	0.95
LAR	47	10.1%	100	21.5%	319	68.5%	466 (64.8%)	
None	193	100%	0	0%	0	0%	193 (26.8%)	
Radiation, *n* %								
Yes	9	14.1%	21	32.8%	34	53.1%	64 (8.9%)	<0.01
No	238	36.3%	92	14.0%	325	49.6%	655 (91.1%)	
Median days to radiation (IQR)	211.0 (174.0–242.0)		71.0 (56.0–160.0)		91.0 (59.0–115.0)		92.0 (58.0–135.5)	<0.01
Chemotherapy, *n* %								
Yes	7	8.9%	28	35.4%	44	55.7%	79 (11.0%)	<0.01
No	238	36.3%	92	14.0%	325	49.6%	655 (91.1%)	
Median days to chemotherapy (IQR)	182.0 (155.0–227.0)		88.0 (63.0–119.0)		63.0 (45.5–95.5)		76.0 (53.0–126.0)	<0.01

Note: *n*, number of patients.

Abbreviations: APR, abdominoperineal resection; IQR, interquartile range; LAR, low anterior resection; LE, local excision.

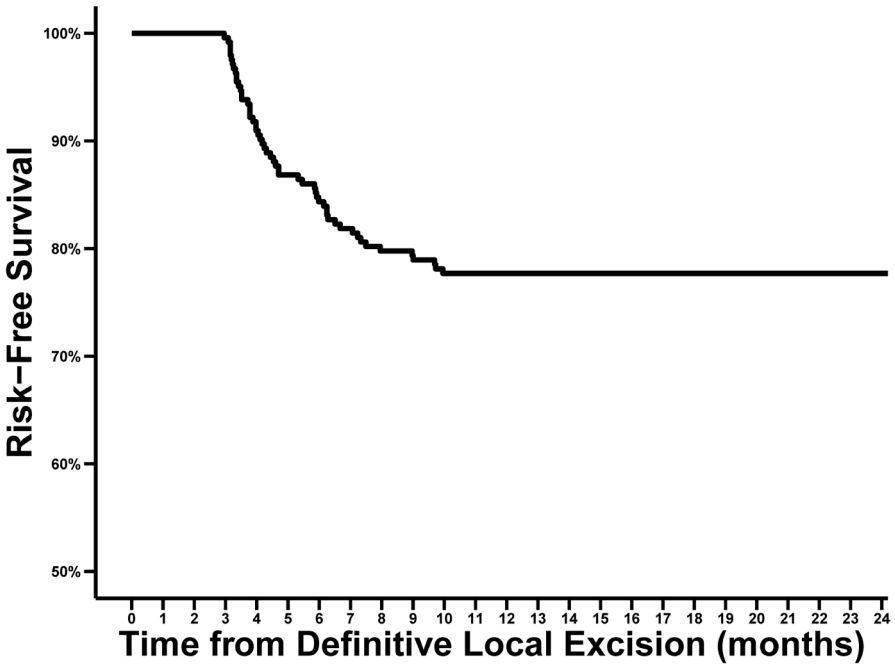

FIGURE 2 Resection-free survival curve in those undergoing definitive local excision.

p = 0.95] (Table 5). Surveillance endoscopy and imaging is provided by treatment group in Table S1.

A sensitivity analysis comparing those with definitive LE and those with LE and immediate surgery was completed. After adjusting for indications for major resection (piecemeal excision, poorly differentiated, LVI), no significant association between OS and treatment type was identified [definitive LE HR 1.23 (95% CI 0.75–2.01), LE with immediate resection (ref); *p* = 0.41].

DISCUSSION

This study has determined outcomes for patients with T1Nx rectal cancer in the real world and a current setting. The cohort is divided into those who underwent LE with definitive intent, LE followed by immediate surgery and those who had upfront major resection. Despite risk factors for nodal disease commonly being identified in those undergoing LE alone, there was no discernible difference

TABLE 4 Three- and 5-year survival data.

	LE alone		LE + immediate resection		Radical resection	
	n = 247	34.4%	*n* = 113	15.7%	*n* = 359	49.9%
Overall survival (95% CI)						
3-year	88.2%	(83.5%–91.7%)	85.8%	(77.9%–91.1%)	89.7%	(86.0%–92.4%)
5-year	83.3%	(78.1%–87.4%)	82.3%	(78.1%–87.4%)	82.4%	(78.0%–86.0%)
Cancer specific survival (95% CI)						
3-year	88.2%	(83.5%–91.7%)	85.8%	(77.9%–91.1%)	89.7%	(86.0%–92.4%)
5-year	83.3%	(78.1%–87.4%)	82.3%	(78.1%–87.4%)	82.4%	(78.0%–86.0%)

Note: *n*, number of patients.

Abbreviation: LE, local excision.

FIGURE 3 Overall survival in those with T1NX rectal cancer.

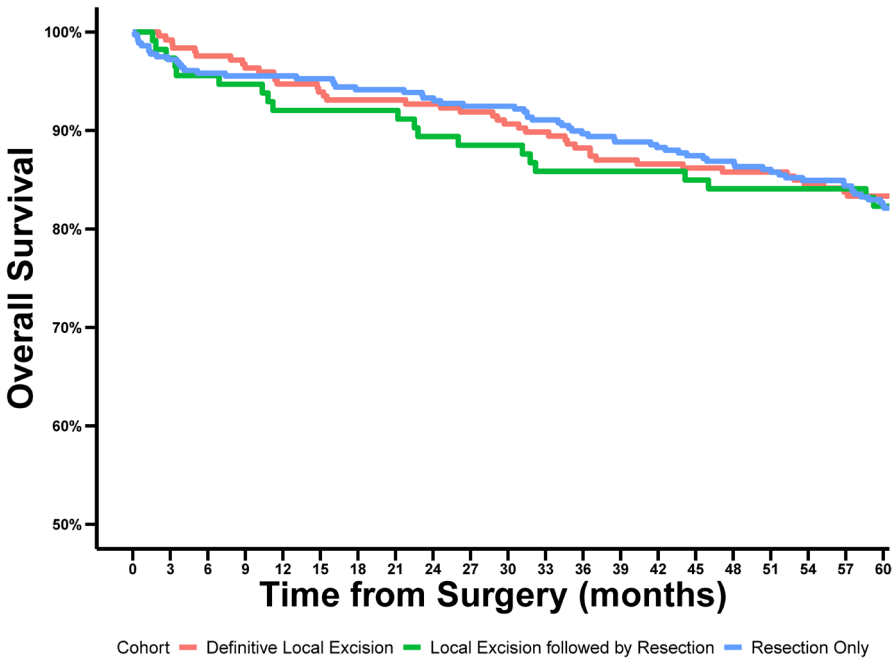

TABLE 5 Univariable and multivariable predictors of overall survival for all three treatment modalities (major resection, 10 208 patients).

	Univariable		Multivariable	
Predictor	**OR (95% CI)**	***p***	**OR (95% CI)**	***p***
Mean age, per 10 years	1.07 (1.06–1.09)	<0.01	1.07 (1.06–1.09)	<0.01
Charlson comorbidity score				
Low (0–2)	Ref.	<0.01	Ref.	<0.01
Mid (3)	2.84 (1.94–4.16)		2.33 (1.58–3.42)	
High (>3)	7.20 (4.21–12.33)		5.26 (3.05–9.06)	
Treatment cohort				
LE alone	0.89 (0.65–1.23)	0.30	0.95 (0.69–1.32)	0.95
LE + immediate resection	0.69 (0.43–1.11)		0.95 (0.59–1.53)	
Radical resection	Ref.		Ref.	

Abbreviations: LE, local excision; OR, odds ratio.

in survival between the three groups. This challenges the current standards of care regarding the role of radical resection for T1 rectal cancers.

There are a number of strengths of this study. First, it is a population-based study that includes all rectal cancers in the province of Ontario, with accurate recording of outcomes and patient

characteristics. This reduces the risk of selection bias in that all eligible patients were included, and also allows for generalizability of these results to similarly resourced settings. In addition, this study has few lost to follow up due to the ability to link patient data, regardless of location of residence, treatment location or eventual outcomes. In addition, the OntaReCC contains a near complete capture of treatments (including surgery, chemotherapy and radiation) as these are provided within a single-payer healthcare system. Linking administrative data to detailed histopathology data allowed for a comprehensive assessment of risk factors for nodal disease. These pathological risk factors are essential for surgical decision-making with regard to radical resection or observation alone and allows assessment of the appropriateness of the treatments offered. Finally, this study reports real-world survival of the three surgical options for those with T1Nx rectal cancer, which can help clinicians and patients understand the expected outcomes in this group.

This study is not without limitations inherent to population studies using linked administrative databases. Limitations included a lack of clinical context, missing information and residual confounding. The clinical context surrounding decision-making was unknown. It is unclear how decisions were made regarding which procedure to pursue (or not pursue) and whether this was based on patient preferences, surgeon preferences or both. It is interesting to note that the median age was higher in those undergoing major resection, despite the increased risks of this procedure and the common perception that younger patients would prefer more aggressive treatments. We also did not have information regarding whether these patients were presented at a multidisciplinary tumour conference. Similarly, we did not have the details of the staging MRI (or transrectal ultrasound), only whether one was completed or not. Presumably, those with obvious nodal disease on MRI would be more likely to be offered radical resection, while those with favourable findings would be more likely to be offered LE. Another issue was incomplete reporting of all risk factors (margin status, LVI, differentiation, perineural invasion, tumour budding) for nodal disease in the histopathology reports. Notably, we identified a high risk of 'unknown' margin status (i.e. margin status not provided) for those undergoing both definitive LE and LE followed by resection. This is not unique to this study. Gimon and colleagues found that only 66.4% of pathology reports at their institution included all the required components for a complete assessment of nodal risk [19]. It is important to note that during the study period (2010–2014), Ontario began mandating synoptic reporting for cancer pathology reports. Residual confounding is also an issue for this population level study. We attempted to adjust our survival analysis for known confounders, such as age and comorbidity score, but these variables provide only a limited assessment of the frailty of the patient. Finally, there was a high proportion of endoscopic resections that were included in this study. This may not reflect the modern management of rectal neoplasms. There have been a number of advances in transanal and endoscopic techniques, including TAMIS, TEM and ESD [7]. Increased use of these techniques would result in a reduction in the number of piecemeal excisions and positive margins and likely increase the number of those eligible for definitive LE.

Previous studies have shown poorer outcomes for patients who underwent LE for early rectal cancers [20–22]. Paty and colleagues found that the survival rates for T1 rectal cancers was 74%, and 72% for T2 cancers [20]. In addition, in 2002 Friel and colleagues reported low rates of salvage for regrowths after LE, with only 79% undergoing curative resection [21]. In the nearly 20 years since those early reports, multiple systematic reviews have suggested similar long-term OS, despite high rates of local recurrence [23]. The current study supports the suggestion that T1 rectal cancers treated without radical resection may have similar long-term survival to those undergoing radical resection. As both imaging and endoscopic assessment continue to improve, many patients who might have been thought to require radical resection may be potentially amenable to close observation. While the rates of adjuvant chemotherapy and radiotherapy were low in our study, recent studies such as the NEO trial and GRECCAR2 may also allow for greater possibilities of organ preservation without decreasing oncological outcomes [24, 25].

Society guidelines such as the American Society of Colon and Rectal Surgeons recommend that patients should be offered a radical resection when found to have poor differentiation, LVI, tumour budding or deep submucosal invasion [26]. The current study reflects the inherent challenges of balancing the potential risk of lymph node metastases with the morbidity of a radical resection, as reflected in the real-world patterns of these patients. One potential strategy to improve the accuracy of prediction would be the development of a risk nomogram, like those developed for breast cancer and prostate cancer [27, 28]. Additionally, the routine use of synoptic reporting for pathology is critical to ensure that surgeons have sufficient information to determine if a radical resection is recommended [19]. Finally, all rectal cancers should be presented at a multidisciplinary tumour board, where imaging, pathology and the clinical scenario can be reviewed [29, 30].

In conclusion, this study reports the outcomes of patients with T1 rectal cancers who underwent definitive intent LE, LE followed by radical resection and upfront radical resection. There was no discernible difference in OS. The results were generated from a 'real-world' setting, and are likely to be generalizable to similarly resourced settings and patient populations. The study calls into question the reflexive decision to offer radical resection for those with suspected T1Nx rectal cancer. Despite poor LE techniques (i.e. high risks of positive margins and piecemeal excisions), survival was no different between those undergoing index resection (or immediate resection) and those who underwent LE with definitive intent. In the era of increased interest in organ preservation, LE for suspected early stage rectal cancers should be considered.

AUTHOR CONTRIBUTIONS

Kelly E. Brennan: conceptualization; methodology; writing—original draft; writing—review and editing; visualization. Ameer O.

Farooq: writing—review and editing. Tyler J. Mckechnie: writing—original draft; writing—review and editing; visualization. Vanessa H. Wiseman: writing—review and editing. Weidong Kong: formal analysis; data curation; methodology; validation. Clare R. Bankhead: supervision; writing—review and editing. Carl J. Heneghan: supervision; writing—review and editing. Mandip S. Rai: conceptualization; methodology; writing—review and editing. Sunil V. Patel: supervision; resources; project administration; writing—review and editing; writing—original draft; investigation; conceptualization; methodology.

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None to report.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data are not publicly available due to institutional and provincial privacy regulations on the use of administrative data.

ETHICS STATEMENT

The study was approved by the Research Ethics Board (REB) of Queen's University, Kingston, Canada. A waiver of informed consent was granted based on the Personal Health Information Protection Act, Section 44(1).

DISCLAIMER

The analyses, conclusions, opinions and statements expressed herein are solely those of the authors and do not reflect those of the funding or data sources; no endorsement is intended or should be inferred. Parts of this material are based on data and/or information compiled and provided by the Canadian Institute for Health Information. However, the analyses, conclusions, opinions and statements expressed in the material are those of the author(s) and not necessarily those of the Canadian Institute for Health Information. Parts of this material are based on data and information provided by Ontario Health (OH). The opinions, results, views and conclusions reported in this article are those of the authors and do not necessarily reflect those of OH. No endorsement by OH is intended or should be inferred.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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