ORIGINAL CONTRIBUTION

Locally Excised T1 Rectal Cancers: Need for Specialized Surveillance Protocols

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BACKGROUND: Local excision of T1 rectal cancers helps avoid major surgery, but the frequency and pattern of recurrence may be different than for patients treated with total mesorectal excision.

OBJECTIVE: This study aims to evaluate pattern, frequency, and means of detection of recurrence in a closely followed cohort of patients with locally excised T1 rectal cancer.

DESIGN: This study is a retrospective review.

SETTINGS: Patients treated by University of Minnesota-affiliated physicians, 1994 to 2014, were selected.

PATIENTS: Patients had pathologically confirmed T1 rectal cancer treated with local excision and had at least 3 months of follow-up.

INTERVENTIONS: Patients underwent local excision of T1 rectal cancer, followed by multimodality follow-up with physical examination, CEA, CT, endorectal ultrasound, and proctoscopy.

MAIN OUTCOME MEASURES: The primary outcomes measured were the presence of local recurrence and the means of detection of recurrence.

RESULTS: A total of 114 patients met the inclusion criteria. The local recurrence rate was 11.4%, and the rate of distant metastasis was 2.6%. Local recurrences occurred up to 7 years after local excision. Of the 14 patients with recurrence, 10 of the recurrences were found by ultrasound and/or proctoscopy rather than by traditional methods of surveillance such as CEA or imaging. Of these 10 patients, 4 had an apparent scar on proctoscopy, and ultrasound alone revealed findings concerning for recurrent malignancy. One had recurrent malignancy demonstrated on ultrasound, but no concurrent proctoscopy was performed.

LIMITATIONS: This was a retrospective review, and the study was conducted at an institution where endorectal ultrasound is readily available.

CONCLUSIONS: Locally excised T1 rectal cancers should have specific surveillance guidelines distinct from stage I cancers treated with total mesorectal excision. These guidelines should incorporate a method of local surveillance that should be extended beyond the traditional 5-year interval of surveillance. An ultrasound or MRI in addition to or instead of flexible sigmoidoscopy or proctoscopy should also be strongly considered. See **Video Abstract** at http://links.lww.com/DCR/A979.

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Funding/Support: None reported.

Financial Disclosures: None reported.

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Dis Colon Rectum 2019; 62: 1055–1062
DOI: 10.1097/DCR.0000000000001439

ANTECEDENTES: La escisión local de los cánceres de recto T1 ayuda a evitar una cirugía mayor, pero la frecuencia y el patrón de recurrencia pueden ser diferentes a los de los pacientes tratados con escisión mesorectal total.

OBJETIVO: Evaluar el patrón, la frecuencia y los medios de detección de recidiva en una cohorte de pacientes con cáncer de recto T1 extirpado localmente bajo un régimen de seguimiento especifico.

DISEÑO: Revisión retrospectiva.

AJUSTES: Pacientes tratados por hospitales afiliados a la Universidad de Minnesota, 1994–2014

PACIENTES: Pacientes con cáncer de recto T1 confirmado patológicamente, tratados con escisión local y con al menos 3 meses de seguimiento.

INTERVENCIONES: Extirpación local del cáncer de recto T1, con un seguimiento multimodal incluyendo examen físico, antígeno carcinoembrionario (CEA), TC, ecografía endorrectal y proctoscopia.

PRINCIPALES MEDIDAS DE RESULTADO: Presencia de recurrencia local y medios de detección de recurrencia.

RESULTADOS: Un total de 114 pacientes cumplieron con los criterios de inclusión. La tasa de recurrencia local fue del 11,4% y la tasa de metástasis a distancia fue del 2,6%. Las recurrencias locales se presentaron hasta 7 años después de la escisión local. De los 14 pacientes con recurrencia, 10 de las recurrencias se detectaron por ultrasonido y / o proctoscopia en lugar de los métodos tradicionales de vigilancia, como CEA o imágenes. De estos diez pacientes, cuatro tenían una cicatriz aparente en la proctoscopia y el ultrasonido solo reveló hallazgos relacionados con tumores malignos recurrentes. En una ecografía se demostró malignidad recurrente, pero no se realizó proctoscopia concurrente.

LIMITACIONES: Revisión retrospectiva; estudio realizado en una institución donde se dispone fácilmente de ultrasonido endorrectal

CONCLUSIONES: Los cánceres de recto T1 extirpados localmente deben tener una vigilancia específica distinta de los cánceres en etapa I tratados con TME. El régimen de seguimiento deberá de extender más allá del intervalo tradicional de 5 años de vigilancia. También se debe considerar la posibilidad de realizar una ecografía o una resonancia magnética (IRM) además de la sigmoidoscopía flexible o la proctoscopía. Vea el Resumen del video en http://links.lww.com/DCR/A979.

KEY WORDS: Local excision; Rectal cancer; Outcomes; Transanal endoscopic microsurgery; Transanal excision.

Rectal cancers that are T1 tumors with favorable pathologic features can sometimes be treated with local excision rather than total mesorectal excision (TME). Local excision of rectal cancer using transanal excision (TAE) has remained controversial in light of earlier studies showing a high rate of lymph node metastases and cancer recurrence.[1,2] More recent work looking at alternative techniques, such as transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS), have found oncologic results similar to radical resection for early-stage cancers.[3,4] There is also a reported lower rate of local recurrence compared to TAE,[5,6] although we have found this to be equivalent in previous work from our institution.[7] Overall, the local recurrence rate after local excision of T1 adenocarcinoma ranges between 0% and 23%, whereas, in general, local recurrence rates for T1 cancers treated with TME are <10%.[5,8–11]

Thus, locally excised T1 cancers may be more prone to local recurrence than T1 cancers treated with TME. In addition, local recurrence may be more difficult to detect than distant recurrence with the usual modalities used in surveillance such as CEA, CT, and colonoscopy. Despite this, very limited guidelines exist on appropriate surveillance of early rectal cancers excised locally. Many major societies' guidelines do not advocate any surveillance other than colonoscopy, because these are stage I tumors. The purpose of this study is to report on a cohort of patients who underwent local excision of T1 tumors and were followed under an intensive surveillance regimen to determine whether such a surveillance regimen may be warranted for T1 tumors treated with local excision.

METHODS

Study Design and Patient Selection

For this retrospective cohort study, all patients with a pathologically staged T1 rectal adenocarcinoma (within 15 cm of the anal verge) treated with local excision by University of Minnesota-affiliated surgeons, between January 1994 and December 2014, were identified. Patients with a preoperatively staged T2-4 rectal cancer, those with clinical signs of nodal metastasis, those with neoadjuvant treatment, and those with less than 3 months of postprocedure follow-up were excluded from consideration. Patients operated on after 2014 were not included in the cohort because they would have had a short interval of follow-up. Preoperative staging was completed with either endorectal ultrasound (ERUS) or, less frequently, pelvic MRI, or both studies. In addition, a CT scan of the chest, abdomen, and pelvis was performed to exclude metastatic disease. Local excision was performed by either TAE, TEM, or TAMIS at the discretion of the operating surgeon.

Postoperative follow-up was performed according to the plan listed in Table 1. In most instances, the operating

TABLE 1. Guidelines

Organization	*Rectal cancer*	*History and physical*	*CEA*	*Imaging*
American Society of Clinical Oncology (ASCO) Cancer Care Ontario (CCO)[24,25] American Joint Committee on Cancer (AJCC) American Society of Colon & Rectal Surgeons (ASCRS)[25]	Stage 1 with high risk of recurrence[a]	Every 3–6 mo for 2 y, then every 6 mo until 5 y	Every 3–6 mo for 2 y, then every 6 mo until 5 y	CT chest/abdomen/pelvis: annually for 5 y Colonoscopy[b]: annually after preop colonoscopy; 3–6 mo after surgery if incomplete colonoscopy preop Proctoscopy (± ERUS) Resection and anastomosis: every 6–12 mo for 3–5 y Local excision: every 6 mo for 3–5 y
National Comprehensive Cancer Network (NCCN)[26]	Stage 1 with full surgical staging	No	No	Colonoscopy[c]: annually after preop colonoscopy
	Local excision	No	No	Colonoscopy[c]: annually after preop colonoscopy Proctoscopy (with ERUS or MRI with contrast): every 3–6 mo for 2 y, then every 6 mo until 5 y
University of Minnesota Colon and Rectal Surgery Associates	Stage 1, local excision	Every 3–6 mo for 2 y, then every 6 mo until 5 y	Every 3–6 mo for 2 y, then every 6 mo until 5 y	CT chest/abdomen/pelvis: annually for 5 y Colonoscopy[b]: annually after preop colonoscopy; 3–6 mo after surgery if incomplete colonoscopy preop Proctoscopy + ERUS or MRI: every 4 mo for 3 y then every 6 mo until 5 y, then flexible sigmoidoscopy yearly until 8 y

ERUS = endorectal ultrasound; preop = preoperative.
[a] As defined by the provider taking into consideration margin status (<1 mm), poor differentiation, lymphovascular invasion, or T2 disease.
[b] Subsequent colonoscopies dependent on findings at initial postoperative study. Repeat colonoscopy in 1 year for patients found to have adenomas and in 3 years for those without adenomas. Annual colonoscopies are recommended in patients with familial cancer syndromes who have not undergone a total proctocolectomy.
[c] If advanced adenoma, repeat colonoscopy in 1 year. If no advanced adenoma, colonoscopy should be repeated in 3 years then every 5 years.

surgeons or their partners performed digital rectal examination, proctoscopy, and ERUS. Computed tomography and CEA were monitored either by the operating surgeon or the patient's oncologist, if applicable. A retrospective review of the medical record was conducted to construct a database containing all patient demographics, operative details, postoperative course, pathology results, and follow-up data. The Social Security Death Index was queried in December 2017 to help determine whether patients were alive or dead. This study was approved by the Institutional Review Board of the University of Minnesota.

Outcome Measures

Our primary outcome was local recurrence as determined by multimodal clinical follow-up, and the means of detection of said recurrence. Secondary outcomes included distant metastases, postoperative morbidity, need for future procedures, and mortality.

Statistical Analysis

Patients with local recurrence were compared with those who did not have recurrence. χ^2 or Fisher exact tests were used to compare categorical variables. Wilcoxon rank-sum test was used to compare continuous variables. Throughout all analyses, statistical significance was determined by a criterion of $p < 0.05$. Kaplan-Meier curves were utilized to demonstrate time to local recurrence and overall survival. All analyses were conducted by using IBM SPSS Statistics version 24.0.0.1 for Macintosh (IBM Corp, Armonk, NY).

RESULTS

Patients, Preoperative Staging, and Pathology Results

A total of 308 patients underwent local excision of a rectal malignancy during the study period. One hundred eighty-six patients with either unavailable preoperative staging or preoperative staging > T1N0 were excluded. Patients with initial staging >T1N0 were excluded, because there may have been patient factors that led surgeons to choose a local excision approach rather than TME and could thus have introduced significant bias into the patient cohort. Another 7 patients were excluded for follow-up less than 3 months. This left 114 patients for analysis (Fig. 1). Patient demographics are summarized in Table 2. Of the 114 patients, 40% were female and the mean age was 64.9 years. Preoperative staging was done using ERUS in 85% of patients, whereas 15% had a pelvic MRI. Average tumor size was 2.4 cm, and tumors were a mean of 7.9 cm from the anal verge. Sixty-six percent of tumors were

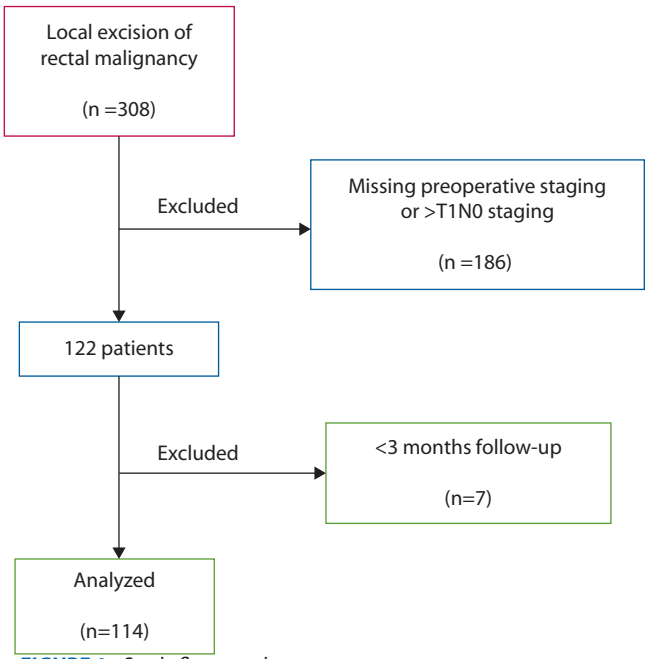

FIGURE 1. Study flow graph.

removed using TAE, and, in the majority of the remaining patients, tumors were removed by TEM. All TAMIS resections were performed after 2011 and by a single surgeon.

Details from pathologic evaluation of the tumors are presented in Table 3. A negative margin of >1 mm was achieved in 103 of 114 patients (90%). The specimen included a lymph node in 6 patients (7%) with all of these being negative.

Complications

Fifteen patients (16%) experienced a complication. Eleven of these were Clavien-Dindo grade 1 or 2, and 4 patients had grade 3 or 4 complications. Of those with grade 3 or 4 complications, one had non–ST-segment–elevation myocardial infarction requiring stenting, one had leakage requiring fecal diversion, one had bleeding managed endoscopically, and one had an abscess managed with CT-guided drainage.

Recurrence and Survival

Patients were followed for a median of 64 months (range 5–178 months). Although follow-up was intended to be according to the plan in Table 1, because of patient compliance, the interval between follow-up ranged from 3 to 10 months (Supplemental Figure 1, Supplemental Digital Content, http://links.lww.com/DCR/A980). The median number of ultrasounds performed in the entire cohort was 7 (range 0–20). Clinic visits consisted of a full history and physical examination, including a digital rectal evaluation. Until 5 years after diagnosis, patients also received either an ERUS or proctoscopy or, most often, both studies. Between 5 and 8 years after diagnosis, patients received flexible sigmoidoscopy rather than ERUS and proctoscopy. The surveillance protocol is given in Table 1. Fourteen patients had recurrent disease: 11 of these were local recurrences, 1 systemic and 2 with both local and systemic disease at the time of diagnosis (Table 4). Thus, the local recurrence rate was 11.4% and the rate of distant metastasis was 2.6%. Of the 14 patients with recurrence, 10 of the recurrences were found by ultrasound and/or proctoscopy rather than by traditional methods of surveillance such as CEA or imaging. Of these 10 patients, 5 had a lesion visible on both ultrasound and proctoscopy. Four had an apparent scar on proctoscopy, and ultrasound alone revealed findings concerning for recurrent malignancy. One had recurrent malignancy demonstrated on ultrasound, but no concurrent proctoscopy was performed. Among the patients with recurrence found by ultrasound and/or proctoscopy, the recurrences were stage I in 2, stage II in 2, stage III in 5, and stage IV in 1. Among the patients with recurrence found by other means, the recurrences were stage I in 1, stage III in 1, and stage IV in 2.

There was no statistically significant difference in demographics between patients who did not develop recurrence compared with those who did develop recurrence

TABLE 2. Preoperative patient and tumor characteristics

Preoperative variable	*All (n = 114)*	*No local recurrence (n = 100)*	*Local recurrence (n = 14)*	*p value*
Female; n (%)	46 (40)	40 (40)	6 (43)	1.0
Age, y, mean (SD)	64.9 (12.2)	65.0 (11.8)	64.4 (15.5)	0.85
Malignant preoperative histology, n (%) [a]	84 (76)	75 (77)	9 (69)	0.50
Resection method, n (%)				0.77
Transanal	75 (66)	66 (66)	9 (64)	
TEM	36 (32)	31 (31)	5 (36)	
TAMIS	3 (3)	3 (3)	0 (0)	
Distance from anal verge, cm, mean (SD) [b]	7.9 (2.8)	7.9 (2.8)	7.4 (2.3)	0.50
Tumor size, cm; mean (SD)[c]	2.4 (1.5)	2.3 (1.4)	2.8 (2.0)	0.51

TAMIS = transanal minimally invasive surgery; TEM = transanal endoscopic microsurgery.
[a]Preoperative histology unavailable for 4 patients.
[b]Distance from anal verge unavailable for 2 patients.
[c] Tumor size unavailable for 4 patients.

TABLE 3. Pathology details

Tumor characteristic	*Missing*	*All (n = 114)*	*No local recurrence (n = 100)*	*Local recurrence (n = 14)*	*p value*
Tumor differentiation, n (%)					
Well	7 (6)	20 (19)	19 (20)	1 (8)	0.28
Moderately		84 (79)	73 (78)	11 (85)	
Poorly		2 (2)	1 (1)	1 (8)	
Mucinous		1 (1)	1 (1)	0 (0)	
Depth of submucosal invasion, n (%)					
sm1	65 (57)	26 (53)	24 (56)	2 (33)	0.58
sm2		11 (22)	9 (21)	2 (33)	
sm3		12 (24)	10 (23)	2 (33)	
Vascular invasion, n (%)	27 (24)	10 (12)	7 (9)	3 (27)	0.11
Lymphatic invasion, n (%)	31 (27)	10 (12)	7 (10)	3 (27)	0.12
Perineural invasion, n (%)	79 (69)	0 (0)	0 (0)	0 (0)	-
Tumor budding, n (%)	75 (66)	9 (23)	8 (23)	1 (25)	1.00
Margin, n (%)					
Negative >1 mm	0	103 (90)	91 (91)	12 (86)	0.62
Positive, or negative <1 mm		11 (10)	9 (9)	2 (14)	

over the study period (Table 2), including no difference between patients who had negative vs positive margins (Table 3). Time to recurrence ranged from 4 to 84 months (Table 4, Fig. 2A). Salvage involved a repeat local excision in 4 patients, with 2 of these going on to develop a second recurrence (Table 4). Among the patients undergoing salvage TME, an R0 resection was achieved in all but one. Among the 5 patients undergoing salvage TME where preoperative ultrasound had suggested positive lymph node(s), 4 of the 5 had positive lymph node(s) on final pathology. Eight of the 14 patients (57.1%) with local recurrence died during the study period (Fig. 2B). Three of the deaths were attributed to recurrent rectal cancer. Of the 100 patients who did not develop a recurrence, 22 deaths were reported (22.0%).

DISCUSSION

This study of a closely followed cohort of patients with locally excised T1 rectal cancers demonstrates an 11% local recurrence rate; the majority of these recurrences were found by

TABLE 4. Recurrence and outcomes

Patient	*Time to recurrence (months)*	*Site*	*Method of detection*	*Salvage procedure(s)*	*Outcome*	*Cause of death if known*
1	23	Local	ERUS	LAR	Dead	
2	19	Local	Symptomatic (rectal bleeding)	Repeat TEM 2nd recurrence: observed	Dead	
3	17	Local	ERUS	Chemoradiation, LAR	Dead	
4	22	Local	ERUS	Chemoradiation, APR	Alive	
5	7	Local	ERUS, scope	APR	Dead	Metastatic rectal cancer
6	84	Local	ERUS, scope	Chemoradiation, LAR	Dead	
7	9	Local	ERUS	Chemoradiation	Dead	Hemorrhage from varices
8	21	Local	ERUS, scope	Repeat TEM	Alive	
9	9	Local	ERUS, scope	Repeat local excision 2nd recurrence: chemoradiation, LAR	Alive	
10	47	Local	Scope	Repeat local excision with LVI then chemoradiation, LAR	Alive	
11	37	Local/systemic	Symptomatic (rectal pain)	Chemoradiation, APR	Dead	Metastatic rectal cancer
12	4	Local	ERUS	Chemoradiation, LAR	Alive	
13	47	Systemic	Symptomatic (back pain; difficulty ambulating)	Radiation	Dead	Metastatic rectal cancer
14	9	Local/systemic	CEA	Lung resection, chemotherapy	Alive	

APR = abdominoperineal resection; ERUS = endorectal ultrasound; LAR = low anterior resection; LVI = lymphovascular invasion; TEM = transanal endoscopic microsurgery.

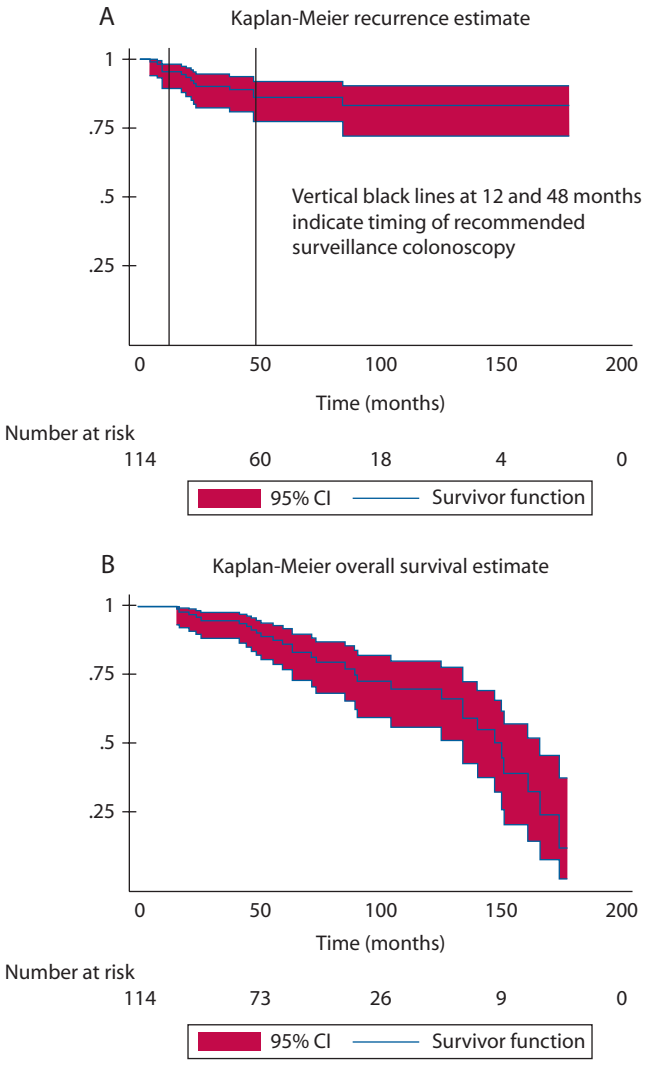

FIGURE 2. A, Kaplan-Meier curve of recurrence-free time in months after local excision of early staged rectal cancer. B, Kaplan-Meier curve of overall survival in months after local excision of early staged rectal cancer.

local surveillance methods (ultrasound and/or proctoscopy) that are not currently a component of many societies' guidelines for surveillance of stage I cancers. Traditional surveillance methods such as CEA or imaging were responsible for detection of a minority of the recurrences. Endorectal ultrasound appeared to have an additional benefit beyond proctoscopy or flexible sigmoidoscopy alone for surveillance, because 5 of the 11 patients with isolated local recurrence were found by ultrasound and 4 of these had no concerning findings on proctoscopy (proctoscopy was not performed in the fifth). Recurrences also occurred after the traditional 5-year surveillance window. As a whole, these findings suggest that locally excised T1 rectal cancers should have specific surveillance guidelines distinct from stage I cancers treated with TME.

The study provides comprehensive evidence to support its findings because this is a carefully selected group of patients with pathologically staged T1 tumors who underwent intensive surveillance over a long median follow-up period. The number of patients included is larger than most other studies of local excision of T1 tumors.[9,10,12–14] Only 3 of the 14 patients presented for evaluation because of rectal bleeding. The rest were completely asymptomatic, with early recurrence detected only by adhering to the frequent multimodality surveillance protocol we have at our institution. This allowed for a second salvage procedure in addition to chemoradiation therapy with curative intent in most cases. Among the 14 patients with recurrence, 6 were alive at the end of follow-up, including 4 of the 9 who underwent salvage TME. This is similar to the salvage rates reported in the literature, where salvage rates are generally <50%, even though, in general, these studies have shorter periods of follow-up than the follow-up duration in this study.[15–17] Thus, although it is difficult to prove that the more intensive surveillance resulted in improved outcomes, it would be difficult to gather a large enough patient population to demonstrate improved survival with intensive surveillance because recurrence after local excision of rectal cancers is already a relatively rare event.

Thirty-six percent (5/14) of patients who had a recurrence did so within the first 12 months, and 71% by 24 months. Time to recurrence occurred as early as 4 months to as late as 7 years from the date of initial surgery, so the long follow-up period was crucial to detecting some of the recurrences.

There are several limitations to our study including the retrospective design used, which meant that we did not have detailed data on CEA and CT results for some patients who received this portion of their follow-up with other providers. We did not see a difference in rate of local recurrence in tumors with less favorable characteristics such as larger size, poorer differentiation, or lymphovascular invasion. This is likely because of the lack of power from the population size and amount of missing data. It is possible that, for low-risk tumors, the risk of recurrence is low enough that such an intensive surveillance strategy is not needed. We also saw temporal effects on the type of procedure done with more TAE performed throughout the study period by all 21 of our surgeons. Transanal endoscopic microsurgery was introduced early but with more cases performed during the second half of the study, reflecting increased adoption in our own community. Only 1 surgeon performed all 3 TAMIS procedures. Despite the potential bias this introduces, no difference was seen in recurrence looking at the type of procedure.

Another limitation is that our program has a well-established pelvic floor center that is staffed by colorectal surgeons who perform and interpret our ERUS studies. As such, most of our surgeons favor this imaging modality for staging and surveilling rectal cancers over MRI, despite having similar sensitivities for detecting early T-staged disease.[18,19] This might limit the generalizability of our surveillance recommendations, especially in institutions where only pelvic MRIs are done. Obtaining pelvic MRIs

every 3 to 6 months may also be more expensive and will be met with varying degrees of compliance.

We found an 11% local recurrence rate after local excision of early staged T1 rectal cancers. This is consistent with figures reported in published studies.[3–5,8] As seen in prior work from our institution,[7] the type of surgical approach used had no significant impact on local recurrence rate. That said, other studies[6,20] have found statistically significant lower rates of local recurrence after TEMs than after TAEs. These studies, however, usually include T1 to T3 tumors treated with local excision, unlike our study that was limited to T1 tumors.

Radical resection of rectal cancers with either a low anterior or abdominoperineal resection is associated with high morbidity and mortality.[21] This has increased the appeal and performance of local excision methods such as TAE, TEM, or TAMIS that allow organ preservation, helping to avoid long-term complications seen with more traditional approaches.[22–25] Similar oncologic outcomes have been noted in early T1 rectal cancers treated with TEM.[26,27] However, other studies demonstrate an increased risk of local recurrence for T1 tumors treated with local excision rather than TME,[9,10,12] meaning that these patients may need closer surveillance for local recurrence than patients treated with TME.

Most surveillance regimens are skewed toward detecting systemic recurrence rather than local recurrence, relying on methods such as CEA and imaging, because systemic recurrence is the greater risk for more advanced cancers. Because the overall recurrence risk for stage I cancers is low, some societies' surveillance guidelines do not recommend any surveillance other than colonoscopy. For instance, both the American Society of Clinical Oncology and Cancer Care Ontario recommend no surveillance for patients with stage I rectal cancer[28] (Table 1). This is based on the lack of sufficient data to help provide guidance. The American Society of Colon & Rectal Surgeons, on the other hand, supports the recommendations put forth by the American Joint Committee on Cancer.[29] However, this is also based on low-quality evidence (Grade of Recommendation: Weak. 2C). Their recommendations do make a distinction between stage I rectal cancers with high risk of recurrences, allowing for surveillance of these patients using the same parameters for stage II and III diseases. The National Comprehensive Cancer Network advocates for colonoscopy at 1 year and a repeat in 3 years if no advanced adenoma is appreciated.[30] In their most recent guidelines from June this year, a separate recommendation is made for lesions removed via TAE only. In addition to a colonoscopy at 1 year, a proctoscopy with either an ERUS or MRI every 3 to 6 months for the first 2 years is recommended. This is then done every 6 months up to a total of 5 years. None of the guidelines recommend surveillance beyond 5 years, and only the National Comprehensive Cancer Network makes MRI or ultrasound a routine part of the surveillance of locally excised T1 cancers.

From our own experience performing local excisions of rectal tumors over the past 2 decades and the knowledge we have gained from evaluating our outcomes in this study, we strongly believe that more stringent guidelines need to be adopted. This is especially important as more surgeons embrace TEM/TAMIS and offer these procedures to patients as an acceptable treatment for early-stage disease. Patients need to be made aware of the 0% to 23%[3,5,8,11] associated risk for local recurrence and the importance of close follow-up to ensure early detection if this should occur.

Because recurrence is skewed toward local rather than systemic recurrence in these patients, surveillance regimens should place an emphasis on including methods designed to detect local recurrence rather than the traditional reliance on CEA and imaging. Ultrasound or MRI and either proctoscopy or flexible sigmoidoscopy should be a routine part of this surveillance. We believe ultrasound or MRI has an important role in surveillance, because nearly half of the patients in this study who experienced local recurrence had this recurrence detected on ultrasound alone, often in the setting of a "normal" proctoscopy. Surveillance should also continue beyond the traditional 5-year window, because we observed local recurrences up to 7 years after local excision. In Table 1, we outline the protocol recommended at our institution. However, it might prove challenging to ensure both surgeon and patient compliance with a more frequent and longer surveillance protocol, as has been our experience.

CONCLUSIONS

The results of this study show that T1 rectal cancers recur after local excision in approximately 11% of patients. Most recurrences are local rather than systemic and are asymptomatic. It is important to surveil these patients closely, because they are at increased risk for recurrence compared with patients with stage I cancer treated with TME. More defined guidelines are needed from our governing bodies. Surveillance guidelines should incorporate a method of local surveillance, should strongly consider ultrasound or MRI in addition to or instead of flexible sigmoidoscopy or proctoscopy, and should extend beyond the traditional 5-year interval of surveillance.

ACKNOWLEDGMENTS

The authors thank Ruth Elling for her assistance with data collection.

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