Diagnostic accuracy of high-resolution MRI as a method to predict potentially safe endoscopic and surgical planes in patients with early rectal cancer

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ABSTRACT

Introduction: Early rectal cancer (ERC) assessment should include prediction of the potential excision plane to safely remove lesions with clear deep margins and feasibility of organ preservation.

Method: MRI accuracy for differentiating ≤T1sm2 (partially preserved submucosa) or ≤T2 (partially preserved muscularis) versus >T2 tumours was compared with the gold standard of pT stage T1sm1/2 versus ≤pT2 versus >pT2. N stage was also compared. The MRI protocol employed a standard surface phased array coil with a high resolution (0.6×0.6×3 mm resolution). The staging data were analysed from a prospectively recorded database of all ERC (≤mrT3b) treated by primary surgery.

Results: Of 65 <mrT3b tumours, 45 were ≤pT2 and 14 were ≤pT1sm2. MRI accuracy for ≤T1sm2 was 89% (95% CI 63% to 87%), positive predictive value (PPV) 77% and negative predictive value (NPV) 92%, and for ≤T2 89% (95% CI 79% to 95%), PPV 93% and NPV 81%. Interobserver agreement between two experienced radiologists was >0.7 suggesting good agreement. 44 out of 65 patients underwent radical surgery and 22 out of 44 were ≤mrT2. MRI accuracy to predict lymph node status was 84% (95% CI 70% to 92%), PPV 71% and NPV 90%. Among the 21 out of 65 (32%) patients undergoing local excision or TEM, 20 out of 21 were staged as MR≤T2 and confirmed as such by pathology. On follow-up, none had relapse. If the decision had been made to offer local excision on MRI TN staging rather than clinical assessment, a significant increase in organ preservation surgery from 32% to 60% would have been observed (difference 23%, 95% CI 9% to 35%).

Conclusions: MRI is a useful tool for multidisciplinary teams (MDTs) wishing to optimise treatment options for ERC; these study findings will be validated in a prospective multicentre trial.

Summary box

What is already known about this subject?

- ► The proportion of detected T1 colorectal cancers is highly increasing due to a number of screening programmes with up to 30% of screen-detected cancers being identified as Dukes' A.
- ► Endoluminal ultrasound has not proven to be effective, as preoperative staging does not offer sufficient accuracy or influence the rate of R1 resection and outcomes.
- ► High-resolution MRI is widely accepted as a gold standard of advanced rectal tumours spread assessment; however, MRI is not always relied on as a primary tool for staging early rectal cancer (ERC) as a tendency to inaccurately stage lesions as T1/2 without precisely specifying the depth of invasion has previously been observed.

What are the new findings?

- ► High-resolution MRI enables differentiation of partial versus full submucosal invasion with 89% accuracy when tested prospectively in patients with ERC.
- ► Eighty-nine per cent accuracy was observed of detection of partial or full preservation of the muscularis propria.
- ► MRI specificity to predict node-negative disease in ≤pT2 tumours was 84%.

How might it impact on clinical practice in the foreseeable future?

- ► This paper suggests that MRI could be used as a guiding tool to plan endoscopic and surgical planes in ERC and can be a useful tool for multidisciplinary teams (MDTs) wishing to optimise treatment options for ERC.

INTRODUCTION

The slow evolution of cancer in polyps was first reported in 1975 by Muto et al[1] at St Marks Hospital in 1975 and led directly to the implementation of colorectal screening.

Through screening, an increase in detection of early rectal cancers (ERC) and significant polyps may improve survival outcomes by intercepting the polyp to cancer sequence. An unfortunate consequence of screening has been the high rate of patients with ERC

being subjected to major total mesorectal excision (TME) surgery, permanent stomas and even preoperative radiotherapy despite early disease; the National Bowel Cancer Audit (NBOCAP report, 2015)[2] showed that a significant proportion of patients with ERC had T1N0 disease, yet underwent major resection surgery without any option for less radical treatments. Conversely, the UK transanal endoscopic microsurgery (TEM) database suggests that ~30% of tumour considered as ERC based on clinical endoscopic assessment had more advanced disease, with evidence of spread beyond the muscularis propria (MP) on histopathology following TEM excision. No significant difference has been found in the depth of TEM excision or R1 rate between the patients who underwent endoluminal ultrasound (EUS) before TEM and those who did not (p=0.73) with EUS understaging taking place in 32.7% of patients.[3] Therefore, the current standards of endoscopic and EUS assessment appear insufficient to identify patients suitable for potentially less radical treatment and the lack of any current robust preoperative staging method means that decision and discussion of such treatment options cannot currently be offered consistently.

The national SPECC (Significant Polyp and Early Colorectal Cancer) initiative was a consequence of a major problem we are currently facing—an overtreatment and undertreatment of ERC/significant polyps. MRI has largely been disregarded as a method of staging ERC; however, the majority of publications have reported that MRI is not as useful compared with EUS for staging these lesions, although this has not been supported by significant evidence in either direction.[4–7] In the late 1990s, a high-resolution technique for staging advanced rectal cancers and the principles for staging advanced rectal cancers were developed that enabled identifying the layers of the rectal wall with sufficient resolution to assess the submucosa and the MP.[8] In subsequent studies, when formally compared with pathology, the depth of spread on MRI has been found to agree with the corresponding histopathology measurements to within 1 mm.[9 10] The degree of agreement was the best for the earlier stage tumours; therefore, if the attempt is made to make these measurements within the rectal wall, it is logical to assume that the performance should be similar. We therefore hypothesise that by using high-resolution MRI, it should be possible to identify tumour depth of invasion within the rectal wall to enable identification of patients suitable for local excision approaches. The aim of this study was therefore to test the MRI diagnostic accuracy of ERC staging in terms of assessing the submucosa, MP and the depth of tumour invasion within the rectal wall against the gold standard of histopathology in a cohort of patients prospectively staged in our institution. The clinical impact of this assessment would determine if the plane of excision needed to achieve a clear deep margin proposed using the MRI is accurate enough for surgeons and endoscopists to plan their intervention that could result in greater numbers of patients undergoing organ preservation.

MATERIAL AND METHODS
Study design
Our study protocol was prospectively registered with our local research and development office and approved as a service evaluation project. We reviewed our prospectively collected and scored database of imaging and pathology records between 2010 and 2014. Since the data had been recorded prospectively prior to MDT and surgical resection, the scans were centrally reviewed by a consultant radiologist (observer 1) with more than 15 years of gastrointestinal (GI) radiology experience who was blinded to final histopathology data. Results of the prospectively collected MRI reports were compared with final histopathology of the resected specimens. All MRIs were scored separately by a second radiologist (observer 2) with 8 years of GI radiology experience.

Participants
The Royal Marsden Hospital Rectal Cancer database was used to identify patients with rectal cancer staged by MRI as ≤T3b. Inclusion criteria were as follows: patients under 18, had rectal cancer MRI staging and underwent surgical resection. Patients were excluded if they: had other primary cancers found at or before diagnosis, if no preoperative MRI was available or preoperative MRI T stage was >T3b, mrCRM and mrEMVI positivity, or if they received any preoperative therapy.

Test methods
Since 2010, our policy was to report ERC using a specific reporting pro forma. Tumours staged as T2 or less were prospectively documented using the following 'sm' classification:

- ▶ no MR-macroscopic evidence of submucosal invasion —benign polyp;
- ▶ macroscopically visible spared submucosa (at least 1 mm or more) and fully intact MP—T1sm1/ T1sm2;
- ▶ no submucosa preserved (<1 mm) with macroscopically intact fibres of outer layer of the MP—sm3/early T2.

MRI technique
MR examinations were performed on a 1.5 T MR system (Siemens) with a body-matrix coil centred over the pelvis. High-resolution T2w turbo spin echo (TSE) scans were acquired in coronal and sagittal planes, followed by oblique-axial scans (perpendicular to the long axis of the rectum with 160 mm field of view (FOV), 3 mm slice thickness, no interslice gap, a matrix of 256×256 and a minimum of 4 number of signal averages (NSA)). No contrast was used during MRI examination. No diffusion-weighted images (DWI) were undertaken.
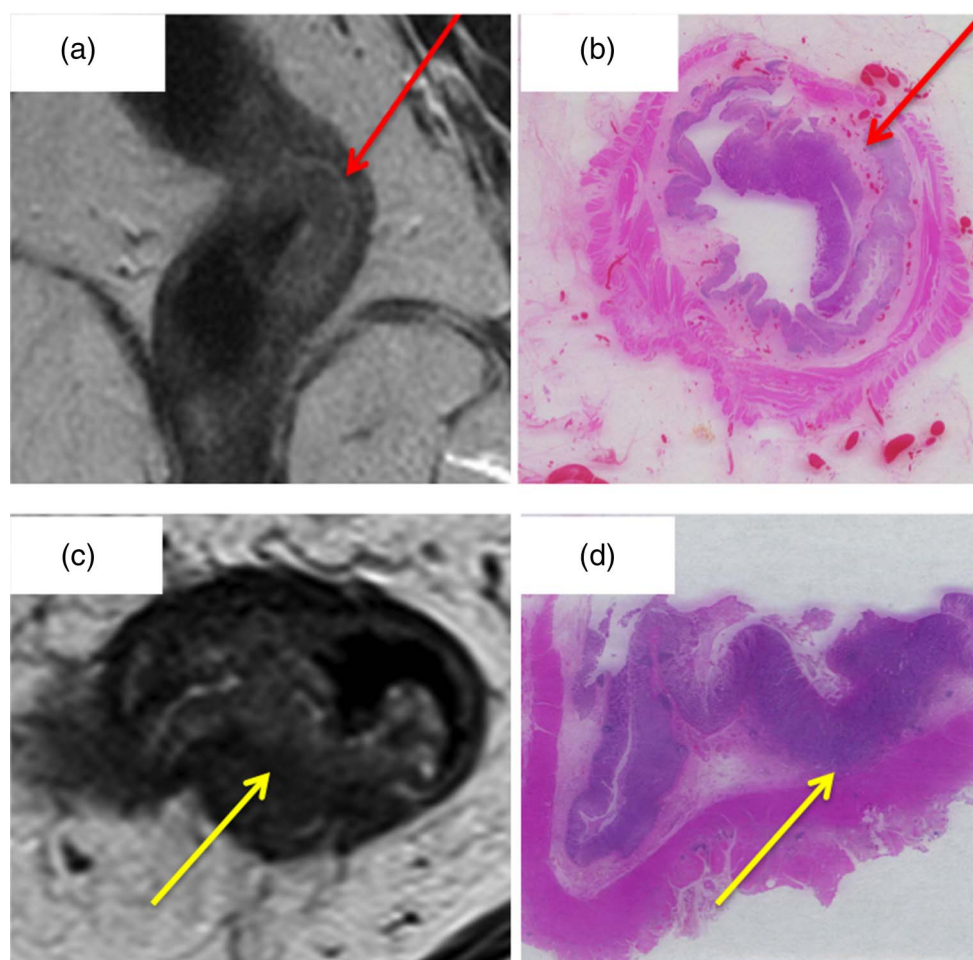
Figure 1 (A) Submucosa has a hyperintense signal on MRI (red arrow) which should be considered partially or fully preserved if at least 1 mm visible on high-resolution T2-WI. Findings confirmed on histopathology (B). (C) If no hyperintense signal present between the tumour invasion portion and muscularis propria, full invasion of the submucosal layer should be considered. Findings confirmed on histopathology (D).

Image interpretation

MRI assessment of tumour depth was performed at the level of the invasive border in semianular tumours or at the level of fibromuscular stalk if a polypoidal lesion was suspected. For semianular tumours, the presence or absence of a preserved submucosal layer at the central invasive portion was the main staging factor (in accordance with previously published guidelines[11]).

The degree of preservation of the submucosal layer seen on MRI as a hyperintense plane between tumour and MP (figure 1A,B) was recorded. A measurement of (≥1 mm) preserved submucosa was used as a definition for partial rather than full submucosal invasion and any such tumour would then be classified on MRI as T1 sm1 or sm2, depending on the maximal degree of preservation of the submucosal layer in any one plane. If no hyperintense submucosal layer was identified between the tumour and the muscularis but the muscularis layer was completely preserved (figure1C,D), the tumour was staged as T1sm3/early T2.

Tumours with >1 mm preservation of MP were classified as T2, and those with <1 mm MP preservation or spread beyond the muscularis as T3a-b (depending on the depth of mesorectal invasion in millimetres).

Original pro-forma reports as discussed and presented at colorectal weekly MDT were analysed for the purposes of this study. The policy of the MDT was to offer primary surgery for ERC without any preoperative radiotherapy regardless of nodal status provided that no extramural venous invasion (EMVI) or circumferential resection margin (CRM) involvement was evident on MRI. However, there was no implemented policy to offer local excision based on MRI assessment during this audit period.

We subsequently evaluated the accuracy of MRI in defining endoscopic/surgical planes for ERC on the basis of the tumour depth invasion into the rectal wall comparing MRI results to final histopathology findings. We tested two models of possible endoscopic/surgical intervention based on preoperative MRI (figure 2 and table 1 for two scenarios).
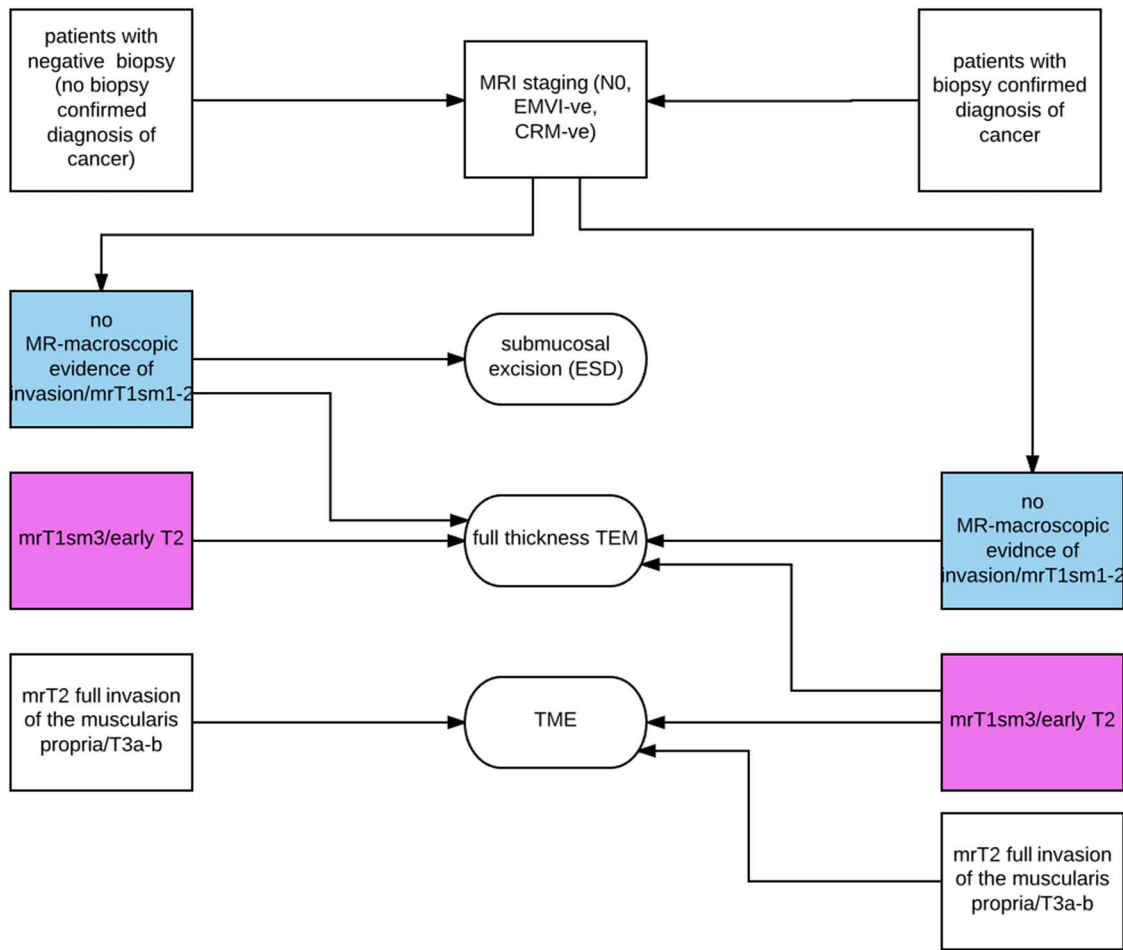
Figure 2 Flow chart demonstrating potential treatment algorithms based on MRI-defined endoscopic and surgical planes. Blue colour indicates scenario 1 and pink colour indicates scenario 2.

In the final analysis, we calculated MRI accuracy for two scenarios regardless of preoperative biopsy findings (scenario 1: feasibility of MRI to identify tumours with minimal submucosal invasion ($\leq$T1sm2); scenario 2: feasibility of MRI to identify tumours with no submucosal preservation but partial or full invasion of the MP ($\leq$T2)).

In patients who had undergone total mesorectal resection during the evaluation period, we also compared the accuracy of MRI in identifying patients with malignant lymph nodes.

The MRI scans were read by a second independent observer to measure interobserver agreement of MRI staging accuracy of ERC. Anonymised scans were scored by the observer 2 who was blinded to the histopathology results and results of the MRI reports from the observer 1. All of the scans were analysed during three sessions with 20±3 cases per session using the same reporting pro forma as by the observer 1. Scans were staged according to the TNM classification and then categorised into three groups ($\leq$T1sm2, $\leq$T2, >T2).

Statistical analysis

Data were tabulated and entered into a spreadsheet. All statistical analyses were performed using Microsoft Excel V.14.4.5 (Redmond, Washington, USA 2011) and IBM SPSS V.23.0 (IBM Corp, New York, USA, 2013).

The primary end point was the sensitivity, specificity and accuracy of MRI calculated for both scenarios.

MRI accuracy for staging and defining endoscopic and surgical planes for local excision was calculated from histology data using cross tables. CIs for the sensitivity

Table 1 MRI vs histopathology in identifying rectal cancer with partial submucosal invasion (T1sm2 or less)

	Histo $\leq$T1sm2	Histo >T1sm2
(A) Scenario 1		
MR $\leq$T1sm2	**True +ve**	False +ve
MR >T1sm2	False −ve	**True −ve**
	$\leq$**Histo T2**	**Histo >T2**
(B) Scenario 2		
$\leq$MR T2 ($\geq$1 mm clear to MP)	**True +ve**	False +ve
MR T2 (<1 mm clear to MP+)	False −ve	**True −ve**
MP, muscularis propria.		
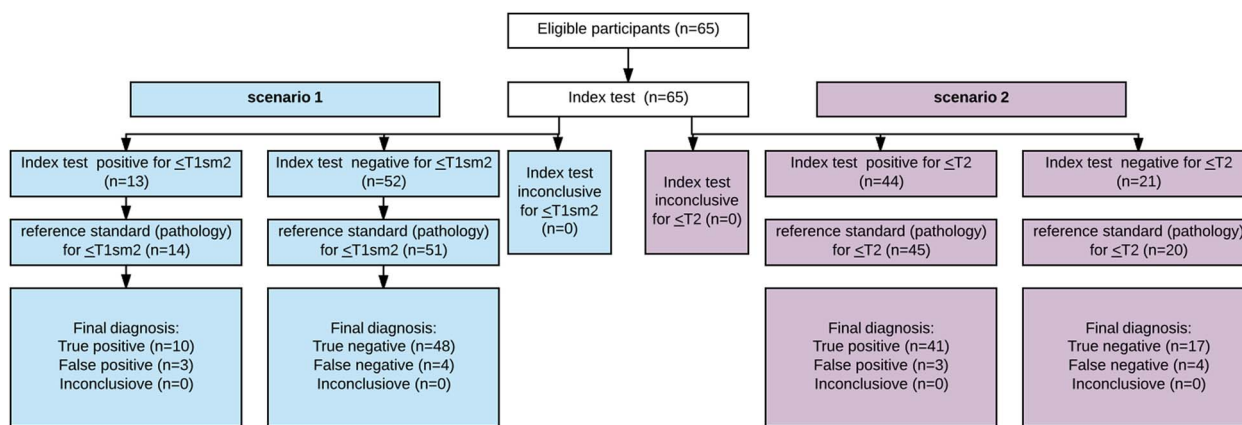
Figure 3 Diagram reporting flow of participants though the study (according to STARD recommendations).

and specificity for a binomial probability were calculated using the exact method.

For those patients treated by TME, sensitivity analysis was performed to evaluate MRI accuracy in assessing lymph node status.

The hypothetical effect of an MRI-directed assessment of likely suitability for a local excision pathway rather than the actual MDT decision based predominantly on clinical data was also calculated as a secondary end point. Differences in proportions of patients undergoing radical surgery according to clinical assessment and proposed having radical resection according to MRI staging were calculated using Newcombe method 10.[12]

For the interobserver agreement between the two radiologists, Cohens κ level was used to calculate results. A value of p<0.05 was chosen as the significance level for κ statistics. The value of κ statistics was interpreted according to Altman.[13] Agreement lies between 0 and 1, where 0 is indicative of no agreement and 1 indicates complete agreement. 'Very good/near perfect' agreement is considered as a κ of 0.81–1.00; 'good' agreement as a κ of 0.61–0.80; 'moderate' agreement as a κ of 0.41–0.60; 'fair' agreement as a κ of 0.21–0.40; and 'poor' agreement as a κ of <0.2.

RESULTS
Participants
Overall, 65 patients with a median age of 69 (34–91) fulfilled the MRI staging inclusion criteria of mrT3b or less (figure 3 presents a flow chart of participants according to STARD); demographics are presented in the table 2.

In 20% (13/65) of the patients, tumours were preoperatively MR-categorised as lesions with no or minimal invasion of the submucosal layer (no invasion, T1sm1, T1sm2). Of these 13 patients, 10 were confirmed as such on pathology. Thirty-one patients (47%) had mr T1sm3-T2 stage with no MR-evidence of tumour breaching through the MP. Of these 31 patients, 24 were proven to be pT1sm3-T2 on histopathology, and 21 patients had mrT stage >T2 with 17 out of 21 confirmed to be pT3 disease.

Overall 44 out of 65 patients underwent radical surgery (table 3) and 22 were staged as T2 or less by MRI. Pathological nodal status was positive in 7 out of 22 patients, 4 of whom had been staged as node-positive on MRI. Thus 15 out of 18 patients were correctly predicted as pT2 or less and pathology node-negative. Among the 21 out of 65 (32%) patients undergoing local excision or TEM, 20 out of 21 were staged by MRI as T2 or less and confirmed as such by pathology. On follow-up, none had lymph node relapse. If the decision had been made to offer local excision on MRI TN staging rather than clinical assessment, a significant increase in organ preservation surgery from 32% to 58% would have been observed (difference 26%, 95% CI 9% to 41%).

In one case, AP resection was performed for a benign large lower rectal adenoma, which was not proven to be malignant on the preoperative biopsy but was clinically too large and difficult for removal by local excision (the patient was counselled with regard to radical surgery for a benign lesion).

Test results
Results of MRI accuracy to predict safe resection plane
According to the table 4 results, MRI accuracy in identifying a safe submucosal plane for non-invasive adenomas, T1sm1-sm2 tumours (scenario 1—tumours ≤T1sm2) was 89% (95% CI 63% to 87%), sensitivity 71%, specificity 94%, PPV 77% and NVP 92%.

When compared with histopathology data, MRI showed 89% (95% CI 79% to 95%) accuracy, 91% sensitivity, 85% specificity, 93% PPV and 81% NPV in identifying a safe MP plane, therefore differentiating tumour with full submucosal invasion but confined to MP versus tumour with spread beyond the MP (tumour ≤T2—scenario 2).

Results of interobserver agreement
Results of the κ statistic for the second observer when compared with the central reviewer (observe 1) can be seen in table 5. κ Agreement was calculated of value 0.734, with p<0.005 indicating a good agreement (weighted κ was 0.741).

Table 2 Patient demographics

Patient demographics	No invasion on MRI, Tsm1/sm2	mrTsm3/T2	mrT3a-T3b	Total
Age (year)				
<65	6	9	7	22
≥65	7	22	14	43
Sex				
Male	8	17	15	40
Female	5	14	6	25
Tumour distance from the anal verge				
≤6 cm	6	14	4	24
>6 cm	7	17	17	41
mr N Stage				
mrN0	13	26	11	50
mrN1-N2	0	5	10	15
p N stage				
pN0	3	14	14	31
pN1-N2	0	7	6	13
n/a	10	10	1	21
Type of surgery performed				
LE	6	5	0	11
TEMS	4	5	1	10
AR	3	21	18	42
Exenteration	0	0	2	2
Quadrant of rectal wall infiltrated by tumour				
Anterior	4	7	6	17
Lateral	6	15	12	33
Posterior	3	9	3	15
pT stage				
Benign adenomas	4	0	0	4
T1sm1	1	0	0	1
T1sm2	5	4	0	9
T1sm3	2	7	0	9
T2	1	17	4	22
T3*	0	0	4	4
T3a	0	2	4	7
T3b	0	0	5	4
T3c	0	1	3	4
T4	0	0	1	1
Total	13	31	21	65

*Missing histopathology data about the depth of tumour invasion into the mesorectum.
AR, anterior resection; LE, local excision; n/a, not applicable (patients were treated with local excision), TEMS, transanal endoscopic microsurgery.

Result of MRI accuracy to predict lymph node status

When compared with final histopathology in patients who underwent radical resection, MRI accuracy in predicting lymph node status was 84% (95% CI 70% to 92%), PPV 71% and NPV 90%.

Overall MRI results to predict eligible patients for organ preservation treatment

Overall radical surgery was undertaken in 68% (44/65) of patients and 32% (21/65) patients were treated with local excision. According to MRI findings (T and N MR-staging), another 18 patients could potentially have

been offered local excision as their tumours were staged as T2N0 or less (table 3). Therefore, if the decisions had been made to offer local excision based on MRI findings rather than clinical assessment, a further 26% of patients would have received less radical surgery, making a total of 38 out of 65 eligible on MRI compared with 21 out of 65 from clinical assessment alone. This would have corresponded to a significant increase in organ preservation surgery from 32% of clinically staged ERC to 58% of MRI-staged ERC (95% CI 9% to 41%).

DISCUSSION

Implementation of bowel cancer screening has increased the proportion of colorectal cancer identified as early stage. About 30% of screen-detected cancers are Dukes' A[14] compared with 10% of the non-screened population. Patients with ERC can only be offered the correct treatment modality if they are identified and accurately staged before resection. Organ preservation avoids the extra mortality of TME and abdominoperineal excision of rectum (APER) and morbidity such as permanent stoma, sexual dysfunction and a prolonged hospital stay and if appropriate patients can be safely identified, the option of organ preservation is a preferable option for the majority.[15] Preoperative assessment of tumour depth invasion is crucially important in determining endoscopic and surgical planes. Paris morphology, pit pattern and the lift signs are used by expert endoscopists to stratify the risk of submucosal invasion. However, the interobserver variability and accuracy of these tools in routine UK practice have not been audited or investigated. It is likely that other methods may well improve outcomes given that 33% of locally excised lesions in the TEM registry were unexpectedly malignant having been assessed by experienced endoscopists and that removal of such lesions was associated with a statistically significantly higher chance of an involved margin.[16 17] Preoperative imaging, based on endorectal ultrasound (ERUS), has not been proven to be reliable in selecting the correct patients, for example, in a multicentre German study of over 3500 patients' EUS, Ptok et al found an accuracy of 65% for T staging.[18] At present, ERUS has not established itself in assessing ERC in UK practice, for example, of 487 patients undergoing TEM, only 148 were staged by ERUS with no difference in the rates of resection margin positivity or outcomes in patients having ERUS.[3]

MRI is the gold standard for advanced disease; however, it is not yet used as a staging tool for an early disease.

Internationally accepted standards suggest that only T1 rectal tumours with minimal invasion of the submucosal layer—sm1 according to Kikuchi classification—should be considered eligible for local excision. However, the reality shows a different practice. Haboubi and Salmo[19] previously reported that thickness of the submucosal layer varies greatly among the individuals

Table 3 Type of surgery performed

pT stage AR	Type of surgery LE	TEMS	Exenteration		Total
Benign adenoma Nx	0	2 (2—mr no invasive cancer)	1 (1—mr no invasive cancer)	0	3
Benign adenoma N0	1 (1—mr no invasive cancer)	0	0	0	1
T1sm1	0	0	1 (1—mrTsm2N0)	0	1
T1sm2Nx	0	3 (3—mrT1sm2-3N0)	3 (3—mrT1sm2-T2N0)	0	6
T1sm2N0	3 (3—mrT1sm2-3N0)	0	0	0	3
T1sm3Nx	0	5 (5—mrT1sm3N0)	1 (1—mrT1sm3N0)	0	6
T1sm3N+	1 (1—mrT2N+)	0	0	0	1
T1sm3N0	2 (2—mrT1sm3N0)	0	0	0	2
T2Nx	0	1 (mrT1sm3N0)	3 (3—mrT1sm3-T2N0)	0	4
T2N+	5 (2—mrT2N+, 1—mrT3bN+, 2 -mrT2N0)	0	0	0	5
T2N0	13 (9—mrT1sm3-T2N0; 4—mr>T2N0)	0	0	0	13
T3aN+	1 (1—mrT2N0)	0	0	0	1
T3aN0	5 (5—mrT3a-bN0)	0	0	1 (1—mrT3aN0)	6
T3bNx	0	0	1 (1—mrT3bN+)	0	1
T3bN+	3 (3—mrT3bN+)	0	0	0	3
T3cN+	1 (1—mrT2N+)	0	0	0	1
T3cN0	2 (2—mrT3bN+)	0	0	1 (1—mrT3bN+)	3
T3N+	1 (1—mrT3bN+)	0	0	0	1
T3N0	3 (2—mrT3N0; 1—mrT3bN+)	0	0	0	3
T4N+	1 (mrT3bN+)	0	0	0	1
Total	42	11	10	2	65

*Depth of invasion into mesorectum not recorded by pathologist.
AR, anterior resection; LE, local excision; TEMS, transanal endoscopic microsurgery; TxNx, patients who potentially could have less radical surgery according to mrTN stage.

and cannot be appropriately assessed in the absence of MP within the surgical specimen. Whenever the MP is lacking in the specimen, histopathological assessment of the submucosal depth invasion and differentiation of T1sm1/sm2 and even sm2/sm3 become challenging. It has also been stated that budding, lymphovascular invasion and tumour differentiation are prognostic factors that determine the need for either adjuvant therapy or subsequent completion/salvage surgery but the validity of these prognostic measures has been questioned because of the lack of reproducibility of these factors.

This has resulted in the review of the current standards of assessing such lesions. The emerging consensus is that rather than using a method with poor inter-observer agreement, absolute measures of depth and width are more reliable and therefore prognostically more secure.[20] It has also been shown that depth and width of mucosal invasion predict the lymph node metastasis in ERC.[21]

There is a paucity of good-quality data evaluating the performance of high-resolution MRI in staging ERC. Traditionally, it has not been relied on as a primary tool

Table 4 MRI accuracy in identifying patients with minimal and full invasion of the submucosal layer when compared with final histopathology

mrT stage		pT stage						
		T0	T1sm1	T1sm2	T1sm3	T2	≥T3a	Total
Partial invasion of the submucosa (scenario 1)	mrT0,T1sm1,T1sm2	4	1	5	2	1	0	13
Full invasion of the submucosa, partially or fully spared MP (scenario 2)	mrT1sm3-T2	0	0	4	7	17	3	31
	≥T3a-T3b	0	0	0	0	4	17	21
	Total	4	1	9	9	22	20	65

Table 5 Interobserver agreement

Observer 1	Category	≤T1sm2	≤T	>T	Total
	≤T1sm2	10	3	–	13
	≤T	3	24	4	31
	>T		1	20	21
	Total	13	28	24	65

Column header "Observer 2" spans ≤T1sm2, ≤T, >T, Total.

κ=0.734.
Z=10.021.
κ w=0.741.
p<0.0005.
Agreement: good.

for staging ERC as it is perceived that MRI should not be used for staging ERC, with a tendency to overstage or inaccurately stage lesions as T1/2 without precisely specifying the depth of invasion. On imaging, differentiation between 'sm' subcategories remains challenging; nevertheless we wanted to test the ability of MRI to identify potentially safe submucosal and MP planes. In this analysis, we reviewed the hypothetical impact on patient treatment if an MRI-directed approach to local excision had been followed. Therefore, a retrospective hypothesis-generated study to determine if the criteria for identifying suitable patients are accurate was undertaken. Results have shown that 89% patients were correctly identified for partial submucosal invasion and 89% were accurately staged as potentially suitable for full thickness excision (patients with full submucosal invasion but spared MP); therefore, MRI shows better results than current standards that identify accurately only about a third of patients. Furthermore, the identification of patients suitable for primary local excision based on MRI node-negative prediction is such that only 3 out of 18 patients with node-positive status were missed but a further 15 patients were correctly identified as node-negative. This has implications for patient discussions on the use of adjuvant radiotherapy in ERC rather than completion radical surgery. In our institution, adjuvant radiotherapy is reserved only for those staged on final pathology as pTsm3 or more or where there is margin involvement and surveillance offered to the remainder. Following this policy, we have not observed disease recurrence after a minimum of 3.5 years follow-up.[22] This paper suggests a new approach to MRI imaging of early disease and the findings support that MRI may be able to accurately identify the safe resection plane for ERC.

One of the limitations of this study is that κ for the radiologists has been assessed among radiologists experienced in reporting rectal cancer as this is a single-centred study and this needs to be prospectively tested in order to determine whether this can change practice nationally and globally. However, there are studies under way and are in the prospective MINSTREL (MrI iN Staging RECTAL poLyps) study which is completing its recruitment using precisely these definitions. If it is proven that MRI performance is reproducible in different centres, then it will lead to an important improvement in staging.

It is considered that the depth of the submucosal invasion predicts the rate of lymph node metastases. The concern of occult lymph node metastases in tumours >T1sm1 has limited organ-sparing treatment. Results of this study show that MRI prediction of node-negative status is >80% when morphological characteristics are evaluated on high-resolution MRI scans and the question is whether patients should be deprived of the opportunity to undergo organ preservation based only on the degree of tumour invasion into the submucosa, bearing in mind that 80% of patients with pT1sm2-sm3 tumours will have no metastases within the mesorectal lymph nodes or even less if there are no other adverse features. Furthermore, the potential to relapse within the mesorectum could then be monitored by MRI surveillance (which was not available in older TEM and local excision studies).

All these potential risks and benefits of organ preserving treatment should be discussed with patients and decision to treat should be based on patients' choice as well.

It has been suggested that radiotherapy can be offered to all ERC defined as T2 or less prior to TME surgery because first, there is no reliable staging method to distinguish between T1 and T2 tumours and second, complete responders following TME could avoid further surgery. If this policy had been followed, over 36 out of 44 patients with mrT2N0 or less would have been irradiated for node-negative disease and potentially would have suffered a higher comorbidity rates associated with TEM defect healing in an irradiated rectum.[23] As the SPECC programme has highlighted, the overtreatment of ERC may not be in the patients' interest. This study, therefore, shows the use of preoperative imaging in preventing overtreatment and providing patients with robust prognostic information to make an informed choice about the decision and to understand the risk versus benefits of treatment options/surgical decisions.

The next phase is to determine whether this is reproducible in the multicentre setting and finally if it proves to be reproducible in the multicentre study (the MINSTREL study), then this will be used as a basis for offering more patients with ERC the possibility of organ preservation.

CONCLUSION

This analysis shows that high-resolution MRI assessment, with particular attention paid to the degree of preservation of the submucosa and MP layers at the invasive margin of the tumour, is a reliable method of staging depth of invasion in ERC. If reproducible and confirmed in the prospective MINSTREL trial, there are very few resource barriers to prevent wider UK adoption of MRI as a standard of care for ERC.

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