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A population-based study of the management of rectal malignant polyps and the use of trans-anal surgery

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Key words

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Introduction

Rectal malignant polyps represent early development of rectal adenocarcinoma with carcinoma restricted to being within the adenomatous polyp. Any endoscopically complete resection of a polyp containing carcinoma invading through muscularis mucosae is considered a malignant polyp. However, those that invade beyond submucosa are no longer defined as malignant polyps.^{1,2}

Abstract

Introduction: Rectal malignant polyps can be managed by use of trans-anal resections (TAR). Traditional techniques of resection have been replaced by use of platforms such as trans-anal minimally invasive surgery (TAMIS) or trans-anal endoscopic microsurgery (TEM). This study reviewed the management of rectal malignant polyps, in particular focussing on when clinicians used TAR.

Methods: A population wide cohort study of all malignant rectal polyps diagnosed in Queensland, Australia from 2011 to 2018 was undertaken. Patient and pathological factors were compared across the management strategies of polypectomy, TAR and rectal resection.

Results: Overall 430 patients were diagnosed with a malignant rectal polyp during the study period, with 103 undergoing a TAR. There was increasing use of TAR across the study period as a management strategy ($P < 0.001$). Polypectomy alone was more likely to be the management strategy over TAR or rectal resection if there were clear margins ($P < 0.001$). The distance to the closest polypectomy margin was also significantly higher in the polypectomy group with mean clearance 2.09 mm in polypectomy group versus 0.86 mm in TAR group and 0.99 mm in resection group ($P < 0.001$). Rectal resection was more likely to be the management strategy over TAR if there was LVI ($P < 0.001$), depth of invasion was deeper ($P < 0.001$) and there was tumour budding ($P = 0.001$).

Conclusion: TAR is an effective management strategy for rectal polyps and is utilized particularly in rectal malignant polyps when there are close or involved margins. Future guideline development should consider incorporation of TAR given the advances in techniques afforded by TAMIS or TEM platforms.

Rectal malignant polyps can be managed with three techniques—polypectomy alone, rectal resection or with a trans-anal resection (TAR).³ There are several methods to perform a TAR of a rectal malignant polyp. Trans-anal resections may be performed using direct visualization of the lesion with the assistance of retractors such a Parks Retractor but this technique is limited by poor visualization, particularly for any rectal polyps higher than 8 cm above the anal verge.³ In 1983, Gehard Buess introduced trans-anal

endoscopic microsurgery (TEM) and this technique facilitated excision of higher rectal polyps, and significantly improved visualization of all lesions within the rectum.³ The use of TEM was limited by steep learning curves and the prerequisite specialized and expensive TEM equipment. Subsequently, Trans-Anal Minimally Invasive Surgery (TAMIS) was developed which addressed many of these barriers—decreasing costs by using disposable ports and using traditional laparoscopic equipment that surgeons were already familiar with; thus reducing the learning curve.⁴

The aim of all TAR platforms is to improve the margin clearance of malignant polyps. TAR is associated with lower morbidity and mortality than an anterior rectal resection,⁵ however, it does not address any lymphatic metastatic disease. All TARs require a general anaesthetic, with its associated risks of morbidity and mortality.⁶

Therefore, the management of rectal malignant polyps is dependent on a considered risk assessment by clinicians—balancing the risk of residual disease in the bowel wall, the risk of metastatic disease to lymphatics with operative and anaesthetic risks. Guidelines have been developed to assist clinicians in the clinical decision making as to when to recommend colorectal resection for malignant colorectal polyps.⁷ There have been few population wide analyses of the management of colorectal malignant polyps, and few have specifically investigated the role of trans-anal excisions as part of the management strategy.^{2,8,9} In Queensland, Australia, the reporting of cancer data to the Queensland Cancer Registry (QCR) is mandated by law. This data is linked with over 60 other population level information sources, to form the Queensland Oncology Repository (QOR). Utilization of data from QOR, facilitated a complete population wide assessment on the management of rectal malignant polyps.

Methods

This study was a retrospective population-wide cohort study using data from the QOR, and ethics approval was granted by the Metro North Human Research Ethics Committee (HREC/17/QRBW/483). The QOR encrypted database was accessed for initial screening and all data extractions were stored locally in a de-identified format.

Population

All patients with a rectal malignant polyp diagnosed in Queensland between 2011 and 2018 were eligible for this study. To identify all malignant polyps, a screening algorithm was developed to identify all colorectal adenocarcinomas (ICD-10 C18, C19, C20) diagnosed via endoscopy (Australian Classification of Health Interventions (ACHI) - ICD-10 codes 3 209 001, 3 209 300, 328 401, 3 208 401, 3 208 700, 3 207 501, 3 207 800, 3 208 100) or endoluminal excisions (e.g., ICD-10 code 3210500).

All patient records were then screened to identify those with malignant polyps located within the rectum. Exclusion criteria were those with synchronous malignant polyps or other colorectal malignancies, prior colorectal malignancy, those with inherited polyposis syndromes, history of inflammatory bowel disease or those patients post neoadjuvant therapy. Patients who had a rectal polyp biopsied revealing a malignancy, were considered to have an early T1 rectal

cancer, rather than a malignant polyp, and were excluded from this study.

Variables extracted

All patient pathology reports were reviewed and patient demographic and pathological details were extracted. The Association of ColoProctology of Great Britain and Ireland (ACPGBI) guidelines for management of malignant polyp were appraised and all variables required to assign an ACPGBI risk category for residual disease were extracted. Patients were then separated into the categories of *very-low*, *low*, *moderate*, *high* and *very-high* risk of residual disease using the ACPGBI guidelines. Pathological details extracted were tumour size (in millimetres), lymphovascular invasion (LVI), tumour differentiation, presence of mucinous differentiation, presence of tumour budding, underlying polyp type, Haggitt/Kikuchi level of depth of invasion, direct measure of depth of invasion (in millimetres), mismatch repair immunohistochemistry results, margin status and distance to the closest margin (in millimetres). Patient details extracted were age at diagnosis, American Society of Anesthesiology (ASA) Score, gender, type of facility where the colonoscopy was performed, location where the colonoscopy was performed, the patient socioeconomic status (assigned according to the Australian Bureau of Statistics Socioeconomic index for Areas—SEIFA)¹⁰ and patient's residence. Additionally, the number of comorbidities was summed from hospital admission data. The management strategy and results of any subsequent colorectal resection were also recorded. This study did not differentiate between the differing types of TAR - trans-anal excision (TAE), TEM or TAMIS.

Analysis

Patient and tumour characteristics were assessed between the different definitive management strategies for malignant polyps—polypectomy alone, TAR (including all operative platforms) or rectal resection. Comparisons were performed using ANOVA, chi-squared or Fisher's exact tests as appropriate. Change in TAR use over time was assessed with Pearson correlation and linear regression. Statistical analysis was performed using STATA v17.0 (StataCorp, College Station, Texas). A *P*-value of less than 0.05 was considered statistically significant.

Results

There were 430 patients with a rectal malignant polyp. Of those, 103 underwent a TAR during their care with 35 patients initially having a polyp biopsied only in which the histology was benign, and then proceeded to a TAR for complete excision of the polyp, and this specimen was then found to contain adenocarcinoma. In this situation, TAR was utilized as a method of polypectomy for what was a presumed benign polyp, rather than the definitive management strategy of a known malignant polyp. Of these 35 patients, 23 had no further procedures, 11 proceeded to rectal resection, and one patient proceeded to a repeat TAR procedure. The remaining 68 patients had a complete polypectomy at the time of colonoscopy, which diagnosed the malignant polyp, and then underwent subsequent TAR as the final management strategy for that malignant

polyp. One of these patients then proceeded to rectal resection. Thus, 67 patients were considered to have a malignant polyp diagnosed following colonoscopic polypectomy, who then proceeded to a TAR as the final management strategy. Therefore, only these 67 patients, along with the one patient who had a repeat TAR following initially benign biopsy and polypectomy by TAR, totalling 68 patients, were considered to have a TAR as the final management strategy for a malignant polyp (Fig. 1). Figure 2 shows the increasing numbers of rectal malignant polyps, along with the increasing utilization of TAR as a definitive management strategy during the study period ($r^2 = 0.88, P < 0.001$).

Table 1 compares the patient characteristics based upon the final management strategy. Those patients who underwent subsequent rectal resection following a TAR procedure, were considered in the rectal resection group. When directly comparing the characteristics between patients who had a TAR compared to rectal resection, the only significant difference was that the mean age of those undergoing rectal resection was significantly lower at 61.38 compared to 66.31 for the TAR group ($P = 0.0037$).

Table 2 assesses the pathological factors which may have influenced the management decision for rectal polyps. It compares the pathological features post initial polypectomy and whether patients have surveillance only (after polypectomy), or proceed to TAR or rectal resection. Those with LVI were more likely to proceed to resection, over all other management techniques

($P < 0.001$). Those with close or involved margins were more likely to proceed to TAR or resection, as opposed to those with a clear margin at polypectomy ($P < 0.001$). Furthermore, there were

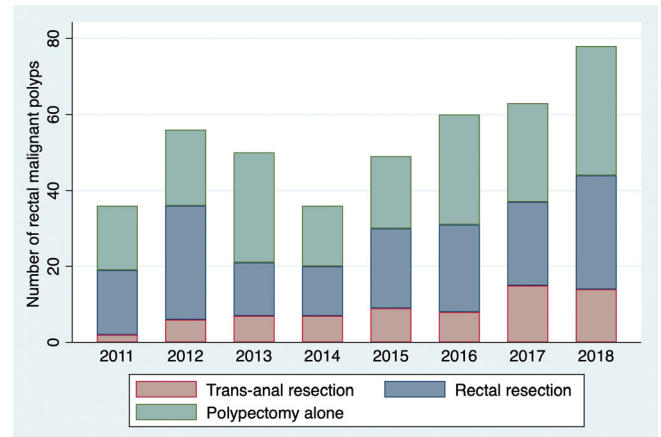


Fig. 2. Shows the application of trans-anal resection (TAR) and other management strategies over the period 2011–2018. There were increasing numbers of rectal malignant polyps diagnosed over the study period. Figure 2 Demonstrates that TAR is increasingly being utilized as a management strategy for rectal malignant polyps. If patients had proceeded from polypectomy, to then having a TAR and then finally a rectal resection they were considered in the rectal resection group.

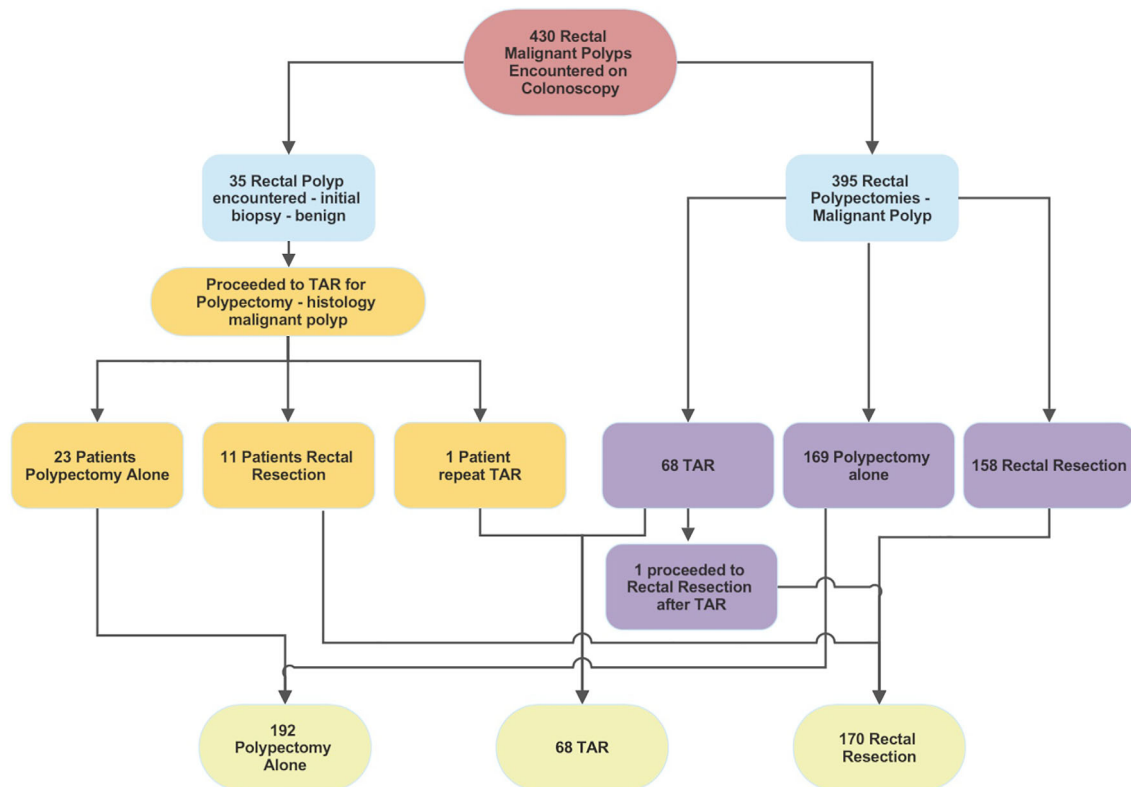


Fig. 1. Final management strategy for patients with rectal malignant polyps. Flow chart of management strategy choices for rectal malignant polyps, including the use of trans-anal resection (TAR). Note that the 35 patients who (left side of flow chart), initially had a rectal polyp identified on colonoscopy, which was biopsied only (no polypectomy performed during colonoscopy). That biopsy was benign (e.g., tubular adenoma or sessile serrated lesion). Those patients then proceeded to a TAR for the purposes of polypectomy, for the presumed benign lesion at the time of TAR. The TAR histology revealed a malignant polyp in these patients.

Table 1 Patient characteristics and management strategy

Variable (n = 430)	Definitive management strategy			Difference between polypectomy TAR and resection P-value	Difference between TAR and Resection P-value
	Polypectomy alone n = 192 (%)	Trans-anal resection (TAR) n = 68 (%)	Rectal resection n = 170 (%)		
Age—mean	68.55	66.31	61.38	<0.001	0.0037
95% CI	66.91–70.19	63.79–68.82	59.60–63.19		
ASA score (n = 326)				<0.001[†]	0.15
1	23 (35.38)	6 (9.23)	36 (55.38)		
2	70 (39.77)	31 (17.61)	75 (42.61)		
3	52 (65)	12 (15)	16 (20)		
4	2 (40)	1 (20)	2 (40)		
Comorbidity count (n = 430)				0.69	0.81
0	132 (42.72)	52 (16.83)	125 (40.45)		
1	40 (48.19)	12 (14.46)	31 (37.35)		
2+	20 (52.63)	4 (10.53)	14 (36.84)		
Gender (n = 430)				0.038	0.74
Male	128 (49.61)	36 (13.95)	94 (36.43)		
Female	64 (37.21)	32 (18.6)	76 (44.19)		
Type of facility for colonoscopy (n = 423)				0.007	0.19
Public	71 (55.04)	21 (16.28)	37 (28.68)		
Private	119 (40.34)	45 (15.25)	131 (44.41)		
Socioeconomic status (n = 425)				0.99	0.96
Affluent	22 (43.14)	8 (15.69)	21 (41.18)		
Middle	117 (44.66)	40 (15.27)	105 (40.08)		
Disadvantaged	52 (46.02)	18 (15.93)	43 (38.05)		
Residence (n = 425)				0.009	0.12
Major city	96 (39.67)	39 (16.12)	107 (44.21)		
Inner regional	72 (56.25)	21 (16.41)	35 (27.34)		
Remote	23 (41.07)	6 (10.71)	27 (48.21)		
Location of colonoscopy (n = 429)				0.041	0.93
Metropolitan	114 (40.28)	48 (16.96)	121 (42.76)		
Regional/Rural	78 (53.06)	20 (13.61)	49 (33.33)		

Abbreviation: ASA: American Society of Anesthesiology – assessment of anaesthetic risk²¹

[†]Fisher's exact test used.

Bold values denote significant values ($p < 0.05$).

significant differences in the selection of management strategy for malignant polyps with the presence of budding ($P = 0.005$), higher depth of invasion both when measured directly ($P < 0.001$) or by Haggitt or Kikuchi levels ($P < 0.001$). Finally, a higher ACPGBI risk category also significantly predicted management strategy ($P < 0.001$), with those with malignant polyps classified as high or very-high risk more likely proceeding to resection.

When directly comparing the pathological characteristics of patients treated by TAR compared to rectal resection, greater invasive tumour width ($P = 0.024$), presence of LVI ($P < 0.001$), high grade differentiation ($P < 0.001$), budding ($P < 0.001$) and higher depth of invasion ($P < 0.001$) were all significant predictors of proceeding to rectal resection over TAR.

Of the 68 patients who had TAR as their final management strategy, four patients (5.8%) had residual disease identified on the TAR specimen. Of those who proceeded to rectal resection, 18 (10.7%) patients had evidence of residual disease on the resection specimen, 22 patients (13.0%) had metastatic disease in draining lymph nodes.

Discussion

Over time there has been an evolution in strategies to endoluminally manage rectal malignant polyps, from direct visualization to TEM to the newest addition—TAMIS. This study

presents one of the largest cohorts of patients who have undergone TAR of malignant polyps. It found that TAR is a commonly utilized technique for management of malignant polyps. Its use is predicted by advanced Haggitt/Kikuchi levels and close or involved margins. The presence of LVI, greater depth of invasion (when directly measured below the muscularis mucosae) and tumour budding were more likely to result in patients proceeding to rectal resection over TAR.

In reviewing the literature for the comparison of management strategies of colorectal polyps, a series of meta-analyses documented that LVI, poor differentiation and close or involved margins were significant predictors of resection.² When reviewing the articles included in those meta-analyses, only five studies had mentioned the inclusion of TAR techniques in their review. In two of these studies, TAR techniques were combined with polypectomy as the overall management strategy.^{11,12} One study included TAR, but combined TAR patients in the surgical management group.¹³ The remaining two studies either specifically excluded TAR from their assessment,⁸ or it was unclear how patients managed with TAR were assessed.⁹ Thus, this study investigating rectal malignant polyp management, reflects one of the few published works directly assessing the role of TAR as part of the overall management strategy for rectal malignant polyps.

TAR has utility in excising large malignant rectal polyps. It is noted that, compared to those who had polypectomy alone,

Table 2 Comparison of pathological factors between differing management strategies

Variable <i>n</i> = 430	Definitive management strategy			Difference between polypectomy TAR and resection <i>P</i> -value	Difference between TAR and Resection <i>P</i> -value
	Polypectomy <i>n</i> = 192 (%)	Trans-anal resection <i>n</i> = 68 (%)	Resection <i>n</i> = 170 (%)		
Tumour width (mm)	5.16	5.01	6.86	0.014	0.024
95%CI	4.37–5.94	2.96–7.05	5.98–7.73		
Lymphovascular invasion (LVI) (<i>n</i> = 375)				<0.001	<0.001
LVI+	11 (16.92)	4 (6.15)	50 (76.92)		
LVI–	160 (51.61)	49 (15.81)	101 (32.58)		
Differentiation				<0.001	<0.001
High Grade	14 (25.45)	2 (3.64)	39 (70.91)		
Low Grade	144 (46.15)	53 (16.99)	115 (36.86)		
Mucinous (<i>n</i> = 430)				0.21 [†]	1.00 [†]
Present	5 (83.33)	0 (0)	1 (16.67)		
Absent	186 (44.6)	62 (14.87)	169 (40.53)		
Budding (<i>n</i> = 185)				0.005	0.001
Present	31 (37.8)	7 (8.54)	44 (53.66)		
Absent	48 (46.6)	22 (21.36)	33 (32.04)		
Polyp type (<i>n</i> = 391)				0.30 [†]	0.55 [†]
TA	42 (43.75)	15 (15.62)	39 (40.62)		
TVA/TSA	120 (48.39)	32 (12.9)	96 (38.71)		
VA	13 (37.14)	8 (22.86)	14 (40)		
SSA	3 (25)	4 (33.3)	5 (41.67)		
Haggitt/Kikuchi Level (<i>n</i> = 215)				<0.001	0.79
Haggitt 1–3 or Sm1	62 (62)	10 (10)	28 (28)		
Haggitt 4 or Sm2-3	35 (30.43)	20 (17.39)	60 (52.17)		
Depth (mm)	2.04	1.72	3.12	<0.001	<0.001
95%CI	1.67–2.42	1.27–2.18	2.78–3.47		
Mismatch repair (<i>n</i> = 222)				0.81 ^a	0.57 ^a
Proficient	82 (38.5)	32 (15.02)	99 (46.48)		
Deficient	1 (25)	0 (0)	3 (75)		
Margins (<i>n</i> = 373)				<0.001	0.27
Involved	20 (18.52)	22 (20.37)	66 (61.11)		
Clear	151 (58.08)	35 (13.46)	74 (28.46)		
Closest margin (mm)	2.09	0.86	0.99	<0.001	0.56
95%CI	1.73–2.44	0.42–1.30	0.71–1.27		
ACPGBI Risk Score Grouped (<i>n</i> = 430)				<0.001	0.36
High and Very-High (3 & 4)	82 (30.94)	51 (19.25)	132 (49.81)		
Low and Very-Low (0 & 1)	103 (69.13)	16 (10.74)	30 (20.13)		

Abbreviations: ACPGBI, Association of ColoProctology of Great Britain and Ireland–malignant polyp guidelines⁷; SSA, sessile serated adenoma/lesion; TA, Tubular adenoma; TVA/TSA, tubulovillous adenoma/traditional serated adenoma; VA, villous adenoma.

[†]Fisher's exact test used.

typically patients proceeded to TAR when the original polypectomy histology demonstrated close or involved margins. There was no difference in the rate of close or involved margins when comparing TAR to rectal resection. The rate of residual disease in the bowel wall was low in both the resection and TAR groups. The rate of residual disease in the TAR group was 5.8%, which is similar to previous research.¹⁴

TAR does not address the risk of metastatic lymphatic disease spread. This study demonstrated that LVI ($P < 0.001$), greater tumour width ($P < 0.001$) and depth of invasion ($P < 0.001$), high grade differentiation ($P < 0.001$) and budding ($P = 0.001$) were significant predictors of resection over TAR. This is a logical progression in disease management as LVI, high grade differentiation and budding are predictors of increased risk of lymphatic disease.^{15,16} The depth of invasion is also a predictor of increased risk of lymphatic disease, however the choice in management strategies were conflicting depending on the measure of the depth of

invasion.⁷ Depth of invasion as a direct measure below the muscularis mucosae was significantly higher in the rectal resection group ($P < 0.001$), but when measured as a Haggitt or Kikuchi level, there was no significant differences in the management strategies ($P = 0.79$). Both depth of invasion and greater tumour invasive tumour width have been associated with increased risk of lymph node metastasis from malignant polyps.^{7,17} Overall, it appears that patients are proceeding to rectal resection, when there are factors which increase the risk of metastatic lymphatic spread.

The choice to proceed with rectal resection is major, with numerous risks to the patient, of which some are long term. Anastomotic leak, colostomy, sexual dysfunction and low anterior resection syndrome (LARS) are all potential consequences of rectal resection.^{18,19} TAR procedures minimize many of these risks, however still pose an anaesthetic risk to the patient as the procedure requires a general anaesthetic. Of note the average age of those undergoing TAR was significantly higher than the group who underwent rectal

resection ($P = 0.0016$). This may have been driven by the longer anticipated life expectancy of younger patients, and the decision to suggest rectal resection to reduce the risk of recurrent disease. Furthermore, advanced age increases the general and specific risks from rectal resection and the risk of mortality is significantly higher for older patients when they do experience complications from rectal resection.²⁰ This may further explain the choice to offer a surgery with lower morbidity risk in those of advanced age.

It was noted that there were 30.8% of patients with *very-low* or *low* risk disease, as assessed by the ACPGBI scoring, who still proceeded to TAR or rectal resection.⁷ The recommendations to clinicians from these guidelines are for those with *very-low* or *low* risk malignant polyps can be safely managed with polypectomy and surveillance alone. By proceeding to TAR or rectal resection, these *very-low* and *low* risk patients are potentially being placed at unnecessary anaesthetic and operative risk. These guidelines were published in 2013, only a few years after the introduction of the TAMIS platform. This study demonstrated the increasing use of all types of TAR, coinciding with the implementation of the TAMIS platform. Future guideline development needs to consider the benefits that all forms of TAR offer, particularly with the introduction of TAMIS.

A limitation to this study was the retrospective nature of data collection, which precluded the ability to collect the individualized decision making for each rectal malignant polyp. It would have been of use to understand when clinicians felt that TAR or rectal resection was an appropriate choice, especially in light of the over 30% with *very-low* or *low* risk disease who proceeded to further therapy. A further limitation to this study was some of the missing data. Of the patient and demographic details, the majority of patients had complete demographic data available apart from the ASA score, in which only 326 of the 430 patients with a rectal malignant polyp had an ASA score recorded on the hospital admission data in QOR. Without access to the original anaesthetic documentation, these details were unable to be retrieved. There were a number of missing pathological details for the malignant polyps. In particular, the most under-reported feature was tumour budding, with only 185 of the 430 reports containing this feature. However, these were the same pathological reports that were available to clinicians who were assessing risk and advising patients on appropriate management strategies. Therefore, this study reflects a true representation of the information that was available to treating clinicians at the time of clinical care. Verbal discussions with reporting pathologists may have occurred, which would have potentially allowed clinicians to have a more complete pathological understanding of the malignant rectal polyp. These discussions would then not have been recorded in the QOR system. A detailed understanding, and quality improvement project for the pathological reporting of malignant polyps is currently underway.

Conclusion

TAR offers an alternative management strategy for the treatment of rectal malignant polyps. In Queensland, Australia, the use of any form of TAR was predicted by the close or involved margin,

reflecting the utility of TAR in ensuring the complete resection of disease from the bowel wall. In light of the technological improvements offered by TAMIS, future guideline development should include TAR as a valid treatment option for rectal polyps, particularly for malignant polyps with low risk of lymphatic disease.

Author contributions

Ian Brown: Methodology; supervision; writing – review and editing. **John D. Hooper:** Methodology; supervision; writing – review and editing. **David A. Clark:** Conceptualization; project administration; supervision; writing – review and editing. **Andrew P. Riddell:** Conceptualization; project administration; supervision; writing – review and editing.

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Conflict of interest

None declared.

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