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ORIGINAL ARTICLE



Pelvic exenteration for locally advanced rectal cancer and associated outcomes in England between 1995 and 2016: Analysis of a national database

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Abstract

Aim: The clinical burden of pelvic exenteration (PE) for locally advanced rectal cancer (LARC) is nationally under-reported. The widespread use of pelvic MRI since 2005 has increased the accuracy of local staging and awareness of the need for 'beyond TME (total mesorectal excision)' surgery. The aim of this study was to assess the volume of patients undergoing PE within England, which factors affected survival outcomes and whether the use of MRI has influenced these outcomes.

Method: The volume of patients undergoing PE and associated survival outcomes across England between 1995 and 2016 was evaluated from Public Health England Hospital Episode Statistics data.

Results: A total of 2996 patients were recorded as undergoing PE. The 5-year overall survival rate improved after 2005 compared with prior to 2005 (61.7% vs. 37%, p < 0.001), with no significant difference between cancer registries throughout England. After 2005, the volume of patients undergoing PE and undergoing preoperative MRI increased, as did the number of non-T4 cancers operated on. After 2005, age, preoperative MRI and preoperative radiotherapy were the significant factors influencing 5-year overall survival on multivariate analysis.

Conclusion: This review of national data confirms that PE outcomes are under-reported. MRI staging aids with the identification of patients suitable for perioperative treatment, surgery or palliation and facilitates treatment planning. Since 2005, MRI, likely in combination with advances in surgery and perioperative treatment, has improved survival outcomes. It is imperative that detailed information from patients with LARC undergoing PE is captured and reported in order to optimize care and future service provision.

KEYWORDS

locally advanced rectal cancer, locally recurrent rectal cancer, pelvic exenteration

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INTRODUCTION

Treatment of locally advanced rectal cancer (LARC), in the form of 'curative' surgery by pelvic exenteration (PE), is not offered by all centres within England. The aim of this surgery is to achieve complete oncological clearance of tumour, and encompasses radical en bloc dissection to remove the rectum and additional involved pelvic viscera, depending on the site and extent of spread of the primary tumour.

The clinical burden of PE across England remains unknown and is not included in the annual National Bowel Cancer Audit (NBOCA) reports [1]. Routine collection of data relating to patients undergoing PE does not take place within England, nor in many other countries. In more recent years a lexicon has been developed to describe PE, due to heterogeneity with regard to the types of surgical procedures included, and this updated lexicon can be utilized to improve documentation within and between institutions [2]. These can broadly be described as 'conventional exenteration', now regarded as a 'major surgical procedure where all or most organs in the pelvic cavity are removed' or 'high-complexity PE' which 'encompasses conventional PE with the extension of surgery to remove bony structures or structures in the pelvic sidewall' [2].

Data submitted to Public Health England (PHE) provide the best national opportunity to report on prevalence, outcomes and trends in relation to PE within a specific time frame. In 2005, MRI staging of rectal cancer was widely used in England, possibly leading to greater awareness of the need for PE in patients predicted to have tumours extending to and beyond the circumferential resection margin (CRM) [3].

The aim of this review is to assess the prevalence of PE performed for LARC between 1995 and 2016, the perioperative and pathological factors affecting survival outcomes and whether the introduction of pelvic MRI for local staging influenced outcomes.

METHOD

Objective

This article focuses on the use of MRI between 1995 and 2016 and whether there has been a difference in the volume of PE being performed since the introduction and widespread use of MRI for staging rectal cancer in 2005. This may have resulted in greater awareness of the possibility of curative PE surgery, but also improved surgical planning.

Primary outcome

The primary outcome was assessment of the volume of PE performed in England between 1995 and 2016.

What does this paper add to the literature?

This review is the first to look at the volume of patients undergoing pelvic exenteration for locally advanced rectal cancer across England over a 21-year period. It demonstrates the associated survival outcomes and how the use of pelvic MRI may have affected these outcomes.

Secondary outcomes

The secondary outcomes were determination of the following:

- where PE was being performed in England
- 30-day mortality and 5-year overall survival (OS) after PE
- the volume of T4 and non-T4 cancers undergoing PE
- whether preoperative MRI was being performed
- perioperative treatment in those undergoing PE
- the proportions of patients with R0 or R1/R2 resection and associated survival outcomes
- comparison of survival outcomes before and after the widespread introduction of MRI in 2005.

Some of these data were compared with available NBOCA registry data in order to understand how they correlate with nationally published data.

Creation of the dataset

The source data were requested and obtained from PHE in the form of Hospital Episode Statistics codes between 1995 and 2016. This time frame was chosen to incorporate a 20-year period prior to and following the introduction of MRI. PHE was dissolved in 2021 and replaced by the UK Health Security Agency and Office for Health Improvement and Disparities. Analysis was performed on 20 September 2020 as per Figure 1.

Imaging-specific information

The final cohort of 2996 patients was analysed to determine the following:

- patients undergoing MRI within 3 months prior to resection
- patients undergoing chemotherapy within 12 months prior to and up to 12 months following resection
- patients undergoing radiotherapy within 24 months prior to resection.

Within the dataset, patients undergoing surgery before 1 January 2005 formed the 'pre-2005' cohort and those undergoing





surgery on or after 1 January 2005 formed the 'post-2005' cohort. Postsurgical excision margins were defined as 'good', assumed to be RO, and 'bad', assumed to be R1/R2.

> HES codes obtained from PHE between 1995 - 2016. cross referenced and duplicates excluded (~14million patient visits, 677,000 individual tumours)



HES dataset filtered for patients with rectosigmoid cancer (C19) and rectal cancer (C20) = 250,000 patients



Cross-referencing of HES data treatments against systemic anti-cancer therapy and radiotherapy dataset tables selecting for: 1) radiotherapy, 2) chemotherapy, 3) imaging, 4) other treatments



HES dataset filtered by OPSC4 codes:

Any tumour where patient had a PE or any pelvic colectomy / left hemicolectomy AND pelvic visceral or bony excision



Above datasets combined to identify patients with rectal cancer (C19 / C20) who had undergone pelvic exenteration = 2.996

FIGURE 1 Data collection methodology flow chart.

Inclusion/exclusion criteria

Exclusion criteria were those tumour/patient IDs for which/whom the resection date was unavailable, as this information was required for the assessment of perioperative imaging and treatment within the specified time frames. Right hemicolectomy/subtotal colectomy, for example, even if combined with a pelvic visceral excision, were also excluded as it was deemed that these operations were not for LARC.

Left hemicolectomies were included, as for a sigmoid tumour requiring PE the primary colectomy may be coded as left hemicolectomy, sigmoid colectomy or anterior resection dependent on the extent of mobilization and sacrifice of blood supply.

As per Figure 1, this paper describes patients with any OPSC4coded PE (X14.1, Total PE; X14.2, anterior PE; X14.3, posterior PE; X14.8, other specified clearance of pelvis; or X14.9, unspecified clearance of pelvis) OR pelvic colectomy/left hemicolectomy AND pelvic visceral or bony excision.

These 2996 patients form the cohort from which information on PE, treatment received and associated outcomes was evaluated. The eight available cancer registries within the dataset form the demographic basis for analysis.

Statistical analysis

Descriptive statistics were used to describe the numbers of PEs performed. Subgroup analysis was performed for PE procedures undertaken before and after 2005. Survival outcomes were assessed by 5-year OS. Differences in staging characteristics between groups were analysed using Fisher's exact test and chi-square test, where appropriate. Survival curves for 5-year OS were calculated using the Kaplan-Meier product limit method; differences between survival curves were tested for significance using the Mantel-Cox log-rank test. An event was death from any cause as recorded by the PHE data. Time to event was recorded from the date of surgery. Univariate and multivariate analyses were performed using Cox regression for the impact of perioperative factors affecting 5-year OS pre- and post-2005. A p-value of <0.05 was considered significant. Hazard ratios were recorded with 95% confidence intervals. Statistical analysis was performed using Excel and SPSS.

RESULTS

Demographic information was reported within the cohort and survival data were censored to 60 months (5 years). Overall, 2996 patients underwent a PE between 1995 and 2016, with 573/2996 (19%) defined as primary rectosigmoid (C19) and 2423/2996 (81%) as primary rectal (C20) cancers. Of these, 912/2996 (30%) patients had surgery pre-2005 and 2084/2996 (70%) post-2005. The cohort comprised 1032 (34%) men and 1964 (66%) women, with an average age at diagnosis of 62 and 65 years, respectively. The age at diagnosis for both men and women remained stable over this time period. Despite rectal cancer being more prevalent within men in the UK [1, 4], from this data considerably more women underwent a PE. Within the PHE data, patients were grouped into eight cancer registries according to their place of diagnosis (Figure 2), differing from the 21 NHS cancer alliances currently coordinating cancer care within the UK, as reported by NBOCA. To enable accurate comparison between these reports, trusts within the 21 cancer alliances were re-grouped within these corresponding eight cancer registries. Figure 2 shows regional variations in PE performed in the eight English cancer registries, although this does not take into account the population within each registry region.

The 30-day mortality in patients undergoing PE was 4.6%. The mean OS was 48 months, with 54% of patients alive at 5 years postsurgery and a mean OS of 48 months. The 30-day mortality post-PE was 4.3% (39/912) prior to 2005 and 3% (62/2084) post-2005. This mortality rate is higher than the 30-day mortality for rectal cancer patients following all major resectional surgery, which was 2.6% as per the 2011 NBOCA report [5] and 1.8% as per the 2013 report [6], the last report in which 30-day mortality for rectal cancer surgery was specifically documented.

Better OS was demonstrated after 2005 (Figure 3), with 61.7% of patients alive at 5 years following surgery compared with 37% of patients prior to 2005 (p < 0.001). There was no significant difference in mean OS between the various cancer registries, with the

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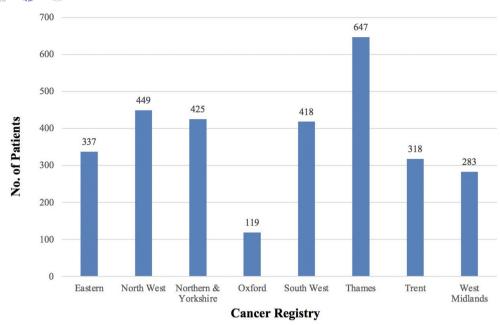


FIGURE 2 Number of patients undergoing pelvic exenteration according to cancer registry. Key: Eastern - Eastern Cancer Registration and Information Centre; North West - North West Cancer Intelligence Service; Northern & Yorkshire - Northern and Yorkshire Cancer Registry and Information Service; Oxford - Oxford Cancer Intelligence Unit; South West - South West Cancer Intelligence Service; Thames - Thames Cancer Registry; Trent - Trent Cancer Registry; West Midlands - West Midlands Cancer Intelligence Unit.

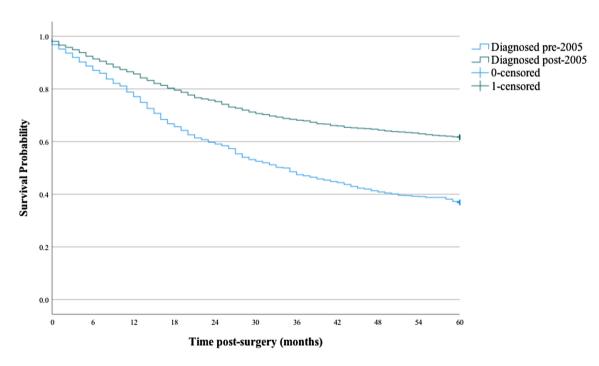


FIGURE 3 Kaplan–Meier overall survival curve before or after 2005 (p < 0.001).

maximum being 46 months within the Trent Cancer Registry and 40 months within the Thames Cancer Registry.

T-stage

Of 2996 patients, 1474 (49%) had pathological T-stage documented (Table 1). In 1522/2996 (51%) patients this could not be assessed or

was unknown, and these cases were excluded from analysis. There were 804/2996 (27%) non-T4 cancers and 2192/2996 (73%) T4 cancers in patients who underwent PE. Dukes stage, was documented in 2100/2996 (70%) of patients.

The proportion of patients with T4 versus non-T4 cancers was evaluated within each cancer alliance (Figure 4). Every cancer alliance had more patients undergoing PE post-2005 than prior to 2005.





Post-2005, both the total number of PEs per cancer alliance and the proportion of non-T4 cancers undergoing PE increased. There was a significant difference in OS, with 50.9% of patients with T4 cancer surviving at 5 years compared with 71.6% with a non-T4 cancer (p<0.001). The 5-year OS for non-T4 cancers significantly improved after 2005 compared with before 2005 (53.1% pre-2005 vs. 75.2% post-2005; p < 0.001), as did that for T4 cancers (30.7% pre-2005 vs. 56.3% post-2005; p < 0.001).

MRI

Overall, 395/2996 (13%) patients had documented preoperative MRI within 3 months of surgery. Only 4/395 (1%) of these patients had an MRI scan documented prior to 2005 and 391/395 (99%) after 2005.

TABLE 1 Pathological T-Staging pre- and post-2005.

Pathological T-staging	Pre-2005, n (%)	Post-2005, n (%)
T0	0 (0)	13 (1)
T1	7 (1)	46 (2)
T2	25 (3)	145 (7)
T3	98 (11)	457 (22)
T3a	O (O)	2 (0)
T3b	O (O)	6 (0)
T3c	O (O)	4 (0)
T3d	O (O)	1 (0)
T4	138 (15)	284 (14)
T4a	1 (0)	156 (7)
T4b	1 (0)	91 (4)
Unknown	642 (70)	879 (42)
Total	912 (30)	2,084 (70)

Figure 5 demonstrates the 5-year OS of the whole patient cohort according to preoperative MRI status. In patients undergoing preoperative MRI, 5-year OS was 69.9% compared with 51.7% in those who did not undergo preoperative MRI (p < 0.001). The difference in 5-year OS was not significant in those who did or did not undergo preoperative MRI prior to 2005, probably due to the small number of patients having preoperative MRI prior to 2005. The 5-year OS was significantly higher in those undergoing preoperative MRI after 2005 (70.1% vs. 59.7%; p < 0.001).

Perioperative treatment

Overall, 530/2996 (18%) patients had preoperative chemotherapy within 1 year of surgery. Of these 178/530 (34%) had preoperative chemotherapy alone, 352/530 (66%) had chemoradiotherapy and 674/2996 (22%) had postoperative chemotherapy. A total of 1502/2996 (50%) patients had no documented chemotherapy pre- or postoperatively. Overall, 1075/2996 (36%) patients had preoperative radiotherapy within the 2 years prior to resection

The 2017 NBOCA report (reporting data from 1 January to 31 December 2015) showed that of 4622 patients undergoing major surgical resection for rectal cancer, 38% underwent neoadjuvant treatment, with wide variation 'between Cancer Alliances from 23% to 58% of patients' [7]. Of these, 26% underwent neoadjuvant long-course radiotherapy, 8% underwent neoadjuvant short-course radiotherapy and 3% had another neoadjuvant treatment including chemotherapy, brachytherapy or radiotherapy with an unknown course length [7].

Table 2 lists perioperative treatment measures administered to patients pre- and post-2005, showing that the associated 5-year OS significantly improved for each treatment measure after 2005.

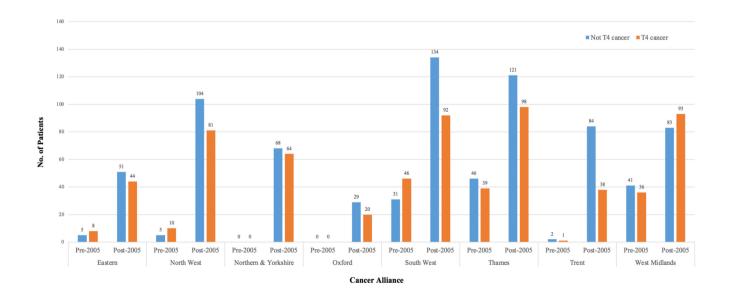


FIGURE 4 Patients operated on per cancer alliance according to pathological T4 status.

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FIGURE 5 Kaplan–Meier curve of overall survival according to preoperative MRI status (*p* < 0.001) and the use of MRI scanning between 1995 and 2016.

TABLE 2 Perioperative treatment pre- and post-2005 with associated 5-year OS.

	Pre-2005	Pre-2005		Post-2005	
	Yes, n (%)	Alive at 5 years, n (%)	Yes, n (%)	Alive at 5 years, n (%)	p-value for 5- year OS
Preoperative chemotherapy	112 (12)	40 (37.5)	418 (20)	257 (61.5)	<0.001
Preoperative radiotherapy	138 (15)	52 (37.7)	937 (45)	626 (66.8)	< 0.001
Postoperative chemotherapy	164 (18)	67 (40.9)	510 (24)	302 (59.2%)	< 0.001

Oncological clearance

Only 418/2996 (14%) patients had their 'excision margin' documented from the available data (Figure 6). Of these, 349/418 (83%) had an R0 resection compared with 69/418 (17%) with an R1/R2.

The 5-year OS in patients who had an R0 resection was 58.2% compared with 36.2% in those who had an R1/R2 resection (p<0.001). The 5-year OS of those with R0 resection was significantly different after 2005 compared with before (pre-2005 40.6% vs. post-2005 62.1%; p<0.001); however, this was not the case for patients with R1/R2 resection (21.1% pre-2005 vs. 42% post-2005; p=0.092).

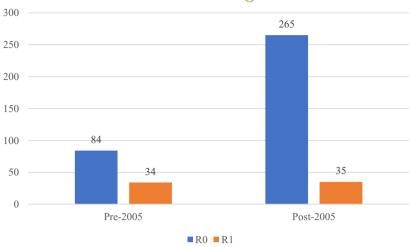
The impact of perioperative factors affecting 5-year OS pre- and post-2005 was assessed (Table 3). T4 and resection status were excluded as these were pathological findings. Prior to 2005 the only significant parameters with a sustained significant difference in

5-year OS were age and sex, compared to age, preoperative MRI and preoperative radiotherapy remaining significant post-2005.

DISCUSSION

These nationally reported data captured patients undergoing PE across England over a 21-year period, representing a small proportion of those undergoing major resectional surgery for rectal cancer during this time. Between 2008 and 2021, from NBOCA reports, over 112300 patients were diagnosed with rectal cancer, with approximately 4400 (51%) patients per year undergoing major resectional surgery [1]. Although NBOCA data include patients from England and Wales, these PHE data imply that when identifying patients undergoing PE only a small proportion are being documented or that many patients are not being offered surgery. This suggests

FIGURE 6 Resection status pre- and



that not all PEs were being performed in specialist centres, and whether these were conventional or highly complex PE procedures is also unclear as analysis was based on OPSC4 codes and intraoperative information regarding the radicality of surgery was unavailable. The 30-day mortality rates of 4.7% and 3% pre- and post-2005 are higher than the international rates from the PelvEx group (1.5%) [8] and recent multicentre international analysis of 16 specialist centres (1.7%) [9], the results from high-volume centres specializing in PE. These specialist centres are likely to have improved patient selection, operative techniques and postoperative management compared with nonspecialist centres.

Prior to 2005, patients requiring PE were often overlooked, as an understanding of the CRM and use of pelvic MRI were not widely accepted. The MERCURY studies [10, 11] increased awareness of what defined the limits of resectable, clear margin rectal cancer and, therefore, a greater awareness for the need for 'beyond TME (total mesorectal excision)' surgery to ensure that margins were not involved with tumour. Because the mesorectal fascia, which forms the boundary of dissection, is not classified as a T4 structure, T3 tumours abutting or extending beyond the fascia could be selected for PE.

Traditionally, LARC would often only be discovered intraoperatively, which would be too late to plan for PE. To account for the early patients within these data, it is assumed that after discovery of extensive disease intraoperatively, excision of the bladder/uterus en bloc in addition to rectal cancer surgery was being performed. Unless surgery for these patients is being recorded as PE then it is likely to be under-reported and we are unlikely to fully understand the scale of the problem or whether improvements can be linked to wider uptake and referrals for PE. The Pelican IMPACT programme was an initiative developed in collaboration with the Association of Coloproctology of Great Britain and Ireland to increase awareness of multidisciplinary teams across the UK and Ireland regarding management options for patients with advanced colorectal tumours in addition to the available referral process [12].

The observed regional variation of patients undergoing PE cannot entirely be attributed to differences in population density and may reflect expertise in PE within each region. The development of PE services needs to take these considerations into account. Equally, the low numbers undergoing PE may reflect not just under-reporting of patients in need of PE, but also the lack of access to expertise in close geographical proximity.

T-staging is not informative in selecting and understanding the disease burden of patients undergoing PE, mainly because it does not assist in treatment or prognostic preoperative planning. It is clear that 5-year OS for T4 disease is worse when compared with that for non-T4 disease. In this report 5-year OS improved over time for patients with both T4 and non-T4 disease, which therefore cannot be attributed to over-staging. Dukes stage was recorded in 70% of patients; however, more recently national TNM pathology guidelines mandated reporting of T-stage, indicating poor compliance. Documentation of pelvic compartmental involvement enables better assessment of disease burden when PE is required [13, 14], providing robust anatomical assessment to aid treatment planning. CRM status was not documented in these data nor within the NBOCA reports prior to 2017, and its involvement is another obvious indication for PE. Non-T4 cancers requiring PE reflect those beyond the mesorectal fascia, and it is probable that more patients were identified using rectal MRI post-2005, with more patients undergoing surgery and therefore with better survival outcomes. If disease burden in these patients is to be captured within national registry data in the future, vigorous anatomical assessment including information on CRM status and compartment involvement should be provided.

Only 13% of patients underwent preoperative MRI, which was probably in specialist centres and does not reflect its current widespread use. Patients undergoing preoperative MRI had a significant improvement in 5-year OS compared with those who did not. The survival gain associated with the use of MRI is a reflection of its role in improving the selection of patients suitable for neoadjuvant therapy and in facilitating surgery, but it is difficult to draw conclusions from these data due to small numbers undergoing MRI. Future strategies need to ensure that MRI usage and assessment in these patients is monitored and captured. Improved survival rates after 2005 also naturally reflect a combination of





TABLE 3 Univariate and multivariate analysis on perioperative factors affecting 5-year OS.

		Univariate analysis 5-year OS			Multivariate analysis 5-year OS		
Time point	Parameter	HR	95% CI	p-value	HR	95% CI	p-value
Pre-2005	Age (years)						
	<65	Ref.			Ref.		
	≥65	0.701	0.594-0.828	<0.001	1.463	1.238- 1.729	<0.001
	Sex						
	Female	Ref.			Ref.		
	Male	0.771	0.638-0.932	0.007	1.356	1.121- 1.640	0.002
	Preoperative	Preoperative MRI					
	No	Ref.					
	Yes	1.629	0.406-6.528	0.491			
	Radiotherapy	2 years p	reresection				
	No	Ref.					
	Yes	0.985	0.783-1.238	0.895			
	Chemotherap	y 1 year p	reresection				
	No	Ref.					
	Yes	0.942	0.736-1.206	0.634			
	Chemotherap	y 1 year p	ostresection				
	No						
	Yes	1.241	0.997-1.543	0.053			
Post-2005	Age < 65 or ≥ 65						
	<65	Ref.					
	≥65	1.382	1.203-1.589	<0.001	1.323	1.149- 1.523	<0.001
	Sex male vs. f	Sex male vs. female					
	Female	Ref.					
	Male	1.132	0.982-1.300	0.089			
	Preoperative	MRI					
	No	Ref.					
	Yes	1.407	0.156-1.712	<0.001	1.316	1.079- 1.505	0.007
	Radiotherapy	2 years p	reresection				
	No	Ref.					
	Yes	1.364	1.183-1.572	<0.001	1.267	1.096- 1.465	0.001
	Chemotherap	y 1 year p	reresection				
	No	Ref.					
	Yes	0.990	0.833-1.177	0.913			
	Chemotherapy 1 year postresection						
	No	Ref.					
	Yes	0.947	0.808-1.109	0.497			

Abbreviations: CI, confidence interval; HR, hazard ratio; OS, overall survival. Statistically significant results are in bold.

factors in addition to preoperative staging, such as the development of surgical techniques and opportunity for those with less advanced disease, surgical optimization and the introduction of total neoadjuvant therapy (TNT).

These data show that 66% of patients underwent neoadjuvant chemoradiotherapy and 36% preoperative radiotherapy prior to PE. These volumes are higher, as expected, than the NBOCA report from 2017 [7]; however, with LARC the use of neoadjuvant treatment would







be expected to be higher. These data do not reflect the use of TNT, which is now at the forefront of treatment of patients with LARC, increasing disease-free survival and pathological complete response rates as evidenced in the RAPIDO and PRODIGE-23 studies, for which MRI is a necessary tool in selecting patients and monitoring response [15–17].

The small proportion of patients (14%) with available information on margin status data confirmed that those with RO resection had an improved 5-year OS compared with those with R1/2 resection (p < 0.001), and it has been well described that RO resection is one of the most important predictors for OS [8, 18].

The ways to improve survival for patients with LARC requiring PE are to ensure that (1) they do not undergo surgery resulting in a positive CRM and (2) they are able to benefit from the expertise and outcome data available for this surgery, which in the majority of patients (80%) achieves RO status [8]. This leaves us to develop methods to improve outcomes for the remaining 20% of patients, for whom an improved pathway is imperative.

Based on the findings the recommendations would be that given the prevalence of patients presenting with LARC who require PE (and the impact of PE on survival) there needs to be better national documentation, which should include

- MRI staging at presentation including compartmental involvement
- the use of selective preoperative treatment
- timing of referral and access to tertiary PE services
- · documentation of compartments resected on pathology
- CRM status and distance of tumour/treated tumour to compartments adjacent to the mesorectum on MRI

A limitation of this work is that information on whether this surgery was being performed in specialist tertiary centres only was not evaluated, which would help to inform the development of current and future services, particularly with regard to funding and volumes of activity.

CONCLUSION

These data show that the volume of PE performed since 1995 has increased over time with significant improvements in survival. Increased utilization of perioperative therapy and surgical specialization since 2005 coincide with the introduction of pelvic MRI. By multivariate analysis the use of preoperative MRI, along with preoperative radiotherapy and age, were the only significant factors influencing 5-year OS. There is ongoing geographical variation in the volume of PE performed and an ongoing requirement for national and international PE working groups to document, plan and deliver current and future needs. Pelvic MRI is the gold standard for the assessment of LARC requiring PE [19].

AUTHOR CONTRIBUTIONS

Zena Rokan: Conceptualization; data curation; validation; formal analysis; methodology; writing - original draft. Anita Wale: Data curation; formal analysis; validation; writing - review and editing. Nigel

Day: Conceptualization; data curation; formal analysis; methodology; writing - review and editing. Christos Kontovounisios: Supervision; writing - review and editing. Brendan Moran: Supervision; writing - review and editing. Gina Brown: Conceptualization; methodology; supervision; writing - review and editing.

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None to declare

CONFLICT OF INTEREST STATEMENT

There are no conflicts of interest to declare from any of the authors of this manuscript.

DATA AVAILABILITY STATEMENT

The data that supports this manuscript are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Not applicable.

RESOURCES CONTRIBUTION

Trym Consulting.

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