

Rectal Cancer

The Basingstoke Experience of Total Mesorectal Excision, 1978-1997

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Objective: To examine the role of total mesorectal excision in the management of rectal cancer.

Design: A prospective consecutive case series.

Setting: A district hospital and referral center in Basingstoke, England.

Patients: Five hundred nineteen surgical patients with adenocarcinoma of the rectum treated for cure or palliation.

Interventions: Anterior resections (n = 465) with low stapled anastomoses (407 total mesorectal excisions), abdominoperineal resections (n = 37), Hartmann resections (n = 10), local excisions (n = 4), and laparotomy only (n = 3). Preoperative radiotherapy was used in 49 patients (7 with abdominoperineal resections, 38 with anterior resections, 3 with Hartmann resections, and 1 with laparotomy).

Main Outcome Measures: Local recurrence and cancer-specific survival.

Results: Cancer-specific survival of all surgically treated patients was 68% at 5 years and 66% at 10 years. The local recurrence rate was 6% (95% confidence interval, 2%-10%) at 5 years and 8% (95% confidence interval, 2%-14%) at 10 years. In 405 "curative" resections, the local recurrence rate was 3% (95% confidence interval, 0%-5%) at 5 years and 4% (95% confidence interval, 0%-8%) at 10 years. Disease-free survival in this group was 80% at 5 years and 78% at 10 years. An analysis of histopathological risk factors for recurrence indicates only the Dukes stage, extramural vascular invasion, and tumor differentiation as variables in these results.

Conclusions: Rectal cancer can be cured by surgical therapy alone in 2 of 3 patients undergoing surgical excision in all stages and in 4 of 5 patients having curative resections. In future clinical trials of adjuvant chemotherapy and radiotherapy, strategies should incorporate total mesorectal excision as the surgical procedure of choice.

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THE SURGICAL management of rectal cancer has been a challenge from the time of Miles¹ to the present. The standard surgical approaches of abdominoperineal (AP) resection or anterior resection (AR) have produced disappointing results, both in local control and in overall survival. This has prompted the development of adjuvant strategies using radiotherapy, chemotherapy, or both to improve outcomes. In 1978, one of us (R.J.H.), working in Basingstoke, England, questioned the traditional operations and began to develop the procedure that is now known as total mesorectal excision (TME) in an effort to reduce the rate of local recurrence (LR) of rectal carcinoma in the pelvis. Refinements of precise surgical dissection from above developed after the introduction of surgical stapling for the anorectal muscle tube. The procedure was

developed with an awareness of the importance of complete excision under direct vision of the envelope of lymphovascular fatty tissue surrounding the rectum and its mesorectum. It was postulated that LR was more a result of leaving mesorectal residue than of the inherent nature of rectal cancer to spread beyond the confines of perimesorectal dissection. The results of these efforts yielded the lowest rate of LR yet published in the literature²⁻⁴ and challenged the surgical community worldwide to recognize the importance of meticulous dissection in the management of this disease. The trend toward the acceptance of TME⁵⁻¹¹ attests to the validity of the original concept and sets a new gold standard that future adjuvant strategies must meet. We review the results obtained in 519 consecutive operations, mostly at the Colorectal Research Unit, The North Hampshire Hospital in Basingstoke between 1978 and 1997.

PATIENTS AND METHODS

Five hundred nineteen patients with histologically proven rectal adenocarcinoma (from the anal verge to 15 cm proximal, as measured by rectosigmoidoscopy) were operated on by 1 surgeon (R.J.H.) between August 1, 1978, and January 31, 1997, and were observed to January 1, 1998 (average, 8.3 years).

Preoperative assessment was by standard history and physical examination, and the search for metastatic disease outside the pelvis was accomplished by chest radiography, liver biochemistry studies, ultrasonography, and computed tomographic scan where appropriate.

All patients were prepared for surgical procedure with standard mechanical bowel preparation, having been given antibiotics perioperatively. The operations performed were 465 ARs, 37 AP resections, 10 Hartmann procedures, 4 local excisions, and 3 laparotomy only. A covering stoma was performed in 382 patients, most being closed within 2 months of the original procedure.

A prospective database was used to record the characteristics of the patients and their histopathological diagnoses. Follow-up was accomplished on a regular basis with events noted. Only 1 patient has been unavailable for follow-up. Complications were recorded, and dates of recurrence were entered for local and distant disease, as well as for death and cause of death. The operative mortality (30-day) was 3.3%. Operative specimens were analyzed histopathologically for the Dukes stage, including the number and status of nodes, tumor differentiation, and extramural vascular invasion (EVI). The Dukes stage distribution was as follows: 102 Dukes A, 167 Dukes B, 142 Dukes C, and 108 Dukes D (residual disease or metastases).

Of the 519 patients, 49 underwent preoperative radiotherapy, usually for fixation or "inoperability." Five more patients had radiotherapy but are excluded from the 519 because they never reached the operating room, ie, they died during radiotherapy or immediate follow-up. Of the 49 patients who reached the operating room, 45 underwent either AR or AP resection, 3 were found to have more extensive disease than anticipated and received palliative Hartmann procedures, and 1 had colostomy only. Twenty-seven patients received long-course radiotherapy of 40 to

55 Gy during 6 weeks, and 22 received 25 Gy during 5 days. Three quarters of these treatments (36/49) have been offered since January 1994.

In 58 of the 465 patients in the AR group, TME was not completed. Each of these patients had cancer in the upper third of the rectum and underwent dissection in the perimesorectal plane circumferentially around the enveloping mesorectum for at least 5 cm below the distal tumor margin: the distal mesorectum was omitted from the excised specimen in the interests of reducing the magnitude of the procedure.

SURGICAL TECHNIQUE

The essence of the surgical technique is the painstaking development under direct vision of the avascular plane between the mesorectum and the surrounding parietal tissues right down to the distal extremities of the pelvis. The excised specimen thus includes the whole posterior, distal, and lateral mesorectum out to the plane of the inferior hypogastric plexuses, which are carefully preserved. Anteriorly it includes the intact Denonvilliers fascia and the peritoneal reflection. The characteristic bilobed encapsulated appearance of the intact mesorectum posteriorly and distally reflects the contours of the pelvic floor and the midline anococcygeal raphe. The ideal specimen has a smooth unbroken surface like that of a lipoma. This is achieved by meticulous sharp dissection in the avascular areolar plane surrounding the mesorectum. Finally, great importance is attached to preventing implantation by the use of sterile water to wash out the rectal stump below a clamp before the anorectum is divided and the pelvis itself, both before and after the division.

STATISTICS

Statistical analyses were performed using specifically designed and commercially available software (Patient Management and Analysis System, Practical Automation Management Ltd, Princes Risborough, England). Kaplan-Meier survival curves with 95% confidence intervals were constructed for various groups of patients, and significant differences between categories were determined by Cox regression analysis. The χ^2 test was used to check for significant differences in paired variables.

RESULTS

The average operating time was 4 hours. Cancer-specific survival in all 519 patients treated surgically was 68% (median, 62%-74% at 95% confidence intervals) at 5 years and 66% (56%-76%) at 10 years (**Figure 1**). The LR (or persistence rate) was 6% (2%-10%) at 5 years and 8% (2%-14%) at 10 years (**Figure 2**). Analyzed by the type of operation, the LR rate was 5% at 5 and 10 years for 465 patients (89.6%) undergoing AR, compared with 17% at 5 years and 36% at 10 years for 37 patients (7.1%) undergoing AP resection ($P < .001$).

Cancer-specific survival was 80% at 5 years and 78% at 10 years in patients treated for cure compared with 31% at 5 years and 26% at 10 years following noncurative procedures ($P < .001$). At this time, no patients with metastatic disease have survived beyond 5 years.

The overall 5- and 10-year LR rate was 2% in the 380 patients selected for AR, which was judged curative (**Figure 3**). Following curative AR, 81% of patients survived 5 years and 80% survived 10 years (**Figure 4**). Within this group, neither the Dukes stage, tumor grade, anastomotic leak rate, height of tumor above the dentate line, nor anastomotic height affected the LR rate, while the presence of EVI was associated with a significantly higher LR rate ($P < .001$) of 9% in the 56 patients in whom EVI was found, compared with 1% when it was absent. Within the same group of 380 patients with curative AR, only the Dukes stage and the presence of EVI were significant predictors of overall failure, whereas the tumor grade, nonfatal anastomotic leak, height of tumor, and anastomosis did not affect the tumor prognosis. When the results of the first 10-year period were compared with those of the second, the LR rate as a percentage of the

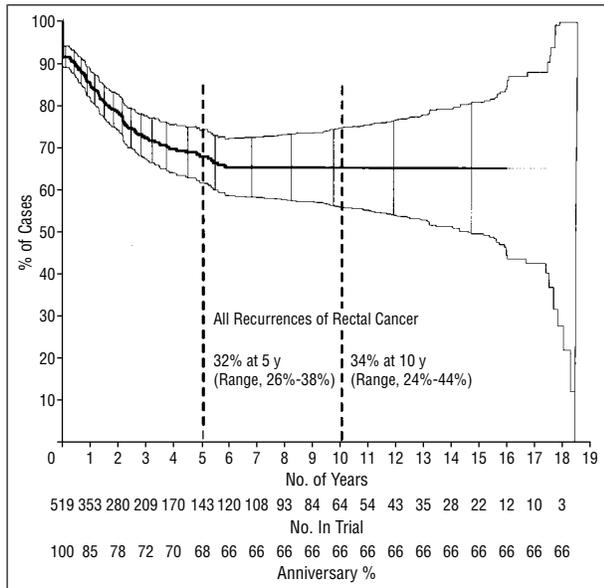


Figure 1. Overall recurrence rate in 519 patients—1998 update.

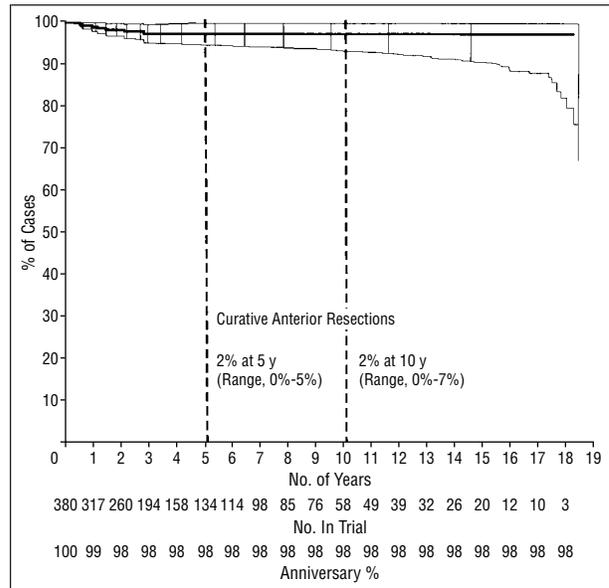


Figure 3. Local recurrence rate in 380 curative anterior resections—1998 update.

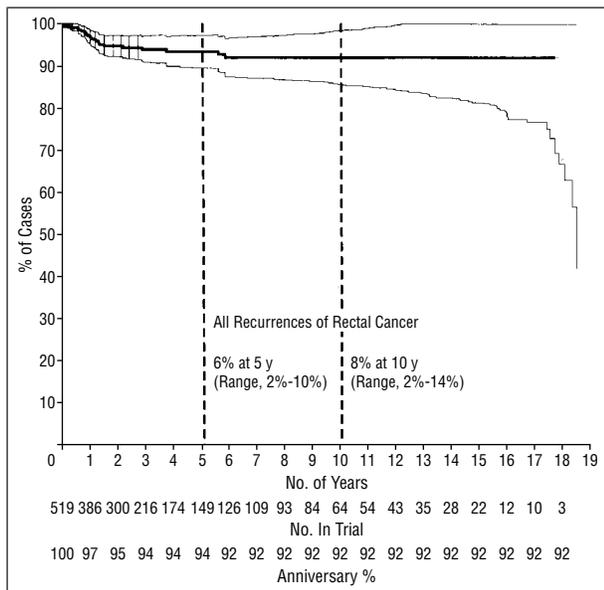


Figure 2. Local recurrence rate in 519 patients—1998 update.

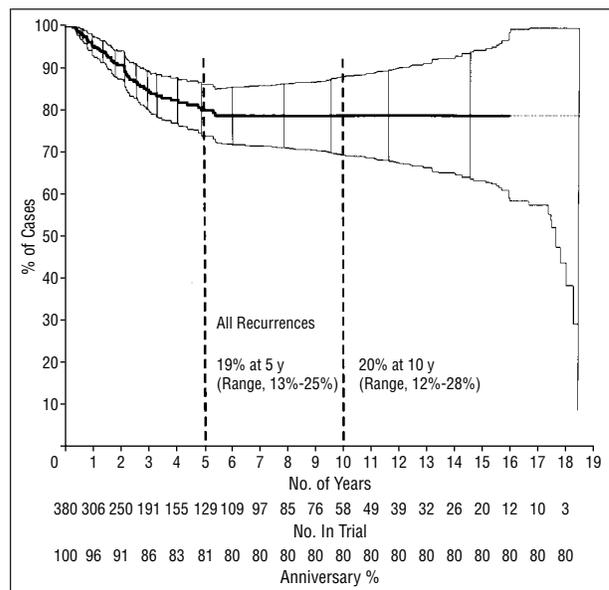


Figure 4. Overall recurrence rate in 380 curative anterior resections—1998 update.

operations appeared to show a marked improvement: 8.5% down to 3% in all patients, and 4% down to 0.5% in the patients receiving curative AR. Radiotherapy had been used in only 4 patients in the first period compared with 45 patients in the second period.

COMMENT

The objective verification¹² of the Basingstoke results by a Canadian professor of surgery on a sabbatical in 1992 is probably unique in the history of surgery. This 1998 update now spans almost 20 years and comprises more than 500 consecutive operations by 1 surgeon (R.J.H.). Adjuvant therapies have been used in so few patients and so recently that they can have had only minimal effect on the overall data. Radiotherapy has been used, preop-

eratively only, mostly in selected fixed or inoperable tumors (9% of the series), and this has probably contributed to the reduction of LR rates in the second 10-year period. There has been slight difficulty in producing precise figures of the number of patients receiving postoperative chemotherapy in other centers. A recent calculation, however, suggested that only 6%, either within or without Basingstoke, have received chemotherapy. No improvement is measurable as a result, although this is the subject of an ongoing study. Patient-led pressures make it improbable that a relatively "pure" surgical series of this kind will ever be possible again.

These data test the fundamental hypothesis that the principal predictor of cure is the completeness of the me-

sorectal specimen. The use of sharp dissection replaces the manual extraction of the past: traction on the specimen is gentle and applied to its surface with gauze swabs; retractors on surrounding pelvic wall structures are used so that every step is visualized; and 2 experienced colorectal surgeons are optimal.¹³ The specimen is monitored by the detailed histopathological examination of the margins by the methods of Quirke and colleagues.¹⁴⁻¹⁶ In a trial now under way in Holland,¹⁷ circumferential margin involvement is being carefully monitored as a surgical outcome.

Substantial improvements on all previously published, comprehensive, unselected series now appear confirmed beyond all doubt by these data. In addition, it becomes clear that low LR rates have a substantial effect on overall survival. For the entire series, including patients with inoperable tumors and those with metastases, an LR (or local tumor persistence) rate of 6% at 5 years and 8% at 10 years provides an overall cancer-specific survival of 68% and 66%, respectively. This contrasts markedly with a national figure of 38%.¹⁸ The data from operations for cure are even more striking. The LR rate of 3% leads to a cure rate of 80% at 5 years, and at 10 years an LR rate of 4% leads to a cure rate of 78%. In the group having curative AR, a 2% LR rate translates to an 80% cure rate. Subgroup analysis reduces the LR rate to 1% in 324 patients without EVI compared with 9% in 56 patients with EVI. Should presence of EVI and the circumferential margin involvement be indicators for early postoperative radiotherapy? We prefer to avoid this except in high-risk situations in the interests of pouch and sphincter function. Tumor and anastomotic height had no effect on the cancer outcomes, provided an AP resection did not become necessary.⁴

The underlying philosophy of this series has been to maximize sphincter preservation by an ultralow stapled anastomosis. More recently, short colon pouch reconstruction has been used (2 × PI 30 linear cross staplers plus 1 CEEA31 circular stapler, US Surgical, Norwalk, Conn). As published elsewhere, 75% of cancers less than 5 cm from the anal verge have been thus managed, and no patient with cancer more than 4 cm has had an AP resection.⁴ In fact, only 7% of the 519 patients have had an AP resection, an operation that we avoid using whenever technically possible. The anastomotic leak rate in the 380 patients with curative AR was 6.5% (apparent clinically) plus 5.5% (determined only radiologically), and temporary stomas were constructed in 73%.

The markedly inferior cancer cures in patients with AP resections deserve comment. Total mesorectal excision has had an effect only in patients in whom an AR plus TME has been possible. The fact that perineal recurrence is invariably in an AP wound and does not occur after an AR with ultralow stapling suggests that implantation may be important.⁴ Does the perianal purse-string suture protect adequately against this? Does the absence of surrounding mesorectum and, thus, of a definable dissection plane less than 3 to 4 cm from the anal verge remove an important safety factor? Should all AP resections be preceded by radiotherapy? Finally, although we have always tried to combine AP resection with

TME, it is misleading to suggest that this is done in conventional practice. Variability in the outcomes related to the height of the initial tumor, widely accepted as inevitable, reflects technical variation, particularly in the completeness of the mesorectal excision. Conventional AP resection makes TME more difficult and imprecise, with an increased risk of tearing the surface of the specimen.

Total mesorectal excision and precise perimesorectal plane dissection are being introduced in all the major countries of Europe.¹³ It is now generally accepted that an improved surgical procedure directed toward mesorectal excision is the principal determinant of outcome. One of us (R.J.H.) has undertaken 125 television workshop demonstration operations in 17 countries. Why is the situation so different in North America? We suggest that it is a prime example of the failure of managed health care in which the priorities are determined by people who are not physicians and who do not understand the long-term issues. The real cost of rectal cancer lies in the management of failure, particularly local failure, and in multimodality therapies that will not be necessary when more money is available for surgical time and training. Total mesorectal excision at least doubles the operating time, uses \$1000 of surgical staplers, and is a challenge to surgical skill. Purchasers of health care need to recognize that investing in surgical skill is best for patients and for the long-term costs of managing rectal cancer.

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DISCUSSION

Jan H. Wong, MD, Honolulu, Hawaii: The authors have reported an overall survival of 68% at 5 years and 66% at 10 years, and LR rates of 6% and 8% at 5 and 10 years, respectively. In patients who underwent a "curative" operation, the LR rate was only 3%, and the 5-year survival approaches 80%. This, you must remember, is in the absence for the most part of any adjuvant local or systemic therapies. The authors are certainly to be congratulated on their outstanding results! The results and, in particular, their LR rates are far superior to those that have been historically reported in surgery only series and in many instances exceed that achieved with adjuvant and radiation and chemotherapy approaches.

These results however are not truly unbelievable as others appear to be duplicating Mr Heald's results. However, these results are not achieved without some potential downsides. Mortality in this series was 3.3%, and 73% of these patients had a diverting colostomy. Having said that, however, these outcomes really are what we should all be striving for.

Are these outcomes the result of outstanding surgical technique as the authors have suggested, or are other factors present that may contribute to and/or explain these outcomes? Numerous factors, including Dukes stage of disease, tumor margins of resection, location, histological grade, involvement of lymph nodes, blood vessel invasion, and age, have all been suggested as adverse prognostic indicators. In a previous report, Mr Heald and Dr MacFarlane have analyzed high-risk rectal cancers, ie, Dukes B₂ and C₂ tumors, and reported very similar results. Their data today indicate that only the presence of EVI was associated with significantly higher LR rates in patients who were felt to have undergone a curative resection. Even these individuals with this pathological finding had only a 9% LR rate.

I would ask the authors to speculate on why this pathological feature is predictive of local failures in light of the dissection technique and the absence of adjuvant therapies. Did the authors identify any difference between the Dukes stage and perhaps number of nodes involved with respect to local failures and systemic failures?

The most powerful predictor, however, of local failure would appear to be whether the procedure was felt to be "curative" and whether or not the patient had an AR as opposed to an abdominal perineal resection. I would ask the authors what determines whether a resection is "curative." As an example, are patients with multiple clinically positive lymph nodes curative? Is invasion of the prostate a curable lesion? What are the characteristics other than the systemic metastasis of the 108 individuals, which represent roughly 20% of the study group, that made them "noncurative"?

Now the observation that abdominal perineal resection appears to be a powerful indicator of local failure would seem to

be somewhat of an unexpected finding. The authors suggest an AP resection may violate the "holy plane" and lead to implantation. I would ask the authors if they have analyzed the subset of patients further and were there other factors that might explain or contribute to this finding, or is it solely the inability to perform a TME in an AP resection concomitantly? Are any of the prognostic indicators such as Dukes stage or EVI particularly prevalent in this group?

Since the NSABP published results indicating that local regional treatments did not impact upon survival in breast cancer, the model that lymph nodes are indicators of and not instigators of disease has generally been widely accepted, particularly by our chemotherapy colleagues. Is that tumor model applicable to rectal cancer? Approximately one third of your patients had nodal metastases. Your data would strongly suggest the curative potential of TME in patients with metastatic disease to lymph nodes and would seem to contradict the breast cancer model of tumor dissemination. I would ask the authors to speculate and comment on possible mechanisms of metastasis in rectal cancer.

Finally, it would seem important to recognize their excellent results are achieved with experience. The authors were able to improve upon their already outstanding initial experience during this second decade of TME.

My final question would be, how many procedures should we be performing to become accomplished at the intricacies of this procedure? Is TME a laparoscopically doable procedure?

Theodore R. Schrock, MD, San Francisco, Calif: I would like to congratulate the authors for this paper and commend Bill Heald, particularly for 2 decades of work to focus the attention of surgeons worldwide on the importance of TME in resecting rectal cancer. Critics have accused the Basingstoke group of selecting only the most favorable patients, but I am convinced now that this charge is unfounded. What we have here is superior surgical technique, and the principles that have been established should be adhered to by all of us. I would agree also with the authors that TME should be the surgical standard in any adjuvant trial program.

One question: What is the upper limit of tumor location that requires TME vs leaving some mesorectum distally?

Lee L. Swanstrom, MD, Portland, Ore: My question is regarding new developments in preoperative and intraoperative imaging and how that has impacted your practice which extends over such a long range of time. In particular, do you use intraoperative ultrasound? Do you use immunoguided assays or scintigraphy, and if you did find wider spread nodal disease, would that change your approach? In that case would you still subject the patient to what is admittedly a more extensive procedure?

My second question is the same as Dr Wong's. It seems like the hallmark of this technique is exposure and precise dissection under visualization. In some ways that is what we achieve with laparoscopy. Could it have a place in TME?

Lawrence D. Wagman, MD, Duarte, Calif: Since much of LR depends on how one looks for it, what are the follow-up tests that are done either on a protocol type basis or in general for these patients?

Thomas R. Russell, MD, San Francisco: Mr Heald is certainly to be congratulated, and he is well known in the field for advancing this whole subject. I have a couple of questions. With the use of preoperative ultrasound, is it necessary to do TME on all patients? Some patients with low rectal tumors have superficial tumors as revealed on ultrasound without transmural extension and without apparent lymph nodes. Do you approach such a patient transrectally?

I would also like to ask a question about radiation therapy preoperatively. Does that affect the ability to do TME?

I would also like to add editorially that the American College of Surgeons is getting involved with clinical trials in various

types of cancers. This is the first actual study group that has been approved in years and has just recently been funded. This is going to be one of the clinical trials that the College is going to be involved in, hopefully involving surgeons all over the United States, involving TME.

Dr MacFarlane: My original visit to Basingstoke in 1992 was stimulated by a review of our own UBC data in terms of LR and we were astounded to find 36% which was clearly unacceptable. Even the use of radiotherapy in that group of patients failed to reduce that rate below 29%. So a reduction of that rate seemed possible if Mr Heald's results were to be believed, and having gone there and understanding what is going on, I certainly do believe them.

My subsequent own experience with an admittedly small number of cases has yielded to date no LRs since I began using TME as my standard operation.

Dr Wong has focused on many of the key issues in our study and has asked us to speculate on some basic biology. On the question of risk factors for LR, the presence of EVI predicts a higher local failure rate as well as systemic failure. We don't really have an explanation for this phenomenon. Perhaps it relates to the difference between lymph node involvement in the mesorectum and soft tissue involvement. We have not done yet a multivariate analysis and I suspect that this may have to be done in order for us to get a handle on what EVI is actually doing. The analysis of Dukes stage reveals a significantly worse overall prognosis, but did not affect LR as long as AR could be completed. We are currently analyzing the actual number of nodes in that subgroup of patients.

Curative resection: curative, what does that mean? It's a difficult definition, and it confounds many of the reports in the literature in this disease. This is why we wanted to report our overall experience so that we could assess the effect of the operative procedure in all cases in a traditional group of rectal cancer referrals. It was defined in this series only by the surgeons' impression of whether or not tumor was left behind in the pelvis or at metastatic sites. Local invasion of pelvic organs did not define noncurative unless tumor was judged to have been left behind.

Abdominoperineal resection was done only for tumors whose lower margin was within 4 cm of the anal verge. Overall, half of such patients have been treated with low ARs. The mesorectum ceases to exist below the levators, and we feel that tumors below this point have the potential of lateral spread into the perianal tissues where anatomical definition is much more difficult. TME was performed in each of these cases before the perineal

part of the operation was carried out. These patients should probably all be radiated preoperatively, but this has not been up until now the practice in Basingstoke except in selected patients who have fixed, and large low-lying tumors. We have not done a separate analysis of our APs and perhaps this should be done although with just 37 cases meaningful comparisons may not really be possible.

The final question from Dr Wong is the most interesting one as an oncologist and relates to the fact that 65% of our Dukes C cases are cured by surgery alone. This would seem to suggest that lymph node involvement in rectal cancer does not predict for distant metastatic disease with any consistency. I agree that this certainly does not fit with the breast cancer paradigm and the behavior of rectal cancer may be fundamentally different—more akin perhaps to head and neck cancer where local and regional treatment also produces surprisingly long-term cures.

Dr Wong, it takes 5 to 6 cases with proctoring before becoming comfortable with this operation, but clearly the longer one has to do this operation, the better one gets at it. The use of the laparoscope is interesting and some people have tried laparoscopic TME. We have not had the opportunity personally to do it. Certainly laparoscopic-assisted AR is something that requires some attention.

Dr Schrock, thank you for your kind remarks. The upper limit of our tumor resection margin is 5 cm so that if a tumor in the midrectum can be cleared 5 cm distal, we will transect the mesorectum at a 90° angle and leave a longer distal rectal pouch.

Dr Swanstrom asked about preoperative imaging. We have recently been looking at the possibility of using MR imaging, which is absolutely fabulous in defining these planes and may help us to assess preoperatively those patients in whom an operation is not going to be curative, perhaps then indicating preoperative radiation therapy.

Dr Wagman, the follow-up testing is 100% in these patients. They all come back to the clinic where they are seen on a regular basis with physical examination and selective (there is no routine) follow-up. Testing for metastatic and other disease is selective, and all patients with recurrence have had histologically proven disease.

Dr Russell, I think I covered the question of the height of the tumors above which we would allow for something less than a TME. In terms of transrectal excision of cancer, we have not been practicing that to any extent in the curative cases. This is certainly something that could be subjected to further study.