Quality assurance measures in rectal cancer: caveat utilitor

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Table 1  Distribution of biopsy site in 199 patients of different age and gender

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of specimens</th>
<th>Number of patients</th>
<th>Age range (years)</th>
<th>Gender (M:F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large intestine</td>
<td>21</td>
<td>21</td>
<td>18–75</td>
<td>08:13</td>
</tr>
<tr>
<td>Small intestine</td>
<td>195</td>
<td>151</td>
<td>04–92</td>
<td>46:105</td>
</tr>
<tr>
<td>Stomach</td>
<td>29</td>
<td>27</td>
<td>17–79</td>
<td>05:22</td>
</tr>
<tr>
<td>Total</td>
<td>245</td>
<td>190</td>
<td>(104–92)</td>
<td>59:140</td>
</tr>
</tbody>
</table>

Figure 1  Rectal mucosa in a man aged 27 years with coeliac disease and collagenous colitis, stained with haematoxylin and eosin (A), van Gieson (B) and visualised with a conventional light microscope. H&E stained section as seen with a fluorescence microscope (C). Biopsy specimen from the same patient showing the tenascin immunoreactivity pattern characteristic of collagenous colitis with labelling of the broad subepithelial band (D).

Quality assurance measures in rectal cancer: caveat utilior

The delivery of surgery has never been more focussed on quality. Patients deserve consistent standards regardless of where they live or are treated. The pursuit of excellence requires the definition of standards and the search is on to find what parameters best guarantee equal patient outcome and care. In a recent paper in Gut, the careful work by Morris et al highlights how wide variation in outcome can occur and shows the importance of population-based audit to monitor trends.1 Certainly, while sphincter preservation is often considered a patient priority Morris et al illustrate that operative choice can profoundly affect quality of care and therefore careful monitoring can indicate room for improvement. A separate area of controversy is the role of lymph node evaluation as a marker of quality assurance. Undoubtedly lymph node evaluation is important but opinions differ as to the exact role that lymph nodes play in rectal cancer management.

TOTAL MESENTERIC EXCISION: A NEW PARADIGM

In the early 1980s local recurrence of rectal cancer was 20–40%.2 In an attempt to address this issue a more radical local excision was trialled to assess whether careful removal of the whole of the mesorectum would cause a beneficial effect. This work, performed at Basingstoke and now known as total mesorectal excision, revolutionised rectal cancer, reducing local recurrence to 5–10%.3 It was postulated at that time that radical local excision resulted in eradication of disease prior to systemic spread, therefore negating the need for adjuvant chemotherapy even in node positive disease.4 While the beneficial effect was undoubtedly this explanatory theory was at odds with many notions of the natural history of cancer and attention subsequently turned to the extensive lymph node dissection inherent in total mesenteric excision (TME) as an alternative reason for reduced local recurrence.5

LYMPH NODE NUMBER: A COMMON DENOMINATOR?

Patient outcome seems to be directly proportional to the number of nodes removed and based on these findings,6 lymph node numbers are now being promoted as good measures of quality of surgery.7 However, can this conclusion be justified? If a TME is performed does it matter how many nodes are removed? The proponents of node counting would suggest that increased nodal yield increases the accuracy of staging. Based on this assumption, the National Institute for Clinical Excellence, in the UK, recommends that a median of 12 lymph nodes should be removed with a rectal cancer specimen. A similar guideline has emerged from the

[2] Slezak P. The subepithelial band in normal, collagenous colitis and collagenous sprue patients, using tenascin expression gave almost the same values compared with that using routine histological and histochemical staining and illumination methods on the same samples, yet less new and archival H&E sections.

REFERENCES

National Cancer Institute, in the USA, with a minimum of 12 nodes, the required number. However, while the association between survival and node number is evident, the theory of stage migration is lacking in support. Furthermore, statistical analysis of the actual number of nodes needed to accurately determine nodal status (85% probability) puts the figure closer to 30. This data coupled with large-scale figures from the US showing that less than 50% of institutions adhere to the guidelines brings the radical lymph node dissection theory into doubt. Therefore, it would appear that once more we have provided a flawed explanation for a very real finding. The question remains: What is it that is causing increasing survival?

**LYMPH NODES: NUMBER VERSUS FUNCTION**

Rather than scrutinise surgical techniques it is possible that the answer lays in the pathologist’s laboratory and the processes behind lymph node retrieval. The search for lymph nodes is primarily performed by vision alone. Fat clearing techniques are much vaunted but in reality are rarely used. Accordingly, larger nodes are easier to find whether they are infiltrated or not and patients with bigger nodes will have higher lymph node counts. It is possible that it is the ease by which nodes are found rather than their absolute number that has a bearing on prognosis. This concept is neither new nor controversial yet is consistently overlooked in the consideration of the role of lymphatics in cancer control. It is counter-intuitive to think that cancer causes no immune response and that lymphatics act only as vehicles of malignant spread, yet this is the role to which they are most commonly assigned. Innate immune response to colorectal cancer has been shown to be an independent prognostic indicator, possibly superior to our current tumour/node/metastasis staging system. Genes associated with surveillance and immune response are differentially downregulated in more advanced rectal tumours, indicating prediction of tumour invasion based on genetic profiling of the primary cancer.

Faced with these exciting advances, the search for lymph nodes purely to register their absolute number represents a missed opportunity to gain real insight into prognosis.

**NEOADJUVANT THERAPY AND LYMPH NODES: AN UNHAPPY ALLIANCE**

A further note of caution, regarding the use of lymph node number as a measure of quality, must be raised in the era of neo-adjuvant therapies. Combination radiotherapy and chemotherapeutics cause tumour regression in a significant proportion of rectal cancers. This can result in tumour shrinkage allowing for sphincter-saving surgery or, in a small cohort, complete clinical and histological response which may negate the need for surgery altogether. The anti-tumoural effects are not confined to the rectum, however, and have been shown to cause inversion of regional lymph nodes. Not surprisingly, TME specimens from patients post neo-adjuvant therapy consistently contain fewer nodes. Therefore, the surgical procedure is not the dependent variable; however, the current guidelines do not allow for this ever-growing patient cohort. Indeed we have no data to confirm whether lymph node number post neo-adjuvant therapy still impacts on survival, the premise on which the guidelines are based. While the need for long-term prospective data is implicit the unfortunate drive toward surgeon assessment based on lymph node retrieval rates behoves us to address the issue now. Are we creating an environment where the need to produce consistently high nodal harvests may impact on our operative timing or compromise the use of chemo/radiotherapy? Sphincter preservation has untold positive impact on patient quality of life and it is essential that any questioning of this intervention is performed in an evidence-based manner. Regardless of the uncertain validity of an isolated quality measure in the age of multidisciplinary patient management, the application of guidelines based on an incomparable patient cohort must raise concern.

**CONCLUSION**

There is an over-riding drive to find parameters of quality in surgery for rectal cancer. The need for standardised care motivates the search and wide variance in survival data validates it. When faced with such an imperative, solutions are required; however, it may now be the time to hasten slowly. The high standards we seek for our patients must also be applied in the ongoing search for performance benchmarks and quality control.

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Study background and organisation
RK is a registrar in general surgery with a special interest in colorectal disease. DCW is a consultant laparoscopic colorectal surgeon in a university teaching hospital. This article originated from a discussion following a multidisciplinary meeting in our hospital. DCW noted that international guidelines were quoted by all interest groups and we wanted to satisfy ourselves that the literature supported this uniform acceptance. Analysis of the literature was performed by RK and both authors contributed to drafting and editing. DCW is guarantor.

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**REFERENCES**


**CORRECTION**

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