

TOTAL MESORECTAL EXCISION - ITS ROLE IN RECTAL CANCER SURGERY

HEALDJ. R.

DEPARTMENT OF SURGERY, BASINGSTOKE, ENGLAND

The concept of total mesorectal excision (TME) has grown over twenty years from a surgical hypothesis into a major international training initiative. Throughout this period scepticism and sometimes outright antagonism have slowed progress and threatened to strangle the idea that surgical detail might be more important than the combined multidisciplinary might of the adjuvant modalities. As always, the arguments for surgical precision are easy to dismiss because of the absence of prospective randomised trials. As Silen pointed out in a letter to the Lancet (1). The likelihood that a proper randomised trial will ever be carried out to test whether total mesorectal excision (TME) provides an advantage over conventional operation is remote. He went on to express the opinion that. Is it then appropriate to dismiss the comparison with retrospective controls and eschew the use of a procedure which seems so superior in terms of both local recurrence and survival? In my view it is unconscionable to do so (1).

It is sad to reflect that statistical scientific brains in many countries continue to dismiss the lack of controlled trials as indicating that the claims for TME can be safely ignored Wolmark, evidently contemplating the dubious fruits of various NSABP trials with great satisfaction, expresses his current view that „in the light of these results it is difficult to rationalise surgical techniques such as mesorectal resection". The Basingstoke response is a lifetable from a twenty year follow up programme of 480 consecutive rectal cancer operations with no

significant contribution from adjuvant therapies. Concentration on TME has delivered a 78% 5 year cure rate in those without obvious metastases at the time of presentation with $\pm 4\%$ at 95% confidence intervals. At ten years the figures became $73\% \pm 8\%$. These data make it possible to state that rectal cancer is a locoregional disease in three quarters of those who have not already spread to the liver or elsewhere. Such patients after surgery should honestly be told that there is a three to one chance that they do not need chemotherapy, and a three to one chance that it will not work if they are the unlucky one who needs it.

In discussing advances in surgical technique in this way other workers ignore the realities of surgical practice and the fact that no improvement in the detail of surgical technique has ever come about as a consequence of a prospective randomised trial. None of the established operative procedures in daily practice has been established in this way. It is not difficult for a practical surgeon to comprehend why the prospective randomised trial a „non starter" in this setting. If randomisation is between different surgeons the superiority of one over the other may reflect any of a hundred differences in their technique. If the TME surgeon, taking 3-4 hours to produce a perfect TME specimen, is asked to switch in a half of his patients to a rapid „wrenchout" of yesteryear he simply refuses to do so. One can randomise drugs or adjuvants, or even surgical methods such as incisions or the use

of the laparoscope - in rectal cancer one cannot randomise what is so important - the surgeon's worth moment, his worth cut or tear into malignant tissue.

Thus the progress of TME in particular has been substantially slowed by insistence on randomised trials as the gold standard for progress. Indeed it is crucial that the very evidence which rated highest on the quality of evidence scale in the recent guidelines issued by the Association of Coloproctology and The Royal College of Surgeons have in fact led to progress in what most doctors most closely concerned with the actual patients would consider a harmful direction - the more widespread use of chemotherapy, particularly as an adjuvant modality, and the use of radiotherapy in the post-operative setting. When applied thus to the new pelvic contents after reconstructive sphincter preserving operations it leads to debilitating side effects and has a very cruel impact on the patient's quality of life. Despite this it is widespread use throughout the U. S. and Germany, although real evidence of oncological benefit is largely lacking.

We thus have two major international trends which owe their reality to our obedience to what one Japanese Professor has called the „English randomising disease". The care of rectal cancer patients is indeed a multidisciplinary process, but each discipline's skills and concentrations depend entirely upon the policy which is decided upon in relation to the surgery. In Norway, Sweden, Denmark and Holland formal national TME projects are underway, whilst in Germany, Austria, the UK, and several other countries major initiatives are being undertaken to implement training in the detail of the technique of the surgery. The role of the other key disciplines in each of these countries is thus bound to be completely different. In Norway neither radio nor chemotherapy is in regular usage except as a component of the Nordic trials. In Sweden pre-operative short course radiotherapy 5x5 Gy in 5 days as an immediate pre-operative modality is almost standard for all except T1-2 tumours. In Holland the major trial of supervised and standardised TME surgery with randomisation of short course pre-operative DXT will certainly become a classic milestone.

In most countries the idea has gradually become accepted that the fixed advanced and perhaps even locally „inoperable" tumour should receive long course radiotherapy of 50-55 Gy over six weeks followed by a period of another 4-8 weeks for anatomical regression to occur and for hyperaemia to settle. During this time a desmoplastic reaction and a sclerosing process around the margin of the TME specimen make the „holy plane" less areolar and a little more difficult - but not usually impossible. In many cases the surgeons may well surmise that the original advanced tumour would have made dissection more difficult or the production of an uninvolved TME margin impossible, or even that pre-sacral venous bleeding may have been prevented by DXT occlusion of the veins. We are left then with the reality that we must manage patients with methods and protocols that are based upon inadequate evidence. If TME is indeed becoming as MacFarlane recently predicted, the new „Gold Standard" then the surgeon's job is technically difficult but intellectually easy. If Quikels circumferential margin involvement (CMI) examination becomes the immediate audit tool then the key role of the histopathologist will become similarly established. Reports from individuals and groups will begin to include, as is becoming standard in Holland, the percentage of CMI positives as a quality measurement.

In the future the refinement of MRI with various enhancement modalities will combine with CMI histology and „Holy Plane" surgery to focus attention on the interface between mesorectum and surrounding tissues during the planning stage. The key role of the radiologist will be to predict the threatened or involved margin. MRI will become the key investigation for the fixed or tethered tumour. Nodal involvement will remain an important component of pre-operative staging, but more to define the relationship of nodes to margins than

to count their numbers. Total mesorectal excision is the appropriate block dissection for rectal cancer and there is no evidence that the existence of involved nodes constitutes an indication for radiotherapy before surgery. In rectal cancer, in contradiction to colon cancer, there seems little evidence that nodes constitute an indication for chemotherapy afterwards either, though its use in this situation is widespread. Endorectal ultrasound will probably lose ground to MRI because of its relative inability to define the mesorectal margin, though it may remain useful in the region of the sphincters for identifying T1 tumours for local excision. Where expertise has been built up it will remain useful but the dream of an „off the shelf" MRI analysis of all the details of the tumour must surely be achievable within the next decade. Its key advantage will be that MRI prediction of an involved or dangerous margin will ultimately become the selection factor for pre-operative irradiation, since radiotherapy has the key advantage of „sterilising" the margins which Quirke has shown to be key focal points of surgical failure. As Pahlman points out „radiotherapy fails centrally, surgery fails at margins". The science of radiation oncology is developing so as to dictate better co-operation between the disciplines in other important ways too. For far too long pre-operative radiotherapy has been ordered without the radiotherapist even being told whether the surgeon plans to preserve the anal canal or remove it. In their classic paper from the Karolinska Holm et al pointed out the desirability of anal sparing which has hitherto not been a part of the routine even in that distinguished institute. It must surely become standard practice for both the surgeon's plan and the full MRI analysis of marginal tumour proximity to be the key components of the workup for radiotherapy planning in future. With the great advances in anaesthesia and the widespread use of epidural analgesia operative mortalities have fallen despite surgery on older and sicker patients. The single biggest killer however, stands out even more glaringly as improvements in other areas become apparent - anastomotic leakage. The advent of the colon pouch has reduced the leakage rate in the Basingstoke series from 11% (clinical) plus 6% (radiological only) to 2.5% plus 2.5%, but almost all of these have been defunctioned. The Basingstoke Unit is currently running a randomised trial between conventional defunctioning by proximal stoma and a new soft silicone anal stent. It is my personal view that leakage in the ultra low anastomosis is quite simply explained by the tightly closed anal sphincter, made more dangerous by the absence of the recto-anal inhibitory reflex after surgery. If the stent solves the problem by making positive intra rectal pressures impossible then the reluctance of so many surgeons to defunction will perhaps cease to cost a small but persisting trickle of unnecessary deaths.

Summary: Surgeons face a special challenge in implementing the long demanding precision of a good TME. Histopathologists are already rising to the unique opportunity of becoming the principal auditor of these surgical skills. If TME is accepted as the relevant block dissection for rectal cancer and the key importance of margins in selection for radiotherapy becomes established then the way forward for the radiation oncologists and the radiologists becomes clear. The place of chemotherapy in rectal cancer has yet to become clear, but its use as a neo-adjuvant pre-operative modality offers the most exciting prospects, and may well eclipse the rather small achievements of its use hitherto in the post-operative setting. The author's personal view is that the ability of all the disciplines to influence survival in rectal cancer has been largely exercised by the time the surgeon retires to bed on the night after the operation.

References:

1. Silen W. Mesorectal excision for rectal cancer. Lancet 1993; Vol 341, May 15: Letters to the Editor.