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Arbiter:

U. Metzger

Triemli Hospital, Department of Surgery, CH-8063 Zurich, Switzerland

ADJUVANT TREATMENT from its early days has been considered an additive treatment to radical or so-called 'curative' surgery in order to prolong either disease-free and/or overall survival or—at best—to increase the cure rate. It is directed against micrometastatic disease not visible at surgery, either local or distant [1, 2]. But what is the meaning of 'curative' surgery? By definition, radical surgery includes negative resection margins, an R0 resection, without microscopic (R1) or macroscopic (R2) residual disease. The importance of achieving an R0-resection is well accepted, not only for rectal cancer but with similar or even greater prognostic magnitude for other tumours, e.g. breast cancer, sarcomas. Whether a resection is 'curative' or not can only be determined after prolonged follow-up of 5 years in the case of a rectal carcinoma or 10 or even more years in the case of a breast cancer.

There is increasing evidence from multivariate statistical analysis that the individual surgeon is an independent prognostic factor in the outcome of common solid tumours such as rectal cancer [3–5]. With the introduction of modern diagnostic tests using PCR (polymerase-chain-reaction) technique [6], it may well be possible in the very near future to diagnose micrometastatic disease in the abdominal cavity, in the bone marrow and in the circulating blood and to re-establish the role of the surgeon on the incidence of these microscopic deposits and their prognostic relevance, thus serving as a further quality management tool in cancer surgery.

In contrast to colon cancer, there is a significant risk of symptomatic local-regional failure as the only or first site of recurrence in patients with radically resected rectal cancer. One of the reasons for local recurrence appears to be related to the anatomical constraints in obtaining wide radial margins, but it is difficult to explain the wide variation in the incidence of local recurrence rates, ranging from around 5% [7, 8] to 34–46% [9, 10], only by selection bias, referral patterns or anatomic variations. In a prospective study, the German study group for colorectal carcinoma clearly showed wide inter-institutional variations in the frequency of locoregional recurrence and survival stage by stage [11]. Excellent results have mostly been published in retrospective analyses from single centres or institutions [7, 8].

Despite the fact that pathohistological investigations indicate the need for total mesorectal excision [12, 13], this technique has never been tested in a randomised comparison to previous surgical techniques in terms of local recurrence and/or surgical morbidity (e.g. urological complications). This may be due to its sound principles and anatomical surgical feasibility.

From randomised controlled clinical trials, there is enough evidence that radiation therapy—either pre- or postoperative—significantly reduces the incidence of local recurrence [14]. The 'pure' surgeon might consider this adjuvant treatment a substitute for adequate surgery. Interestingly, the

reduction of the local recurrence rate had no influence on overall survival with the exception of the very recently published Swedish rectal cancer trial [15]. This is surprising because lower local recurrence rates are usually followed by a better survival [16]. If radiation therapy—with one exception—had no impact on overall survival, it seems reasonable that adjuvant radiation is a valuable additive to 'less than optimal' surgery but does not—as well as surgery itself—control the systemic component of the disease. For that purpose, adjuvant systemic chemotherapy is needed and again, several randomised control-led trials have shown that postoperative radiochemotherapy in high-risk (node-positive) patients is superior to surgery alone or to surgery plus radiotherapy [17–20]. The early results (median follow up 4 years) of the NCCTG-study 864751 comparing continuous infusion with bolus administration of 5-fluorouracil (5-FU) during radiation indicated that the infusion resulted in a significant improvement in both the rate of recurrence and survival and the rate of local recurrence was reduced to only 8% [21]. If these results are sustained, they will serve as a new standard for adjuvant treatment for patients with rectal carcinoma. If a single centre or institution does achieve a local recurrence rate of similar magnitude without adjuvant treatment it seems acceptable for such an institution to omit radiation therapy and to study the role of systemic treatment in node-positive rectal carcinoma. Unfortunately, the great majority of completed trials have not addressed the question of morbidity (especially late side-effects) and costs of adjuvant therapy which should be done in modern trials.

Whether pre-operative radiochemotherapy will be as effective as postoperative combined treatment remains to be answered. Our own experience using the NCCTG design prior to surgery in a phase II trial with several histologically documented complete responses are promising.

My answer to the 'pure' surgeons would be that their results would be even better with adjuvant therapy.

My recommendations and conclusions are:

1. Optimal treatment of rectal cancer requires experience and an interdisciplinary approach. It should therefore be restricted to institutions where such an approach is easily feasible and where adequate numbers of patients are being treated.
2. Before entering a single patient in a clinical trial, each institution/centre should be fully aware of their surgical results for the last 5–10 years (numbers of patients, R0-resections, number of lymph nodes examined, TNM-stages, tumour grading, sphincter-sparing-procedures, local recurrence rate, overall survival etc.).
3. Rectal cancer patients should—whenever possible—be treated in randomised controlled clinical trials, in which not only time to relapse and survival but also quality of life and costs should be measured.

4. Participation of institutions in such trials should be stratified and of course be based on the figures given under (2).
 5. Forthcoming study protocols should ensure that surgery within the trial adheres to guidelines such as those published by the Royal College of Surgeons of the U.K. or the German Cancer/Surgical Society and surgery/pathology data should be collected and be published as proposed by the German colorectal cancer study group or the U.K. Co-ordinating Committee on Cancer Research.
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