positive value [12], but should it be expected (or regarded as desirable) that as a result of this process the patient be solely responsible for arriving at a treatment decision? Since this question applies both within and without research protocols, the currently accepted informed consent process could be seen to be a somewhat pathetic and superficial response to the dilemma.

In the third group, there may be even stronger reasons for avoiding full discussion of the treatment options. The differences on offer are likely to be relatively minor, yet the anxiety engendered by the discussion considerable. Patients in fear of their lives do not, for the most part, want or need to know that treatment regimens, while sometimes effective, are by no means fully established, and may be unsuccessful despite the harrowing side-effects; they are often just embarking on a lengthy course of treatment, and uncertainties of outcome, although often understood by all parties at this early stage, are possibly better left unexplored. It is in this group, perhaps, where the doctor should reveal as much or as little about the trial details as he/she feels appropriate — rather than being bound by an 'ethical' imperative which insists on full and total disclosure for all. This point has been recently argued by Souhami and one of us (JST), and recognises the needless cruelty that uniform insistence on fully informed consent can impose upon many of our vulnerable patients [11].

The same general principles apply in the fourth group. Do patients really need to know that a formal randomised comparison is being made between one group of antibiotics and another, and that they are expected to agree to random allocation? These very same patients may well, of course, have been through one (or more) random allocations already! How many random choices can we reasonably expect patients to take on board, understand, and calmly accept? Not long ago, in one of the shabbiest episodes in British medical journalism, an outstanding and innovative medical scientist was pilloried by the press after disclosure that, in a study attempting to assess the value of breast cancer counselling, half the patients had not received it and had not therefore known that it was available [13]. At the time of the study, not only had it not been unequivocally proven to be beneficial, it was only made available because the the clinical researcher had raised private funding for its provision! Expensive services such as this should always be properly evaluated before becoming the new standard of care.

Patients certainly wish for, and deserve, better cancer treatment than that which we currently have on offer. The constraints of universal 'informed consent' can obstruct the doctor–patient partnership and inhibit both good doctoring (the pastoral aspects of care, if you like) as well as making essential research more difficult. In the lofty interests of helping the patient towards a well-informed insightful judgement we seem to have thrown out common sense somewhere along the line; it is high time we gave it back its rightful place.

1. Williams CJ, ed. *Introducing New Treatments for Cancer: Practical, Ethical and Legal Problems*. John Willey & Sons Ltd, 1992.
2. Hellman S, Hellman DS. Of mice but not men: problems of the randomized clinical trial. *New Engl J Med* 1991, **324**, 1585–1589.
3. Frei E, III, Freireich EJ. The clinical cancer researcher—still an embattled species. *J Clin Oncol* 1993,**11**,1639–1631.
4. Royal College of Physicians. *Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects*, 2nd edition. London, RCP, 1990.
5. Chalmers I, Silverman WA. Professional and public double standards on clinical experimentation. *Controlled Clin Trials* 1987, **8**, 388–391.
6. Fisher B, Redmond C, Edwin R, *et al.* Ten-year results of a randomised clinical trial comparing radical mastectomy and total mastectomy with or without radiation. *New Engl J Med* 1985, **312**, 674–681.
7. Le Fanu J. The breast cancer trial that nobody wants but everybody needs. *Med News* 1983, **12**, 30–31.
8. Ingelfinger FJ. Arrogance. *New Engl J Med* 1980, **303**, 1507–1511.
9. Zelen M. A new design for randomized clinical trials. *New Engl J Med* 1979, **300**, 1242–1245.
10. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. *Ann Intern Med* 1980, **92**, 832–836.
11. Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993, **307**, 119–201.
12. Kerrigan DD, Thevasagayam RS, Woods TO, *et al.* Who's afraid of informed consent? *BMJ* 1993, **306**, 298–300.
13. Raphael A. A trial the doctors can't lose. *Observer* 1988, **11**, 8.

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Aggressive Superficial Bladder Cancer

S.J. Harland

ABOUT 80% of bladder cancer is superficial at presentation, being confined to the epithelium (Ta) or invading the lamina propria (T1) [1]. The term "superficial" is a pragmatic one implying that there is a good chance of the disease being controlled by transurethral means alone. However, 15–20% of these patients will eventually progress to the muscle invasive form of bladder cancer from which the majority will die. Identifying such patients in advance is an important part of good management. Patients with T1 disease which displays the severest form of dysplasia (G3) comprise only 6–23% of superficial lesions [2] and yet account for 60% of those who progress [3]. The notion that these patients should be "regarded as a separate group in need of special treatment" [4] is one which will receive widespread sympathy. There, unfortunately, the concensus will cease for there are widely varying opinions on what form the "special treatment" should take [5]. At one extreme are a few urologists who favour early radical surgery whilst at the other there are those who would manage T1 G3 disease with transurethral resection (TUR) alone. In between are surgeons who would give some form of adjuvant therapy, usually intravesical chemotherapy or BCG, or less commonly radiotherapy.

Correspondence to S.J. Harland at the Institute of Urology and Nephrology, University College London, London, U.K.
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The efficacy of early cystoprostatectomy is not in question [6, 7] but most surgeons have avoided this route, no doubt questioning its justification in older patients whose chance of remaining progression-free after 5 years is perhaps 60% [2].

Not surprisingly, the divergence of opinion is founded on uncertainty. Because of the relative scarcity of T1 G3 disease there have been no large series reported, so the crucial questions remain unanswered: what is the true risk of progression? Are some forms of the disease more at risk than others? To what extent do conservative treatments reduce the risk?

The report in the current issue of the *European Journal of Urology* from the Dutch South East Urological Oncology Group on 121 patients with T1 G3 bladder cancer — twice the size of any previously reported study — is therefore welcome. Interesting points emerge but, frustratingly, the answers to the above questions remain elusive. The superficial recurrence rate following TUR alone in T1 G3 disease is confirmed as approaching 80%. Adjuvant therapy with intravesical agents or radiotherapy has a modest effect on reducing recurrence rate, and this benefit may be durable. The only independent determinant of recurrence is the presence of multiple and multifocal tumours at the outset. Whereas the progression rate was fairly high in patients with recurrent disease, 43%, the overall progression rate was only 25% after a median follow-up period of 4 years. Of those who died, only 36% did so from bladder cancer. These figures give little support to the early cystectomists. Performing radical surgery on patients with recurrent disease seems justifiable. It will not obviate disappointments however. A report from Uppsala described a series of patients who progressed from superficial disease where 43% showed progression at first recurrence [8].

Presumably because progression was a relatively uncommon event in the current series, Mulders *et al.* have not performed a multivariate analysis on this end point. Gloomily they point out that treatment had no influence on rate of progression. Was treatment not determined by severity of disease? They claim not, which is surprising since a recent survey in the U.K. [5] found that whereas 86% of urologists would treat with TUR alone when a single tumour was present, 37% would choose this treatment when there were multiple tumours and only 17% when there was associated carcinoma *in situ* — a condition which was present in 24% of the Dutch pT1 G3 patients. Also, as only 17 of their patients received radiotherapy, it is to be expected that the trend towards the lower progression rate in this group was not significant. The point is well made, however, that apart from an unacceptably aggressive policy of early radical surgery, there is no certain way of saving lives in T1 G3 transitional cell carcinoma of the bladder.

In the past, clinical uncertainty has been an important impetus to recruitment into randomised trials. Let us hope that current and future studies addressing the question of management of this dangerous condition will be supported.

1. Union Internationale Contre le Cancer. *The TNM Classification of Tumours* 1992. Geneva, UICC, 1992.
2. Birch BRP, Harland SJ. The pT1G3 bladder tumour. *Br J Urol* 1989, **64**, 109–116.
3. Smith G, Elton RA, Chisholm GD, *et al.* Superficial bladder cancer: intravesical chemotherapy and tumour progression to muscle invasion or metastases. *Br J Urol* 1986, **58**, 659–663.
4. Hall RR, Parmar MKB, Richards AB, Smith PH. Proposal for changes in cystoscopic follow up of patients with bladder cancer and adjuvant intravesical chemotherapy. *Br Med J* 1994, **308**, 257–260.
5. Lynch TH, Waymont B, Dunn JA, Wallace DMA. Urologists' attitudes to the management of bladder cancer. *Br J Urol* 1992, **70**, 522–525.
6. Stockle M, Alken P, Engelmann U, *et al.* Radical cystectomy — often too late? *Eur Urol* 1987, **13**, 361–367.
7. Bracken RB, McDonald MW, Johnson DE. Cystectomy for superficial bladder cancer. *Urology*, 1981, **18**, 459–463.
8. Malmstrom P, Busche C, Norlen BJ. Recurrence, progression and survival in bladder cancer. *Scand J Urol Nephrol* 1987, **21**, 185–195.

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Breast Conservative Surgery: Towards More Personalised Treatments

A. Costa and A. Filiberti

INTRODUCTION

A CENTURY after the publication of Halsted's paper on mastectomy, the approach to primary breast cancer treatment has dramatically changed as a result of two "conceptual revolutions" in the 1970s. The first concerns the biological concept of breast cancer as a systemic disease involving a complex spectrum of host–tumour interrelations. This is in stark contrast to the concepts of Halsted's thesis, and was proposed by Fisher in 1970 [1, 2]. This new concept ushered in the era of combined treatments for breast cancer, providing a rationale for adjuvant chemotherapy and other systemic approaches. The second major innovation, developed in Europe and at the Milan Cancer Institute since 1968, was the idea of preserving the breast in patients with small tumours. This hypothesis was verified in the first randomised trial (1973) to address the issue and the results were published by Veronesi *et al.* in 1981 [3]. The new technique

Correspondence to A. Costa at the Breast Cancer Division, European Institute of Oncology, via Ripamonti 435, 20141 Milan, Italy.
A. Filiberti is at the Psychological Division, National Cancer Institute, via Venezian 1, 20133 Milan, Italy.

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