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Comments and Critique

Auditing Palliative Cancer Chemotherapy

BACKGROUND

CYTOTOXIC DRUGS can be used for the curative, adjuvant or palliative treatment of cancer. Curative chemotherapy is used in a few uncommon cancers, such as acute childhood lymphoblastic leukaemia or metastatic testicular cancer, when intensive use of cytotoxic drugs has a high chance of eradicating the disease. With cure as a realistic objective, the severe toxic effects of treatment are usually judged acceptable. In adjuvant chemotherapy, drugs are given to supplement surgery in patients at high risk of recurrence. This can delay recurrence and improve survival, most notably in premenopausal, lymph-node positive breast cancer in which five year survival prospects are improved by about 10%. Here, a judgement is needed on whether the benefits of treatment outweigh its side-effects. For palliative chemotherapy, costs and benefits become particularly finely balanced and there is scope for doing more harm than good in the closing stages of a patient's life. What are the issues in palliative chemotherapy and how can we evaluate systematically the cost-effectiveness of this type of treatment?

Palliative chemotherapy is used in the following types of cancer: breast (other than adjuvant use), lung, alimentary tract, liver, pancreas, gynaecological (ovary, endometrium, cervix), sarcomas, head and neck, kidney, urinary bladder, brain and melanoma, and low-grade non-Hodgkin lymphoma, relapsed high-grade non-Hodgkin lymphoma and relapsed Hodgkin disease. Excluded are leukaemias, testicular cancer and childhood tumours.

The intention of treatment should be clear. Normally, it will be to relieve symptoms from progressive malignant disease or to prevent or delay anticipated problems. The intention will not usually be to prolong life, although this may be achieved when the pattern of metastasis is immediately life-threatening, such as the presence of lymphangitis carcinomatosa. Sometimes, treatment may be given because this is perceived to be the wish of the patient or relatives even when the doctor believes that there can be no realistic chance of the disease regressing. Here, time spent on an honest and sympathetic explanation could be of greater value and much appreciated.

Unlike surgery and radiotherapy, cytotoxic drugs may be freely prescribed by any medical practitioner, specialist and non-specialist. In oncology centres, clinical practice is often highly structured with many patients in clinical trials. This facilitates the assessment of the cost-effectiveness of these treatments. These centres also have an invaluable infrastructure of nurse specialists and counsellors. Attendance at such centres may be difficult for patients with advanced cancer when long distances are involved and, for them, available local facilities may be more relevant and helpful. However, away from specialist centres, experience of the use of cytotoxic chemotherapy will be less and expertise lower. Moreover, the less regular use of these treatments without structured protocols is likely to make it more difficult for cost-effectiveness to be audited.

AUDIT

Comprehensive audit of the cost-effectiveness of palliative chemotherapy is daunting. Dedicated manpower is needed for such a labour intensive exercise and this is not readily found at current staffing levels. A way forward came in 1989 from an invitation by the UK Department of Health for applications for funding for medical audit. A proposal was submitted for a systematic review of case records to estimate benefits (symptom relief, objective response, improved performance of activity status, extension of survival) and costs (physical toxicity, psychological morbidity, social disruption and economic), to evaluate the contribution of investigations, to assess the adequacy of support services and to formulate patient-benefit-month costs. Funding was granted because the project "concentrates on an important aspect of health care and offers scope for changes in clinical practice should the results of audit indicate the need to do so".

A project co-ordinator (a senior nurse with oncology training and computing skills) was appointed and a project office and computer set up. 72 cytotoxic-drug prescribers in the South East Thames Region were identified with the assistance of regional and district pharmaceutical officers. The doctors were informed of the project and invited to participate. Of 52 replies, 46 indicated considerable interest and expressed a wish to be involved, 2 declined to do so and 4 were found not eligible.

Data collection

Forms for data collection were designed, piloted and revised in the Clinical Oncology Unit at Guy's Hospital. The forms are designed to enquire into the following important aspects of palliative chemotherapy. Was the intention of treatment explained to the patient and recorded in the case notes? What were the drugs used and the schedule? Was treatment planned on an inpatient or outpatient basis? Were there unplanned admissions? Was treatment within a clinical trial? What was the toxicity and were modifications to the planned regimen necessary? What was the compliance with and the feasibility of the plan? Were there other treatments which confounded the assessment of response? The financial costs of the treatment programme are recorded. Investigations done before and during treatment are noted in detail so that judgements can be made on whether they were essential or non-contributory for patient management or whether they were done purely for research purposes. Data on details of patients' access to hospital for treatment are also collected. The quality of case records are noted with attention to whether they are structured, whether quality of life assessments were made and the adequacy of communication with other personnel involved in the patients' care (local support teams, general practitioners, other specialists).

The data are extracted from the case records by the project co-ordinator or research assistant (also an oncologically trained nurse). Quality control is by two consultants (one internal and one external) checking, in detail, the data forms against the case records. This is done for one in ten records audited, selected by the external consultant from a listing of case record numbers (essentially a "random" check).

Outcome judgements

All the data forms are scrutinised by the consultant team so that a number of judgements can be made about the outcome from the use of palliative chemotherapy. These include: (1) acceptability of the treatment plan for the cancer itself, (2) reasonableness of the treatment plan for the patient in question, (3) contribution of investigations, (4) adequacy of support services, (5) global assessment of the usefulness of treatment and whether this was predictable, (6) duration of any benefit, and (7) patient–benefit–month costs.

Appropriateness criteria

A planned treatment programme can be considered appropriate for a patient when the benefits are expected to exceed any unwanted effects by a worthwhile margin. What is worthwhile is difficult to define, but perhaps the duration of benefit should at least be greater than the duration of treatment. It is clear that even when a regimen can be considered, in general terms, to be an acceptable plan for a given cancer, the reasonableness of it for a given patient could be modified by several factors. These include the activity status of the patient (which may be related to age), co-existing diseases, the pattern of metastatic disease, adequacy of bone marrow, biliary and renal function and the views of patients or relatives.

How do we decide what is appropriate investigation or treatment? Ideally, this should be known from published reports, in particular clinical trials. Unfortunately, because clinical trials are designed as scientific experiments to produce readily interpretable results, they invariably contain many exclusions and so give selective information which may not reflect the wide spectrum of clinical pictures seen in medical practice. Also, publication bias may give prominence to studies that are eventually shown to have had false-positive results and such erroneous claims can have a strong influence on medical practice and patients' perceptions. While clinical trials can produce clear and specific results, they are just one of several sources that need to be considered in planning treatment for an individual patient. We therefore need other means of determining appropriateness. A potential way to achieve this is for a panel of experts to determine appropriateness based on clinical trial evidence and clinical experience.

For our project, a panel comprising oncologists, physicians, surgeons, palliative care specialists and nurses has been convened to establish criteria of appropriateness for prescribing palliative chemotherapy, what factors modify these criteria and which investigations are appropriate. These variables will be used as standards for the audit and should eliminate potential observer bias which could be a problem if only an individual judgmental approach was adopted. This approach should enable, in due course, a correlation to be made between alleged appropriateness and outcome.

We have concentrated so far on appropriate use of treatments, but we should not ignore the possibility of inappropriate non-use. Are some patients being denied effective treatments? This is a difficult problem to research, but an attempt is being made by acquiring information from the Thames Cancer Registry on patients dying from cancer so that records of those who had not received palliative chemotherapy can be traced for audit.

Prospective validation of audit

Audit is, by definition, a retrospective process involving peer review of case records. It does not solicit directly the views of patients or relatives on their satisfaction with treatment. Can we have confidence in such a process working for patients? It is pertinent to enquire, when judging the usefulness of treatment, whether or not the views of patients are the same as those of their relatives, nurses and doctors. Also, what do we mean by "relatives"? We probably take this to mean the person closest to the patient, but this could be a friend, a priest, a nurse or a general practitioner. And is this person the primary carer or the patient's confidante or both?

These are difficult issues to study scientifically, but they are so important that an attempt must be made. To this end, as part of the South East Thames project, a prospective study will be conducted in patients about to start palliative chemotherapy for the first time. The information given to patients about disease status, the aims of treatment and its possible side-effects will be monitored. Before treatment, a semi-structured interview will be done by a research nurse to assess the patient's understanding of his or her disease, the intention of treatment and what are understood to be its adverse effects. A self-assessment questionnaire will be used for the patient to provide information on physical symptoms of the disease, psychological adjustment and functional activity. During treatment, the questionnaire will be repeated when it will also include questions on the adverse physical effects of treatment. After treatment, the questionnaire will again be repeated and a semi-structured interview will enquire into practical aspects of life (travel, work, family, treatment, investigations, financial), adequacy of support services and the global view of the usefulness of treatment. At the post-treatment interview, if there is a relevant relative or "close person", their views will also be obtained.

In due course, the records of patients participating in the prospective study will be subject to retrospective review by auditors ignorant of the results of the prospective study. A comparison will then be possible between the prospective study and the audit for a variety of end-points, including symptom relief, psychological morbidity, activity improvement, practical difficulties, adverse effects of treatment, adequacy of support services, global assessment of usefulness and adequacy of case records.

A high level of correlation between the prospective study and retrospective audit would give considerable validity to the intended value of medical audit for patients given palliative chemotherapy.

SUMMARY

A detailed approach to the gathering of information on the cost-effectiveness of palliative chemotherapy for patients with cancer has been described. The measures are qualitative and so difficult to study scientifically, but several innovations have been incorporated into the programme which should ensure a level of robustness to give reliable and valid information. Making judgements about the usefulness of treatment for patients involves comparing factors that are inherently incomparable and measuring those which are inherently unmeasurable. Nevertheless, it is hoped that this will be found to be a pessimistic view of what can be achieved by audit, particularly in the light of advances that have been made in assessing quality of life. At the least, the project will provide important statistical information and the existence of the audit process itself should enhance significantly standards of medical practice.

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Digitised Video and the Care of Outpatients with Cancer

TELEMED IS a four year European Commission RACE (Research and Development in Advanced Communications Technologies) project, in which the University of London is one of the partners. The overall objectives are to examine the problems that arise when physicians communicate over telecommunications networks by the transmission of medical and video images and data. The University of London with its collaborators—STC Technology Ltd, the Free University of Berlin, the University of Giessen and the University of Paris—is responsible for the video conferencing aspects of the project.

Communication by digitised video has a potential role in the care of outpatients with cancer. Although less than a quarter of cancer patients who develop psychiatric problems spontaneously disclose them to their doctors or nurses [1], the Psycho-social Collaborative Oncology Group [2] found that almost half of a group of 215 patients with cancer had sufficient psychological symptoms to justify the diagnosis of a psychiatric disorder, most commonly anxiety and reactive depression. Patients with breast cancer particularly have considerable psychiatric and social morbidity [3]. They often feel isolated and the uncertainty about diagnosis, treatment and outcome can lead to loss of a sense of control and to low self-esteem. Maguire [4] has demonstrated that the poor recognition by surgeons and general practitioners of anxiety and depression after mastectomy is due to the unwitting use of communication strategies that keep patients at a safe emotional distance. Both doctors and nurses eschew specific enquiries about how women who have surgery for breast cancer are coping psychologically because, according to Maguire, they fear that they lack the skills and the time to deal with emotions such as anger and despair in the middle of a busy outpatient clinic. Bloom [5] has identified social support as being the most important predictor of adjustment in a sample of women with non-metastatic breast cancer, but over a third of another sample of women with breast cancer reported that they had no-one to turn to for emotional support [6]. Counselling tends to have most impact when the sessions take place at the patient's request during the months following discharge [7]. Regular conselling by a nurse, and the monitoring of psychological adjustment, every two months led to earlier recognition and treatment of women with emotional problems and a three-fold reduction in psychiatric morbidity one year after a mastectomy [8]. Surgeons and non-specialist nurses rarely have the time systematically to conduct post-mastectomy counselling, but this important task can be done by a specialist nurse with training in the recognition of anxiety and depression and in the skills required to facilitate rather than suppress the ventilation of anger and grief.

The staff of oncology units already communicate freely with patients and their relatives by telephone. These conversations include requests for information and reassurance, and provide the opportunity for impromptu counselling. However, nurse

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