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EDUCATIONAL SECTION

Risk analysis in surgical oncology—Part II: risk and the practising surgeon

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Surgery for cancer imparts a high risk of morbidity and premature mortality. Inappropriate decisions and inadequate information can have a profound effect on the outcome of interventions. A formal process of appraisal of options, aided by modern information technology, may help rationalize and improve management stratagems and reduce risk. Rigorous and obsessional attention to risks in clinical and surgical procedures and processes, including the selection and training of surgeons, process and human reliability analysis, and ubiquitous error reduction strategies will also help minimize risk. These approaches will have a significant bearing on familiar surgical practice and will need to be extended across the multidisciplinary spectrum of cancer care.

Key words: **risk analysis; surgical oncology; risk management; clinical governance.**

Introduction

Surgery imparts risk. The assessment of the balance of risk and benefit in therapeutic interventions is particularly important in surgical oncology, where interventions with high procedural risk may produce little measurable gain against a low life expectancy. We have reached the end of the era of the autonomous surgeon and the brave surgeon. Evidence-based practice is supplanting personal whim and opinion in treatment planning. We are accountable for optimal risk management to the individual patient, to the public in general, to our colleagues and the profession at large, to managers and to their political and economic masters.

The previous paper in this series addressed the tools and concepts of risk analysis.[1] This paper considers the practical issues of risk reduction in surgical oncology, the processes and established systems which facilitate risk reduction, and the implications for clinical practice. Most of the physical risk of any procedure is borne by the patient. Reverse infection by agents such as the HIV and Hepatitis B viruses can also pose hazards for the operating team. This paper will not further consider medico-legal risk, which usually arises when risk becomes physical consequence through misfortune or inappropriate practice.

Since this paper was accepted for publication, an issue of the *British Medical Journal* (Vol. 320, No. 7237, 18 March 2000) dedicated to the matters of error reduction and safety improvement in clinical practice has been published. This is commended as a source of further study and amplification of many of the topics discussed briefly here.

The decision or action from which all else flows

Clinical risk would not arise if doctors did not interact with patients. Consultation leads to decision, and the cumulative sequence of surgical risk begins with the critical decision to intervene or not. This decision should be influenced by evidential data supporting the various management options, tempered by the expectations of the patient and the particular skills of the clinician. The clinician must have an adequate appreciation of the disease process and its ramifications. In few cases is there one 'best buy'. Professional advice cannot be a precise science, as unsuspected, undeclared and undetected coexistent conditions may intervene to affect the outcome. There is always the option of non-intervention, and the first question that the clinician might ask at the point of decision is 'should I be here at all?' This question becomes particularly important in considering procedures which may be secondary to the primary objective of preserving life or eradicating disease, such as reconstructive or cosmetic procedures.

The choice of a more complex rather than less complex procedure will add a layer of risk which may lead to technical

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complications and put the patient on a slippery slope to morbidity and further procedures with complications of their own. The question posed by the surgeon must not be 'what are my best results?' but 'what is the worst case consequence of this procedure?' Thus, for example, a worst case scenario for a competently performed conventional extra-abdominal inguinal hernia repair might be local recurrence. In electing to undertake a transabdominal laparoscopic procedure, a surgeon adds a raft of additional risks such as intra-abdominal organ damage, adhesion obstruction or incarceration which, while very infrequent in expert hands, have profound consequences for the patient when they do occur.

Risk appraisal: the estimate

All organizations must be aware of the environment in which they operate, the risks which they face and the consequences of those risks. The terminology and the extent to which risk assessment and management is formalized varies from one organization to another. For example, one form of assessment of risk is to conduct an 'estimate', a technique drawn from military planning. The 'estimate' flows from the appraisal of the strategic intentions. It has practical utility as a discipline in clinical practice, where those intentions are the expectations of the patient and his or her advisors; and the intentions and expectations of the advising clinician. The estimate should evaluate a range of options, and the consequences and implications of each option. It should appraise each of the relevant factors, such as the operating environment and the resources available. The estimate is a dynamic process, as the progress of a malignant disease and the consequences of our treatment interventions will change our options with time. Much of the content of the clinical estimate is subliminal and intuitive with experience, but its formal expression might lead to a more rigorous, multidisciplinary evaluation of all the options in any one case.

The patient's overriding intentions in respect of a putative curative procedure usually relate to a longer life of good quality with minimal morbidity. In the case of procedures with palliative intent, intentions include freedom from distressing symptoms, leading to a comfortable and peaceful death. The patient may be distracted by secondary considerations such as cosmetic appearance or avoidance of a stoma, but all efforts should be made to provide the patient with a formal risk appraisal for each choice.

A patient with cancer must balance two categories of personal risk in respect of the strategic intentions; those risks associated with disease progression, and those associated with treatment. There are many circumstances where inaction or minimal intervention will produce a longer life expectancy than major surgery. Such is the experience of some patients undergoing complex surgical oncological procedures.

The surgeon's intentions will include a good clinical outcome consistent with the patient's intentions, by which a professional reputation will be protected or advanced. We know that matters are not always this simple. The surgeon may wish to be innovative, and try new procedures which carry a greater or unquantifiable risk to the patient. The surgeon may also be exposed to other distractions from the primary intentions, such as peer pressure or personal ambition. The surgeon's attitude to the cancer process can influence his or her immediate risk assessment. This may vary from fatalism to over-optimism and over-enthusiasm.

Real world data and risk appraisal

Reliable data on the probability of outcome of any one intervention or combination of interventions for any one patient with any one disease or combination of diseases is the key to the assessment of risk. The use of global historic data or that derived from controlled clinical trials may be insufficient for local decision-making purposes. Data is needed which reflects the immediate experience of the individual surgeon, which changes with time and casework; which reflects the age, condition and health of the individual patient at the specific stage of the particular disease; and which reflects the specific treatment mechanisms selected for that patient. Such data is available to the profession in the form of all the stored current and historic medical records of individual patients in individual hospitals. Unfortunately, these records are not generally in a form which render them interrogable for our purposes. The growth of computer networks and standard data languages may render this cumulative clinical experience much more accessible in future, but we cannot usefully access this mass of 'lost' knowledge of risk management at present.

Clinical outcome is influenced by the interaction of the disease process, the efficacy of specific interventions, the skills and judgement of the managing clinicians; and by 'luck', which is the intervention of unforeseen and unquantifiable factors relating to the patient's health, personality and response to treatment. Absolute accuracy in risk prediction would occupy unacceptable time and resources, so we must compromise both in our search for accuracy and in the number of steps which we can take to minimize risk for each individual. We can nevertheless implement strategies for risk reduction for each component of clinical outcome.

Risk reduction and the disease process

We can seek to reduce risk from the disease process by early diagnosis and intervention, by the implementation of screening strategies and by health education to encourage earlier presentation. We can seek to develop better adjuvant strategies to counter established disease, which can often be relentless in the case of solid malignancy. These global factors are outwith the remit of further discussion in this paper.

We can attempt to estimate survival times based on our incomplete knowledge of the metastatic process and the specific stage of disease in each patient. Such predictions are intrinsically inaccurate. It is thus difficult to assess the likely contribution to shortening or prolonging survival of any therapeutic intervention. Moreover, survival time is not the only factor determining outcome. Palliation of distressing symptoms by a high-risk procedure may be considered worthwhile even in the likelihood of shorter

survival. Other factors such as the patient's personality and assessment of risk will influence the clinician's intervention.

The professional culture and risk

Errors may arise in a clinical intervention from the clinical environment, due to the equipment and resources employed, and the skills and procedures adopted by the surgeon and the multidisciplinary team. The component of risk management most under our immediate control is the individual surgeon, whose technical skills and judgement will influence the immediate outcome of the intervention; whose use of available data and knowledge of the disease process will determine the most appropriate (or inappropriate) intervention; and whose adoption of preventive strategies will minimize the adverse influence of 'luck' on outcome.

We may also seek to change the cultural environment in which we work. Surgical practice remains broadly empirical and unsystematic. We accept a level of risk in complications, morbidity and mortality for surgical procedures which would be entirely unacceptable in other fields of human responsibility, such as structural, aerospace or nuclear facilities engineering. For example, a 1% mortality rate translated to a 1% crash rate in the airline industry would lead to the cessation of commercial passenger flying. There are difficulties in drawing too close an analogy between ill health and engineering, as the body is subject to a much wider variation in component processes during the inexorable progress to system failure and death than are found in the materials sciences. Medical interventions lack the precision and controllability of materials sciences. Nevertheless, we must explore and adopt those aspects of the engineering process which seek to minimize risk. We must also create a much more systematic risk averse culture.

All procedures requiring human intervention can be broken down into component processes with differing risks. Human Reliability Analysis (HRA)[2] aims to quantify and assess each of these components in terms of their contribution to outcome, the consequences of failure, the likelihood of their occurrence, and the steps to be taken to minimize adverse outcome. Any activity which increases avoidable risk must be considered an error. Some errors may occur relatively frequently but be of little consequence. Others may be relatively infrequent but catastrophic when they occur.

Many serious complications and unwanted outcomes are the consequence of cumulative errors, none of which are damaging in themselves, but together can be catastrophic. Other catastrophic complications can arise from the most simple and singular technical errors or misjudgements.

The surgical component of risk

The operating surgeon is a critical factor in surgical outcomes, and hence a component of the risk. Many studies have shown significant variations in crude outcome data between surgical peers, between generalists and specialists, and between senior and trainee surgeons.[3,4] There are different national approaches to the devolution of surgical responsibility for decision making and action. In some countries decision making is centralized and hierarchical within individual units, while in others decision making is broadly based and devolved. Specialist training and a risk averse culture will ensure that all procedures are undertaken by appropriately skilled surgeons and are carefully conducted. Optimal case management by a surgeon encompasses a number of stages, within each of which are the risks which can be addressed and minimized. An algorithmic approach helps to formalize risk management.

The selection of surgeons

The surgical personality is the key to risk reduction, and thus the selection of appropriate individuals during higher professional training is critical. Much can be taught, but much also depends upon aptitude. While no two individuals can be entirely alike, it should be possible to identify characteristics which optimize selection across a range of personal and professional skills and knowledge appropriate to likely future tasks. Psychosomatic tests may have their limitations, but they may also offer significant improvements over the current arbitrary and costly form of training by 'natural selection'. Aptitude testing is well established in other professions posing high risk to the general public, such as aircrew and air traffic controllers. It need not be a tool to enforce conformity and risk aversion. Innovation and originality are important aspects of clinical progress when conducted in a disciplined, risk conscious way.

Surgical skills

A surgeon must possess technical and attitudinal skills for operating which are generic to all tasks, and skills which are specific to special interests and particular operations. Core aspects of hand-eye coordination, handedness, manual dexterity and physical fitness for a task can be developed with training in techniques of tissue and instrument handling, suturing, knot tying and the creation of safe anastomoses, for example. Much can be done to improve repetitive tasks in the training laboratory in advance of service experience, and on simulators during service work, to enhance technical skills. The introduction of laparoscopic and video-assisted surgical techniques in recent years has done much to demonstrate what is needed and what is possible in training. Motor skills can be developed, rehearsed and reviewed. Techniques can also be rehearsed in cadaveric dissection.

The working environment and general clinical risk

Safe oncological surgery must take place in appropriate clinical facilities, where all members of hospital staff are drilled and working to appropriate standards of practice and to basic risk reduction protocols. The composition of the clinical team is important. Weak human links, interpersonal problems, and unsatisfactory hierarchical and professional interactions may contribute to poor decision making and unnecessary errors. Basic protocols

should ensure the safety of the scene of the operation, the equipment and standards of hygiene. Extraneous noise, superfluous persons in theatre, and other parallel activities or concurrent commitments and time pressures may distract the surgeon.

Basic protocols should address adequate pre-operative evaluation, and the completion and checking of all necessary investigations and test results. Standard tasks should be undertaken to minimize non-specific complications, such as thrombosis prophylaxis, respiratory exercise training, and control of anticoagulation. Anaesthesia should be appropriate and safe. Supporting staff should be adequately trained and rehearsed in the safe use of complex and novel equipment, and in the conduct of complex procedures.

Pre-operative factors

Cancer surgery should be planned in the light of the full medical evaluation and be appropriate to the condition, to the common and specific risks, and appropriate to the available local skills and technologies. The appropriate work environment for the surgeon will include freedom from fatigue, freedom from distractions, adequate time to complete the task and adequate human skills support, including technical and nursing support.

Intraoperative factors

We have tended in the past to leave much intraoperative decision making to the personal preference of the operating surgeon of whatever experience. Thus, within one hospital, there can be considerable variations in techniques of access, tissue dissection, anastomosis, drainage and closure. A systematic approach to all critical components of all operations may help minimize error. Deviations from standard procedures in each operation can then be documented and justified by the operating surgeon. This is particularly important where surgeons are undertaking operations in suboptimal circumstances, such as 'out of hours' emergencies.

Post-operative factors

The post-operative management can have a profound influence on outcomes. There should be ready access to an appropriately staffed recovery area, Intensive Therapy or High Dependency Unit where necessary, and wards should be staffed by doctors and nurses able to recognize and act upon complications. The appropriate management of morbid complications particularly includes prompt action on anastomotic leaks, major post-operative haemorrhage and respiratory problems. Responsibility for decision making can be a particular problem in the complex environment in ITU, where a number of specialists may be supervising components of the case management; appropriate onward referral to other specialists may be needed.

Surgical process analysis

The suboptimal performance of a cancer operation can make a critical difference to the risk of short-term complications, such as from anastomotic dehiscence, and of long-term treatment failure, such as due to local recurrence or tumour dissemination. For many operations, an optimum technique has been identified but may not be universally implemented. The performance of a particular operation by an experienced specialist is not always an option. Guidelines for the standard conduct of the procedure by skilled but non-specialist surgeons might thus help improve outcomes and reduce risk.

One tool for this objective is the use of the standardized checklist for each operation. Work sheets and systematic checklists are used on all flights by aircrew of all skills levels, and there is no reason why this should not apply in surgery. Such a list, validated by evidence and expert review, would address each of the 'mission critical' components of the pre-operative assessment. Such checklists are already established in nursing practice, and reduce the risks of omission, such as the oversight of pre-morbid conditions, the availability of cross-matched blood, thrombosis prophylaxis, and surgeon/operation specific resources and instruments whose absence or malfunction may not be recognized until too late.

Checklists may also produce real benefits peroperatively, as might access to experiential databases both on common and uncommon situations and pathologies encountered during surgery. We are now well accustomed to operating in the presence of video screens, and computer terminals in the operating theatre hold no terrors. The direct access to experiential information is now feasible through advances in technology and public systems such as the Internet. Such knowledge-based systems may be particularly useful to trainees or non-specialists, and even be a valuable guide to experienced surgeons, whether in the pre-operative planning or even peroperatively.

The consequences of a risk averse culture

Risk management is not the same as risk avoidance or risk aversion. A culture in which surgeons declined to take on any significant risk would do no service to patients in a risky world. We are seeking a sensible medium wherein extreme and aggressively interventionist practices are tempered and regulated, while risk averse practitioners are given a framework for risk management which may increase interventions which offer a good prospect of satisfactory outcomes.

The zero error culture and the individual surgeon

The minimization of error in surgical oncology stems from a process of critical evaluation of all aspects of practice and of the surgical personality. The surgeon is a critical component of surgical risk, but the individual surgeon is not a constant. A surgeon goes through phases of basic training, skills acquisition, skills refinement and skills decline

over a period of 30–40 years in line with the processes of maturation and aging. The peak of skill attainment will differ from individual to individual. Age, physical and mental health, personal circumstances including psychological influences, the 'midlife crisis', external life events and depression can affect even robust individuals and affect their professional performance.[5]

We have tended to regard long hours worked and crowded professional schedules as a measure of surgical success. The locally prevailing culture of professional isolation or supportive colleagues can profoundly affect a surgeon's behaviour and approach to risk, as can interprofessional conflict. The robust culture of independence militates against preventive action and support in difficult situations, such as the handling of complications and complaints. There is thus a cultural issue of protection and adaptation which needs to be addressed in training and throughout a surgeon's working life. Internal and external audit and comparative performance studies may help identify problems at an early stage and be used as a supportive tool to sustain and modify individual practice. Issues of timetabling, adequate resourcing for the surgical task, and the minimization of administrative stress arising from multi-tasking and multi-site working can be addressed at the organizational level.

Adjuvant therapy and risk

The risk management strategies here addressed also apply to all other components of the treatment process or 'care pathway'. Adjuvant therapies carry particular risks of commission and omission which must be mitigated by treatment strategies optimized by medical evidence; and by clinical practices optimized to reduce risk to the patient. Where commissioned, appropriate radiotherapy carries short- and long-term risks to normal and healthy tissues and organs. Inappropriate radiotherapy may result from technical errors in calibration, field misalignments and scheduling. Cancer chemotherapy imposes a high risk of morbidity and mortality, exacerbated by dosage and scheduling errors and inappropriate use.

Risk management and the multidisciplinary team

Most complex clinical situations and outcomes are influenced by the performance and practice of a multidisciplinary team. Few clinical outcomes in cancer management are ultimately determined by one individual. Nevertheless, we have tended to focus on audit of the performance and practice of individual surgeons. Continued medical education also focuses on updating the individual. Specialization continues to marginalize the generalist who has been trained to take a broad view of complex clinical matters. The divergence of surgery, anaesthesia and nursing as proud and autonomous professions obliges greater effort to achieve mutual understanding and convergence of practice. We thus need to examine the issues of training, education and risk management in these more complex social structures, such as through group educational exercises and team rehearsals.[6]

Establishing the culture of surgical risk management

The formal aspects and terminologies of risk management are relatively novel, even though good clinicians will have been using them intuitively for years. The political and managerial exhortations to clinical excellence and governance provide the stimulus but not the vehicles to implement beneficial change. The culture of risk management must permeate the entire clinical service structure. At local, unit and hospital level, individual clinicians can review their practice in the light of the principles of risk management, and can contribute their experiences to the clinical literature. At national level, professional governing bodies can set standards and supervise training, educational courses, examinations, comparative datasets and continuing professional education. At international level, the pan-national cancer bodies can similarly promote and supervise approaches to standardized risk management. The Internet provides new and convenient opportunities for data exchange and performance comparisons.

The implementation of change using evidence-based medicine can nevertheless be complex. Life would be simple if most risk-reducing strategies were direct, linear cause and effect relationships. Unfortunately, many clinical management strategies introduce new complications and problems of their own, for which sophisticated, computer-supported algorithms may be needed.[7]

Conclusions

Risk reduction is an important objective of modern oncological practice. New mechanisms may reduce the freedom of action and opinion of operating surgeons, as we strive to minimize surgeon variability, but they should help minimize surgical risk to patients. We need to work towards a change in the endemic culture of surgery and to maximize the information available on individual risk, for which computer-based tools are now available. However, in the management of cancer, rigid, data-driven directives cannot replace compassion and common sense; nor are the measurable clinical endpoints upon which we may base risk analysis the only guides to optimum outcomes in all dimensions of care and case management. In the final analysis, all roads in modern professional practice, be they educational, political, managerial, technical or clinical, lead to better risk management. It is time for us to acquire and to talk the new language of risk.

Key learning points

Clinical risk is an unavoidable consequence of the interaction of cancer specialists with cancer patients

The formal appraisal of strategies may help clarify risk and treatment options in advance of cancer therapeutic procedures

Better use of clinical data will help focus and improve treatment strategies

Risk reduction strategies can be implemented in the pre-, per- and post-operative environment

The surgical personality, skills and judgement are key factors in risk

Clinical practices and surgical technique can be studied and improved by formal and quantitative tools of error reduction and reliability analysis

Error reduction and the target of a zero error culture will become an obligatory aspect of surgical practice in all its forms

Many errors are multifactorial. Error reduction techniques will extend from the individual clinician to the multidisciplinary team

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