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FOCUS ON: ENHANCED RECOVERY

Monitoring surgical outcomes: How and why?

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SUMMARY

Reliable and valid measures of risk and outcome are essential prerequisites for the effective monitoring of outcome following surgery and the evaluation of innovations in perioperative care. Enhanced Recovery (ER) programs raise the exciting prospect of reduced resource utilisation in combination with improved (or at least equivalent) outcomes. Careful monitoring of process (compliance with ER elements) and outcome are essential if this goal is to be achieved without unintended harm to patients (e.g. increased readmission due to postoperative morbidity arising in the community).

Risk (case-mix) adjustment is necessary to separate the influence of patient and care factors and thereby minimise the effects of case-mix variation on evaluation of care quality. Outcome measures that are useful when evaluating ER programs include: length of hospital stay, readmission rate, total hospital stay, morbidity/complications, patient reported outcome measures and death. Description of post-operative morbidity should use validated measures, rather than *ad hoc* lists of medical diagnoses.

1. Introduction

"Fast-track" surgery within Enhanced Recovery (ER) programs has achieved increasing prominence in Europe and the US during the last decade.[1] The central theme of ER is the delivery of a multimodal care package of perioperative interventions (predominantly evidence based) aimed at accelerating recovery following surgery and reducing length of stay, morbidity and mortality.[2] Whilst impressive results have been demonstrated in some studies, the clinical trail data remains relatively weak. For example the most recent published systematic reviews of ER in colorectal surgery identified between four and eleven clinical trials (randomised and non-randomised, all unblinded) including 376–1021 patients.[3,4] Meta-analysis of this pooled data suggested that ER programs result in a consistently shorter length of primary and total hospital stay and probably reduced postoperative morbidity, with no change in mortality and possibly an increase in readmission rate. Given the questionable validity of combining heterogenous measures of postoperative morbidity to produce a summary statistic (see below), the most convincing results are the reductions in duration of hospital stay. Moreover, the increased rate of readmission raises the possibility of elevated adverse outcome in some patients. ER packages raise the exciting prospect of reduced resource utilisation in combination with improved (or at least equivalent) outcomes. However, the weakness of the current supporting evidence emphasises the need for careful monitoring of the consequences of the introduction of ER if the potential of such an approach is to be realised without unintended harm occurring. Uncertainty about which elements of the multimodal package confer benefit and which patients (if any) might be harmed demand two parallel initiatives:

- High-quality pragmatic multicentre (cluster?) randomised controlled trials to demonstrate the efficacy of multimodal care packages and of individual elements of these packages
- Reliable and valid risk-adjusted monitoring of delivered care and patient outcomes in centres introducing this approach.

This article reviews issues relating to the monitoring of perioperative outcomes in general, and specifically in relation to ER programs. The scope of ER continues to expand but some themes are consistent. Although elements of ER have been applied to patients after emergency surgery, the vast majority of patients within ER programs are undergoing elective surgery. Similarly enthusiasts have taken ER into almost all surgical specialities, but current clinical activity is mainly in the areas of colorectal, orthopaedic, urological, and gynaecological surgery. Consequently this review will focus mainly on elective surgery, and on those

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specialities most commonly associated with ER. Specifically this article will focus on general concepts in outcome reporting and review the commonly used risk and outcome measures in the context of ER programs. The use of specific quality control techniques to monitor changes in outcomes over time (e.g. Control Chart, Cumulative Sum Chart and Funnel Plots) is reviewed elsewhere.[5]

2. Concepts in outcome monitoring

2.1. Surgery, risk and benefit

The goals of surgical intervention are to increase length (e.g. colorectal tumour resection) or quality of life (e.g. lower limb joint replacement). However, these benefits need to be weighed against the consequences of surgical intervention, which may be harmful. The tissue trauma of surgery and the physiological disturbance of anaesthesia and other perioperative interventions result in serious adverse outcome in susceptible patients. For example the hospital mortality associated with elective and scheduled colorectal resections in England and Wales during 2007–2008 was 3.0%.[6] Therefore, quantifying the both beneficial and adverse effects of surgery is essential if rational decisions balancing risk and benefit are to be made.

2.2. Value of outcome monitoring

Monitoring of outcomes following major surgery within an ER program has a number of potential merits. First and foremost, it allows comparison of the quality of the process of care delivery between peers (people, teams or institutions). This highlights best practice, which can be disseminated, and less good practice, which can be remediated, thereby improving the overall standard of healthcare delivery. Outcome monitoring also facilitates informed choice for patients, rational resource distribution, and effective evaluation of innovations in practice (e.g. ER programs) as well as informing and improving clinical decision-making. Finally, reporting of outcomes may also have direct value in engaging healthcare professionals (clinicians and managers) more closely with the consequences of their actions, and thereby drive improvements in care at a local level.[7]

2.3. Levels of outcome monitoring

Outcome following surgery may be viewed at a variety of different levels of detail. "Broad brush" approaches utilising routinely collected administrative data are appealing for their simplicity and scale. But empirical data are consistent with anecdotal reports that caseload and mortality data are poorly correlated when such data are compared with high-quality databases.[8] Administrative databases also commonly lack the detail to provide clinically relevant information about operative risk and outcomes. High-quality dedicated initiatives are required to provide the detail and precision required to provide data that is clinically useful at the level of individual practitioners, units and institutions. Conversely the resource implications of collecting patient data with detail and precision required for a clinical trial are currently beyond the resources of any normal institution. A pragmatic balance must be found between the quest for quality data and the resources available. The advent of electronic patient records holds the prospect of a wonderfully rich data environment in which many of these challenges will be overcome. Currently, this is a reality for few.

2.4. Dimensions of healthcare

Healthcare can be described in terms of structure, process and outcomes.[9] Structure is the environment in which healthcare is delivered (e.g. building, staff). Process is the actions of healthcare providers in relation to patients (e.g. preoperative preparation, postoperative care). Outcome refers to the patient's subsequent heath status (e.g. morbidity and mortality).

There is controversy about which dimension of healthcare (structure, process, outcome) is the most suitable for assessing quality of care. Structural measures are stable over time and therefore of limited value for quality monitoring. Process measures such as the monitoring of compliance with evidence-based recommendation have been associated with better outcomes.[10] However, changes in practice driven by monitoring of process measures may cause harm by encouraging interventions subsequently shown to be harmful (e.g. perioperative beta-blockade)[11] or by perverse incentives leading to unintended consequences (e.g. excess healthcare costs associated with the 4 h wait limit in emergency departments).[12]

Process measures have some advantages in comparison with outcome measurement including ease of recording and avoidance of the methodological complexities and controversies associated with risk (case-mix adjustment). But ultimately the validity of process measures of clinical care rests on their relationship with outcome: world-class outcomes in association with imperfect processes are self-evidently preferable to perfect processes with poor outcomes.

In the context of ER, comprehensive outcome monitoring should involve both process and outcome measures. ER program compliance data (a process measure) is an essential component of such a package for two reasons. First, to ensure that clinicians are delivering the care they think they are, in order to avoid incorrectly attributing credit for any measured outcome differences to a program that may not be being delivered. Second, because this information may improve understanding of which elements of the ER package are conferring benefit, and which might be redundant (or at least optional).

3. Methods of evaluating outcome following surgery

High-quality monitoring of surgical outcome providing clinical useful information requires risk and outcome measures which are both reliable (reproducible and able to distinguish between cases) and valid (validity: the degree to which a test is measuring what it is intended to measure).[13]

3.1. Risk (case-mix) adjustment of outcome following surgery

A surgical episode can be considered as having a number of inputs to a process that has a defined output (or outcome).[14] The inputs include both patient factors and quality of care. Risk adjustment (or case-mix adjustment) allows separation of patient and care factors and thereby permits improved evaluation of care quality. In other words, without risk adjustment any comparison of outcome data would be open to the legitimate criticism that observed differences simply related to baseline differences in case-mix. Theoretically risk adjustment compensates for all inter-individual differences between patients and removes confounding of the assessment of effectiveness of care. In practice, residual confounding remains due to the effect of unmeasured and/or unanticipated but influential patient factors.[15] It has been suggested that residual confounding cannot be overcome (the so-called "risk-adjustment" fallacy) and that the consequent