Patient-centred outcomes in clinical research: does it really matter?

‘It does not matter whether the degree of patients’ satisfaction reflects the competence of the physician or the quality of care. The important thing is that if patients are dissatisfied, health care has not achieved its goal’.1

This statement, which was published 16 yr ago, reflects the (growing) importance of the technical and non-technical dimension of outcome.2 The technical aspect attempts to assess the skill and competence of professionals, and the ability of diagnostic or therapeutic procedures to accomplish what they are meant to, or, from the patients’ perspective: do they really get what they need? Patients quite rightly expect that the care they receive is methodologically sound and up-to-date, even though it may be very difficult for them to judge ‘technical’ qualities of this sort.3 The non-technical aspect relates to subjective experience, in other words, healthcare as experienced through the patient’s eyes. In this context, patient satisfaction is certainly the most clinically relevant measure of outcome.4 5 But, does that really matter at all?

In 2007, the BJA published several papers measuring patient satisfaction as a ‘secondary’ outcome.6–11 Surveys which simply assess overall satisfaction show that almost all patients are satisfied.12 13 However, we have learned that this is an over-optimistic picture, because single-item ratings lead to highly skewed distributions, with an overestimation of satisfaction. Patients are apparently satisfied (ceiling effects) when asked only for ‘global’ measures, that is, ‘surveys which are less than excellent should give rise to concern’.14 Moreover, knowing that more than 95% of all patients are satisfied makes it almost impossible to set improvement measures.

So, what is the right way to measure patient satisfaction? To answer that question, we must first of all understand what is meant by the term ‘satisfaction’. Many include patient expectations as the basic concept of satisfaction,15 16 and therefore define satisfaction as the degree of congruence between expectation and accomplishment.17 18 This means that we must know what patients expect before we ask about satisfaction with the care they have received.

Research ethic committees, editors, reviewers, and last but not least, readers share a common problem: they have to assess whether a special instrument—normally a self-report questionnaire—is actually able to measure what it claims, in our case, patient satisfaction. The development process of health measurement scales is rather complex and must follow a rigorous step-by-step approach.19–21 Basically, it should include at least elements of content validity, construct validity, and reliability. Content validity implies that the instrument must contain all relevant factors important to the trait under study. To assure high content validity, a literature search, expert’s and patient’s view should therefore be included. Construct validity assesses whether the instrument really measures what we think it should measure. A major point in this context is whether the aspects being assessed are ‘translated’ in a comprehensive way into questions. Another method to check for construct validity is the inclusion of already validated scales in the test questionnaire. The relationship between similar constructs in the new questionnaire with gold standard scales then becomes a measure of the external or concurrent validity. The basic concept of reliability is simple. It is a way to reflect the amount of error which is inherent in any measurement. In principle, there are two approaches to evaluate reliability; stability refers to the reproducibility of an instrument, in terms of administration by different scorers or by the same scorer on different occasions or time-intervals (e.g. test–retest reliability), scale reliability evaluates the extent that the items incorporated into a scale actually measure the underlying construct. The correlation between items measuring the same construct is usually described by internal consistency. A classic approach to measure internal consistency of a scale is to determine the Cronbach α reliability coefficient. A coefficient of 0.7, for example, tells us that 70% of the variance in scores is due to true variation and 30% is due to measurement error (i.e. inaccuracy in measurement). In general, values greater than 0.70 are considered acceptable.

As mentioned above, single-item ratings are unqualified to measure patient perceptions. Patient satisfaction (with
anaesthesia care) should therefore be measured multidimensionally using a multi-item technique for each dimension.22–24

Patient satisfaction surveys in anaesthesia which are performed with psychometrically developed questionnaires have shown that ‘information’ is by far the most important dimension to assure high patient satisfaction in the perioperative period.24 As most ‘information’ is communicated in the preoperative phase, the measurement of the performance of a preoperative assessment clinic makes a major contribution to a total satisfaction score.

In the November issue 2007 of the British Journal of Anaesthesia, Edward and colleagues25 described the development of an instrument to measure patient experience of a preoperative assessment clinic. Their study provides evidence for a psychometric development process and the whole questionnaire is shown in the appendix. Although the primary goal was to deliver a ‘recipe’ of how to develop a valid and reliable instrument, the strength of the paper could have been improved by presenting the detailed results. Roughly speaking, there is a wonderful cake, but you do not know how it tastes. Nevertheless, we have to appreciate Edward and colleagues’ work, and we would recommend using their cost-free recipe to assess the experience of your patients.

A further problem with surveys of patient satisfaction is the use of surrogate endpoints.26 This means incidents (e.g. postoperative pain, nausea, and vomiting) or activities (e.g. pain management) are used instead of the true outcome measure (e.g. patient satisfaction). The main problem is the wrong and, in most cases, unproven assumption of a positive relationship between the surrogate endpoint and the true outcome.27 Researchers often take it for granted that patients with postoperative pain are automatically dissatisfied with pain management or, worse, that postoperative pain is directly linked to patient dissatisfaction. For example, Svensson and colleagues28 studied the influence of expectations and pain experiences on patient satisfaction with pain management. Even though 91% of patients expected moderate to severe pain and 76% reported such pain, only 8% were dissatisfied. Although pain management contributes to global satisfaction, its influence is far less than, for instance, information or continuity of care.

Patient satisfaction is beyond doubt an important non-technical outcome measure. However, statements about patient satisfaction should be based only on results from surveys with valid and reliable instruments. Single-item ratings do not give a true indication of care. The use of surrogate endpoints instead of valid outcome measures must be regarded very cautiously until a definite correlation has been scientifically established.

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References

Anaesthetic techniques have always had to adapt to changing surgical interventions. Several developments over the last 15 yr have changed practice in cardiac surgery. First, standard access to the heart via median sternotomy can often be replaced by less invasive approaches, as used in minimally invasive direct coronary artery bypass surgery, robotic surgery, or endovascular valve surgery. Secondly, perioperative management strategies have adopted more ‘physiological’ techniques, such as normothermic extracorporeal circulation or blood cardioplegia. Thirdly, off-pump aorto-coronary bypass grafting (OPCAB) avoiding extracorporeal circulation has been shown to have the potential to decrease postoperative morbidity. The absence of extracorporeal circulation has made our anaesthetic management change rapidly towards a more balanced form of anaesthesia, as practised for other major surgery, be it major abdominal, thoracic, or vascular surgery.

Have these novel changes in cardiac surgery practice been accompanied by a change in anaesthetic techniques?

Fast-track cardiac anaesthesia, meaning tracheal extubation within 8 h after cardiac surgery, has been established as routine in many centres worldwide, resulting in less resource utilization and intensive care (ICU) costs while providing the same security and safety as prolonged postoperative ventilation. In addition, several reviews have shown significant potential benefits for patient outcome. The positive effect of fast-track anaesthesia on early tracheal extubation and adequate pain management has largely been possible because of the use of short-acting anaesthetic drugs, mainly short-acting opioids, short-acting neuromuscular blocking agents, and the introduction of highly soluble volatile anaesthetic agents. Regrettably, fast-track anaesthesia has not had a major impact on postoperative outcome other than some