Routine testing of FBC, U&E and PFTs before elective surgery: a systematic review

What is the value of routinely testing full blood count, electrolytes and urea, and pulmonary function tests before elective surgery in patients with no apparent clinical indication and in subgroups of patients with common comorbidities: a systematic review of the clinical and cost-effective literature

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Executive summary

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Executive summary

Background

In 2003 the National Institute for Health and Clinical Excellence (NICE) published Clinical Guideline 3, which reviewed the use of routine pre-operative tests prior to routine surgery. Prior to the guideline preparation, a systematic review was undertaken by Munro *et al.* [Munro J, Booth A, Nicholl J. Routine preoperative testing: a systematic review of the evidence. *Health Technol Assess* 1997;**1**(12)] on behalf of the Health Technology Assessment programme in 1997. The guideline development group undertook their own review of the literature. These two reviews defined and updated the purpose of pre-operative testing of apparently healthy patients.

Of the evidence base used to produce the guideline, >50% was graded as amber (i.e. the benefit of the test was unknown). Therefore, despite the existence of some primary research, the evidence on which to base pre-operative testing protocols was inconclusive. Alongside this there has been an increasing awareness of the possibility of subjecting patients to unnecessary tests, and of the issues involved in dealing with the results of tests that may alarm patients but have little clinical significance.

Aims and objectives

The aims of this study were to estimate the clinical effectiveness and cost-effectiveness of routine pre-operative testing of full blood count (FBC), electrolytes and renal function [urea and electrolytes test (U&E)] and pulmonary function [pulmonary function test (PFT)] in adult patients classified as American Society of Anaesthesiologists (ASA) grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures; to compare NICE recommendations with current practice; to evaluate the cost-effectiveness of mandating or withdrawing each of these tests in this patient group; and to identify the expected value of information. This would determine whether or not there is value to the NHS in commissioning further primary research into the use of these tests in this group of patients.

Methods

Systematic reviews of the literature relating to the clinical effectiveness of routine pre-operative testing of FBC, electrolytes and renal function and pulmonary function in adult patients classified as ASA grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures, and of the adverse effects of such testing, were carried out. Comprehensive literature searches were undertaken in March to April 2008 and June 2009 to retrieve studies that evaluated the clinical effectiveness of routine pre-operative utilisation of these tests in each of the pre-defined patient/intervention combinations. The searches were not limited by language or location, but were restricted to studies published from 1980 onwards.

Data were extracted by a single reviewer using a customised data extraction form based on that proposed by the NHS Centre for Reviews and Dissemination for studies published in English. Extracted data were checked by a second reviewer and disagreements were resolved by discussion. Quality assessment was performed using a customised tool. Results were presented

in a narrative summary; meta-analysis was not possible because of the diversity of outcome measures used in the different studies.

A systematic review of the cost-effectiveness of the specified pre-operative tests in the above patient group was also undertaken in order to identify papers in which cost-effectiveness of these tests in the pre-defined indications had been modelled. The primary function of the review of cost-effectiveness studies was to inform the development of a de novo cost-effectiveness model. An exemplar cost-effectiveness model was constructed to identify the parameters for which evidence would be required from the published literature.

Routine patient-level data sets of utilisation of pre-operative tests and patient outcomes were identified at the Leeds Teaching Hospitals Trust. These data sets were linked and regression models were used to estimate the impact of routine pre-operative tests on patient outcomes.

Finally, a postal survey of current practice pre-operative testing for the designated patient/procedure combinations was sent to all UK NHS trusts in 2008. The survey was based on the survey undertaken by NICE in 2005.

Results

The systematic literature searches identified a large number of potentially relevant studies of clinical effectiveness. However, when these studies were subjected to detailed review, the evidence base was found to be extremely small: only six observational studies met the review's inclusion criteria, none of which had been conducted in the UK. Five studies assessed the use of both FBCs and U&E; only one study assessed the use of routine PFT. This limited evidence suggests that few apparently healthy patients who undergo routine testing have abnormal test results, and even fewer have both an abnormal result and a consequent change in clinical management.

The systematic review of adverse effects indicated that those most commonly reported in relation to diagnostic venepuncture (pain and bruising, and, more infrequently, vasovagal reactions) are generally not serious. However, nerve injuries may also occur; although these appear to be rare, they are potentially disabling. Adverse events associated with PFT also appear to be unusual. However, male patients with inguinal hernias appear to be at increased risk of incarceration of that hernia.

The systematic literature searches of the cost-effectiveness literature identified a large number of potentially relevant studies. Of 5151 references, only 282 papers were assessed as potentially relevant after review of the title and abstract. Review of the full texts identified eight possible papers, including one full economic evaluation and seven partial economic evaluations. None of these eight papers provides data on the three tests under consideration for the specific patient groups.

The postal survey had a 17% response rate. The majority of responding hospitals were district general hospitals, and they reported that in ASA grade 1 patients aged < 40 years with no comorbidities undergoing minor surgery did not undergo routine tests for FBC, electrolytes and renal function and pulmonary function.

Analysis of the routine data indicated that that frequency of test use is not consistent with the hypothesis of their routine use. FBC tests were performed in only 58% of patients in the data set and U&E tests were carried out in only 57%.

The primary limitation of the studies reported is driven by the paucity of the published evidence. Although we included non-UK studies, we excluded non-English-language studies. These studies may have been relevant to this review although concerns about equivalence of practice with regard to characterisation of patients and clinical response to a given test result between the UK NHS and non-English-speaking health-care systems meant that this would be a substantial assumption. Owing in part to the almost complete absence of randomised data, we included observational studies in the review and studies of this type are associated with an increased risk of bias and confounding.

Conclusions

The paucity of the published evidence combined with the low response rate to the survey on current practice means that conclusions from this study can be made only with great caution. It is clear that there is not a robust evidence base to support the use of these tests in low-risk patients undergoing ASA grade 1 and grade 2 elective surgery. Beyond this, the survey results suggest that current practice has moved on and that the time of universal utilisation of pre-operative tests for all surgical patients has passed. This routine data set provided by Leeds Teaching Hospitals Trust is certainly consistent with this. However, these are data from only one trust.

The analysis of the Leeds Teaching Hospitals Trust routine data indicates that these tests are used in patients in whom there is a reason to consider an underlying raised risk of a clinical abnormality that should be taken into account in their clinical management. Although credible that this strategy has led to substantial resource savings for the NHS, there is no published evidence base to establish that this is the case. The total expenditure on pre-operative tests across the NHS remains significant; however, this may well reflect increasing volumes in surgery in an increasingly comorbid population owing to changing population demographics.

Recommendations for further research

Given the almost complete absence of published evidence on the clinical effectiveness, safety and cost-effectiveness of routine use of these tests in uncomplicated patients undergoing ASA grade 1 and grade 2 procedures, any well-designed research would add to the current state of knowledge. However, to recommend specific research questions it would be necessary for us to have a view as to the value of additional information to decision-makers in the UK NHS. To assess the likely value of such research it would be necessary to have a robust assessment of the current scale of the routine use of these tests in patient/procedure combinations of interest.

The low response rate to our survey, despite significant efforts at follow-up, suggests that this type of survey will not be a satisfactory strategy for scoping the scale of the research opportunity. A systematic identification of routine test databases held by UK NHS trusts is necessary to establish the feasibility of undertaking a multicentre version of the routine data analysis that we report for Leeds Teaching Hospitals Trust.

If feasible, this would allow the identification of the scale of the use of these tests in practice and the degree to which they are being used in otherwise healthy patients, rather than in response to a specific clinical indication. Only once this information is available will it be possible to establish whether or not any further research in this area is required and, if so, which research questions have the greatest potential value to the UK NHS.

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Publication

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NIHR Health Technology Assessment programme

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 06/84/01. The contractual start date was in January 2008. The draft report began editorial review in February 2011 and was accepted for publication in May 2012. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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