Randomised controlled trial of the effect of standard and detailed risk disclosure prior to bronchoscopy on peri-procedure anxiety and satisfaction

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ABSTRACT

Background: Deciding what risks to disclose before a procedure is often challenging for clinicians. Consecutive patients undergoing elective fibreoptic bronchoscopy were randomised to receive simple or more detailed written information about the risks of the procedure and the effects on anxiety and satisfaction levels were compared.

Methods: A 100 mm anxiety visual analogue scale (VAS) and a modified Amsterdam preoperative anxiety (scored 4–20) scale (APAIS) were completed before and after reading the designated information leaflet. Following bronchoscopy, subjects completed a satisfaction questionnaire.

Results: Of 142 consecutive patients, 122 (86%) (mean age 57.8 years, 53% male) completed the study. Baseline demographic, clinical and anxiety measures were similar in the two groups. Those who received more detailed risk information had significantly greater increase in anxiety levels than those who received simple information on both the VAS (mean 14.0 (95% CI 10.1 to 17.9) vs 2.5 (95% CI −1.4 to 6.4), $p<0.001$) and the APAIS (1.73 (95% CI 1.19 to 2.26) vs 0.57 (95% CI 0.05 to 1.10), $p<0.001$). Almost twice as many of those receiving detailed risk information reported that they felt they had received too much information about complications or that the information they had received about bronchoscopy had been worrying.

Conclusions: Provision of more detailed risk information before bronchoscopy may come at the cost of a small but significant increase in anxiety.

It is an accepted legal, professional and ethical principle that doctors should obtain informed consent from patients before treating them, and that this requires that patients receive sufficient information, in a way they can understand, about the aims, risks and benefits of the proposed intervention as well as of not receiving that intervention.[1] This approach, as well as benefiting patients, should also reduce the likelihood of successful litigation in the event of an adverse outcome from the treatment.

Despite this consensus, the legal and ethical ideal of informed consent is difficult to achieve in practice. The issue of what level of risk to disclose to patients is particularly troublesome. In recent years the ethical and, in many countries, legal standard has shifted from a "professional standard", where the question is what a reasonable doctor would disclose to the patient, to a "patient standard", where the question is what a reasonable patient would expect to be told.[2] This is true of Ireland, where the most recent important ruling on the matter quoted approvingly Lord Steyn's comment in the House of Lords in Chester v Afshar that: "In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery".[3 4]

Just as alarming variations have been reported in the amount of information provided by doctors about procedures,[5] individual patients differ greatly in their desire for information and in their willingness to participate in decision-making.[6–9] Many patients have difficulty in evaluating risks,[10 11] and clinicians may fear that undue emphasis on rare complications may lead to unnecessary anxiety and discourage patients from accepting procedures that seem to be in their best interests.

These considerations are particularly relevant to elective procedures such as fibreoptic bronchoscopy. In an emergency there may be little time to provide—and the patient may be in a poor condition to receive—detailed information about a potentially life-saving procedure. No such constraints exist in elective cases. Also, when elective procedures are perceived to be safe, patients may not expect and may be less forgiving of those complications that do occur, even if there is no negligence by the operator. Thus, for example, gastrointestinal endoscopy accounts for a sizeable proportion of cases taken against gastroenterologists, and inadequate informed consent is at the root of many such cases.[12]

In this study we compared the effects of providing a standard and a more detailed risk information sheet to patients undergoing bronchoscopy at a tertiary respiratory referral centre. Outcomes of interest were patient anxiety and satisfaction with the information provided.

METHODS

Participants

All patients aged 18 years or more undergoing elective day-case fibreoptic bronchoscopy in the respiratory unit of a university teaching hospital were eligible for the study. Patients with dementia, limited command of English or with other major communication problems were excluded. Patients were asked to participate in the study on arriving in the day ward on the morning of the bronchoscopy.

Baseline assessment

Demographic details, the indication for bronchoscopy and whether or not patients had been seen

previously by the respiratory team to discuss the bronchoscopy were recorded. Those who agreed to participate in the study underwent a baseline assessment by a study doctor consisting of an anxiety visual analogue scale (VAS), a modified Amsterdam preoperative anxiety and information scale (APAIS)[13] and the Degner Control Preferences Scale.[14]

- The VAS (range 0–100) consisted of a 100 mm line with 0 at the left end representing no anxiety and 100 mm on the right end representing extreme anxiety.
- The original APAIS consisted of six Likert-type questions, each scored from 1 to 5, with higher scores indicating increased anxiety levels or increased desire for information.[13] Three questions dealt with anaesthesia and three with surgery. This distinction is not relevant to a study of bronchoscopy. Instead, given that investigation of possible lung cancer was the purpose of the bronchoscopy for many patients, we created separate questions to examine anxiety related to the procedure and anxiety related to what the procedure might find (see online Appendix 1). For purposes of analysis, the information desire questions (3 and 6) were separated from the anxiety questions (questions 1, 2, 4 and 5).
- The Degner scale involves presenting individuals with five cards describing increasing levels of patient involvement in treatment decision-making in a random order.[14] Patients' most preferred card (card 1 = most active and card 5 = most passive role) was used in the analyses.

Randomisation

Patients were randomly assigned to receive one of two information sheets about bronchoscopy from clerical staff in the bronchoscopy unit. The allocation sequence was generated by the random placement of thoroughly shuffled marked cards into sequentially numbered, sealed, opaque envelopes by staff not involved in the rest of the trial. The information sheets both contained the same information about the purpose and procedure of bronchoscopy and differed only in the degree of information provided about the risks of the procedure. The control group received relatively little information and the intervention group more detailed information about complications (Appendix 2); the former risk information was adapted from the Addenbrooke's Hospital consent form[15] and the latter from the Queensland Health consent form for bronchoscopy.[16]

Follow-up assessment

Patients were given 30–40 min to read the information sheet before the study doctor returned and repeated the anxiety VAS and the modified APAIS. After this was completed, the doctor who was to perform the bronchoscopy checked to see if the patient had any questions or concerns about the procedure.

During bronchoscopy all patients received standard sedation and local anaesthesia consisting of lidocaine/phenylephrine nasal spray and atropine 600 μg, afentanil intravenously based on body weight (maximum dose of 1 mg) and a standard dose of midazolam 2 mg intravenously.

Following recovery from the procedure and before discharge or any discussion of the findings at bronchoscopy, patients were asked to complete a post-procedure satisfaction questionnaire consisting of four questions on a 5-point Likert scale ranging from strongly agree to strongly disagree. Answers were recoded for analysis so that higher scores indicate more satisfaction.

Clinically significant differences and sample size estimation

The empirical rule effect size approach was used to predefine minimal clinically significant changes in outcome measures.[17] This method, a modification of the effect size approach, defines a clinically significant change in a health-related quality of life tool as equivalent to 8% of the theoretical range of that tool. Thus, for our primary outcome measure (the VAS), a change of 8 mm was defined as clinically significant. All other outcomes were based on a number of 5-item Likert scales, each with a theoretical range of 4 and a clinically significant change of 0.32 units. Clinically significant change was therefore defined as 1.28 for the total satisfaction score and the APAIS total anxiety score.

A power calculation suggested that a total sample size of 122 patients would have 80% power to detect an 8-point difference in VAS score change between the two groups at a significance level of $p<0.05$.

Analysis of data

Data were analysed using SPSS 14.0 for Windows. Parametric, non-parametric or χ^2 statistics were used as appropriate to examine matching between the groups and the effect of baseline characteristics on the anxiety score at enrolment. Analysis of covariance (ANCOVA), with the baseline measures as covariates, or change scores were used to examine differences in outcome measures between control and intervention groups.

RESULTS

Of 142 consecutive patients presenting for bronchoscopy, 122 (86%) completed the study. Nine potential participants were considered ineligible due to cognitive or other major communication problems, eight refused to participate and three failed to complete both assessments due to logistical problems.

Of the remaining 122 subjects, 60 were randomised to receive the standard information sheet (control group) and 62 the more detailed information sheet (intervention group). Baseline characteristics did not differ significantly between the two groups (table 1).

Baseline VAS levels were strongly correlated with baseline APAIS anxiety scores (Spearman's rho 0.68, $p<0.001$). Patient age, sex, the indication for bronchoscopy, previous experience of bronchoscopy and Degner score did not influence anxiety scores at baseline. However, baseline VAS scores were significantly lower (mean difference 10.2 (95% confidence interval (CI) 0.0 to

Table 1 Baseline characteristics of patients

	Control (n = 60)	Intervention (n = 62)	p Value
Age (years)	57.3 (13.2)	58.2 (11.9)	0.71*
Male sex (%)	48.3%	58.1%	0.28**
Suspected cancer (%)	50.0%	53.2%	0.87**
Prior discussion (%)	48.4%	51.6%	0.86**
Prior bronchoscopy (%)	20%	14.5%	0.42**
Anxiety VAS (median (range))	39.0 (30.0)	37.4 (27.6)	0.84***
Degner score	3.8 (1.1)	3.6 (1.1)	0.39*
APAIS procedure (median (range))	4.8 (2.7)	4.7 (2.3)	0.77***
APAIS outcome	5.4 (2.7)	5.4 (2.3)	0.88*
APAIS information	7.6 (2.0)	8.1 (2.2)	0.26*
APAIS anxiety total	10.2 (4.9)	10.1 (4.3)	0.91*

Data are mean (SD) unless otherwise indicated.
*t test; **χ^2 test; ***Mann-Whitney U test.
APAIS, Amsterdam preoperative anxiety and information scale; VAS, visual analogue scale.

20.3), p = 0.05) when the procedure had previously been discussed with patients by a respiratory physician.

Table 2 shows the results of the follow-up assessments in the two groups. Anxiety levels on the VAS and on the total APAIS anxiety score as well as the APAIS procedure and outcome subscores were significantly higher to a clinically significant degree in the intervention group. All between-group differences on these outcomes were significant. APAIS information scores were not significantly different either between or within the groups. Because there were some, albeit non-significant, baseline differences between the groups, a multiple linear regression analysis with backward selection was performed to determine the effects of age, sex, prior discussion, previous bronchoscopy, suspected cancer and the risk information provided on the change in VAS anxiety scores; this analysis confirmed that only the risk information provided was a significant predictor of change in anxiety score.

There was a clear divergence in the regression slopes relating baseline and follow-up VAS (fig 1) and APAIS total anxiety scores in the two groups, with a greater difference in those with greater anxiety at enrolment. Analyses (not shown) confirmed that these divergences were significant ($p<0.001$) and breached the assumption of homogeneity of regression slopes required for ANCOVA.

All 122 patients ultimately consented to undergo bronchoscopy. No significant complications or difficulties were reported during the procedure. Although satisfaction levels were high in both groups after the procedure, the intervention group reported significantly less satisfaction (mean (SD) 16.0 (2.8) vs 17.1 (2.8); p = 0.03). Examination of the responses to individual questions (table 3) showed that almost twice as many subjects in the intervention group felt they had received too much information about complications or that the information they had received about bronchoscopy had been worrying.

DISCUSSION

Previous studies of the effects of providing detailed information before a procedure have found reduced,[18] unchanged[19 20] and increased anxiety associated with the procedure.[21] Differences in study design and in how information was provided and in the patient populations studied make it difficult to compare such reports. Also, the information intervention in many studies was explicitly or implicitly designed to try and minimise patient anxiety. For example, an information video which reduced anxiety in those randomised to watch it 1 week before colonoscopy included an interview with a patient who had had a, presumably uneventful, colonoscopy.[22]

In contrast, the focus of the current study was specifically on whether increased risk disclosure might have an adverse impact on patient anxiety.

In this study, provision of more detailed risk information led to a significant increase in reported anxiety. This increase, while modest, exceeded the predefined minimal clinically significant difference for the main outcome measures. The difference in impact on anxiety levels between intervention and control groups was most marked in those with higher baseline anxiety. Post-procedure satisfaction was lower among those receiving more detail, although not to a clinically significant degree, and such patients were more likely to say that they had received too much information.

Our results have some similarities to those reported by Kerrigan *et al* in a randomised study of increased risk disclosure in men undergoing elective inguinal hernia repair under general anaesthesia.[23] They also found a significant difference in anxiety levels between those receiving detailed and simple risk information, and that the difference was greatest among those with greater baseline anxiety. However, in their study the difference between the groups resulted from a small, perhaps clinically irrelevant, decline in anxiety in those receiving limited information rather than, as in the current study, from increased anxiety among those receiving more information. One possible explanation for this difference may be that, compared with hernia repair, both the indications for bronchoscopy and the procedure itself may be more threatening to patients.

A combination of oral and written information is probably the best approach to obtaining informed consent.[23] In order to eliminate potential biases, follow-up assessments of anxiety in this study were performed after patients had seen the written information but before they had the opportunity to discuss, and possibly receive reassurance about, the procedure. This approach might have exaggerated the effects of risk disclosure in the intervention group.

Table 2 Changes in outcome measures at follow up assessment in those receiving simple and detailed risk information

	Difference scores		Between-group
	Control	Intervention	p Value
Anxiety VAS	2.5 (−1.4 to 6.4)	14.0 (10.1 to 17.9)	<0.001*
APAIS – procedure	0	1.0	0.003**
Median (range)	(0–8)	(0–6)	
APAIS – outcome	0	1.0	0.03**
Median (range)	(0–8)	(0–11)	
APAIS – anxiety total	0.57 (0.05 to 1.10)	1.73 (1.19 to 2.26)	<0.001*
APAIS – information	0.28 (−0.03 to 0.60)	0.03 (−0.30 to 0.36)	0.8*

Data are mean (95% confidence intervals) unless indicated.
*t test; **Mann-Whitney U test.
APAIS, Amsterdam preoperative anxiety and information scale; VAS, visual analogue scale.

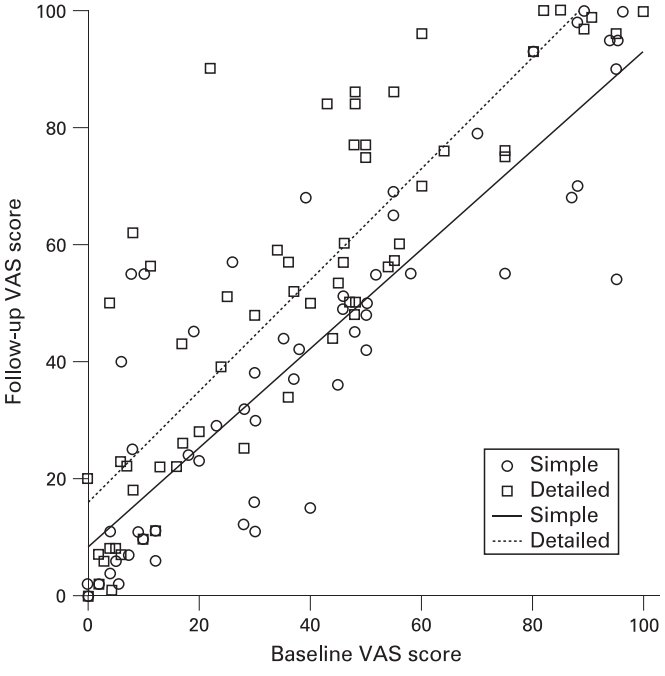

Figure 1 Scatterplot of baseline and follow-up anxiety visual analogue scale (VAS) scores.

Table 3 Responses to post-procedure satisfaction questionnaire

	No (%) reporting moderate or strong agreement		
	Control (n = 60) (%)	Intervention (n = 62) (%)	p Value
I received as much information as I needed to make a decision regarding bronchoscopy	60 (100)	61 (98)	0.98
I received too much information regarding complications of bronchoscopy	8 (13)	18 (29)	0.03
The information I received about bronchoscopy was helpful	60 (100)	61 (98)	0.98
The information I received about bronchoscopy worried me	15 (25)	30 (48)	0.01

p Values computed using χ^2 test.

Anxiety before a procedure may not only be unpleasant for the patient but may increase analgesic requirements and contribute to adverse outcomes.[24 25] Hence, reduction in situational anxiety is an important aim of providing information before a procedure. The amount of information provided to the intervention group might be criticised in this regard. However, there is an inherent tension between the goal of minimising anxiety and that of providing sufficient risk information to allow patients to make an informed choice and to protect doctors from litigation if a complication does occur. Arbitrary numerical thresholds (eg, 1/1000 or greater) for which risks should be disclosed are not helpful since the ''patient standard'' for consent holds that patients should be told of even small risks of serious complications, and this is consistent with reports of patient preferences regarding risk information.[8] However, a justifiable criticism of all standardised information is that risk and benefits for individuals always depend on personal characteristics.[26] Thus, some patients in the intervention group may have received risk information that was not applicable and was unnecessarily frightening to them.

It is possible that a different approach to framing and communicating risk information might, without shirking adequate discussion of risk, minimise the potential for increasing anxiety. This remains an important subject for future research. Nevertheless, it is also possible that respect for patient autonomy (and protection for physicians) may come at the inevitable cost of an increase in anxiety. Since the amount of anxiety produced by giving more detailed information in the current study was small and there were no obvious clinical consequences, this seems a price worth paying for most patients.

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