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Informed consent: the assessment of two structured interview approaches compared to the current approach

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Abstract

We prospectively studied 190 patients undergoing tonsillectomy or nasal surgery to assess the value of two structured interview techniques. There were four groups: Group A did not have a consent interview during the study period. Group B had an informal interview. Group C had a structured interview and Group D had a structured interview and were given an information sheet. Anxiety assessments were made and patients' recall of the operation name, details of the operation and its complications was assessed.

Patients had higher than normal anxiety levels when admitted, but several hours after the interview anxiety was normal for Groups B, C and D. Group A maintained a higher anxiety level.

Only 37 per cent correctly recalled the operation name, where as 87 per cent of all groups recalled the explanation of the operation. However, Groups C and D recalled a higher mean number of complications per patient.

A structured interview when obtaining informed consent increases the number of complications recalled without increasing pre-operative anxiety.

Introduction

A doctor has a duty to explain to the patient in non-technical language the nature, purpose and material risks of the proposed procedure. The patient must be capable of understanding the explanation given (Medical Defence Union, 1986). The practice of informed consent, has evolved over the last two and a half centuries (Rose, 1986); currently English law allows clinicians to use their judgement when deciding how much to tell a patient when seeking consent to administer a treatment. This allows a clinician to accommodate the patient's anxieties so that a necessary treatment is not refused because of fears aggravated by the patient's limited understanding of the pathology and the proposed remedy.

Ideally all patients should understand the explanation given to them and be able to come to a rational decision based upon discussion with their doctor. This is not so. Many studies have shown that despite a careful pretreatment explanation a number of patients have little understanding of their treatment (Bryne *et al.*, 1988; Villar and Hume, 1988). This casts doubts upon whether it is possible to achieve true informed consent. Even though this is a difficult (perhaps impossible) goal to achieve, it is important to try and improve the process that leads to patients consenting to a recommended treatment. This would have a mutually beneficial outcome. A patient would better understand his or her illness and its treatment which may lead to better compliance and clinicians may find that patients were less inclined to seek legal redress to an unsatisfactory treatment outcome. It is generally accepted that the patients who sue their doctors are those to whom the least explanation has been given before and after treatment (Morrison, 1990).

Patient information sheets are a recognized way of increasing patients understanding of an illness or treatment. They have been shown to be useful when prescribing drugs and can lead to improved treatment compliance (Gibbs *et al.*, 1990). This study was designed to evaluate the use to information sheets when consenting patients for common ENT operations. We aimed to answer the following questions:

1. Does using information sheets increase patients' pre-operative anxiety?
2. Does using information sheets improve patients' recall of the explanation of their proposed surgery?
3. Does using information sheets increase the number of possible treatment complications remembered by the patient?

Method

The project had local ethics committee approval. All patients were admitted to the ENT ward of Southmead Hospital. Verbal consent was sought from all patients before they entered the study.

Patients

Patients over 16-years-old were eligible provided they

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were admitted the day before their operation which was to be performed under general anaesthesia. Patients who did not understand the study or who understood English poorly were excluded from the study. We studied the following operations: Tonsillectomy, Intranasal polypectomy, Submucosal diathermy/Trimming of the inferior turbinates, Submucosal resection of the nasal septum, Septoplasty and Intranasal antrostomy. If a combination of the nasal procedures was to be performed patients were still included in the study, but they were 'consented' for the most major of the procedures. Two hundred patients entered the study. Initially major ear surgery was an additional operation being investigated. However, only ten patients had ear surgery so we have excluded their results because the nature of the information given was substantially different from that for nasal and throat operations.

Study groups

Group A Patients in this group did not have a consent interview until the study was complete.

Group B Patients had an informal interview prior to giving their consent. This interview reflected current practice, patients were told the name of the operation, briefly what would be done and some of the possible complications. A record was kept of the number of complications named. All patients were seen by P.J.D. Dawes who had two years 'post fellowship' experience. He took great care to maintain his usual interview technique and gave the same information to these patients as had been his usual practice before the study.

Group C A written information sheet was used to guide the interview with the patients before they signed the hospital consent form. It explained why the operation was being done, what it involved, listed and explained complications, explained how the patient would feel after their operation, the chance of success and any alternative treatments. The information sheet was not read by the patient and was not given to the patient. In practice more information was included on the information sheet than was given to the patient during the informal interview used in Group B.

Group D The written information sheet, described above was read with the patient before they signed the hospital consent form. The information sheet was then given to the patient so they could read it that afternoon. It was returned in the evening before the last part of the study.

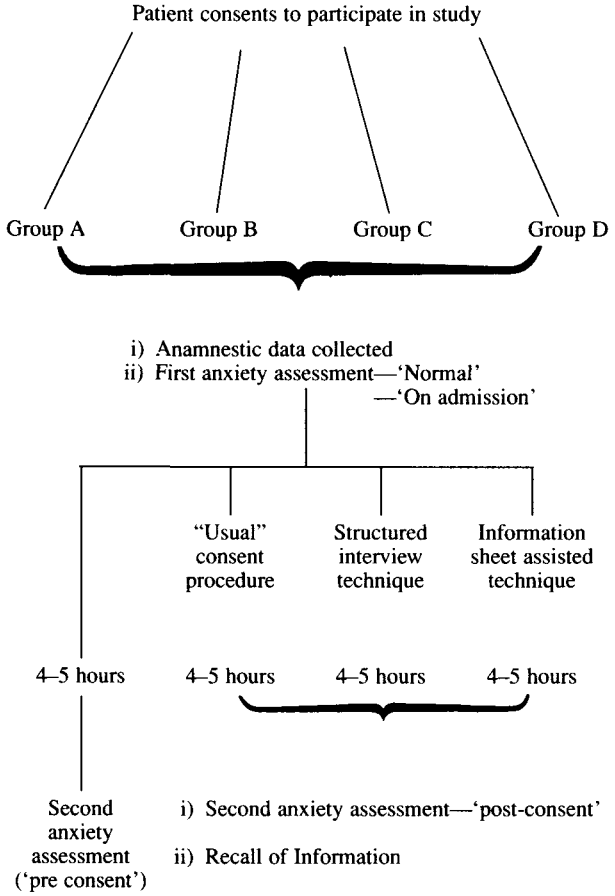

FIG. 1

Protocol of informed consent study.

Allocation of patients to study groups

Communication of information between patients in different groups could have biased the results so we took precautions to reduce this to a minimium. Groups A and B were each recruited separately from other groups. Patients entering Groups C and D were randomly allocated to either group. However, to prevent patients in Group D showing their information sheet to patients in Group C undergoing the same surgery we ruled that patients having the same operation on the same day could only be allocated to one of these groups.

Study design

Once entered into one of the above groups patients followed the protocol shown in Figure 1. The methods used for assessing anxiety and recall are described below. Each patient was seen within two hours of admission and four to five hours after the first interview. At the first interview the following data was collected: name, age, sex, educational level and previous operations. The first anxiety assessment was then completed.

At the second interview another anxiety assessment was made and patients in groups B, C and D were questioned to ascertain their recall and understanding.

Anxiety assessment

A linear analogue was used to assess anxiety. A 100 mm scale was used, the extremes being marked 'not anxious at all' and 'most anxious possible'. Patients were asked to mark the line at a point they thought represented their anxiety level. At the first anxiety assessment patients gave an estimate of their normal anxiety level and of the anxiety level at that time (*i.e.* soon after admission to hospital). At the second assessment patients gave an estimate of their anxiety at that time (*i.e.* Pre-consent: Group A or Post-consent: Groups B, C and D).

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TABLE I
DEMOGRAPHIC DATA

	A	B	C	D
MEAN AGE (YEARS)	30.6	37.2	37.1	35.9
95% Confidence interval	27.19 to 34.01	32.01 to 42.39	32.59 to 41.61	31.33 to 40.47
SEX				
M:F	29:20	29:18	24:26	24:20
EDUCATION				
Nil	7	15	23	11
CSE	14	8	10	10
'O'	22	18	10	14
'A'	3	1	6	6
Higher	3	5	1	3
PREVIOUS SURGERY				
None	25	14	13	12
Yes	14	21	22	21
Yes—ENT operation	10	12	15	11

The anxiety score was the measured distance, in millimetres, from the lower extreme of the scale. Mean Anxiety Scores were calculated for each estimation in each group.

Recall assessment

After the second anxiety assessment patients were asked the operation name, to describe what would be done, to name the possible complications and to state whether they thought they understood what they were told. Their responses were recorded and scored in this fashion:

Operation name	Correct or incorrect
Recall of explanation	Good or poor
Complications	The number recalled
Understanding	Good or poor

Statistics

Confidence intervals were used to demonstrate the changes in anxiety for each group. Chi-squared tests were used to assess any differences of information recall and confidence intervals were used to demonstrate any differences in mean recall of complications per patient.

Results

One hundred and ninety patients entered the study. There were 49 patients in Group A, 47 in Group B, 50 in Group C and 44 in Group D. The groups were similar for age and sex distribution. They had a similar educational profile and similar proportions had had previous surgery. This information is shown in Table I.

Anxiety

The anxiety changes during the day of admission to hospital are shown in Table II and displayed graphically in Figure 2. Patients in all groups have a higher than normal mean anxiety when admitted to hospital. If they do not have their operation explained to them, and do not sign the consent form their anxiety remains elevated. The patients who give informed consent for their surgery show a fall in their mean anxiety back to the normal level. It does not matter which of the three methods is used for gaining consent the fall in anxiety is the same.

Recall of explanation

Table III shows the number of patients who recalled the operation name and the explanation given to them. Chi-squared tests show no significant difference between the groups. It is interesting that although only about 37 per cent of patients correctly recall the operation name, 87 per cent of patients have good recall of the explanation of their operation. Nearly all patients thought they understood what they had been told.

Table IV shows how potential complications were recalled. Group B remembered a significantly greater proportion of the complications they were told about ($P<0.01$) but were told of fewer complications. If the mean number of complications recalled per patient is examined, then groups C and D recalled more complications than Group B, the difference being marked.

Discussion

We have shown that explaining the proposed surgery to our patients before obtaining consent reduces anxiety to

TABLE II
CHANGES IN MEAN ANXIETY SCORES OF THE STUDY GROUPS (95% CONFIDENCE LIMITS)

	Group A	Group B	Group C	Group D
Mean Normal anxiety	29.10 (22.29 to 35.21)	35.09 (28.24 to 41.94)	35.24 (29.29 to 41.19)	24.75 (18.31 to 31.19)
Mean Admission anxiety	50.35 (42.68 to 58.02)	44.09 (34.82 to 53.36)	54.34 (46.48 to 62.20)	49.84 (41.09 to 58.59)
Mean Anxiety 4 to 5 hours after admission	50.86 (42.78 to 58.94)	29.83 (22.01 to 37.65)	35.34 (27.27 to 43.41)	30.93 (23.69 to 38.17)

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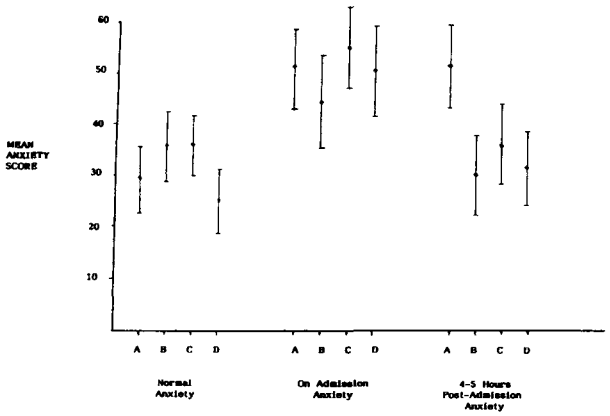

FIG. 2
Changes in anxiety score during study period.

normal levels. It did not matter which technique we used for presenting our explanation. We measured anxiety using linear analogue scales (Aitken, 1969). This was considered the most practical method available as our study involved assessing changes in anxiety over a short period of time.

Our mean admission anxiety scores are similar to those of Mackenzie (1989) who used a linear analogue scale to assess the anxiety of patients admitted for day case surgery. On the day of admission his patients had a mean anxiety score of 46.7 mm (95 per cent confidence interval: 42.4–51.0).

The use of a linear analogue anxiety scale is also supported by Baczkowski (1989) commenting upon research by Antrobus (1988). He showed that a single linear analogue anxiety measurement correlates positively with a simultaneous 'state' anxiety assessment using the Speilberger State-Trait anxiety inventory ($r = 0.75$).

Only between about 34 per cent and 42 per cent of patients recalled the name of their operation yet 81 per cent to 94 per cent had good recall of the explanation of the proposed surgery. It is encouraging that so many patients had a good memory of what was going to be done. It does not necessarily follow that they understood what they were told, but it is probable that most patients understood the explanation well enough to give valid consent on the basis of knowing what would be done. The poor recall of the operation name probably is because we used medical terminology when naming the operation but lay language when describing the operation. (If we considered whether the patient knew or had a good idea of the operation name then between 56 per cent and 74 per cent remembered most or all of the operation name).

The results for recalling complications are less encouraging. Group B remembered a greater proportion of the complications they were told about than Groups C and D. This is probably because Group B had fewer complications to remember. However, it may be more important to aim for a greater recall of complications by each patient. Groups C and D recalled more complications per patient than Group B. Patients in Group C did not see the list of complications on the information sheet so the increased recall is related to increasing the number of complications told to a patient.

TABLE III
RECALL OF INFORMATION ABOUT THE PROPOSED OPERATION

Number of patients	Recall of operation name		Recall of Explanation		Subjective assessment of understanding	
	Yes	No	Good	Poor	Good	Poor
B	16	31	38	9	45	2
C	21	29	47	3	50	0
D	15	29	41	3	50	0

The problem of ensuring that patients are adequately informed prior to treatment is well recognized and several studies have shown how poorly patients recall information that they were given before consenting to treatment. Robinson and Merav (1976) demonstrated that patients recalled about one third of the information given to them before thoracic surgery. Villar and Hume (1988) tested recall of preoperative information when patients were discharged after total hip replacement; they found that a patient information booklet made little improvement to the answers patients gave to their questions. Only about 30 per cent could remember at least one complication of the operation. Muss *et al.* (1979) questioned 100 patients who had consented to chemotherapy for breast cancer. Only 34 per cent could correctly name all their drugs and 25 per cent could not remember any of them. Only 28 per cent of these told that the treatment aimed to cure them could remember this. Byrne *et al.* (1988) interviewed 100 general surgical patients who were recovering from their operations. Twenty-seven did not know which organ had been operated on and 44 were unaware of the basic facts relating to the operation.

All these studies approached patients some time after they had had their treatment and consequently have limited validity when commenting upon the patients understanding at the time consent was given. Other studies have assessed patients understanding closer to the time they consented to their treatment. Simes *et al.* (1986) interviewed patients soon after entering a randomized protocol for assessing the treatment of cancer. Two consent procedures were compared; an individual approach against total disclosure. Patients receiving total disclosure of information were significantly better informed, but were significantly more anxious and significantly less likely to participate in the randomized trial of treatment. Cassileth *et al.* (1980) interviewed 200 cancer patients within one day of signing consent forms for one of various treatments. Only 60 per cent understood the purpose and nature of the treatment and only 55 per cent correctly listed one major risk. Given that patients forget a proportion of what they are told and this increases as time passes, some way of improving their memory would be useful.

Information sheets are a recognized way of reinforcing information given to patients. They can be kept for future reference and are generally well accepted. Gibbs *et al.* (1990) have demonstrated that prescription information leaflets significantly improve patients knowledge about their medication and the possible side effects. The need for a concise and structured presentation has been demonstrated by Epstein and Lasagna (1969) who found that the comprehension of a consent form was inversely related to its length. Hopper and Tyler (1989) showed that a short consent form provided information equally as well as either a long form or a detailed verbal counselling from a physician.

Our information sheets were designed to improve recall; we used non-medical language (except for the

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TABLE IV
RECALL OF POTENTIAL COMPLICATIONS (95% CONFIDENCE INTERVAL)

	B	C	D
Total number of complications told	106	259	239
Total number of complications recalled	64	105	102
% Recall	60.4	40.5	42.7 $P<0.01$ χ^2 test
Mean recall per patient	1.36 (1.34 to 1.38)	2.10 (1.93 to 2.71)	2.32 (1.84 to 2.36)

operation name), the information was concise and we used a question and answer format. We did not give total disclosure, but presented the information that the consultants, whose patients we studied, considered was necessary for their patients to make a valid decision to have the recommended treatment without being frightened by warnings of remotely possible complications. We think this represents a 'majority approach' and we are supported by Maran (1990) who found that very few ENT surgeons warned their patients of the rare but serious complications of six different operations.

We have shown that a structured interview technique helps improve the recall of potential complications of an operation and does not increase pre-operative anxiety. This supports Morrison's (1990) suggestions that information sheets could be used when recommending surgical treatment. There is a medicolegal aspect to this as the information sheet provides written documentation of what a patient was told as well as encouraging a full discussion of the proposed treatment. This in itself is said to reduce the chances of a patient seeking redress for an unsatisfactory outcome, probably because they have a more realistic expectation of the treatment and its limitations. We appreciate that there will be some patients for whom this approach will be unsuitable. However, none of the patients who had a structured consent interview refused to have their operation. We took no account of the patients potential anxiety when entering them into the study. Those patients who would be better served by having a limited explanation of the proposed treatment should be indentifiable during consultation(s) prior to recommending treatment.

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