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A double-blind randomized placebo-controlled study of therapeutic suggestions during general anaesthesia

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Evidence increasingly suggests that operating theatre sounds are registered in some areas of the cortex during general anaesthesia and that these sounds may influence recovery from surgery [1]. Cortical auditory evoked responses are not abolished by inhalational anaesthetic agents even at concentrations above those required for surgery [2] and, although very few patients can recall intraoperative events [3-6], a more sensitive assessment of learning found significant postoperative recognition of words presented during general anaesthesia [7]. Furthermore, patients who are unable to recall instructions made during surgery may still obey them postoperatively [8,9]. Patients may also respond to therapeutic suggestions made during anaesthesia. Two uncontrolled studies reported that such suggestions improved recovery from surgery [10,11], a conclusion supported by two double-blind randomized controlled studies. Pearson [12] found that patients who heard tape-recorded therapeutic suggestions left hospital significantly sooner than those played music or blank tapes, but the suggestion and control groups had not been matched for the type of surgery performed. Bonke and colleagues [13] reported similar findings with cholecystectomy patients but only in older people. However, a replication study [14] and a smaller study with patients undergoing hysterectomy [15,16] found no significant improvement in recovery following therapeutic suggestions during anaesthesia.

We therefore conducted a double-blind randomized controlled study to examine further the hypothesis that the quality and dura-

tion of recovery from surgery would be improved by therapeutic suggestions made during general anaesthesia.

Patients and Methods

Patients. Every patient admitted to St Thomas' Hospital for a total abdominal hysterectomy over a twelve week period was invited to take part in the study which was approved by the West Lambeth Health Authority Ethics Committee. Four patients declined to consent, two failed to complete the questionnaires and one was excluded owing to the need for a second operation. The characteristics of the remaining 39 subjects are summarized in Table 1.

Materials. Patients were randomly played a suggestion tape or a visually indistinguishable blank control tape. It was not known which type of tape had been played to each patient until the end of the study. A waterproof auto-reverse tape player (Sony WM F-63) was used in the operating theatre with purpose-built headphones which made operating theatre sounds inaudible to the patient and prevented the tape contents being overheard by the anaesthetist.

Twelve minutes of therapeutic suggestions were repeated three times on each side of the suggestion tapes: the major section described for nine minutes the normal postoperative procedures with advice on how best to cope with them [12] (e.g., "...How quickly you recover from your operation depends upon you; the more you relax, the more comfortable you will be..."); then two minutes of direct suggestions [11,13] (e.g., "...You will not feel sick, you will not have any pain ..."); and one minute of third person suggestions [13] (e.g., "...The operation seems to be going very well and the patient is fine..."). A complete transcript of the suggestion tape is available on request.

Procedure. On the day preceding surgery, each subject completed a questionnaire which consisted of: a short form of the Profile of Mood States Questionnaire [17,18] which provides six individual mood scores (tension, depression, anger, fatigue, vigour and confusion) and an overall negative mood score; the 'state' version of the State-Trait Anxiety Inventory [19]; and a 10 cm Visual Analogue Scale [20] assessing how distressing it was to come into hospital.

Each patient was randomly allocated to hear a suggestion or control tape which was played from the time of the first incision to the start of wound closure. Normal anaesthetic and clinical procedures were not modified and the anaesthetist recorded the duration of

surgery, the intraoperative blood loss, the anaesthetic agents used and whether the patient showed any signs of consciousness during surgery.

When each patient got up for the first time after surgery a nurse filled in a six-point mobilization rating scale assessing the amount of help required and any occurrence of vomiting was recorded. The number of half days on which a temperature above 37.3°C occurred was recorded for the first five postoperative days together with analgesia usage. On the fifth day after surgery each patient was asked to complete the Mood and Anxiety Questionnaires again and to make visual analogue scale ratings of: pain intensity; distress caused by pain; difficulty with micturition, flatulence and defaecation; and severity of nausea. Each patient was asked whether she had any memories or dreams from the time of the operation and these were recorded. Finally, each patient was asked to guess whether she had been played an instruction tape or a blank tape. The date of discharge was recorded to the nearest half day and the nurses were asked to assess whether the patient had made a recovery that was poorer than expected, as expected, or better than expected.

One-way analyses of variance and covariance were used to compare the mean scores of the suggestion and control groups on all continuous variables. The Fisher Exact Probability Test [21] was applied to all 2 x 2 contingency tables for the analysis of categorical variables.

Results

There were no significant differences between the preoperative mood and distress scores for the suggestion and control groups. Table 2 displays the agents administered by the anaesthetist: both groups received similar anaesthetics. The volatile anaesthetics were given with nitrous oxide and oxygen. No significant differences between the two groups were found for the distribution of ward or bed (single room vs open bay) or allocation to surgical teams. Table 1 summarizes other potentially confounding variables: no significant differences between the suggestion and control groups were found for age, ethnic origin, preoperative anxiety, intraoperative blood loss, duration of surgery, anaesthetist's and surgeon's experience.

Table 1. Potential confounding variables.

	Mean (standard deviation)		F	Statistic	
	Control group	Suggestion group		df	P
Age (yr)	43.80 (7.1)	41.79 (6.5)	1.3	1,37	ns
Preoperative Anxiety (20-80)	43.95 (12.9)	41.00 (9.4)	<1	1,37	ns
Intraoperative blood loss (ml)	309.17 (221.2)	314.80 (181.5)	<1	1,25	ns
Duration of surgery (min)	66.31 (16.8)	70.63 (23.9)	<1	1,27	ns
	Number of Patients		Fisher	Exact	P
	Control group	Suggestion group			
Ethnic origin of patient					
Caucasian	9	13			
Afro-Caribbean	11	6			ns
Anaesthetist's experience					
Consultant	8	10			
Trainee grade	12	9			ns
Surgeon's experience					
Consultant	18	12			
Trainee grade	2	7			ns

Table 2. Agents administered by the anaesthetist (numbers of patients; some patients received more than one agent for induction of anaesthesia and for neuromuscular blockade).

	Control Group	Suggestion Group
Induction agents		
Thiopentone	20	19
Midazolam	0	2
Neuromuscular blockade		
Vecuronium	9	12
Suxamethonium	4	4
Tubocurarine	5	3
Pancuronium	4	1
Atracurium	2	0
Volatile anaesthetics		
Enflurane	18	15
Halothane	2	4
Opioids		
Fentanyl	18	17
Other	2	2

Table 3. Dependent variables.

	Mean (standard deviation)		Statistic		
	Control group	Suggestion group	F	df	P
Postoperative stay (days)	8.38 (1.3)	7.05 (1.0)	11.92	1,37	<0.002
Pyrexia (half days)	3.90 (2.2)	2.16 (1.2)	9.25	1,37	<0.005
Difficulties with bowels (0-100) ^a	55.70 (34.1)	31.26 (29.2)	5.75	1,37	<0.03
Flatulence (0-100) ^a	57.90 (33.1)	63.37 (36.4)	<1	1,37	ns
Mobilization rating (0-5) ^a	2.55 (1.1)	3.11 (0.88)	2.87	1,37	ns
Urinary difficulties (0-100) ^a	26.45 (32.7)	13.68 (19.6)	2.17	1,37	ns
Nausea (0-100) ^a	43.35 (40.3)	28.26 (31.6)	1.68	1,37	ns
Pain intensity (0-100) ^a	26.50 (25.4)	23.89 (20.0)	<1	1,37	ns
Pain distress (0-100) ^a	20.80 (27.4)	18.19 (18.2)	<1	1,37	ns
	Number of Patients		Fisher Exact P		
	Control group	Suggestion group			
No vomiting	12	14			
Vomited	8	5	ns		
Nurses' assessment of recovery poorer than or as expected ^b	14	1			
better than expected	6	16	<0.002		
Patient guess of tape contents blank tape	11	1			
instruction tape	9	18	<0.004		

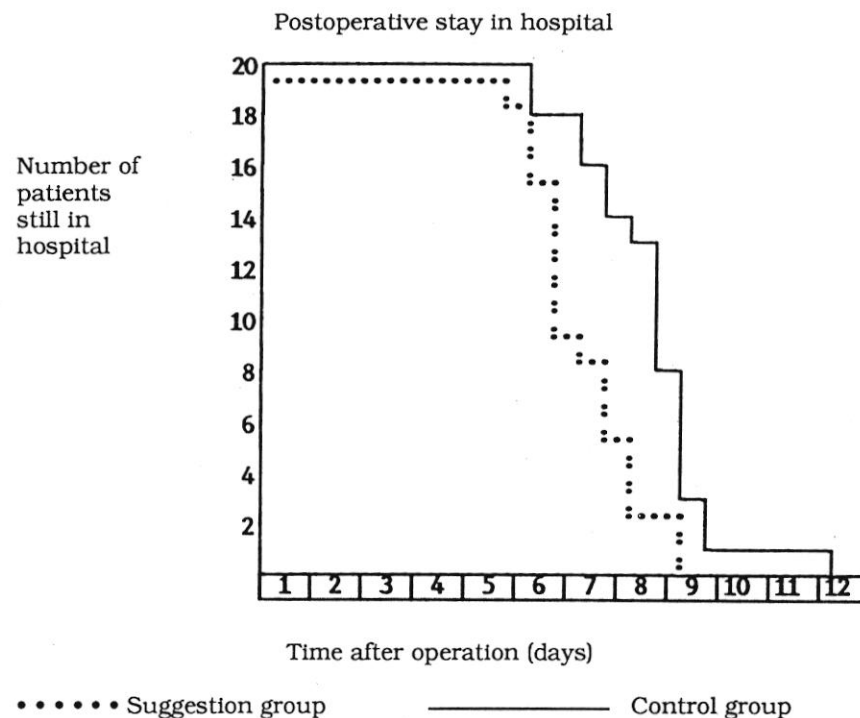
^a Higher scores = less favourable outcome.

^b Only three patients (all control group) were reported to have made a worse than expected recovery; the poorer than and as expected groups were therefore combined because this small cell size prevented the chi-square test from being used.

Table 3 displays the mean scores and the distribution of the main dependent variables for the suggestion and control groups. The mean postoperative stay for the suggestion group was 1.33 days (16%) less than the control group - a highly significant difference

($P < 0.002$). Patients' age was not significantly associated with the duration of postoperative hospitalization; introducing age as a covariate in the analysis yielded a non-significant F-ratio ($F = 3.41$; $df = 1,36$; n.s.). Postoperative stay for the two groups is shown in the figure. The suggestion group patients also experienced 1.78 (45%) fewer days of pyrexia ($P < 0.005$) and reported a reduction in gastrointestinal problems ($P < 0.03$).

Figure 1. The number of patients still in hospital each day after hysterectomy.



No significant differences were detected between the suggestion and control groups for the quality of mobilization or difficulty with micturition. Two patients in each group required urinary catheterization. Reported nausea, the incidence of vomiting and analgesia requirement did not differ significantly between the two groups, nor did severity of, and distress from, pain on the fifth postoperative day. Mood and anxiety scores on the fifth postoperative day did

not differ significantly between the two groups and the introduction of the preoperative scores as covariates did not alter this pattern of significance.

Almost every member of the suggestion group was rated by nurses as having made a better than expected recovery; in contrast, most controls were rated as having made typical or poorer than expected recoveries from surgery ($P < 0.002$). No patient was able to recall any intraoperative events or conversation. All but one of the suggestion group patients guessed correctly that they had been played an instruction tape during surgery, whilst the control group guessed no better than chance would predict ($P < 0.004$).

Discussion

The results of this study imply that therapeutic suggestions during anaesthesia may significantly reduce the duration and improve the quality of recovery after hysterectomy. This conclusion is consistent with previous controlled research involving different types of surgery [12,13]. The members of the suggestion group left hospital significantly sooner than those of the control group, suffered from significantly fewer days of pyrexia, were generally rated by nurses as having made a better recovery and guessed accurately that they had been played an instruction tape. No significant differences were detected between the suggestion and control groups on postoperative measures of pain, mobilization, urinary and gastrointestinal complications, mood or anxiety.

Many factors determine the quality and duration of recovery and observer error may have affected some of the measures, but these factors should have been equally distributed between the randomly allocated suggestion and control groups who were assessed in a double-blind fashion. Surgical patients are usually exposed to operating theatre sounds rather than silence and the control condition does not therefore represent normal clinical practice. However, earlier studies (for instance [12]) found that silence and operating theatre sounds have similar effects upon recovery. The nursing assessments of the quality of recovery also imply that the control condition was equivalent to normal clinical practice and that the patients who were played suggestions during surgery made better recoveries than expected. Furthermore, over half of the suggestion group were discharged within a day of suture removal in contrast with only one tenth of the control group.

None of our patients was able to recall any intraoperative events or sounds and the ward staff had no access to the visually indistinguishable tapes played in the operating theatre. The accuracy with

which the suggestion group patients guessed that they had been played an instruction tape therefore suggests that registration of sounds at some level took place during general anaesthesia. The distinction between recall and registration of auditory stimuli presented during general anaesthesia is central to research in this area. Recall of intraoperative events is almost invariably absent; but lack of verbal recall does not necessarily indicate lack of registration [22] (see the Chapter by Kihlstrom and Schacter for a thorough discussion of this issue).

Inappropriate or misinterpreted operating theatre comments may have a harmful effect upon recovery (see the Chapter by Bonke for an overview of psychological consequences), and it has been suggested that patients' ears should be plugged during surgery [1,23,24]. Our results suggest that registration of sounds during anaesthesia, without awareness, may instead be employed to the benefit of the patient.

Our findings are consistent with research concerning psychological preparation for surgery. More than 30 studies have been comprehensively reviewed [25,26] and subjected to meta-analysis [27]: it is clear that psychological interventions, especially those including the coping strategies which constituted three quarters of our suggestion tape, may improve recovery from surgery. The stress associated with an operation can affect resistance to infection, rate of blood clotting, and other mechanisms likely to be involved in the physical recovery from surgery [28]. Psychophysiological mechanisms [29-31] may have accounted for the suggestion group's improved and accelerated recovery. The health behaviours that were recommended on the suggestion tape (e.g., frequent mobilization) may also have contributed to these effects.

Further research is required to establish the nature and incidence of the registration of sounds during anaesthesia, to investigate any association with the depth of anaesthesia (see the Chapter by Jones) and to study the psychophysiological mechanisms involved. There is some information concerning the most effective type of suggestions (see the Chapter by Bennett on 'unconscious hearing'), and future studies may find ways of increasing their therapeutic effect. It is possible that the effectiveness of therapeutic suggestions may be increased by exposure during induction of anaesthesia and during recovery in addition to the deeper period of anaesthesia which was used in the present study [32,33].

The difference between the cost of hospitalization [34] for the experimental and control groups in the present study was approximately £140 per patient, £2,680 in total. Over 66,000 hysterectomies are performed each year in England alone [35], suggesting

that an annual saving of over nine million pounds (approx. 16.5 million US-dollars) may be possible. This saving of hospital and financial resources, together with an improvement in the quality of recovery, is clearly of considerable potential importance. If it is possible to demonstrate a similar improvement with other types of surgery then the implications for improved medical care and financial savings may be widespread.

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Multi-modal content analysis of post-anaesthetic hypnotic regressions

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Numerous reports indicate that patients under general anaesthesia may be susceptible to intraoperative suggestions and/or conversations [1-10]. These reports are usually based on behavioural criteria, i.e., the number of postoperative days to hospital discharge, requirement for analgesics and frequency of specific psychomotor responses during a later interview. Objective assessment, in the absence of standard psychometric evaluation, of the influence of intraoperative suggestion on the patient's subjective state, however, may be more elusive. Previous researchers using postoperative hypnotic age-regression techniques have suggested that the patient's overall psychological well-being may be influenced by intraoperative conversation and suggestions [1,4,5,8,10]. The evidence however, may be equivocal, i.e., waking from hypnosis, failure to return to the clinic when previous behaviour would have predicted otherwise or development of overt psychological disturbance. Thus, more objective evaluation of patients' subjective state following intraoperative suggestion or conversation might be useful.

Although objective assessment of another's subjective experience is often difficult, Oxman et al. [11] analyzed 83 lexical word categories used by subjects to describe previously experienced altered states of consciousness. The three groups compared included persons who had had previous drug-induced hallucinations, schizophrenic hallucinations, or mystical ecstasy experiences.

Memory and Awareness in Anaesthesia

Edited by:
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Bonke, Fitch & Millar (eds.) **Memory
and Awareness in Anaesthesia**

This volume presents the proceedings of an international symposium on the most recent developments in research concerning the phenomena of auditory perception and awareness during general anaesthesia. The chapters are centered around the phenomenon that some patients who are apparently adequately anaesthetized have memories of intraoperative events and demonstrate unconscious perception during drug-induced change in consciousness. Contributors to this volume include leading clinicians and scientists (i.e. anaesthetists, experimental psychologists and others) whose expertise ranges from anaesthesiological to behavioural and electrophysiological approaches to the problem. The book provides a fully comprehensive and up-to-date account of empirical findings and theoretical stances.

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