

# A Randomized Controlled Trial to Assess the Effect of Audiotaped Consultations on the Quality of Informed Consent in Cardiac Surgery

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**Objective:** To evaluate the effect of audiotaping outpatient consultations on informed consent for cardiac surgery.

**Design:** Randomized controlled trial.

**Setting:** Tertiary health care center in Scotland.

**Participants:** Eighty-four patients who had first-time coronary artery surgery conducted by 1 surgeon from February 10, 2005, through March 15, 2006, whose consultations before surgery were audiotaped.

**Intervention:** Randomization to 3 trial arms. The control group (n=29) received no tape. The generic group (n=25) received a tape about coronary artery surgery, which we scripted to include information covering the domains described by the General Medical Council. The consultation group (n=30) received a tape of their consultation interview. On admission to the hospital, patients were interviewed with the Knowledge Questionnaire, the Multidimensional Health Locus of Control, and the Hospital Anxiety and Depression Scale.

**Main Outcome Measures:** The effect of audiotaping in improving the informed consent process for cardiac surgery.

**Results:** The mean knowledge score of patients in the consultation group was much higher than that of the control individuals ( $P < .001$ ). Patients in the consultation group reported a significantly greater sense of control with regard to their own health ( $P < .001$ ) and being less anxious and depressed overall.

**Conclusion:** Providing an audiotaped recording of the consultation before cardiac surgery appears to improve patients' knowledge and perceptions of control of their health status and to reduce anxiety and depression.

**Trial Registration:** isrctn.org Identifier: ISRCTN20081026

*Arch Surg.* 2010;145(4):383-388

**M**AKING AN AUDIOTAPED recording of the consultation between physician and patient and allowing the patient free access to it have been used to improve the quality of informed consent in some specialties.<sup>1</sup> Emerging evidence suggests audiotaped recordings may be helpful, although evidence of their effectiveness in improving informed consent is weak and limited to a few studies only.<sup>2</sup> Patients facing heart surgery are understandably anxious in the outpatient clinic and, as a consequence, are unlikely to absorb all the information presented to them. They also find it difficult to remember the various percentage figures quoted for risk of complication, success rate of alternative therapeutic options, and other pertinent facts.<sup>3-5</sup>

For consent to be truly valid, it should be obtained from a patient who is ad-

equately informed about the proposed treatment, the alternatives to that treatment, and the nature of the underlying condition. Various professional bodies in the United Kingdom have published guidelines dealing with the consent process.<sup>6</sup> On the basis of the 16 domains described by the General Medical Council, we developed a questionnaire that tests the extent of knowledge of patients at the time they give consent for coronary artery bypass graft (CABG) surgery.<sup>7</sup> A study has previously been published<sup>7</sup> in which we demonstrated the validity of this questionnaire.

To our knowledge, the only existing published research on this subject in relation to cardiac surgery is a small study looking into qualitative aspects of patients' experiences when their heart surgery consultation was audiotaped.<sup>2</sup> In the present study, we used the Knowledge Questionnaire to assess the effect of providing patients with an audiotaped record-

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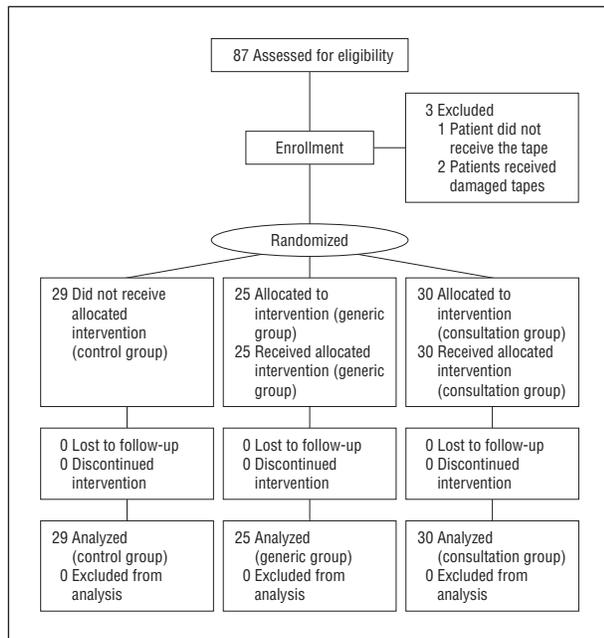


Figure. Flowchart for the randomized controlled trial.

ing of the surgical outpatient consultation before their operation.

## METHODS

The study was approved by the Institutional Ethics Committee. It was funded by the Department of Cardiothoracic Surgery, Glasgow Royal Infirmary, Glasgow, Scotland.

### PATIENTS

We included patients undergoing elective first-time CABG at a tertiary health care center in Scotland under the care of 1 surgeon (A.M.). All suitable patients were sent a letter before their outpatient visit providing them with details of the trial. On the day of the outpatient visit, patients received further information about the study; if they signed a consent form, they were included in the study.

### RECORDING THE CONSULTATION

For all patients in the study, the outpatient consultation was audiotaped using a simple handheld dictating machine. English was the first language for all patients. The recording was transferred onto a cassette that could be played on any cassette player. A copy of the cassette was kept by the researchers for analysis of the consultation's content.

### RANDOMIZATION

Patients were randomized after the consultation was completed (**Figure**) so that during the consultation, the surgeon and patient were blinded to the arm of the trial to which the patient was allocated. Randomization was performed by minimization using age and sex as the stratification factors.<sup>8</sup> Patients were randomized to 1 of 3 groups.

The control group (n=29) received no tape. The generic group (n=25) received a copy of a tape containing general information about CABG, which we scripted to include infor-

mation covering each of the domains described by the General Medical Council. The consultation group (n=30) received a tape of their consultation interview.

The tapes were mailed to patients after their clinic visit. Patients in the control arm were informed they would not receive a cassette. Patients in the 2 tape groups received, along with the tape, a letter encouraging them to listen to the tape as many times as they wished, either alone or with their friends or relatives.

## KNOWLEDGE MEASUREMENT

On admission, the patients were seen by nurses, members of the surgical team, an anesthetist, and a physiotherapist a day before surgery, and consent was obtained in the usual way. None of these personnel was involved in the trial; they performed their tasks according to their usual routine.

Within 2 hours of signing the consent form, patients were interviewed using the Knowledge Questionnaire. A previous study<sup>9</sup> demonstrated that patients are best informed within 2 hours of signing the consent form. Personnel administering the interventions and assessing the outcomes were blinded to group assignment.

### KNOWLEDGE QUESTIONNAIRE

A description of the Knowledge Questionnaire was previously published<sup>7</sup>; it was designed to test the various domains of knowledge described by the General Medical Council in patients about to undergo CABG, who are expected to be covered by the consent process. In addition to a description of the Knowledge Questionnaire, we also demonstrated its construct validity by comparing it with the Area Deprivation Index<sup>10</sup> and scores obtained from the National Adult Reading Test (NART),<sup>11</sup> which provides a proxy measure of intelligence. We also demonstrated interobserver reliability by using 4 different interviewers.<sup>7</sup> The questionnaire is designed to be administered in a face-to-face interview. Each question is scored from 0 to 3, depending on where the respondent's score could be found between the extremes of inadequate level of knowledge (score=0) and very good level of knowledge (score=3). The maximum total score for the questionnaire is 48.

### MULTIDIMENSIONAL HEALTH LOCUS OF CONTROL

Patients completed the Multidimensional Health Locus of Control questionnaire (MHLC), which assesses the extent to which they believe that their state of health is influenced by their own control (internality), the external influence of health care professionals (powerful others), or chance circumstances.<sup>12</sup> The score range for each subscale is 6 to 36.

### HOSPITAL ANXIETY AND DEPRESSION SCALE

Patients completed the Hospital Anxiety and Depression Scale (HADS), a self-report assessment of anxiety and depression.<sup>13</sup> The score range for anxiety and depression is 0 to 21.

### NATIONAL ADULT READING TEST

Each patient completed the NART, which assesses the ability to pronounce unfamiliar words correctly. Reading ability is known to correlate with intelligence, and scores on the NART correlate with full-scale assessments of intelligence.<sup>11</sup> Its use

**Table 1. Demographic Characteristics of the Study Patients**

Characteristic	Group A (Control; n=29)	Group B (Generic Tape; n=25)	Group C (Consultation Tape; n=30)
Age, mean (range), y	67 (63-68)	67 (64-71)	66 (62-69)
Male sex, No. (%)	22 (76)	17 (68)	21 (70)
Additive EuroSCORE score, mean (95% CI)	3.0 (2.5-3.5)	3.1 (2.6-3.6)	3.0 (2.4-3.5)
NART score, No. correct, mean (95% CI)	41 (40-41)	41 (39-43)	41 (39-43)
ADI, mean (95% CI)	8.2 (7.1-9.4)	8.0 (6.6-9.4)	8.1 (6.6-9.6)

Abbreviations: ADI, Area Deprivation Index; CI, confidence interval; EuroSCORE, European System for Cardiac Operative Risk Evaluation; NART, National Adult Reading Test.

in the present study allows confirmation of the groups' equivalence in intellectual ability, which is important in the context of the Knowledge Questionnaire.

### AREA DEPRIVATION INDEX

The Area Deprivation Index was obtained for each patient. It was determined on the basis of the postal code of his or her place of residence.<sup>10</sup>

### STATISTICAL ANALYSIS

In a previous study,<sup>7</sup> in which the subjects were patients examined prior to CABG surgery who had received no particular intervention with respect to information provision, we found a mean (SD) score of 25 (8). If an intervention raised the mean score by 20% to 30, this score, although somewhat arbitrary, might be considered a clinically relevant improvement. We calculated that a study with an 80% power to detect a 20% difference between the control and consultation groups at  $P = .05$  would require each group to include 28 patients and therefore have a combined patient total of 84 for the 3 groups.

Statistical analyses of the Knowledge Questionnaire, MHLC, HADS, NART, and Area Deprivation Index were conducted using SPSS statistical software, version 13.0 (SPSS Inc, Chicago, Illinois). The raw data were subjected to 1-way analysis of variance. Where significant main effects were found, the Tukey honestly significant difference procedure for post hoc comparisons was used to establish where significant differences could be found between treatment means.

## RESULTS

Brief demographic details of the 3 groups of patients, including NART score and Area Deprivation Index, are given in **Table 1**. European System for Cardiac Operative Risk Evaluation is a risk stratification model that provides a way to compare risk of mortality after cardiac surgery.<sup>14</sup> No significant differences were found among the 3 groups of patients for any of these baseline variables.

All patients who received the audiotapes confirmed they had listened to them. The duration of the consultation tapes ranged from 13 to 32 minutes (mean, 24 minutes), whereas the duration of the general tape was 11 minutes.

**Table 2** gives the mean scores (including 95% confidence intervals) for the Knowledge Questionnaire, MHLC, and HADS as a function of the 3 treatment groups. It is evident from the HADS score ranges that no participants in any group scored above the threshold of 8, denoting clinically significant levels of anxiety or depression. Analysis of variance confirmed there were

significant main effects of treatment for all assessment measures (Knowledge Questionnaire,  $P < .001$ ; MHLC internality,  $P < .001$ ; MHLC powerful others,  $P = .001$ ; MHLC chance,  $P = .001$ ; HADS anxiety,  $P = .003$ ; and HADS depression,  $P = .004$ ). Post hoc comparisons confirmed the following significant differences among treatment means for each assessment measure (all comparisons  $P < .05$ ).

### Knowledge Questionnaire

The group receiving the consultation tape scored significantly better than the generic tape and control groups. The latter groups also differed significantly from each other, reflecting the lower knowledge score of the control group.

### Multidimensional Health Locus of Control: Internality, Powerful Others, and Chance

The group receiving the consultation tape had a significantly higher internalized health locus of control than the other groups and, correspondingly, a significantly lower perception that their health was controlled by powerful others or chance. The generic tape and control groups did not differ on any MHLC measure.

### Hospital Anxiety and Depression Scale

The consultation tape group had significantly lower scores on anxiety and depression on HADS than the generic tape group. The control group did not differ significantly from the consultation or generic tape group. A qualitative assessment of all 84 tapes was made to assess content and the patients' responses during the consultation. Particular findings were that 18 patients were not interested in knowing the therapeutic options, believing the surgeon was the best person to decide. Eight patients raised specific questions about the success rates of other therapeutic options. Twenty-five patients did not ask any specific question, stating that the information provided during the consultation was adequate. Twenty-eight patients asked questions about the surgical procedure itself (such as site and length of incision and number of grafts required), whereas 33 patients asked questions related to consequences of not undergoing surgery. The most common question, raised by 44 patients, was when they would be able to return to work after surgery.

**Table 2. Test Scores**

	No. of Patients	Mean (SD)	SE (95% CI)	Minimum	Maximum
Knowledge questionnaire					
Control	29	13.79 (5.354)	0.994 (11.76-15.83)	6	35
Generic	25	19.64 (3.451)	0.690 (18.22-21.06)	13	27
Consultation	30	31.97 (5.922)	1.081 (29.76-34.18)	21	46
<b>Total</b>	<b>84</b>	<b>22.02 (9.300)</b>	<b>1.015 (20.01-24.04)</b>	<b>6</b>	<b>46</b>
MHLC internality					
Control	29	14.00 <sup>a</sup> (3.655)	0.679 (12.61-15.39)	6	25
Generic	25	15.20 <sup>a</sup> (3.797)	0.759 (13.63-16.77)	8	25
Consultation	30	21.17 (4.639)	0.847 (19.43-22.90)	12	32
<b>Total</b>	<b>84</b>	<b>16.92 (5.156)</b>	<b>0.563 (15.80-18.04)</b>	<b>6</b>	<b>32</b>
MHLC powerful others					
Control	29	16.72 <sup>a</sup> (5.338)	0.991 (14.69-18.75)	8	28
Generic	25	15.80 <sup>a</sup> (5.220)	1.044 (13.65-17.95)	7	28
Consultation	30	12.20 (2.858)	0.522 (11.13-13.27)	6	18
<b>Total</b>	<b>84</b>	<b>14.83 (4.938)</b>	<b>0.539 (13.76-15.90)</b>	<b>6</b>	<b>28</b>
MHLC chance					
Control	29	16.38 <sup>a</sup> (3.941)	0.732 (14.88-17.88)	7	25
Generic	25	16.48 <sup>a</sup> (6.615)	1.323 (13.75-19.21)	7	32
Consultation	30	12.03 (4.351)	0.794 (10.41-13.66)	7	28
<b>Total</b>	<b>84</b>	<b>14.86 (5.384)</b>	<b>0.587 (13.69-16.03)</b>	<b>7</b>	<b>32</b>
HADS anxiety					
Control	29	2.66 <sup>b</sup> (1.818)	0.338 (1.96-3.35)	0	8
Generic	25	3.20 <sup>a</sup> (1.871)	0.374 (2.43-3.97)	0	8
Consultation	30	1.57 <sup>c</sup> (1.569)	0.286 (0.98-2.15)	0	6
<b>Total</b>	<b>84</b>	<b>2.43 (1.858)</b>	<b>0.203 (2.03-2.83)</b>	<b>0</b>	<b>8</b>
HADS depression					
Control	29	2.38 <sup>b</sup> (1.613)	0.299 (1.77-2.99)	0	7
Generic	25	3.00 <sup>a</sup> (1.780)	0.356 (2.27-3.73)	0	7
Consultation	30	1.50 <sup>c</sup> (1.480)	0.270 (0.95-2.05)	0	7
<b>Total</b>	<b>84</b>	<b>2.25 (1.714)</b>	<b>0.187 (1.88-2.62)</b>	<b>0</b>	<b>7</b>

Abbreviations: CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; MHLC, Multidimensional Health Locus of Control.

<sup>a</sup>Means that do not differ significantly on the basis of post hoc comparisons but are significantly different from those labelled with footnote c.

<sup>b</sup>Means do not differ from each other.

<sup>c</sup>Means that do not differ significantly on the basis of post hoc comparisons but are significantly different from those labelled with footnote a.

### COMMENT

In our study, as in the study by Leahy et al,<sup>2</sup> all patients who received the audiotaped recording reported having listened to it. This finding contrasts with those of a study in oncology in which substantial numbers of patients did not listen to the recording at all.<sup>3</sup> Provision of the consultation tape in the present study imparted significant benefit to the patients' degree of knowledge.

Concerns have been raised that detailed information can cause undue anxiety and distress to patients.<sup>15-17</sup> Indeed, some patients express a desire to avoid excessive information,<sup>18</sup> in particular, information about risks associated with surgery.<sup>19</sup> A study<sup>20</sup> has shown sex differences in reactions to the wait for coronary surgery. However, it has also been shown that a well-informed patient copes more effectively with surgery, and this factor can result in earlier discharge and decreased incidence of psychological problems.<sup>18</sup> A positive correlation has also been demonstrated between audiotape provision and mood state and quality of life.<sup>3,21</sup> In this context, the consultation tape imparted further benefit in terms of the patients' greater sense of self-control with regard to their health status, as assessed by the MHLC. Moreover, patients who were provided with the consultation audiotape had lower mean scores on the anxiety and depression subscales, although

the difference was only significant in comparison to those having the generic tape; neither group differed significantly from the control group. These marginal differences probably reflect the fact that the mean levels of anxiety and depression reported by all 3 groups were low and well below the HADS cutoff score of 8, which denotes mild anxiety or depression of clinical significance.

Treating a patient based on inadequately informed consent constitutes negligence,<sup>22</sup> and consultants have been suspended for not obtaining valid informed consent for cardiac procedures.<sup>23</sup> In the current era, informed consent has become a complex issue<sup>24</sup> to the extent that some authors have suggested the fulfillment of the doctrine of informed consent under the intent of law may be mythical.<sup>4</sup>

On the one hand, patients must understand, evaluate, and retain complex information to participate in decisions about their own care,<sup>25</sup> whereas individuals who are experiencing emotional and physical pain are seriously impaired with respect to their ability to absorb and retain information.<sup>4</sup> The communication process is limited by the time that health care professionals and patients have available to them in the clinical setting.<sup>4,5</sup> Besides, memory is selective and patients continually make choices, conscious and unconscious, about the packets of information to be absorbed and those to be ignored.<sup>4</sup> In particular, patients tend to ignore and suppress infor-

mation that provokes anxiety,<sup>4</sup> a situation that certainly pertains in the setting of cardiac surgery, whereas the opportunity for repetition is scarce in a busy outpatient clinic.<sup>4,25</sup>

Recently, there has been a proliferation of aids to facilitate patients' understanding of the disease process and treatment. On the basis of the present results and those of other studies,<sup>3-5</sup> one of the more promising information and decision-making aids is the consultation audiotape. The Kennedy report<sup>26,27</sup> described the findings of an inquiry into a reported increase in mortality after pediatric cardiac surgery in Bristol, England. Highlighting deficiencies in the consent process, the report recommended that tape-recording facilities should be provided by the National Health Service. However, the Society of Cardiothoracic Surgery of Great Britain and Ireland expressed doubts about the practicability of the proposal,<sup>28</sup> and the United Kingdom Department of Health rejected the recommendation, arguing that such a provision could undermine the relationship of trust between the patient and health care professional.<sup>27</sup>

There may also be a concern that provision of a recording could increase the risk of legal ramifications in the case of an adverse event. We would argue that improving patient information is just as likely to engender greater trust between the physician and patient, which, in turn, might lead to a reduced risk of inappropriate litigation.

Consultation audiotaped recordings offer patients a chance to listen to information that might have been missed during the consultation and refresh their memory; the recordings facilitate understanding of illness and treatment.<sup>3,29-32</sup> They also encourage patients to seek clarification of previously imparted information in subsequent encounters with health care professionals.<sup>3,33</sup>

The addition of an audiotaped recording of an outpatient consultation to written communication significantly increases patients' recall of information and satisfaction level, particularly in elderly patients.<sup>3,5,21,34</sup> However, one study<sup>35</sup> failed to demonstrate a recall benefit from the audiotaped recording of a consultation when compared with a summary letter. In our study, the fact that patients given an audiotaped recording of their consultation performed significantly better on the Knowledge Questionnaire (compared with those given a generic tape or no tape at all) implies the use of the recording improved retention and recall of information.

The purpose of informed consent is to promote patient autonomy by promoting meaningful decision making.<sup>36,37</sup> In recent years, many authors have emphasized that knowledge guides health-related behavior and that this knowledge, in turn, is driven by information.<sup>38</sup> This emphasis has led to a shift in clinical practice to a more patient-centered approach, whereby patients' perspective of their illness and its implications are taken into consideration.<sup>38</sup> Studies<sup>38,39</sup> evaluating cardiac patients' sense of control with regard to their illness have demonstrated that lower levels of perceived control led to negative health effects. In patients undergoing cardiac transplantation, retention of control was positively correlated with optimism, well-being, and satisfaction with life and negatively correlated with anger and depression.<sup>40</sup> Helplessness was related to

deterioration in physical health and an increase in the effect of the disease condition on patients' lives.<sup>38</sup> Asking questions and seeking explanations, which the audiotaped recordings encourage, may constitute part of autonomous authorization for treatment.<sup>15</sup> In our study, patients provided with consultation audiotaped recordings had significantly greater perception of autonomy (internality) and thought they could exert more control with regard to their health, whereas use of the generic tape did not influence the health locus of control when compared with the control group.

This intervention is inexpensive, easy to implement, relatively unobtrusive, and does not significantly alter the duration of the consultation.<sup>3,18</sup> Further studies are required to confirm our findings. It remains to be seen whether the application of this intervention has a similar effect in the setting of interventions other than CABG. It would also be interesting to determine the full extent of additional benefits accruing to patients, the type of patient who may benefit most, and the best way to incorporate audiotaping of outpatient consultations into existing health care systems.<sup>18</sup>

Audiotaping involved 1 consultant surgeon for all patients, whereas consent for surgery was taken by a variety of physicians. Hence, inconsistent information could have been given at the time consent was obtained. The process of audiotaping or participation in the trial itself could have altered patient behavior, affecting the retention and recall of information, although this effect might be expected to be seen in all 3 groups. Trial participants had a variety of sources of information, such as personal communication, literature, or the Internet, although there was no reason to believe this would be more or less of an influence on any of the 3 patient groups. The trial involved a relatively small number of patients.

This study suggests the use of audiotaped recordings could be a useful adjunct in improving the quality of informed consent. Better-informed consent, apart from being a legal requirement, seems to promise several advantages, including decreased levels of anxiety, reduced litigation, readier acceptance of failure, and increased autonomy and self-determination on the part of the patient. The potential disadvantages could be that it is time consuming, could increase anxiety level in some patients, and may reduce the perceived professional influence of the physician.

Further research is required to evaluate the role of audiotaped recordings in communication and informed consent, to confirm our results, and to ensure that the intervention has no adverse effect on any subgroup of patients. It will also be necessary to evaluate the best way to incorporate audiotaping of outpatient consultations into health care systems.

**Accepted for Publication:** May 26, 2009.

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**Author Contributions:** Messrs Mishra and Murday had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Mishra, Math-

ias, Millar, and Murday. *Acquisition of data*: Mishra, Mathias, Nagrajan, and Murday. *Analysis and interpretation of data*: Mishra, Millar, and Murday. *Drafting of the manuscript*: Mishra, Mathias, Millar, Nagrajan, and Murday. *Critical revision of the manuscript for important intellectual content*: Mishra, Millar, and Murday. *Statistical analysis*: Mishra, Millar, and Murday. *Obtained funding*: Mishra, Mathias, and Murday. *Administrative, technical, and material support*: Mishra, Mathias, Nagrajan, and Murday. *Study supervision*: Mishra and Murday. **Financial Disclosure**: None reported. **Previous Presentation**: Presented at the Society of Cardiothoracic Surgeons of Great Britain and Ireland meeting; March 13, 2007; Manchester, England.

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