

Official Title: Assessment of Satisfaction and Experiences in Patients Undergoing Awake
Intubation

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Title of the Study

Assessment of Satisfaction and Experiences in Patients Undergoing Awake Intubation

Rationale for the Study

In patients with known or suspected difficult airways, the risks of hypoxaemia, brain damage and death are higher than in the general population, and awake intubation is the safest method for securing the airway in these patients. (1) Awake fiberoptic intubation is regarded as the gold standard for patients expected to have a difficult airway. During awake fiberoptic intubation, topical anaesthetics or regional anaesthesia are applied to the upper airway. (2) Conscious sedation is administered during the procedure, in addition to topical and regional anaesthesia, to reduce airway reflexes while preserving spontaneous breathing. Short-acting anaesthetic drugs, which can be easily titrated, are ideal for conscious sedation. (3) Patient experiences are important for the development of the awake intubation technique and the improvement of patient care services. Studies in the literature investigate the experiences and satisfaction of patients who have undergone awake intubation. However, due to the small number of participants and the requirement for practitioner experience, the data from these studies are limited. In these studies, patients undergoing conscious intubation reported greater discomfort, sensations of choking, hoarseness, and fear compared to those undergoing traditional intubation methods. Another study noted that maintaining eye contact with patients and providing sufficient information about the procedure were factors that facilitated the process.

Aim of the Study

There is a significant gap in the Turkish literature regarding the satisfaction and experiences of patients undergoing awake intubation. Our hospital is a tertiary referral centre that frequently admits head and neck surgery cases – which are not accepted at many other centres – as well as patients scheduled for various surgical procedures known to involve difficult airways. Where indicated, conscious intubation procedures are routinely performed by experienced academic staff from the Department of Anaesthesiology and Resuscitation. For this reason, we aimed to evaluate the satisfaction and experiences of patients undergoing conscious intubation at our hospital during the postoperative period. We believe that our study will contribute to the scientific literature in our country, to the technique of conscious intubation, and to the development of patient care services.

Research Materials and Methods

Research Location

Department of Anaesthesiology and Resuscitation, Hacettepe University Hospital

Study Population, Sample, and Study Group

The study will include patients aged 18 years and over who have an indication for awake intubation and who consent to participate. Patients with communication difficulties, emergency cases, and those who do not consent will be excluded. Awake intubation is indicated in patients where difficult intubation is anticipated according to the 2022 ASA Difficult Airway Guidelines, and/or where difficult mask ventilation, difficult laryngeal mask placement, high risk of aspiration, or rapid desaturation are expected. The decision regarding awake intubation for patients included in the study will be made by the responsible academic staff member based on the patient's preoperative assessment, independently of the study. Researchers will not be involved in this decision-making process. We plan to recruit a total of 100 patients for the study.

Type of Research

Prospective observational survey study

Research Methodology and Data Collection Tools

Patients who meet the study criteria will be visited on the ward within the first 24 hours of the postoperative period. During this visit, they will receive information about the study.

Informed consent will be obtained from those who agree to participate. Patients will then be asked to complete a questionnaire covering demographic details, socio-economic status, trust in medical staff (8), personality types (9), pre-procedure concerns, their relationship with the healthcare staff performing the procedure, their feelings during the procedure, their level of recall of the procedure, and their post-procedure thoughts (Appendix: Questionnaire Questions). Information regarding the type of sedation administered during the procedure, complications, whether intubation was oral or nasal, and the number of attempts required for intubation will be obtained from the patient's medical records.

Survey on Trust in Healthcare Professionals

The Survey on Trust in Healthcare Professionals, developed by Dugan and colleagues (2005), assesses patients' trust in doctors, the health insurance system, and healthcare professionals.(8) This scale comprises five items and uses a five-point Likert scale (1: strongly disagree, 5: strongly agree). The first item is a negative statement: "Sometimes doctors prioritise what is convenient for themselves over their patients' medical needs," and is reverse-coded. Participants can score between 5 and 25 points, with higher scores indicating greater trust in healthcare staff. The scale's Cronbach's alpha is 0.77.(8) There is no Turkish adaptation of the scale in the literature. For the Turkish adaptation, the scale will first be translated into Turkish independently by an academic specialising in linguistics and a

professional translator. The translated scale will then be administered to 10 individuals to test its comprehensibility. After its application in our study, Cronbach's alpha values will be reported in the statistics section.

Ten-Item Personality Scale

The Ten-Item Personality Scale was developed by Gosling and colleagues (2003).(10) This scale is a seven-point Likert-type measure (1 = strongly disagree, 7 = strongly agree) comprising 10 items designed to assess personality traits. Each of the five distinct personality traits that constitute the scale's sub-dimensions (Extraversion, Agreeableness, Conscientiousness, Emotional Stability, Openness to Experience) is measured by two items. The Turkish adaptation of the scale was carried out by Atak (2013).(11) In the Turkish adaptation, Cronbach's alpha values range from 0.81 to 0.89.(11)

Data Collection

Research data will be collected from face-to-face questionnaire forms and patient records.

Data Analysis

In this prospectively planned study, SPSS 24.0 will be used for recording and statistical analysis of patient data. The conformity of numerical data to a normal distribution will be assessed using the Shapiro-Wilk test. Depending on whether the assumption of normal distribution is met for numerical data, descriptive statistics such as mean and standard deviation or median (minimum–maximum) will be used. Categorical variables will be presented as counts and percentages. For quantitative measurements, the Student's t-test will be applied to independent pairs of groups where normal distribution is met, and the Mann-Whitney U test will be applied to independent pairs of groups where normal distribution is not met. Qualitative measurements will be compared using the chi-square test and Fisher's exact test for independent pairs of groups. For comparisons within dependent groups, the repeated measures t-test, the Wilcoxon test, and the McNemar test for categorical variables will be used. A significance level of $p < 0.05$ has been set for all statistical analyses.

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APPENDIX 1

INFORMED CONSENT FORM FOR RESEARCH PURPOSES

(Physician's Explanation)

We are conducting a research study entitled "Assessment of Patient Satisfaction and Experiences Following Awake Intubation". We invite you to participate in this study with your consent. Before you decide, we will provide you with information about the study. Please read and understand this information; if you wish to participate, please sign the form. We wish to conduct this study to gather information that will help identify areas for improvement, enabling us to provide a more comfortable and pleasant experience for patients undergoing conscious intubation in the future and to develop our skills accordingly. Your participation in this study, conducted by the Department of Anaesthesiology and Resuscitation at Hacettepe University Hospital, is essential to the success of the research. If you agree to take part in the study, you will have a face-to-face consultation with doctor, and your answers will be recorded anonymously. After the consultation, you will be included in the study if your doctor considers it appropriate. You will be asked questions tailored specifically to you, and your answers will be recorded. If you agree to participate, information required for the study may be obtained from your medical records and patient files. Completing the questionnaire will take approximately five minutes. You will not be held responsible for your answers, and your contribution will help ensure a better post-operative period for future patients. You will not be asked to pay any fees to take part in this study, nor will you receive any additional payment for agreeing to participate. We assure you that your personal information will remain confidential. Data collected during the study may be used for scientific publication without disclosing names or identifying details.

You may choose not to participate in this study. Participation in this research is entirely voluntary. You also have the right to withdraw your consent at any stage of the study.

(Patient's Statement)

I was informed by Dr that a medical research study would be conducted at the Department of Anaesthesiology and Resuscitation, Faculty of Medicine, Hacettepe University, and the information above regarding this study was provided to me. After receiving this information, I was invited to participate in the study as a 'participant'. If I agree to take part in this study, I am confident that my personal information will be treated with the utmost care and respect throughout. I have been assured that my personal information

will be carefully protected when the study results are used for educational and scientific purposes.

I assume no financial liability for any expenses incurred in relation to the research. I will not receive any payment.

If I encounter a health issue during the research, I am aware that I can contact the doctor on 05396674959 and the doctor on 05325546801 at any time, as well as the Department of Anaesthesiology and Resuscitation at HÜTF via the provided address and on 03123051265.

I am not obliged to consent to participating in this study and may choose not to do so. I have not been subjected to any coercive behaviour regarding my participation in the study. I am also aware that if I refuse to participate in the study, this will not adversely affect my medical treatment. I have fully understood all the explanations provided to me. After a period of careful consideration, I have decided to participate in this research project as a 'participant'. I accept this invitation with great pleasure and of my own free will. A copy of this signed form will be provided to me.

Participant

First name, surname:

Address:

Tel.

Signature

Witness to the interview

First name, surname:

Address:

Tel.

Signature:

Doctor who interviewed the participant

First name, surname, title:

Address:

Tel.

Signature

APPENDIX 2

DATA COLLECTION FORM

Participant No:

Age:

Gender:

Educational status:

Medical or surgical history:

Do you have a history of conscious intubation? (yes/no)

QUESTIONS ABOUT THE PROCEDURE

Please rate the questions asked of you on a scale from 1 to 5.

General Process

1. How would you rate the conscious intubation procedure you underwent? (1: Very poor, 5: Very good)
2. Do you remember the procedure? (1: I do not remember at all, 5: I remember it completely)
3. If you do remember, does recalling this process cause you distress? (1: Not at all, 5: Very much so)
4. If you were to undergo conscious intubation again, would you agree to it? (1: I would never agree, 5: I would definitely agree)

Pre-Procedure Process

5. Did you have any concerns about the conscious intubation procedure beforehand? (1: None at all, 5: A great deal)
6. If you had any concerns regarding the procedure, to what extent did these concerns compare to those regarding the surgical procedure performed on you? (1: My concerns about conscious intubation were much greater, 5: My concerns about the surgical procedure were much greater)

Staff Relations

7. Did you understand the reason for undergoing conscious intubation? (1: I did not understand at all, 5: I understood completely)
8. How much confidence did the staff performing the procedure inspire in you? (1: Not at all, 5: Very much)
9. How adequate was the information and discussion provided before the procedure? (1: Not at all adequate, 5: Very adequate)

Procedure

10. Did you experience any pain during conscious intubation? (1: No pain at all, 5: A lot of pain)
11. How much did the numbing of your mouth or nose bother you? (1: Not at all, 5: A lot)
12. How much did the passage of the tube through your mouth or nose bother you? (1: Not at all, 5: Very much)
13. How long do you think the procedure lasted? (1: Very short, 5: Very long)
14. Did you feel nauseous during the procedure? (1: Not at all, 5: Very much)
15. Did the number of people in the room bother you? (1: Not at all, 5: Very much)

Post-operative Process

Please answer the questions I have asked with 'yes' or 'no'.

16. Have you experienced any psychological problems, such as sleep disturbances or anxiety disorders, following the procedure?
17. Have you experienced any problems with your voice or speech following the procedure?
18. Did you experience any throat pain following the procedure?
19. Did you experience any breathing difficulties following the procedure?

How would you describe your experience during the conscious intubation procedure? What aspects made you feel comfortable or uncomfortable during the procedure? Do you have any suggestions for improving the process?

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QUESTIONS ABOUT THE PATIENT

Socio-economic Status Questionnaire

Please imagine a staircase representing where people stand in the society in which you live. Those at the top of the ladder have the best of everything (the most money, the best education, the most respected positions, etc.). Those at the bottom of the ladder have the worst conditions (the least money, the least education, the least respected positions, etc.). Being in a higher position on this ladder means you are closer to those at the top; being lower down means you are closer to those at the bottom. Please indicate where you place yourself on this ladder: 1 is the bottom of the ladder, 10 is the top.

Survey on Trust in Medical Staff:

Please rate the following statements on a scale of 1 to 5 (1: Strongly Disagree, 5: Strongly Agree)

1. Sometimes doctors prioritise what suits them rather than their patients' medical needs.
2. Doctors are extremely meticulous and attentive.

3. Doctors' decisions about which medical treatment is best can be fully trusted.
4. A doctor will never mislead you on any matter.
5. Ultimately, doctors are completely trustworthy individuals.

Ten-Item Personality Scale

Below are various personality traits that may or may not describe you. Please indicate on the scale to what extent each trait reflects you. (1 = Strongly Disagree, 7 = Strongly Agree)

1. I see myself as open to new experiences and complex.
2. I see myself as conventional and creative.
3. I see myself as sympathetic and warm.
4. I see myself as critical and argumentative.
5. I see myself as calm and emotionally balanced.
6. I see myself as anxious and easily disappointed.
7. I see myself as reliable and self-disciplined.
8. I see myself as disorganised and careless.
9. I see myself as outgoing and enthusiastic.
10. I see myself as shy and quiet.