

Effect of Informed Consent on Patient's Anxiety Regarding Third Molar Surgery

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ABSTRACT

Objective: To assess mean change in anxiety of a patient undergoing 3rd molar surgery before and after disclosure of information regarding procedure.

Study Design: A descriptive study

Place and Duration of Study: This study was conducted on 50 patients that were presented to the outpatient department of a tertiary care hospital in FUCD between December 2018 to November 2019.

Methods: Patients reporting to OMFS department of FUCD for surgical removal of impacted 3rd molars were selected after history, clinical examination & radiographic evaluation. Informed consent form was given to the patients starting by explaining the brief overview of procedure, benefits and racial complications. Patients were asked to sign the informed consent form. Anxiety of patient after taking informed consent is evaluated by STAI form. The level of anxiety by using STAI on first visit and later again using the STAI on the day of procedure was compared.

Results: A total of 50 patients where 13(26.0) males and 37 (74.0) female patients having mean age (years) 29.00 ± 6.96 were included in the study. Our study finding showed that mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure was 35.06 ± 2.25 and 45.60 ± 2.50 respectively with mean change 10.53 ± 0.25 .

Conclusion: The study concluded that patient experienced anxiety when underwent molar surgery. So there is a need of patient counseling about the procedural risks and associated complications regarding 3rd molar surgery in a sequential manner.

Key Words: Surgical extraction, Anxiety, Impaction

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INTRODUCTION

The significance of a patient-doctor relationship may be highlighted by educating patients about the processes that must be done during any surgery. This enlightenment occurs prior to the actual process. To correct some inconsistencies and malpractices observed

on the part of medical professionals throughout the years, it became important to keep patients aware of the whole process prior to medical operations, as well as gain patients agreement, which all indicate patients being involved in their own medical care.¹

An informed consent is the process of engaging in a dialogue between the patient and healthcare practitioner about a proposed medical treatment, including the nature of the treatment, its potential benefits, harms, and risks, as well as alternative healthcare services to a patient after which they have granted permission, and it includes three critical components: voluntarism, information disclosure, and decision-making capacity.²

Patients must have a thorough understanding of the necessary steps involved in their treatment before the actual procedure. This is crucial both to prevent any discrepancies or malpractices by medical professionals and to involve patients in their own medical care. It provides them with a sense of control, increased confidence, and a feeling of cooperation in the surgical process. Ultimately, informed consent strengthens the bond between patient and doctor, promotes a more positive surgical experience, and improves treatment outcomes.³

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Studies have revealed that patient anxiety levels can be significantly reduced when they are provided with thorough preoperative information. This is essential as anxiety is directly related to the perception and tolerance of pain. Elevated anxiety levels may also impair how well the practitioner performs delicate and complex treatment procedures. Dentists, in particular, prioritize patient comfort and stress reduction, which greatly contributes to the technical superiority of the treatment.⁴

For instance, anxiety is an undesirable psychological experience that provokes tension, sweating, and increased pulse rate. Before any surgical intervention, patients may experience anxiety which affects their overall wellbeing. Hence, it is critical to obtain informed consent to access the anxiety level of a patient before surgery. The surgical extraction of third molars is the most common minor oral surgical procedure performed worldwide; making it a useful model for studying informed consent.⁵

Patients undergoing the surgery experience anxiety and it is essential to provide them with relevant information such as the procedure, its benefits, risks, complications, and alternatives.

However, communicating intricate details about surgical procedures and their potential complications can prove problematic. It can often be challenging to relay complex medical information to patients, which can have negative consequences.⁶ One study found that patients became more anxious when presented with step-by-step information before the surgical removal of impacted third molars. This information typically details the potential unfavorable outcomes of the surgical procedure, such as temporary or permanent nerve damage, infection, dry socket, hemorrhage, trismus, mandible fractures, adjacent tooth damage, and pain. Disclosing this information to patients before surgery can be distressing, thereby increasing anxiety levels^{7,8}.

Therefore, the purpose of this study is to investigate the level of anxiety patients experience before and after being counseled about the procedural risks, associated complications, and alternative management strategies regarding third molar surgery in a sequential manner. This study will help improve the quality of healthcare services by providing patients with adequate information about the procedures and their potential consequences.

METHODS

Patients between the age range of 18-45 years, requiring at least one lower third molar that showed symptoms of mild to severe inflammation or decay and the absence of a prior history of third molar surgery will be considered for inclusion. Whereas patients having systemic diseases or compromised immune systems, pregnant females and those who refuse to participate in

the study were excluded. The research has received ethical approval from the hospital's Ethical Committee. At their first appointment, patients were asked to evaluate their anxiety by completing the Spielberger's State-Trait Anxiety Inventory (STAI) form. The STAI-S is a 20-item self-evaluation questionnaire that analyses transitory emotional states or situations as characterized by subjective emotions of tension and anxiety that can fluctuate in duration and intensity. It is scored using a 4-level frequency scale ranging from 1 to 4 (1 calm, 2 somewhat anxious, 3 fairly anxious, 4 extremely anxious). Informed consent form was given to the patients starting by explaining the brief overview of procedure, benefits and racial complications. Then patient was also informed about following options whether to postpone the extraction or to undergo extraction of 3rd molar. Once the patient was confirmed that they understood the procedure. They were asked to sign the informed consent form. All patients were asked to evaluate their anxiety prior to surgery.

The minimum required sample size ($n=50$) was calculated with by Open Epi collections of epidemiologic calculators, considering a 95% level of confidence, 5% alpha error, 90% study power, Population mean after informed consent=42.46, Population SD after informed consent=7.076.

Results were analyzed using SPSS version 20.0 for quantitative variable like age whereas qualitative variables like gender, education and socioeconomic status (SES) was measured as frequency and percentage. Paired sample t-test was applied to compare pre and post STAI score. Effect modifier like age, gender, SES, education level was controlled by stratification. Post stratification paired sample t-test was applied. P-value <0.05 was considered significant.

RESULTS

Out of 50 patients, 13 (26%) were males and 37 (74%) were females as shown in Fig No 01. Mean age (years) of the patients in this study was 29.00 ± 6.96 . Frequency and percentage of education level was assessed in the study in terms of education (primary, middle, matric, and graduation, post-graduation) and non-education. Majority of the patients have education background, following by 12 (24%) primary education, 10 (20%) middle education whereas there were 11 (22%) patients had no education background. Socio economic status was in the study in terms of frequency and percentage of low ($<20,000$ PKR), middle (20,000-50,000) and upper level ($>50,000$) of socio economic status. Majority of the patients 37 (74.0) belonged from low income status and 12 (24.0) patients belong to middle income status (20,000-50,000), as shown in Table 1.

The objective of the study was to assess mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure. Our study finding showed that mean change in anxiety

of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure was 35.06 ± 2.25 and 45.60 ± 2.50 respectively with mean change 10.53 ± 0.25 , as shown in Table. No.02.

Table No.1: Descriptive statistics of Demographic data.

Variable		Frequency	Percentage %	Mean age 29 ± 6.96
Gender	Male	13	26.0%	
	Female	37	74.0%	
	Total	50	100%	
Education level	Uneducated	11	22.0%	
	Primary	12	24.0%	
	Middle	10	20.0%	
	Matric	8	16.0%	
	Graduated	8	16.0%	
	Post graduate	1	2.0%	
	Total	50	100%	
Socio-Economic status	Lower class	37	74.0%	
	Middle class	12	24.0%	
	Upper class	1	2.0%	
	Total	50	100%	

Effect modifier like age was stratified and compared with mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure. Among patient with age 31 – 45 years, mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure was 35.09 ± 1.9 and 45.44 ± 2.13 respectively with mean change 10.35 ± 2.11 . Effect modifier like gender was stratified and compared with mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding 3rd molar surgery and after disclosure of information regarding procedure was 35.03 ± 2.59 and 45.78 ± 2.92 respectively with mean change 10.74 ± 2.14 .

Effect modifier like education level was stratified and compared with mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure. Among patients who have primary education background, mean change in anxiety of patient undergoing 3rd molar surgery and after disclosure of information regarding procedure was 35.10 ± 2.01 and 45.16 ± 2.82 respectively with mean change 10.35 ± 2.04 , as shown in Table. No.3.

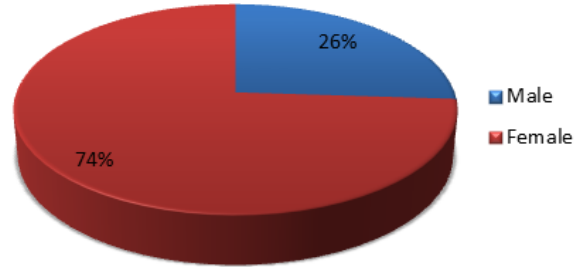


Figure No. 1: Pie Chart of Gender Distribution.

Table No.2: Descriptive statistics of STAI-S scale (before and after).

	N	Min.	Max.	Mean	Std. Deviation
STAI scale (before)	50	30.20	40.20	35.06	2.25
STAI scale (after)	50	38.00	49.00	45.60	2.50
Anxiety (STAI scale score)	before	after	mean change	p-value	
	35.06±2.25	45.60±2.50	10.53±0.25	0.000	

Table No.3: Demographic data stratification with comparison of mean change in anxiety of a patient undergoing 3rd molar surgery before and after disclosure of information regarding procedure.

Variable	Anxiety (STAI scale score)			p-value	
	Before	After	Mean change		
Age	18-30years	35.09 ± 1.97	45.44 ± 2.13	10.35 ± 2.11	0.000
	31-45years	35.03 ± 2.59	45.78 ± 2.92	10.74 ± 2.14	0.000
Gender	Male	35.03 ± 2.59	45.78 ± 2.92	10.74 ± 2.14	0.000
	Female	35.10 ± 2.25	45.51 ± 2.39	10.41 ± 2.07	0.000
Education level	Uneducated	35.48 ± 2.56	45.00 ± 3.16	9.51 ± 2.56	0.000
	Primary	35.10 ± 2.01	45.16 ± 2.82	10.05 ± 2.04	0.000
	Middle	34.17 ± 2.70	45.70 ± 1.88	11.53 ± 2.31	0.000
	Matric	35.10 ± 1.47	4.37 ± 1.40	11.27 ± 1.08	0.000
	Graduation	35.91 ± 2.17	46.75 ± 2.12	10.83 ± 1.64	0.000
	Post-graduation	35.82 ± 2.02	45.21 ± 2.30	9.39 ± 0.28	0.000
	Socio-Economic status	Low	35.24 ± 2.15	45.86 ± 2.28	10.61 ± 1.84
Middle	34.33 ± 2.53	44.66 ± 3.08	10.33 ± 2.94	0.000	
Upper	34.29 ± 2.24	44.59 ± 3.12	10.30 ± 0.88	0.000	

DISCUSSION

There is a belief that providing patients with detailed information about their treatment could exacerbate their anxiety and lead to a reluctance to undergo the procedure. Conversely, studies have shown that doctor-patient communication fosters a collaborative relationship and can help alleviate anxiety. However, it is important to note that this communication can have a reciprocal effect, where the doctor can be influenced by the patient's anxiety and vice versa. Thus, the purpose of this study was to assess how an informed consent protocol impacts patient anxiety levels.⁹

Informed consent is crucial for clinical practice. It is still primarily a legal and ethical concept. The key consideration in any informed consent is its substance. By content, we mean the informed consent's material, which must always transmit two sorts of information. The first type is the therapy or operation that the patient will get. In other words, the patient is educated about the various stages of the procedure: pre, intra, and postoperative. The second piece of information is on the feelings that the patient is likely to have: pain, somnolence, stiffness, and so on. The importance of risks disclosure in the informed consent process cannot be overstated, as it is necessary to highlight potential adverse effects and avoid medical malpractice litigation cases.¹⁰

It has been shown that the efficacy of informative procedures is heavily influenced by patients' attitudes. The information provided has been shown to have positive effects on those who try to overcome stressful situations by gathering as much information as possible about them, but it may have negative effects on "avoidant" patients (those who reject all information in order to overcome anxiety by not thinking about the problem).¹¹

Patients appear to be more interested in information related to benefits and post-procedure complications than risks, which are more important from an ethical standpoint. The study's findings showed a mean change in anxiety levels of 35.06 ± 2.25 and 45.60 ± 2.50 before and after disclosing information regarding the procedure. Casap et al.¹² the influence of informed consent on stress levels linked with the removal of impacted mandibular third molars was evaluated. They discovered that presenting excessively thorough lists and disclosures prior to excision of impacted mandibular third teeth might enhance patient anxiety. Another study reported a mean change in anxiety levels of 36.6 and 42.4 before and after information disclosure regarding the procedure.¹³⁻¹⁵

Overall, the informed consent process is a critical component of any surgical procedure. However, it is essential to recognize the potential anxiety-inducing nature of this process and to take steps to alleviate patient anxiety in the hours and days leading up to the procedure. Vigilant patients who seek out information benefit more from the informed consent process. The

timing of information disclosure may not be as critical as once thought and patients appear to be more interested in benefits-related information than risks.¹⁴⁻²⁰

This study has several limitations. First, the sample was selected from a single local hospital. The patients included in this research were relatively young, which may have caused a selection bias. The representativeness of the sample might be restricted, and our results may have poor generalizability. Secondly, the exposure and outcome variables were collected through self-completed questionnaires, which may not accurately reflect the situation. For sample selection, it would have been ideal to conduct the study in a multicenter setting. Finally, no postoperative pain evaluation technique was intended for this study, and grading surgical difficulties in connection to anxiety level was not addressed.

CONCLUSION

The study concluded that patient experienced anxiety when underwent molar surgery. So there is a need of patient counseling about the procedural risks and associated complications regarding 3rd molar surgery in a sequential manner. Indeed, the informed consent form itself was a major contributor to elevate patient anxiety. The presentation of detailed information and nonsurgical treatment options might dissuade patients from undergoing extractions.

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