ORIGINAL ARTICLE

Impact of informed consent on patient decisions regarding third molar removal

G Göçmen, O Atalı, O Gonul, K Goker

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Marmara University, Istanbul, Turkey

Abstract

Purpose: We investigated whether the order in which patients learned about complication risks affected their anxiety about and willingness to undergo the removal of their third molar.

Materials and Methods: In total, 171 patients (65 males, 106 females) were included in the study. The distributions of gender and the position of mandibular third molars were recorded. The Amsterdam Preoperative Anxiety and Information Scale and Spielberger's State–Trait Anxiety Inventory were used to evaluate anxiety. Associations of anxiety with timing (pre/post), gender, and the order in which the information was presented in the consent form were analyzed.

Results: The most common angulations were horizontal (26.3%) and mesioangular (60.2%), and these were more common in women. All patients obtained significantly higher anxiety scores after reading the consent form. There was no significant difference in anxiety scores, according to the order of information. In total, 88 patients underwent surgery, whereas 83 postponed the extraction after reading the consent form. Women were significantly more anxious than men before the procedure. Patients showed lower anxiety levels after the procedure ($P < 0.05$).

Conclusion: Increased anxiety was not associated with the order in which information was presented in the informed consent form. However, the informed consent form itself was a major contributor to increased patient anxiety. Further studies regarding the contents of consent forms and their effects on patient anxiety and decisions regarding third molar removal are needed.

Key words: Anxiety, informed consent, third molar extraction

Date of Acceptance: 22-Jun-2015

Introduction

Informed consent is a basic right held by patients. It involves information about diagnosis, prognosis, purpose of treatment, benefits, associated risks, possible alternative treatments, and the option and effects of no treatment.[1] Disclosure of sufficient information in a way that is understandable to the patient is central to the ability to grant informed consent. A verbal explanation is necessary if the patient asks for additional information. However, the provision of detailed information about every potential risk and complication might affect patients' decision-making process.

In general, informed consent forms involve common expressions of probability and present lists of complications as open-ended disclosures. These statements might have different meanings to different people at different times.[2] Indeed, the content of disclosures may be in the form of medical jargon and cause misunderstandings. Given the potential of a series of postoperative complications and risks after the surgical extraction of mandibular third molars, it is possible that the informed consent form for this surgical procedure may lead to misunderstandings, misinterpretations, and manipulation.[3]

The purpose of this study was to investigate whether patients' anxiety about and willingness to undergo a procedure to remove their third molar were influenced

Address for correspondence:
Dr. G Göçmen,
Department of Oral and Maxillofacial Surgery,
Faculty of Dentistry, Marmara University, Buyuk Ciftlik Sk.
No: 6, 34365 Sisli, Istanbul, Turkey.
E-mail: gocmengokhan@hotmail.com

Access this article online

Quick Response Code:

Website: www.njcponline.com

DOI: 10.4103/1119-3077.164354

by the order in which they learned about complication risks. We hypothesized that information and the order in which information about risks in particular appeared in the informed consent form would affect the judgments and the anxiety of patients and that the informed consent form would affect patients' decisions about the removal of their third molar.

Materials and Methods

This study enrolled 171 patients at the Department of Oral and Maxillofacial Surgery of the Dentistry Faculty, Marmara University, Istanbul, Turkey between 2013 and 2014. Criteria for inclusion were having 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. The only exclusion criterion was refusal to participate. This research was approved by the Clinical Research Ethics Committee (No. 10840098-55) and was performed in compliance with the World Medical Association Declaration of Helsinki as it relates to medical research protocols and ethics.

At their first appointment, patients were asked to evaluate their anxiety by completing the Amsterdam Preoperative Anxiety and Information Scale (APAIS) and Spielberger's State–Trait Anxiety Inventory (STAI).[4,5] We used the 20-question state anxiety component of the STAI (s-anxiety) (range: 20–80) and the four questions addressing surgery and the desire for information on the APAIS (range: 4–20). Then, the position of the tooth was explained to the patients. Angulations were recorded according to the combination of Winter's and the Pell–Gregory classification.[6] The inclination of the third molar to the long axis of the second molar was classified as mesioangular, distoangular, horizontal, vertical, and buccal-lingual obliquity. The level of impaction was classified according to the Pell–Gregory classification, from which only the relationship with the level of the second molar classification (A, B, and C) was used[7] [Table 1].

Two informed consent forms (groups A, B) presented information in a different order. The form for group A started by explaining the background, benefits, and potential complications of third molar surgery. This was followed by the presentation of the following options: (1) Postpone the extraction, (2) undergo a coronectomy procedure, and (3) undergo extraction of the tooth (accompanied by a description of all possible complications). The consent form for group B initially presented the options and the associated risks, benefits, and general information. It had the same content as the form used for group A, but it presented it in a different order. This step was followed by confirmation of the initially chosen treatment option. Dysesthesia, trismus, edema, pain, and infection risks in the area were explained in detail using the nontechnical terminology. Once the patients confirmed that they understood the procedure and the possible risks that were presented in the written form, they were asked to sign the informed consent form. Patients were randomly assigned to group A or B [Figure 1].

Patients who refused extraction, any particular treatment, or asked whether it was possible to perform symptomatic treatments for caries or local periodontal disease rather than extraction were counted as having postponed the extraction. Patients accepting the removal of the clinical crown and leaving the roots were admitted to the coronectomy procedure. Then, appointments were scheduled for the patients who wanted to undergo extractions or who opted for coronectomies.

All patients were asked to evaluate their anxiety prior to surgery. Patients who had the tooth removed or underwent coronectomies were asked to complete the STAI only once more to compare pre- and post-operative anxiety 1-week after surgery.

Results were analyzed using SPSS software (version 12.0; SPSS Inc., Chicago, IL, USA). The Chi-square test, one-way analysis of variance, and paired-sample *t*-tests were used to assess differences among patients. Results were considered statistically significant when $P < 0.05$.

Results

In total, 171 patients were included in this study. The most common angulations were mesioangular (60.2%) and horizontal (26.3%). The distribution of the mesioangular angulation of impaction in the mandible differed significantly in men and women ($P < 0.05$). The mesioangular position was more common in women than in men. There were no significant sex differences in the frequency of the other angulation types of impaction. The most common level of impaction was level B (63.1%). There were no significant sex differences between levels B and C in the mandible [$P = 0.79$; Table 1].

There were no significant differences in the anxiety scores of groups A and B. The APAIS and s-anxiety scores of men and women in both groups A and B reflected strong significant differences ($P < 0.05$). The scores of the women indicated that they were significantly more anxious than were the men before the procedure. All patients showed a significant difference in their anxiety scores after reading the consent form [$P < 0.05$; Table 2].

Of the 171 patients, 12 patients underwent coronectomies, 76 had the tooth extracted, and 83 postponed the extraction. Comparison of s-anxiety levels 1-week after surgery showed a statistically significant difference. Patients

Table 1: Distribution of sex, age, and position of third molars in chosen treatment options

	Gender		Mean age		Angulation										Level					
					Horizontal		Mesio-angular		Vertical		Disto-angular		Buccal-lingual		A		B		C	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Postpone and follow-up	28	55	25.9	23.2	10	7	11	23	1	1	0	2	0	1	0	0	26	32	12	26
	83		24.5		17		34		2		2		1		0		58		38	
Extraction	32	44	24	25.8	14	12	21	41	3	5	2	4	1	0	1	5	17	30	4	6
	76		24.9		26		62		8		6		1		6		47		10	
Coronectomy	5	7	25.5	28.4	0	2	2	5	1	2	0	0			0	0	1	2	4	5
	12		26.9		2		7		3		0		0		0		3		9	
Total	65	106	25.1	25.8	24	21	34	69	5	8	2	6	0	2	1	5	44	64	20	37
	171		25.4		45		103		13		8		2		6		108		57	
P					>0.05		<0.05		>0.05		>0.05		>0.05		>0.05		>0.05		>0.05	

Table 2: Correlation of anxiety levels with sex and timing of the consent form

				Before procedure								Postoperative		
Groups	s-anxiety mean (SD)	APAIS mean (SD)	*t*-test	Patients	s-anxiety mean (SD)	APAIS mean (SD)	*t*-test	Consent form	s-anxiety mean (SD)	APAIS mean (SD)	*t*-test	Patients	s-anxiety mean (SD)	*t*-test (pre-post)
A (*n*: 85)	46.06 (8.8)	14.7 (4.4)	>0.05	Male (*n* :35)	42.4 (7.07)	12.7 (4.07)	<0.05	Before	36.6 (6.9)	8.5 (4.3)	<0.05	Male (*n*: 21)	37.8 (6.4)	<0.05
								After	42.4 (7.07)	12.7 (4.07)			32.9 (6)	
				Female (*n*: 51)	48.5 (9.1)	16.1 (4.1)		Before	44.3 (9.6)	10.8 (5.7)	<0.05	Female (*n*: 31)	43.6 (8.1)	<0.05
B (*n*: 86)	46.09 (10.6)	14.9 (5.1)		Male (*n*: 30)	41.3 (9.9)	12.2 (4.3)	<0.05	Before	37.9 (9.2)	8.6 (4.9)	<0.05	Male (*n*: 16)	36.9 (8.8)	<0.05
								After	41.3 (9.9)	12.2 (4.3)			30.7 (9.3)	
				Female (*n*: 55)	49.01 (10.1)	16.4 (5.01)		Before	45 3 (10.3)	9.8 (5.07)	<0.05	Female (*n*: 20)	46.3 (9.2)	<0.05
								After	49.01 (10.1)	16.4 (5.01)			37.4 (7.1)	

SD=Standard deviation; APAIS= Amsterdam Preoperative Anxiety and Information Scale

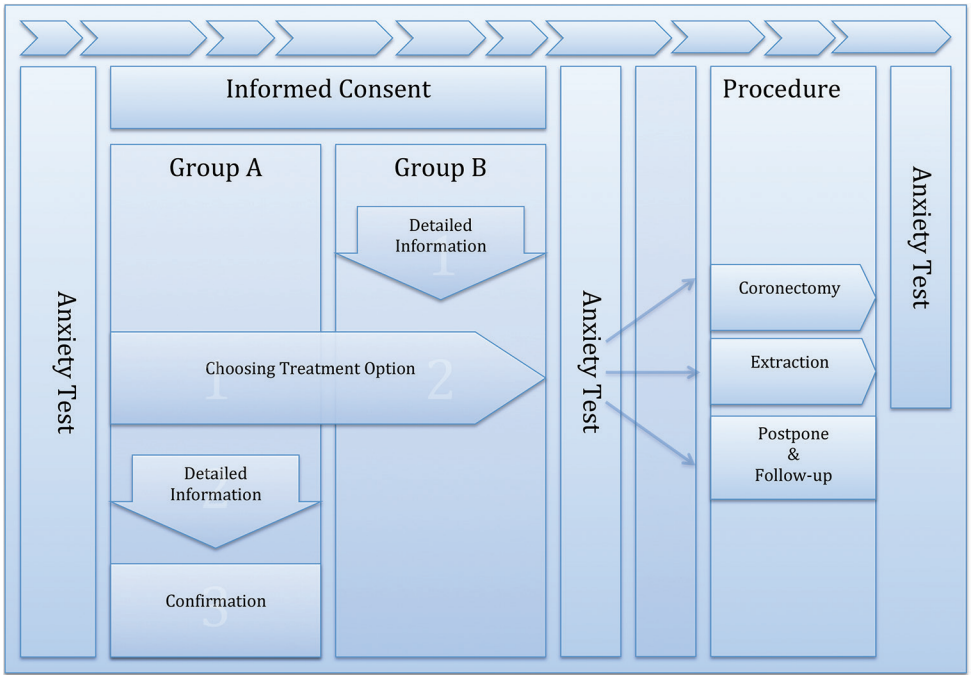

Figure 1: Scheme of study protocol

showed less anxiety after the procedure ($P < 0.05$). There were no significant differences in the anxiety scores of males and females after the procedure [Table 1].

Discussion

It is commonly said that telling patients about their treatment may increase their anxiety and may eventually dissuade them from undergoing treatment.[8] However, it is also known that conversations about medical procedures initiate a collaboration between patients and practitioners. Some studies have indicated that doctor–patient communication is the best way to relieve the patient's anxiety, but the doctor might affect the patient or be affected by the patient's anxiety.[9] The aim of this study was to evaluate the effect of the informed consent protocol on patient anxiety.

A conversation about the procedure and the way in which the patient understands it is critical to the final decision of the patient. It is easy to manipulate and abuse this process. The current literature includes various methods (oral, written, video) to enhance the informed consent process. However, there is still no consensus about the presentation of the informed consent form. An cochrane review update reported that the value of audio–visual interventions as a tool to explain consent forms remains largely unclear.[10] Written statements appear to be the best option to prevent the patient from being affected by the doctor's statements, but confirmation that all the information in written statements is understood remains necessary. However, there is also evidence that many patients do not absorb information during stressful situations and that a better quality of informed consent can be obtained by combining oral and written information.[11] In addition, dealing with an informed consent form immediately prior to the intervention might provoke patient anxiety. Reading all the details in the informed consent form just before a procedure may lead patients to think that they should ignore all the critical information about the operation. Layton and Korsen[12] reported that it seemed to make no difference whether this information was given to the patient a week before, at a preadmission clinic, or on admission day. Our study evaluated the effect of the order of the information presented in the consent form rather than the method used to present it or its format, and all patients were asked to read the informed consent form at least 1-week prior to admission for the surgical intervention.

Information has positive effects on "vigilant" patients (those who overcome stressful situations by obtaining as much information as possible about the origin of the stress) but not on "avoidant" ones (those who reject information and try not to think about what is going to happen).[2] In our study, patients reported higher anxiety levels after reading the detailed informed consent form, and half postponed the surgical intervention. The provision of detailed information about extraction and the presentation of conventional treatment options that can be chosen instead of prophylactic extractions might have led patients to consider the conventional options more reasonable and less painful. In addition, our inclusion of patients complaining of mild symptoms and offering them the possibility of symptomatic treatments of the caries or local periodontal disease rather than an extraction may have led to numerous postponements. Likewise, Casap *et al.*[8] evaluated the effect

of informed consent on the stress levels associated with the removal of impacted mandibular third molars. They reported that the presentation of excessively detailed lists and disclosures before extraction of impacted mandibular third molars can increase patient stress.

Standardization of an informed consent protocol is essential for accomplishing the objective of such documents. Anxiety may affect not only the patient but also the operating surgeon. The initial delivery of the consent form to the patient should be performed by someone other than the operating surgeon, who might be influenced by patient anxiety and might not provide the "right" explanation, as judged by patient reactions. However, the surgeon should address grey areas in and answer questions about information in the consent form to satisfy and establish a collaborative relationship with the patient. Torres-Lagares *et al.*[13] proposed that informed consent should be obtained through a mixed format (oral/written), which would also facilitate contact between the patient and physician. In our study, the operating surgeon provided verbal explanations in response to questions after the initial delivery of the consent form.

Conclusion

Increased anxiety was not associated with the order in which the information in the informed consent form was presented. Indeed, the informed consent form itself was a major contributor to increased patient anxiety. The presentation of detailed information and nonsurgical treatment options might dissuade patients from undergoing extractions. Additional studies regarding the effects of presenting treatment alternatives and detailed information in the written consent form on patient anxiety and decisions regarding third molar removal are needed.

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How to cite this article: Göçmen G, Atalı O, Gonul O, Goker K. Impact of informed consent on patient decisions regarding third molar removal. Niger J Clin Pract 2017;20:158-62.

Source of Support: Nil, **Conflict of Interest:** None declared.