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RESEARCH ARTICLE

Informed Consent In a Dental Outreach Program -What patients want to know before their dental treatment?

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Abstract

Background: Before providing care or treatment to a patient, the dentist must obtain the individual's informed consent. This requirement is based on two principles: personal inviolability and free will. Early determination of issues important to patients could therefore be the first step towards provision of an effective and meaningful care.

Methods: This is a cross-sectional study to determine what patients really want to know when dental treatment was advised to them in the outreach programs conducted by Manipal College of Dental Sciences, Mangalore in Mangalore city. A convenient sample of 140 subjects was selected for the study. A self-assessment questionnaire of Dawes which was modified was used for the study. The assessment of pre-operative anxiety of patients presenting to the outreach program is assessed with Modified Dental Anxiety Scale.

Results: A total of 131 respondents answered the questionnaire with a response rate of more than 90 percent out of which, 39 % were male respondents. Majority of the patients knew about the informed consent (93%) and thought it was a legal document (74.8%), with the mean anxiety score of 9.31. There was significant association between levels of knowledge and anxiety scores in individual (P= 0.23) and difference between knowledge between different socioeconomic status and knowledge (p= 0.01).

Conclusion: This study explores a very vital link in the treatment of patients, the results demonstrate that there is substantial void in the knowledge of patients attending dental outreach program in Mangalore.

Introduction

Progress in medicine and information technologies have enabled patients to be better informed about all aspects of healthcare. Increasingly, they are more likely to question their doctors, dentists, and other healthcare professionals and to express their different points of view, in order to understand their diseases and/or conditions. (Avramova N *et al.*, 2011)

In this turbulent environment of changing health care delivery structures, and with new decisions involving genetic medicine on the horizon, informed consent will be a critical element in the provision of appropriate treatment information and quality medical decision making.(Bottrell MM *et al.*,2000) Informed consent is a process by which a person about to undergo a procedure agrees to proceed based on a clear understanding of what the procedure entails, the alternative treatments that are available, and the possible consequences that may occur. This decision involves the patient having been provided with sufficient information and adequate time for its consideration. (Degerliyurt K *et al.*,2010). There are many definitions of informed consent and it is difficult to concisely define the concept of consent to dental treatment as it is not a simple agreement to treatment. Lord Diplock, described medical consent as 'a state of mind personal to the patient whereby he agrees to the violation of his bodily integrity' (Corless-Smith D,2000).Of the many definitions of consent the one provided by the US Department of Health, Education, & Welfare (DHEW) which defines. “Informed consent as a means of knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion”. (Federal Register, 1975.)

The concept of informed consent evolved from battery, which is the unauthorized touching of another person. A landmark case from New York in 1914 laid the foundation for informed consent, stating: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.” In the Schoendorff vs. Society of NY Hospital (Schoendorff. Nd) formed the core foundation of informed consent.

In order to achieve an ethically valid consent three requirements must be satisfied:

1. ***Patient must be competent to consent to treatment.***
2. ***Patient must have sufficient knowledge of the proposed treatment and its alternatives.***
3. ***Patient must voluntarily agree to the treatment without undue influence.*** (Corless-Smith D,2000)

Although informed consent is basic right of a patient it is often taken for granted that most patients are contented to follow their physician advises, informing patients about their treatment serves to increase their anxiety and may even deter them from undergoing therapy. Minimal knowledge is available as to determine either what patients want to know or their attitude about informed consent. The challenge for the clinician is to adequately explain the risks and benefits of an intervention without disproportionately increasing the patient’s anxiety. As there is an ethical and legal requirement to obtain informed consent before treatment, patients who do not want information about complications must participate in a discussion concerning the risks and benefits of an intervention, as well as the expected outcomes of treatment before they can legally consent to a procedure. The patients who want information about all the complications must not be given so many details that it causes anxiety and/or confusion that interferes with considered and unencumbered decision making. (Degerliyurt K *et al.*,2010)

If dentists know the issues important to their patients, they may be able to endorse this knowledge, incorporate it into their management plan and provide care that is more meaningful. Early determination of issues important to patients could therefore be the first step towards provision of an effective and meaningful care. Hence this study was designed with the objectives as to determine what patients really want to know when dental treatment is advised to them and to assess their attitudes and opinions towards the informed consent forms provided to them and as to any relation exists between the anxiety and their opinion regarding the informed consent. (dentalprotection.org,2013).

Materials and Methods

This is a cross-sectional study to determine what patients really want to know when dental treatment was advised to them in the outreach programs conducted by Manipal College of Dental Sciences, Mangalore in Mangalore city. The Manipal College of Dental Sciences conducts outreach programs in both the rural and urban areas in the city of Mangalore as part of its commitment towards the greater good of the society and all the treatment offered in the outreach program is done for free. The study was conducted in a stipulated period from December 2011- July 2012,

All the patients attending the outreach programs in the selected period and fulfilling the inclusion criteria were invited to participate in the study. Ethical committee clearance was obtained from the institutional ethical committee of Manipal College of Dental Sciences, Mangalore prior to the study process. Informed consent is obtained from the subjects prior to distribution of questionnaire. The patients who were willing to participate in the study and who could read and understand English and /or the local language Kannada were included in the study. Despite an extensive search of literature, a previously validated questionnaire that would adequately assess our objective of determining issues important for dental patients in an outreach setting was unavailable.

The questionnaire had basically three parts the first part included demographic details , the second part consisted a questionnaire of Dawes (Dawes PJD et al ., 1994) which is modified as to suit the treatment options in dentistry regarding the information, The patients were first given an informed consent form and then the questionnaire. This form was also written in both languages- English and Kannada. It stated the nature and objective of the study with a clear statement that participation or refusal to participate would not affect their rights of care in any form. If they refused, they were excluded from the study. The questionnaire was handed to those who agreed to sign the consent form. The participants were required to fill questionnaires before starting their consultation with the dentist. The third part of the questionnaire was the assessment of pre-operative anxiety with Modified Dental

Anxiety Scale. (Humphris GM et al., 2000)The socio economic status of the patients was established by Modified Kuppuswamy scale. (Kumar N et al., 2012)

A pilot study was performed to determine the quality of the questionnaire. This pilot study contained 31 completed questionnaires. The findings from the pilot study were that the instructions on answering the questionnaire were not uniform. Therefore, the instructions were modified, and the open-ended questions were eliminated so as to bring about a valid response. The questionnaire was constructed and administered in English and was translated into the local language (Kannada) using appropriate and simple words. For validation the questionnaire was translated back into English. The interval between the test and retest ranged from 3 to 18 days. Kappa values for test-retest of the questionnaire ranged from 0.85. The process of the informed consent interview and answering the questionnaire was standardized. A single instructor would conduct the informed consent interview. The information was given in particular order and the subjects had an opportunity to ask for clarification during the entire interview. Immediately after the interview, the patient was requested to answer the questionnaire. If a question was ambiguous, the patient had the opportunity to ask for clarification.

Results

All of 131 subjects responded to the questionnaire. There were 51 (38.9 %) males and 80 (61.1 %) were females. The average age of the patients was 37.40 years (±14.53), ranging from a minimum of 18 years to a maximum of 82 years, of all the respondents 57 (43.5%) were semi-skilled workers, 40(30.5%) were skilled workers. The average monthly income of the participants was Rs 5814.09 (±1008), expectedly one hundred fourteen (87%) respondents were of lower social strata, (table 1)

Anxiety score

The mean anxiety scores were 9.13 (4.70) as assessed by the MDA scale. The preoperative anxiety scores differed variably between the different socioeconomic strata's with highest anxiety scores observed in the middle income category 11.13 (6.66) than the lower income category which was 8.85 (4.31) and the difference among these observations were statistically significant (Table 2). However, there is a significant association with preoperative anxiety and subjects who thought information given to them was inadequate ($P< 0.05$) and 62 (47.3%) ($P< 0.05$) subjects admitted that the information given to them either increased their worry so as to not take the treatment, the subjects who were highly anxious were the ones who did not want to know about the complications of the procedure.

33 (25.2) People did not know of the informed consent, more than 53% of the sample just wanted to do what the dentist told without knowing what treatment was involved, and only 13 people (10%) wanted to get treatment after agreeing pros and cons of the treatment. 79.2% of the sample who did not want to know of their treatment were of lesser anxiety than the people who wanted to know of their complete treatment the difference of which was statistically significant. Most of the patients just wanted to know the nature of their illness, and only 8 (6.1) patients wanted to know all of their complications.58.8% people either did not now that they can or could change the decisions after signing the informed consent. There was a great urban and rural divide when asked the significance of signing the forms 28 (69.5%) urban population did not know the significance of informed consent form which was statistically significant.

Table 1: Demographic Details of the study participants.

Gender	Male 51(38.9%)	Female 80(61.1%)
Occupation	Unemployed	3(2.3%)
	Unskilled worker	40(30.5%)
	Semi-skilled worker	57(43.5%)
	Skilled worker	25(19.1%)
	Professional	6(4.6%)
Socio Economic status	lower class	114 (87%)
	Middle class	16(12.2%)
	Higher middle class	1(0.8%)
Location	Urban	41(31.3%)
	Rural	90 (68.7%)

Mean anxiety		
	lower class (114)	8.85(SD4.3)
	middle class(16)	11.43(6.6)

Table 2: Association between socio economic status and anxiety .

Socio Economic Status	Number	Mean	Standard Deviation	
Lower Class	114	8.85	4.31	P= 0.003
Middle Class	16	11.43	6.66	

Table 3: Significance of Anxiety and Satisfaction about the information provided before treatment.

	Anxiety Scores					Total	
	1	2	3	4	5		
Too much information (Number)	6	4	4	0	3	17	P=0.03
% within group	12.5%	13.8%	12.1%	.0%	27.3%	13.0%	
Just the right amount(Number)	40	24	25	10	6	105	
% within group	83.3%	82.8%	75.8%	100.0%	54.5%	80.2%	
Too little information (Number)	1	0	4	0	0	5	
% within group	2.1%	.0%	12.1%	.0%	.0%	3.8%	
Don't know(Number)	1	1	0	0	2	4	
% within group	2.1%	3.4%	.0%	.0%	18.2%	3.1%	
Number	48	29	33	10	11	131	
% over all within group	36.6%	22.1%	25.2%	7.6%	8.4%	100.0%	

Discussion

The informed consent was propagated as early as 1917 in the case of Schloendorf vs. Society of New York Hospital and was the setting stone for the great Nuremberg Code (1947) which was established as a result of inhuman practises by the Nazi scientist who coerced the prisoners into participating in experiments who did not willingly volunteer. These experiments resulted in death, mutilation or permanent affliction of the subjects which were illustrations of medical torture. This led to a multitude of voices that vouched informed consent as the only way to assure autonomy of the patients.

Informed consent for treatment is only valid if the individual has capacity to consent at the time of treatment. It is conjectured that all adults have the capacity to consent unless otherwise proven. The main barrier for obtaining an informed consent is the lack of objective measures or tests, numeric or otherwise to determine if an individual has capacity ("capacity" is used in informed consent rather than the term "competence" although the two are often synonymously used, because the latter often refers to a legal determination made by a court, and the former refers to a clinical judgment) (Appelbaum PS , 2007) and specifically to consent at the time of treatment. The point being capacity is a judgement of an individual's ability to understand the consequences and nature of a specific decision which is subjective and can vary in the same individual at differing times. The present study focussed on what patient actually wants to know before consenting for the treatment and factors associated with the same. There are several factors effecting informed consent starting from age of the patients, the level of anxiety, comprehension and knowledge of treatment (health literacy).

The present study was an unique one that it was done in the outreach programmes in the rural and semi urban areas which forms the soul of any developing country. The subjects were from varied socioeconomic status, varied educational background. The mean age of the subjects was 37.4 years with an average monthly income of Rs 5814.09 (79 USD) at the time of the data collection. The majority of subjects who attended these camps from a lower socioeconomic stratum as the dental outreach programs offer free dental care. Many studies (Vashisth S et al., 2012. Devaraj CG et al., 2011, Cohen LA et al., 2011) have dwelled into this facet but the socio economic characteristics of the groups attending dental outreach program remains unclear .The preoperative dental anxiety scores were higher in the middle income category than the lower income category. the attitude towards information provided to the patients 47% of respondents thought that the information provoked anxiety of which made them resist treatment antithetical to the scores for dental anxiety which showed that patients who thought that the information was inadequate had an higher rate of anxiety. No studies were obtained regarding dental anxiety and informed consent was obtained but studies done on informed consent in gynaecological surgery, (Antrobus JH, 1988).diagnostic cardiac electrophysiological studies (Goldberger JJ et al., 1997), showed higher anxiety after the information and related complication was informed to them. this according to As informing about the procedure and related complication might prove to provoke anxiety Jawaid et al in surgery might be owing to the fact that Preoperative anxiety is related to fear of the unknown, unfamiliar place, loss of control of situation, and fear of death. The outcomes of our study in relation to pre operative anxiety were similar to studies conducted by Gillies et al and Bondy LR, but contrary to that of Kiyohara LY et al and Jawaid et al who proposed that anxiety was reduced in patients who had prior information as 'anxiety' by definition is fear of unknown. (Bondy LR et al . 1999, Gillies et al.,2001, Jawaid M et al 2007)

When asked about informed consent more than 33(25%) did not know what informed consent was and they signed the form just as any other document, and when asked about what they felt for alternative treatment 70 (53.4) told that they just follow what the dentist. The legality of consent should be highly appreciated here as courts in Europe consider violating consent as battery (Battery is a criminal offense involving unlawful physical contact David Corless-Smith). Which were similar to studies of Dawes et al, Cassileth et al, (Dawes PJD et al., 1994)
Most of the subjects feel that the informed consent is just a formality and a small but significant number of subjects feel that it protects doctors from being sued , there is an analogy in these statements as according to lawal et al and Irabor et al .(Irabor et al)(Lawal Y Z et a., 2011)most patients feel that signing the form will mitigate the doctors from their duty towards the patients and reverts all the burden back on the patients, this shows a lack of knowledge on the part of the subjects as informed consent is meant to protect patients interests not antagonistically.

When inquired what they wanted to know before a dental surgery most of the patients (44.2%) wanted to know just nature of illness and treatment, six percent subjects wanted to know just important complication and only 8(6.1%) subjects wanted to know all potential complications which interestingly points out to the fact that most of the patients avoid knowing the potential complications as it might inflate their level of anxiety, not surprisingly (Knott Nd), advise that known common complications can be explained as systematically describing every complication may prevent patients from undergoing a procedure. When enquired about changing of mind after signing the form for treatment most subjects thought that they can't change their mind after signing the forms and had to undergo the procedure and when asked about the importance of the informed consent 59 (45%) it provides information and substantiates things known to them and 19 % feel that it is not important as they have come for treatment any way and would do as the doctor says this again amplifies the faith the patients have on the dentists and demonstrates a submissive attitude or an ignorant attitude as they feel that their lack of knowledge of this specific field might hinder their decision making and leans towards the 'doctor knows best' attitude.

There are some limitations in our study. Small sample size could explain our failure to detect any significant association between the attitudes on informed consent and different demographical variables. Most of the patients were from the lower socio economic levels hence the opinions may be skewed. This is a pilot study and is the inceptive step to further enhance our understanding of issues vital for a developing population. Research with stronger scientific measures, larger sample size and inclusion of differing socio economic strata's is likely to enhance and empower our understanding of this cardinal area and its potential appropriateness in developing countries.

Conclusion

This study explores a very vital link in the treatment of patients, the results demonstrate that there is substantial void in the knowledge of patients attending dental outreach in Mangalore; This study has evoked differing opinions and questions focussing on many issues that need further exploration. As there is no clear criteria as to who is competent to provide consent the their dentists should place themselves in the patient's place and ask himself what he would want to know about the procedure if he were the patient so as to provide comprehensive at exact information of the procedure.

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