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PUBLIC AWARENESS AND ATTITUDE OF INFORMED CONSENT BEFORE ELECTIVE SURGERY: A CROSS SECTIONAL STUDY IN SAUDI ARABIA.

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Abstract:

Background*: Lack of awareness regarding the importance of informed consent might generate conflicts between the patients and their physicians with consequent negative effects on the patient's compliance, recovery and overall outcome.*

Objective*: to estimate the awareness and attitude among the Saudi general population towards informed consent before elective surgery.*

Methods*: This study was a cross-sectional study was performed over 3 months period starting from January to April 2018. Adults from the public from Saudi Arabia were consecutively contacted through social media platforms using an electronic survey questionnaire.*

Results*: This study included 822 adults (80% females), 44.6% had previous exposure to consent. They considered consent as very important (78%), not routine (76%), essential for decision making (61.1%), better to be verbal and written (83.2%), and should be detailed (92.3%), however, 53% did not know their right to change decisions after consent. Those with previous exposure felt consent as routine compared to those without (p=0.043) and had defective areas in consent including time of consent (44% done at day of surgery), place (29.8% in operation room) and 50.6% received proper informed consent.*

Conclusion: *The Saudi public are aware and has positive attitude towards informed consent before surgery. However, Full awareness regarding all aspects of the consent is not fully understood to some. Unfortunately, the current practice of consent is viewed by some patients as routine, improper time, place and not informed. We recommend physicians to fulfill the public desire to deliver consent as informed rather than routine before elective surgery.*

Key words: *elective surgery, informed consent, public awareness, public attitude, Saudi Arabia.*

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INTRODUCTION:

Medical ethics stress on obtaining informed consent from each patient before any intervention. This is to ensure the patient rights, autonomy, optimal care, and to create trust between physicians and patients. [1]

Preoperative consenting process should serve as an expression of patients' autonomy. [1] Previous studies found a limited awareness of the importance, legal consequences as well as the patient's rights of informed consent among patients. [1,2] Moreover, researchers found defective understanding, awareness and interest in informed consent among public. [1-3]

Patients prefer verbal explanation to their surgical procedures rather than written information [4]. Therefore, most patient will not read their consent prior. [5] Most patients prefer to hear about the positive outcome of their procedures rather than risks and complications. [4]

Many researchers [6-8] have shown poor integration of physicians' consent behavior into practice with limited knowledge of the ethical and legal needs of informed consent. [9] This limitation in consenting could lead to improbable expectations of the benefits and risks of the surgery. [10]

Therefore, our study aimed to estimate the attitude and knowledge among the Saudi general population towards informed consent.

METHODOLOGY:

This cross-sectional study was performed over 3 months period starting from January 2018 to April 2018. Participants were consecutively contacted through social media platforms using an electronic survey questionnaire. The target population was Saudi and non-Saudi adults of any gender residing the Western region of Saudi Arabia. Health care workers were excluded from the study. The questionnaire was constructed by an expert using a review of Informed consent for elective surgery. [11] It consisted of 3 sections; first: personal data, second: questions measuring the population awareness about their rights, and the third one for those with previous experience of signing a consent.

Good knowledge or positive attitude were considered if the total response of the participants to particular questions was at or above 60%. The sample size was 822 participants with confidence level of 95% and confidence interval of 3.42% (<5%). The study was approved by the ethical committee of Ibn Sina National College and all the data of the participants were dealt with confidentially.

Statistical analysis:

Statistical analysis was performed using SPSS for Windows 22.0 (SPSS Inc., Chicago, IL, USA). Frequency tables for categorical variables and descriptive statistics for numerical variables were used. Given the cross-tabulation statistics between groups, level of significance was detected by chi-square test. Statistical significance was accepted as $p<0.05$.

RESULTS:

A detailed electronic survey is usually conducted for the purpose of extracting information regarding public attitude, awareness & understanding towards informed consent and their legal issues. Questions were framed to determine the patients' attitude, what patients prefer to know, patient's knowledge about their rights, patients understanding to what has been explained to them by their physicians as well as the quality of information given by the doctors during the process of informed consent. Questions were framed and points were allocated to their answers. A score was calculated.

Table 1: Demographic data and the response of participants with and without previous exposure to informed consent before general surgery concerning attitude.

		All respondents N = 822 (%)	Participants with previous exposure N = 367 (%)	Participants without previous exposure N = 455 (%)	P
Gender	Males	20	21	19	0.716
	Females	80	79	81	
Age	< 20 years	6	7	5	0.215
	20-40 years	61	57	66	
	40-60 years	31	34	28	
	> 60 years	2	2	1	
Importance	Not important	4	4.2	3.9	1.000
	Important	18	18.2	18	
	Very important	78	77.6	77.8	
Consent is a routine legal requirement	Yes	24	27	22	0.043
	No	76	73	78	
	Verbal	7	9	5	0.170
How do you prefer to know about consent	Written	10	10	10	
	Both	83	81	85	
Do you know that you can change your mind regarding the procedure after filling the consent?	No	53	52	54	0.553
	Yes	47	48	46	

Table 2: Response of participants concerning their role in decision making about the treatment:

	All respondents N = 822 (%)	Participants with previous exposure N = 367 (%)	Participants without previous exposure N = 455 (%)	P
Do not want to know about treatment plan & will follow doctor	3	4	2	0.468
Want to know about treatment plan & will follow the doctor	36	36	35	
Will take the final decision after discussion of treatment plan with doctor.	61	60	63	

Table 3: **What do patients really want to know about their treatment through informed consent?**

	All respondents N = 822 (%)	Participants with previous exposure N = 367 (%)	Participants without previous exposure N = 455 (%)	P
Operation outcome only	3	4	2	0.662
Operation details & steps only	2	2	1	
Operation complications and risks only	3	3	4	
All details	92	91	93	

Table 4: Response of participants with previous exposure to informed consent.

Question		Percentage (%)
When informed consent was taken?	On day of surgery.	44
	One day before surgery.	30.4
	One week before surgery.	25.6
Where informed consent was taken?	At the operating room	29.8
	On ward	32.1
	On clinic	38.1
Who explained the informed consent to the patient?	An intern	8.8
	A resident	16.6
	Your physician	74.6
How much information retained from doctor explanation and words written in the consent?	=< 30%	24.3
	50%	34.7
	70%	41
Has the doctor emphasized the importance of written consent?	Yes	79.1
	No	20.9
Has the doctor explained all informed consent points?	Yes	50.6
	No	49.4
Did the doctor give you enough time to read?	Yes	63.8
	No	36.2

This study included 822 participants from the pubic with 367 (44.6%) of them had previous exposure to the process of signing an informed consent before elective surgery (Table 1). Most of our participants were young adults (61.2% aged 20-40 & 30.8% aged 40-60 years) and mostly females (80%). The majority considered consent as very important (78%) and (75.7% of participants) considered consent as not routine. Comparison between those with previous exposure to consenting to those without, found a significant difference only in their view of consent as a routine (p=0.043) (Table 1). Most (83.2%) preferred combined verbal and written way of consent delivery. Unfortunately, more than half of our participants were not aware of the right to change their decisions even after signing the consent of agreement (Table 1). In table 2, 36% of participants needed to know treatment plan to follow orders and 61.1% wanted to take their final decisions based on discussion with their physicians. In table 3, only 3% were not interested to know the operation details before giving the consent. However, almost all (92%) need to know every detail about the operation, outcome, complications and risk. Table 4 showed the response of participants with previous exposure to informed consent. It revealed some defective areas in consenting including the time of consent (44% signed the consent at the day of surgery), place (29.8% gave consent in the operation

room), and the content of the consent (49.4 did not receive enough information).

DISCUSSION:

This study found that participants from the public had positive attitude and were aware of the value of pre-operative informed consent as they viewed consent as a very important (78%), and not a routine legal requirement (76%) and they preferred both verbal and written way of consent delivery (83.2%). Moreover, they needed to discuss with their surgeon the treatment plan to follow orders (35.8%) and to take their final decisions (61.1%). Participants, also, preferred to know every detail regarding the operation, outcomes, complications and risks (92.3%). However, they were not aware of their full rights of withdrawal & changing their decisions after signing the agreement of the informed consent (53%).

On the other hand; when we viewed the attitude of those from the public who experienced preoperative consent many defects were found. The most striking findings were defective time (44% signed the consent at the day of surgery), place (29.8% gave consent in the operation room), and content of the consent (49.4 did not receive enough information). Moreover, participants with previous exposure, viewed of consent as a routine process (73%) significantly decreased compared to those without previous experience (76%) (p=0.043).

The high level of awareness, among our public participants, was in contrast to other population in various studies [2,12,13] who considered informed consent as just a legal requirement (75.0%)[2] or not very important (>50%). [12,13] This positive attitude among our participants could be explained by their young age and using social media.

In our results, 61% preferred to discuss each detail with their physicians before taking decision for treatment plan compared to only 11.6% in another study from India[2]; in which most participants preferred to allow physicians to determine for their treatment after explaining. This should not be taken as a major doctor-patient trust as was explained in the Indian study [2]. Instead, it could indicate a great awareness and exactness among our young adult participants.

Cassileth et al from Japan [13] found that one-third of their older patients thought consent explanations were fiddling and would do what their physician recommended, this was interpreted by the concept of physician paternalism in patients' awareness. Additionally, Researchers found patients to prefer to listen to the positive outcomes and recovery over risks and complications, verbal rather than written information [4], and not to read[4] or express any enquiry about the information mentioned in their consent form. [3]

In this study, most (92%) participants want to know every detail regarding their treatment plan including operation steps, results, complications and possible risks before giving informed consent. This aligned with the results of the Indian study [2], in which participants needed to know the duration of the operation, and cost of treatment. Cassileth et al [13] found that majority of patients preferred not to have information regarding complications. It was explained by the fact that Japanese people generally tend to avoid encountering risks directly.

Considerable number of our participants and most of Rajesh DR et al's participants [2] did not know their right to change their decision regarding the surgery after filling and signing the informed consent. This surprising finding indicated a major defect in public knowledge regarding their rights as patients.

International consent guidelines [14] recommend that treating physician is responsible for ensuring that patient has signed a valid informed consent before elective surgery. This task could be deputed to another drilled, qualified and competent person. This was given by our participants who had experienced consenting explained by their physicians (74.6%), residents (16.6%), and interns (8.8%). Junior medical staff may be placed in a position where they fulfill neither of the above two criteria. Certain specialist procedures, such as cataract surgery or elective angiography, have very specific risks, which may not be adequately covered in undergraduate education. A thorough understanding is required to be able to appropriately advise the patient. Instruction in obtaining informed consent is therefore vital. [11] 44% of the exposed participants gave their consent at the day of the surgery. This was not aligned with the international guidelines[14] that figured out that it is better to seek the patients' consent to surgery well in advance, when you have time to respond to their inquiries and give them sufficient information. If a patient is not requested to give informed consent until just before the surgery, there might be a genuine uncertainty regarding its validity. Only 29.8% of our patients gave consent at the operating room; while

70.2% gave their consent either in the clinic or in the patients' ward. Anderson et al's study [11] concluded that informed consent should be acquired in clinics, where the benefits and complications are often explained comfortably with less pressure to the patient to proceed. However, if the consent was conducted in advance, the treating physician has to confirm it at the time of surgery as well. [11] Almost half (50.6%) of our patients were explained to fully regarding all points of informed consent, 63.8% of them stated that adequate time was given to them to read the consent, while 79.1% reported that the doctors have emphasized the importance of written consent. This reflects a sound practice of doctors who pay a great effort to conduct the informed consent process efficiently and this affects the outcome positively. 75.1% of our patients claimed that they could recall at least 50% of the information that was delivered by their doctor or read in the informed consent.

The main limitation of this study was the generalization of the results to all the population residing in Saudi Arabia as our sample included mostly adult females with an access to the social media. The second limitation was the study type, which allowed for recall bias especially for the group with previous exposure. The questionnaire might have been filled long time after the exposed participants had been consented and after the elective surgery had already been performed.

CONCLUSION:

This study found the public to be aware and have positive attitude towards properly informed consent before elective surgery.

However, the Saudi public of the western region, was not aware of their full rights as patients. Similarly, the participants previous exposure to consent was full of defects, which included mainly improper time, place and incomplete information delivered by their surgeon.

Based on this study findings, we can recommend increasing the public awareness of the patients' rights probably though social or other form of media. Moreover, surgeons should be cautious regarding their patients' needs and rights and should explore their concerns and expectations.

Surgeons should implement guidelines of informed consent to meet the needs of their patients.

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