

Comparative Study of Gap Analysis Between Patient and Doctor About Informed Consent to A Procedure

Khan F and Bashir S*

Demonstrator/tutor, Sheri Kashmir Institute of Medical Sciences-Medical College, Srinagar, J&K, India

Volume 4 Issue 12- 2020

Received Date: 08 Aug 2020

Accepted Date: 25 Aug 2020

Published Date: 29 Aug 2020

2. Keywords

Informed consent; Doctor; Patient

1. Abstract

1.1. Background: Consent is the most important factor in determining the legitimacy of any treatment offered by the doctor. Increasing advancement in medical technology and use of complicated intervention rendered the patients to adverse and unintended complications and therefore it became necessary for the patient to understand the details of the intervention/procedure and to agree and give permission. Providing any treatment or performing any surgery/procedure by a medical professional, without the patient's consent may be held liable for assault, battery or medical malpractice as the case may be. In 20th century, the process of informed consent started as a reaction to various human research experiments which were conducted without the consent of the participants. Autonomy, beneficence, nonmaleficence and justice are the four principles of bioethics based on the 1975 Declaration of Helsinki and the 1947 Nuremberg Code. The development of contractual relationship between doctor and patient from paternalistic approach was an important achievement.

1.2. Aim: This study was conducted to understand the gap between the doctor (surgeon) and patient to assess the understanding of informed consent in a tertiary care hospital.

1.3. Method: A questionnaire study was carried out using a pre-validated questionnaire consisting of ten questions. Similar questions were asked to 30 surgeons and 30 patients undergoing the same surgical procedure in order to maintain a uniform pattern. Before conducting the study informed consent was taken from each participant and sufficient time was given to complete the questionnaire. The results were tabulated using Microsoft excel sheet separately for doctors and patients. It was then subjected to analysis using Chi Square Test to find out the P Value.

1.4. Result: The finding of this study revealed that many of the patients were not knowing the importance and meaning of informed consent. It was found that there was a major gap in the opinion of patients and doctors.

1.5. Conclusion: The patient should be free to take decision and doctor should understand and respect the concerns of the patient. In order to make better understanding regarding the surgical procedure which the patient is suppose to undergo, structured visual aids should be used by the doctor. The language of informed consent should be as simple as possible. Informed consent should be truly informed and not just a procedure.

3. Introduction

Informed consent implies that the person giving the consent has a clear understanding of the facts and reasoning ability, significant knowledge about the procedure, its implications and risks involved. In the past few decades the importance of informed consent has grown due to the increasing explication of medical practice. The shift to a contractual relationship between the doctor and the patient from paternalistic approach was an important milestone [1]. The principlistic approach i.e. autonomy- the right of an individual

to make his own decision, beneficence- principle of acting in the best interest of the patient in the mind, non-maleficence - the principle of 'above all do no harm' and justice-concept that emphasizes fairness and equality among individuals; upholds human dignity [2]. Section 13 in The Indian Contract Act, 1872 defines consent as "Two or more persons are said to consent when they agree upon the same thing in the same sense" [3]. Consent form is written, dated and signed by the patient after he had completely understood the process and where the patient is a minor or incapable of giving

*Corresponding Author (s): Somia Bashir, Demonstrator/tutor, Sheri Kashmir Institute of Medical Sciences-Medical College, Srinagar, J&K, India. E-mail: somia24bashir@rediffmail.com; firdousdr786@gmail.com

Citation: Khan F and Somia Bashir. Comparative Study of Gap Analysis Between Patient and Doctor About Informed Consent to A Procedure. Journal of Clinical and Medical Images. 2020; V4(12): 1-4.

ing consent his or her guardian or legal representative can sign the consent form [4]. In developing countries like India many patients are poor and illiterate as a result of which the doctors adopt a paternalistic approach and sometimes the patients are frightened to give consent without knowing their rights [5]. This study is an attempt to investigate the degree to which patients have knowledge regarding the informed consent.

4. Methodology

A questionnaire study was carried out with a sample size of 30 patients and 30 doctors, to understand the perception of informed consent among both surgeons and patients. Two questionnaire (pre-validated) [6] consisting of ten similar questions were asked to both the surgeons and patients. In order to maintain a uniform pattern those patients were included in the study who had undergone similar surgical procedures. Before conducting the study informed consent was taken from each participant and sufficient time was given to complete the questionnaire. The results were tabulated using Microsoft excel sheet separately for doctors and patients. It was then subjected to analysis using Chi Square Test to find out the P Value. (Table 1)

Table 1

Questions	Categories	N	Patient/Doctor(1/2)		Chi square	P value
			PATIENT (N (%))	DOCTOR (N (%))		
1. Whether the diagnosis was explained in detail	NO	12	11 (36.7)	1 (3.3)	10.417	0.001
	YES	48	19 (63.3)	29 (96.7)		
2. Whether the surgical procedure was explained in detail	NO	17	16 (53.3)	1 (3.3)	18.468	<0.001
	YES	43	14 (46.7)	29 (96.7)		
3. Whether the explanation of total treatment cost was adequate	NO	34	27 (90)	7 (23.3)	27.149	<0.001
	YES	26	3 (10)	23 (76.7)		
4. Awareness of which part of the body was being operated.	NO	6	6 (20)	0 (0)	6.667	0.01
	YES	54	24 (80)	30 (100)		
5. Whether the risks and complications of the recommended surgery and other and treatment options were explained in detail?	NO	27	21 (70)	6 (20)	15.152	<0.001
	YES	33	9 (30)	24 (80)		
6. Did the treating surgeon explain about adverse outcomes associated with the surgery?	NO	27	20 (66.7)	7 (23.3)	11.38	0.001
	YES	33	10 (33.3)	23 (76.7)		
7. Whether the time duration of hospital stay and post operative recovery was explained in detail?	NO	31	16 (53.3)	15 (50)	0.067	0.796
	YES	29	14 (46.7)	15 (50)		
8. Whether the post operative care to be taken after discharge was explained in detail?	NO	25	18 (60)	7 (23.3)	8.297	0.004
	YES	35	12 (40)	23 (76.7)		
9. Whether information was provided on whom to contact in case of any problems post surgery?	NO	22	17 (56.7)	5 (16.7)	10.335	0.001
	YES	38	13 (43.3)	25 (83.3)		
10. Whether the contact details of the concerned was made available?	NO	34	20 (66.7)	14 (46.7)	2.443	0.118
	YES	26	10 (33.3)	16 (53.3)		

5. Result

A total of 30 patients and 30 doctors participated in the study at a tertiary care hospital in Srinagar belonging to age group of 30 to

52 years. Both doctors and patients were asked ten similar questions and their answer was analysed using chi square test which was found to be significant (P value of 0.001) in eight out of ten questions.

On comparison of patient and doctor groups in relation to the question no 1, whether the diagnosis was explained in detail, it was found that there were 12 no and 48 yes numbers in each category. The number of no was higher in patient group with a percentage of 36.7 and the number of yes was higher in doctor group with a percentage of 96.7. This comparison is statistically significant with a p value of 0.001.

When asked whether the surgical procedure was explained in detail, there were 17 no and 43 yes numbers in each category. The number of no was higher in patient group with a percentage of 53.3 whereas the number of yes was higher in doctor group with a percentage of 96.7. This comparison is statistically significant with a p value of <0.001.

When inquired whether the explanation of total treatment cost was adequate, there were 34 no and 26 yes numbers in each category. The number of no was higher in patient group with a percentage of 90 and the number of yes category was higher in doctor group with a percentage of 76.7. This comparison is statistically significant with a p value of <0.001.

When asked, about awareness of which part of the body was being operated, there were 6 no and 54 yes numbers in each category. The number of no was higher in patient group with a percentage of 20 and the number of yes category was higher in doctor group with a percentage of 100. This comparison is statistically significant with a p value of 0.01.

When asked, whether the risks and complications of the recommended surgery and other and treatment options were explained in detail, it was found that there were 27 no and 33 yes numbers in each category. The number of no was higher in patient group with a percentage of 70 and the number of yes category was higher in doctor group with a percentage of 80. This comparison is statistically significant with a p value of <0.001.

When asked, did the treating surgeon explain about adverse outcomes associated with the surgery it was found that there were 27 no and 33 yes numbers in each category. The number of no was higher in patient group with a percentage of 66.7 and the number of yes category was higher in doctor group with a percentage of 76.7. This comparison is statistically significant with a p value of 0.001.

When asked whether the time duration of hospital stay and post operative recovery was explained in detail it was found that there were 31 no and 29 yes numbers in each category. The number of no was higher in patient group with a percentage of 53.3 and the number of yes category was higher in doctor group with a percent-

age of 50. This comparison is statistically not significant with a p value of 0.796.

When asked whether the post-operative care to be taken after discharge was explained in detail it was found that there were 25 no and 35 yes numbers in each category. The number of no was higher in patient group with a percentage of 60 and the number of yes category was higher in doctor group with a percentage of 76.7. This comparison is statistically significant with a p value of 0.004.

When asked whether information was provided on whom to contact in case of any problems post-surgery it was found that there were 22 no and 38 yes numbers in each category. The number of no was higher in patient group with a percentage of 56.7 and the number of yes category was higher in doctor group with a percentage of 83.3. This comparison is statistically significant with a p value of 0.001.

When asked whether the contact details of the concerned doctor was made available it was found that there were 34 no and 26 yes numbers each category. The number of no was higher in patient group with a percentage of 66.7 and the number of yes category was higher in doctor group with a percentage of 53.3. This comparison is statistically not significant with a p value of 0.118.

6. Discussion

The finding of this study revealed that many of the patients were not knowing the importance and meaning of informed consent. It was found that there was a major gap in the opinion of patients and doctors. Majority of the patients responded that they were not aware of the details of surgical procedure 53.3%, total treatment cost 90%, risk and complication of recommended surgery and other treatment options 70%, adverse outcome of surgery 66.7%, duration of stay in hospital 53.3% and post-operative care to be taken after surgery 60% but 80% of patients were aware of the part of the body to be operated. When same question were asked to the doctors it was found that the doctors responded that they have explained in detail about the diagnosis 96.7%, surgical procedure 96.7%, total treatment cost 76.7%, risk and complications 80%, adverse outcome of surgery 76.7% and post-operative care 76.7%. In 2012, Shubha Kumar et al conducted an interview based study through audio recording on 14 patients and 8 doctors and found that the understanding of informed consent was moderate and inadequate [5]. The results were similar to the present study. Doctors considered poor literacy and language to be the most important hindrance in communicating with the patients. The language and words used in the conversation of informed consent should be as simple as it can be understood by a child of 9th grade [7, 8, 9]. Studies carried out by Rogers AE (2000), Sutherland H A (1990) and Lloyd A (2001) have showed that cognitive and emotional limitations were the reasons behind the lack of patients understanding of their health condition, prognosis, treatment and risk involved [10, 11, 12]. In a study conducted by Fink et al in 2010, it was found

that elderly patients belonging to African-American or Hispanic races were having difficulty in apprehending the details of surgical procedure because of their low education level however when they were asked to 'repeat back' i.e. when the patients were asked to repeat the details of the consent form explained to them in their own words, it improved the patients understanding significantly [13]. In 2010 Krankl et al concluded that in order to ensure better understanding of the clinical information by the patient, more importance should be given to the educational background of the patient [14]. In India most of the patients do not read the consent form because of low level of education and due to their belief that the doctor will not intentionally harm them and knows what is best for the patient. Studies have also shown that during the process of informed consent use of additional educational material improves patient's understanding and knowledge about their condition, decisional conflicts and reduced use of electric procedure [15, 16, 17]. Sanyal et al reported that Indian patients are able to understand the informed consent and that it should be explained in detail and repeatedly. Informed consent should be a continuous process and not a single event [18].

7. Conclusion

This study was carried out to understand the gap between patients and surgeons regarding informed consent and it was found that the patients were not completely aware about the surgical procedure, total treatment cost, risk and complication of recommended surgery and other treatment options, adverse outcome of surgery, duration of stay in hospital and post-operative care to be taken after surgery. Majority of patients were aware of the part of the body to be operated. Study conducted by Shuba Kumar revealed that patients should play a forethoughtful role in their treatment process and doctor should provide information in such a way that could be easily understood by the patient. The patient should be free to take decision and doctor should understand and respect the concerns of the patient. In order to make better understanding regarding the surgical procedure which the patient is suppose to undergo, structured visual aids should be used by the doctor [5]. As argued by Doyal L, despite of problems being faced by the patient in understanding the clinical information, the responsibility completely lies on the doctor to improve the method of communication by using different educational aids for better understanding of the procedure and to facilitate the informed consent process [19]. The language of informed consent should be as simple as possible and in English as well as local language. Informed consent should be truly informed and not just a procedure.

References:

1. Jacob KS. Informed consent and India. *Nat Med J India*. 2014; 27: 35-8.
2. Rao KHS. Informed Consent: An ethical obligation or legal com-

- pulsion? *J Cutan Aesthet Surg.* 2008; 1: 33-5.
3. Vij K. Identification. In: *Textbook of Forensic Medicine and Toxicology.* Sixth edition, Reed Elsevier India Private Limited. 2014; Pp 59-61: 202-3.
 4. Beauchamp TL, Childress JF. In *Textbook of principles of biomedical ethics.* 4th Ed, Oxford: Oxford University Press. 1994.
 5. Kumar S, Mohanraj R, Rose A, Paul MJ, Thomas G. How 'informed' is informed consent? Findings from a study in South India. *Indian J Med Ethics.* 2012; 9: 180-6.
 6. Shetty VA, Vaswani V. Comparative study of gap analysis between patient and surgeon about informed consent to a procedure. *Indian journal of forensic medicine and toxicology.* 2017; 11: 101-5.
 7. Morrow G, Gootnick J, Schmale A. A simple technique for increasing cancer patients' knowledge of informed consent to treatment. *Cancer.* 1978; 42: 793-9.
 8. Young DR, Hooker DT, Freeberg FE. Informed consent documents: increasing comprehension by reducing reading level. *IRB: Ethics & Human Research,* 1990; 12: 1-5.
 9. Kent G. The role of psychology in the teaching of medical ethics: The example of informed consent. *Med Edu.* 1994; 28: 126-31.
 10. Rogers AE, Addington-Hall JM, Abery AJ, McCoy AS, Bulpitt C, Coats AJ et al. Knowledge and communication difficulties for patients with chronic heart failure: qualitative study. *BMJ.* 2000; 321: 605-7.
 11. Sutherland H, Lockwood G, Till J. Are we getting informed consent from patients with cancer? *J R Soc Med.* 1990; 83: 439-43.
 12. Lloyd A. The extent of patients understanding of the risk of treatments. *Qual Healthc.* 2001; 10: I 14-I18.
 13. Fink AS, Prochazka AV, Hendereson WG, Bartenfeld D, Nyirenda C, Webb A et al. Predictors of comprehension during surgical informed consent. *J Am Coll Surg.* 2010; 210: 919-26.
 14. Kankl JT, Shaykevich S, Lipsitz S, Lehmann LS. Patient's predictors of colposcopy comprehension of consent among English and Spanish speaking women. *Women's Health Issues.* 2011; 21: 80-5.
 15. Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systemic review. *Med Decis Making.* 2011; 31: 151-73.
 16. Volk RJ, Hawley ST, Kneuper S, Holden EW, Stroud LA, Cooper CP et al. Trails of decision aids for prostate cancer screening: a systemic review. *Am J Prev Med,* 2007; 33: 428-34.
 17. O'Connor AM, Bennett CL, Stacey D, Barry M, CoI NF, Eden KB et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2009;3: CD001431.
 18. Sanwal AK, Kumar S, Sahni P, Nundy S. Informed consent in Indian patients. *JR Soc Med.* 1996; 89: 196-8.
 19. Doyal L. Informed consent: moral necessity or illusion? *Qual Healthc.* 2001; 10: i29-i33.