

Pictorial Consent in Cardiac Surgery: A far better option rather than Standard Informed Written Consent

**Dr Debmalya Saha, Dr Pawan Singh, Dr Soumyaranjan Das, Dr Ravi Kumar Gupta, Dr Satyajit Samal,
Dr Muhammad Abid Geelani**

Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

DOI: 10.29322/IJSRP.10.09.2020.p10544
<http://dx.doi.org/10.29322/IJSRP.10.09.2020.p10544>

Abstract- Because of the complexity of the procedures, high level of clarification for the patients as well as their attendants while taking consent is a must as cardiac surgery is associated with significant morbidity and mortality. Pictorial consent with pre-operative education is a far better option in this regard. We randomly took a total of 150 patients within the age group of 18 to 70 years, and they were explained with standard consent followed by pictorial consent and vice versa by the same informant. And they were given a preset questionnaire format after both consents. Later, based on their answers, comparison in relation to the level of clarity was done. Questionnaire was formatted after rigorous modification from the reviews of literature.

Key words: Consent, Informed, Pictorial, Cardiac, Legal

I. INTRODUCTION

A New York Court gave a verdict in 1914 that every human has a right to know what shall be done with his body & without proper consent he will be liable for damages(1). The concept of "consent" was first given by Salgo V. in 1957 as one of the most important aspects of legal, ethical and fundamental documentation in the context of medical practice(2). Proper communication, justified explanation of benefit-risk & possible alternative options of the planned procedure are actually neglected while focusing just on taking signature on written standard consent(3). In the current era, the process of consent is not adequate(4,5,6). Other interactive tools such as freehand diagrams, leaflet, booklet, audiovisual tapes, computer programs

and interactive power-point presentations are much more effective than the conventional standard consent (7,8). Numerous studies, planning, work-up, follow-up have been made for improving the consent process, as the regular update in the consent process is mandatory in the present day of global digitalization. Several guidelines and recommendations have come but with a similar basis (9,10). The process of taking consent is truly based upon the strong Doctor-patient relationship. Just signing on a consent paper does not signify that patient has fully understood the fact (11).

II. MATERIALS & METHODS

We randomly took a total of 150 patients within the age group of 18 to 70 years, and they were explained with standard consent followed by pictorial consent and vice versa by the same informant. And they were given a preset questionnaire format after both consents. Later, based on their answers, comparison in relation to the level of clarity was done. Questionnaire was formatted after rigorous modification from the review of literatures.

III. RESULTS

After the explanation of both consents, a questionnaire (table 1) was given and the result is depicted in table 2. Age group of the study population was 18-70 years. Level of literacy was defined as per Gov Of India.

Table 3 shows the time taken for explaining the two consent. Enrolled patients are summarized in table 4. The result is noticeably clear as we can see here; and the level of clarity was much better after the pictorial consent.

TABLE 1.

Serial No	Knowledge	Standard Consent/Pictorial Consent
1.	Diagnosis of the disease	Yes/No
2.	Operative procedure planned	Yes/No
3.	Alternative options	Yes/No
4.	Approaches/incisions	Yes/No
5.	Monitoring lines/devices	Yes/No
6.	Pacing wires/temporary pacemaker	Yes/No
7.	Drains	Yes/No
8.	Comorbidities increasing the risk	Yes/No
9.	Blood products & complications	Yes/No
10.	Cardioversion	Yes/No
11.	ICU stay	Yes/No
12.	Post-operative events	Yes/No
13.	Long-term outcomes-survival/morbidity/mortality	Yes/No

TABLE 2.

SERIAL NO.	KNOWLEDGE	STANDARD CONSENT	PICTORIAL CONSENT
1.	Diagnosis of the disease	80	145
2.	Operative procedure planned	51	142
3.	Alternative options	71	138
4.	Approaches/incisions	91	148
5.	Monitoring lines/devices	48	132
6.	Pacing wires/temporary pacemaker	61	129
7.	Drains	101	141
8.	Comorbidities increasing the risk	78	123
9.	Blood products & complications	78	141
10.	Cardioversion	41	129
11.	ICU stay	96	131
12.	Post-operative events	79	137
13.	Long-term outcomes-survival/morbidity/mortality	68	128

TABLE 3.

TIME TAKEN (minutes)	STANDARD CONSENT	PICTORIAL CONSENT
Maximum	12	29
Minimum	7	13
Average	10	21

TABLE 4.

PATIENTS	MALE	FEMALE
AGE GROUPS 18 - 35	26	38
36 - 55	32	23
56 - 70	21	10
LITERATE	45	15
ILLITERATE	34	56

IV. DISCUSSION

In clinical ground “informed consent” is the legal and ethical conceptual process by which the patient is provided with information relevant to a proposed diagnostic or therapeutic intervention; and should be elaborated sufficiently that the patient can come to a decision for making a rational choice among the possible available options. In actual clinical scenario the informed consent has just become a process of taking signature on consent form due to huge and increasing work load in the hospital(12).Because of global digital advancements, the patients are now much aware ,and they come to clinic or hospital with different queries regarding different therapeutic options, after exploring their problems in the internet; as a result the process of consent has been complex(13,14,15).

That is why the decision making must be customized according to the patient’s ability to understand (16). It should involve active contribution of both the doctor and the patient but choice making must be done voluntarily without any external influence to avoid legal conflicts(17,18).Another important issue while taking standard written consent is language barrier when both the informant and the patient are from two different geographical areas; in that situation self-explanatory pictorial consent is a better option(19,20).

While explaining the pictorial consent, the facts were more easily clarified and understood such as:

- 1.Diagnosis: Perception level was far better after simple illustrations while disclosing the diagnosis.
- 2.Proposed treatment plan and possible alternative: Patient was satisfied after being explained in pictorial form, power-point presentation including audiovisual clips.
- 3.Approaches/incisions: Confusion of leg wounds in post-operative CABG patients were cleared when they were explained with free-hand diagrams prior to surgery.
- 4.Monitoring devices/pacing wire/drains: The necessity of neck lines, invasive(arterial) blood pressure monitoring, infusion pumps with inotropes or supporting medications, basics of all parameters projected on the monitors were explained in a simplified manner with the help of illustrations. It was also explained that the pacing wire that come out from the body is for temporary pacing to treat the transient heart blocks, and it will be cut before discharge. The functions of both mediastinal and chest drains were explained along with the probable time of its removal.
- 6.Cardiopulmonary bypass: It was better understood in pictorial form.

7.Cardioversion and its possible complications were explained.

8.Blood product transfusion and its complications: They had a few queries regarding their preoperative donated blood, and it may give better recovery if transfused, but they were explained about the complications of unnecessary transfusions.

9.Diet: Dietary modification is an important aspect in post-operative CABG patients; and food stuffs were better understood in pictorial form for the illiterate.

People must understand that there is no procedure that is risk-free (12). Although the level of clarity is far improved for the patients after being explained the pictorial consent.

V. LIMITATIONS

The pictorial consent we tried to utilize had its own limitations. The questionnaire format, that was used to assess the level of clarity, did not cover so many significant aspects of the surgical plans.

VI. CONCLUSIONS

As patient can understand and remember a very few information provided during informed consent, the standard consent in cardiac surgery should be improved with the implementation of interactive and self-explanatory measures such as simple pictures, diagrams, illustrations, audiovisual tapes. It is not assured that the patient will go through the facts in the written consent completely even it may contain the detailed information, while the pictorial consent being interactive in nature involves the patient for active participation for achieving possible highest level of clarity in understanding. A good consent process would help better in avoiding ethical and legal conflicts. More studies should be carried out to improve and standardize the concept of pictorial consent as it is a newer advancement in the field of medical practice.

REFERENCES

[1] Herz DA, Looman JE, Lewis SK. Informed consent: is it a myth? Neurosurgery 1992; 30:453-458.
 [2] Berg JW, Appelbaum PS. Informed consent: legal theory and clinical practice. 2nd ed. Oxford: Oxford University Press;2001

- [3] Shubha Dathatri, PhD, Luis Gruberg, MD, Jatin Anand. Informed Consent for Cardiac Procedures: Deficiencies in Patient Comprehension With Current Methods Department of Surgery, Baylor College of Medicine, Houston, Texas; Division of Cardiovascular Diseases, Department of Medicine, and Department of Surgery, Stony Brook School of Medicine, Stony Brook, New York; and The Texas Heart Institute, Houston, Texas *Ann Thoracic Surg* 2014;97:1505–12. 2014 by The Society of Thoracic Surgeons
- [4] Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ* 1993;306:885–90.
- [5] Leclercq WK, Keulers BJ, Scheltinga MR, Spauwen PH, van der Wilt GJ. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World J Surg* 2010;34:1406–15.
- [6] Braddock CH III, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA* 1999;282:2313–20.
- [7] Tait AR, Voepel-Lewis T, Moscucci M, Brennan- Martinez CM, Levine R. Patient comprehension of an interactive, computer-based information program for cardiac catheterization: a comparison with standard information. *Arch Intern Med* 2009; 169:1907–14.
- [8] Morgan MW, Deber RB, Llewellyn-Thomas HA, et al. Randomized, controlled trial of an interactive videodisc decision aid for patients with ischemic heart disease. *J Gen Intern Med* 2000; 15:685–93.
- [9] General Medical Council. Seeking patient's consent. The ethical considerations. London: GMC; 1998.
- [10] Department of Health. Reference guide to consent for examination or treatment. London: Department of Health; 2001. p10.
- [11] Pankaj Kumar Mishra, Faruk Ozalp, Roy S. Gardner Informed consent in cardiac surgery: is it truly informed? *Journal of Cardiovascular Medicine* 2006, 7:675–681
- [12] Daniel E. Hall MD MDiv, Allan V. Prochazka MD MSc, Aaron S. Fink MD Informed consent for clinical treatment *CMAJ*, March 20, 2012, 184(5) p533-540
- [13] Newton-Howes PAG, Dobbs B, Frizelle F. Informed consent: What do patients want to know? *N Z Med J* 1998; 111:340-2.
- [14] Sulmasy DP, Lehmann LS, Levine DM, et al. Patients' perceptions of the quality of informed consent for common medical procedures. *J Clin Ethics* 1994; 5:189-94.
- [15] Schneider CE. The practice of autonomy: patients, doctors, and medical decisions. New York (NY): Oxford University Press; 1998. p. 35-75, 92-9.
- [16] Leeper-Majors K, Veale JR, Westbrook TS, et al. The effect of standardized patient feedback in teaching surgical residents informed consent: results of a pilot study. *Curr Surg* 2003; 60: 615-22.
- [17] Schenker Y, Fernandez A, Sudore R, et al. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. *Med Decis Making* 2011; 31:151-73.
- [18] Fink AS, Prochazka AV, Henderson WG, et al. Enhancement of surgical informed consent by addition of repeat back: a multicenter, randomized controlled clinical trial. *Ann Surg* 2010; 252: 27-36.
- [19] Hopper KD, TenHave TR, Tully DA, et al. The readability of currently used surgical/procedure consent forms in the United States. *Surgery* 1998; 123:496-503.
- [20] Weston J, Hannah M, Downes J. Evaluating the benefits of a patient information video during the informed consent process. *Patient Educ Couns* 1997; 30:239-45.

AUTHORS

First Author – Dr Debmalya Saha, MCh Senior Resident, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Second Author – Dr Pawan Singh, MCh Senior Resident, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Third Author – Dr Soumyaranjan Das, MCh Senior Resident, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Fourth Author – Dr Ravi Kumar Gupta, MCh Senior Resident, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Fifth Author – Dr Satyajit Samal, MCh Senior Resident, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Sixth Author – Dr Muhammad Abid Geelani, Director & Professor, Head of the Department, Department of Cardiothoracic & Vascular Surgery, G.B. Pant Institute of Postgraduate Medical Education & Research (GIPMER), New Delhi-110002, India

Correspondence Author – Email: debmalya.cmc@gmail.com