

Original article:

Effectiveness of standard consent vs pictorial consent in cardiac surgery

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ABSTRACT:

In cardiac surgery consent is not just a signing document rather a process as it is associated with significant mortality & morbidity(1). Hereby pictorial consent is better understood than the standard consent. Thus this study was conducted to compare its effectiveness. Total of 110 patients age group 18 to 82 years were included. Randomly patients were explained about standard consent followed by pictorial consent and vice versa. They were informed both times by the same informant. And after both consent explanation they were given questionnaire. And later comparison was done on the basis of questionnaire. Questionnaire was modified after review of literature.

INTRODUCTION:

In 1957 Salgo V. first gave the concept of consent since then it has been fundamental ethical principle & legal foundation in medical procedure(2). Poor communication skills & understanding, brief explanation of risk benefit & alternatives about the procedure and being more focused on written documents have largely flawed the consent process(3). Current consent process is inadequate.(4-6) Audiovisual & other interactive measures like diagrams, booklet is more effective than standard consent(7-9). Various studies have been conducted for improvement in consent process, thus the need of regular advancement in consent is required. In 1914 a New York Court gave a verdict that `every human has a right to know what shall be done with his body & without proper consent he will be liable for damages(10). Various recommendations & guidelines have been laid but its base is same(11-13). Process of obtaining consent maintain`s strong patient & physician relationship. Signing a consent form does not state that patient is fully aware of the procedure and risk benefit(14).

MATERIAL AND METHODS:

Total of 110 patients age group 18 to 82 years were included. Randomly patients were explained about standard consent followed by pictorial consent and vice versa. These pictorial charts were validated and use for further process.

They were informed both times by the same informant. And after both consent explanation they were given questionnaire.

And later comparison was done on the basis of questionnaire. Questionnaire was modified after review of literature.

RESULTS:

After the consent explanation questionnaire was given and its result is described in table 2

Age group was 18-82 years. Illiteracy level was defined as per Gov Of India(86).

Patient enrolled are summarised in table 3.

Table 4 shows time taken to explain the two consent

Table1

S.NO	KNOWLEDGE ABOUT	STANDARD/PICTORIAL CONSENT
1	DIAGNOSIS	YES/NO
2	PROCEDURE	YES/NO
3	INCISIONS	YES/NO
4	DRAINS	YES/NO
5	MONITORING LINES	YES/NO
6	PACING WIRE	YES/NO
7	COMORBIDITIES INCREASING RISK	YES/NO
8	BLOOD PRODUCTS & COMPLICATIONS	YES/NO
9	CARDIOVERSION	YES/NO

TABLE 2

S.NO	KNOWLEDGE ABOUT	STANDARD CONSENT	PICTORIAL CONSENT
1	DIAGNOSIS	96	104
2	PROCEDURE	91	108
3	INCISIONS	53	93
4	DRAINS	41	84
5	MONITORING LINES	36	100
6	PACING WIRE	39	96
7	COMORBIDITIES INCREASING RISK	48	86
8	BLOOD PRODUCTS & COMPLICATIONS	34	85
9	CARDIOVERSION	31	84

TABLE 3

	MALE	FEAMLE
AGE GROUP 18-40	19	16
41-60	58	11
61-82	5	1
ILLITERATE	21	12
LITERATE	61	16

TABLE 4

TIME TAKEN(in mints)	STANDARD CONSENT	PICTORIAL CONSENT
MAXIMUM	11	19
MINIMUM	6	10
AVERAGE	9	15

DISCUSSION:

Informed consent is primarily a legal and ethical concept for patient awareness & avoiding litigations. Due to increased workload in hospital the informed consent has only become a signing document(15). With the advancement in electronic media most importantly internet, patients are more aware & different subgroup have different queries and multiple therapeutic options which have created consent more complex(15-26). Patients are more worried about the post procedural events rather than focusing on the decision making, while some makes decision so straightforward & irrational that they do not consider the risk benefit ratio for an instance : I don't care what you tell me DOCTOR the cancer has to come out(27-30).

For this reason the decision making should be tailored for patient's ability and interest(31). It should actively need both patient and doctor active contribution but choice being made voluntarily without any influence to avoid legal problems(2,32-38).

Geographical variations introduces language barrier while informing consent thus more readable, self explanatory , multimedia aids, discussions can help in consent process. Language barrier is when both the informant and recipient are from different topographical backgrounds, thus limits consent process(31,39-45).

While in pictorial consent many were easily understood and queries cleared for instance:

1. Procedure: Patient justified two valve surgery on the basis of finances they have arranged but after seeing the picture they were well aware of the procedure
2. Incision layouts: there was a situation when two different patient's one came for CABG and other for valve replacement admitted in same post op ward saying both have gone heart surgery but one has incision on the leg wound also. After layouts they were satisfied about the incision.
3. Diagrammatic representation of organs related complications was easier for the doctor to explain

4. Representation of organs that may be affected after surgery and cardiopulmonary bypass
5. Cardioversion and its complications
6. Drains: there were wide variety of queries about the drain as few had only mediastinal and other had pleural drains too. The anxiety level were low in pictorial group
7. Monitoring lines: it was the other issue which was highly discussed, as patient were confusing arterial lines with infusion lines and were least aware its complication. Few had a query whether neck line is necessary.
8. Pacing wire: it was a new thing and were afraid whether after surgery the pacemaker will be permanent or not. The wire coming out of the body was a surprise to many of them.
9. Dietary modifications: this heading was discussed in detail aspect but the pictorial representation of different food stuff was easier to identify for the illiterate group.
10. Cardiopulmonary bypass was better understood.
11. Blood transfusion & related complications: were easily explained and some had a query that they have donated blood to the hospital for the patient & it should be transfused for early strength and recovery, but they were shown about the complications their priority changed.

Patient queries pertaining to disease was explained in easier manner. Although patient interest and understanding improved after pictorial consent. But questionnaire were not able to represent the many important aspects of surgery. This shows even pictorial consent which we try to emphasize had its own limitations. People should know that no procedure is free of risk(15). Also there have been group of patients for which consent was inadequate for the procedure(46). At the same time inadequate consent have always been troublesome and defined as negligence for clinician(47-48).there is school of thought where there have been consensus that fully informed consent can be needlessly cruel(49).

CONCLUSION:

Better consent process would avoid legal conflicts. Providing detailed and complete information even cannot assure that patient will read it complete. But a constant awareness and improvement is necessary. Pictorial consent can be new enhancement for efficient health care system and maintain physician and patient rapport.

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