Short research article

Awareness of knowledge, attitude and practices of medical students and surgical trainees regarding surgical informed consent: a cross-sectional multi-centric study from northern India

Running Title: SIC KAP of Students and Trainees

Abstract: 215 words

Background: Informed Consent is the cornerstone of modern medical and surgical care. All patients have the right to be involved in decisions about their treatment and care. Obtaining SIC (surgical informed consent) is an important and essential skill that one must acquire in medical training, yet many residents receive very little formal education.

Methods: Multiple choice questionnaire designed and after pretesting circulated on Google forms™ having questions pertaining to knowledge, attitude and practice. Total 463 responses obtained and appropriate statistical tests applied in Microsoft Excel and StataSE.

Result: Knowledge-score remained constant for medical students and trainees, Attitude-score (18.59 to 18.93) and Practice-score (2.30 to 3.62) statistically significant increase in score with clinical exposure was noted. Gender wise difference were in A-score, females scored higher 18.87 and males scored 18.49. For trainee doctors unlike P scores, K and A scores did not increase with experience.

Discussion: Early intervention in undergraduate years and continuous upskilling is the need to bridge the hiatus of doctor-patient relationship. This necessitates scenario and role play based teaching, student teaching patient based learning regarding the SIC.

Conclusion: There is a Knowledge attitude practice gap present not only in undergraduate students but postgraduates residents regarding SIC, for which the current curriculum and the ongoing practical training is insufficient to bridge. Indian curriculum must make amendments to bridge it.

Keywords: consent, questionnaire, medical education, ethics, India, jurisprudence

Introduction

Informed consent(IC) is the cornerstone of modern medical and surgical care and is a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can. Serious harm can result if patients are not listened to, or if they are not given the information they need and time and support to understand it[1]. Although obtaining SIC (surgical informed consent) is an important and essential skill that one must acquire early in medical training, many residents receive very little to no formal education on this subject[2–4]. Most residents learn from observing co-residents or faculty. This requires nuances of SIC to be understood so that one can obtain SIC effectively with empathy. There are moral, ethical and legal repercussions with poor SIC and it is considered as an important factor in waning doctor-patient relationship and rising medico-legal suits. The current scenario of high demand of medical services and limited manpower in government hospitals creates high turbulence among young doctors and makes them amenable to errors. From last decade there has been an increase in medical negligence cases in India by 400%, a major bulk of which is the improperly taken IC [5,6].

The current scenario in different parts of world reveals the deficit in training and consequently in practice of SIC. A study from New Zealand revealed a number of senior medical students disclosed observing or performing sensitive examinations on patients without the patients'

knowledge or consent[7]. Another study from USA stated that undergraduate medical students and postgraduate students who are new interns are not confident or competent in their ability to perform an appropriate informed consent discussion[8]. Although vital, the content, training and the teaching methodologies for this important skill during undergraduate training are inadequate. There is hardly any attempt in teaching this vital skill effectively. This may result in otherwise well-trained medical professionals lacking this vital skill thus exposing them to professional and legal hassles. Lack of medicolegal literacy among the patients is the hiatus in the existing doctor-patient relationship, for which few theory lectures are not sufficient to bridge, early intervention in undergraduate years and continuous upskilling is the need. The process of obtaining SIC in India is different as compared to developed countries it requires a combination of factors involving patients' background, the value they assign to health and their beliefs about personal autonomy, determine their positions on the 'right to know'–'right not to know' spectrum[9]. Consequently, all patients need to be assessed for their value systems and individualization of SIC process is needed. These characteristics are unique to Indian society and thereby this multifactorial analysis combined with effective communication of important facts to the patient requires training. Since no such study has been done in India, we thereby aim to do in-depth gap analysis in Knowledge, attitude and practice domain of seven consecutive educational and trainee years.

Method

A cross-sectional study was carried out (after obtaining ethical clearance and consent) via online questionnaire (Google form™) conducted on medical students and surgical trainees of 7 medical teaching institutes of Delhi, India. It was conducted between September 2021 and October 2021. Inclusion criteria consists of any consenting medical student who have been exposed to clinics for more than 6 months. Exclusion criteria: students less than 6 months clinical exposure. Trainees other than surgical specialties will be excluded.

Questionnaire was prepared in English, validated and pre-tested, consisted of 4 sections: demography, knowledge, attitude and practice questions. There are total 12 closed ended questions. Each correct option yielded 4 points and negative 1 for incorrect option. Maximum score is 72 (44, 20, 8 for K, A, P domain respectively). The Cronbach alpha coefficient was 0.71 (acceptable). Question wise analysis was done and suitable graphs obtained. Descriptive analysis was done on K (knowledge), A (attitude), P (practice), SIC KAP scores with variables: gender and designation. Scores and P values were calculated using unpaired t-test using Stata SE16.1™. (P-value <0.1 significant).

Results

Table 1: Percentage distribution of correct responses among participants

Question number	Question	Medical Students					Trainee doctors					
		5th semester	7th semester	9th semester	Males	Females	Interns	1st year trainee	2nd year trainee	3rd year trainee	Male	Female
1	Who is capable of taking SIC?	54.41%	59.86%	50.00%	52.65%	59.17%	50.00%	68.42%	42.86%	73.33%	58.82%	58.06%
2	What all is to be mentioned in SIC?	71.32%	70.00%	53.33%	65.49%	63.31%	70.00%	63.15%	52.38%	86.67%	73.50%	58.06%
3	Which type of procedures require IC?	61.76%	71.83%	58.33%	65.93%	61.54%	70.00%	52.63%	66.67%	60.00%	64.70%	58.06%
4	For how long is the SIC valid?	62.50%	61.98%	73.33%	65.48%	65.08%	40.00%	47.36%	47.61%	86.67%	67.65%	42.00%
5	What is the ideal place for taking SIC?	47.80%	32.39%	45.83%	37.61%	47.33%	60.00%	21.05%	57.14%	26.67%	32.35%	48.40%
6	Who is capable of giving SIC?	8.82%	18.30%	16.67%	12.80%	15.98%	10.00%	15.79%	14.29%	20.00%	11.76%	19.35%
11	An illiterate patient insists on explaining SIC document, what will you do?	53.67%	42.25%	52.25%	49.56%	49.11%	40.00%	52.63%	80.95%	73.33%	61.76%	67.74%
12	Which consent is ideally required to perform examination of intimate areas?	32.35%	37.32%	60.00%	45.57%	38.46%	70.00%	63.15%	71.43%	33.33%	50.00%	70.97%

Most frequently missed question was ‘who can give the SIC?’ 10-20% students and trainees chose the correct answers. More than 90% students and trainees said taking SIC is very important. About 70-80% students and >80% trainees agree that properly taken SIC increases patient participation in clinical care. When questioned with SIC being legal requirement >90%

students and trainees strongly agreed. A sharp rise in correct answers was observed in practice domain and it correlated with the more clinical exposure.

SIC KAP scores

Table 2: Mean and Standard Deviation of different scores

Score	Designation	Mean	Standard Deviation
K score	5th semester	30.63	8.44
	7th semester	31.32	7.06
	9th semester	29.90	7.37
	Intern	31.00	6.78
	1st year trainee	29.84	6.25
	2nd year trainee	30.14	6.18
	3rd year trainee	33.46	7.31
A score	5th semester	18.59	1.77
	7th semester	18.50	1.47
	9th semester	18.93	1.30
	Intern	19.20	0.91
	1st year trainee	18.73	1.32
	2nd year trainee	18.47	1.88
	3rd year trainee	19.00	1.13
	Female	18.87	1.36
	Male	18.49	1.64
P score	5th semester	2.30	3.28
	7th semester	1.97	3.34
	9th semester	3.62	3.40
	Intern	3.50	3.68
	1st year trainee	3.78	2.50
	2nd year trainee	5.61	4.06

	3rd year trainee	3.33	3.51
SIC KAP score	5th semester	51.53	9.98
	7th semester	51.80	8.34
	9th semester	52.46	8.31
	Intern	53.70	8.81
	1st year trainee	52.37	7.48
	2nd year trainee	54.24	8.32
	3rd year trainee	55.80	7.02

For the K-score of 5th, 7th, 9th semester students after looking at the mean, SD and the *P* 0.454 statistically significant difference could not be established. Interesting findings were observed in A-score, descriptive analysis unveiled two trends. First, with the *P* 0.013, there was a statistically significant increase in the A-score semester-wise. Second, statistically significant difference (*P* 0.011) between the male and female A-scores were seen, where females scored higher. As far as P-score is concerned it was statistically significant higher for 9th semester students (*P* 0.0001) was seen. Mean SIC KAP score increased semester-wise however the difference wasn't statistically significant.

Discussion

The study illustrated that among the medical students and trainees the K-score remained constant. Both A-score and P-score increased with clinical exposure of students. Gender wise difference was also noted in A-score where females scored higher. Among the trainee doctors unlike the P scores, the K and A scores did not increase with experience.

Primal fact about SIC is who is capable of taking a SIC, to which only 50-60% students and 40-75% trainees answered correctly. Trainees are not just any operating personnel, they learn a variety of procedures every day and hence actively take part in SIC taking. Since the trainees are in the learning phase and may not consider themselves as trained surgeons, this can be the reason behind them answering 'any personnel from operating team' as the second most chosen answer. According to the GMC guidance SIC should include the diagnosis, prognosis, course of treatment, the other options available with the failure rate and complications, benefits of the procedure and the outcome wherein no treatment is given[1]. A Nigerian study showed that only 5.93% mentioned that consequences of not having the surgery should be part of the informed consent process, which is even lower than our setting[10]. All relevant information must be explained in the language of the patient so as to assist him/her in making the decision.

Just like treatments are customized, SIC must be customized too so that the patients choose best for themselves and can make an informed decision based on proper rationale. In our study, 'other alternatives' to the suggested treatment was not given the attention it deserved, most likely due to assumption made by the consent taker that patient lacks expertise and can get confused with options. This reflects the increasing paternalistic attitude of the trainees[11]. To scale down this apprehension, one should ask questions to encourage patients to express what concerns them and patient's needs should be prioritized while offering a choice, this will increase the acceptability of treatment. Other aspect to consider is the risks patients would and wouldn't be prepared to take to achieve a desired outcome. Validity of SIC is the least discussed topic which is evidenced by 'not sure' being chosen most commonly for this question. Decision-making process is a circumstantial process and has influence from surrounding environment, therefore a quiet isolated place with adequate decision-implementation time is ideal. Special rooms can be made for this purpose which can also have a facility of scheduling counsellor support for sensitive cases.

Ethically, any person other than the patient can't take a decision on their behalf as long as the patient is capable. The ability of capacity can vary depending on a patient's condition and it changes with context of time and on the nature of the decision[1]. It should be presumed that every patient has capacity irrespective of differences. If language barrier exists every attempt must be made to give required information so as to come down to a decision. A study showed that the patients and attendants who passively participated in passive decision-making were associated with anxiety and depression, thereby every attempt must be made to actively engage the patient[12]. As SIC is a tailored process thereby, scenario-based training is necessary

to improve patient care. Surveys on doctors regarding informed consent were done in United Arab Emirates and India showed scenario-based deficiencies in knowledge and synonymous need for teaching was observed[6]. SIC is an important component of clinical care and when properly taken will improve the patient participation towards his/her own care.

There is a need to start sensitization from the first-year of medical training about need and importance of respecting autonomy of the patient and regularly boost this through trainings both in medical jurisprudence as well in clinics so as to improve functional outcomes, patient and caregiver satisfaction and also reduce cases of patient- doctor conflicts. Respecting patients' autonomy and complying with statutory legal regulations will also improve the functional outcome for the surgeon. Once the doctor understands the gravity of the situation wherein only s/he can bridge the medicolegal awareness gap among the patients, only then the medical education policy makers will address ethics in curriculum. It's high time to allocate special clinical training in form of role play based learning and students teaching patients programs[13,14].

Conclusion

Amidst the growing medicolegal cases in poverty stricken developing India, taking an SIC from the patient is becoming increasingly difficult by the overburdened doctors. Taking SIC is not just translation to patients' language but also it also includes careful assessment of their value systems and moreover presenting in an understandable way. The whole process requires skill training starting from undergraduate years. Current curriculum is insufficient and this study shows KAP gap starting from undergraduate years till residency years.

Ethical Approval:

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

Consent

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

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