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Original Research Article

Assessment of study among radiography students about how to take informed consent

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ABSTRACT

Background: Consent form is an integral first step before any radiological procedure that engages methods that can be threatening to patients. Future radiographers i.e., radiography students should have sufficient and appropriate knowledge regarding obtaining an informed consent. The aim of my study is to evaluate and assess the knowledge and impart the importance of informed consent form among Radiography students under various conditions.
Methods: A questionnaire based retrospective cross-sectional was used to assess the knowledge of informed consent among radiographic students. The study was carried out in radiology department of Maharishi Markandeshwar University. The questionnaire comprised of self-structured MCQs questionnaire consisted of demographic data and basic questions regarding informed consent.
Results: Out of 156 undergraduate and postgraduate radiology paramedical students, 87 took part in the study. It was assessed how much information radiography students possess on taking informed consent. The gender ratio was allocated into 2 groups. First group was female consisting of 45 (51.72%) number of participants and second group male consisting of 42 (48.28%) number of students with mean of 21 years.
Conclusions: Indulging on the subject of consent form, almost all of the students understood the concept of consent form or had heard about the concept of informed consent to some extent. Maximum students were in favour of classes being held discussing consent form. The statistical data of all participants who gave the correct answer is 81.20%, indicating that radiography students understand and grasp the concept of consent very well.

Keywords: Informed consent, Patient, Radiography students

INTRODUCTION

Radiology procedures are performed to obtain diagnostic information about the abnormal unidentified condition of the patient. Radiological examinations like X-ray, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US) is performed to acquire the diagnostic data about the internal structures of the body, like for fractures, lesions, tumours etc., Some of these examinations require contrast media and other intravenous compounds that can cause adverse effects like allergic reactions to the patient. Also, they are sometimes quite complex for the patient to understand the logic of the examination. They do not fully comprehend the risks and benefits of the procedure. Even after verbally explaining about the procedure, the patient may still be unsure. If anything happens during the procedure, the patient can put allegations that he/she was not told about it and it may have legal concern. So, a document was introduced that ensure in writing that the procedure have been fully explained to the patient and by signings the patient certify that he/she is attentive to complete process including its risks and benefits. This document is termed informed consent.

Informed consent is a process in which a patient or his/her attendant learns all the significant details about a clinical

trial, diagnostic and therapeutic procedures like contrast studies, including potential risks and benefits, before deciding whether or not to participate in a study. Informed consent continues throughout the procedure and it does not end at the beginning only after the signature on the consent form.

Informed consent is a legal procedure to ensure that a patient knows all of the perils and expenditures involved in a procedure. It is a legally binding document that can be used in a court of law in case of any judicial matter. It ensures that the hospital administration is protected from any lawsuits.

The informed consent ensures that the patient have all the knowledge regarding the procedure beforehand and will not be surprised or shook in between the procedure by any steps. It ensures that the procedure will be concluded without any obstruction arising from partial or inadequate knowledge about the procedure in relation to the patient.

In order for informed consent to be considered binding, the client must be capable and the consent should be given voluntarily. The following are the required elements for certification of the informed consent discussion: the nature of the procedure i.e., does the procedure requires contrast or any method that can be risky to the patient; the risks and benefits of the procedure i.e., the risk and benefits of the procedure must be assessed and explained to the patient and the procedure must only be done if the benefits outweigh the risks; reasonable alternatives i.e., are there any alternative procedures that are less hazardous than the one prescribed; risks and benefits of alternatives; and evaluation of the patient's understanding of elements 1 through 4, it is the responsibility of the radiographer to make it clear that the patient is partaking in the decision-making process and avoid making the patient feel forced to agree.

There are three elements of informed consent, viz: information; comprehension and volition. Informed consent is a process, not just a form. Information must be presented in a manner that is well understood. It is a fundamental mechanism to ensure respect for persons through the provision of thoughtful consent for a voluntary act.[1]

Taking an informed consent is a multi-step process and requires proper understanding of the steps involved in the obtaining of consent. Some key aspects are mentioned below in Figure 1.[2]

The process of consent needs to be correct and followed strictly as it is commonly treated as an annoyance and a convention. The patient and families often are not explained the importance of the procedure and neither they show any interest. They do not fully grasp that the consent is for their benefit and they have a choice to say no. Informed consent must be obtained correctly and according to principals in the radiology department and it depends on the capability of the patient to make an informed decision. It means that the patient must have competence and the right to decide. The patient must be able to make and commune a choice. The patient must be capable to understand key information about his/her condition, options for procedure and its benefits and risks.

An informed consent is obtained before conducting a procedure because of the use contrast media during certain procedures. Like in X-ray, CT, MRI, and US like IVU, Barium (Ba) swallow, RGU, MCU, CECT brain, CECT thorax, contrast enhanced MRI brain (CEMRI) brain.

The General Medical Council (GMC) suggests that written consent should be taken in cases where: "The treatment or procedure is complex and involves significant risk and/or side-effects, providing clinical care is not the primary purpose of the investigation or procedure (in particular, where the examination or procedure is for non-therapeutic purposes), there may be significant consequences for the patient's employment, social or personal life, the treatment is part of a research program. Written consent for some procedures is also required by the mental health act and the human fertilization and embryology act".[2,3] Keeping above information in mind, informed consent is a very crucial step in radiological procedures.

In the radiology department of MMU, consent form is obtained before every procedure that require the use of contrast media. As the radiography students have posting in different modalities (X-ray, CT, and MRI), they assist in the procedures and learn them practically. Although technician is in supervision, these students also take part in the process of obtaining consent form. They should have knowledge about how to take correct informed consent for various modalities in different condition as they are future radiography technicians.

METHODS

Study type

A retrospective, comparative, questionnaire-based investigation was carried out in the department of radiology at the MM Institute of Medical Science and Research, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India. This study was to assess the knowledge of informed consent among radiographic students. To check the knowledge of undergraduate students and postgraduate radiography students about the proper procedure of obtaining consent.

Study design

This study was designed to check the knowledge of radiography undergraduate second year, final year, and postgraduate first-year and final year students in the MM Institute of Medical Science and Research, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India.

Study area

This study was conducted in the radiology department among radiography paramedical students of BSc. 2nd and 3rd year and MSc. 1st and 2nd year of Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala, Haryana.

Study duration

This questionnaire-based study was conducted for the time period of six months from November 2021 to April 2022 at the at the MM Institute of Medical Science and Research, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India.

Study population

The study population consisted of radiography students excluding the students who fell under exclusion criteria. There were 87 students studying radiological and imaging techniques at the undergraduate and graduate levels. The approach used to gather samples was probability sampling. Some batches are disqualified since they have not yet finished the theoretical portion of their curriculum, which includes the subjects covered in this research. The number of participants in each course were: BSc. 2nd year – 33, BSc. 3rd year – 42, MSc. 1st year – 6, and MSc. 2nd year – 5.

Method of data collection

The study was carried out among radiography paramedical students of BSc. 2nd and 3rd and MSc. 1st and 2nd year at the MM Institute of Medical Science and Research, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India. The aim of the research was explained to each and every individual. Verbal form was acquired from all respondents included in this research. The questionnaire was structured by using google form and was distributed in different WhatsApp groups via internet. The inquiries were joined subsequent to going through different writing identified with that, which comprised of self-structured questionnaire divided into two sections. the first section of questionnaire consisted of demographic data including name, age, course, department, the second section of questionnaire consisted of basic questions regarding informed consent.

Inclusion criteria

In this study students of BSc. 2nd year, BSc. 3rd year, MSc. 1st year, and MSc. 2nd year who volunteered, of the radiology department were included in the study.

Exclusion criteria

In this study following radiography students were excluded: unavailable and those students who did not acknowledge the study and students of BSc. 1st year.

Statistical analysis

The data collected was compiled, tabulated, graphical, analysed, and subjected to statistical tests. Analysis was done using Google form.

RESULTS

Out of the 156 participants, 87 students (55.76%) studying radiological and imaging techniques at the undergraduate and graduate levels completed the questionnaire. The study was done to evaluate students' theoretical understanding and experience gained from hospital postings about obtaining informed consent from patients. There were 45 (51.72%) females and 42 (48.28%) males, ranging in age from 18 to 32, with a mean age of 21. the demographics of the participants are represented graphically in the form of a pie chart graph of gender and a bar graph of participants' ages (Figures 2 and 3).

Table 1: Qualification (undergraduate and postgraduate) and respective percentage of participants who gave the correct answers to the questions.

Qualification	Undergraduate	Postgraduate
Mean values	78.30	84.1

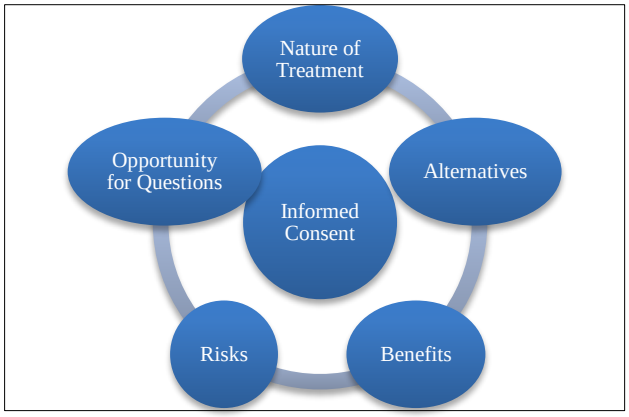

Figure 1: Key aspects of informed consent.

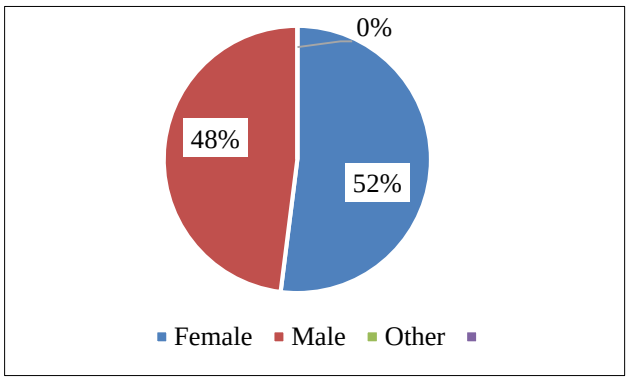

Figure 2: Percentage of male and female participants in this study.

Table 2: Comparison between undergraduate and postgraduate.

Question no.	Undergraduate (%)	Postgraduate (%)
1	100	100
2	37.33	58.33
3	98.67	100
4	72.00	41.66
5	96.00	100
6	52.00	75
7	98.67	100
8	48.00	41.66
9	96.00	100
10	96.00	100
11	65.33	50
12	80.00	83.33
13	88.00	91.66
14	85.33	91.66
15	97.33	100
17	61.33	66.66
18	81.33	100
19	58.67	58.33
20	80.00	58.33
21	82.67	100
22	16.00	58.33
23	52.00	58.33
24	92.00	100
25	94.67	100
26	92.00	100
27	96.00	100
28	88.00	100
29	56.00	50
30	84.00	91.66
31	85.33	100
32	81.33	100
33	80.00	100

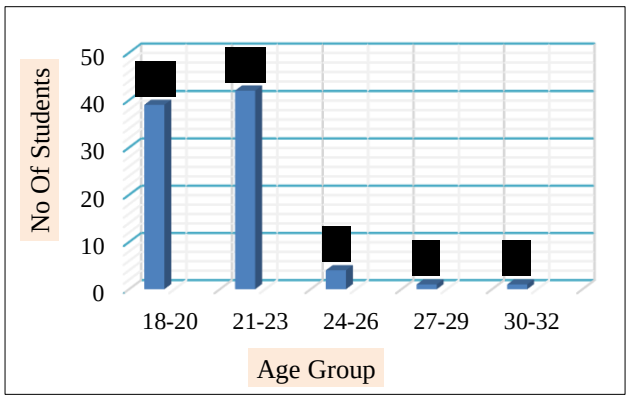

Figure 3: Graphical representation of the age group of participants in this study.

The academic qualification and work experience of participants were varying. There were undergraduate and postgraduate students of department of radiology at the MM Institute of Medical Science and Research, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India. There were students of BSc. second year, BSc. third year, MSc. first year and MSc. second year courses. Undergraduate students were 42 (48.28%) BSc. third year and 33 (37.93%) BSc. second year students. Postgraduate students were of MSc. first year and MSc. second year students with 6 (6.90%) number of students each (Figure 4).

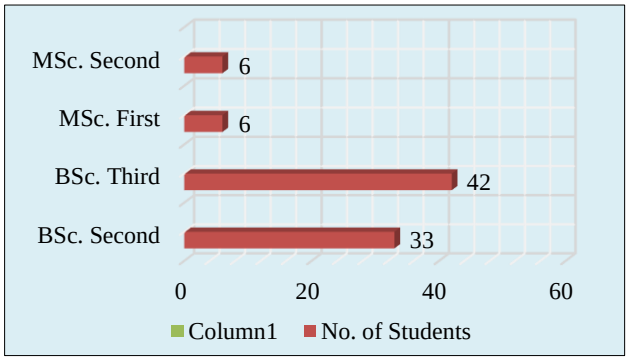

Figure 4: Year-wise undergraduate and postgraduate participants.

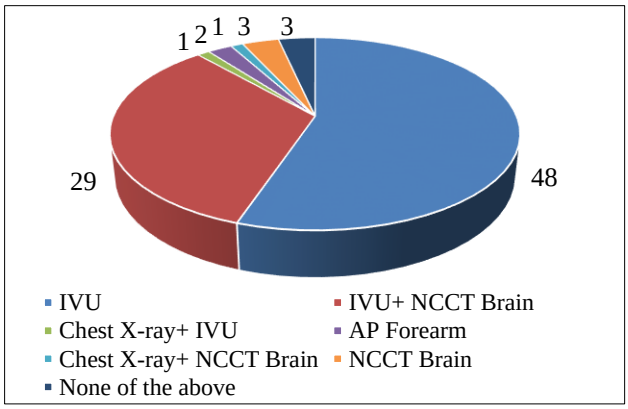

Figure 5: 3D pie chart of requirement of consent before which procedure.

Among 33 questions related to informed consent, the maximum and minimum scores obtained were 100% and 16% correct answers for undergraduate students and 100% and 41.66% for postgraduate students, respectively. The percentage mean value of batch-wise participants who gave the correct answers is illustrated in Table 1. The question-wise mean values of participants who answered correctly are demonstrated in the form of a comparison between undergraduate and postgraduate in Table 2. The statistical data of all participants who gave the correct answer is 81.20%, indicating that radiography students understand and grasp the concept of consent very well. The comparison between undergraduate and postgraduate radiological imaging techniques students' knowledge and cognizance of informed consent bears the following data: postgraduate gave a correct answer of 84.10% and undergraduate gave a correct answer of 78.30%. Finally, it

can be postulated that postgraduates have excellent comprehension and perception of taking proper consent.

In response to the query that informed consent is required before which procedures, IVU was checked against by 48 students (55.17%). Intravenous urography (IVU) and non-contrast computed tomography (NCCT) brain was selected by 29 students that is approximately 33.33%. One student (1.15%) chose chest X-ray and IVU as the response. One student (1.15%) chose chest X-ray and NCCT brain as the response. AP forearm was selected by 2 students (2.30%). Three students preferred NCCT brain as the response with 3.45%. And 3 students chose none of the above as the option with 3.45% (Figure 5).

A question was asked to ascertain the knowledge of students about the importance of informed consent. Forty-one students (41.13%) checked options for patient's concern, for staff's concern and for legal purpose. Fourteen students (16.09%) chose for patient's concern and for legal purposes as their option. Six students (6.09 %) opted for the option that is for patient's concern. Around 12 students (13.79%) chose for staff's concern and for legal purposes as their answer and 12 students (13.79%) selected for legal purposes. Only two students (2.30%) chose for patient's concern and for staff's concern as their response. No student chose none of the above as their option, so 0.00% (Figure 6).

In response to the question about asking contents of the consent form, 55 students (63.22%) selected information about procedure, information about its risks and column for patient's details as their answer. Information about procedure and information about its risks was chosen by 13 students and it came to 14.94%. Five students (5.15%) selected information about its risks and column for patient's details. Information about its risks was selected by Eight number of students (9.20%). Four students checked against information about procedure (4.60%). Column for patient's details was selected as their answer by 2 students (2.30%). No student i.e., 0 chose none of the above as their answer (0.00%) (Figure 7).

The need for lectures discussing informed consent, 71 (81.60%) checked against 'yes' and 16 students choose 'no' (18.40%) (Figure 8).

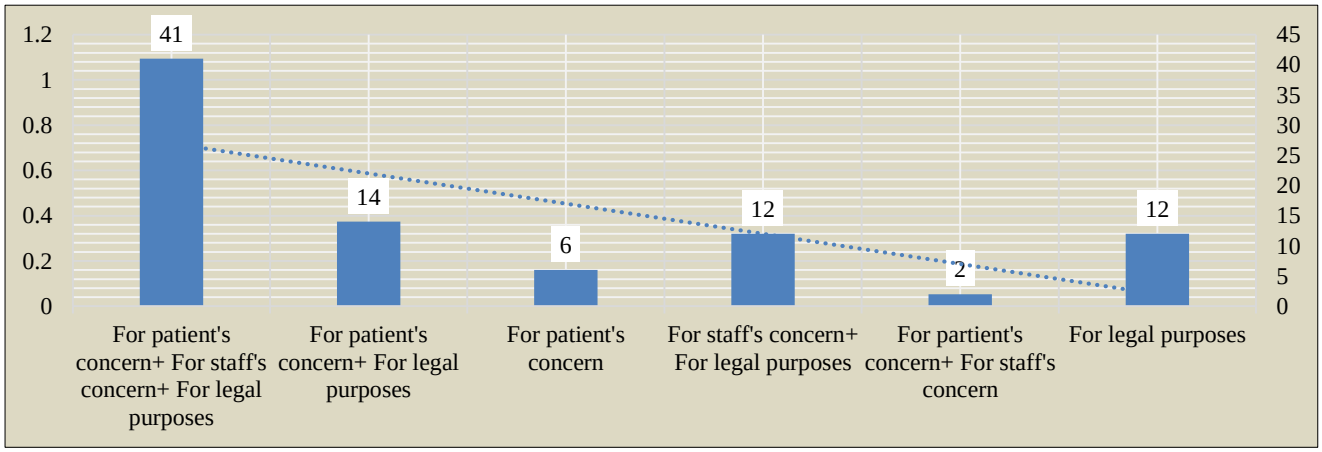

Figure 7: Horizontal bar graph of contents of consent form.

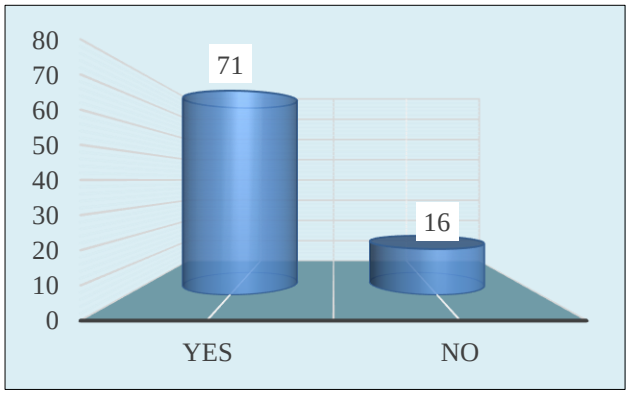

Figure 8: Cylindrical bar graph representing need of lectures of consent form.

The result of this study established that postgraduate students have admirable knowledge, but undergraduate students have information regarding consent to a lesser extent in comparison to postgraduate students.

DISCUSSION

The research on the thesis, 'assessment of study among radiography students about how to take informed consent' shows that the 96.60% students agreed that the content of consent form should be explained before the start of the procedure to the patients. 85.10% gave preference to 'yes' as their response to withdraw from the procedure even after giving consent. 86.20% gave inclination to 'no' as their answer on the subject of forcing the patient to go through the procedure even if he/she is not comfortable after signing consent. Similar conclusion was made in the article "informed consent in research by Nnebue" that every subject of the research is fully attentive of the procedure and outcomes of the research and a participant is not intimidated or coerced into succumbing to the

research and a subject's inexperience or mental ineptitude is not abused during the procedure.[1] 96.60% students responded 'yes' to understanding on the subject of consent form and 3.40% chose 'no' as their response. 41.13% students checked three options that were for patient's concern, for staff's concern and for legal purpose.

96.60% students responded 'yes' to the importance of explaining the procedure and its potential risks beforehand to the patient. 88.51% selected one choice as their reply that is patient's attendant to deeming obtaining consent form if the patient is not conscious. 97.70% checked against 'yes' as their answer to maintaining the consent record after procedure is over. On the subject of difference in the contents of consent form for different modalities, 78.20% agreed on it. Near to same as to this research, it was also concluded in the article "informed consent for clinical treatment by Hall et al" that informed consent means diverse things in different situations, is unpredictably practiced, and seldom achieves the hypothetical ideal.[20] Simple consent necessitates that a patient (or attendant) with judgement -making ability without restraint approves a treatment plan intended at a conjointly accredited medication goal. The agreement is "informed" when the doctor divulges and the patient comprehends the process, the appropriate options for treatment (including no treatment) and any particular risks and benefits. The informed consent process should be recorded thoroughly, using medical confirmation, procedure precise consent forms, patient instruction constituents and other possibilities whenever conceivable.

In article "making informed consent an informed choice: training for health care leaders," it was concluded that there is need to "cultivate, disseminate, and intermittently review a distinct and comprehensive policy on informed consent and effectual patient interaction guidelines. And also, deliver structure and sustenance to persons in responsibility of cultivating the informed consent process".[6] In relation to above paragraph, our research showed that to explain the content of consent form before the start of the procedure to the patients or not 96.60% of students responded 'yes' and 3.40% students chose 'no' as their response. In terms of clarifying the procedure and its probable risks before the commence of the procedure to the patients or not, 96.60% of students selected 'yes' and 3.40% 'no' as their answer.

In "standards for patient consent particular to radiology (second edition): The Royal College of Radiologists", it was mentioned that consent form should be kept safe in the records, information should be given to patients regarding the risks and benefits of the imaging, the capacity to give consent should be properly assessed, child or paediatric patients' consent form should be taken by elder attendant, patient should be free to refuse to sign consent and withdraw from the procedure whenever he/she wants and it should be asked if any problem was met by patient during earlier scans.[13] Similarly in our study it was asked from who consent should be taken if the patient is unconscious and incapable to provide an informed consent, 88.51% selected patient's attendant. Only 1.15% choose nurse, doctor, and patient's attendant and 3.45% doctor. Doctor and patient's attendant was by 4.60% and 2.30% students checked none of the above.as their response. In case of a paediatric patient and consent form is to be acquired, 86.21% selected patient's attendant, 9.20% cancel the procedure and 4.60% went with no need for consent and 0.00% with none of the above. In retort to question of asking if the patient has faced any discomfort during previous scans, 93.10% agreed on asking this from patient and 6.90% did not agreed. In relation to previous comment, it was enquired to analyse if the students believe they should probe if the patient is claustrophobic or not, 95.40% said 'yes' and 4.60% 'no.'

In the article titled "using video-taped examples of standardized patient to teach medical students taking informed consent," the conclusion was that "lecture-based education is still effective in teaching medical ethics, but it is far more effective when linked with standardized patient care. It should be acknowledged that mixed teaching approaches should be utilized in conjunction for the best results." [19] In our study also, regarding having enough information in terms of gaining proper consent, 83.90% went with 'yes' and 16.10% with 'no.' The need for classes conversing informed consent, 81.60% checked against 'yes' and 18.40% 'no'.

Limitations

The study is limited by its sample size, as there are only 87 participants from one institution. If there had been more participants, the result might have varied a little. As the participants included students, their age range was narrow, with the lowest being 18 and the highest being 32. This limited the study to a particular range of ages. The study pool included only students, and their lack of clinical experience results in the responses being less accurate. The last limitation was the analysis. The result relied on a quantitative analysis of the data.

CONCLUSION

The conclusion of this study was majority of students (81.20%) understand the effects of radiation and contrast and the requirement of properly obtained consent form from the patient before the procedure. All the students knew about the radiation meaning all 87-study pool have a grasp on what radiation is but it does not necessarily mean that they fully understand the concept of radiation.

In response to the probe that informed consent is required before which procedures, correct response IVU was checked against 55.17% of students and it signifies that more than half of strength understood the appropriate criteria of procedure with regards to entailing consent. While rest 44.83% selected other variations of responses and it can be supposed that they were not sure about the

examinations that require consent and maybe did not understand the conditions vital for it.

A question was asked to ascertain the knowledge of students about the importance of informed consent. Maximum (41.13%) study pool checked right options for patient's concern, for staff's concern and for legal purpose and it can be assumed that they have studied in the region of the necessary benefits of taking informed consent thus, they are enlighted in the art of advantages of consent. And other inadequate combination of options that students have selected can only be expected that they were ill-informed in this sense and did not bother to acquire knowledge concerning it.

On the subject of having enough information regarding gaining proper consent, 83.90% went with 'yes' and 16.10% with 'no.' It can indicate that main stream of students have adequate knowledge in this regard but it might be superficial knowledge and not deep. Remaining fraction of participants accepted that they did not have proper information on the topic of obtaining informed consent. The need for lectures discussing informed consent, 81.60% checked against 'yes' and 18.40% 'no.' So, greater part of students is in the favour of classes being held discussing all the aspects of consent form. While some amount is in the mindset that they know everything about the consent or there is no requirement of allotting time to the lectures of it.

The knowledge about informed consent was satisfying with definite possibilities for further improvement of radio-imaging and radio-diagnosis students and professionals. Regular conferences, symposiums, seminars, workshops, and continuing medical education (CME) should be organized and implemented through collaboration between national and international organizations should take prompt actions conducting education practical and theoretical courses through Open University and training courses.

Recommendations

This type of study was less done in Indian Institutes and universities. These goals are primarily focused on improving patient care through adequate communication between caregiver and patient in order to reach an ultimate diagnosis in radio-imaging and radio-diagnosis departments. Practical training, theoretical and skill training should be organized by national and international conferences and CME to improve the knowledge regarding taking an informed consent.

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