Original Article

Investigating the impact of multimodal training on surgical informed consent in final year medical students: A quasi-experimental study

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Abstract

Background & Objective: : In clinical practice, obtaining informed surgical consent is rooted in respecting a person's dignity, and failure to obtain informed consent has been labeled as medical negligence. Teaching this process to undergraduates can improve doctor[–patient relationships, thereby decreasing medico U -legal litigation. This study investigated whether a multimodal training module for teaching final-year medical students surgical informed consent was effective in improving this skill. It aimed to determine the students' perception of multimodal training in taking informed consent for surgical procedures.

Material & Methods: This single-group quasi-experimental study was conducted in the authors' teaching hospital in Kerala, India, among 35 final-year medical students from January to July 2022. It evaluated their ability to obtain surgical informed consent and the improvement following an educational intervention based on a multimodal training module using a prevalidated Directly Observed Procedural Skills assessment.

Results: Following the intervention, students showed an improvement in their ability to take surgical informed consent and in assessment scores, which was found to be statistically significant ($p < 0.001$). Male students showed a greater improvement in the Knowledge subcomponent of assessment score as compared to females, which was statistically significant ($p < 0.001$). All the students, in their feedback, felt the training was feasible, made learning interesting, helped identify weaker sections, and retained concepts in memory. They opined that it made them confident in taking consent and that they would prefer this type of learning in the future.

Conclusion: Multimodal modular training enhanced the proficiency of final-year medical students in obtaining informed surgical consent from simulated patients. This enriched their professionalism and interaction with simulated patients. Utilizing faculty as simulated patients needs further exploration. We recommend that the undergraduate medical curriculum incorporate a prevalidated multimodal training module and assessment tool for surgical informed consent.

Keywords: communication skills, directly observed procedural skills, multimodal training module, surgical informed consent

Introduction

Communication skills are one of the seven skills for physicians, and they are known as the 'Global Minimum Essential Requirements' (GMER) set out by The Institute for International Medical Education (IIME) (1). These skills are also an integral part of learning patient care and management (2). Physicians are required by the General Medical Council to "work in partnership with patients," which entails combining effective clinical communication skills with a respectful and supportive attitude toward patients (3). A competent doctor with a professional commitment to good practice, the transfer of focused information about the planned invasive

procedure, and clear communication between doctor and patient are the keys to obtaining informed consent, which is integral to any medical or surgical procedure. Lack of effective communication results in mistrust and leads to conflicts between patients and doctors (4). Surgical Informed Consent (SIC) is the communication method between a patient and doctor that eventually results in the patient's agreement to undergo a surgical procedure with knowledge of the possible risks and benefits.

Current consent processes are not ideal for many doctors, and it is common for consent to be taken immediately prior to surgery (5). Surgeons must conduct a SIC discussion with patients prior to surgery (6). However, barriers to effective consent-taking reported include a shortage of time, clinician inexperience, and patients' reluctance to be involved (5). Ideally, the operating surgeon should obtain consent, but in practice, it is often the junior doctors who complete this task (5, 7). They often need more confidence in obtaining consent for surgical procedures and require more guidance to undertake this task (5). Moreover, SIC is an underappreciated element of surgery, and both surgeons and patients need to fully understand its significance. Hence, a big gap exists between the daily practice and the theoretical or legal best practice of SIC, as surgeons need to gain the competence to guide patients through a legally correct SIC process (8).

SIC is traditionally taught to undergraduates in the form of didactic lectures (9). Effective doctor-patient communication skills are a core competency and a certifiable skill to be acquired during undergraduate medical education (4). Nonetheless, training in communication skills is a critical component that needs to be added to the traditional undergraduate and postgraduate medical curricula in India (2). Medical students acquire the competence of obtaining informed consent through observation, and their training in this critical concept needs to be revised (9). It has been noted that students' acquisition of these clinical abilities is largely left entirely to chance since there is no formal assessment to confirm that skill learning has actually occurred (10). Moreover, as training in SIC is not included in the curriculum, this skill is found to be deficient among practitioners and interns (10, 11).

Previous research has shown that curriculum-based training is essential to instill in undergraduates the habit of developing effective communication skills since the majority of the students who were evaluated were given "fair" or "poor" performance ratings (12). The teaching of communication skills to medical students can improve their competency, patient satisfaction, and clinical outcomes (13). Teaching SIC to medical students can improve doctor-patient relationships and thereby decrease medico-legal litigation (9). Furthermore, suggestions have been made to design curriculum projects with the specific objective of assisting undergraduate students in cultivating, improving, and perfecting their communication abilities while undergoing training (14). The Medical Council of India (MCI) Vision 2015 has recommended more interactive sessions like modular teaching and group discussions than lectures (15). Small group discussions with role-playing and video demonstrations have a positive effect on students while teaching communication skills (16). Integrated modular teaching is effective, as various teaching-learning methodologies can be effectively combined with active student participation (17).

Hence, there is a need for training and formative assessment, which offer undergraduates feedback. With this background, we intend to determine the effectiveness of a multimodal training module among final-year Bachelor of Medicine and Bachelor of Surgery (MBBS) students in augmenting their skills to obtain surgical informed consent.

Therefore, the present study aimed to assess the improvement in the ability to obtain SIC and, in addition, the knowledge and communication with attitude subcomponents by implementing multimodal modular training for SIC and comparing the students' skills before and after training using pretests and posttests. It was also aimed at determining the final MBBS students' perception of multimodal training in taking informed consent for surgical procedures.

Material & Methods

Design and setting(s)

This one-group quasi-experimental study was conducted in the Surgery Department at the authors' tertiary and teaching hospital in Kerala, India, from January to July 2022. This design mimics experimental research and provides a high level of evidence without randomization. We found this design more appropriate in medical education, as it is preferable not to randomize participants for practical and ethical reasons.

Participants and sampling

Final MBBS Part 1 {non-Competency-Based Medical Education (CBME) curriculum} students of the 2017 and 2018 batches (regular and supplementary) who have passed the II MBBS university examination and were

posted to the general surgery department were included in the study after written informed consent.

Inclusion Criteria: Final MBBS Part 1 (non-CBME curriculum) students of the 2017 and 2018 batches (regular and supplementary) who have passed the II MBBS university examination

Exclusion Criteria: Final MBBS Part 1 (non-CBME curriculum) students of the 2017 and 2018 batches (regular and supplementary) who have not passed the II MBBS university examination

Based on the mean and standard deviation of assessment scores from an earlier publication, with 80 % power and 5% type I error, the minimum sample size was 30 (18). A total of 36 final MBBS students with consecutive roll numbers (consecutive sampling) were included in the study and were divided into small subgroups of six each. The consecutive sampling method was chosen as the students were posted in small batches (six students each) to general surgery so that the study could be conducted without disrupting their scheduled posting to other departments. In addition, this sampling method was considered a more practical and ethical approach as the research was based on a medical education intervention. Following the absence of one student due to illness, a total of 35 students were studied, and the data of the students was analyzed (Consort Flow Diagram1 given as an annexure).

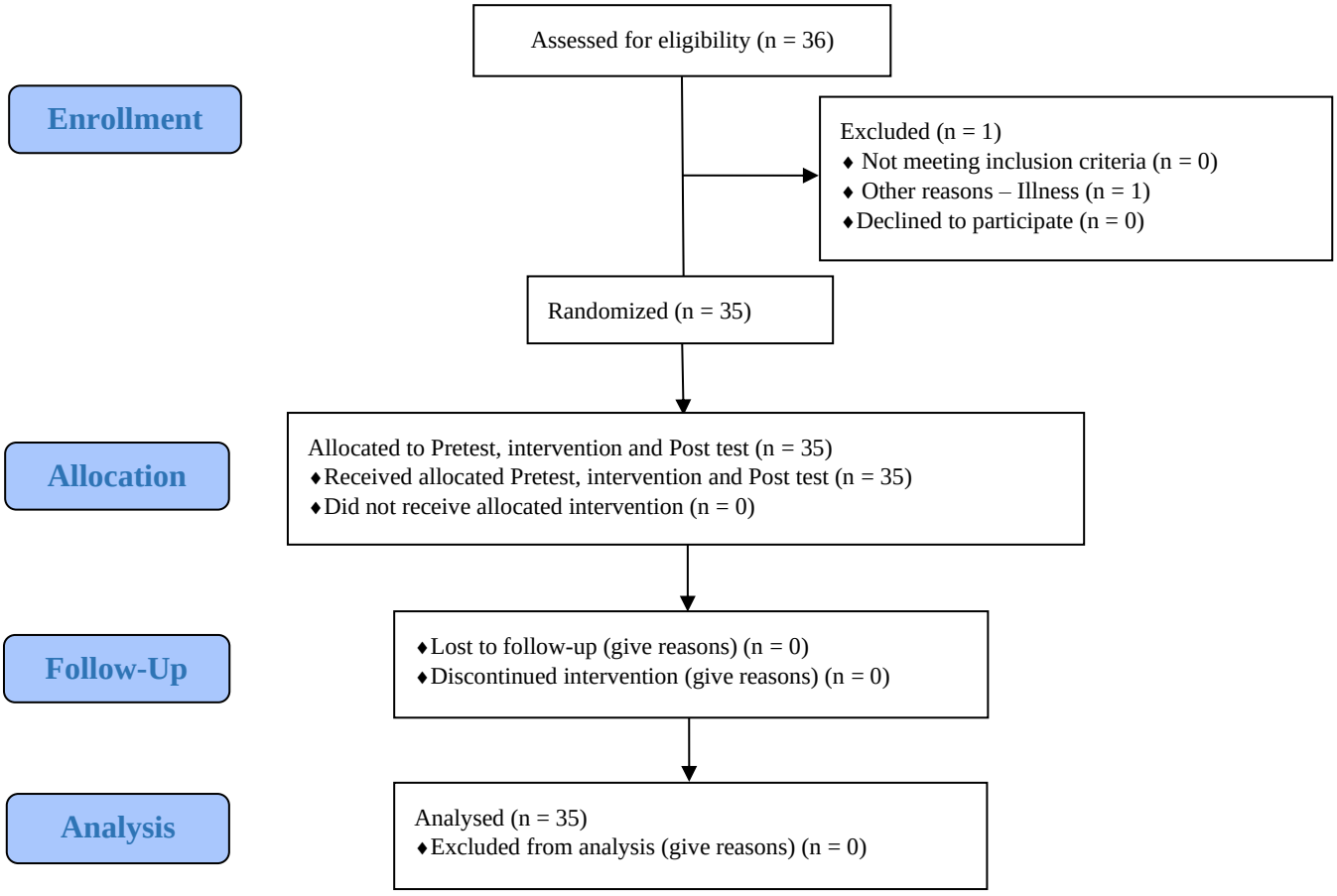

Figure 1. Flow diagram of the study

Tools/Instruments

Based on a literature review, the basic training module utilized in comparable research by Kumar et al. (9) and Murugan et al. (19) with minor changes was used for preparing the SIC training module for the present study. The literature review helped to obtain evidence-based training topics and methods that contained information on the role of undergraduate medical students as future doctors, the training of undergraduates in communication skills, the procedure for obtaining SIC, and the training skills needed by teachers.

The multimodal SIC training module for open inguinal hernia surgery and laparoscopic cholecystectomy was based on the basic skills needed to obtain SIC and intended to offer experiential learning to undergraduates in accordance with the recommendations made by K. Aspegren (20). It incorporated an interactive PowerPoint lecture with a video demonstration of informed consent and small group discussions based on case scenarios. The module provided experiential learning on informed consent by means of observing, role-playing, and modeling in both the local language and English in small groups (Table 1).

Table 1. Training module synopsis

Training method	Duration
Interactive Lecture with PowerPoint	30 minutes
Video demonstration	20 minutes
Small group discussion	15 minutes
Roleplay	30 minutes

The module content covered the relevant aspects of communication skills, respectful behavior, empathy, willingness to discuss and clarify doubts, theoretical knowledge of the disease, indications for surgery, operative procedure, risks, benefits, complications, and documentation of SIC. Expert judgment elicited from three senior members of the Department of Medical Education Technology in our medical college confirmed that the module had satisfactory content validity, and approval from the Institutional Research Committee provided the necessary validation for the training module. The judgment and opinion of these faculty members were considered necessary as they had prior experience in interventional studies in medical education. In addition, they were capable of providing relevant inputs to the content and method of training within the module. Thereby, it was ensured that the training module had good efficacy, and this will further enhance the learning process.

The overall aim of the training module is to introduce and equip undergraduates with basic communication skills in order to obtain SIC, which they will need to perform in their future roles as junior doctors. The training module acts as a preparatory course and does not replace any further supervision or training at a later phase.

The concept of a multimodal training module and Directly Observed Procedural Skills (DOPS) assessment (Appendix A) using interns as simulated patients were introduced to the faculty members prior to the educational intervention. The faculty members included one professor, two assistant professors, senior residents, and junior residents, who were sensitized to their role as assessors. In small subgroups of six students at a time, the pre-intervention session commenced with an overview regarding the value of communication and the principles of surgical informed consent. An effort was made to review the student's prior knowledge. They were then assigned to an intern who played the role of a simulated patient, from whom they were asked to obtain surgical informed consent for an open inguinal hernia repair and laparoscopic cholecystectomy. The pre-intervention session was observed and monitored, and the student's performance was assessed by the faculty team using the DOPS assessment sheet (pretest).

The students were then instructed to use the SIC training module. After the training, they were directed to obtain SIC for the two surgical procedures from the same intern who had previously been assigned to them as a simulated patient. This session was observed, and the faculty assessed the participants' performance using DOPS (posttest).

Applying one's knowledge and performing learned clinical skills in a simulated environment in DOPS leads to increased confidence in participants, which can be further helped by receiving feedback from the assessors. This type of assessment becomes more significant if we are dealing with training where the risk to patients or clinicians is immense if real clinical scenarios are to be considered. DOPS is a distinct approach to ability assessment that was primarily developed by the Royal College of Physicians in the United Kingdom (9) and is a proven method to assess procedural skills, including communication skills and the informed consent process (10, 21). DOPS assessments can be utilized because of their appropriate validity and reliability, positive impact on learning, and higher satisfaction of students (22). Three senior members of the Department of Medical Education Technology in our medical college confirmed that the DOPS assessment tool had satisfactory content validity and fulfilled the statistical requirements. Statistical analysis of our study results showed that Cronbach's alpha reliability coefficient for the DOPS assessment tool was 0.878 and 0.852 (Good grade) for the two procedures.

Data collection methods

The faculty administered the DOPS assessment (pretest) to the students while they obtained SIC from simulated patients. A prevalidated DOPS assessment sheet (pretest) from earlier research using fifteen items in two subcompetencies on a scale of 1–9 (one being the lowest and nine being the highest), as given in Annexure 1, was used before the intervention (9). An arbitrary scoring

system was devised where a total score above 60 and an average above four were considered satisfactory. A final assessment using the DOPS sheet to evaluate the ability to take SIC was conducted (posttest) after the multimodal training. Pre- and post-training DOPS scores were recorded for 35 students.

Feedback on how the training changed students's perceptions of obtaining SIC was collected using a questionnaire (Appendix B). A peer-validated feedback questionnaire for acquiring students' perceptions of obtaining informed consent based on the Likert scale, as given in Annexure 2, was used (9).

Data analysis

The data entered in M.S. Office Excel was analyzed using the SPSS 25 version. Pre- and posttest DOPS scores were expressed as mean + standard deviation. Overall and gender-wise comparisons of pre- and post-intervention scores were done using a paired t-test. Pre-intervention results were compared to see if there was parity in the pre-existing knowledge for the two surgical procedures. Gender-wise comparison pre- and post-training, for both knowledge and attitude, along with communication subcomponents, was done, and a $p < 0.05$ was considered significant. Feedback on the students' perceptions was obtained as descriptive statistics using a Likert scale and expressed in frequency and percentages. A statistical analysis of our study results using Cronbach's alpha reliability coefficient was used to confirm the reliability of the DOPS assessment tool.

Results

Of the 35 students, 12 were males and 23 were females, and this proportion was similar to the M: F ratio of 1:2 in their class. The mean difference in DOPS scores for inguinal hernia surgery and laparoscopic cholecystectomy before and after training was 42.8 and 43.4, respectively, which was statistically significant ($p < 0.001$) (Table 2).

Table 2. Mean Total DOPS scores before and after training and the mean difference in total DOPS scores for inguinal hernia surgery and laparoscopic cholecystectomy

Surgery	n	DOPS Score			t Value	p Value
		MeanTotal	SD	Mean Difference		
I had Inguinal hernia surgery						
Before training module	35	51.14	9.98	42.8	20.89	< 0.001**
After training module	35	93.94	13.63			
II Laparoscopic cholecystectomy						
Before training module	35	49.86	10.06	43.4	20.42	< 0.001**
After training module	35	93.26	13.35			

Note: ** Signifies statistical significance.
Abbreviations: n, number of participants; SD, standard deviation; t Value, t-test value; p Value, probability-value.

The difference between male and female mean total pre- and post-training DOPS scores for inguinal hernia surgery and laparoscopic cholecystectomy, when compared, was not found to be statistically significant ($p > 0.05$) (Table 3). Analysis of mean sub-component DOPS scores showed improvement in knowledge and communication, along with attitude sub-components, post-training for both procedures, and this was found to be statistically significant ($p < 0.001$). The improvement after training in the overall DOPS score for both procedures was also statistically significant ($p < 0.001$) (Table 4).

Table 3. Comparison of Mean Total DOPS scores before and after training in male and female students for inguinal hernia surgery and laparoscopic cholecystectomy

DOPS Score	Male (n = 12)		Female (n = 23)		p Value
	Mean Total	SD	Mean Total	SD	
Pre Test					
I had Inguinal hernia surgery	46.33	13.79	53.65	6.30	0.104*
II Laparoscopic cholecystectomy	45.17	13.70	52.30	6.66	0.111*
Post Test					
I had Inguinal hernia surgery	98.92	15.90	91.35	11.83	0.120*
II Laparoscopic cholecystectomy	98.33	12.24	90.61	13.39	0.105*

Note: *Signifies statistical significance.
Abbreviations: n, number of participants; SD, standard deviation; p Value, probability-value.

Table 4. Mean DOPS scores pre and post-training in knowledge and communication with attitude sub-components and of overall DOPS scores for inguinal hernia surgery and laparoscopic cholecystectomy

DOPS scores	n	Before		After		p Value
		Mean	SD	Mean	SD	
I had Inguinal hernia surgery						
Knowledge	35	22.77	5.41	41.57	4.94	< 0.001**
Communication with attitude	35	28.06	6.43	52.37	9.46	< 0.001**
Overall	35	51.14	9.98	93.94	13.63	< 0.001**
II Laparoscopic cholecystectomy						
Knowledge	35	22.11	5.60	40.51	5.18	< 0.001**
Communication with attitude	35	27.74	5.86	52.54	10.17	< 0.001**
Overall	35	49.86	10.06	93.26	13.35	< 0.001**

Note: **Signifies statistical significance.
Abbreviations: n, number of participants; SD, standard deviation; p Value, probability-value.

The difference in sub-component DOPS scores between the pre-and post-training assessments based on gender revealed that male students showed a greater improvement post-training in the knowledge sub-component of the DOPS score for both surgeries. This difference in improvement between males and females was statistically significant ($p < 0.001$). Similarly, the improvement in the DOPS scores post-training for both surgeries in the communication with attitude sub-component was greater in males than in females. However, this was not statistically significant ($p = 0.062$). Male students also showed a greater improvement than females after training in the overall DOPS score for both procedures, which was statistically significant ($p < 0.001$). (Table 5). In the feedback obtained, all the students felt the training was feasible, helped identify weaker sections, and that they would prefer this type of learning in the future. All the students except two felt the training was useful for understanding and retaining concepts in memory, made them confident in taking consent, and was an effective tool for feedback. 91.4 percent of students said the training module should be utilized as an assessment tool in addition to making learning engaging.

Table 5. Difference in the mean DOPS scores pre and post-training for knowledge and communication with attitude sub-components and in overall DOPS scores for male and female students for both procedures.

Change in DOPS score	n	Mean	SD	Mean Difference	p Value
Inguinal hernia surgery					
I Knowledge					
Male	12	24.83	4.28	9.18	< 0.001**
Female	23	15.65	4.22		
I Communication					
Male	12	27.75	6.86	5.23	0.094
Female	23	22.52	9.23		
I Overall					
Male	12	53.17	8.51	14.86	< 0.001**
Female	23	38.3	11.36		
Laparoscopic cholecystectomy					
II Knowledge					
Male	12	24.17	4.20	8.78	< 0.001**
Female	23	15.39	4.50		
II Communication with attitude					
Male	12	29.17	6.15	6.65	0.062
Female	23	22.52	10.98		
II Overall					
Male	12	52.58	8.83	14.89	< 0.001**
Female	23	37.7	10.42		

Note: **Signifies statistical significance.
Abbreviations: n, number of participants; SD, standard deviation; p Value, probability-value.

Discussion

In the traditional curriculum, soft skills like ethics, professionalism, and communication are not formally taught to medical students, who usually learn them through willful and passive observation (23). SIC is taught in the form of didactic lectures during forensic medicine in II MBBS and does not include hands-on training (9). In addition, to further confirm that skill learning has truly occurred, there is no statutory assessment (10).

Following the nationwide implementation of CBME in the modern medicine stream in 2019, the assessment of

student communication skills is crucial for establishing and improving teaching-learning strategies that will facilitate medical students acquiring good communication skills (12). The Graduate Medical Education Regulations 2019 envisage that these skills are prerequisites for graduation. While obtaining SIC, explaining the diagnosis, planned surgical procedure, risks involved, and prognosis to the patient and relatives is important for developing a good rapport with the patient, thus ensuring patient satisfaction. The time has come for our clinical communications approach to move from a paternalistic (doctor-centered) model to a patient-centered one (24). Failure to obtain informed consent from a patient to quote Henry Johnson Jr. is an "ethical violation" (9).

'Surgical informed consent' is a phrase recognized by both domestic and international law that authorizes the intended surgical procedure (8). The most effective strategy to prepare qualified physicians to respect patients' rights is to educate them about legal issues and incorporate these issues into student curricula (25). Moreover, an adequately informed patient will be more satisfied, file fewer lawsuits, and have more reasonable expectations about a surgical procedure and its associated risks (8).

The attitude and communication module (ATCOM, July 2015) was introduced by MCI in order to provide training in communication skills for medical students. Prior research has emphasized the need for structured communication skills training, which has been demonstrated to be very successful in enhancing health outcomes and fostering partnerships between doctors and patients. Medical students will greatly benefit from the inclusion of such modular training in the curriculum, as they will also acquire the critical skill of communication for the purpose of obtaining informed consent for surgery (13, 14, 18, 19, and 24). In multimodal training, students with specific communicative problems are detected early, remediation is provided, and role play presents an opportunity for rehearsal, leading to better skill acquisition (16). This will enable them to acquire competency in communication and facilitate the retention of knowledge (19).

In medical education, simulation is being increasingly used for training and assessment as a result of patient awareness, improved patient safety, and medical litigation (26). Before exposing medical students to patients, they can be taught soft skills of communication in a controlled environment using simulated patients, who in turn can offer helpful feedback for enhancing and evaluating their communication abilities (27).

Novel workplace-based performance assessment techniques, like DOPS, are highly beneficial in evaluating medical student's readiness for professional obligations and ensuring that their education is adequate. DOPS is regarded as a high-quality assessment method because it provides supervised learning and evaluates the "DOES" level of Miller's Pyramid (28). In addition, DOPS provides a focused observation, or "snapshot," of a trainee undertaking a practical procedure in the workplace. Because DOPS is a great source of immediate, in-depth, private, and non-threatening feedback in addition to being observed and examined, it presents an opportunity for improvement. It is this feature that gives DOPS its high educational value (29).

The low pretest scores in this prospective study established the need for formal training on the SIC procedure. A similar study among interns showed an average pretest score below three and the need for further training (9). The improvement observed in mean total DOPS scores after training in SIC for inguinal hernia surgery and laparoscopic cholecystectomy was statistically significant ($p < 0.001$). Krishnappa R. et al. reported a significant improvement post-training in their study among interns (18). Studies have shown a positive effect on the communication skills of students following structured training during the early phase of medical studies (16). Joekes et al. reported that training in professional skills and attitudes, as well as opportunities to practice basic communication skills, contribute towards improvement in observed communication skills (3).

When the influence of gender on SIC training was examined, the difference between pre-and post-training DOPS scores showed a greater improvement in males as compared to females, which was statistically significant ($p < 0.05$). Our findings were in concordance with the study results of Rajavel et al., who found that males scored higher than female interns due to an unknown reason (19). We observed that male students improved more than females in the knowledge component of the final DOPS scores for laparoscopic cholecystectomy and inguinal hernia surgery by 9.18 and 8.78 points, respectively, and this mean difference in improvement was also determined to be statistically significant ($p < 0.001$). In our study, the training module enhanced the knowledge component, including the ability for short-term memory and recall, to a greater extent in males than in females, the reason for which could not be explained.

For laparoscopic cholecystectomy and inguinal hernia surgery, respectively, the mean difference in the improvement of the Communication with Attitude subcomponent in final DOPS scores after training was 5.23 and 6.65 marks higher in males than females, but this difference was not statistically significant (p-value 0.062). However, Knut Aspegren noted that men are slower learners of communication skills than women and should be given special attention (20). Our findings were also in contrast with the observations of Wiskin et al. and others, who reported that female students achieved higher grades in clinical communication tasks than their male counterparts (30, 31). We can presumably attribute this gender impact on the result to the small sample size, the use of the same examiners across all sessions, and the brief duration of training.

In the present study, the feedback obtained from the study participants was in agreement with earlier research, which reported that training in SIC was well accepted by students, who in turn felt a need for further similar programs to strengthen their communication skills (32). Kumar et al., in their experience, found that both the interns and faculty gave favorable views, recommended teaching informed consent for future batches, and advocated the use of DOPS as a tool for assessment and teaching (9). Our findings from the feedback with respect to effective communication and attitude were in concordance with a previous study, which revealed heightened perception among the final year medical students of the need for greater attention to be paid to informed consent education and training (33). It has been shown that students' skills and confidence in communicating with patients increased after training (23). However, the faculty needs to be sensitized, as the teachers must exert extra effort.

Our study showed overwhelming evidence of improvement in the ability to obtain SIC following multimodular training for undergraduates. The consecutive sampling utilized was a non-probability sampling technique, which allowed the researcher to choose the sample. We observed that the interactive sessions in small groups improved attention span, provided an easy pace of learning, offered clarity, and reinforced learning. In addition, the students in their feedback noted that it provided them with an opportunity to learn from mistakes and improve their communication skills before using the SIC procedure on patients. Above all, the module created an awareness among participants of their difficulties in communication and the need to improve, as was seen in their written feedback. This study provides valuable insights into the utility of simulated patients. The major strength of the study is that it can be done in a limited resource setting while still achieving desirable results in all domains of learning. This study supports the use of DOPS as a tool for posttest assessment in the training program to increase the learning and skills of participants.

This study has some limitations. A literature review did not yield results for a prevalidated training module for SIC. Hence, the training module used in prior similar research with minor changes was utilized for the study. The opinions of three senior faculty members from the Department of Medical Education Technology and approval from the Institutional Research Committee were obtained prior to the commencement of the study. Although the number of experts for the judgment of content validity has met the minimum requirement of consensus, it can be increased to receive more variation in feedback and input for modification in the training module. Possible internal bias may stem from the use of a single measurement tool for the ability to obtain SIC, repeated as a pretest and posttest. The participants' responses may be affected by this measurement design. The main limitation of the present study was the small sample size, which allowed only a limited interpretation of the results. Limitations also lie in possible subject selection bias, where the experiment group was chosen by consecutive sampling. Another limitation we noted was that this study design was quasi-experimental. Efforts to overcome this limitation include the involvement of a control group with a provision for modular training to be provided after collecting the data from the posttest and before the conclusion of the study. A randomized trial would have been less subject to bias than the cohort design used in our study. In addition, as the procedure was a simulation as opposed to a real patient encounter, it restricted the generalizability of our findings with respect to a clinical context. Furthermore, we also noted a lack of feedback from the teachers regarding the training. Obtaining feedback from the teachers would give us valuable input for improvement in future studies. We want to recommend that this sort of training module on consent taking be incorporated into undergraduate training, as the outcome of this study is very encouraging.

The use of a training module that has been developed based on a standard model of instructional design and prevalidated would be desirable for future research. In the future, research should strive for a pure experiment design with randomized sampling to obtain stronger

evidence. Simulated patients are not commonly used for the training and assessment of communication skills in India, and such an intervention was found to be helpful in improving the communication skills of undergraduates. Hence, this can act as a baseline for large-scale implementation in the future. The standard and quality criteria that are followed while preparing the simulated patient for the assessment can be utilized to guide future research (26, 34). The present study did not evaluate the long-term memory or retention of the ability to take SIC in these students, which needs consideration in future studies.

Conclusion

In this study, utilizing a multimodal intervention to teach final MBBS students SIC contributed towards an improvement in the observed ability to take informed consent from simulated patients. The effectiveness of the multimodal training program was increased by having a structured DOPS assessment tool at the end of training. The students benefited from the opportunity to practice basic communication skills with simulated patients and demonstrated better communication skills and attitudes. This approach is feasible and engaging, and, in addition, it provides fulfillment for learning, as reported by the students. This will enable them to consolidate their professional learning and establish improvements in their routine behavior on a one-to-one basis with patients. Choosing the appropriate education and assess¬ment methods can enhance medical students' skills in order to become more competent physicians in terms of respect for patient rights and reducing legal problems, besides saving time and money.

Future research should be directed towards a true experimental study with randomized sampling to obtain stronger evidence. We advocate that a prevalidated multimodal training module and assessment tool for consent taking be incorporated in the undergraduate training curriculum. Utilizing faculty as simulated patients to augment learning is beneficial and needs exploration in future. Further long-term follow-up during the residency phase, if possible, for the lasting effect of training in the ability to obtain SIC is highly recommended.

Ethical considerations

This study was conducted after obtaining approval from Institutional Ethics Committee, JMMC & R.I. (Ref: 89/21/IEC/JMMC& R.I.). It should be noted that participation in the study was voluntary, and informed consent was obtained from all participants. Moreover, no personal information was collected from the participants, and the data were completely anonymous during the study.

Artificial intelligence utilization for article writing

The authors declare that AI-based tools have not been used in the research and preparation of this manuscript.

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Conflict of interest statement

The authors declare that they have no conflict of interest.

Author contributions

A.N.O., R.T., S.S., S.M., U.U.G. conceptualized and designed the study, A.N.O., S.S., S.M., R.R.J., Y.G.B., conducted the study and collected the data, A.N.O., R.T., U.U.G. analyzed the data, A.N.O., and R.T., prepared the main manuscript text and A.N.O., R.T., S.S., S.M. Reviewed and Edited the main manuscript. The authors met the criteria for authorship and played a role in preparing the manuscript. Also, the authors approved the final manuscript.

Supporting resources

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Data availability statement

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

References

1. Abbasi M, Shirazi M, Torkmandi H, Homayoon S, Abdi M. Impact of teaching, learning, and assessment of medical law on cognitive, affective and psychomotor skills of medical students: a systematic review. BMC Medical Education. 2023;23(1):703. [https://doi.org/10.1186/s12909-023-04695-2]

2. Singh V, Khandelwal R, Bohra S, Gupta R, Gupta BS. Evaluation of communication skills of physicians about asthma. Journal-Association of Physicians of India. 2002;50:1266-9. [PMID: 12568212].

3. Joekes K, Noble LM, Kubacki AM, Potts HW, Lloyd M. Does the inclusion of 'professional development' teaching improve medical students' communication skills? BMC Medical Education. 2011;11:41. [https://doi.org/10.1186/1472-6920-11-41]

4. Chichirez CM, Purcărea VL. Interpersonal communication in healthcare.
Journal of Medicine and Life. 2018;11(2):119-122. [PMID: 30140317; PMCID: PMC6101690]

5. Wood F, Martin SM, Carson-Stevens A, Elwyn G, Precious E, Kinnersley P. Doctors' perspectives of informed consent for non-emergency surgical procedures: a qualitative interview study. Health Expectations. 2016;19(3):751-61. [https://doi.org/10.1111/hex.12258]

6. Gabay G, Bokek-Cohen Y. Infringement of the right to surgical informed consent: negligent disclosure and its impact on patient trust in surgeons at public general hospitals - the voice of the patient. BMC Medical Ethics. 2019;20(1):77. [https://doi.org/10.1186/s12910-019-0407-5]

7. Uzzaman MM, Tayeh S, Sinha S, Ratnasingham K, Stoker DL. Consenting practice for laparoscopic cholecystectomy - are we doing enough to warn patients about their operation? International Journal of Surgery. 2011;9(8):643-7.
[https://doi.org/10.1016/j.ijsu.2011.08.004].

8. 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 Journal of Surgery. 2010;34(7):1406-15. [https://doi.org/10.1007/s00268-010-0542-0]

9. Kumar R, Moudgil T, Arora R, Attri A, Singh S. Introduction of module on informed consent training for interns during compulsory surgery rotation. Acta Medica International. 2020;7(1):19-30. [https://doi.org/10.4103/ami.ami_11_20]

10. Moudgil T, Bansal Y, Arora R, Bandhu S. Assessment of clinical competence of interns using work place based assessment in ophthalmology rotational posting. Journal of Clinical And Diagnostic Research. 2019;13(6): NC01-NC08. [https://doi.org/10.7860/JCDR/2019/40981.12926]

11. Colbert-Getz JM, Baumann S. Changing medical students' perception of the evaluation culture: is it possible? Journal of Educational Evaluation for Health Professions. 2016;13:8. [https://doi.org/10.3352/jeehp.2016.13.8]

12. AthavaleAV. Baseline assessment of communication skills of undergraduate medical students at a medical college in Bhopal. Journal of Medcal Education Development. 2022;15(45):1-7 [https://doi.org/10.52547/edcj.15.45.1]

13. Choudhary A, Gupta V. Teaching communications skills to medical students: introducing the fine art of medical practice. International Journal of Applied & Basic Medical Research. 2015;5(Suppl 1):S41-4. [https://doi.org/10.4103/2229-516X.162273]

14. Reshma S, Srinivasan K, Sushith S, Kumar K, Prathima MB, Janice D. Effect of an interprofessional approach on the communication skills of undergraduate medical students. Journal of Medical Education Development. 2021;14(43):1-8. [https://doi.org/10.52547/edcj.14.43.1]

15. Under Graduate Medical Education. Vision 2015 [MCI Booklet]; 2011, 7-22.
[https://www.nmc.org.in/wp-content/uploads/2018/01/MCI_booklet.pdf.]

16. Deveugele M, Derese A, De Maesschalck S, Willems S, Van Driel M, De Maeseneer J. Teaching communication skills to medical students, a challenge in the curriculum? Patient Education and Counseling. 2005;58(3):265-70.
[https://doi.org/10.1016/j.pec.2005.06.004]

17. Karthikeyan K, Kumar A. Integrated modular teaching in dermatology for undergraduate students: a novel approach. Indian Dermatology Online Journal. 2014;5(3):266-70. [https://doi.org/10.4103/2229-5178.137774]

18. Krishnappa R, Rajagopalan S. Designing a module for improving communication skills amongst interns in a surgical setting. International Surgery Journal. 2020;7:2218-21. [http://dx.doi.org/10.18203/2349-2902.isj20202824]

19. Rajavel MP, Padmavathi T. Effectiveness of educational intervention to enhance communication

skills among interns. Panacea Journal of Medical Sciences 2016;6(1):20-25
20. Aspegren K. BEME Guide No. 2: Teaching and learning communication skills in medicine-a review with quality grading of articles. Knut Aspegren Medical Teacher. 1999;21(6):563-70. [https://doi.org/10.1080/01421599978979]
21. Rahim AA, Anitha PM, Govindaraj GM, Laila KV. Identifying core competency areas to assess communication skills among interns at a tertiary teaching hospital in southern India. The National Medical Journal of India. 2017;30(6):332-336. [https://doi.org/10.4103/0970-258X.239076]
22. Erfani Khanghahi M, Ebadi Fard Azar F. Direct observation of procedural skills (DOPS) evaluation method: Systematic review of evidence. Medical Journal of the Islamic Republic of Iran. 2018;32:45. [https://doi.org/10.14196/mjiri.32.45]
23. Bhagat PR, Prajapati KM, Bhatt RB, Prajapati VK, Dureja R, Tank GP. Development and introduction of a communication skills module for postgraduate students of ophthalmology. Indian Journal of Ophthalmology. 2019;67(11):1810-1815. [https://doi.org/10.4103/ijo.IJO_366_19]
24. Patil AM, Patil AS. Effect of communication skills training for obtaining written Informed consent: an Indian experience. Journal of Obstetrics and Gynecology Research. 2016;3(4):314-7. [https://doi.org/10.18231/2394-2754.2016.0003]
25. Abbasi M, Shirazi M, Torkmandi H, Homayoon S, Abdi M. Impact of teaching, learning, and assessment of medical law on cognitive, affective and psychomotor skills of medical students: a systematic review. BMC Medical Education. 2023;23(1):703.. [https://doi.org/10.1186/s12909-023-04695-2]
26. Cleland JA, Abe K, Rethans JJ. The use of simulated patients in medical education: AMEE Guide No 42. Medical Teacher. 2009;31(6):477-86. [https://doi.org/10.1080/01421590903002821]
27. Beigzadeh A, Bahmanbijari B, Sharifpoor E, Rahimi M. Standardized patients versus simulated patients in medical education: are they the same or different. Journal of Emergency Practice and Trauma. 2015;2(1):25–8. [https://doi.org/10.15171/jept.2015.05]
28. Farajpour A, Amini M, Pishbin E, Mostafavian Z, Akbari Farmad S. Using modified Direct Observation Of Procedural Skills (DOPS) to assess undergraduate medical students. Journal of Advances in Medical Education & Professionalism. 2018;6(3):130-136. [PMID: 30013997; PMCID: PMC6039823]
29. McLeod RA, Mires GJ, Ker JS. The use of the Direct Observation Of Procedural Skills (DOPS) assessment tool in the clinical setting - the perceptions of students. International Journal of Clinical Skills. 2011;5(2):102-107.
30. Wiskin CM, Allan TF, Skelton JR. Gender as a variable in the assessment of final year degree-level communication skills. Medical Education. 2004;38(2):129-37. [https://doi.org/10.1111/j.1365-2923.2004.01746.x]
31. Wright KB, Bylund C, Ware J, Parker P, Query JL, Baile W. Medical student attitudes toward communication skills training and knowledge of appropriate provider-patient communication: a comparison of first-year and fourth-year medical students. Medical Education Online. 2006;11(1):4594. [https://doi.org/10.3402/meo.v11i.4594]
32. Hamzah MS, Pa MN, Sepehr S, Yusoff MS, Abd Aziz R, Yaacob NA. Experience from a Communication Skills Workshop for Medical Students. Education in Medicine Journal. 2010;2(1).e37. [https://doi.org/10.5959/eimj.2.1.2010.wr2]
33. AlMahmoud T, Hashim MJ, Almahmoud R, Branicki F, Elzubeir M. Informed consent learning: needs and preferences in medical clerkship environments. PLoS One. 2018;13(10):e0202466. [https://doi.org/10.1371/journal.pone.0202466].
34. Peters T, Sommer M, Fritz AH, Kursch A, Thrien C. Minimum standards and development perspectives for the use of simulated patients–a position paper of the committee for simulated patients of the German association for medical education. GMS Journal For Medical Education. 2019;36(3). [https://doi.org/10.3205/zma001239]

Appendixes:

Performance evaluation:

- Appendix – A DOPS assessment
- Appendix – B

Feedback Questionnaire for Students

- Supplementary Material

CONSORT 2010 checklist of information to include when reporting a randomized trial

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