A randomised controlled trial study on the effectiveness of high-fidelity simulation in enhancing skills among undergraduate medical students

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ABSTRACT

Introduction: High-fidelity simulation (HFS) provides a high level of interactivity and realistic experience for the learner by means of using full scale computerised patient simulators. It imitates clinical experience in a controlled and safe environment that closely resembles reality. The purpose of this study was to compare the efficacy of HFS versus video-assisted lecture (VAL) based education in enhancing and consolidating retention of skills among undergraduate medical students.

Materials and Methods: A randomised controlled trial (RCT) study involving 111 undergraduate medical students was conducted where the competency of skills was assessed by objective structured clinical examination (OSCE) in the first, fourth and seventh/eighth weeks. A cohort of 12-14 students was enrolled for each session. The randomisation of the participants into control (VAL-based teaching) and intervention (HFS-based teaching) groups was achieved by implementing the computer-based random sequence generation method. VAL-based teaching module was a fully interactive face-to-face teaching session where a pre-recorded video clip was used. The video clip detailed the diagnosis of tension pneumothorax in an acute medical emergency and its management by performing needle decompression on a high-fidelity patient simulator (METIman). HFS-based teaching module was delivered as a fully interactive hands-on training session conducted on the same METIman to demonstrate the diagnosis of tension pneumothorax in an acute medical emergency and its management by performing needle decompression. OSCE scores were compared as the denominator of learning (enhancement and retention of skills) between two groups who underwent training with either VAL-based or HFS-based teachings. The OSCE assessments were used to evaluate the participants' performance as a group. These scores were used to compare the enhancement and medium-term retention of skills between the groups. The outcome was measured with the mean and standard deviation (SD) for the total OSCE scores for skills assessments. We used General Linear Model two-way mixed ANOVA to ascertain the difference of OSCE marks over assessment time points between the control and the intervention groups. ANCOVA and two-way mixed ANOVA were used to calculate the effect size and the partial Eta squared. p value less than 0.05 was taken to be statistically significant.

Results: The two-way mixed ANOVA showed no statistically significant difference in mean OSCE scores between intervention and control groups (p=0.890), although the mean score of the intervention group was better than the control group.

Conclusion: Our study demonstrated that HFS was not significantly effective over VAL-based education in enhancing skills and consolidating retention among undergraduate medical students. Further research is needed to determine its suitability for inclusion in the course curriculum considering the cost-effectiveness of implementing HFS that may supplement traditional teaching methods.

KEYWORDS:
High-fidelity simulation, simulation-based medical education, high-fidelity simulators, video-assisted lecture, undergraduate medical education, RCT, OSCE

INTRODUCTION

Healthcare simulation is a process that creates a situation where the learners are facilitated to experience a prototype of a real clinical event for the purpose of learning, practice and evaluation.[1] It nurtures a sense of critical thinking and problem-solving qualities in the learners that helps them to take an active role in the skill development processes. Simulation-based training provides an opportunity for the learners in practicing complex skills and is an important tool to facilitate effective learning by the process of scaffolding.[2] It is deemed to be more effective in achieving the learning outcomes in long-term when compared to other traditional training programmes.[3] At present, simulation-based medical education (SBME) is considered an effective tool in intensive care training.[3] It aids in providing opportunities for students to practise technical skills repeatedly in a safe environment that ultimately helps learners to attain proficiency in high-risk, less commonly encountered situations without harming

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the patients.[4] Simulation offers the opportunity to learn appropriate clinical skills without any harmful effect on the patients. Thus, it may diminish the occurrence of clinical errors that may impact negatively in the well-being of the patients in real settings.[5] SBME is crucial in the development of vital cognitive and behavioural skills.[6] In addition, it also helps in improving teamwork skills which is crucial in enhancing patient's safety.[7] The recently developed more advanced technologies like high-fidelity simulation (HFS) is an important tool in SBME for acquisition of skills and confidence.[2] HFS-based medical education offers an excellent interactive and complex learning system that supports the very essence of experiential learning pedagogy.[8] Experiential learning helps in enhancing the capability of the learners to develop clinical judgment. The reflective practice exercise after the simulation sessions assists learners in acquiring insights in developing clinical reasoning and judgment.[9] HFS-based education may contribute positively to the learners' understanding of self-efficacy, skills, confidence and critical thinking.[10] A study by Lee et al.,[11] showed that the acquisition of both technical and non-technical skills are the determining factors in judging the efficacy of HFS. They opined for its inclusion into training courses that involves in the learning of acute medical emergencies.[11] Although many studies showed the efficacy of HFS training modalities in acute medical set-up, there is lack of uniformity in research methodologies and selection of appropriate tools for outcome measurements. Also, little is known about the retention of the learning outcome.[12] There is paucity of standardised approaches and subsequent evidence for determining the competence and the learning outcomes among the learners in a safe environment outside the real clinical sites. HFS teaching strategies may complement the bedside teaching practices but the dearth of strong evidence that supports its effectiveness in acquisition of clinical competence results in a challenging situation for the faculty, especially, in justifying the cost of HFS acquisition and educational benefits.[13] The evidence suggesting the efficacy of HFS on learning abilities is lacking, specifically, its effectiveness in acquisition of skills for acute medical situations has not been substantially evaluated.[14] Consequently, more effective studies are needed to justify the importance of HFS and its efficacy on students' learning outcomes. In this context, our study had been designed to explore the effectiveness of HPS-based teaching when compared to a conventional classroom teaching method.

MATERIALS AND METHODS

Description of Trial Design: The study was designed as a randomised controlled trial (RCT) having parallel groups with 1:1 allocation. An important change to 'methods' was made from the pilot study involving 56 students with the same protocol by the current researchers in 2018-19.[15] There were two objective structured clinical examination (OSCE) assessments on the second week and the fourth week in the preliminary study. This study is an extension of the preliminary study with a different cohort of students where three OSCE assessments were conducted for both the control and the intervention groups, first one immediately after the randomisation on the first day, the second one after fourth week and the third one after seventh/eighth week. The modification was made following the suggestion of the institutional research committee after reviewing the results of the preliminary study.

Eligibility criteria for participants: All final year medical students at our institute who had consented for this study were enrolled after obtaining written informed consent.

Settings and locations where the data were collected: The clinical skills simulation laboratory of Manipal University College Malaysia (formerly Melaka-Manipal Medical College) was the venue for this research study. The study period was from March 2019 to February 2020.

Interventions:
Video-assisted lecture-based teaching module was used for the 'control group'. It was conducted as a small group (6-7 students) fully interactive face-to-face teaching session by a facilitator where a pre-recorded video clip was shown. The 20-minute video clip demonstrated the diagnosis and the management of tension pneumothorax on the high-fidelity simulator METIman (pre-hospital) in an acute medical emergency. The procedure of performing needle decompression on the simulator followed the guidelines as mentioned in the Advanced Trauma Life Support Manual developed by the American College of Surgeons (ATLS Subcommittee et al., 2013).[16] The video session was followed by a 20-minute interactive discussion session with the same facilitator.

HFS-based teaching module was used for the 'intervention group'. A small group of 6-7 students participated in a fully interactive hands-on training session conducted on the high-fidelity patient simulator (METIman) for the diagnosis and the management of tension pneumothorax in an acute medical emergency. Needle decompression was demonstrated on the said simulator for the management of tension pneumothorax adhering to the Advanced Trauma Life Support Manual developed by the American College of Surgeons (ATLS Subcommittee et al., 2013). The 20-minute demonstration session was followed by hands-on training on the METIman for another 20 minutes where students were provided with the opportunity to practice by themselves on METIman under proper guidance.

The total duration of teaching for both groups was 40 minutes. During these interactive teaching sessions, all the participants were made aware of the importance of pathophysiology and clinical presentation of tension pneumothorax, leading to arriving at the diagnosis and its subsequent management in the emergency set-up. OSCE assessments were conducted for both the control and the intervention groups, after the teaching session.
The participants were encouraged to reflect on their learning experiences in the form of immediate debriefing in both modes of teaching. Due emphasis was made on the teaching points related to the outcome of the study by the respective facilitator who was involved in each mode of teaching. The participants were not provided with other additional hands-on practice or video-assisted lecture sessions during the research study.

Outcome: In this study, our aim was to compare the OSCE scores as the denominator of learning (enhancement and retention of skills) between two groups who underwent training with either VAL-based or HFS-based teachings.

The sample size was calculated by using G*Power software.[17] The effect size was medium (0.323) based on our preliminary study that was conducted in 2018 and a power of 0.95 yielded a sample size of 114. Randomizer.com was used to generate the computerised random sequence numbers to randomise the participants into control (video-assisted lecture-based teaching) and intervention (HFS-based teaching) groups. A block randomisation process with a block size of two was used. The opaque envelopes containing the allocated interventions were sequentially numbered and sealed. Two independent investigators were used to enrol the participants and assign them to the interventions. The outcome assessor was kept blinded to the randomisation.

Statistical analysis

Microsoft Excel was used for data entry and SPSS software (version 25) for data analysis. The mean of each group's difference in score across the three assessments was used to compare VAL-based and HFS-based teachings. General Linear Model two-way mixed ANOVA was used to determine the difference of OSCE marks over assessment time points between the control and the intervention groups. We included one within-participant factor which is the assessment time points (1st, 2nd, and 3rd assessments) and one between-participant factor (control or intervention). The effect size and the partial Eta squared was calculated in ANCOVA and two-way mixed ANOVA; where the effect size 0.01 is small, 0.06 is medium and 0.14 is large. The effect size, Cohen’s d was calculated for the comparison of the independent means and Cohen’s dz was calculated for the comparison of the dependent means; where the effect size 0.20 is small, 0.50 is medium and 0.80 is large (Ellis P D 2010).[18] Unpaired t-test was used to assess intergroup difference of OSCE score at 1st, 2nd and 3rd assessment. Repeated measure ANOVA and post-hoc analysis was used to determine intragroup comparison of OSCE scores at 1st, 2nd and 3rd assessment among control and intervention groups. The level of significance was set at 0.05. The null hypothesis was rejected if $p<0.05$.

After the briefing session, each cohort of 12-14 students were randomised into control and intervention groups. Each group consisted of six to seven participants. The participants were briefed about the sessions and expected learning outcomes on the first day. The study focused on the importance of performing skills (diagnosis and managing the situation) as a group activity (forming a team). All the participants were apprised of the confidentiality of the HFS sessions, the video-assisted lecture sessions and the ethical issues involved during the briefing process. The participants were made aware of the functions and handling of the METIman. The students were assured that the evaluation scores during the research study was not part of the surgical curriculum assessment process. For the simulation sessions, METIman Pre-Hospital HI-Fidelity Simulator (MMP-0418) was used. It was an adult METIman with modelled physiology for advanced simulation functionalities and designed specifically for learners to practice, gain experience and develop skills. The simulator was suited to offer training solutions for teaching prehospital clinical skills, including airway management, chest tube management and needle decompression.

The validation of the OSCE checklist was also done during the preliminary study. It was validated after looking into the range to which the items in the checklist satisfactorily covered the specific area of interest.[19] Ten content experts in medical education reviewed the items in the OSCE checklist to determine whether they were relevant or important. The items were subjected to the calculation of the scale-level content validity index (SCVI), item-level content validity index (ICVI) and mean ICVI. As per the standard reference, the SCVI and ICVI were kept at 0.943 and 0.9 respectively.[20] The OSCE sessions were conducted with a 30-item checklist of the validated scenario where all items had equal weightage. The items in the OSCE checklist included the assessment of clinical presentation, diagnosis, management (needle decompression), documentation and professionalism. The OSCE assessment of the simulated sessions was designed to be completed within 20 minutes. The participants were debriefed by the facilitators at the end of their simulated sessions to attain the learning outcomes. The OSCE assessments were used to evaluate the participants’ performance as a group (either control or intervention). These scores that were achieved were subsequently used to compare the enhancement and medium-term retention of skills between the groups (Flowchart, Figure 1).

RESULTS

The median age was 24 years for the 123 students who participated in the study. The drop-out rate was 12 (9.77%). Two students dropped out after the first OSCE assessment and 10 students dropped out after the second OSCE assessment. 111 students completed the study, out of which, 50 (45.05%) were males and 61 (54.95%) were females. We could not continue the study to achieve the minimal sample size of 111 due to the COVID-19 lockdown that was enforced on 18 March 2020 in Malaysia. The baseline demographic characteristics are shown in Table I.

Two-way mixed ANOVA was used to determine the difference of OSCE marks between intervention and control groups over assessment time points. There was one outlier in the first assessment but not in the rest, as assessed by examination of standardized residuals for values greater than ±3. OSCE marks were normally distributed in second and third assessment but not in first assessment, as assessed by normal Q-Q plot. There was homogeneity of variances, as assessed by Levene’s test of homogeneity of variance ($p>0.05$). There was no homogeneity of covariances, as assessed by Box’s test of equality of covariance matrices ($p=0.042$). Mauchly’s test of sphericity indicated that the assumption of sphericity was met for the two-way interaction, $X2(2) = 1.578$, $p=0.454$.

Table II shows that there was no statistically significant interaction of the groups between the intervention and assessment time on OSCE scores.

Table I: Baseline demographic characteristics of the participants.

		Gender		Age (years)		Type of students		Total	
		Male	Female	Range	Median	Local	International		
Enrolled	Intervention	27	35	22 - 26	24	60	2	62	123
	Control	29	32	22 - 26	24	58	3	61	
Dropped out	Intervention	3	4	24 - 26	25	7	0	7	12
	Control	3	2	24 - 26	25	4	1	5	
Completed	Intervention	24	31	22 - 26	24	53	2	55	111
	Control	26	30	22 - 26	24	54	2	56	

Table II: The interaction between intervention groups and time points of assessment (Two-way mixed ANOVA).

Variable	Interaction	p-value	Partial η^{2} #
OSCE score	Assessment time point*intervention	0.063	0.158

#Partial Eta squared

Table III: Intergroup comparison of intervention and control groups on OSCE score at 1st, 2nd and 3rd assessment (unpaired t-test).

Variable	n*	OSCE score		Mean difference (95% CI)	p-value	Partial η^{2} @
		Mean (SD)	Median			
1st assessment						
Intervention	9	22.67 (2.83)	24.0	2.11 (-2.29, 6.51)	0.324	0.061
Control	9	20.56 (5.55)	22.0			
2nd assessment						
Intervention	9	21.57 (4.45)	24.0	-1.78 (-5.67, 2.11)	0.347	0.055
Control	9	23.33 (3.24)	24.0			
3rd assessment						
Intervention	9	22.89 (2.47)	24.0	0.33 (-2.95, 3.62)	0.833	0.003
Control	9	22.56 (3.94)	23.0			

* Number of groups # Standard deviation
$ 95% confidence interval @ Partial Eta Squared

Table IV: Intragroup comparison of OSCE score at 1st, 2nd and 3rd assessment among intervention and control groups (repeated measure ANOVA).

Variable	n*	OSCE score Mean (SD)	p-value	Partial η2 @
Intervention				
1st assessment	9	22.67 (2.83)	0.568	0.068
2nd assessment	9	21.57 (4.45)		
3rd assessment	9	22.89 (2.47)		
Control				
1st assessment	9	20.56 (5.55)	0.017	0.399
2nd assessment	9	23.33 (3.24)		
3rd assessment	9	22.56 (3.94)		

*Number of groups
#Standard deviation
@Partial Eta squared

Table V: Post-hoc comparison of OSCE score at 1st, 2nd and 3rd assessment among intervention and control groups (repeated measure ANOVA).

Comparison		Mean difference (95% CI)	p-value
Intervention			
1st assessment	2nd assessment	1.11 (-2.25, 4.47)	0.468
1st assessment	3rd assessment	-0.22 (-2.25, 1.80)	0.807
2nd assessment	3rd assessment	-1.33 (-4.86, 2.19)	0.408
Control			
1st assessment	2nd assessment	-2.78 (-5.14, -0.42)	0.027
1st assessment	3rd assessment	-2.00 (-4.34, 0.34)	0.084
2nd assessment	3rd assessment	0.78 (-0.36, 1.92)	0.154

#95% confidence interval
The data of this study is available at https://data.mendeley.com/datasets/pxp2w28zkm/1.[21]

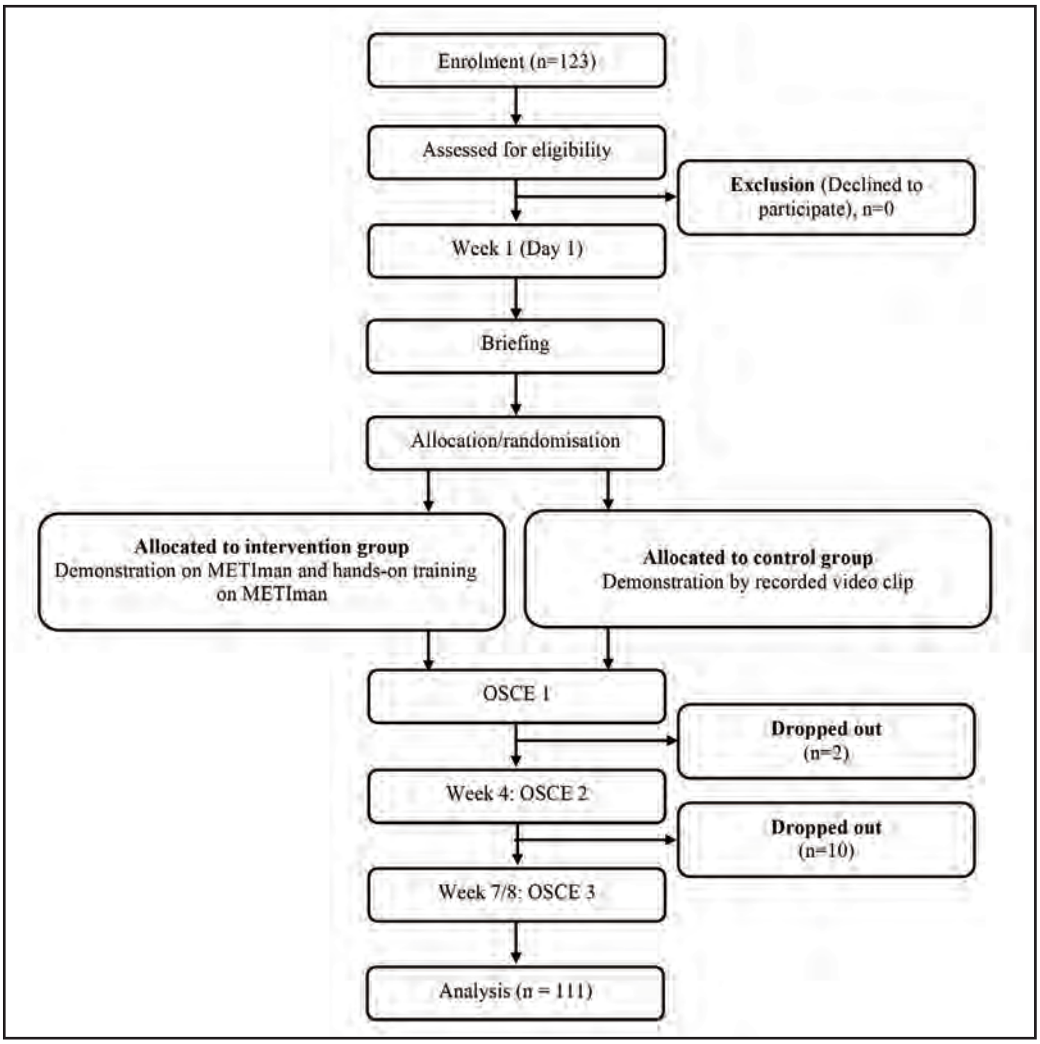

Fig. 1: Flow chart (n = number of students).

Table III shows the intergroup comparison of intervention and control groups on OSCE scores at 1st, 2nd and 3rd assessment. At first assessment, the intervention group had higher OSCE scores than the control group, but it was not statistically significant. The effect size was medium. At second assessment, the intervention groups had lower OSCE scores than the control groups, but again it was not statistically significant. The effect size was small. At third assessment, the intervention group had higher OSCE score than control group, but it was not statistically significant. The effect size was small.

Among intervention groups, OSCE scores were highest in 3rd assessment followed by 1st and 2nd assessments respectively, but it was not statistically significant. The effect size was medium. Among the control groups, there was statistically significant difference of OSCE scores between the three assessments where OSCE scores was highest in 2nd assessment followed by 3rd and 1st assessments respectively. The effect size was high (Table IV).

Table V shows post-hoc comparison of OSCE score at 1st, 2nd and 3rd assessment among intervention and control groups. There were no statistically significant differences of OSCE scores between three assessments among the intervention groups. However, among the control groups, OSCE scores were significantly higher in the 2nd assessment than the 1st assessment, but there were no statistically significant differences between 1st and 3rd assessments as well as between 2nd and 3rd assessments.

DISCUSSION

Multiple studies demonstrated that OSCE as a method of skills evaluation, is superior to other traditional assessment tools, especially, in judging student satisfaction, self-confidence and clinical knowledge acquisition.[22] OSCE is a well-recognised technique to evaluate the clinical technical and non-technical skills by judging students' performance in simulated exercises.[23] Several studies had been conducted in the domain of medical education that used simulation-based teachings for advancement of diagnostic capabilities and acquisition of psychomotor skills for future doctors, especially in acute medical emergencies.[24,25] The evidence for efficacy of simulation-based evaluation methods in the field of medical education was sparse and its advantage was mainly validated in specific specialties using specified tools for assessment when compared to other traditional evaluation methods.[24] HFS may be an appropriate teaching aid to complement traditional educational techniques if the learners are provided with best practice methods for decision-making and learning psychomotor skills in a safe atmosphere who can meet future challenges in real life without causing any harm to the patients.[26] HFS significantly enhanced the performance and psychomotor skills of learners when compared to the control groups without HFS with a medium-to-large effect size as shown in a meta-analysis study by Shin et al. (2015).[27] Another meta-analysis and systemic review by Lei et al., demonstrated that HFS significantly increased critical thinking ability, communication skills and clinical judgement ability among the learners.[28] A study by Guerrero et al., showed that learners who had undergone HFS-based teaching along with clinical training performed better in OSCE when compared with the cohort who was exposed to clinical training only.[29] Another study also proposes the incorporation of high-fidelity simulation into advanced resuscitation training program as it was shown to help pharmacy residents achieve competency through active learning of practical skills.3[0] The combination of deliberate skill practice during HFS scenarios shows improved skill competency and retention in prelicensure nursing with reduction in errors when performing urinary catheter insertion.[31] However, in our study, there was no significant difference in enhancement of psychomotor skills when HFS was compared to video-assisted learning.

In the other hand, a RCT study conducted did not support the superiority of HFS in achieving better patient outcome and that more research is required to set the standards of HFS-based training modules.[32] Another meta-analysis study showed inconsistent evidences of HFS as an effective educational technique compared to other traditional teaching methods and therefore, more superior quality RCTs are required to validate its inclusion into the curricula.[33] In this context, our study showed no significant difference in acquisition and retention of skills in HFS when compared to VAL-based teaching in all three assessments.

The training session for HFS students involves more hands-on active participation, and thus supports psychomotor learning, as compared to video-assisted learning group. Simulation with added emotional stressors led to greater anxiety during ACLS training that correlated with enhanced performance. The anxiety generated by a simulated scenario may enhance retention through well-established learning pathways,[34] though it did not yield an edge over the conventional teaching methods in our study. However, the effects of emotion on learning and memory are not always univalent, as studies have reported that emotion either enhances or impairs learning and long-term memory.[35]

The OSCE scores for intervention group in the 1st assessment were markedly higher than the control group, though statistically not significant. This may be explained by the fact that the control group was not exposed to the hands-on training on METIman prior to the 1st assessment and there was lack of situational awareness among these students. The significant increase in OSCE scores of the VAL group from the 1st to the 2nd assessments may be due to the students getting more familiar with the simulator combined with increased situational awareness during the second assessment. There is a drop of OSCE scores from 2nd to 3rd assessment in the VAL group, though statistically insignificant. On the other hand, there is a statistically insignificant increase of OSCE scores from 2nd to 3rd assessment for the HFS group. The causes for these differences of OSCE scores in the repeat assessments were unable to be identified. Repeated exposures at 4 and 8 weeks after the initial teaching session did not consolidate the skills or enhanced its retention significantly at 8th-week, for both groups. In this context, our study does not support HFS as an effective tool to strengthen skills taught earlier. This has been corroborated by the findings of a study that showed a significant loss of cardiopulmonary resuscitation skills in HFS group as compared to traditional teaching methods in nursing students, three months after training.[36] Rather, continuous repetitive practice is possibly the key to acquisition of skills in the long run. The difference in the simulator fidelity, the complexity and the variability of the skills being taught, or the potential ceiling effect of the OSCE as an assessment tool might have affected the outcome of this study. Additional explorative studies are crucial to provide convincing evidence in determining the superiority of HFS-based education that improves technical and non-technical skills in the learners. A standardised curriculum and identical evaluation tools with established statistical validity may help in the process.[37] The most important reason for inclusion of SBME in the curricula is to minimise the risk of learners committing errors in their future clinical practice by exposing them to a variety of clinical simulated environment where they were permitted to make mistakes and consequently learn from the mistakes.[38] This needs to be considered even though our study did not provide enough evidence about its superiority over conventional educational approaches in determining the learning outcomes of clinical skills. Further studies may determine the impact of simulation learning over time and assess transference of simulation into day-to-day clinical practice. There is a need to verify its worth in promoting clinical skills retention, in addition to its potential role in enhancing knowledge, judgement, professionalism, self-motivation, reflective learning, competence, and confidence.

LIMITATIONS

Several limitations were considered in interpreting the outcomes of this study. First, the study was confined to one region of a country. Although a positive publication trend on this topic emerged in the last decade, most of the research had been conducted in North America. Consequently, generalisability of results is limited given the differences in many academic and curriculum aspects in this part of the world. Second, the comparison of learning effectiveness between traditional teaching strategy and HFS-based education for long-term retention of skills was unexplored. Apart from the sample size, there were other potential confounders in terms of students' individual learning capacities, diligence, cross-discussion before the reassessment, and respective small group dynamics. There is a need for a more comprehensive measurement of HFS activities that evaluates clinical competencies and patients' satisfaction in longitudinal studies, as well as the cost-effectiveness of implementing HFS in healthcare setting.

CONCLUSION

Integration of High-fidelity simulation (HFS) in medical education programme provides an invaluable opportunity for students to experience in real-time, a simulated, dynamic clinical scenario and to develop clinical skills in a rather controlled environment. Questions have lingered, however, regarding its effectiveness as compared to other pedagogy. Our study was designed to provide insights in this respect, as well as to contribute to the future development and improvement of HFS teaching among healthcare students. This study did not demonstrate clear advantage of HFS over video-assisted learning in clinical skills enhancement and retention.

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DECLARATION OF INTEREST

The authors have not received any funding or benefits from industry or elsewhere to conduct this study and have no conflicts of interest.

ETHICAL APPROVAL AND REGISTRATION

Ethical approval was duly obtained from the Ethical Committee/IRB of MUCM and Manipal Academy of Higher Education (MAHE). Informed consent was taken from all the participants. All information about the participants was kept confidential. The protocol of the research study was registered with the MUCM/MAHE research committee. Approval number: MMMC/FOM/Research Ethics Committee- 11/2018.

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