INSTRUCTIONAL DESIGN AND ASSESSMENT

Comparing Effectiveness of High-Fidelity Human Patient Simulation vs Case-Based Learning in Pharmacy Education

Ken Lee Chin, MPharm, BCPS, Yen Ling Yap, MScCPIPP, BCPS, Wee Leng Lee, PhD, and Yee Chang Soh, MPharm, BCPS

Faculty of Pharmacy, Universiti Teknologi MARA, Bandar Puncak Alam, Selangor, Malaysia

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Objective. To determine whether human patient simulation (HPS) is superior to case-based learning (CBL) in teaching diabetic ketoacidosis (DKA) and thyroid storm (TS) to pharmacy students.
Design. In this cross-over, open-label, single center, randomized control trial, final-year undergraduate pharmacy students enrolled in an applied therapeutics course were randomized to HPS or CBL groups. Pretest, posttest, knowledge retention tests, and satisfaction survey were administered to students.
Assessment. One hundred seventy-four students participated in this study. The effect sizes attributable to HPS were larger than CBL in both cases. HPS groups performed significantly better in posttest and knowledge retention test compared to CBL groups pertaining to TS case ($p<0.05$). Students expressed high levels of satisfaction with HPS sessions.
Conclusion. HPS was superior to CBL in teaching DKA and TS to final-year undergraduate pharmacy students.

Keywords: human patient simulation, case based learning, diabetic ketoacidosis, thyroid storm, pharmacy education

INTRODUCTION

Over the last decade, there has been a growing, worldwide acceptance of the use of high-fidelity human patient simulators in pharmacy education. Pharmacy educators are entrusted with the responsibility of ensuring graduates are professionally competent to provide high-quality patient care.[1] The Accreditation Council for Pharmacy Education Standards and Guidelines states that the development of critical-thinking and problem-solving skills through active learning strategies and other high level pedagogical strategies should be supported throughout the curriculum. Active learning strategies include the application of computer and other instructional technologies, laboratory experiences, case studies, guided group discussions, simulations, and other practice-based exercises.[2]

There has been a growing body of evidence supporting the use of human patient simulation (HPS) in pharmacy education.[3-20] HPS activity provides students with hands-on experience close to real life clinical settings, allowing students to gather patient data actively, make real-time decisions, learn about the roles of other health care providers, and implement concurrent interventions with no potential for harm to the patient.[3,13] Evidence indicates that students who participated in HPS activities demonstrated better understanding of the relevant topics with high levels of satisfaction and improved confidence in skills.[7,9,11-16,21]

From an educator's standpoint, teaching interventions should accommodate students' learning styles to achieve desired learning outcomes.[22] HPS significantly benefits visual, auditory and kinesthetic learners because active participation in the learning process forms the main core of HPS methodology.[23] In concordance with andragogy principles introduced by Malcolm Knowles,[16,24] students tend to gain better understanding and knowledge retention the more they immerse in HPS activity. The use of case-based learning (CBL) is well documented in health profession education including pharmacy.[25-28] The purported advantages of CBL are myriad and include helping learners focus on key points of a clinical case, encouraging a structured approach to clinical problem solving, allowing scientific enquiry, integrating knowledge and practice, and developing learning skills.[25,29] Introduction of CBL sessions are reported to have significantly improved students' knowledge acquisition in various courses.[25,26,28] However, pharmacy education is lacking a conclusive, quantitative comparison of the effectiveness of HPS against CBL as a teaching pedagogy. The need to compare these two teaching modalities becomes heightened as investment in HPS

Corresponding Author: Ken Lee Chin, Universiti Teknologi MARA, Bandar Puncak Alam, Selangor Malaysia 42300. Tel: +6019-5641803. Fax: +603-32584602. E-mail: ken_usm@yahoo.com

equipment is expensive and requires relatively greater logistic support compared to CBL.

HPS technology is relatively new to pharmacy programs in developing countries. To date, many institutions offering bachelor of pharmacy programs in Malaysia have successfully established conventional teaching pedagogy such as didactic lecture, CBL, problem-based learning and ward attachments. Over the last decade in Malaysia, however, pharmacists' role have been evolving from product-centered services to patient-centered care, in tandem with global transformation of the pharmacist's role. Clinical pharmacists are now expected to participate actively in medication therapy management to improve patient outcomes in the Malaysian health care system. Institutions offering pharmacy programs in Malaysia are entrusted to produce graduates who are competent to contribute to patient care.

To the authors' knowledge, we are the first pharmacy faculty in Malaysia to incorporate HPS in a BPharm program. In this manuscript, we report data comparing comprehension of diabetic ketoacidosis (DKA) and thyroid storm (TS) among final year undergraduate pharmacy students following HPS and CBL experiences.

DESIGN

Human patient simulation was introduced to the Applied Therapeutics in Gastrointestinal, Renal and Endocrine Course in March 2013. The objective of this final year comprehensive, disease-based course is to prepare students to identify primary medical problems, formulate pharmacotherapy strategies, and prevent drug-related problems in gastrointestinal, renal, and endocrine diseases.

Previously, CBL was used in this course to complement didactic lectures before students were sent to various hospitals for clinical practice experience. Facilitators often posed trigger questions to promote active discussion and participation among students who were divided into small groups. Students' incorrect assumptions were corrected immediately by the facilitators. HPS was incorporated into the course to provide students with the opportunity to gain knowledge, develop critical-thinking skills, and practice patient-care skills in a realistic setting. Simulation sessions were conducted at the Clinical Skill Simulation Laboratory in the Faculty of Pharmacy at Universiti Teknologi MARA. The HPS used was SimMan 3G (Laerdal Corporation, Stavanger, Norway). This study was approved by Institutional Review Board.

From March 2013 to July 2013, a total of 176 final year pharmacy students enrolled in the Applied Therapeutics course. A lecture on DKA was delivered in the first week of the semester. On the following week, students were randomly divided into 2 groups and given a patient case of DKA. Group 1 participated in HPS sessions while group 2 participated in CBL sessions. In both arms, students were further divided into groups of 11. In the fourth week of the semester, group 1 participated in CBL sessions, while group 2 participated in HPS sessions with a patient case of TS. No lecture on TS was provided to the students prior to the HPS or CBL sessions (Figure 1). The cases were created according the learning objectives of the course. The HPS and CBL sessions utilized the same vignettes. The DKA case depicted a 38-year-old male with type 1 diabetes mellitus admitted to an intensive care unit following admission for community acquired pneumonia. The TS case was that of a 60-year-old male admitted to the emergency department with TS. Students were provided with reading materials on both topics prior to the HPS or CBL sessions. They were also encouraged to find more articles on these topics on their own. Students who failed to attend the sessions were excluded from the study.

For each patient case, HPS sessions were conducted with 2 groups per day for 4 consecutive days. All 4 authors, working in pairs, were rotated to conduct all HPS sessions. For each session, 1 person acted as instructor to conduct the HPS session while another person helped to control the SimMan 3G controller. All authors had same level of simulation experience. Standard discussion flow protocols for both cases were developed to avoid interinstructor variability. A briefing was provided on the current condition of the patient in each encounter. Based on clinical presentations and laboratory and electrocardiogram findings, the instructor guided the discussion by asking the students questions about pathophysiology of the respective diseases and pharmacotherapy options. Students were encouraged to suggest pharmacologic treatment, implement the suggested treatment plan, and observe the "patient's" clinical response. Following completion of the teaching sessions, debriefings were conducted to consolidate and reinforce the learning experiences. The total time spent in each HPS session was approximately 40 minutes. All sessions were recorded on DVD to facilitate program evaluation.

CBL sessions were facilitated by another 4 faculty members familiar with the topics and experienced in conducting CBL sessions. The facilitators were briefed on the cases prior to the CBL sessions. For each patient case, each facilitator conducted 1 CBL session per day for 2 consecutive days. Student participation was solicited to discuss the pathophysiology of the respective diseases and to determine the pharmacotherapy management of each case. The total time spent in each CBL session was approximately 1 hour.

All students before the DKA and TS sessions were required to assess their baseline knowledge with a pretest.

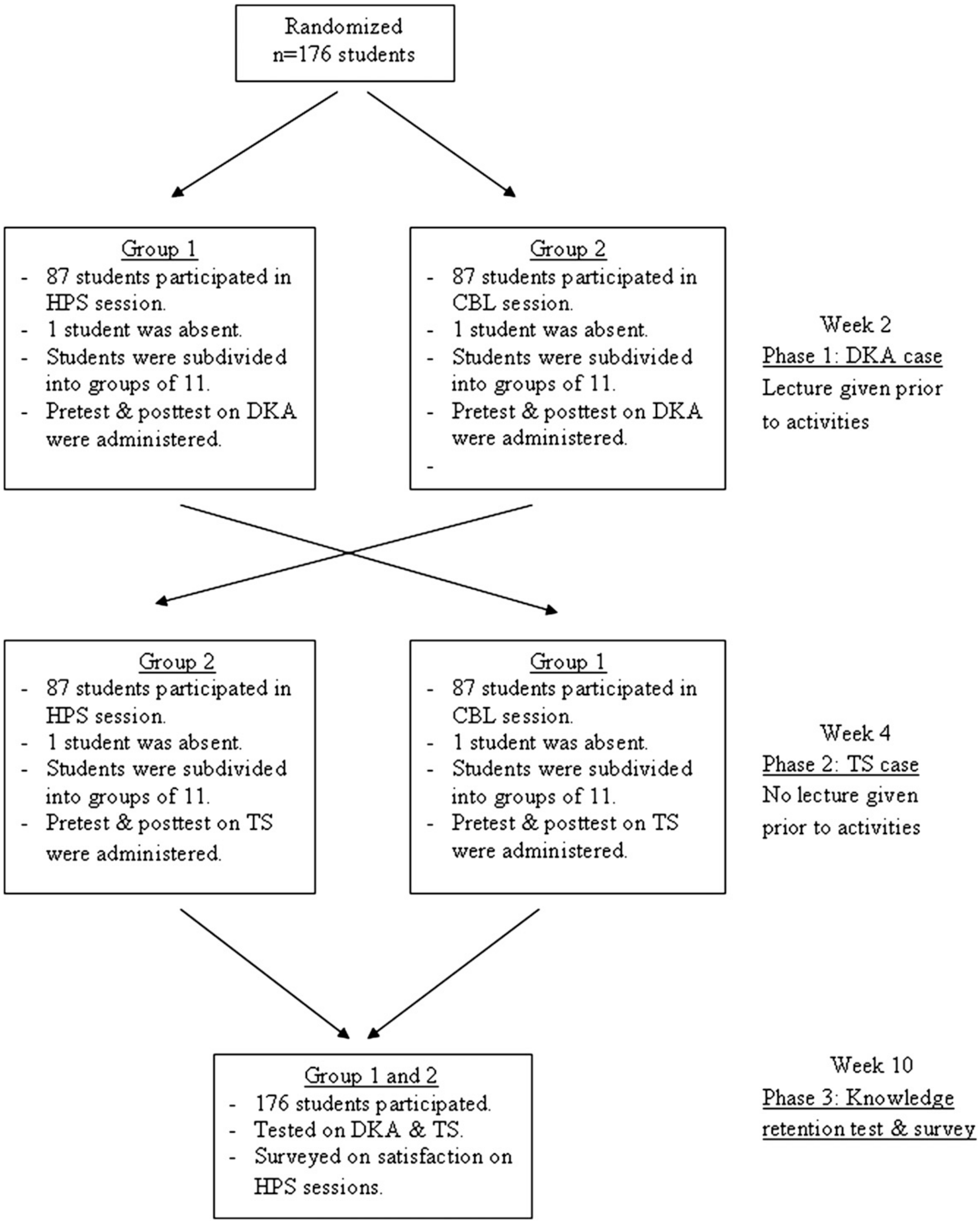

Figure 1. Schematic of Study Design.

The same test was repeated immediately after the HPS debriefing or CBL sessions as a posttest and again in week 10 to measure knowledge retention. Knowledge retention tests for both topics were conducted on the same day. A total of 20 true/false questions were developed for DKA session while 15 multiple choice questions were developed for TS session. The students were tested on the domains covered in the HPS or CBL sessions. The tests constituted recall and application type of questions. Students were informed that results from all tests were for study purposes only and would not affect their final grades in the course.

In addition to the tests, all students were asked to complete a satisfaction survey on HPS sessions anonymously and voluntarily. The survey instrument consisted of a section A: 10 questions regarding perception on HPS session, each with Likert scale responses (ranging from strongly disagree (1) to strongly agree (5)); and a section B: 4 open-ended questions seeking suggestions for future

HPS sessions. Students' academic achievement data were collected from the college's academic office.

Data analysis was performed with SPSS, version 21.0 (SPSS Inc., Chicago, IL). We used descriptive statistics, independent *t* test, and a Kruskal-Wallis test where appropriate. A p value <0.05 was considered significant.

EVALUATION AND ASSESSMENT

A total of 174 students participated in this study. As seen in Table 1, students did not differ significantly in their age and academic achievement. However, a significant difference was found for gender distribution ($p=0.02$).

The HPS arm scored significantly lower than the CBL arm in the baseline knowledge assessment (ie, the pretest) for both cases ($p<0.05$). In phase 1, group 1 and group 2 did not differ statistically in the posttest, in the knowledge retention test, or in the test scores for the DKA case. However, in phase 2, group 2 (assigned to the HPS arm) performed significantly better compared to group 1 (assigned to the CBL arm) in both the posttest and knowledge retention test, as well as in test scores for TS case ($p<0.05$). Both HPS and CBL sessions successfully improved students' understanding on both cases, especially when no lecture on TS was delivered to the students prior to the HPS and CBL sessions. In addition, the effect sizes attributable to the HPS intervention were greater than CBL in both cases (Table 2).

Overall, students' responses to the HPS sessions were positive. One hundred sixty-three usable questionnaires were collected. Table 3 illustrates student survey responses. Reliability analysis was performed and the Cronbach alpha coefficient was found to be 0.960 for section A questions. More than 60% of the students strongly agreed that HPS sessions stimulated them to learn more about and improved their understanding of the cases. The same percentage of students responded that the facilitators were helpful in their HPS learning experience and that the HPS sessions were satisfying. Nearly 80% of the students felt that HPS sessions should be further incorporated into pharmacy curriculum. Ninety-seven percent agreed or strongly agreed that they would like to participate in other HPS activities in the future if given the opportunity. Mean rank score for male students was significantly higher than female students when asked whether HPS should be further incorporated into pharmacy curriculum ($p=0.022$). When we categorized the students based on their age and cumulative grade point average (CGPA), no significant difference was found in their perception of HPS sessions.

From the open-ended questions in section B, general themes regarding HPS included interesting, enjoyable, realistic, fun, inspiring, and excellent teaching method. Students commented that HPS made them think critically and better understand the flow of treatment, enabled deep discussion, provided preceptors to guide students whenever needed, and allowed for mistakes before treating real patients. Some students suggested that future HPS activities include non-emergency and pediatrics/neonatology cases and other students suggested that groups be even smaller (3 per group instead of 11). Regarding the duration of each HPS session, 71.8% felt that it should be conducted for 1 hour, 15.3% for 45 minutes, 12.3% for 30 minutes, and 0.6% for 15 minutes.

Table 1. Student Demographic Data

Demographic	Group 1 (n=87)	Group 2 (n=87)	*P*
Gender, No. (%)			
Male	14 (16.1)	27 (31.0)	
Female	73 (83.9)	60 (69.0)	0.020[a]
Age, Average (SD)	24.0 (1.6)	24.0 (1.8)	0.79
CGPA, Average (SD)	3.1 (0.2)	3.0 (0.3)	0.076

Abbreviations: CGPA=Cumulative Grade Point Average; SD=standard deviation.
[a] $p<0.05$.

DISCUSSION

Across the globe, increased demand for knowledgeable and skilled clinical pharmacy practitioners has transformed pharmacy education in recent years. Barriers such as limited availability of clinical settings suitable for effective bed-side teaching and confidentiality of patients' data have prompted many pharmacy educators to explore the potential use of HPS as an alternative resource for clinical teaching. SimMan 3G, a high-fidelity human patient simulator, is capable of presenting a palpable pulse, audible heart beat, lung and abdominal sounds, and hemodynamic parameters. Instructors are able to program the simulator with desired physiologic changes, including responses to drug administration that closely mimic real-life situations. We used SimMan 3G in our BPharm program as it provided a controlled and safe learning environment for the students. It also addressed patient safety issues and the college's need for clinical sites.

There are several important points worth mentioning based on our findings. First, our findings on the use of HPS are similar to results from earlier studies that were carried out among PharmD and BPharm students.[10,13,19-21,30] These similarities include improved posttest scores from baseline, increased participation and interaction from students compared to usual teaching pedagogy, and positive responses to and high levels of satisfaction with HPS sessions.

Second, both teaching modalities were effective in improving students' understanding of the topics, especially when the students did not receive a lecture on TS. The

Table 2. Comparison of Test Scores, Differences Between Test Scores, and Effect Sizes

	Group 1 Average (SD), %	Group 2 Average (SD), %	
	HPS	**CBL**	***P***
Case 1: DKA			
Pretest	84.1 (11.0)	87.7 (8.4)	0.02[a]
Posttest	92.3 (7.2)	93.5 (6.9)	0.28
KR	82.0 (12.5)	84.5 (10.0)	0.16
Posttest – Pretest	8.2 (10.5)	5.7 (8.6)	0.10
KR – Posttest*	-10.1 (13.3)	-9.2 (9.3)	0.61
KR – Pretest*	-1.6 (15.5)	-3.6 (9.6)	0.34
Effect size	0.90	0.76	
	CBL	**HPS**	
Case 2: TS			
Pretest	57.6 (14.9)	52.2 (15.2)	0.018 [a]
Posttest	75.1 (9.6)	78.5 (11.5)	0.033 [a]
KR	53.3 (14.9)	58.5 (14.2)	0.022 [a]
Posttest – Pretest	17.5 (14.9)	26.4 (14.2)	0.000 [a]
KR – Posttest	-21.9 (16.9)	-19.6 (15.3)	0.36
KR – Pretest	-4.6 (17.8)	6.9 (18.9)	0.000 [a]
Effect size	1.43	1.97	

Abbreviations: HPS = human patient simulation; CBL = case-based learning; DKA = Diabetic ketoacidosis; TS = Thyroid storm; SD = standard deviation; KR = Knowledge retention test.

[a] $p<0.05$.

* For each student, differences between knowledge retention and both post- and pretest scores were calculated, then these differences were averaged to get mean value.

effect sizes attributable to HPS in both cases were greater than CBL, implying that HPS interventions were more effective than those of CBL in improving student comprehension of the cases. Moreover, the use of standardized discussion flow protocols were effective in reducing inter-instructor variability, ensuring HPS sessions were conducted systematically, and reminding instructors of key discussion points when conducting HPS sessions.

Table 3. Student Responses to Satisfaction Survey Post Human Patient Simulation (HPS) Session

	Student Response, No. (%)				
Question	**Strongly Disagree (1)**	**Disagree (2)**	**Uncertain (3)**	**Agree (4)**	**Strongly Agree (5)**
The HPS session stimulated my interest to learn more about the case.	3 (1.8)	0	0	55 (33.7)	105 (64.4)
The HPS session was effective in improving my understanding about the case.	3 (1.8)	0	0	60 (36.8)	100 (61.3)
The HPS session helped me formulate a solution for the case.	3 (1.8)	1 (0.6)	7 (4.3)	73 (44.8)	79 (48.5)
The HPS effectively reinforced previously learned concepts in a meaningful manner.	3 (1.8)	0	2 (1.2)	68 (41.7)	90 (55.2)
HPS enhanced my confidence level in patient care.	2 (1.2)	1 (0.6)	22 (13.5)	65 (39.9)	73 (44.8)
HPS should be further incorporated into pharmacy curriculum.	3 (1.8)	0	1 (0.6)	29 (17.8)	130 (79.8)
The facilitators were helpful in my HPS learning experience.	3 (1.8)	0	3 (1.8)	43 (26.4)	114 (69.9)
I am satisfied with the HPS sessions.	3 (1.8)	1 (0.6)	2 (1.2)	54 (33.1)	103 (63.2)
Compared to CBL, I learned clinical patient care better using HPS.	3 (1.8)	1 (0.6)	7 (4.3)	37 (22.7)	115 (70.6)
If given the opportunity, I would participate in other HPS activities in the future.	3 (1.8)	0	1 (0.6)	41 (25.2)	118 (72.4)

Third, it was surprising to note that students' confidence level was not markedly enhanced compared to other items in the questionnaire that were enhanced, albeit more than 84% of the students indicated a positive response to the sessions. When we categorized students based on gender, age and CGPA, no significant difference was found in their response to the statement about confidence level. The HPS sessions were in fact their first hands-on experience making real-time decisions in an environment that closely mimicked real clinical settings. Based on our observation and conversation with students, we noticed that some were nervous during the HPS sessions, and this could have affected their confidence levels in providing patient care.

Fourth, male students appeared to be more agreeable than female students to incorporating HPS into pharmacy curriculum. However, we postulated that gender wasn't a significant factor influencing overall perception about HPS sessions because there was no significant difference between male and female student perception of other items in the questionnaire. Previous studies on learning styles reported that pharmacy students demonstrated a strong preference for more pragmatic application-directed approaches, which emphasize the practical use of knowledge.[31,32] Pungente et al reported that convergers and accomodators made up the majority of their pharmacy students.[33] Convergers' greatest strength lies in problem solving, decision making, and practical application of ideas, while accomodators preferred to participate actively in learning experiences and apply their learning to real life situations. We did not measure our students' learning styles, but we believe they are similar to those reported previously based on the overall responses to HPS sessions.

Lastly, it is interesting to note that some students proposed including non-emergency cases, smaller groups, and limited guidance from instructors in the HPS sessions. These suggestions reflected student enthusiasm for trying to manage patients independently and seek more opportunities to participate actively in the discussion process.

Our study had several potential limitations. While the Faculty of Pharmacy at the Universiti Teknologi MARA has the largest enrollment in a BPharm program in Malaysia, the generalizability of the results from this study may be difficult as they are representative of students from a single pharmacy school. Further studies of students from other institutions are warranted to confirm our findings.

The design of our simulation sessions was instructional. Students were informed that test results were only for study use so students would concentrate on learning in a real-time clinical environment that reflected the urgency in managing critically ill patients. Although our study demonstrated improved student understanding, we were not able to measure the students' ability to execute acceptable patient care skills independently from the study.

Logistics was a major challenge in conducting the HPS sessions with small groups. Simulation equipment, including mannequins, facility space, and software licenses, were expensive to purchase and properly maintain. Preparing for a simulation session was also time intensive. It was necessary to make specific arrangements for all students to have an opportunity to participate in simulation sessions as there was only one SimMan 3G simulator for the large class, as well as time constraints and limited number of faculty members with training in high fidelity HPS.

Finally, students were unable to appreciate interdisciplinary team approaches to managing acutely ill patients because developing such team skills was not the aim of the simulations. Instead, our primary objective was to teach pharmacotherapy principles in managing acutely ill DKA and TS patients.

CONCLUSION

This paper describes the successful use of HPS and CBL sessions to enhance students' understanding of pharmacotherapy in DKA and TS patient cases. HPS sessions appeared to be more effective in improving student understanding and knowledge retention compared to CBL sessions. HPS sessions resulted in high levels of satisfaction as well as improved critical-thinking skills among the students.

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