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EXPERIMENTAL TRIALS

Low-cost *versus* high-fidelity pediatric simulators for difficult airway management training: a randomized study in continuing medical education

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Abstract
Background: High-fidelity (HF) pediatric patient simulators are expensive. This randomized study aimed to compare the quality and educational impact of a full-scale simulation workshop with an HF infant simulator (SimBaby™, Laerdal) or with a low-cost (LC) simulator composed of an inert infant manikin with SimBaby™ software that displays respiratory/hemodynamic parameters on a monitor for medical education in pediatric difficult airway management.
Methods: After written informed consent, anesthetists and emergency or ICU physicians participated in teams (4 to 6 participants) in a training session that included direct participation and observation of two difficult intubation scenarios. They were randomized into two groups (HF group, n = 65 and LC group, n = 63). They filled out a simulation quality score (SQS, 0 to 50), self-evaluated their anesthetists' non-technical skills (ANTS) score (15 to 60), and an educational quality score (EQS, 0 to 60) immediately (T0, main criteria), as well as 3 (T3) and 6 (T6) months after the training session.
Results: We enrolled 128 physicians. Direct participation SQS (39 ± 5 HF group *versus* 38 ± 5 LC group), observation SQS (41 ± 4 H F group *versus* 39 ± 5 LC group), ANTS scores (38 ± 4 HF group *versus* 39 ± 6 LC group), T0 SQS (44 ± 5 HF group *versus* 43 ± 6 LC group), T3 and T6 SQS were not different between groups.
Conclusion: Our low-cost simulator should be suggested as a less expensive alternative to an HF simulator for continuing medical education in pediatric difficult airway management.

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Introduction

Tracheal intubation is frequently performed in children in anesthesia, intensive care, and emergency medicine. Despite the development of guidelines,[1] difficult intubation remains a major cause of morbidity[2] owing to the physiological characteristics of infants and young children, thereby contributing to the rapid onset of hypoxia during apnea.[3] The incidence of laryngospasm is especially increased when the anesthetist is insufficiently experienced.[4] Continuing education in difficult intubation is more necessary since it is less common in children.[5] High-fidelity simulation (HF) is a positive contribution to the management of pediatric emergencies with scenarios that recreate the clinical context as closely as possible.[6–8] HF patient simulators such as the SimBaby™ (Laerdal, Stavenger, Norway) include electromechanically controlled systems with computer software in order to mimic physiological functions including respiratory, hemodynamic, and pathological events. Multiple studies have demonstrated their interest in initial training and continuing medical education to improve technical and behavioral performance.[9,10] Their major inconvenience is cost, especially since this very fragile equipment requires technical maintenance. We propose a low-cost (LC) alternative consisting of an inert infant manikin with limited functionalities and a monitor which displays the progression of respiratory and hemodynamic parameters using SimBaby™ software.

We aimed to compare whether the quality and the educational efficacy perceived by HF SimBaby™ simulator learners are superior or not to an LC simulator for pediatric difficult airway management simulation training in a continuing medical education course.

Methods

This single-center open randomized study was performed in the High-Fidelity Simulation Center of our University after approval by our Institutional Ethical Committee (February 7, 2012). After informed written consent, all the anesthesiologists and emergency or intensive care physicians (certified health professionals or anesthesiologists, or emergency medicine residents at the end of their training) who participated in pediatric difficult airway management simulation training in 2012 and 2013 were included. None of the participants was at his or her usual hospital workplace. Exclusion criteria were refusal of a physician to participate in the study. In that case, he or she participated in the course without completing the evaluation questionnaires.

Pediatric simulators

Each simulation training session was scheduled for a team of 4 to 6 participants from the same medical specialty. The random allocation sequence was generated using a random-number table with three equilibrated blocks. Only one investigator generated the random allocation sequence, enrolled and assigned the teams as HF or LC groups. Allocation was implemented using sequentially numbered envelopes which were opened immediately before the simulation session.

In the HF group, the simulator was a SimBaby™. Briefly, airway configuration, pulmonary and cardiac auscultation, thoracic movements could be modified in order to simulate lingual or pharyngeal edema, difficult or accidental selective right main bronchus intubation, closed vocal cords, laryngospasm, bronchospasm, or acute respiratory distress. It was possible to mobilize the head in extension and rotation, jaw trust, insert a stomach tube and use all of the airway devices. If insufflation pressure was excessive, stomach dilatation occurred and facial mask ventilation became difficult. Peribuccal cyanosis appeared when SpO_2 was below 85%. A microphone built into the simulator made it possible to hear prerecorded sounds (screaming, crying, moaning, complaining, and vomiting). The evolution of events (dyspnea, apnea, obstruction, thoraco-abdominal asynchrony, laryngospasm, bronchospasm) and the monitor display of hemodynamics (electrocardiogram, blood pressure) and ventilation (respiratory rate, cyanosis, SpO_2, capnogram, O_2, N_2O, sevoflurane, and CO_2 inspiratory and expiratory fractions) was controlled by an instructor using predefined scenario scripts.

In the LC group, the simulator consisted of an inert infant manikin (Stat Baby, Simulaids Ltd, Leicestershire, United Kingdom) with non-movement and limited functionalities. There was no spontaneous ventilation or color change. The stomach could not be insufflated. It was only possible to close the vocal cords or generate labial edema using a pneumatic system by air through a 50-ml syringe in a long tube connected to the manikin. All the airway management devices described above were usable. The manikin was not connected to a computer system. However, the changes in physiological parameters displayed on the monitor were also controlled by an instructor with SimBaby™ software in the same manner as in the HF group.

Proceedings of the simulation session

The environment, equipped according to the scenario (at the patient's home, operating room, or pediatric emergency room and progression of the simulation was strictly identical whatever the simulator. The simulation was preceded by a briefing with presentation of the educational objectives, simulator, equipment, and environment. To ensure the reproducibility of simulation training, the briefing, control of the simulation software, and debriefing were always carried out by the same instructor. The facilitator's role was always performed by one of the three investigators. His or her mission was to provide the participants with additional information to manage the case and help them with the environment. In the LC group, the facilitator communicated clinical data that could not be transmitted by the manikin (cyanosis, apnea, thoraco-abdominal asynchrony, auscultation characteristics).

Physicians participated in the workshop in groups of 4 to 6 in the same specialty. Half of the group was equipped with microphones and participated directly in the first scenario while the other half observed the scenario in another room with simultaneous audio–video retransmission. The reverse procedure was applied to the second scenario. Each learner

was directly involved in one scenario and was an observer for the second. After each scenario, the debriefing was carried out with the entire group. The total duration of the simulation session was 60–70 minutes, with two 10-to-15-minute scenarios and two 20-minute debriefings.

Scenarios

Two scenarios were used for the anesthesiologist sessions and two others for the emergency and intensivist physicians. For each scenario, technical and non-technical educational objectives, briefing elements, script, information given to the learners, initial state of the simulator, standardized evolution of the simulator's behavior according to learner actions, and facilitator role were specified. The educational objectives of the scenarios were the evaluation and anticipation of difficult intubation, ventilation and oxygenation, the appropriate choice of anesthetic agents and intubation technique, equipment preparation task prioritization, and distribution and communication within the team.

For the anesthesiologists, the first scenario was a 12-month-old infant with 50% burned body surface and moderate cervical edema who had undergone a first dressing with surgical debridement under general anesthesia with tracheal intubation in the operating room of a regional pediatric burn center. Participants were informed of milk ingestion just before the accident and a slight inspiratory draw with tachypnea possibly due to moderate cervical edema. SpO_2 was 100% with a high concentration oxygen mask. The expected actions were preoxygenation, rapid sequence induction, and orotracheal intubation. The oropharyngeal sphere was slightly edematous and laryngoscopic view of the glottis was grade 3 according to the Cormack-Lehane classification system. Intubation was supposed to be performed using a long gum elastic bougie. The second case was a planned difficult intubation in a 9-month-old infant with Pierre Robin syndrome, undergoing surgical treatment of cleft lip and palate. Expected management was induction of general anesthesia by inhalation of sevoflurane with spontaneous ventilation and fiberoptic intubation with local glottic anesthesia.

For emergency room and intensivist physicians, the first scenario took place at the patient's home with a 12-month-old boy without difficult intubation who was found unconscious in his grandparents' bathroom after accidental ingestion of a sedative. The second scenario was, as above, a 12-month-old child with 50% burned body surface in the emergency room of a general hospital. Participants had to intubate the child in anticipation of a long transfer to a specialized burn center.

Evaluation

Participants evaluated their educational experience with three surveys that included Simulation Quality Score (SQS), Anesthetists' Non-Technical Skills (ANTS) score,[11] and Education Quality Score (EQS). SQS and EQS were derived from the French College of Anesthesia and Resuscitation questionnaire for evaluation of continuous medical education. ANTS score was described by Fletcher et al. for evaluation of non-technical performances.

The SQS questionnaire was a 5-item survey (realism of the patient simulator and the scenario, relevance of the medical crisis, participant comfort, and appreciation of the scenario. The participants filled out the SQS at time 0 (T0) immediately after the workshop for simulation direct participation (direct SQS) and simulation observation (observation SQS). Each item was rated using a modified Likert scale graded from 1 (poor) to 10 (excellent). The SQS, graded from 10 to 100, was the sum of the direct SQS and observation SQS.

The EQS was self-evaluated by the participants with six questions on the acquisition of new data, the correlation between the announced and processed objectives, the quality of teaching materials and teaching resources, the interest of the subject and the intended changes by the participant for his or her subsequent clinical practice. The answers were also given using a modified Likert scale graded from 1 to 10. EQS graded from 6 to 60 was the sum of scores for each of its 6 items. In addition, the magnitude of subsequent intended clinical practice changes was also rated on a scale from 1 (slight) to 10 (radical).

ANTS score was self-evaluated by the participants at T0.[11] This score included 15 items classified into four categories: task management (planning and preparing, prioritizing actions, providing and maintaining standards, identifying and utilizing resources), teamwork (coordinating activities with team members, exchanging information, using authority and assertiveness, assessing capabilities, supporting others), situation awareness (gathering information, recognizing and understanding, anticipating), decision-making (identifying options, balancing risks and selecting options, re-evaluating). Each item was graded from 1 (poor) to 4 (excellent) and ANTS score ranged from 15 to 60.

Finally, EQS was also evaluated by the participants 3 (T3) and 6 (T6) months after the workshop. T3 and T6 questionnaires were sent by e-mail. If there was no response, reminders were sent 2 and 4 weeks after the initial message.

Information on the study, the obtaining of informed consent and collection of questionnaires and demographic data (age, medical specialty, workplace, professional status, duration of practice, frequency of pediatric activity, and previous experience in simulation training) were carried out by a single investigator.

Statistical analysis

Statistical analysis was performed using Statview® 5 software (Abacus Concept, Inc. Berkeley, CA). The T0 EQS was the primary outcome. The other scores were secondary endpoints. T0 EQS was 46 $\pm$ 6 for 107 participants between 2008 and 2011 in similar pediatric difficult airway workshops with a SimBaby™ simulator (unpublished personal data). The number of participants needed to objectify a 4-point score variation with a 0.05 α risk and a 0.9 power with a two-tailed test was 33 participants per group. Given the potential of a high number of refusals to participate in the study and participants lost to follow-up, we chose to include all the participants in a pediatric difficult airway management workshop organized in our simulation center between January 2012 and April 2013. Data are expressed by medians and percentiles 25–75% or number (percentage) of parti-

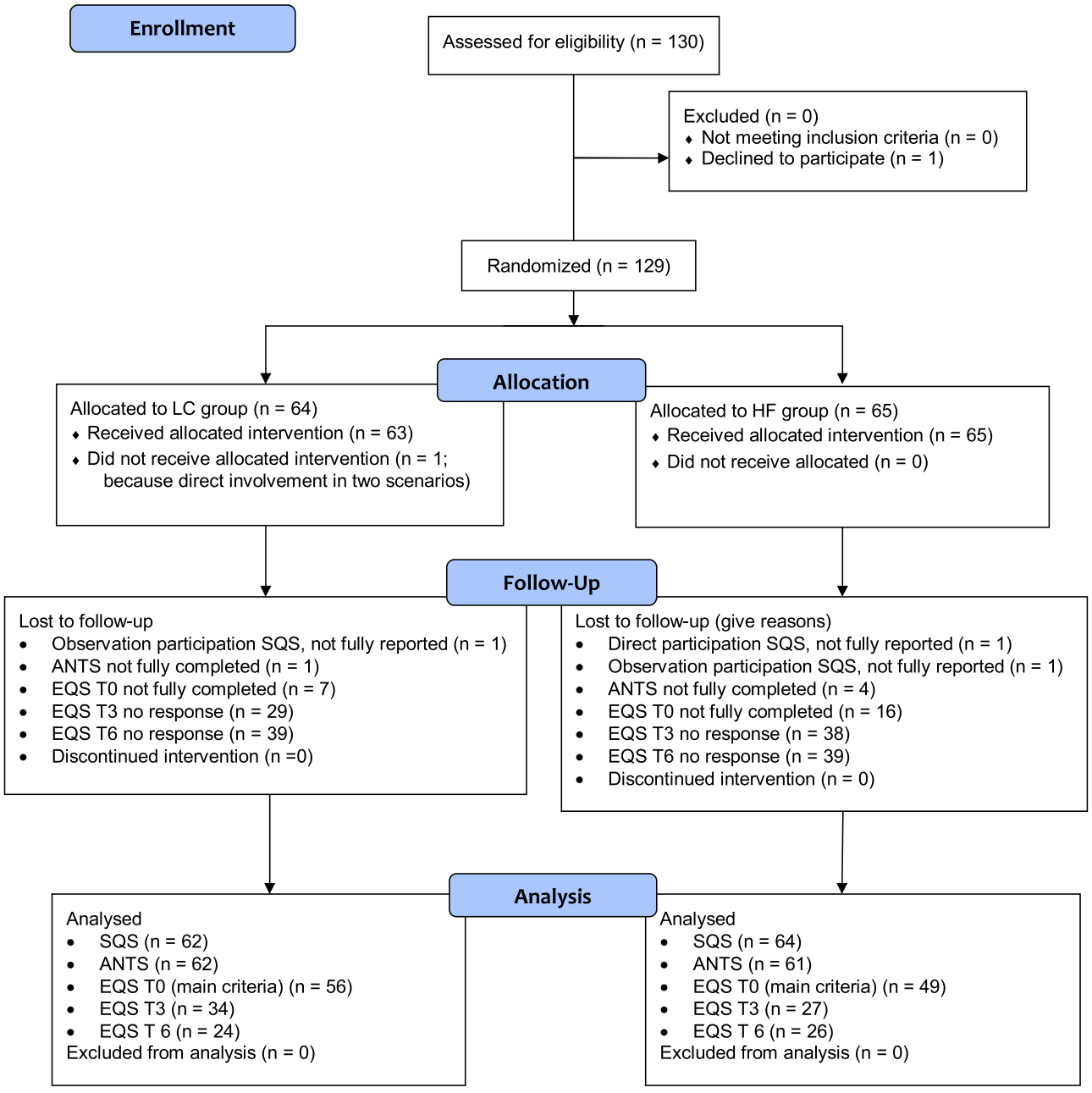

Figure 1 Consort Flow diagram.

cipants. Comparisons of demographic data and T0 scores between the LC and HF groups were performed with a Mann-Whitney U test or Chi-square as appropriate. A $p < 0.05$ was considered significant. Comparison of T0, T3, and T6 EQS between groups was performed using a repeated variance analysis followed by Bonferroni-Dunn tests.

Results

During the 13-month inclusion period, 130 participants attended pediatric difficult airway management workshops at our high-fidelity simulation center and were invited to join the study (Fig. 1). Only one participant, who did not sign the informed consent form, was not included. Another was excluded owing to direct involvement in two scenarios. Finally, 128 participants were enrolled, of whom 72.6% had been graduates for a median of 9 (4–17) years (Table 1). Response rates at T0, T3 and T6 to the EQS questionnaire (respectively 82.0%, 47.6%, and 39.1%) decreased over time in a comparable manner in the LC and HF groups (Fig. 2). EQS could be analyzed at T0 for 56 and 49 of the participants respectively in the LC and HF groups (Table 2). The EQS of the other participants could not be analyzed because some of the items had not been completed.

There was no difference in T0, T3, and T6 between LC and HF groups for the primary and secondary endpoints. An analysis of variance for repeated measures followed by the Bonferroni-Dunn test was made possible only for the

Table 1 Demographic characteristics and previous pediatric experience of the participants (n = 128).

Simulation group	Low-cost (n = 63)	High-fidelity (n = 65)	*p*
Medical discipline (%)			0.029
anesthesia	43 (68.2)	41 (63.1)	
intensive care medicine	5 (7.9)	0 (0)	
emergency room	15 (23.8)	24 (36.9)	
Age, years	36 (31–44)	33 (29–41)	0.0952
Sex ratio, F/M, n (%)	36 (57.1)/27 (42.9)	35 (53.8)/30(46.2)	0.7255
Graduate/fellow n (%)	13 (20.6)/50 (79.4)	22 (33.8)/43 (66.2)	0.1140
Previous simulaition experience, n (%)	36 (57.1)	37 (56.9)	> 0.999
Structure, n(%)			0.1628
University hospital	35 (58.3)	42 (64.6)	
General hospital	22 (36.7)	14 (21.5)	
Private hospital	1 (1.6)	(9.2)	
Mixed	2 (3.2)	1 (1.5)	
Pediatric practice, n (%)			0.3291
exclusive	3 (4,8)	1 (1.5)	
mixed with adult	41 (65.1)	38 (58.5)	
none	19 (30.2)	26 (40)	
Pediatric practice < 1 year, n (%)			0.4965
frequent	6 (9.5)	6 (9.2)	
occasional	9 (14.3)	6 (9.2)	
rare	19 (30.2)	15 (23.1)	
exceptional	28 (44.4)	38 (58.5)	
Pediatric practice 1 to 3 years, n (%)			0.5604
frequent	13 (20.6)	11 (16.9)	
occasional	20 (31.7)	15 (23.1)	
rare	14 (22.2)	19 (29.2)	
exceptional	16 (25.4)	20 (30.8)	
Pediatric practice > 3 years, n (%)			0.5000
frequent	19 (30.2)	13 (20.0)	
occasional	21 (33.3)	21 (32.3)	
rare	12 (19.0)	15 (23.1)	
exceptional	11 (17.5)	16 (24.6)	

Data are expressed as medians and percentile 25–75% or number (percentage) of participants.
Comparison of low-cost *versus* high-fidelity groups by Chi^2 or Mann-Whitney U test, as appropriate.
$p < 0.005$ was considered as significant.

Table 2 Educational Quality score (EQS) immediately (T0), 3 months (T3), and 6 months (T6) after the workshop.

Simulation group	Low-cost (n = 63)			High-fidelity (n = 65)			*p*[a]
	T0 (n = 56)	T3 (n = 34)	T6 (n = 24)	T0 (n = 49)	T3 (n = 27)	T6 (n = 26)	T0
Acquisition of new data	8 (7–9)	8 (6–8)	8 (5–8)	8 (8–9)	8 (7–8)	7 (6–8)	0.2058
Agreement of objectives with those announced	9 (8–10)	9 (8–9)	9 (7–9)	8 (8–10)	8 (8–9)	8 (8–9)	0.6712
Educational material quality	9 (8–10)	8 (7–9)	8 (7–9)	9 (8–9)	8 (7–9)	8 (7–9)	0.9263
Educational resource quality	9 (8–9)	9 (8–9)	8 (8–9)	9 (8–10)	9 (8–9)	9 (7–9)	0.2271
Level of interest of subject	9 (8–10)	9 (8–9)	9 (8–9)	9 (9–10)	9 (7–10)	8 (7–9)	0.4903
Learners who want to change their practices, n (%)	51 (91.1)	28 (82.3)	18 (75.0)	59 (90.8)	25 (92.6)	21 (80.8)	> 0.9999
Amplitude of change in practices	8 (5–8)	5 (4–7)	6 (0–8)	7 (6–8)	6 (5–7)	6 (5–7)	0.8830
EQS	49 (45–54)	47 (41–50)	45 (39–50)	50 (47–54)	47 (42–51)	45 (41–49)	0.3940

Data are expressed as medians and percentiles 25–75% or number (percentage) of responder participants.
EQS is the sum of the scores assigned to the 6 items.
[a] T0 comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test, *ns*.

Table 3 Simulation quality score (SQS) evaluated by the participants during direct participation and observation.

Simulation	Low-cost	High-fidelity	*p*
Direct participation SQS	(n = 63)	(n = 64)	
Simulator realism	7 (5–8)	8 (7–9)[a]	< 0.0001[a]
Scenario realism	9 (8–10)	9 (8–10)	0.5990
Relevance of the critical situation	8 (7–9)	8 (8–9)	0.2955
Participant comfort	7 (5–8)	5 (4–6)[a]	0.0020[a]
Appreciation of the scenario	9 (8–10)	9 (8–10)	0.7084
Total	38 (35–41)	39 (37–42)	0.2617
Observation SQS	(n = 62)	(n = 64)	
Simulator realism	7 (5–8)	8 (7–9)[a]	< 0001[a]
Scenario realism	9 (8–10)	9 (8–9)	0.6317
Relevance of the critical situation	8 (8–9)	9 (8–10)	0.1959
Participant comfort	7 (6–8)	7 (5–8)	0.1121
Appreciation of the scenario	9 (8–10)	9 (8–10)	0.5643
Total	39 (35–43)	40 (38-44)	0.0850
SQS	(n = 62) 77 (73–83)	(n = 64) 80 (75–6)	0.1517

Data were expressed as median and percentiles 25–75%.
A direct participation SQS not completely filled in the HF group was not analyzed.
An observation SQS, not fully reported in each group, was not analyzed.
SQS being the sum of the participation and direct observation SQS, it was only analyzed when both of its components were reported.
Comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test.
[a] $p < 0.05$ was considered as significant.

Table 4 Anesthetists' Non-Technical Skills (ANTS) core self-evaluated by the participants.

Groups	Low-cost (n = 62)	High-fidelity (n = 61)	*p*
Task management	11 (10–12)	11 (9–11)[a]	0.0195[a]
Teamwork	14 (12–15)	14 (13–15)	0.5257
Situational awareness	9 (8–9)	9 (8–9)	0.6220
Decision making	8 (7–9)	9 (7–9)	0.3508
ANTS score	42 (38–45)	41 (38–43)	0.4452

Data were expressed as median and percentiles 25–75%.
The ANTS score is the sum of the 4 items.
The ANTS score was not fully completed by one participant in the low-cost group and by 4 participants in the High-fidelity group and was not analyzed.[a]
Comparison of low-cost *versus* high-fidelity simulation groups with a Mann-Whitney U test.
[a] $p < 0.05$ was considered as significant.

participants who completed all of the T0, T3, and T6 EQS questionnaires, i.e., 18 in the LC group and 12 in the HF group. No group effect was noted ($p = 0.6624$). In contrast, a time effect was observed ($p = 0.0001$) with a T0 EQS higher than the T3 and T6 EQS. T3 and T6 EQS were not different (Fig. 2). SQS (Table 3) were not different between the groups regardless of the component (direct participation or observation) and their items except for two of them. Realism of the manikin was higher and participant comfort was lower in the HF group. The ANTS score (Table 4) was not different between either group. It was the same for all of its items *except for ẗask managementc̈onsidered easier in the LC group with a slightly higher score* (*p= 0.0195*).

Discussion

The main finding based on our results is that the quality of the simulation and educational impact of our low-cost pediatric simulator evaluated by the participants was not different from that of a high-fidelity patient simulator when used for training in pediatric difficult airway management in continuing medical education.

The originality of this study lies in its design and theme. Randomization and participants of diverse origins reinforce our findings. Some studies have concluded that the efficacy of high-fidelity simulation is not systematically higher than a well-built low-fidelity simulation,[12–15] but this has never been shown in the management of pediatric airways. Owing to the high incidence of respiratory complications, intubation remains a challenge for anesthesiologists and emergency physicians who only occasionally have pediatric practice.[4] The very heterogeneous prior experience of our participant population underlines the need for simulation training in this field of activity.[16]

Analysis of the questionnaires identified only a difference for two EQS items. The realism of SimBaby™ was obviously higher. The lower participant comfort score in the HF group could be related to the greater vulnerability of the SimBaby™ and fear of damaging it during intubation maneu-

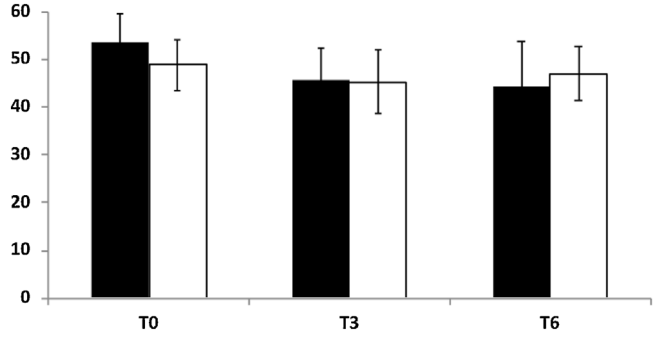

Figure 2 Comparison of the Educational Quality (EQS) score immediately (T0), 3 (T3) and 6 months (T6) after the training sessions for the participants of the HF group (n = 12) (■) and LC groups (n = 18) (▭) who responded to the survey 3 times. Variance analysis for repeat measurement, group effect ns, time effect with T3 and T6 versus T0, $p < 0.0001$. Data are mean ± SD.

vers – leading to overprotection of the simulator by the instructor. Another explanation is that the HF group participants had to see some medical simulation change (cyanosis, apnea), interpret it and act on it, whereas in the LC group these modifications were described by the instructor. The higher comfort score in the LC group may be related to an easier task. Lower comfort in the HF group may also reflect higher anxiety. The pedagogical impact of stress in simulation is controversial. While a moderate level of stress can facilitate the mobilization of mental capacities, an excessive level is deleterious.

These low simulation quality differences did not influence the perceived efficacy. As Seropian et al. pointed out, simulation cannot be reduced to a manikin.[17] Multiple factors are likely to influence the quality of a simulation such as the reliability of the equipment, the environment, the relevance of the script, or the quality of the briefing and debriefing. The contribution of these elements to the fidelity of the simulation probably has a greater amplitude than the technical features of the manikin itself. Individual and team reflective feedback is strongly responsible for the passage of concrete experience to abstract conceptualization and is the main component of cognitive memory processes.[18]

Iterative laryngoscopy exposes SimBaby™ airways to irreversible damage in the glosso-epiglottitis folds and corners of the mouth. The relative cost ratio between low and high-fidelity simulators is approximately 1 to 10.[19] The maintenance of an infant HF simulator includes regular replacement of vulnerable airways while the maintenance cost of a low-fidelity patient simulator is insignificant. Our results confirm that the absence of an HF simulator should not hinder the implementation of a pediatric difficult airway management program. The objectives of simulation training in crisis resource management are not limited to the development of technical skills. A meta-analysis emphasized its interest in improving behavioral skills in airway management.[20] The performances described in the ANTS score significantly contribute to the favorable outcome of a life-threatening situation.[21]

Limitations should be discussed. Our results are valid only for the described scenarios. Facilitation should be carried out by an experienced trainer with sufficient knowledge of the scenario to communicate additional information about the patient's condition (e.g., respiratory arrest, cyanosis). However, once apnea occurs, whatever the mechanism, the only difference between the two simulators is the appearance or not of cyanosis. Visualization of the evolution of SpO_2 on the monitor compensates for it and the capnogram keeps track of the quality of ventilation. A relevant rating of the ANTS score requires training.[22] To the best of our knowledge, self-assessment in such situations has never been described. In the same manner, SQS and EQS have not been validated. Finally, evaluation of the efficacy of the workshop was only based on self-assessment by the participants and not on their clinical practice. This first level analysis according to the Kirkpatrick pyramid does not prejudge the acquisition of new skills in clinical practice, but it is nevertheless necessary to verify that the learner favorably reacts to the pedagogical technique.

HF simulators probably have a place for training participants who already have a certain expertise. A randomized study on peripheral venous catheter management highlighted the positive impact of a gradual increase in the fidelity of simulation tools on the performances of workshop participants.[23]

A low response rate is commonly observed in surveys several months after training. The decrease over time of the perceived educational impact is inevitable regardless of the teaching method used. The persistence of a long-term effect passes exclusively through regular training.[24,25]

Finally, various studies have demonstrated the interest of high-fidelity simulators in adults as well as in pediatrics for the development of technical and non-technical skills. However, our study is the first to propose and evaluate an alternative to a high-fidelity simulator for pediatric airway management scenarios. A very large number of anesthesiologists and emergency physicians have no access or access only with insufficient frequency to pediatric high-fidelity simulation training owing to the cost, especially in developing countries, but this is also true in all countries. The major contribution of our article is to propose a less expensive alternative that is easily accessible.

The substitution of an HF simulator with a low-cost device in a full-scale HF accredited continuous medical education workshop did not affect learner perception of the quality and impact of difficult pediatric airway simulation training.

Ethical approval

Approval by our Institutional Ethical Committee (Groupe Nantais d'Ethique dans le Domaine de la Santé) on February 7, 2012 and written informed consent of all participants.

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Conflicts of interest

The authors declare no conflicts of interest.

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