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Original Article

Fetal biometry in ultrasound: A new approach to assess the long-term impact of simulation on learning patterns

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ABSTRACT

Context: Simulation-based education (SBE) has demonstrated its acceptability and effectiveness in improving ultrasound training. Because of the high cost of its implementation (investment in equipment and supervision), a pragmatic assessment of the transfer of skills learned in SBE to clinical practice and the identification of its optimal scheduling conditions have been requested to optimize its input.
Objectives: To quantify the long-term impact of simulation-based education (SBE) on the adequate performance of ultrasound fetal biometry measurements (I). The secondary objective was to identify the temporal patterns that enhanced SBE input in learning (II).
Methods: Trainees were arbitrarily assigned to a 6-month course in obstetric ultrasound with or without an SBE workshop. In the SBE group, the workshop was implemented 'before' or at an 'early' or a 'late-stage' of the course. Those who did not receive SBE were the control group. The ultrasound skills of all trainees were prospectively collected, evaluated by calculating the delta between OSAUS (Objective Structured Assessment of Ultrasound Skills) scores before and after the course (I). Concomitantly, the accuracy of trainees' measurements was assessed throughout the course by verifying their correlation with the corresponding measurements by their supervisors. The percentage of trainees able to perform five consecutive sets of correct measurements in the control group and in each SBE subgroup were compared (II).
Results: The study included 61 trainees (39 SBE and 22 controls). Comparisons between groups showed no significant difference in the quantitative assessment of skill enhancement (difference in the pre- and post-internship OSAUS score: 1.09 ± 0.87 in the SBE group and 0.72 ± 0.98 in the control group) (I). Conversely, the predefined acceptable skill level was reached by a significantly higher proportion of trainees in the 'early' SBE subgroup (74%, compared with 30% in the control group, $P < 0.01$)(II).
Conclusions: The quantitative assessment does not support the existence of long-term benefits from SBE training, although the qualitative assessment confirmed SBE helped to raise the minimal level within a group when embedded in an 'early' stage of a practical course.

Introduction

Ultrasound is used in many specialties because of its accessibility [1, 2] and the ability to study items moving in real time at the patient's bedside [3]. These advantages give it a key role in the monitoring and management of pregnancies, especially by fetal biometric measurements [4–9]. It is nonetheless operator-dependent [10, 11], a characteristic that causes errors and inaccuracy that can account for more than 10% of the variability of some parameter measurements [11]. Improving intra- and interobserver reproducibility is therefore a major objective in obstetrics.

As we await the automated measurement techniques currently under development [12–14], it remains essential to improve the teaching of fetal biometry to limit the variability and optimize the quality and quality control of these measurements [15]. High-fidelity simulation-based education (SBE) in ultrasound appears to be a promising solution [16]. Its acceptability and its short-term utility for improving performance have now been established [17–21], al-

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though its benefits for the quality and cost of obstetric care have not been clearly confirmed [22]. Currently, only Tolsgaard et al. have used an experimental approach to explore these aspects, offering pathways for assessing the medico economical impact of SBE [23]. Their approach relies especially on the demonstration of a potential synergistic effect of SBE [16] that could make it possible to accelerate progress for the same quantity of teaching.

SBE remains expensive (both the equipment and logistics). It is therefore important to verify how the positive impacts of SBE on progression modify clinical practice in the long term and to assess the importance of the potential synergistic effect as a function of the timing of its use during the learning process.

Accordingly, the principal objective of our study was to compare the clinical progress over the long term between students who were or were not exposed to simulation training. The secondary objective was to study the effect of the timing of the exposure (by comparing the different timing of the SBE workshops relative to the course) on the capacity to acquire and maintain the level of competence required.

Methods

A systematic, prospective, and continuous collection of data about the practice of ultrasound for measuring fetal biometry during the initial phase of learning these skills took place at the University Hospital of Nancy in the maternity ward between November 1, 2017, and October 31, 2018.

Participants

The participants were student sonographers recruited during their initial training in the departments of obstetrics and gynecology, medical gynecology, and midwifery of the University of Lorraine. The inclusion criteria were enrollment in the specialized diploma program in obstetrics and gynecology or medical gynecology (first through eighth semester of their internship-residency, or enrollment in the second cycle of their midwifery studies). The exclusion criteria were: the failure to undergo an initial assessment or absence from the course for a duration exceeding one month during the study period.

Description of the method project

This study is part of a university project aimed at optimizing the teaching and learning of ultrasound measurements of fetal biometry (METHOD project: MEasurement TeacHing in Obstetrics Design). French students currently learn ultrasound as apprentices in practical clinical training courses. For the METHOD pedagogical project, workshops with ultrasound simulators were progressively included into this curriculum. None of the participants included in the project had previously received this type of instruction. Three teachers (OM, CB and GA) coordinated this project and ran the clinical course. During the courses, students were supervised by experienced clinicians (obstetricians or midwives). The simulation workshop was developed and led by an instructor trained in teaching by simulation (GA).

2- Theoretical instruction

Before the clinical training course, all participants attended in person a two-hour theoretical presentation, the same for all, about the methodology and practice of ultrasound fetal biometry.

2- Pedagogical program of the simulation workshops

As recommended by Tolgaard et al., the workshops were conducted in groups of two participants. During a single 3-h workshop with a simulator (Simbionix US Mentor®), the participants practiced a series of increasingly difficult exercises under the constant supervision of the teacher (GA). The program included in particular exercises of hand-eye coordination and of knobology [24], as well as the performance of fetal biometry.

2- Pre- and post-course quantitative evaluations

All participants included in the study were assessed by an OSAUS score before and after the course (Fig. 1). The conditions of a stand-alone examination were reproduced with pregnant women (15–41 weeks of pregnancy) who volunteered, and each participant was assessed individually by one of the instructors (OM, CB or GA) as they took ultrasound fetal biometry measurements. The METHOD OSAUS score (customized for fetal biometry) was used to rate their skill level from 0 through 5 [25]. The examination could not exceed 10 min, and no supervision or suggestions were offered during it. The pre-workshop assessments were scheduled early during or before the course and always before the simulator workshop (double-blinded assessment, both instructor and participant blinded about exposure to the simulation). The post-course assessments were scheduled after the last day of the course. To limit the potential evaluation bias associated with knowledge of the student's exposed-unex-

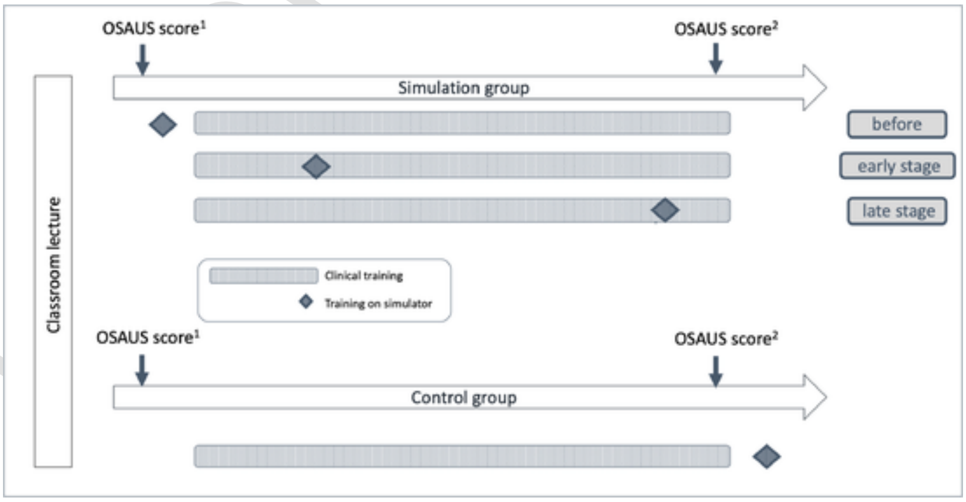

Fig. 1. Presentation of the different timing of the METHOD cohort participants' simulation exposure and of their assessments.

posed status for the post-course OSAUS scores, these were assessed by four clinicians not involved in the study (single-blinding).

2- Continuous qualitative assessment

An online platform (the METHOD Logbook) was available to participants to enable the continuous collection of data about the instruction. It enabled participants to report in real time the results of the fetal biometry measurements they performed themselves during their training course (head circumference - HC, abdominal circumference - AC, femur length – FL, and estimated fetal weight – EFW). These examinations were systematically verified by an experienced clinician. For each examination performed, the students recorded both their set of measurements and that of their supervising clinician in the METHOD logbook. The METHOD Logbook platform determined the validity of each parameter measured, based on the difference between the student's measurements and those of the supervisor, that is, on the agreement of the student's and supervisor's measurements, with the latter considered as the reference measurements. Validation depended on an interoperator variability less than 0.8 of the Z-score for the EFW and less than 0.8, 0.7 and 0.6 of the Z-scores for FL, AC and HC, respectively. These cutoffs were defined by taking into account the variability inherent to each biometric parameter. These differences in variability are explained by their different levels of technical difficulty and the different distributions for each type of measurement [11].

Each time students completed a set of measurements and entered it into the Logbook, they received feedback (for each parameter measurement and for EFW), presented as an LC–CUSUM (Learning Curve Using Cumulative Sum control charts) [26–28]. The display setting for the METHOD Logbook showed a rising curve for each validated examination (strong agreement with the reference measurement) and a falling curve for each non-validated measurement (low agreement with the reference measurement) (Fig. 2).

Study plan and procedures

2- Timing of exposure

The participants were randomly allocated to the control (no simulation workshop exposure during the observation period) and simulation (exposure to SBE) groups. The SBE workshops were planned randomly at different times on the course schedule, with the participants distributed within both the control and simulation (SBE exposure) groups. Within the simulation group, participants were distributed into three subgroups, the 'before' group (exposure before the course), the 'early ' course group (interval between the beginning of the course and exposure < 2 months) and the 'late' course group (interval between exposure and the end of the course < 2 months); these groups defined different exposure timing patterns (Fig. 1).

2- Endpoints

The primary endpoint was the percent delta (that is, percent change) in progression during the clinical training course, defined by the difference between the pre- and post-course OSAUS scores. We hypothesized that the mean change in progression differed between the simulation and control groups. The secondary endpoint was defined by the proportion of participants exposed to SBE able to acquire a threshold skill level according to their exposure timing pattern. This threshold level was defined by the validation of five consecutive EFW in the METHOD Logbook.

Statistical analysis

2- Calculation of study size

In the usual learning conditions of initial training, the student's skill level is expected to progress. When this progression is assessed by a score, a delta/change between the scores obtained before and after the training expresses this progression (corresponding to the progression delta described above).

For the METHOD project, the expected progression was estimated from data from preliminary studies assessing the validity and predictive value of the METHOD OSAUS score [25]. Based on these studies, the skill level in fetal biometry of a beginner in obstetric ultrasound corresponded to OSAUS scores ranging between 1.5 ± 0.4 and 1.8 ± 0.7. After practice experience for longer than 6 months or > 20 supervised examinations, the operators reached an intermediate skill level corresponding to scores of 3.3 ± 0.6 and 3.3 ± 0.8 respectively [25, 29].

Given these data, we estimated the expected progression of participants without SBE to be at least 1.25 points on the OSAUS. Our hypothesis was that SBE would enable greater progress for the exposed participants (delta 1.75 points on the OSAUS). We calculated that we required a minimum of 20 participants in the exposed and unexposed groups to validate this hypothesis. In the SBE group, at least 8 participants were necessary in each subgroup to enable a comparative qualitative analysis between the different timing patterns. This required that we increase the size of the SBE group. The modest headcount within subgroups did not allow to lead a relevant quantitative assessment for each timing pattern.

2- Statistical tests

The quantitative data are expressed as their means and standard deviations, with their range (minimum and maximum). The normality of the data was tested by the Shapiro Wilk test. Intergroup differences were studied by Student's t-test (with equal variance). For the qualitative variables, Chi-square or Fisher tests were used according to the distribution of the data. A P value less than 0.05 was considered significant.

The statistical analysis was performed with R software, version 3.6.2 (2019–12–12).

2- Ethics and reporting of the results

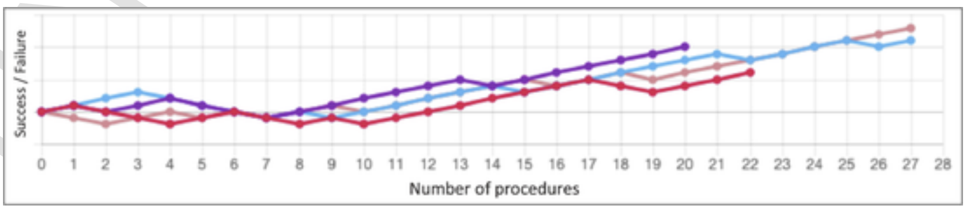

Fig. 2. Example of four LC–CUSUM (Learning Curve Using Cumulative Sum control charts) obtained at the end of the course for the measurement of the estimated fetal weight (each curve represents the individual progression of one participant).

This study was reported to the CNIL (no. A2017-3). It is presented in accordance with the guidelines for Health Care Simulation Research and CONSORT (extension for pragmatic trials).

Results

Participants

The study included 61 participants (36 residents and 25 midwifery students) (Fig. 3). Details of the cohort demographic characteristics are available in Table 1. The mean observation period was 5 months and 15 days ± 62 days.

After the allocation of the minimum number of individuals within each group and subgroup, there remained 18 additional participants. These participants were distributed between the control group, and the early and late course subgroups (3, 14 and 1 additional participant, respectively). The distribution of the additional participants favored, for pedagogical reasons, early access to SBE.

At the beginning of the study, the pre-course OSAUS scores were similar in the exposed and control groups (2.61 vs 2.7 respectively, $P = 0.83$) (Table 2).

Quantitative assessment

The final post-course OSAUS score and the global delta for progression did not differ significantly between the SBE and control groups (Table 2). In comparison with the estimates from preliminary studies, the initial skill level of the participants was better than expected (2.63 ± 1.01 versus 1.25) and the global progression lower (0.95 ± 0.92 versus 1.75).

Qualitative assessment

The METHOD Logbook platform was used by 51 (82%) participants who generated LC-CUSUM, a percentage that did not differ between the SBE (79%) and control (87%) groups (Table 3). The proportion of participants able to reach the expected skill level (five consecutive validated examinations) was significantly higher in the 'early' group (74% vs 30% in the control group, $P < 0.05$).

The mean number of examinations necessary to reach this skill level ranged from 8.2 ± 3.5 to 13.5 ± 4.8 and did not differ significantly between the groups (Table 3).

Discussion

Main findings and interpretation of results

At the end of a long observation period, the participants exposed to the simulation workshop did not progress significantly more than the control group. Nonetheless, the effect of the simulation might have been masked, especially because the participants' initial level was higher than expected, which left less margin to observe progression.

Moreover, the proportion of participants able to reach the skill level expected was significantly higher in the subgroup of participants exposed to SBE near the beginning of the course. This result is crucial for understanding the impact of SBE on clinical practice. Standardizing the skill level guarantees a minimum threshold level of practice and is thus a major step toward improving the global quality of care. The number of practitioners able to reach this threshold skill level thus constitutes a more useful outcome measure than the mean or individual progression for assessing the potential clinical impact of a training activity.

These differences observed between the different timing patterns suggest the existence of different learning processes. This is probably explained by the optimized use of SBE by the participants who faced these clinical situations around the same time. This observation raises the question of the relevance of the "never the first time on the patient" adage, which was initially an argument for the development of simulation in the training of health professionals (HAS report 2012) [30]. If this approach remains ethically justified for invasive procedures, it fails to incorporate the benefit of learning from mis-

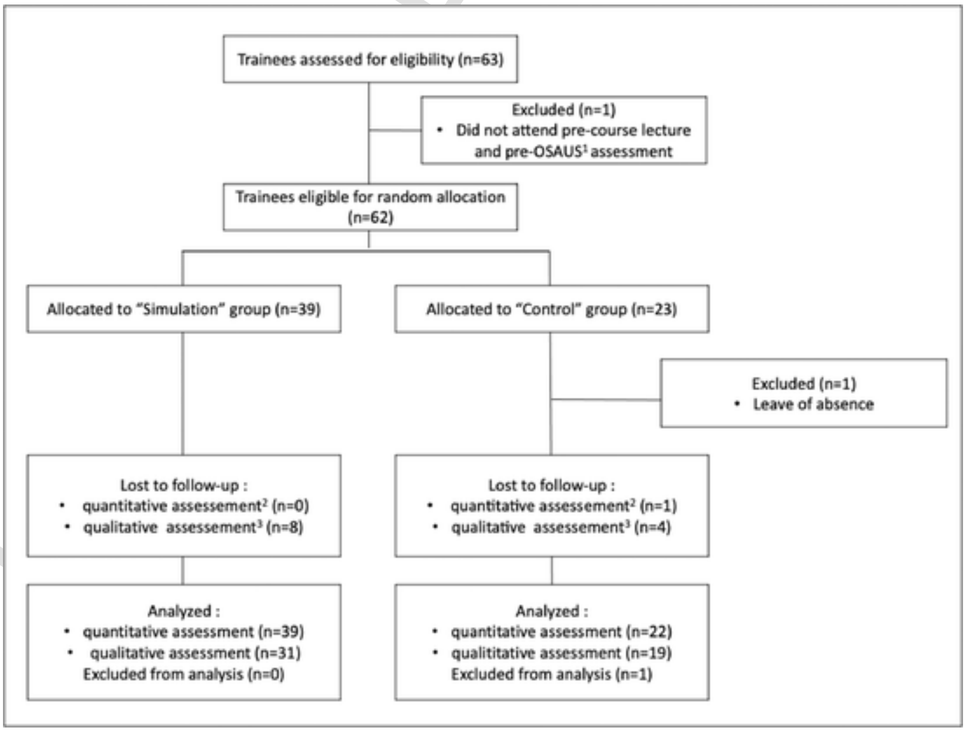

Fig. 3. CONSORT3 flow diagram of enrollments, allocations, follow-up and analysis for METHOD study.

Table 1
Demographic characteristics of the trainee cohort.

Training curriculum	Mean age [1]	Mean year of medical education [1]	Gender [2]	
			Female	Male
Midwife trainees (n = 25)	26.2 ± 0,6	4 ± 0	22	1
Residents (n = 36)	29.9 ± 2.1	8.8 ± 1.9	29	7

[1] Results are presented as mean ± standard deviation.
[2] Results are presented as absolute numbers.

Table 2
Allocation and results of pre- and post-course assessment in the different groups.

	Total (n = 61)	Control group (n = 22)	SBE* group (n = 39)	P-value
Pre-OSAUS1	2.63 ± 1.01 [0.4; 4.8]	2.7 ± 1.1 [0.4; 4.2]	2.61 ± 0.97 [0.4; 4.8]	0.83
Post-OSAUS2	3.58 ± 0.72 [1.8; 4.8]	3.38 ± 0.69 [1.8; 4.8]	3.7 ± 0.72 [1.8; 4.8]	0.1
Delta3	0.95 ± 0.92 [−1; 3.2]	0.71 ± 0.98 [−1; 2.6]	1.09 ± 0.72 [−1; 3.2]	0.41

Results are reported as mean ±SD (range).
[1]OSAUS, pre-course assessment via OSAUS METHOD score (Objective Assessment of Ultrasound Skills – Measurement TeacHing in Obstetrics Design).
[2]Post-OSAUS, post-course assessment via OSAUS METHOD score (Objective Assessment of Ultrasound Skills – Measurement TeacHing in Obstetrics Design).
[3]Difference between post-course and pre-course OSAUS scores.
*Simulation based education (in ultrasound).

Table 3
Logbook utilization rates and LC-CUSUM (learning curve cumulative sum) analysis.

	Control group (n = 21)	SBE* group (n = 39)	'Before' (n = 8)	'Early' stage (n = 22)	'Late' stage (n = 9)
Logbook users [1]	20 (95)	31 (79)	4 (50)	19 (86)	8 (89)
Effective skill level reached [2]	6 (30)	17 (55)	2 (50)	14 (74)	1 (13)
Numbers of exams required to reach the skill [3]	10.7 ± 4.5 [5; 16]	9.5 ± 4.3 [5; 18]	11 ± 2.8 [9; 13]	8.6 ± 4 [5; 18]	18 /

*Simulation based education.
[1] Results are presented as absolute numbers (percentages).
[2] Effective skill level is considered as reached when 5 consecutive correct exams were performed (correct exam corresponding to a difference less than 0.8 Z-score between trainee and supervisor for estimated fetal weight). Results are presented in absolute numbers (percentage).
[3] Results are presented as means ±SD [range].

takes, as described by L. Dyre et al. [31]. Learning from errors probably helps to optimize SBE, with students using the simulator to resolve problems encountered in clinical practice. This mechanism appears to optimize on the one hand training on the simulator, and on the other hand, increase the ability to transfer the skills acquired on the simulator to clinical practice. Among the skills used for ultrasound, hand-eye coordination and visual-cognitive skills (ability to mentally represent an ultrasound diagnosis) may comprise the major elements that explain this synergistic effect [16]. A lower effect of learning from mistakes at the end of the course and a short interval between SBE and the final assessment may explain the less good performance observed in the late-course group.

Strengths and limitations

The substantial number of participants combined with the duration of the observation in the METHOD study is one of its strengths. Only a single other study had a similar sample size [32], and for all of the observations concerning abdominal ultrasound [33], the mean observation periods were less than a month, compared with more than five months in ours.

This study also represents the first assessment of the effect of the timing of the exposure (by comparing the different timing of the SBE workshops relative to the course) on the capacity to acquire and maintain the level of competence required. The simultaneous use of quantitative outcome measures (score) and qualitative measures (LC-CUSUM), all relevant to clinical practice and not to performance on the simulator, is the second major strength of this study. This methodological choice enabled us to avoid the known bias that results from the extrapolation to clinical settings of performance observed with a simulator [21].

The improvement of the performance of participants exposed to SBE as well as the clinical training course is due partly to the supplementary effect induced by the addition of training support for the SBE group. This inequality bias in principle is a limitation attributable to the fact that all studies up to now have simply assessed the interest of SBE, with no experiments proposing randomization between SBE alone and clinical practice alone [34]. Because learning ultrasound is indissociable from access to clinical practice, these conditions cannot ethically be reproduced outside of an experimental context; this bias is thus inevitable. It should nonetheless be noted that the experimental and short-term comparison between SBE alone (i.e. without clinical practice) and practical training alone confirmed that SBE augments the students' progress [35].

The methods and the pedagogical process used in the METHOD study can be implemented easily in other medical schools and institutions. But the single-center nature of the data collection limits the possibility of generalizing the results, especially because of possible biases associated with local particularities in education methods and in the practice of obstetric ultrasound.

Practical applications

The experience acquired with the METHOD project also provides valuable information about the practical use of the OSAUS score. At the conclusion of the study, the investigators identified in particular pitfalls related to the difficulty in quantifying the participants' progress with a delta between two scores: the magnitude of this delta depends principally on the operator's initial level rather than on his or her weekly progress. This effect is explained by the nonlinear nature of the progress (more rapid and marked in the early learning phase). Given the intrinsic difficulty of obstetric ultrasound, progression later on appears slower and more difficult to quantify, and it is characterized by a lower rise in the score. This characteristic explains the difficulty in showing a difference in progression in the METHOD study due to the participants' initial skill levels, which were higher than anticipated. In the future, this experience will lead us to limit the use of changes in OSAUS scores to the observation of beginning operators and the comparison of groups with comparable initial levels and similar observation periods.

The continuous massive expansion of simulation in training health professionals calls for the development of scientific tools making it possible to reinforce the practical applicability of experimental results and the relevance of the studies. The publication of guidelines for Health Care Simulation Research [36] constitutes a first step, but the question of the cost-benefit relation for SBE must be explored in greater depth [37, 38]. In the light of the results of the METHOD study, this investigation must consider the timing of the SBE. At the same time, the systematization of the outcome measures used to assess the impact of simulation should make it possible to optimize comparisons between the studies as well as the work of meta-analysis. This procedure must be based on a Delphi procedure [39] to define a set of homogeneous outcomes enabling the assessment and comparison of procedures involving SBE. The possibility of concrete application of these results to our educational practices depends on these final two stages.

Conclusion

The assessment of the learning phase by the METHOD OSAUS score does not allow us to conclude that there is a difference in the mean progression between participants exposed to SBE and the control group. On the other hand, the association of SBE with clinical practice at the onset of the learning phase enabled a significantly higher number of participants to reach the required skill level, compared with the control group.

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