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Research article

The efficacy of postpartum tubal sterilization training program with minilaparotomy approach in Ob/Gyn residents

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ABSTRACT

Objectives: To evaluate the efficacy of postpartum tubal sterilization training program with minilaparotomy approach (PTSMA).
Study design: From September 2020 to November 2021, 24 first-year Obstetrics and Gynecology (Ob/Gyn) residents were randomly allocated into 2 groups of traditional apprenticeship learning (watching video clip) versus apprenticeship learning plus PTSMA attending. The program consisted of didactics followed by self-practicing with 2 stations of postpartum tubal sterilization simulators (PTSS). All participants were allowed to perform their first tubal sterilization under supervision within a few days after training. Their surgical skills were blindly evaluated by 2 experts through the recorded videos. Five domains of direct observation of procedural skills (DOPS) score introduced by Royal Thai College of Obstetricians and Gynecologists were assessed. DOPS score, operative time, blood loss and post-op complication were analyzed and compared.
Results: Median of total DOPS score in the PTSMA group was higher than the non-PTSMA group (93 vs. 73, $p = 0.020$). Concerning 2 domains of DOPS score (tubal fishing and tubal sterilization), the PTSMA group had the higher median score than the non-PTSMA group (36 vs. 24, $p = 0.045$ and 40 vs. 32, $p = 0.020$). There was no significant difference observed in the median score of 3 other domains (peritoneal cavity accessing, abdominal wall closure and complication prevention), estimated blood loss and operative time.
Conclusion: Postpartum tubal sterilization training program with minilaparotomy approach using instructive simulators significantly improved the total DOPS score especially tubal fishing and tubal ligation skills in Ob/Gyn residents.
Implications: The study evidently showed the benefit of PTSMA with an inexpensive and simple to prepare models. In unexperienced operators, practicing in model prior to surgery should be encouraged to improve their operative skills.

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1. Introduction

Tubal sterilization is considered as a safe, reasonable and effective method for permanent female contraception regardless of body mass index [1]. Regards to the Collaborative Review of Sterilization (CREST) study, the high effectiveness of postpartum tubal sterilization with 5-year and 12-year failure rate of 5 per 1000 and 7 per 1000 have been reported [2]. Recently, the American College of Obstetricians and Gynecologists (ACOG) have recommended the immediate postpartum period as the optimal time to perform sterilization because of technical ease for the physician and convenience for the patient [3]. Every effort should be made to complete the requested immediate postpartum sterilization in the absence of a medical contraindication to surgery. Puerperal tubal sterilization could be performed right after cesarean or vaginal delivery by several techniques including partial salpingectomy, electrocoagulation, the use of rings or the use of clips [4]. Failure of postpartum sterilization could be a consequence of the spontaneous reanastomosis between the tubal stumps or surgical mistakes. Therefore, the operative skill plays an important role for the achievement of this procedure. For Obstetrics and Gynecology (Ob/Gyn) residents, the effective training program to enhance their surgical proficiencies should be offered with systematic evaluation. Several simulators for laparoscopic tubal sterilization training such as Virtual-Reality Simulator (LapSim) [5] or Train Anywhere Skill Kit (TASKit) [6] have been introduced, shown approvingly reliable, and are able to increase the practitioner's knowledge, skill performance and procedural comfort [7,8]. In our institution, patients who attend antenatal care and desire postpartum sterilization will be informed early in prenatal care. They will be provided comprehensive and accurate information focusing on female sterilization with shared decision making and informed consent. Thereafter, patients with designated postpartum tubal sterilizations will be scheduled within the same day or on the following day after normal vaginal delivery. This routine practice helps decreasing the number of patients who fail to obtain their desired postpartum sterilization and shortening their hospital length of stay. Currently, postpartum tubal sterilization accounted for 5.7% of all live births in our hospital. According to the apprenticeship training, our first-year Ob/Gyn residents have to complete watching a 20-min tubal sterilization video before performing their first operation under attending's supervision. With the approval, they will be allowed to perform surgery on the following cases by themselves with the assistance from their attending obstetricians. In total, each trainee will experience approximately 15–30 cases of postpartum tubal sterilization per ward rotation. Unfortunately, the numbers of postpartum tubal sterilization have dramatically decreased during the COVID-19 pandemic and became a significant educational problem. From our unpublished data, tubal misidentification and surgical mistakes including transection of the round ligament or only partial tubal transection are the

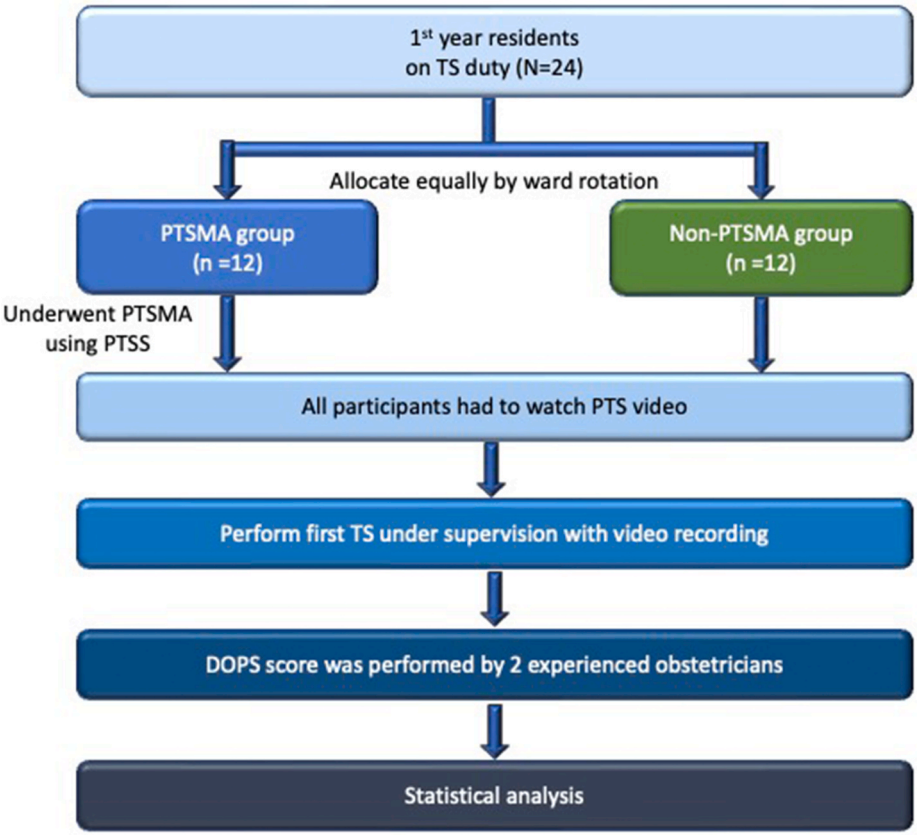

Fig. 1. Study flow.
(PTSMA: postpartum tubal sterilization training program with minilaparotomy approach; PTS: postpartum tubal sterilization; PTSS: postpartum tubal sterilization simulators; TS: tubal sterilization; DOPS: direct objective performance score).

major causes of postpartum sterilization failure performed by residents. Indeed, their operative skills and ability will significantly improve with rigorous practice on real patients. With the limited number of patients, the model training program not only provides the learners with a stress-free environment for hands-on practice, it also gives the student a visual to apply in real life situations without having any risk. As a result, residents will improve their surgical skill and confidence by practicing with the training model. To our best knowledge, postpartum tubal sterilization training program with minilaparotomy approach (PTSMA) for Ob/Gyn residents was never been proposed. Therefore, we have invented an instructive postpartum tubal sterilization simulator (PTSS) for the trainees to practice and obtain their operative skill focusing on tubal fishing and tubal sterilization skills. This study aimed to evaluate the efficacy of our PTSMA using a simulator on operative performance by residents. In addition, the operative time and post-procedural complications between trained and non-trained groups were compared.

2. Material and methods

2.1. Data sources

After Siriraj Institutional Review Board approval [COA no. Si 761/2020], a prospective educational study was conducted at the Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital from September 24, 2020 to November 30, 2021. The sample size was calculated by nQuery Advisor with the two groups *t*-test of equal means (equal n's) formula. From our pilot study, DOPS score of the residents using the current practice (control group) showed that the mean score ± standard deviation was 57 ± 23. In the present study, the increase of DOPS scores more than 50% (~86) is considered as clinically significant. Therefore, 12 trainees were required in each group under the significant level of 0.05 and power of 80%. All first-year residents with total number of 24 were randomly allocated by ward rotation into two groups of traditional apprenticeship learning alone (non-PTSMA group) versus PTSMA with apprenticeship learning (PTSMA group). For apprenticeship learning, all participants had to complete watching 20-min video how to perform postpartum tubal sterilization via web based Siriraj e-Learning and Education Community (SELECx) program (Fig. 1).

2.2. Postpartum tubal sterilization training program with minilaparatomy approach (PTSMA)

The PTSMA consisted of 2 parts including didactic and hands-on sessions. In didactic session, the participants were taught and given step by step explanation on tubal sterilization by the same expert from the abdominal wall access to the abdominal wall closure including the pelvic anatomy and procedural complications for 30 min. For hand-on session, all residents were trained how to use and practice with the simulators (PTSS) for another 30 min.

2.2.1. Postpartum tubal sterilization simulators (PTTS) preparation and practice

The simulators comprised of 2 stations including 1) tubal fishing station (station-1) and 2) tubal ligation station (station-2). The external and the internal appearance of tubal fishing station is demonstrated in Fig. 2(A and B). A 24 × 30 cm plastic box covered by fabric with an elastic band was used to represent the abdominal cavity. An 1-inch opening was created in the middle to make an infraumbilical incision. A 20-week pregnant uterus model was placed inside to mimic female pelvic anatomy while the cervical part was protruding out of the box. Both fallopian tubes, mesosalpinges and round ligaments were made out of condoms and attached to the uterus with silicone glue. The fimbriated end was painted in red color also shown in Fig. 2(B).

At station-1, the trainee had to introduce a skin retractor and sponge forceps through the opening. The forceps tips were inserted underneath the fundus of the uterine model. To find the right fallopian tube, the trainee needed to hold the forceps with the tips pointed inward and the skin retractor together and sweep alongside the uterus from 12 o'clock position (fundus) to 9 o'clock position (the right uterine wall). For right tubal fishing, the right tube was caught with the forceps tips and carefully flipped out close to the opening. The fallopian tube was grasped with a Babcock clamp and followed to the distal end. The red fimbriated end of the right tube

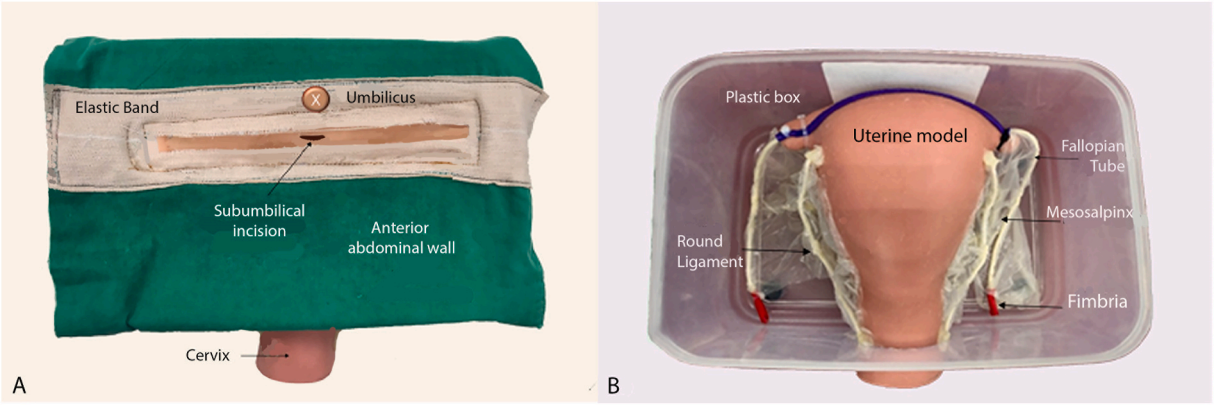

Fig. 2. (A, B). Top view of tubal fishing station of postpartum sterilization simulator (station-1). A) external appearance B) internal appearance.

must be clearly identified to rule out the round ligament. Then, the midportion of the tube was raised to reveal the mesosalpinx through the opening [Fig. 3(A–D)]. For left fallopian tubal fishing, the same procedure was repeated in the opposite side.

The simulator in station-2 was consisted of a 12 × 18 cm plastic box, a cover fabric with 2 openings and 2 tubal loops [Fig. 4(A and B)]. The loop of fallopian tube was made from condom and attached firmly to the base. The trainee had to grasp the midportion of the tube which with a Babcock clamp to form a 1-cm tubal loop above the opening. Then, a suture was placed through the mesosalpinx using chromic catgut no.3 followed by tubal ligation. Tubal resection was made by using scissors then the tubal stump was checked [Fig. 5(A–D)]. The similar procedure was performed in the remaining tube. The trainees were allowed to practice with PTSS as much as possible to earn their confidence before the real operation.

2.2.2. Postpartum tubal sterilization

With patient's informed consent, all participants were allowed to performed their 1st tubal sterilization under supervision within a few days after training with simulators. The operative field of the whole procedure was recorded in video format with patient's permission. All recordings were anonymous and collected for further evaluation.

2.3. Direct observation of procedural skills (DOPS) score evaluation

DOPS is one of the methods of evaluating clinical performance and competency by direct observation by the evaluator. This holistic evaluation is based on the completion and problem-solving skill of each domain of the procedure and proved to increase the clinical skills of trainees [9]. According to the systemic review, the results showed that the validity and reliability of DOPS are acceptable [10]. In this study, DOPS assessment for tubal sterilization derived from Royal Thai College of Obstetricians and Gynecologists (RTCOG) was chosen. This standard format (DOPS OB 04: Tubal sterilization) has been internally validated by Thai Ob/Gyn resident training auditors throughout the country. The second part of RTCOG's DOPS OB4 was utilized. This part consists of 5 domains evaluating the ability to access peritoneal cavity, tubal fishing skill, tubal sterilization technique, instruments counting and abdominal wall closure, complication prevention and problem solving. As tubal fishing and tubal sterilization were considered as the two most important steps, we have designed our instructive models to improve these 2 operative skills. With the total score of 100, each domain was weighed differently according to its significance which included 10 scores on the ability to access peritoneal cavity, 40 scores on tubal fishing skill, 40 scores on tubal sterilization technique, 5 scores on instruments counting and abdominal wall closure and 5 scores on complication prevention and problem solving. Five domains of tubal sterilization skill were evaluated by 2 experienced obstetricians through the recordings based on the completeness of each task. For statistical analysis, the mean DOPS score from each participant assessed by both examiners was used for calculation.

2.4. Statistical analysis

Data analysis was performed by using the 18th version of SPSS program. Mean with standard deviation, median with interquartile range, and proportion were used to evaluate continuous and categorical variables. In comparison, independent T-test or Mann-Whitney U test was applied for quantitative data analysis and the Chi-squared test or Fisher's exact test was performed for categorical data analysis. Various characteristics were compared between two groups. A p-value of < 0.05 was considered statistically significant.

3. Results

There were totally 24 trainees enrolled into the study. Participant's baseline characteristics showed no statistical difference

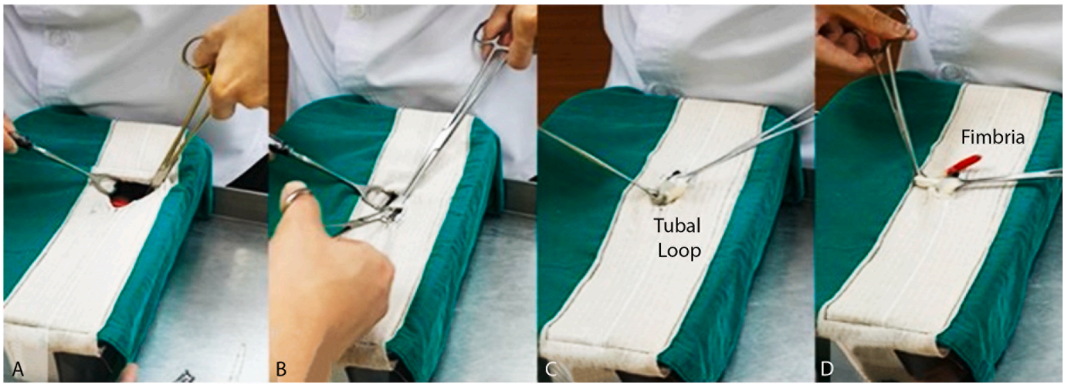

Fig. 3. (A–D). Tubal fishing practice in station-1. (A, B) the trainee tries identify each fallopian tube by using sponge forceps together with a skin retractor (C, D) the tube was grasped with Babcock's forceps and followed through to the fimbria (red color) before the mid-portion of the tube was raised through the opening.

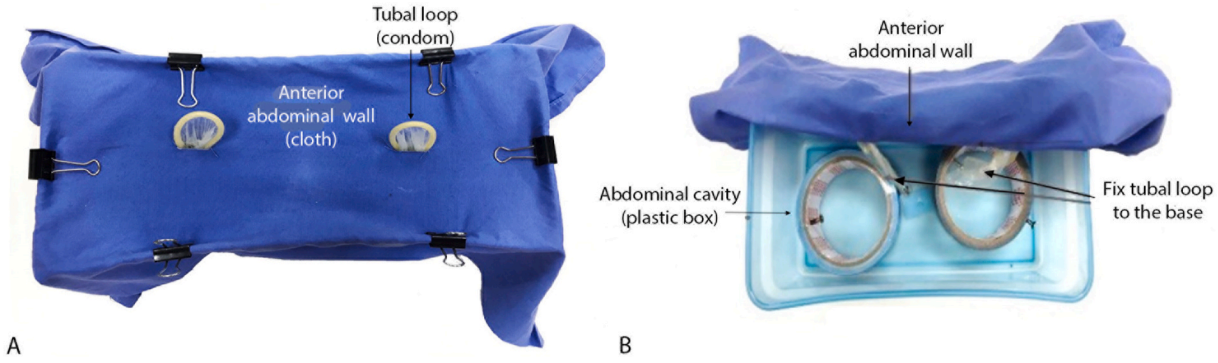

Fig. 4. (A, B) Top view of tubal ligation station of postpartum sterilization simulator (station-2). (A) External appearance (B) internal appearance.

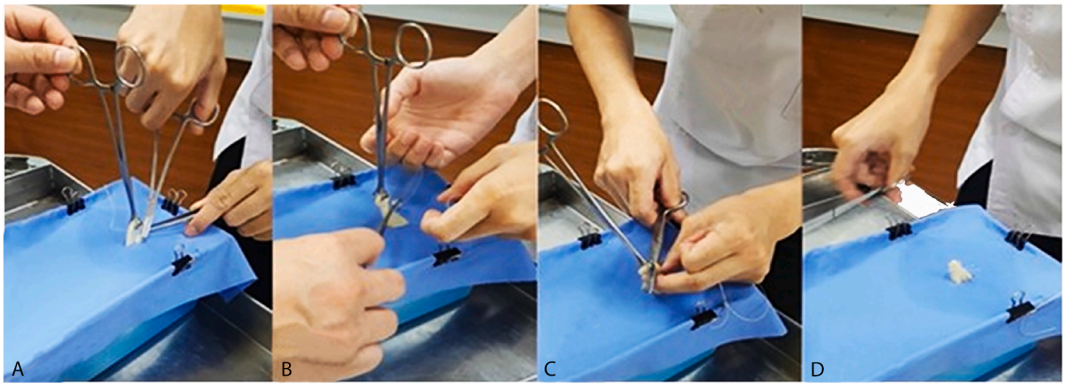

Fig. 5. (A–D) Tubal suturing, ligation and resection practice in station-2. (A) A 1-cm loop of fallopian tube was made and a suture was placed through the mesosalpinx using chromic catgut no. 3, (B) tubal ligation was performed, (C) tubal resection was done, (D) tubal stump was checked.

between two groups (Table 1). Mean age of participants was 27 years old, time after graduation was approximately 2 years with no difference in the level of experience. Most of physicians were female and all of them were right handiness. Patients' characteristics were comparable with no between-group difference. Mean age of the patients was 35 vs 32 years old and mean body mass index (BMI) was 27.68 vs 26.46 kg/m^2, respectively. Tubal sterilization was performed on day 1.17 vs 1.17 after delivery in PTSMA and non-PTSMA groups (Table 2). The intraclass correlation coefficient (ICC) of given DOPS score between 2 examiners was tested with the value of 0.834 indicating good reliability [11]. Concerning the uneven distribution of values, DOPS score was presented in median and inter quartile range (IQR) rather than mean and standard deviation as shown (Table 3). In comparison, median of total DOPS score in PTSMA group was significantly higher than non-PTSMA group (93 vs. 73, $p = 0.020$). Median of 2 domains of DOPS score (tubal fishing and tubal sterilization) were also significantly higher in PTSMA group (36 vs. 24, $p = 0.045$ and 40 vs. 32, $p = 0.020$). There was no significant difference observed in estimated blood loss, operative time and the remaining domains of DOPS score (peritoneal cavity accessing, abdominal wall closure and complication prevention).

4. Discussion

According to medical competency assessment criteria for national license 2012 developed by the medical council of Thailand,

Table 1
Baseline characteristics of physicians.

Physician baseline (mean ± SD)		PTSMA group (n = 12)	Non-PTSMA group (n = 12)	P-value
Age (year)		27.92 ± 1.56	27.33 ± 1.16	0.310
Time after graduation (year)		2.33 ± 0.65	2.58 ± 0.90	0.440
Gender	Male	3	2	
	Female	9	10	
Experience	No	4	5	
	Yes	8	7	
Right handiness		12	12	

PTSMA: postpartum tubal sterilization training program with minilaparotomy approach.

Table 2
Baseline characteristics of patients.

Patient baseline (mean ± SD)	PTSMA group (n = 12)	Non-PTSMA group (n = 12)	P-value
Age (year)	35 ± 4.18	32.58 ± 6.30	0.280
BMI (kg/m^2)	27.68 ± 2.11	26.46 ± 2.77	0.235
Day at surgery after delivery (day)	1.17 ± 0.39	1.17 ± 0.39	1.00

BMI: body mass index; PTSMA: postpartum tubal sterilization training program with minilaparotomy approach.

Table 3
Comparison of DOPS score between model trained and non-model trained group.

Outcome (median)	PTSMA group (n = 12)	Non-PTSMA group (n = 12)	P-value
Total DOPS score (100)	93 (74,100)	73 (66,82)	0.020
Domain 1: Access peritoneal cavity (10)	9 (8,10)	8 (8,10)	0.590
Domain 2: Tubal fishing (40)	36 (24,30)	24 (24,30)	0.045
Domain 3: Tubal sterilization (40)	40 (34,40)	32 (24,32)	0.020
Domain 4: Instruments counting and abdominal wall closure (5)	5 (5,5)	5 (4,5)	0.514
Domain 5: Complication prevention and problem solving (5)	5 (5,5)	5 (4,5)	0.755
Operative time (min)	31.42 ± 10.36	34.33 ± 8.45	0.458
Estimated blood loss (ml)	2.83 ± 1.5	5.42 ± 7.88	0.280

DOPS: direct observation of procedural skills; PTSMA: postpartum tubal sterilization training program with minilaparotomy approach.

postpartum tubal sterilization is classified as a level 2 surgical procedure which is more complicated than general operation. Unexperienced practitioners should do this procedure under supervision unless they have fundamental surgical skill and have already been approved by the expert to perform by themselves.

Between 2019 and 2020, our data showed the declining number of deliveries from 6,997 to 5,749 cases during COVID-19 pandemic. Likewise, the decreasing number of postpartum tubal sterilization from 400 to 325 cases (18.75%) was observed. With this restraint, it will certainly make a negative impact on Ob/Gyn resident training program. Using a simple simulator like the PTSS can be a cost-effective method of training residents for full operative skill tasks considering the current pandemic situation. This approach of surgical training allows residents to practice in their own time by removing barriers associated with the limited cases.

Apparently, our findings have clearly shown that median score of domain 2 (tubal fishing) and domain 3 (tubal sterilization) in the PTSMA group were significantly higher than the control group. Both domains could be considered as the 2 most important skills required for this procedure. The scores of the remaining domains including the ability to access peritoneal cavity, instruments counting and abdominal wall closure, complication prevention and problem solving were not different between groups. As a matter of fact, the simulators were not designed to improve those basic surgical skills. However, the PTSMA did help improving trainee's operative skills of tubal fishing and tubal sterilization.

The strength of our study includes the prospective study design, the innovation of training simulators and the reliable outcome measurement. The simulators can be easily prepared using only simple materials with low expense (1,000 THB or 30 USD). If the silicone uterus model is unavailable, the cloth uterus model can be used as an alternative. Regarding some consumable materials, suture materials or condoms are available for purchasing while some surgical instruments can be derived from the operating room.

To standardize the outcome measurement, we presented DOPS score developed by RTCOG for evaluation tubal sterilization skill in Ob/Gyn residency training program. Aforementioned, DOPS score was assessed by two expert obstetricians in a blind fashion with a high intraclass correlation coefficient of 0.84. Therefore, the outcome measurement of our training program was reliable.

This study still had some drawbacks such as the small number of patients (due to COVID-19 pandemic event), the absence of sample randomization and the pretraining evaluation of basic operation skill of an individual resident. Despite the rather small number of participants, they are adequate for evaluating the efficacy of our PTSMA using a simulator on operative performance by OB/Gyn residents as described in the study objective. However, each participant was randomly designated into a particular group according to ward rotation and operative schedule with no selection bias. Our data clearly showed that there was no significant difference of baseline characteristic of participants and patients in both groups such as mean age, time after graduation and the number of experienced doctors. Due to time constraint, the study was not powered to detect a true rate of adverse events, which would require a substantially larger sample size. Therefore, we were unable to conduct a comparison study that would collect complication data to be measured between groups. Nevertheless, all patients were followed-up until discharge from the hospital without complications. In future studies, the repeated DOPS assessments should be performed to observe the improve of operative skills of all trainees.

Regarding the skill of peritoneal cavity access and abdominal wall closure, another specific design of simulator focusing on this operative proficiency should be applied such as the professional abdominal opening and closure trainer or AOCT (by Norecopa, Norway). The simulator consists of a multi-layered abdominal wall pad held under tension by a balloon which represents the intestines within the peritoneal cavity. In practice, the trainee has to enter the peritoneal cavity and close it again without bursting the balloon underneath. This kind of simulator could improve surgical skill of surgical incision to the abdominal wall or laparotomy which is beyond the capability of our simulators.

In conclusion, postpartum tubal sterilization training program with minilaparotomy approach using instructive simulators significantly improved trainee's operative performance. The data clearly showed that median score of tubal fishing (domain 2) and

tubal sterilization (domain 3) in the model-training group were higher than the control group. Both domains could be considered as the 2 most important skills required for this procedure. Therefore, a model-training program could be a cost-effective method for training and preparing Ob/Gyn residents to achieve their postpartum tubal sterilization skill when time and resources are limited.

Author's contributions

P.S. developed research project, reviewed and wrote the main manuscript.
P.C. developed research project, designed the models, evaluated trainees' skill through recorded videos and wrote the manuscript.
T.L. evaluated trainees' skill through recorded videos.
U.N. prepared the models.
O.S. analyzed data.

Funding information

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Declarations

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by Siriraj Institutional Review Board [COA no. Si 761/2020].

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to lack of ethical approval for sharing but may be available from the corresponding author on reasonable request.

Declaration of competing interest

The authors have no relevant financial or non-financial interests to disclose.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.heliyon.2022.e12722.

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