Evaluation of a Novel Manikin-Based Amniotomy Simulator.
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บทคัดย่อ:
วัตถุประสงค์: เพื่อประเมินการใช้หุ่นฝึกเจาะถุงน้ำคร่ำาที่ออกแบบใหม่โดยสูติแพทย์และนักศึกษาแพทย์ วัสดุและวิธีการ: ประดิษฐ์หุ่นฝึกเสมือนสตรีตั้งครรภ์ในระยะเจ็บครรภ์คลอดที่ปากมดลูกเปิด 3 ซม. บางตัว ร้อยละ 100 และบางตัวซึ่งมีลักษณะไม่แตก หุ่นฝึกประกอบด้วยถุงน้ำสร้างจากถุงยางอนามัยมีสูญญาทางคลอดที่ปากมดลูกเปิด 3 เซนติเมตร เข้ารู้สึกตรงกลางขนาดเส้นผ่านศูนย์กลาง 3 เซนติเมตร และช่องเปิดด้านบนสำหรับใส่และเปลี่ยนถุงน้ำจำลองที่เตรียมจากถุงยางอนามัยรายละ บรรจุน้ำ 50 มิลลิลิตร ประเมินความพึงพอใจของการใช้หุ่นโดยสูติแพทย์และนักศึกษาแพทย์ชั้นปีที่ 5 โดยนักศึกษาแพทย์ประเมินความพึงพอใจในการเจาะถุงน้ำคร่ำา 3 ครั้ง คือ ทันทีหลังจบการฟังบรรยาย ทันทีหลังจบการฝึกกับหุ่น และทันทีหลังจบการเรียนรู้ของวิชาสุขภาพและโรคของสตรี ผลการศึกษา: คะแนนความพึงพอใจของสูติแพทย์ 19 คน เท่ากับ 6.9±1.4 จาก 10 คะแนน (ค่าเฉลี่ย± ส่วนเบี่ยงเบนมาตรฐาน) ความคิดเห็นของปากมดลูกได้คะแนนต่ำสุด เท่ากับ 5.9±2.5 นักศึกษาแพทย์ 148 คน ผ่านการเรียนสุขภาพศาสตร์หลักการเจาะถุงน้ำคร่ำาในปีการศึกษา 2555 นักศึกษาแพทย์ได้คะแนนรวมทุกคนและ 2.7±1.3 ครั้ง ระดับความมั่นใจในการเจาะถุงน้ำคร่ำา เท่ากับ 5.3±2.2 หลังการฟังบรรยาย และเพิ่มขึ้นเป็น 7.9±1.3 หลังฝึกกับหุ่น (p<0.001) นักศึกษาแพทย์ให้คะแนนการมีส่วนช่วยในการเรียนรู้ของผู้ใช้ เท่ากับ 8.3±1.4
Objective: To evaluate satisfaction of a novel manikin-based amniotomy simulator by obstetricians and medical students.

Material and Method: The simulator was designed to simulate pregnant women in the active phase of labor with a 3-cm cervical dilatation, 100% effacement, and intact fetal membrane. The simulator consists of an amniotomy box inserted inside a pelvic training model. The front opening of amniotomy box is covered with a 1.5-mm thick rubber sheet with a 3-cm diameter central hole. The upper opening is for loading a simulated amniotic sac which is made from a male condom filled with 50 ml of water. Experienced obstetricians and fifth-year medical students evaluated satisfaction of the simulator on a scale of 0–10. The medical students evaluated their confidence in performing amniotomy (scale 0–10); immediately after the lecture, immediately after the simulator session, and after completion of the rotation.

Results: Nineteen obstetricians rated the simulator with overall satisfaction score of 6.9±1.4 (mean±S.D.) from 10 with lowest satisfactory score of 5.9±2.5 for cervical consistency. One hundred and forty-eight fifth-year medical students were trained for amniotomy during the Health and Diseases of Women rotation throughout the academic year 2012. Each student practised with the simulator on average 2.7±1.3 times. The confidence level for performing amniotomy was 5.3±2.2 after the lecture and markedly improved to 7.9±1.3 after practising with the simulator (p<0.001). Medical students reported the helpfulness score of this simulator during their training on average of 8.3±1.4.

Conclusion: The simulator can be used for training medical students in amniotomy. Further modifications should be conducted to improve the satisfaction.

Keywords: amniotomy, manikin-based simulator, training model

Introduction

Induction of labor using a mechanical method or amniotomy reduces the risk of a cesarean section when compared with oxytocin. Early intervention with amniotomy and oxytocin appears to be associated with a modest reduction in the rate of a cesarean sections over standard care. A randomized controlled trial study showed that early amniotomy is a safe and efficacious adjunct in nulliparous labor induction. The Thai Medical Council categorizes amniotomy for induction of labor as complicated (level 3 of 4) operative obstetrics that requires for medical degree. Medical students should be correctly instructed on the steps of the procedure, indications, contrain-
dications, and the conditions under which to perform this procedure. Medical students should be assisted when performing this procedure during their study. But practising on pregnant women during the active phase of labor is very difficult to control. It is not possible to hold the medical student’s hand to teach this procedure. So to avoid complications of amniotomy, medical students should have some experience of cervical assessment and how to handle the amniotomy instrument. However, there is no training model that contains an amniotic sac containing a fetal membrane and amniotic fluid which a trainee can use to perform an amniotomy, with water that comes out after successfully performing the procedure. The model should be able to replace a new amniotic sac quickly and easily. The purpose of this study was to develop and assess the results of a manikin-based simulator for amniotomy training of medical students.

**Material and Method**

The manikin-based simulator was developed to simulate pregnant women in the early active phase of labor with a 3-cm cervical dilatation, 100% cervical effacement, and intact fetal membrane. The simulator consists of an amniotomy box (Figure 1) inserted inside a pelvic training model which was designed and produced by Brilliant Rubber Co., Ltd. Songkhla, Thailand (Figure 2). The amniotomy box has front and upper openings. The front opening is made of a 1.5-mm thick rubber sheet with a 3-cm diameter central hole as a cervix. The upper opening is for loading an amniotic sac in and out. When putting the amniotomy box inside the pelvic training model, the front opening is secured to the vaginal canal of the model while the upper opening can be accessed through the hole in the lower abdomen of the model. The simulated amniotic sac is made of a male condom filled with

**Figure 1** Amniotomy box with two openings. The front opening consisted of a rubber sheet to simulate a 3-cm opened cervix and an upper opening for loading and removing the rubber sac filled with 50 ml water.
50 ml of tap water. Thai petty patent number 7488 was granted for the amniotomy box, while a Thai design patent is pending. The simulator was evaluated by experienced obstetricians for satisfaction using a 10-cm visual analog scale. The experienced obstetricians were divided into two groups; ≥10 or <10 years of experience and the satisfaction score for each part of the simulator were compared. Then simulator was used to train fifth-year medical students during an 8-week Health and Diseases of Women rotation for one academic year. The students were divided into 5 groups (29 to 30 students per group). The training was conducted during the first week of rotation. The training course consisted of a 1-hour lecture followed by a 1-hour simulator session. The students were then divided into two groups for the simulator session with one simulator and one trainer in each group. The self-confidence level in the ability to perform an amniotomy maneuver was evaluated 3 times using a 10-cm visual analog scale immediately after the lecture, immediately after the simulator session, and after completion of the rotation in the eight week course. The institutional review board for research at the Faculty of Medicine, Prince of Songkla University, approved the project. A statistical analysis was carried out in SPSS version 17 (SPSS, Chicago, IL). The results are given as frequencies and percentages for categorical data and mean±standard deviations for continuous data. Between-group comparisons were tested with the Student’s t test. The p-value less than 0.05 was statistically significant.

Results

Nineteen obstetricians with 10.2±9.2 years of experience (range 2 to 33) gave an overall satisfactory score of 6.9±1.4 from 10 with the lowest satisfactory score of 5.9±2.5 for cervix consistency. Most of scores were not statistically different regarding 10 years of experience, except for amniotic sac tension (Table 1).
Table 1  Satisfaction score (mean±S.D.) of simulator parts and overall by 19 experience obstetricians using 10-cm visual analog scale.

<table>
<thead>
<tr>
<th>Simulator part</th>
<th>Years of experience</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>≥10 year (n=7)</td>
<td>&lt;10 year (n=12)</td>
</tr>
<tr>
<td>External genitalia</td>
<td>6.2±1.3</td>
<td>7.1±1.8</td>
</tr>
<tr>
<td>Vaginal canal</td>
<td>6.4±1.4</td>
<td>6.9±2.0</td>
</tr>
<tr>
<td>Cervix dilatation</td>
<td>8.2±1.7</td>
<td>6.7±2.6</td>
</tr>
<tr>
<td>Cervix effacement</td>
<td>7.8±2.0</td>
<td>6.5±2.8</td>
</tr>
<tr>
<td>Cervix consistency</td>
<td>6.6±2.9</td>
<td>5.5±2.3</td>
</tr>
<tr>
<td>Amniotic sac texture</td>
<td>8.3±2.4</td>
<td>6.9±1.5</td>
</tr>
<tr>
<td>Amniotic sac tension</td>
<td>8.7±0.8</td>
<td>5.8±1.5</td>
</tr>
<tr>
<td>Overall</td>
<td>7.7±1.2</td>
<td>6.5±1.4</td>
</tr>
</tbody>
</table>

*Statistically significant (p<0.05)

Figure 3  The mean confidence scores for performing amniotomy after the lecture, simulator session, and at the end of Health and Diseases of Women rotation. The confidence score increased significantly after the simulator session (p<0.05).
One hundred forty-eight fifth-year medical students were divided into 5 groups and trained for amniotomy during the first week of their 8-week Health and Diseases of Women rotation throughout the academic year of 2012. Each student practised amniotomy with the simulator on average 2.7±1.3 times (range 1 to 10) during the simulator session. The confidence score for performing amniotomy was 5.3±2.2 out of 10 after the lecture and it markedly improved (49%) to 7.9±1.3 after practising with the simulator (p<0.001) (Figure 3). Confidence score increasing from 7.4±1.1 after one time of practise (n=13) to 8.2±1.1 after two times of practise (n=67) with simulator (p=0.046). But confidence score was not increased significantly after three or more times of practice (n=68) comparing to one or two times of practise.

The confidence level for performing amniotomy after completing the rotation was 7.9±1.2 which was a slight but not significant increase compared to the level after the simulator session. Medical students reflected the helpfulness of this simulator in their training in the evaluation score, which was on average 8.3±1.4 out of 10 at the end of rotation.

Amniotomy performance of all students was evaluated using the simulator during objective structured clinical examination (OSCE) station at the end of the rotation. The simulated amniotic sac can be easily and swiftly changed at the OSCE station. However, student feedback revealed two defects of the model, first the rubber material used to form the simulated vaginal canal is not in the closed position and difficult to separate with fingers and second the water drains quickly after rupture of the simulated amniotic sac.

**Discussion**

The present manikin-based amniotomy simulator was designed, evaluated and used for amniotomy training of fifth-year medical students with good results. The confidence of the students in performing an amniotomy increased significantly after the simulator session. It was also used for an OSCE station at the end of the Health and Diseases of Women rotation.

Simulation is increasingly used to support learning of procedural skills. The most commonly reported simulator type is the manikin, but there are no amniotomy simulators reported in the literature and no patent grant for such a simulator. The simulation provides opportunities to rehearse and learn from mistakes without risk to patients. There are many types of simulators. The present simulator is a low-fidelity model which is simple and inexpensive to make or purchase, but it can provide tactile sensation with visible water leakage to produce reality in greater detail typically provided by high-fidelity simulators. Although high-fidelity simulators are more attractive, in some situations they may not yield better results for the learner than simple, low-fidelity trainers. A very simple model can be perfectly adequate to teach the intended students the desired skill. Deering and colleagues evaluated medical students’ self-perceived comfort with several basic obstetric procedures including artificial rupture of membranes, and found that students who had some time with the simulator had a greater self-reported comfort level with this procedure. The present simulator is cost-effective because of low initial and maintenance costs. A good simulator is not only for education, but also for ongoing assessment of providers. The present
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simulator fulfills this requirement. However, the impact of a simulator on clinical practice should be evaluated in a long-term assessment.

The experts and learners critiqued some features of the simulator that needed modification. The vaginal canal should be narrower and the vaginal wall needs to be more flexible. The cervix should be change to 1.5-mm silicone sheet to make it softer than rubber sheet. Since the simulated amniotic sac has only one layer, it usually burst and water spurted and drained too quickly rather than leaking slowly. Although the exact reason that the obstetricians who had less than 10 years of experience gave low satisfaction score on amniotic sac tension is unknown. The simulated amniotic sac can be modified by using two layers of condom. Further evaluations are needed after modifications. Also there was no fetal head to palpate and there was an inadequate number of simulators and trainers. Like other simulator-based education courses, the key ingredient to a successful simulation program is a dedicated team to develop and conduct it”. The authors’ training used 2 instructors and 2 simulators for each session resulting in 14 to 15 students for each instructor and simulator. Because the confidence score was not increased significantly after two or more times of practise, so each student should have opportunity to practise with the simulator at least two times.

The present simulator can be used simply to teach a skill or task for amniotomy. The simulator can be incorporated into a scenario in which the learner must not only perform amniotomy, but also interact with a patient-actor or a member of the educational team acting as a family member or nurse. A color dye can be added to the water to simulate a clinical situation such as red for bleeding in abruptio-placenta or dark-green for meconium-stained amniotic fluid or put a cord-like structure that protrudes from the cervix to simulate a prolapsed umbilical cord. No simulator is a perfect representation of reality and can always be improved. The present simulator was used only for one academic year by only two instructors. The training program will need to be revised using more instructors and more feedback from the learners. Simulation can only augment, not replace, the learning that occurs by caring for actual patients.

**Conclusion**

A manikin-based amniotomy simulator was developed and can be used to train and evaluate medical students when learning how to perform an amniotomy for the induction of labor. Further modifications should be conducted to improve the satisfaction.

**References**

4. The Medical Council of Thailand. Announcement of the Medical Council of Thailand No. 12/2012: Medical


