Title
A Systematic Review of Randomized Controlled Trials in Obstetrics and Gynecology Medical Education

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A Systematic Review of Randomized Controlled Trials in Obstetrics and Gynecology Medical Education

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**Background:** The volume of obstetrics and gynecology (Ob-Gyn) medical education (MedEd) research is steadily increasing. Systematic reviews of Ob-Gyn MedEd research are limited. No comprehensive systematic review of randomized controlled trials (RCT) has been completed. The purpose of this study was to review the published RCTs in Ob-Gyn MedEd and address the following questions: What topics are being studied? Who is being studied? Where are these studies published? What is the methodologic quality of these studies?

**Methods:** A literature search encompassing Ob-Gyn MedEd RCTs published between January 2000 and July 2015 was performed. MEDLINE database and author references were searched. Inclusion criteria included: the field of obstetrics and gynecology and related subspecialties, and the topic of undergraduate and graduate medical education. Abstracts meeting inclusion criteria were coded based on topics, study subjects, data collection method, method of randomization, journal type and statistical methodology. Each manuscript was independently assessed by 2 of 3 reviewers. The review team followed the PRISMA guidelines for the planning, conduct and reporting of the review.

**Results:** A total of 51 abstracts meeting inclusion criteria were evaluated. The most common RCT topics studied were use of simulation (57%), followed by educator approach or setting (18%), and teaching the clinical sciences (16%). The most common method of data collection was the use of performance scoring and global rating scales (67%), followed by surveys, questionnaires, and written testing (56.9%). Groups studied included residents (53%), medical students (31%), as well as these groups in conjunction with faculty or nurses. The vast majority of studies were published in obstetrics and/or gynecology journals (68%), followed by medical education (10%), surgery (8%), and simulation (8%).

**Conclusion:** There were limited studies with sufficient commonalities to perform meta-analyses. The data serves as a road map for future studies and direction.

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**Purpose**

The purpose of this review was to provide a comprehensive picture of the current trends in randomized controlled trials in obstetrics and gynecology educational research. To identify who was being studied, what topics were being studied, where the studies were being published, and finally what was the methodologic quality of the studies. The secondary goal was to identify any possible areas for improvement in the topics studied and methods of study.
Background
The volume of obstetrics and gynecology education research is constantly increasing. Initial searches show that systematic reviews of obstetrics and gynecology education research are limited. Of those that have been performed no comprehensive systematic review of randomized controlled trials has been completed. The majority of the systematic reviews in obstetrics and gynecology education that have been done investigating randomized controlled trials, focused on specific training methods or means of evaluating students.\textsuperscript{1,2,3,4}

A comparative analysis of medical education research in obstetrics and gynecology showed that of 34,144 medical education manuscripts just 12.7\% were in the field of obstetrics and gynecology. Of the manuscripts identified only one in five were structured research and just 2\% were identified as randomized controlled trials.\textsuperscript{1}

Continual investigation and self-evaluation is vital to improving the quality of education in any field. Professional organizations such as APGO (Association of professors of gynecology and obstetrics) and CREOG (Council on Resident Education in Obstetrics and Gynecology) exist with the goal of improving education in obstetrics, gynecology, and women’s health care. Annual APGO and CREOG meetings serve as a forum for educators to focus on improving medical education for medical students and residents studying women’s health\textsuperscript{8}.

In 1986 a number of educational challenges in obstetrics and gynecology were identified at an Association of Professors of Obstetrics and Gynecology special forum. These included a lack of uniformity in obstetrics and gynecology basic science curriculum, an overemphasis on the knowledge base, a lack of meaningful education in the fourth year of medical school, as well as issues related to identifying, motivating and teaching teachers. A 2001 evaluation of the progress that has been made in addressing these challenges concluded that while progress has been made, the changing healthcare system has constricted the time and funding that are available for medical education\textsuperscript{6}.

Methods
In July 2015 a comprehensive literature search of the MEDLINE database was performed by the primary author. The search strategy used MeSH and keyword terms encompassing the field of obstetrics and gynecology and the topic of undergraduate and graduate medical education. MeSH terms related to subcategories of obstetrics and gynecology and related procedures were included to ensure a comprehensive search. Specific terms used included: obstetrics, gynecology, reproductive medicine, obstetric surgical procedures, gynecologic surgical procedures, undergraduate medical education, graduate medical education, internship and residency, and clinical clerkship. Identified studies were then narrowed to those categorized as randomized controlled trials.\textsuperscript{Appendix A}

Included studies were those randomized controlled trials published between January 2000 and July 15, 2015 that focused on undergraduate and graduate medical education in the field of obstetrics and gynecology. Exclusion criteria included non-English papers, focus on other fields of medicine (eg.
General surgery, urology, anesthesia, family medicine etc.), continuing medical education, and training of non-physicians (nurses, midwives, doulas etc.).

111 potentially relevant studies were identified and screen for retrieval. Of those, 51 met inclusion criteria. Full manuscripts were independently evaluated by two of three reviewers (AD, PW and YL). Discrepancies in results were adjudicated by discussion. Each manuscript was coded based on study subjects, topic, and journal type. Study subject categories included undergraduates, medical students, or residents. Study topics included use of simulation, educator approach or setting, teaching the clinical science, surgical techniques and other. When overlap existed manuscripts were categorized by the primary topic studied. Journal type categories included obstetrics and gynecology, medical education, simulation, surgery, and medicine. Methodologic quality was assessed by adherence to the CONSORT recommendations. Specifically, the reporting of the 25 items on the 2010 CONSORT checklist. Key items assessed related to the measurements and data collection methods, randomization methods, and statistical methodology.

Descriptive statistics was used for the coding and consort reporting frequencies. Chi square and Fisher Exact test were used in the comparison of methodologic quality in OB/Gyn MedEd RCTs vs. Leading Journals. PRISMA reporting guidelines were followed in the planning and reporting of this review.

Results

Studies

111 studies were screened and assessed for eligibility. 51 full manuscripts (n=51) published between January 2000 and July 15, 2015 that met inclusion criteria were evaluated. No individual topic was sufficiently studied to perform a meta-analysis. Figure 1 shows a flow diagram of studies screen, assessed for eligibility, and included in the review along with reasons for exclusions. The most common reasons for exclusion were studies related to non-obstetrics and gynecology fields of medicine, those addressing continuing medical education, and those looking at the training of midwives.

Study Subjects

Table 1 shows the number of manuscripts studying each group. Residents were studied the most frequently (n= 28, 53.1%) followed by medical students (n=15, 30.6%). The remainder of studies included faculty or nurses in addition to medical students or residents.

Topic

Table 2 shows the frequency of topics studied in each manuscript. The majority were simulation trials (n=29, 56.9%). These included both comparisons of simulation with traditional teaching methods as well as comparisons between
different simulation techniques. The second most common topic studied was educator approach or setting (n=9, 17.7%). Manuscripts included in the educator approach category included those that looked at resident vs. peer-led teaching for medical students, influence of surgeon behavior on trainee willingness to speak up, and comparison of educational setting for clerkship students. The third most common topic studied was teaching of the clinical sciences (n=8, 15.9%). Included manuscripts focused primarily on different novel ideas for encouraging interaction or knowledge retention in lectures such as audience response systems, voting systems, or the use of educational games.

**Journal Type**

Two thirds of manuscripts were published in obstetrics and gynecology journals (n=34, 66.6%). The rest were published in medical education journals (n=5, 9.8%) followed by simulation (n=4, 8%), surgery (n=4, 8%), and medicine (6%). The exact journals and number of publications in each is outlined in Table 3.

**Assessment Methods**

The majority of studies utilized performance scoring or global rating scales (66.7%) and/or written assessment tools (56.9%) as their assessment methods. A minority utilized observation (15.7%) or observed structured clinical exams (OSCE)(2.0%) as assessment methods. Many studies utilized more than one method to assess their primary and secondary outcomes.

**Methodologic Quality**

Methodologic quality of each study was assessed based on the reporting of several key components of the 2010 CONSORT guidelines, including methods of randomization and blinding. Aside from statistical methods, which were reported by all studies, the majority of manuscripts were missing many key components of the CONSORT guidelines (Figure 2). The minority of studies reported key components of the randomization methods including: the procedure for obtaining the allocation sequence (47.1%), methods of allocation concealment (37.3%), who generated the allocation sequence (35.3%), who enrolled participants (21.6%), and who assigned participants to interventions (24.5%). With respect to blinding, 43.1 percent blinded those assessing outcomes, and 3.9 percent blinded participants. 54.9 percent of manuscripts included a flow diagram depicting participants randomized, excluded, completing interventions, and those included in the final analysis with explanations for any exclusions.

Mills. et al evaluated the quality of trial reporting in five leading medical journals (Lancet, BMJ, JAMA, Archives of Int. Med., Annals of Int. Med). We compared the reporting trends in obstetrics and gynecology medical education research with those reported by Mills et al. for trials published in leading medical
journals. There was a significantly smaller proportion of obstetrics and
gynecology medical education manuscripts reporting key components of the
CONSORT guidelines when compared to leading journals. This difference was
statistically significant for sequence generation (p < 0.001), allocation
concealment (p = 0.006), blinding of participants (p < 0.001), and inclusion of
flow diagram (p < 0.001).

Discussion

Systematic review of the published obstetrics and gynecology medical
education literature revealed 51 randomized controlled trials of undergraduate
and graduate medical education. The majority were simulation trials, followed by
those evaluating educator approach. Most authors focused on the education of
residents and utilized performance scoring or written evaluation tools to assess
their primary and secondary outcomes. The majority of trials were missing key
components of the CONSORT reporting guidelines. When compared to
randomized controlled trials published in leading medical journals, there was a
significantly smaller proportion of studies reporting methods for sequence
generation, allocation concealment, blinding of participants, and inclusion of a
flow diagram.

The ultimate purpose of research in medical education is to make
improvements in the training of future physicians and ultimately improve patient
care. Given the broad impact on many future patients that a quality education
can provide, it stands to reason that research into improving medical education
should be held to the same standards as basic science research and those
studies reported in leading medical journals. What we found is that the current
body of published research does not meet those standards. Whether this is
secondary to an unawareness of established guidelines or a lack of adherence to
those guidelines is not clear.

Limitations of this study include the use of a single reviewer for the
implementation of the search strategy and selection of articles to be included. In
addition, only the MEDLINE database was utilized. This could have resulted in
incomplete retrieval of relevant articles. Finally just two individuals reviewed each
manuscript with an inter-rater reliability of 76.9% to 85.3% on first pass.
However, this improved to 99% after adjudication by discussion amongst all
reviewers.

In conclusion, there are limited high-quality randomized controlled trials in
the obstetrics and gynecology medical education literature. Future research
could focus on methods to improve the methodologic quality of obstetrics and
gynecology medical education research and increase awareness of an
adherence to reporting guidelines. Furthermore, a comparison of the quality of
obstetrics and gynecology medical education research to that of other medical
education research could be made.
Tables and Figures

<table>
<thead>
<tr>
<th>Characteristics of Study Participants (n=51)</th>
<th>n</th>
<th>Percent</th>
<th>Percent 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduates</td>
<td>1</td>
<td>2.0%</td>
<td>(0, 5.8)</td>
</tr>
<tr>
<td>Medical students</td>
<td>15</td>
<td>30.6%</td>
<td>(18.0, 43.3)</td>
</tr>
<tr>
<td>Medical students &amp; Nurse</td>
<td>1</td>
<td>2.0%</td>
<td>(0, 5.8)</td>
</tr>
<tr>
<td>Residents</td>
<td>28</td>
<td>53.1%</td>
<td>(39.4, 66.8)</td>
</tr>
<tr>
<td>Resident &amp; Faculty</td>
<td>4</td>
<td>8.2%</td>
<td>(0.7, 15.7)</td>
</tr>
<tr>
<td>Resident &amp; Nurse</td>
<td>1</td>
<td>2.0%</td>
<td>(0, 5.8)</td>
</tr>
</tbody>
</table>

Table 1. Study Participants

<table>
<thead>
<tr>
<th>Study Topics (n=51)</th>
<th>n</th>
<th>Percent</th>
<th>Percent 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of simulation</td>
<td>29</td>
<td>56.9%</td>
<td>(43.3, 70.5)</td>
</tr>
<tr>
<td>Educator approach/setting</td>
<td>9</td>
<td>17.7%</td>
<td>(7.2, 28.2)</td>
</tr>
<tr>
<td>Teaching the clinical science</td>
<td>8</td>
<td>15.9%</td>
<td>(5.9, 26.0)</td>
</tr>
<tr>
<td>Surgical techniques</td>
<td>1</td>
<td>2.0%</td>
<td>(0, 5.8)</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>8.2%</td>
<td>(0.7, 15.7)</td>
</tr>
</tbody>
</table>

Table 2. Topics Studied

<table>
<thead>
<tr>
<th>Journal Name (n= 24)</th>
<th>n</th>
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<tbody>
<tr>
<td>Am J Obstet Gynecol</td>
<td>12</td>
</tr>
<tr>
<td>Obstet Gynecol</td>
<td>5</td>
</tr>
<tr>
<td>Sim Health</td>
<td>4</td>
</tr>
<tr>
<td>J Obstet Gynecol Canada</td>
<td>3</td>
</tr>
<tr>
<td>BMC Med Ed</td>
<td>3</td>
</tr>
<tr>
<td>J Min Inv Gyn</td>
<td>3</td>
</tr>
<tr>
<td>BMJ</td>
<td>2</td>
</tr>
<tr>
<td>Acta Obstet Gynecol</td>
<td>2</td>
</tr>
<tr>
<td>Female Pelvic Med Repr Surg</td>
<td>2</td>
</tr>
<tr>
<td>Others</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 3. Number of OB/Gyn MedEd RCT Publications by Journal
Figure 1. Flow Diagram Study Selection

Potentially relevant studies identified and screened for retrieval
n = 111

Studies excluded with reasons
n = 60
- Midwives studied (n = 9)
- CME (n = 24)
- Non-OB/GYN (n = 19)
- Published prior to 2000 (n = 5)
- Abstract not available (n = 1)
- Unable to access manuscript (n = 2)

Studies included in the review
n = 51

Potential for inclusion in meta-analysis n = 0
Figure 2. Methodologic Quality. Percentage of manuscripts reporting key components of the CONSORT guidelines check list.
References


9. Mills et al. The quality of randomized trial reporting in leading medical journals since the revised CONSORT statement. Contemporary Clinical Trials 2005.

Appendix A – MEDLINE Database search strategy

Most recent search date: 7/15/2015

Initial search strategy:

(((((((("Obstetrics"[Mesh] OR "Obstetrics and Gynecology Department, Hospital"[Mesh]) OR "Gynecology"[Mesh]) OR "Reproductive Medicine"[Mesh]) OR "Obstetric Surgical Procedures"[Mesh]) OR "Gynecologic Surgical Procedures"[Mesh]) OR "Female Urogenital Diseases and Pregnancy Complications"[Mesh]) OR "Diagnostic Techniques, Obstetrical and Gynecological"[Mesh]) OR (gynecology[keyword] OR pregnancy[keyword] OR "reproductive medicine"[keyword] OR "obstetrics"[keyword] OR "obstetrics and gynecology"[keyword])) AND ((("Clinical Clerkship"[Mesh] OR "Education, Medical, Graduate"[Mesh]) OR "Education, Medical, Undergraduate"[Mesh]) OR "Internship and Residency"[Mesh]) OR "Teaching Rounds"[Mesh] OR "medical education"[keyword])

Additional potentially relevant studies identified with following search strategy:

("Gynecology/education"[Mesh] OR "Obstetrics/education"[Mesh]) NOT ((((((("Obstetrics"[Mesh] OR "Obstetrics and Gynecology Department, Hospital"[Mesh]) OR "Gynecology"[Mesh]) OR "Reproductive Medicine"[Mesh]) OR "Obstetric Surgical Procedures"[Mesh]) OR "Gynecologic Surgical Procedures"[Mesh]) OR "Female Urogenital Diseases and Pregnancy Complications"[Mesh]) OR "Diagnostic Techniques, Obstetrical and Gynecological"[Mesh]) OR (gynecology[keyword] OR pregnancy[keyword] OR "reproductive medicine"[keyword] OR "obstetrics"[keyword] OR "obstetrics and gynecology"[keyword])) AND ((("Clinical Clerkship"[Mesh] OR "Education, Medical, Graduate"[Mesh]) OR "Education, Medical, Undergraduate"[Mesh]) OR "Internship and Residency"[Mesh]) OR "Teaching Rounds"[Mesh] OR "medical education"[keyword])