A common problem in designating studies: case control or cohort?

TO THE EDITORS: Although I was pleased to see one of the first reports about robotic-assisted radical hysterectomy, and impressed by its considerable sample size, I was quite astounded by the oversight about the study design in the title.[1] This study is not a case-control study. It actually is an attempt at a cohort design because it is going forward in time from the exposure, robotic surgery in this case, to the outcomes. A case-control study, on the other hand, starts from the outcome and looks back to see if the exposure to an intervention is more common in the cases than it is in the controls. Surprisingly, mislabeling the study design is not rare. I have been compelled to write to the editors of other highly respectful journals for the same reason before.[2]

The other issue about the study design is its use of historic controls and the lack of information about their chronologic association with cases. If some of the control cases are from years before, they may not represent the ideal controls for the study. The possible differences between the study arms, such as the surgeons, operating room conditions, and surgical techniques, may confound the results.

I would like to congratulate the authors for their report of a large case series of women who underwent robotic-assisted type III radical hysterectomy. Their detailed discussion of the results in light of their previous experience with women who had open type III radical hysterectomy is still a significant contribution to literature in this early stage of robotic surgery. ■

Oz Harmanli, MD
Baystate Medical Center, Department of Obstetrics and Gynecology
Tufts University School of Medicine
759 Chestnut St., S-1681
Springfield, MA 01199
oz.harmanli@bhs.org

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REFERENCES

1. Boggess JF, Gehrig PA, Cantrell L, et al. A case-control study of robot-assisted type III radical hysterectomy with pelvic lymph node dissection compared with open radical hysterectomy. Am J Obstet Gynecol 2008;199:357.e1-7.

2. Harmanli O. Important features of study design. Fertil Steril 2005;84:1058-9.

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Study methods affect findings of safety trial of blunt suture needles

TO THE EDITORS: Wilson et al[1] assert that blunt suture needles are as likely to cause glove punctures as sharp suture needles during obstetric laceration repair. We believe that their conclusion, which is at odds with previous studies[2], is not supported by their evidence for the following reasons:

First, the investigators greatly overestimated the expected puncture rate (20%), which led them to underestimate proportionately the required sample size. They selected a short procedure in which only 1 or 2 sutures were placed, which minimizes the potential for needlestick occurrence during the study period. Because the actual puncture rate (2%) fell far short of the expected rate and the sample size was insufficient, the conclusion that there was no difference in puncture rates between the 2 groups was a statistical certainty that was based on a flawed study design—not an experimental finding.

Second, the investigators neglected to inspect a control sample of unused gloves for preexisting defects. The perforation rates they reported should have been corrected for the rate of defects that were found in unused gloves. When this study was conducted, the Food and Drug Administration[3] allowed a 2.5% rate of "preexisting defects" in surgical gloves, which exceeds the perforation rates reported by Wilson et al[1] (1.8% and 2.3%). It is possible that most or even all "perforations" that they found were preexisting defects.

Third, the investigators do not state how many of the surgeons in each group wore single or double pairs of gloves or, more importantly, if perforations were to exterior or interior gloves. They do not state whether a perforation to both the exterior and interior gloves of 1 surgeon was counted as 1 perforation or 2. If glove perforation is a proxy for needlesticks, then there can be only 1 needlestick when a needle pierces a double layer of gloves. Similarly, perforation to an interior glove only should not be counted because this could not have been the result of a needle puncture.

A further oversight of this study was that the gloves of other members of the surgical team were not checked for perforations. A multihospital study of injuries in the operating room showed that 25% of sharps injuries were to attending surgeons and that the rest were to other operating room personnel.[4] Suture needles can cause injuries during passing, during disposal, and after disposal. Protective surgical devices have the potential to benefit all operating room personnel, not just surgeons. ■

Janine Jagger, MPH, PhD
University of Virginia Health System
PO Box 800764
Charlottesville, VA 22908-0764
jcj@virginia.edu

Ramon Berguer, MD, FACS
Department of Surgery
University of California at Davis
Davis, CA 95616

Ahmed E. Gomaa, MD, ScD, MSPH
Division of Surveillance Hazard Evaluation and Health Studies
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention
Cincinnati, OH 45226

REPLY DECLINED

REFERENCES

1. Wilson LK, Sullivan S, Goodnight W, Chang EY, Soper D. The use of blunt suture needles does not reduce glove perforations during obstetrical laceration repair. Am J Obstet Gynecol 2008;199:639-42.

2. Berguer R, Heller PJ. Preventing sharps injuries in the operating room. J Am Coll Surg 2004;199:462-7.

3. Food and Drug Administration, HHS. Medical devices; patient examination and surgeon's gloves; test procedures and acceptance criteria: final rule. Fed Regist 2006;71:75865-79.

4. Jagger J, Bentley M, Tereskerz P. A study of patterns and prevention of blood exposures in OR personnel. AORN J 1998;67:979-96.

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The Sunset Industry: obstetrics and gynecology concerns about the shortage of obstetricians and gynecologists

TO THE EDITORS: We read with interest the article by Anderson et al,[1] entitled "Outlook for the future of the obstetrician-gynecologist workforce." Important issues regarding obstetricians and gynecologists may include (1) a significant change of sex distribution, (2) longer working hours per week, (3) an imbalance between outside life and work in obstetrics and gynecology, and (4) the fear of litigation affecting their practice of medicine and the rising malpractice costs.

In fact, the shortage of obstetricians and gynecologists might be an important issue throughout the world. For example, this finding is also apparent in Taiwan. Obstetrics-gynecology was ranked as 1 of the most favored medical specialties by Taiwan medical students in the past; however, extremely few Taiwan medical students are interested in specializing in obstetrics and gynecology now. By contrast, these medical students favor dermatology and other so-called "easy-no-tension" specialties, which is a dramatic contribution to the shortage of residents in obstetrics and gynecology in Taiwan (less than one-third than before).[2]

Although the real reasons for this shortage are still uncertain in Taiwan, some differences between the United States and Taiwan are worthy of attention. The finding that the number of physicians who are dissatisfied with medicine as a career is increasing, and the suggestion that expanding medical education will help to combat this shortage over a long period of time might not be appropriate for Taiwan. The government's policy of expanding medical schools and increasing the number of medical students is continuous; as a result, the total number of medical students increases annually,[3] but we still face a similar problem—the shortage of obstetricians and gynecologists.

Nearly all medical care is covered by the National Health Insurance Bureau in Taiwan. Therefore, medical care reimbursement might be 1 of the reasons contributing to the shortage of obstetricians and gynecologists. For example, the reimbursement for cataract surgery is much higher than that for exploratory laparotomy. The pay for a serum CA-125 test is even higher than that for transvaginal ultrasound.[4] In addition, the number of newborn infants in Taiwan has decreased dramatically in the past 10 years; this trend continues, which suggests that the need for obstetrician specialists may not be as great as before.[2]

To overcome the problem, more effective issues, as mentioned in the article by Anderson et al,[1] should be addressed immediately. ■

Peng-Hui Wang, MD, PhD
Department of Obstetrics and Gynecology
Taipei Veterans General Hospital and National Yang-Ming University School of Medicine
201, Section 2
Shih-Pai Rd.
Taipei 112, Taiwan
phwang@vghtpe.gov.tw

Bor-Ching Sheu, MD, PhD
Department of Obstetrics and Gynecology
National Taiwan University Hospital and National Taiwan University
Taipei, Taiwan

Jiun-Yih Yeh, PhD
Department of Medical Research and Education
Taipei Veterans General Hospital and National Yang-Ming University
Taipei, Taiwan

REPLY DECLINED

REFERENCES

1. Anderson BL, Hale RW, Salsberg E, Schulkin J. Outlook for the future of the obstetrician-gynecologist workforce. Am J Obstet Gynecol 2008;199:88.e1-88.

2. Taiwan Association of Obstetrics and Gynecology. Available at: http://www.taog.org.tw/content_04-1.htm. Accessed June 24, 2008.

3. Annual report of Department of Health, Escutive Yuan, ROC (Taiwan) 2007. Available at: http://www.doh.gov.tw/CHT2006/DM/DM2_2.aspx?now_fod_list_no=10301&class_no=440&level_no=4. Accessed Sept. 17, 2008.

4. Bureau of National Health Insurance. Available at: http://www.nhi.gov.tw/inquire/query2.asp?menu=1&menu_id=8&WD_ID=94. Accessed March 18, 2009.

 doi: 10.1016/j.ajog.2009.04.044