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CURRENT OPINION / UPDATE

Commercial pressures and professional ethics: Troubling revisions to the recent ACOG Practice Bulletins on surgery for pelvic organ prolapse

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Abstract Commercial interests are reshaping the practice of gynecological surgery by promoting the use of trochar-and-mesh surgical "kits" for the treatment of stress incontinence and pelvic organ prolapse. In this article, we discuss the ethical implications of changes in surgical practice that are driven by commercial interests. We point out the dangers inherent in the adoption of new procedures without adequate and documented evidence to support their safety and efficacy. We discuss the most recent American College of Obstetricians and Gynecologists (ACOG) Practice Bulletins on pelvic organ prolapse (numbers 79 and 85) which were altered without explanation to downplay the experimental nature of these commercial products. We suggest that in so doing, ACOG is not meeting its fiduciary responsibilities to patients and is undermining important professional values.

Keywords Medical devices · Ethics · Surgical innovation · Surgical ethics · Surgical mesh · Prolapse · Sling operations

Until fairly recently, there was relatively little commercial interest in the practice of gynecologic surgery aside from companies that manufactured suture or catheters or that made surgical instruments, dressings, adhesive tape, or other kinds of surgical appliances. Times have changed dramatically. While once commercial interests tied to the practice of surgery had little vested interest in the particular operation that was being performed, surgical device manufacturers are now *intensely* interested in specific procedures. Now that they are in the business of providing operation-specific "kits" for surgical use, potentially huge profits are on the table. Almost everything you need to operate (except good clinical judgment and technical skill) is right there, fresh out of the box—and an increasing number of suppliers want to be the ones to sell you the boxes.

This trend toward the performance of "kit" operations in gynecology originally started with urinary stress incontinence, but has now expanded into the related field of prolapse surgery. "Trochar-and-mesh" device kits for the surgical correction of prolapsed female genitalia are now the rage. New variations on this theme arrive in the medical marketplace with stunning frequency. There is now virtually no cavity in the pelvis that cannot have an artificial mesh threaded through it with the use of a strong right arm and a long enough spike. Whether or not this surgical intervention is good for patients and not just good for surgeons' pocketbooks and the balance sheets of surgical device manufacturers is as yet unknown because appropriately powered clinical trials with adequate follow-up have not yet been performed, but it is clear that powerful commercial interests are attempting to reshape the field of pelvic surgery for their financial benefit. Operations tied to specific commercial products are being carried out and promoted by groups who stand to benefit directly from their utilization, irrespective of whether or not the operation in question is in the patient's best interests. This sad reality raises significant ethical questions for pelvic surgeons, for professional associations such as the American College of

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Obstetricians and Gynecologists (ACOG), and for governmental regulators. We contend that these issues are not being adequately addressed.

There are clear differences between what is legal and what is ethical with regard to the use of surgical devices such as the ever-expanding number of trochar-and-mesh kits now marketed for the treatment of incontinence and prolapse. Unlike drugs—which must be shown by clinical trials to be both safe and effective prior to their release—current regulations in the USA do not require medical devices such as the mesh kits for incontinence surgery and prolapse repair to meet this burden of proof [1]. If the Food and Drug Administration decides that a device is "equivalent" to something that has already been cleared for release, it is allowed to enter the market. Independent clinical trials are not currently required. Thus, permission to allow a new device to enter the market is largely a *political* decision; but *legal* permission to market a device is not the same as using it in an *ethical* manner. The recent *ACOG Practice Bulletin no. 79* on pelvic organ prolapse got this distinction exactly right when the committee members took the position that "Given the limited data and frequent changes in marketed products (particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion), the procedures should be considered experimental and patients should consent to surgery with that understanding" [2]. Even better would have been a call to limit surgeries using devices of this kind to controlled clinical trials until definitive evidence of their safety and efficacy has been obtained.

"Experimental" procedures are often not covered by third party insurance because evidence of their safety and efficacy is lacking. Imagine, then, the surprise of attentive readers when any mention of the "experimental" nature of these operations vanished from *ACOG Practice Bulletin no. 79*, which was abruptly withdrawn and replaced by a newer, more convenient version 7 months after it was initially issued. *ACOG Practice Bulletin no. 85* is identical to *Bulletin no. 79*, except that all reference to the "experimental" nature of these procedures has vanished and the last clause of the relevant paragraph has been changed to read: "…patients should consent to surgery with an understanding of the postoperative risks and complications and lack of long-term outcomes data" [3]. Observers may speculate on the reasons why these changes were made, but the bottom line is that in making these changes (the *only* changes the committee made to *Bulletin no. 79*), the ACOG Committee on Practice Bulletins has abandoned its fiduciary duty to be an advocate for patients.

What is wrong with the new language? The experimental nature of these procedures has not changed; rather, in altering the text in this way, the ACOG Committee on Practice Bulletins shifts the responsibility for using these procedures from the *surgeon* (who should be acting as the patient's fiduciary) to the *patient* herself, as if the signing of an "informed consent" document would be some kind of "universal disinfectant" that absolves the surgeon from any responsibility for what might happen afterwards. Because these new devices have been cleared for marketing as "equivalent" to other (largely untested) products now on the market, there are no data relating to their safety and efficacy by which a surgeon or a patient can evaluate the potential harms and risks involved. This limitation means that there is no realistic way of meeting the ethical demands expected from surgeons by the duties of non-maleficence and beneficence, the duties to avoid harm and to promote good outcomes. In fact, the evidence for problems with these procedures has now grown so compelling that in October 2008, the FDA was forced to issue a public health notification on "Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence" (http://www.fda.gov/cdrh/safety/102008-surgical mesh.html). A recent review of the available evidence on the efficacy and complications of prolapse surgery has demonstrated that mesh kit procedures have higher rates of complications requiring surgical intervention than either traditional vaginal surgeries or transabdominal sacral colpopexy in the treatment of apical prolapse [4]. Pushing the decision of whether or not to use mesh kit devices onto the patient is not in any sense "just"; rather, it is an attempt to cloak the use of untested devices with the rhetoric of respecting patient autonomy, effectively allowing the surgeon to get paid for commercially sponsored surgical experimentation that masquerades as "standard" surgical treatment.

The American College of Obstetricians and Gynecologists should throw its considerable weight behind efforts to bring the legal requirements for marketing new devices in line with our profession's ethical obligations to our patients. New medical or surgical devices should not be allowed into the American or any other world market until there is definitive evidence of the devices' safety and efficacy on the basis of properly designed, properly powered clinical trials. Rather than changing policy to accommodate enhanced reimbursement for ethically questionable practices, ACOG should push for more stringent regulatory control of the medical device industry.

Before a new device is released onto the market, its efficacy for treating the condition for which it is designed should be proven in a randomized, controlled clinical trial. Once the treatment has been shown to be efficacious (and assuming that widespread complications have not become obvious during this initial evaluation), the problem of demonstrating long-term safety can be undertaken. Many complications may not appear in small initial studies, but may be uncovered using larger patient cohorts followed over a longer period of time. Once initial permission for

marketing has been granted based on favorable preliminary efficacy data, the safety of such devices should be tracked by requiring all patients in whom such devices have been implanted to be followed in a mandatory product registry until the safety of the device has been ascertained and the product is released for general use. The costs of this process should be borne by industry [5]. Our patients deserve better than what we have been giving them. Professional societies such as ACOG can, and should, do better.

Conflicts of interest None.

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