Commentary

Credentials for Uterine Artery Embolization

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IN the March 2003 issue of Clinical Obstetrics and Gynecology (1), Dr. Bruce McLucas advocated that gynecologists learn the skills to perform the procedure of uterine artery embolization (UAE) as treatment for symptomatic leiomyomas. Although few gynecologists currently have the advanced, specialized catheter and guide wire skills necessary to perform this procedure, McLucas describes a route through which he believes they might attain these skills. His Endovascular Credentialing Standards are apparently his own and do not appear to represent any gynecologic or other professional society. In this commentary, we compare the training standards of the SIR with those suggested by McLucas and provide the standards for outcomes for UAE that physicians performing this procedure should meet.

The Society of Interventional Radiology (SIR) welcomes the acknowledgment by McLucas that UAE is a valuable therapeutic option in the treatment of patients with symptomatic leiomyomata, and we welcome his interest in having this procedure be easily available. His suggestion that it be performed by gynecologists is an additional endorsement of the procedure. From his perspective, the issue is no longer whether this is a useful therapy, but rather who should perform it.

Adoption of techniques from one specialty to another is not a new concept. As noted by McLucas, endovascular procedures for the treatment of peripheral arterial disease were developed by interventional radiologists and are now also performed by cardiologists and vascular surgeons. Procedures such as venous access and port placement were previously offered predominantly by surgeons and are now widely offered by interventional radiologists. The important issue is not which specialist performs the procedure but that the procedure is done well and that patients receive high-quality care.

However, UAE differs from other, more routine endovascular procedures mentioned by McLucas in ways that warrant specific mention.

• First, the pelvic arterial anatomy is among the most complex in the body. Identifying and catheterizing the correct artery for UAE can be extraordinarily difficult even for a physician who routinely does so. Although the gynecologist has the advantage of knowing the vessel from the outside in, as noted by McLucas, this perspective bears little resemblance to angiographic anatomy and, in reality, conveys little advantage to the performance of UAE. If a physician performed a catheterization of the vena cava for the initiation of UAE, as is described by McLucas, the procedure would fail because of a fundamental misunderstanding of vascular anatomy.

• Second, the uterus and ovaries are in the direct radiation beam throughout a UAE procedure and cannot be shielded. The gonads are among the most radiation-sensitive organs in any individual, regardless of age, gender, or fertility, and the potential for genetic injury and malignant degeneration increase directly with exposure.

• Third, UAE often requires a coaxial approach with microcatheters, which requires a much higher level of skill than other selective catheterizations and the use of the highest-quality fluoroscopic equipment.

For all these reasons, adequate training is essential for the physician performing UAE.

The SIR is committed to the concept of clinical competence: procedures must be done safely and effectively and for appropriate indications. As a part of this commitment, the SIR has created standards of practice for multiple procedures, including UAE. These standards include training, reporting, quality assurance, and clinical care (2–5). The SIR training standards for UAE (2) were published in 2001 and were created in a specialty-neutral way so that any physician might offer this procedure after completing appropriate training. McLucas references this standard in his article. Adherence to these SIR standards by physicians will help assure patients that they will receive appropriate care in a safe environment and will reassure institutions that their practicing physicians...
will be qualified regardless of specialty.

Although they appear similar, the SIR training standards for UAE are more rigorous than those suggested by McLucas and the two are compared in Table 1. There are several key differences:

- The SIR requires complete (ie, as primary operator) performance of 25 UAE procedures, but counts as a single procedure the bilateral embolization of the uterine arteries that is almost always necessary for a successful outcome. Although McLucas requires that the physician perform 50 procedures, that physician needs to be the primary operator in only 25 procedures. It is important to understand the concept of primary operator. In this context, a primary operator is the operating physician who performs the procedure. The experience from half the procedures in McLucas’ guideline could be as an assistant. Participating in a procedure as an assistant allows for observation but little in the way of definitive experience—perhaps holding a wire for exchanges or handing syringes to the primary operator.
- McLucas counts each uterine artery embolized as a single procedure. Therefore, a bilateral embolization would represent two procedures. Therefore, although his standard might seem comparable to the SIR requirements, it requires the gynecologist to perform complete procedures in only 12.5 patients. For a specialist with no previous catheter skill training or experience, this is clearly inadequate.
- The SIR requires that the training cases be performed successfully. McLucas makes no mention of whether the physician in training needs to succeed in his or her efforts.
- The SIR requires that the training period be completed with no significant complications for the initial 100 angiographic training cases, and with complication rates no higher than in the published quality assurance standards (4) for the embolization procedures. Training in which one learns “on the job” at the expense of patient care, with failed cases and increased complications, does not qualify a physician to perform UAE. McLucas does not mention complication rates in his standard.

The training numbers suggested by the SIR have been validated in studies that have examined the learning curve for UAE for physicians already trained in interventional radiology and vascular procedures including embolization. For these physicians, the learning curve for UAE, as measured by reduction in fluoroscopy time, was approximately 20 procedures (6,7). This is among physicians who are fully trained in interventional radiology. Certainly, a novice physician with no angiographic experience cannot be trained or credentialed with fewer procedures.

McLucas mentions that gynecologists who perform UAE will need to become familiar with angiographic equipment. As indicated earlier, this is more than just a good idea. Embolization procedures may produce some of the highest patient radiation doses of all fluoroscopically guided interventions, even when performed by highly motivated and appropriately trained operators with use of state-of-the-art equipment with full dose-management capabilities (8). Radiation exposure is sufficiently high that the Food and Drug Administration has issued safety advisories on the risk of radiation during procedures such as embolization (9–11), and there has been at least one case of UAE radiation-induced skin necrosis requiring skin grafting (Shope T Jr, unpublished data, 2001). Radiation injuries from fluoroscopically guided vascular procedures have unfortunately already led to a successful million-dollar lawsuit (12). Although UAE performed by experienced physicians has a moderate fluoroscopy time of only 10–20 minutes, this total can go much higher in inexperienced hands. The potential for patient injury from radiation exposure is real.

The published quality-assurance standards are listed in Tables 2 and 3. A successful procedure requires bilateral UAE (with the exception of the rare patient with only a single uterine

<table>
<thead>
<tr>
<th>Table 1</th>
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<tr>
<td>Comparison of SIR and McLucas Published Qualifications for UAE Experience as Primary Operator</td>
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<tr>
<td></td>
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<tr>
<td>Diagnostic arteriography (no. of patients)</td>
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<tr>
<td>Uterine artery arteriography (no. of patients)</td>
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<td>Uterine embolization (no. of patients)</td>
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<tr>
<td>Acceptable outcomes required</td>
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<tr>
<td>Radiation safety education</td>
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<td>Continuing education</td>
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<th>Table 2</th>
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<tr>
<td>Success Rate Thresholds According to SIR Standards</td>
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<tr>
<td>Success Category</td>
</tr>
<tr>
<td>---</td>
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<tr>
<td>Technical</td>
</tr>
<tr>
<td>Successful embolization of both uterine arteries</td>
</tr>
<tr>
<td>Outcome*</td>
</tr>
<tr>
<td>Anticipated leiomyoma size reduction</td>
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<tr>
<td>Anticipated uterine size reduction</td>
</tr>
<tr>
<td>Anticipated reduction of bulk symptoms</td>
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<tr>
<td>Elimination of abnormal uterine bleeding</td>
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<td>Successful elimination of symptoms</td>
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* In most instances, reduction in uterine and leiomyoma volumes becomes noticeable several weeks after embolization and continues for 3–12 months afterward.
these standards. We welcome the in-
UAE, they need to know and meet

If gynecologists do enter the field of
gynecologists in uterine embolization and rec-

ognize that there will be gynecologists
interested in gaining these skills. However, the training for all providers
of this therapy must be sound, and
there should be demonstrated compe-
tence before privileges to perform
UAE are granted.

<table>
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<tr>
<th>Complication</th>
<th>Reported Rate (%)</th>
<th>Suggested Threshold (%)</th>
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<tr>
<td>Transient amenorrhea</td>
<td>5–10</td>
<td>10</td>
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<tr>
<td>Permanent amenorrhea</td>
<td>0–3</td>
<td>3</td>
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<tr>
<td>&lt;45 Years of age</td>
<td>7–14</td>
<td>15</td>
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<tr>
<td>&gt;45 Years of age</td>
<td>0–3</td>
<td>5</td>
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<tr>
<td>Transcervical fibroid expulsion</td>
<td>1–2</td>
<td>2</td>
</tr>
<tr>
<td>Noninfectious endometritis</td>
<td>1–2</td>
<td>2</td>
</tr>
<tr>
<td>Endometrial or uterine infection</td>
<td>&lt;1</td>
<td>2</td>
</tr>
<tr>
<td>Deep venous thrombosis or pulmonary embolus</td>
<td>&lt;1</td>
<td>2</td>
</tr>
<tr>
<td>Uterine necrosis</td>
<td>&lt;1</td>
<td>&lt;1</td>
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<tr>
<td>Nontarget embolization</td>
<td>&lt;1</td>
<td>&lt;1</td>
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artery). In addition to the complica-
tions and failures that may occur in
the performance of diagnostic arte-
riography, there are complications and
failures that occur from the interven-
tional embolization procedure. Com-

plications such as injury from nontar-
get embolization may occur when
incompletely trained physicians start
offering this procedure. Postemboliza-
tion pain is expected for several hours
after embolization and is not consid-
ered a complication unless it leads to
unexpected admission to the hospital,
but it is the responsibility of the inter-
ventionalist to treat pain adequately
(5). All physicians who perform UAE,
regardless of specialty, are account-
able to these standards for training
and clinical practice.

UAE has many benefits, but it is
neither simple to perform nor risk-free
even when performed well. The Joint
Commission on Accreditation of
Healthcare Organizations requires
that patients receive the same quality
of care regardless of who provides the
care (13). Patients expect their physi-
cian to be appropriately trained and
able to achieve the outcomes required
by national medical society standards.
If gynecologists do enter the field of
UAE, they need to know and meet
these standards. We welcome the in-