Transcervical balloon tuboplasty

Background

Transcervical balloon tuboplasty (TBT) is a noninvasive outpatient procedure used to treat infertility due to fallopian tube blockage or narrowing. During the procedure, a surgeon inserts a catheter and inflates it with a contrast medium or saline solution to dilate the occluded area. Dilation is repeated until tubal patency is established. Because the procedure involves the use of basic angiographic techniques, it is performed by radiologists as well as gynecologists.

One of the most often cited studies regarding TBT was published in the *Journal of the American Medical Association (JAMA)*. In “Transcervical Balloon Tuboplasty, a Multicenter Study” (October 24/31, 1990, Vol. 264, No. 16, pp. 2079–2082), researchers concluded that practitioners can learn the procedure easily during a one-day, hands-on training workshop. Practitioners participating in the study attended a workshop that included performance of the procedure on a uterine model and assistance during the performance of their first few cases.

Involved specialties

Gynecologists, reproductive endocrinology and infertility specialists, and interventional radiologists

Positions of specialty boards

**ABOG**

The American Board of Obstetrics and Gynecology (ABOG) certifies gynecologists. Candidates for certification must submit a case log of 40 office-based patients managed within a 12-month period. Candidates may also submit a list of patients managed over an 18-month period, if 40 patients cannot be gathered from the candidate’s practice within a 12-month period. Patients chosen from the fellowship or senior year of residency may also be used as part of the case list, but these senior log cases may not be the only source of patients. Patients must fall into one of 40 categories, such as infertility management and evaluation and office surgery. Additionally, candidates must submit a log that includes a minimum of 20 gynecologic patients, and it may not include more than two patients from the gynecology categories outlined by ABOG.
In its *Bulletin for Subspecialty Certification in Reproductive Endocrinology and Infertility*, the ABOG notes that candidates for certification must provide case lists prior to taking the examination. Candidates for reproductive surgery are required to prepare a list of 25 reproductive surgical patients, without complications, who presented with problems from at least five of the following categories:

- Laparotomy
- Operative laparoscopy
- Operative hysteroscopy
- Uterine myomas
- Asherman syndrome
- Endometriosis
- Tubal reversal/tuboplasty
- Ectopic pregnancy
- Operative management of pelvic pain
- Congenital abnormalities of the reproductive tract
- Adnexal problems, excluding ectopic pregnancy

According to the ABOG bulletin, candidates for certification in infertility/in vitro fertilization (IVF) should prepare a list of 25 uncomplicated infertility/IVF patients who presented with the following problems:

- Female infertility
- Male infertility
- Recurrent pregnancy loss
- Assisted reproductive technology (ART)

**Positions of societies, academies, colleges, and associations**

**ISGE**

The International Society for Gynecologic Endoscopy (ISGE) lists transcervical tuboplasty under endoscopic procedures using hysteroscopy. The society states that hysteroscopy with concurrent laparoscopy can be used to perform transcervical tuboplasty if proximal tubal occlusion is confirmed. Furthermore, the society states that transcervical tuboplasty is more cost-effective than either transabdominal tuboplasty or IVF.

**SIRS**

The Society of Interventional Radiology (SIRS) states that the most common cause of female infertility is fallopian tube blockage. Plugged or narrowed fallopian tubes prevent successful pregnancy from occurring.

Interventional radiologists can diagnose and treat a blockage in the fallopian tube using selective salpingography. During the procedure, which does not require an incision, a catheter is placed into the uterus. A contrast agent, or dye, is injected through the catheter and an x-ray image of the uterine cavity is
obtained. When the blockage is identified, another catheter is threaded into the fallopian tube to open the blockage.

Positions of subject matter experts

**Edmond Confino, MD**

**Chicago**

Edmond Confino, MD, is a physician in the reproductive endocrinology department at Northwestern Memorial Hospital in Chicago. He was the lead author of “Transcervical Balloon Tuboplasty, a Multicenter Study,” published in *JAMA*. He trains his subspecialists and residents on TBT, and reports that two out of four physicians in his department can perform the procedure.

As part of his 1990 study, Dr. Confino introduced U.S. physicians to the procedure. He says TBT offers a solution for women who have blocked fallopian tubes without requiring costly and invasive IVF or surgery. Confino says that if a woman has two open fallopian tubes, the chances of pregnancy are greatly increased. About one out of five women with tubal occlusion could benefit dramatically from this procedure. He says he often receives patients considering IVF who have a diagnosis of tubal occlusion and actually do not need IVF.

“There are many women who could have benefited from this procedure in lieu of IVF,” Confino says. “It’s definitely a well-established niche procedure that is currently underutilized.”

At the same time he was introducing the procedure, IVF was improving at an erratic pace. This caused many fertility specialists to select IVF prior to attempting TBT. Confino says surgeons have avoided the procedure due to lack of knowledge, training, or experience.

“It was interesting to see that when success rates for IVF went up, less people wanted to open fallopian tubes,” he says. “I would have loved this procedure to gain in popularity. It’s so simple compared to the alternatives.”

Confino says there is no formal training available for TBT, so surgeons typically learn it from an expert. Because the techniques are familiar to radiologists, he says invasive radiologists are able to perform the procedure using guide wires, but notes that they do not get many referrals for it.

“To show a radiologist this procedure is very easy,” says Confino. “To show it to a gynecologist requires the development of skills that are not ingrained in their routine training.”

Confino says there is no need for surgeons to complete a large number of procedures in order to gain competence, although each surgeon will require a different number to gain that competence. He says most surgeons are proficient after
10 procedures. For others, he says five is a sufficient number.

Although the procedure is not widely popular in the United States, Confino reports that other countries, such as India and China, have expressed interest in it due to the preference for natural conception in those countries.

“IVF is still unaffordable to many individuals in places like India and China,” he says. “The same is true in the United States. A lot of women are unaware that there is a procedure that is by far less complicated and inexpensive compared to in vitro.”

Francisco Risquez, MD
Caracas, Venezuela

Francisco Risquez, MD, is an internationally known fertility expert who developed his own system of catheters with applications for diagnosing and treating tubal pathology. He is also the author of many scientific articles.

Before transcervical tubal cannulation, Dr. Risquez reports that the status of the fallopian tubes could only be evaluated using surgical or indirect radiological approaches. He says nonoperative access to the fallopian tubes has created scope for a variety of diagnostic and therapeutic procedures, including TBT. He reports that TBT can be completed by one operator on an ambulatory basis and requires mild or no pre-medication.

TBT is a simple technique to learn and apply to patients, says Risquez. However, fertility specialists prefer to solve problems like tubal obstruction through surgery or IVF. He also states that the technique has not been widely spread because it is not easy for gynecologists and fertility experts to access imaging devices that are usually used in the field of radiology. Furthermore, physicians rarely refer patients with tubal obstruction to radiologists, who also perform TBT.

In regards to education and training, Risquez states that the practitioner must have a general knowledge of gynecology and be qualified or trained in gynecology and radiology with an emphasis on diagnostic procedures and the treatment of tubal pathology.

“So far, the typical path that followed the few practitioners of this new procedure has been learned through direct teaching by the few experts or pioneers, such as Dr. Edmond Confino from Chicago,” he says.

Risquez states that surgeons should perform an average of 10 to 15 procedures in all the variants of transcervical tubal catheterization, including falloposcopy, in order to gain competence. He says surgeons should perform a minimum of 20 interventions per year to maintain competence.
Positions of accreditation bodies

**CMS**

CMS has no formal position concerning the delineation of privileges for TBT. However, the CMS *Conditions of Participation (CoP)* define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ *CoPs* include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.
**The Joint Commission**

The Joint Commission has no formal position concerning the delineation of privileges for TBT. However, in its *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.”

It goes on to state that this process typically includes:
> ➤ Developing and approving a procedures list
> ➤ Processing the application
> ➤ Evaluating applicant-specific information
> ➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
> ➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
> ➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:
> ➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
> ➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
> ➤ Consistent application of criteria
> ➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
> ➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested

Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism

A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)

A process to determine whether there is sufficient clinical performance information to make a decision related to privileges

A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws

Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.
**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for TBT. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for TBT. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff...
membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements
➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status
➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding TBT. The core privileges and accompanying procedure list are not meant to be all-encompassing. They define the types of activities, procedures, and privileges that the majority of practitioners in this specialty perform. Additionally, it cannot be expected or required that practitioners perform every procedure listed. Instruct practitioners that they may strikethrough or delete any procedures they do not wish to request.

**Minimum threshold criteria for requesting privileges in TBT**

- **Basic education:** MD or DO
- **Minimal formal training:** Successful completion of an approved residency training program in obstetrics and gynecology or radiology. If training is in radiology, residency must be followed with a fellowship in interventional radiology.
- **Required current experience:** Demonstrated current competence and evidence
of at least 10 TBT procedures in the past 12 months or completion of training in the past 12 months. Additionally, the applicant must be able to demonstrate that he or she has prior experience in the treatment of patients with infertility problems and (if a gynecologist) prior experience using a hysteroscope.

References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Applicants must be able to demonstrate that they have maintained competence by showing evidence that they have performed at least 20 TBT procedures annually.

In addition, continuing education related to TBT should be required.

For more information

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