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## A Sonographer's Guide to the Use of Transvaginal Ultrasonography for Confirming Permanent Contraception Insert Placement

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During this presentation, I'm going to identify patients who are appropriate candidates for transvaginal ultrasound to confirm proper micro-insert placement, understand the benefits and disadvantages of TVU in the confirmation process for micro-insert placement, and enhance sonographer awareness of the training certification program for the confirmation of appropriate TVU insert placement as requested by the FDA of the device manufacturer.

Hi, I'm Laura Decker from Evansville, Indiana. I am a sonographer for Dr. Cindy Basinski and Rupal Juran, two dedicated board certified gynecologists. Traditionally, female sterilization was only offered in the operating room under general anesthesia. The risks of any surgery in the abdomen include injury to underlying intestines or blood vessels, as well as the risk and recovery of general anesthesia. Fortunately, there is now a new method to permanent contraception, which is the permanent birth control inserts. Traditionally, female sterilization was only offered in the operating room under general anesthesia. The risks of any surgery in the abdomen include injury to underlying intestines or blood vessels, as well as the risk and recovery of general anesthesia. Fortunately, there is now a new method to permanent contraception, which is the permanent birth control inserts. The placement of these inserts can be performed in the physician's office via hysteroscope.

A recent study reported that patients preferred hysteroscopic over laparoscopic sterilization procedures because of the opportunity for an in-office procedure with local anesthesia and a faster return to routine activity. In fact, we perform hundreds, if not thousands, of permanent sterilization procedures right in our office. A confirmation test must be given and done 3 months following the micro-insert procedure to confirm that the devices are properly placed and the woman can rely on the micro-inserts for birth control. In July 2015, the US Food and Drug Administration approved the use of transvaginal ultrasound as an alternative confirmation test for these micro-inserts. Up until the FDA approval of TVU, a modified HSG was required to confirm appropriate placement. I'm going to give some examples of cases that are common in our practice that may reflect permanent birth control inserts ultrasound confirmation test.

As long as a patient falls in the category as an appropriate candidate for transvaginal ultrasound confirmation test, an ultrasound will be done at 3 months post placement. In order for a patient to qualify for TVU confirmation, there are certain criteria that must be met during the actual placement of the PBC inserts. The criteria include 1 to 8 trailing coils on each side, procedure, and placement of PBC inserts must be done in less than 15 minutes, and the procedure must be done with no complications. Ultimately, the performing physician will determine whether the patient qualifies for TVU confirmation. Even if the patient does qualify for TVU confirmation, they still have the option to offer an HSG, as it does provide definitive results.

Just like anything, there are pros and cons of the TVU confirmation process. Being able to have your confirmation test done directly in the physician's office makes many patients more comfortable. Majority of the patients like being familiar with their physician's office and the staff. Also, being able to have this done right in the comfort of those you know helps put some patients at ease. As far as health factors go, using ultrasound also steers clear of radiation and avoids exposing the patient to radiation. An ultrasound is also significantly cheaper than an HSG, which can be a huge deciding factor for many patients.

A modified HSG is definitive, and unfortunately, an ultrasound is not. Although as a sonographer we can tell where the inserts are located and whether they are traversing the uterotubal junction, we cannot tell if the fallopian tube is occluded. Approximately, 10% of TVU patients may be referred and sent for an HSG based on equivocal ultrasound results. Ultrasound also has barriers that may limit what they are able to visualize. We commonly run into barriers of the female pelvis that are inevitable to bypass. These barriers include body habitus of the patient, bowel gas and limited visualization of pelvic structures.

We'll begin case 1. A 23-year-old woman presents to the office for consultation of permanent sterilization. She is engaged to be married and has been pregnant twice with 2 live births. The physicians have discussed the higher regret with PBC inserts since she is a young patient and stressed the permanency and reiterated that this is nonreversible. After consultation, the patient is scheduled as soon as possible for PBC insert placement. The day of the procedure, the patient is prepped accordingly and presents to the procedure room. The placement was done with no complications, and the actual time of the procedure was 4 minutes, which counts for the time the hysteroscope was inserted, the inserts were placed, and the hysteroscope was removed. There were 6 trailing coils on the left and 2 on the right. The blood pressure during the procedure was 115/69, and her pain during the procedure was a 2 out of 10. Three months after the procedure, the patient presents back to our office for her 3-month coil check and confirmation test.

The transvaginal ultrasound shows the bilateral permanent birth control inserts visualized bilaterally, and they appear in optimal position traversing the uterotubal junction. The bilateral coils are visualized as highly echogenic inserts. Based on patient body habitus and experienced scanning skills, the entire length of the insert can be identified, as visualized in the image above. Position of the insert in the cornua in relationship with the endometrium and uterotubal junction should be noted to determine placement. Those are key objects in the ultrasound report to the physician. At this appointment and after patient's ultrasound and confirmation test, she is told that she can rely on the permanent birth control inserts for sterilization purposes. No HSG is required.

On to case 2. A 42-year-old woman presents to the office for consultation of the placement of permanent birth control inserts. This patient desires permanent sterilization after 2 pregnancies and 2 live births. Permanent birth control inserts were discussed and agreed upon at the in-office consultation. This patient had a bilateral tubal ligation, then reversal, and now desires sterilization again, but would like to steer clear of the operating room if possible. Patient presents to the office and is prepped properly. The time of the procedure was 8 minutes where the scope was inserted, the micro-inserts were placed, and the hysteroscope was removed. Her blood pressure during the procedure was 152/84. There were 8 trailing coils on the left and 16 on the right. Her pain during the procedure was a 3 out of 10.

Due to difficulty of placing the PBC inserts and the large number of trailing coils on the right, large being greater than 8, an ultrasound was performed immediately after placement to visualize inserts trailing into the fallopian tubes. However, performing an ultrasound immediately after the PBC placement is off label and should not be performed regularly, as the results are not definitive. Performing an ultrasound immediately after the procedure, specifically after a hysteroscope has been inserted, visualization of the uterus and endometrium can be difficult due to the trauma of the cavity and the water and air that has been projected into the cavity. An ultrasound was performed, and the right micro-insert was visualized adequately, but the left micro-insert was not. In this transverse image, you're able to see the right micro-insert in the correct position, but the left insert is not clearly seen, which means that this exam does not confirm proper position. There is also some air in the pelvis from the recent procedure, which is obscuring optimal views of the PBC inserts.

Due to limited views of the inserts, the patient is sent for a flat plate x-ray that showed both PBC inserts in satisfactory position. Since the patient did not have between 1 and 8 trailing coils bilaterally at the time of the procedure, she does not qualify for the TVU confirmation test, but instead she will be sent for the HSG for confirmation. At the 3-month HSG, she will be told whether she can rely on them for birth control reasons. After the HSG is resulted, results and imaging will be sent to the ordering and performing physician.

Next, we'll discuss case 3. A 32-year-old woman presents to the office desiring permanent sterilization. She has been pregnant 3 times with 2 live births. Options are discussed, and patient ultimately decides on permanent birth control inserts. Patient presents to the office for the procedure, and she goes through the PBC insert procedure with zero complications. The time of the procedure was only 3 minutes. There were 2 trailing coils on the left and 1 on the right. Her blood pressure during the procedure was 115/81, and her pain during the procedure was a 7 out of 10.

Three months later she presents to the office for an ablation, which is the treatment of heavy periods. Her PBC insert procedure went smoothly, and she qualifies for the TVU confirmation and does not require HSG testing. Before an ablation is performed, a confirmation test must be performed to visualize permanent birth control inserts and position must be declared. If PBC inserts were not visualized in proper position, ablation would not be performed just yet. When the transvaginal ultrasound is performed, results demonstrated the left permanent birth control insert in an abnormal position.

In the image above, the insert is visualized parallel to the endometrial stripe when in the sagittal view. Therefore, this signifies a perforation. This is obvious when scanning the uterus for visualization of the micro-inserts. The segment of the linear axis of the insert

appears to be elongated out in an abnormal position. These are key things to look for when performing a confirmation test.

The patient is sent for an HSG where her left coil appeared to be partially in the tube and partially perforated out. While the right micro-insert was in correct position and both tubes were occluded, counseling to the patient is done. Due to abnormal position of the left micro-insert, she cannot rely on the devices for contraception, and it would be suggested we proceed to a bilateral salpingectomy in the operating room for guaranteed sterilization. This would have ultimately been the alternative regardless if the PBC insert procedure would have been performed or not. Patient verbalizes understanding, and she desires to proceed with the bilateral salpingectomy.

A 37-year-old woman presents to the office for counseling and consult for permanent sterilization. She has been pregnant 5 times with 5 live births, which makes for an extremely busy mother. After discussing the options of permanent sterilization, she decides that the permanent birth control inserts done right in the office with no down time would be the best choice for her so she is able to get back to her busy lifestyle the next day. She presents to the office a couple of weeks later for the procedure. The procedure is done with zero complications. Her blood pressure during the procedure was 129/82. She had 4 trailing coils on the left and 4 on the right. The total time of the procedure was 7 minutes, and her pain during the procedure was a 1 out of 10. The low pain scale is no surprise since we make a reference to "on a pain scale of 1 to the worst labor pains you have ever experienced," and she has had 5 children. Due to the ease of the procedure, she left the office with an appointment for an ultrasound confirmation test in just 3 months.

Three months later she visits the office for her transvaginal ultrasound confirmation test. She has had no problems or complaints of her PBC inserts and has resumed her busy lifestyle with her 5 children. When the ultrasound is performed, both inserts are visualized beautifully. The entire insert is visualized traversing the uterotubal junction, and the distal ball tip is even visualized beautifully, which can be unusual in a less than perfect female pelvic anatomy. In the image above, you can see the whole insert trailing from the endometrium out into the uterotubal junction. This is an ideal case for a sonographer like myself and the physician who did the placement. We love to see successful placements, beautiful images, and great results.

In order to perform the transvaginal ultrasound confirmation test, basic TVU skills are required, including the ability to identify normal pelvic anatomy and pelvic structures with sagittal and transverse views of the uterus. Approximately, 10% of TVU patients may be referred and sent for HSG based on equivocal results regardless. This could be based on whether the sonographer can obtain the proper imaging, barriers of the female pelvis, which include patient body habitus, bowel gas or limited visualization of pelvic structures, or if unsatisfactory classification is suspected. Ultimately, there are some challenging factors when performing a confirmation test, and if there is any doubt, further testing should be ordered and performed to ensure that the patient has the contraceptive that they are wanting.

During this presentation, I discussed 4 different cases, all of which are common for an ultrasonographer see during a TVU confirmation test. Cases 1 and 4 are what we hope to see with every patient that has the PBC insert placement. They are ideal cases with no complications or intervention required. Case 2 had minor complications with a large number of trailing coils and difficulty during the placement due to her previous scarring inside the endometrial cavity, so she did not qualify for the TVU confirmation test and was ultimately sent for an HSG 3 months after. Case 3 is the one we luckily see very rarely. Although she had no complications and did qualify for the 3-month TVU confirmation test, once it was performed, the results showed indication of a perforation in which an HSG did need to be performed. The perforation of the micro-insert then resulted in a bilateral tubal ligation in the OR.