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www.reachmd.com
info@reachmd.com
(866) 423-7849

A New and Better Standard of Care Than Blind Biopsy for the Diagnosis of Abnormal Uterine Bleeding

Narrator:

Welcome to this week's medical industry feature sponsored by CooperSurgical's Endosee Office Hysteroscopy system; a new and better standard of care than blind biopsy for the diagnosis of AUB.

Dr. Singer:

We can all agree that diagnosis at the point-of-care is beneficial to both patient and clinician. What is the standard of care for the diagnosis of abnormal uterine bleeding and what diagnostic tools are available to clinicians? I'm your host, Dr. Andrea Singer, and with me today is Dr. Steven R. Goldstein, Professor of Obstetrics and Gynecology at New York University School of Medicine, immediate past President of the American Institute of Ultrasound in Medicine, and a busy clinical practitioner in the Faculty Practice Suites at New York University. Dr. Goldstein, welcome to ReachMD.

Dr. Goldstein:

Thank you very much. It's a pleasure to be here.

Dr. Singer:

So glad you've been able to join us. Dr. Goldstein, you're well-published in the field of abnormal uterine bleeding and especially on the use of transvaginal ultrasound and saline-infusion sonohysterography for the evaluation of the uterine cavity. There have been some recent advances in technology that should significantly change the way physicians are evaluating patients with abnormal uterine bleeding. Can you please share some background and insights for our listeners?

Dr. Goldstein:

I think people need to realize just how important abnormal uterine bleeding is in terms of our patients' health. One-third of patient visits to the gynecologist are for abnormal bleeding and said to account for more than 70% of gynecologic consults in perimenopausal and postmenopausal women. In younger women, between 19 and 39, abnormal bleeding most frequently occurs as a result of pregnancy or benign structural lesions like polyps or myomas, certainly anovulatory cycles in younger women, polycystic ovarian syndrome, abnormalities of hormonal contraception, and occasionally even the patient with endometrial hyperplasia. Endometrial cancer is certainly less common in that age group of under 40, but can occur. It's in the women between 40 to menopause that abnormal uterine bleeding becomes much more of a big issue, and it often is due to anovulatory bleeding which is a normal physiologic response to declining ovarian function. In a paper we published more than a decade ago, in over 400 women between 35 and menopause, 79% of the time after the workup, the cause of the bleeding turned out to be dysfunctional anovulatory bleeding, or what some doctors will refer to as hormone imbalance. But the other 20% of people have some sort of structural abnormality, polyps, fibroids, endometrial hyperplasias, occasionally endometrial carcinoma, and sometimes in postmenopausal women the bleeding can be from endometrial atrophy. Many of your listeners are aware of the fact that for more than 20 years I've really used transvaginal ultrasound and saline-infusion sonohysterography as the basis for triage of patients with abnormal uterine bleeding in order to distinguish this anatomic pathology, in about 20%, from the dysfunctional anovulatory bleeding in the other roughly 80%. So, for me, this has been a point-of-care option and that word gets bantered around a lot, but that means something I can do at the time of the patient visit, with the patient up in stirrups, by myself, saving them time and making it very efficient. I have to admit that I have been, though, disappointed however, that the majority of gynecologists who are utilizing this approach often are doing it as a separate procedure, requiring another visit, in a separate special treatment room, with an ultrasound technician, and this defeats much of what I believe is one of the main advantages of my approach which is that of a point-of-care option done at the time of the patient visit. In addition, I personally have not gotten into

office hysteroscopy because of the space needed for the equipment, the need to be able to sterilize the equipment, the time involved, as well as patient level of comfort or discomfort; thus in my hands, it has not been a satisfactory option and it is definitely not something that I consider point-of-care.

This Endosee device, while technically still a form of office hysteroscopy, is truly revolutionary because it is absolutely a point-of-care option. I mean, it can and should be done with the patient up in stirrups, just as one used to do a Pipelle endometrial biopsy. It's really not much different or more difficult than doing an endometrial biopsy. It requires no real preparation, no special room, and this Endosee is really almost as quick as an endometrial biopsy.

Dr. Singer:

Well you have just given us a wealth of information, and very important information regarding the significance of abnormal uterine bleeding and some of the issues in terms of the approach to evaluation. You just mentioned endometrial biopsy which has really been the standard approach for the evaluation of AUB, can you share some of that history with us?

Dr. Goldstein:

Fortunately, or unfortunately, if you were to put the word Pipelle into *Pub Med*, the first article that shows up is by Cornier. In the mid 1980s, he described this device and he intended to use it to do endometrial dating as part of an infertility workup, something we no longer do. In 1991 a paper by Tom Stovall got a tremendous amount of notoriety. And what he did was he took 40 women with known cancer, he did a Pipelle in the office the week before their hysterectomy. He managed to get cancer in 39 out of 40, hence he said it was 97.5% accurate and since people were coming from D&Cs and Vabra-aspirators, there was a C-Change to using this instrument for ruling out cancer, and it had been that way for the last, oh, 20 or 25 years. I have been talking about the foibles of blind endometrial sampling since 1995. In that year, a study was published in the *Journal of Reproductive Medicine*, *Pipelle endometrial sampling. Sensitivity in the detection of endometrial cancer*. This paper demonstrated that endometrial biopsy has high overall accuracy in diagnosing endometrial cancer when an adequate specimen is obtained and when the endometrial process is global. However, if the cancer occupies less than 50% of the surface area of the endometrial cavity, the cancer can be missed by a blind endometrial biopsy. I was very gratified, finally, in 2012, in July, when *ACOG Practice Bulletin No. 128*, known as *Diagnosis of Abnormal Uterine Bleeding in Reproductive-Aged Women*, which by the way was reaffirmed in 2014, stated that the primary imaging test of the uterus for the evaluation of abnormal uterine bleeding is transvaginal ultrasound. It went on to talk about how, if transvaginal ultrasound images were not adequate, and if further evaluation of the cavity became necessary, then sonohysterography, or what we've been calling saline-infusion sonohysterography, or hysteroscopy, preferably in an office setting, was recommended. It did go on to say that an office endometrial biopsy can be the first-line procedure of tissue sampling in the evaluation of these patients with abnormal uterine bleeding, but it referenced the fact that the literature shows if a cancer occupies less than 50% of the surface area, it can be missed by a blind endometrial biopsy sample. And so, the ACOG Bulletin told us, "These tests, meaning a blind biopsy, are only an endpoint when they reveal cancer or atypical complex hyperplasia." Now that's a huge change in the standard of care and I worry about what percent of practicing OB/GYNs are aware of that. So, now that the standard of care corroborates that a negative blind biopsy is not a stopping point, certainly clinicians can still begin with a biopsy, but unless it is malignant or complex atypical hyperplasia, the endometrial evaluation is not complete.

Dr. Singer:

If you are just tuning in, you're listening to ReachMD. I am your host, Dr. Andrea Singer, and I'm speaking with Dr. Steven Goldstein, Professor of Obstetrics and Gynecology at New York University School of Medicine. Dr. Goldstein, the technology that you've mentioned, this new form of office hysteroscopy, sounds like a breakthrough in abnormal uterine bleeding diagnosis. Please share with our listeners how you have used this in your practice.

Dr. Goldstein:

Certainly. This kind of technology that Endosee provides is something I've looked forward to for a long time. It easily gives us direct visualization of the uterine cavity. It can and should be performed in an office exam room at the time of the point-of-care. And studies have shown that diagnostic hysteroscopy is more accurate than SIS and TVUS in assessing endometrial pathology. Diseases of the endometrium such as hyperplasia and cancer cannot be distinguished by SIS or TVUS. The product consists of a disposable cannula that actually contains the camera, thus avoiding the necessity of cleaning or sterilizing, and it's got a hand piece with a small LCD screen. After I clean the cervix with a Betadine-type solution, I will then stabilize the cervix with a cervical stabilizer. I never ever use a single-tooth tenaculum. Cervical stabilizer is like a wispy little tenaculum that just holds the cervix in place, not for dilatation, but so that it doesn't move. I then insert this cannula, much like I would a Pipelle. And you put the IV tubing from an IV bag on a pole and I utilize a pressure cuff around the IV bag, and then I use that little plastic thumb wheel which I've moved close to my source to control the amount of pressure and thus the flow of fluid. This entire visualization procedure takes a maximum of maybe 90 seconds to get total and adequate visualization. If there's no pathology, the patient can be treated expectantly or hormonally for her dysfunctional anovulatory

bleeding. And then if there is focal pathology, polyps or myoma, focal thickening of tissue, I'll then schedule her for operative hysteroscopy with anesthesia in our outpatient setting.

Dr. Singer:

What, if any, pitfalls about this technology would you like to share with your colleagues

Dr. Goldstein:

In patients who are cycling, timing of the procedure is paramount, but this is just the same as it is with sonohysterography. The procedure should be done just as a bleeding cycle ends to avoid those topographic irregularities that can occur. We've referred to these as endometrial moguls. Understand the uterus is a battle-worn organ. Women have had babies, C-sections, myomectomies, D&Cs, and so as tissue is laid down it is not always topographically homogeneous and so these irregularities to the surface, that we call moguls, can often be mistaken for polyps or focal pathology, so timing is crucial. In addition, when you insert the cannula you need to be careful, because you can create a tunnel-like effect that's not dissimilar to when you put a Pipelle in to the endometrial cavity when there's abundant tissue. Patient selection is paramount and this is true in any invasive procedure. Some nulliparas are not going to be suitable candidates. You've got to judge the size of the cervical os. On occasion I've used small dilators or one of these disposable graduated os finders, but this is going to depend on patient comfort and motivation for the patient to do it in an office setting now as opposed to having to reschedule or going to the operating room and having presurgical testing for anesthesia. If I am going to reschedule for another time, sometimes I will utilize Cytotec or misoprostol to soften the cervix.

Dr. Singer:

Well this is very practical and useful information for our listeners. Do you have any final thoughts or pearls for the audience?

Dr. Goldstein:

When I think about what's really important to take away, Endosee can give us point-of-care direct visualization of the endometrial cavity. As I've said already, though, patient selection is mandatory for success. This has become a very nice tool in my toolbox and I think people need to understand that just as not all uteri lend themselves to a meaningful ultrasound examination: adenomyosis, coexisting fibroids, the axial uterus, not the retroverted uterus, patients with previous surgery, marked obesity, these women do not lend themselves to meaningful ultrasounds. And, so, the Endosee has enabled me, after 25 years, to be able to directly visualize the endometrial cavity in a point-of-care fashion, that is, with the patient in the exam room at the time of my exam. And I think this is extremely advantageous in terms of my time, in terms of her time. And this translates both directly and indirectly to better and more cost-effective medical care, and also really conforms to a new better standard of care than simply old, blind endometrial biopsy by itself which is no longer acceptable unless it's positive for cancer or endometrial hyperplasia.

Dr. Singer:

Dr. Goldstein, many thanks for being with us today and sharing your insights on how clinicians can change the standard of care for the diagnosis of abnormal uterine bleeding.

Dr. Goldstein:

Well, thank you, Andrea, for allowing me to help spread the word to our fellow physicians.

Dr. Singer:

I'm your host, Dr. Andrea Singer. Thank you for listening.

Narrator:

You've been listening to this week's medical industry feature, sponsored by Cooper Surgical, the comprehensive source for women's healthcare. To learn more about Endosee and the diagnosis of AUB, please visit www.CooperSurgical.com and, to download this segment and others in this series, please visit ReachMD.com/AUB. That's ReachMD.com/AUB. Thank you for listening.