MINERVA MINUTES-PHOENIX OBGYN SOCIETY

Greetings fellow obgyns! This past Thursday September 14th, we were honored to have David Clapper join us at Maestro's City Hall for an enlightening discussion on Minerva endometrial ablation.

David Clapper is the CEO of Minerva in Redwood California and has a passion for innovation in gynecologic health. Currently, Minerva is a privately run company with 135 employees. In addition to Minerva, his company is working on other intrauterine gynecologic developments, including Symphion and Meditrina. His history in endometrial ablation is strong. He previously was CEO of Novacept, developer of Novasure ablation device. In 2015, Minerva received FDA approval for the Minerva endometrial ablation device. The device had to pass very rigorous testing prior to approval. This was the first FDA approved ablation device since 2001!

When creating Minerva, the engineers and inventors sought to create a device with improved amenorrhea rates, increased success, decreased alarms, a protected cervical canal, and less risk for complications resulting from uterine perforation.

Getting back to the basics, causes for abnormal uterine bleeding include fibroids, intrauterine polyps, endometrial hyperplasia or cancer, iatrogenic, endometrial ovulatory dysfunction, adenomyosis, and idiopathic. It is always important to appropriately screen patients and have a negative endometrial tissue specimen prior to performing an ablation. Other preoperative testing includes endometrial biopsy, D&C, sonohysterogram, hysteroscopy, and pap smear. Choosing appropriate candidates without contraindications will decrease the risk for surgical complications and provide better outcomes. Prior to performing an endometrial ablation, it is not uncommon for insurance companies to request documentation that patients have failed other options before the procedure. Other treatment options to consider for abnormal uterine bleeding include contraceptive management, progesterone IUD, lysteda, D&C and hysterectomy.

Minerva performed a study to better evaluate their target patients. They determined the ideal patient to be 30-50 y/o, income > 25K, who are done having children. 31% of women complained of heavy menstrual bleeding. 69% stated they would be interested in a 3-minute procedure to treat their heavy bleeding. 65% of women prefer to be asleep for their endometrial ablation. 58% prefer to have the procedure done in-office.

The ideal endometrial ablation is able to destroy the endometrium and superficial myometrium. Traditionally, rollerball treatment has been considered the "gold standard" for endometrial ablation. Different methods currently on the market include cryotherapy, HTA, Novasure and Minerva. Cryotherapy has a low amenorrhea rate and low success rate. HTA shuts off if any fluid is lost and has a lower success rate, but does treat abnormally shaped uterine cavities. This method requires pretreatment. Novasure uses a higher power and there is often more patient discomfort. The radiofrequency array often sticks when coming out of the uterine body. With these methods, hysterectomy rates can be as high as 25% in 5 years.

Minerva works by ionizing the gas, exciting particles, and creating light. This results in "plasma-thermal" ablation. Treatment takes 120 seconds and uses a low power of 40W. Cervical dilation is only 7mm. Additionally, perforation detection uses customized energy to determine compromise to the cavity earlier, before complications can occur. This means improved safety. There is NO pretreatment necessary. The only measurement required is the uterine length. There is no "sticking" of the device and it is safer than prior methods. Minerva has a 70% amenorrhea rate. The success rate is 93%.

Many providers question whether endometrial ablation "masks" the ability to detect endometrial cancer. One study by Dood et.al. evaluated 234,700 women and showed that there was no difference in detecting endometrial cancer in patients who had received endometrial ablation vs. those who had not. Singh et.al. studied 1500 women and actually showed a decrease in the incidence of endometrial cancer.

Minerva is currently not indicated for patients with intrauterine pathology or patients with ESSURE. It is contraindicated for patients with a prior history of myomectomy involving the myometrium. For physicians providing Minerva, there are brochures with questionnaires to better select candidates.

I hope you have enjoyed these minutes! We look forward to seeing you for our next Phoenix OBGYN soiree. The guest speaker will be discussing Prenatal Testing on Thursday, October 19th.

Thank you,

Rachel Spieldoch MD