Photo: Marco A. Pelosi, III, MD

Release the Hounds! What I Found on tv EBD in MAUDE

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Recently, the MAUDE database has been cited as a source of "numerous" reports of adverse events associated with the use of transvaginal energy-based devices (tv-EBD). However, those who have cited the MAUDE database have failed to provide specifics regarding the quality, the quantity, and the nature of these reports. Seeking to satisfy my own curiosity, I conducted a search of the MAUDE database for adverse events for every vaginal EBD device and every manufacturer of such devices since they first appeared on the market in late 2014.

The search was conducted online via the FDA's MAUDE search engine page. The name of each manufacturer, US distributor where relevant, and device was searched individually from 2014 to the present. The number of reports parameter was set to 500, the maximum. Some events had been reported more than once – some by personnel associated with manufacturers, some by physicians, some by patients. I then classified each device by it's technology: Radiofrequency (RF), Radiofrequency with Active Cooling (RFAC), Carbon Dioxide Laser (CO2), Diode Laser (D) Erbium:Yag Laser (ER), Erbium:YAG + Diode Laser (ERD).

These are the results of this search:

Alma Lasers: FemiLift (CO2): no adverse events reported

BTL Aesthetics: Ultra Femme 360 (RF): no adverse events reported

Venus Concept: Fiore (RF): no adverse events reported

Inmode: Votiva (RF): no adverse events reported

Eufoton: LadyLift (D): no adverse events reported

Syneron CO2RE Intima (CO2): no adverse events reported

Thermi: Thermiva (RF):

1 report: Gynecologist bruised her patient with device

Cynosure: DEKA: MonaLisa Touch (CO2)

3 reports of 1 event dated 3/31/2016 of UTI symptoms after treatment by gynecologist

3 reports of 1 event dated 8/23/2017 of urethral pain after treatment #3 by urologist in patient with hx of chronic urethral pain before tx, positive response with first 2 treatments

2 reports of 8/10/2017 & 9/4/2017 of 1 event: physician burned his own hand b/c assembled laser improperly

1 report 2/11/2016 of pt who had pain after treatment by gynecologist and had medical treatment at local urgent care clinic with vaginal creams and oral pills

Sciton: DiVa (ER): 1 report of two non-physician medical staff who gave each other external burns unsupervised event 2/20/2018

Viveve: Geneveve (RFAC):

2 reports of 1 event: patient experienced multiple symptoms with "trial" handpiece after popping noise

Lumenis: FemTouch (CO2):

1 report of patient getting eye infection from eye protection after treatment by gynecologist

1 event of issues cleaning the handpiece

The total number of reports in this search was 15. The total number of events was 9. Two of these were non-physicians burning themselves while "playing doctor" with a laser. The total number of events involving patients undergoing treatment was 6. One of these was an eye infection from dirty eye protectors. This leaves 5 relevant events of vaginal issues.

Let's examine these five adverse events involving patients undergoing vaginal treatments with energy based devices.

1. The Thermiva RF bruise event: In 2016, a woman noticed discomfort after treatment by an unspecified operator then went to her gynecologist who diagnosed bruising. Bruising is not a known complication of any low temperature radiofrequency technology used in the vagina, but it is a common occurrence with excess pressure on the vulvovaginal area. I would suspect the latter. The procedure itself involves a gentle massaging motion of a plastic handpiece and does not involve the application of excess pressure.

2. The MonaLisa UTI event: In 2016, a woman noticed urethral burning and discomfort beginning two days after treatment by her gynecologist and persisting for several weeks. Although urinalysis was performed 3 times, no urine culture was performed and no antibiotic therapy was given. The risk of urinary tract infection exists with any manipulation of the vulvovaginal area and is not unique to any procedure or any device. Procedures in the vagina and vulva are categorized as Class II: Clean Contaminated by the CDC with an infection rate of 4 to 10 percent (ref). Up to 20 percent of UTIs have been reported to show a negative urinalysis and culture is the gold standard (ref). One of the 3 reports of this event states that this patient had an active yeast infection that was being treated at the time of her procedure.

3. The MonaLisa urethral pain event: In 2017, a urologist attempted to treat the symptom of chronic urethral pain with CO2 laser fractional ablation. The patient's symptoms vacillated in response to treatment and overall there was no long term detrimental effect documented. The main issue here was lack of knowledge in the techniques, technology and indications. There is no literature anywhere to support the use of fractional CO2 laser ablation to treat urethral pain and there is no protocol for doing so. This is an example of experimentation.

4. The MonaLisa post-procedure discomfort event: In 2016, A woman experienced discomfort after her procedure and went to an urgent care clinic to have her issue addressed. This report was provided by the manufacturer and was reported because the patient sought and received care from an urgent care clinic. It is not uncommon for patients to seek out care at urgent care clinics. Reasons for doing so may include inadequate pre/post procedure counseling, an inability to contact their treating physician, the suggestion of friend or family member, or convenience.

5. The Geneveve pain event: In 2017, a non-gynecologist treated a woman who had never undergone the procedure before at twice the standard energy dose with a "trial" handpiece that hadn't been used before. A strange "popping" noise was documented

during the procedure, but the procedure was continued. The patient reported pain, sensation issues and urinary incontinence. This event suggests a complete lack of professional judgement and a lack of knowledge of energy based devices on the part of the operator. Although I have no experience with the use of this product, I have 27 years of experience with lasers. Every laser case invokes a strict checklisted laser protocol that involves equipment checking and test firing outside the human body. The latter applies to equipment that is in it's final form, not a trial device. In the case of a trial device, a trial procedure is done outside the human body on a suitable model where the device can be tested. At that stage, it might be ready for a human trial or not. It is not offered as reasonable treatment to anyone as this is purely experimentation. Arbitrarily doubling the energy dose in a treatment-naïve patient is without precedent in any energy-based therapeutic intervention that I am aware of and cannot be justified. Ignoring an inexplicable noise during operation of the device is unfathomable. This unfortunate event can be deemed a compounding of errors stemming from extremely poor clinical judgement.

This analysis of the MAUDE database brings several issues to light. First, is the need to distinguish the number of events from the number of reports of singular events. Every year, my birthday is reported "numerous" times by my Facebook friends. This happy birthday effect does not elevate the magnitude of this singular event. Second, is the need to educate "rookies" to EBD in the technologies they are using, to the indications of the treatments they are providing, and to the counseling and postprocedural support that their patients may require. All of these five adverse events can be classified as human factor errors. My colleagues from other specialties suggest that I am inciting a turf war. To the contrary, I am offering simple advice for staying out of trouble. So many "skin experts" that I know offer elaborate skin imaging and mapping technologies prior to facial EBD treatments, yet offer no vaginal assessment whatsoever prior to firing a laser or other EBD in the vaginal canal blindly. Third, is the need to establish a collective database of experience with the devices. The MAUDE system does not and cannot track the number of procedures performed. It can only offer a glimpse into the issues of reported events and it is severely limited at that. When estimating the unknown frequency of true adverse events, pundits against EBD will exaggerate the numerator and dwell on the few available sad vignettes while those who favor EBD will stress that there is no denominator, but that it's probably large.

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