NovoaMedicalServices, PA

Email Interview with Miguel Jara

Spanish Reporter

The following is the English translation of an email interview Dr. Novoa conducted with Miguel Jara, freelance reporter from Spain regarding His opinions of the ESSURE device.

Miguel Jara:

How did you find out the damages caused by ESSURE?

Dr. Novoa:

Approximately 2 and a half years ago, I was contacted by a member of the Facebook ESSURE Problems forum.

At that time there were less than 5000 members.

I was asked to comment and answer questions regarding the possible association between the ESSURE device and significant complications that were appearing following the insertion of the device.

After reviewing the **ESSURE Clinical Manual for Physicians**, I was shocked to read how high the complication rate was associated with the device, even within the clinical and pivotal studies and could not understand how this device was ever approved by the FDA, let alone approved for Class III PMA classification.

This got me thinking about how many unreported adverse cases were actually out there considering the fact that Bayer had publicly stated that it had sold over 750,000 kits.

For the next 2 years, I spent about 2 hours per day, 7 days a week researching the ESSURE and discussing patient cases associated with complications with the ESSURE.

During this same period of time, I saw the number of new members increase from 5000 to over 28,000.

What I have consistently found is that the survey data collected by the ESSURE Problems forums correlate very closely to the conclusions published by Dr. Jialin Mao, M.D. from Weill Medical College of Cornell University (BMJ)

http://www.bmj.com/content/351/bmj.h5162 and from Dr. Aileen Gariepy, M.D. from Yale Medical School

http://www.cleveland.com/healthfit/index.ssf/2014/04/nonsurgical_sterilization_may_have_higher_pregnancy_risk_than_older_methods_study_shows.html

Each of their studies support what we already know: the ESSURE device is associated with the following side effects even when properly placed and with documented complete occlusion of the fallopian tubes by Hysterosalpingography (HSG).

The top 10 include the following:

1. Chronic Pelvic Pain
2. Abnormal or Dysfunctional Uterine Bleeding
3. Dyspareunia
4. Significant Abdominal Water Retention
5. Chronic Systemic Allergic or Autoimmune Responses to the Metallic or PET fibers mimicking the signs and symptoms of rash, Lupus, dementia, Rheumatoid Arthritis, Chronic Fatigue syndrome, Sjorgan Syndrome, and Hypoactive Sexual Desire Disorder
6. Hair loss
7. Implant failure (proper placement), leading to ectopic pregnancy, stillbirth, induced abortion, premature rupture of membranes, and preterm delivery and fetal death.
8 Implant migration or extrusion.
9. Dental caries, tooth fracturing and tooth loss
10. Endometriosis and Adenomyosis

Miguel Jara:

Of all the adverse effects of this device, which are in your opinion the most serious or disturbing problems?

Dr. Novoa:

1. Chronic Pelvic Pain- pain which occurs daily at levels of 8-9 out of 10 is the most serious since it is debilitating. Little if any relief exists for many women, which is equivalent to daily torture.

2. Failure of the device, estimated to be as high as 9%, or 1 in 12 patients which is 15x higher than the estimated failure rate with traditional tubal ligation.

When failure occurs, the risk of ectopic pregnancy is as high as 50%.

The remaining pregnancies that are considered viable are at risk of miscarriage or ESSURE Induced Abortions (EIA), stillbirth, premature delivery and fetal death.

Miguel Jara:

Do you think the process for ESSURE Approval was properly done?

Dr. Novoa:

Unfortunately, the United States FDA approval system is exceptionally easy to manipulate if you are willing to provide biased results because the FDA relays too heavily on an assumed honor system in the presentation of study information. However, when there are millions of dollars to be made by getting approval for a new product, it is naive to believe that the product maker can be trusted to provide complete and accurate data

about their product.

Based on a series of investigations, allegations have surfaced claiming intentional data manipulation, fraud, failure to notify the FDA of over 16,000 adverse reports not listed in the Manufacturer and User Facility and Device Experience (MAUDE) data.

Miguel Jara:

In Spain Doctors are not properly explaining women about the risks and adverse effects of this device. Do doctors in USA give women a rigorous informed consent form?

Dr. Novoa:

Absolutely not! In the vast majority of cases, doctors are providing little if any informed consent information about the device.

More often than not, doctors are using generic forms commonly used other types of sterilization procedures and having patients sign these forms as ESSURE informed consent forms.

Therefore, doctors are practicing in an unprofessional and unethical manner, and more accurately, engaging in deceptive business practices for monetary gain.

Miguel Jara:

In Spain there is no protocol for safe ESSURE Removal, do you have such a protocol in USA?

Dr. Novoa:

No such protocols exist at a national level. BAYER has provided some general guidelines but these recommendations are not based on a comparison of results from prospective, randomized, double-blind studies.

Based on my experience and after review of the case outcomes of thousands of women, I generally recommend the removal of the ESSURE device by laparoscopic assisted Vaginal hysterectomy, bilateral salpingectomy (LAVH/BS) with an emphasis on maintaining the ESSURE device unaltered inside of the fallopian tubes and the tubes attached to the uterus.

Some colleagues have shown good results with salpingostomy and even tubal ligation reversal, but the risk of coil and PET fibers fragmentation and pelvic contamination may outweigh the benefits leading to additional operations in the future.

This is why I recommend LAVH/BS as the best treatment in order to avoid complications requiring additional surgeries.

Miguel Jara:

Would you recommend ESSURE removal through Hysteroscopy?

Dr. Novoa:

Only before the ESSURE devices have scarred in place which allows for a very short period of opportunity, most often limited to removing the devices during the original implantation surgery or within a few days of the original insertion.

Once scar tissue forms around the coils, there is absolutely no credible reasoning to attempt the removal of the coils via hysteroscopy.

Such attempts are foolish and increase the risk of coil fragmentation and retention.

Further, the hysteroscopic approach does not allow for a complete evaluation of the location and position of the coil inside of the fallopian tube, only a limited view from the endometrial cavity.

In the estimated 14% of cases where the coils are improperly placed, a hysteroscopic removal approach may actually cause more damage to the pelvic organs, especially if the coils have perforated through the uterus or tubes on the distal side of the hysteroscopic field of view.

Bottom line, only in limited cases should any attempt be made to remove the ESSURE coils from a hysteroscopic approach. Attempting to do so, especially once the coils have scarred in place is tantamount to malpractice.

Miguel Jara:

In Spain there are doctors who don't think ESSURE fragments after removal surgery may be dangerous, What do you think about this matter?

Dr. Novoa:

Based on general knowledge of fragment retention, I originally thought the same thing, but after getting a better understanding of the results of ESSURE fragmentation and retention, I absolutely believe that any ESSURE fragments retention is dangerous.

You see, the ESSURE device is not like normal metallic or polyester material. When it fragments, it can leave behind portions of the device too small to be distinguished from normal tissue by any currently available scan, such as ultrasound, CT or MRI.

However, these retained fragments continue to cause the same effects as the original intact device, and if fragments are left in the pelvis, the scarring effect that was desired in the tubal lumen begins to affect the adjacent tissue of bowel and omentum producing abdominal and pelvic pain and scarring as well as continued chronic allergic foreign body reactions, most often seen as abdominal and pelvic pain.

Therefore, any fragmentation and retention of the metallic or PET fiber components or even the associated inflammatory scar tissue can cause problems or be considered

dangerous.

Miguel Jara:
What would you advice all those women who have ESSURE in their bodies and are feeling adverse effects or discomfort?

Dr. Novoa:
A high consideration for the immediate removal of the device before symptoms worsen.

For those without symptoms, a consideration of the 9% estimated failure rate leading to pregnancy and the estimated 4% migration rate which could lead to adjacent organ injury, especially injury to the bowel.

Miguel Jara:
Do you know how many ESSURE victims are there in USA, and how many women are bringing a lawsuit?

Dr. Novoa:
At the current time, just within the ESSURE Problems forum of 28,000 women, at least 100 major surgeries including hysterectomy are being done PER MONTH due to complications from the ESSURE.

Based on the estimated failure rate of 9%, migration rate of 4% and estimated 750,000 kits sold, there could be at least 68,000 women at risk of serious complications associated with the device just in the United States.

Because of Class III protection, BAYER cannot be sued by patients from any complications caused by the ESSURE.

Most lawsuits are being considered against the implanting doctor, similar to those that have occurred due to the complications from the polyester Vaginal meshes.

Miguel Jara:
Are there any mid-term or long-term studies about the possible autoimmune diseases that this device may bring to certain women?

Dr. Novoa:
Unfortunately, there have been no such studies conducted so far regarding these concerns despite the fact that literally thousands of women have these problems following the placement of the ESSURE device.

However, the FDA has recently recommended that a databank regarding autoimmune reactions following the ESSURE device be collected, so hopefully we will have more information in the near future.