Treatment of Preeclampsia by Reducing Intra-Abdominal Pressure

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Abstract: It is quite possible that a major cause for preeclampsia in many pregnant women is an increased intra-abdominal pressure, which compresses the venous system and decreases venous flow throughout the body. Treatment could be accomplished by decreasing this pressure through one of several ways. Maternal-Fetal Medicine physicians have been very reluctant to explore this possibility; however, all possible treatments of this devastating conditions must be tried.

Keywords: Preeclampsia, Increased intra-abdominal Pressure, Compressed venous system; Decreased venous flow, Pregnancy.

FOR MATERNAL-FETAL PHYSICIANS RE: PREECLAMPSIA

I have been trying for several years to study the treatment of pregnant women with preeclampsia, using a device to lower their intra-abdominal pressure (IAP), which I strongly believe to be the cause of this syndrome *vide infra.*

The U.S. has the 7th highest pregnancy death rate (5.9% or about 17,500 women/year) among developed countries. The second biggest cause is preeclampsia (hemorrhage is. About 5-8% (around 15-20 thousand) of all pregnancies develop preeclampsia per year. It may occur as early as the 26th week of gestation, but is more frequent toward the end of a normal gestational period. There are several temporizing treatments, but the only effective one is emergency delivery, usually by C-section, which may lead to a very premature infant with all of its negative consequences. It is estimated that preeclampsia costs the United States Health Care System around $2.3 billion, split almost equally between the mother and the baby [1, 2]. The U.S. has the 7th highest pregnancy death rate (5.9% or about 17,500 women/year) among developed countries. The second biggest cause is preeclampsia (hemorrhage is #1). About 5-8% (around 15-20 thousand) of all pregnancies develop preeclampsia. It may occur as early as the 26th week of gestation, gestations late in life. It Is relative common in the severely obese (both problems increasing at an alarming rate [3-5].) but is more frequent toward the end of a normal gestational period. There are several temporizing treatments (magnesium sulfate and anti-hypertensives, but the only effective one is emergency delivery, usually by C-section, which may lead to a very premature infant with all of its negative consequences.

Why doesn't this happen in all pregnancies? Well, it is much more common in 1st time pregnancies, where the abdomen has not been previously stretched, in multipara Presumably, there is also impaired venous flow from the placenta impairing the fetus, the legs with swelling, the liver, increasing liver enzymes and uric acid levels, the spleen, decreasing platelets, the splanchnic circulation, leading to a decreased blood volume, and heart, decreasing forward blood flow. A manuscript explains this in more detail and provides the references for supportive studies [6, 7].

I have had prior FDA approval (G990053) for an Investigative Device Exemption (IDE). In the past I have tried to study this at the Eastern Virginia Medical School, the University of Mississippi, Padua, Italy and Cuenca, Ecuador, all to no avail. Each of these "failures" was for a different reason: The study was initiated in 2 patients but stopped because of elevated liver enzymes, about 25% above normal. The Obstetricians "on call" did not support the study and no further patients were entered (Virginia, Mississippi), Promised IRB approval not obtained. (Padua); customs problem + the patient decided not to proceed (Cuenca). At each of these institutions, the device was discarded. And then, 5 years ago, I threw in the towel. In both partially treated patients the blood pressure decreased, the urine output increased, as did the platelet count in the one patient. I believe that the increase in liver enzymes was due to a "washout' from the liver

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secondary to prior ischemia from impaired hepatic centripetal and centrifugal venous flow and should not have been a reason to terminate the study.

LOWERING IAP COULD BE ACHIEVED WITH THREE TECHNIQUES.

1: A device consisting of a plastic shell placed over the abdomen connected to a vacuum pump, which pulls the abdomen up and deceases IAP (Figure **1**). The drop in IAP is verified by a decrease in urinary bladder pressure. This has been used in patients with severe headaches secondary to pseudotumor with immediate relief of their headache. They have slept in the device without difficulty and awakened without headache and asked to be placed back in the device when their headache returned later in the day. Following bariatric surgery induced weight loss, their IAP normalized and they were free of further headaches.

2: A mattress with a large central opening, permitting the pregnant abdomen to descend and, thus, lowering the IAP.

3: The BellyBed, which is inflatable and has a large central cut-out for the pregnant woman so she can lie prone; should this become too uncomfortable, an electric controlled central section can be raised making it into a "regular" bed. This has been used over 200 times in Australia without any adverse consequences.

I have had difficulty finding a group of Maternal-Fetal Physicians who would like to enthusiastically support a study to provide "proof of concept". Perhaps that is because this concept is being proposed by a general and. trauma surgeon. The concept is secondary to his experience with trauma and severely obese patients. The only effective treatment for an acute abdominal compartment sydrome was to open the abdomen and leave it open until the causative pathology resolved [8] and in severely obese women about to undergo gastric bypass, who already have an increased IAP that resolves following surgically induced weight loss [6]. As there is enough evidence that preeclampsia is a sub-acute abdominal compartment syndrome, I propose that use of one of these techniques could save thousands of lives and dollars. However, a study demonstrating proof of concept, safety and efficacy would be needed, followed by studies to determine the length of time a patient would need to remain in the device and, if long-term treatment is necessary, perhaps the patient could take the device home for further treatment.

The obstetrical hospital in Orlando, Florida, The Winnie Palmer Center for Maternal Fetal Health, is considering working with me. They apparently have between 12,000 an 15,00 deliveries per year. There should an adequate number of preeclamptic patients patients to study.

COI Disclosure: The author is owner of Maternal-Fetal Health, LLC Florida. He is working with companies involved in the manufacture of each to the devices mentioned, but has had no income from any of them.

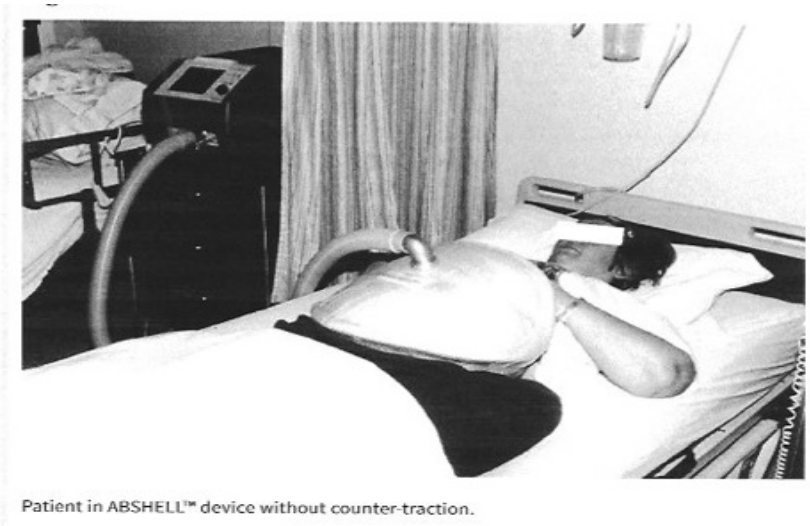

Figure 1: The Abshell.

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