Published in final edited form as:

J Med Device. 2009 March ; 3(1): 014501–014503. doi:10.1115/1.3043791.

The Momedemameter: An Affordable Preeclampsia Detector For Low Resource Environments

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Abstract

Background—Preeclampsia, a pregnancy-specific disorder, is the third leading cause of maternal morbidity and mortality worldwide.

Method of Approach—To develop a device to detect preeclampsia in pregnant women living in low resource environments, a method was needed that had to be very low cost and, preferably, easily monitored by the woman herself. Due to the high cost and expertise involved in monitoring the two diagnostic criteria of preeclampsia (elevated blood pressure and proteinuria), edema, an indicator of preeclampsia was chosen instead.

Results—The general principle of the method is to have each pregnant woman, early in pregnancy, fitted, on either her wrist or ankle, with a detection band, which is set to a preset expansion limit (e.g., expansion by 5%). When edema causes that body part to swell to the limit, the pregnant mother knows that she should seek medical assistance.

Conclusions—The resulting prototype device and calibration method requires little knowledge, and is very durable, cost-effective and portable.

Keywords

preeclampsia indicator; edema detector

1. Introduction

Preeclampsia, a pregnancy-specific disorder characterized by the development of hypertension and proteinuria after 20 weeks of gestation, is the third leading cause of maternal morbidity and mortality, affecting approximately 5 to 10 percent of pregnancies.

The syndrome of preeclampsia was originally defined as hypertension, proteinuria and edema, with eclampsia or seizures the severest form of the syndrome. The current diagnostic criteria for preeclampsia include elevated blood pressure and proteinuria (0.3 g or more in a 24 hour urine collection), occurring after 20 weeks of gestation[1]. Pregnancy outcomes can be improved by early diagnosis of preeclampsia and careful observation.

Currently the only definitive therapy for preeclampsia is delivery: the nidus of this syndrome appears to originate in the trophoblasts (placenta), and delivery of the fetus and placenta is curative. Other therapies include the use of antihypertensive drugs and magnesium sulfate to reduce blood pressure and prevent seizures. Various therapies have also been investigated to prevent preeclampsia including the administration of antioxidants such as vitamin E and aspirin [1].

However, it is estimated that some 50,000 women die annually from eclampsia worldwide. In some low resource environments, eclampsia accounts for up to 40% of maternal mortality [2–4]. Unfortunately, there are no currently available reliable and cost-effective screening tests for preeclampsia in these environments. This results in a significant disease burden among pregnant women in low resource environments.

Although edema occurs frequently in the genesis of the syndrome, and was an original component of the syndrome definition, it is not unique to the syndrome of preeclampsia. Edema is, nonetheless, an indicator of potential pregnancy complications. Moreover, it is more easily clinically monitored than blood pressure or proteinuria, especially in low resource environments where skilled healthcare providers with appropriate technology are not readily accessible.

2. Method of Approach

2.1 Problem Constraints

There are several issues when considering the development of a device to be used as a screening test for preeclampsia in pregnant women living in low resource environments. First, in order for the use of any device to actually be implemented, it needs to be very low cost. Also, it is highly preferable that a woman is able to monitor her own conditions. This is because clinics may be a long distance away and difficult to access. In addition, it is also likely that due to poverty, the clinics are crowded and very busy, and not likely to be able to find the time to monitor a pregnant woman, who is otherwise healthy, on a frequent basis.

Having a woman, who is potentially illiterate, monitor her own condition back in her own village adds additional constraints. It means that any device must be easy to use and require only minimum knowledge. It also must be durable considering the typical exposure to the elements in a village setting, and it must be comfortable and aesthetically pleasing, so as not to deter a pregnant woman from using it.

2.2 Problems with Current Detection Methods for Low Resource Environments

Most importantly in limited resource countries, limited access to skilled providers and equipment for blood pressure monitoring and urine protein measurements limits early detection.

Furthermore, for measuring an elevated blood pressure, a very basic problem is that, both in developing and developed countries, the blood pressure is often wrongly measured and recorded [2,5–7]. In addition, the blood pressure equipment needs to be maintained properly for it to work. For a, potentially illiterate, woman to use this equipment in her own village,

the device is also too costly and makes too many demands on the woman in terms of the expectation of literacy of numbers and a means to record them over time.

For diagnosing proteinuria, evaluating a urine sample (i.e., either by dipsticks or heating over a Bunsen burner [2]) is either too expensive (especially for repeated tests) or likely to be highly inaccessible to a pregnant woman in a low resource environment. This also has several problems for implementation in low resource environments, not least of which, are cultural issues in taking one and the technical skills required to interpret the results.

For using edema as an indicator, one can envision monitoring the size of the hands or face over time through the use of a tape measure and a record book. Again, however, this is too much to assume about a pregnant woman in a low resource environment, i.e., that she is able to read numbers and maintain a written record over time.

3 Results

3.1 System Design

The general principle of our method is to have each pregnant woman, early in pregnancy, fitted, on either her wrist or ankle, with a detection band, which is set to allow a preset expansion percentage (e.g., expansion by 5%). When edema causes the body part to swell to fit the detection band snugly, the pregnant mother knows that she should seek medical assistance. The length of the detection band is set by one of a set of calibration bands placed on the wrist or ankle of the patient at a clinic or by an itinerant health care worker. The time point in pregnancy chosen to do this fitting is between the 16th and 24th weeks, when the diagnosis of preeclampsia is uncommon.

The calibration bands are made of a stretchable material, such as an elastic band used for clothing, so that they stretch uniformly throughout. They are formed in a cuff, which can fit over the hand or the foot. A width of approximately a half an inch was chosen so that the woman's skin is not gathered around the band when sizing her. A few bands are provided, as the band chosen should also not be hanging loosely. However, not many are needed because of the stretchable nature of the elastic band.

Each band should be marked with a reference point, and another mark to indicate the safe expansion percentage (e.g., 5%), (Fig. 1). The stitching and marking of the band (either also by stitching or a printing process) must be done so as not to interfere with the uniform stretching of the band. In this way, the relationship between the reference point and the safe expansion percentage mark will remain at the same ratio, independent of the size of the wrist/ankle on which it is placed.

A measuring tape or similar device can be used in place of the calibration band and the safe expansion percentage calculated mathematically.

The clinical provider will then measure a detection band against the calibration band to obtain a length of 100% plus the safe expansion percentage (e.g., for a percentage expansion allowed of 5% this would mean a total length of 105%). The method of sizing the detection band is to wrap it around the calibration band on the pregnant mother's wrist (or ankle) and attach a clasp and split ring, pre-attached on one side, to the steel chain at the point of 100% plus the safe expansion percentage. Once the detection band is fitted, the calibration band can be removed.

The detection band was chosen to be made of a steel chain because of its affordability and high durability in extreme environments. Multiple sizes of chain are used, of which any extra on fitting can be left to dangle somewhat or cut with cutters (depending on the

availability of cutting shears). Each chain comes with a pre-attached clasp and split ring on one side for easy set-up. The chain links and split ring need to be sufficiently small to ensure accuracy while being easy for the clinical provider to attach manually. A link size of 2mm with a 6mm diameter split ring was found to work well in achieving these goals. In addition, a bracelet charm is added for aesthetic purposes (Fig. 2).

The detection band should then be worn for the pregnant woman to monitor her condition, although it does not have to be worn all the time, and can be easily removed, without effecting the calibration. When the chain expands to fit snug around the wrist (or ankle) the pregnant mother should seek medical assistance.

3.2 Current Status of Clinical Trials

Currently the Momedemameter is undergoing clinical trials at the Obstetrics Clinics at VCU Medical Center. Both pregnant patients at risk of preeclampsia (chronic hypertension, diabetes) and those without any identified risk factors are being recruited. To be enrolled in the study, the pregnancy gestation is required to be less than twenty-four weeks at recruitment. These studies focus solely on the use of a wrist bracelet for monitoring edema. The trials are intended to validate the method of using the Momedemameter, its acceptability, as well as obtaining a first approximation at a safe expansion limit. The sensitivity, specificity and predictive values for our device, along with the accompanying power analysis, will further be determined by these trials.

Acceptance by patients is very high: patients have been very willing to participate and many have commented that they like the bracelet. Of the 43 patients recruited to date, only one has lost her bracelet and was removed from the study.

4. Discussion/Conclusions

The paper presents a novel method of detecting edema, an indicator of pre-eclampsia. The system consists of: (1) a set of calibration bands used to determine a preset safe expansion percentage, and (2) a detection band fitted to 100% plus the safe expansion percentage. When edema causes the calibrated body part to swell to fit the detection band snugly, the pregnant mother knows to seek medical assistance. The detection band designed is not only simple to use but durable and aesthetically pleasing. The last is considered important to ensure the pregnant mother continues to wear it. The whole method, including calibration, requires little knowledge and is extremely portable, two practical issues in reaching out to women in villages of low resource environments. Even the method of production is simple enough to be done by individuals who are illiterate.

It should be acknowledged that lower and upper extremity edema are common in both normal pregnancies and those affected by preeclampsia. The extent of edema can also be influenced by ambient temperature and activity (e.g., vasodilation and dependency of the limbs). The clinical impression is that it is the severity of edema, not simply the presence, that appears to have some correlation with preeclampsia. Edema of the lower and upper extremities is of greater concern when it is associated with generalized edema including the face and hands, and rapid weight gain, the result of water retention, which is manifested by edema. These particular impressions have not been quantified or evaluated as quantifying these physical findings is difficult [9–10]. Thus, the Momedemameter is proposed as a sensitive, but not specific indicator of a potentially serious condition. Its use is proposed as a screening tool, which selects subjects for confirmation testing. As with even an ideal screening tool, the higher sensitivity runs the risk of false positives, but fewer false negative results, which is appropriate for a potentially life-threatening condition that can evolve rapidly [8].

As stated above, the Momedemameter is currently undergoing clinical trials at Virginia Commonwealth University to determine its validity and a first approximation at a safe expansion limit. If trials are successful, this method will also be considered for use in monitoring edema for other conditions, such as congestive heart failure, in low resource environments as well.

Acknowledgments

This work was supported in part by NIH grant P60 MD002256.

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Figure 1.
A Calibration Band.

Figure 2.
Detection Band