THE LABOR ASSISTER SYSTEM™
Automated System to Facilitate Normal Vaginal Delivery

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Abstract— **Childbirth is one of the most painful and exhausting biological processes. Over the years, methods have been developed to "improve" on the natural processes, facilitating labor and delivery in general as well as for pregnancies with special circumstances. A common example is epidural analgesia, which provides significant pain reduction. The application of manually applied abdomen massage (fundal pressure) is common, but its efficacy and safety have been questioned. In the present paper, we describe the Labor Assister, an automated system that augments secondary force with an inflatable belt. The system detects uterine contractions and simultaneously applies pneumatic pressure to the abdomen. A clinical trial measuring intrauterine pressures under various conditions was conducted for comparison. The results showed that the area under the curve during belt inflation (1777±301 mmHg·sec) is comparable with that of voluntary maternal pushing (1945±537 mmHg·sec). In addition, the results of preliminary clinical trials were promising, demonstrating significant reduction of the delivery time and the rate of instrumental delivery. Labor Assister applies secondary force in a safe and controlled manner compared with fundal pressure.**

1. INTRODUCTION

Childbirth takes place by a complex series of natural physiological and biological process. During the second stage of labor, a series of spontaneous contractions expel the newborn from the uterus. The duration and the interval of the contraction may vary, but generally contractions lasting 30~60 seconds take place every 2~10 minutes. The contraction starts by involuntary primary force; the mother's voluntary secondary force can shorten the duration of labor.

If the natural process does not lead to a delivery, forced delivery using instruments such as forceps or vacuum suction as well as cesarean surgery can be used. The utilization of instrumental or cesarean deliveries increases medical costs, may cause trauma to the mother and newborn, and delays maternal recovery.

Over the years, methods have been developed to "improve" on the natural processes, facilitating labor and delivery in general and for pregnancies with special circumstances. Since childbirth is affected by a number of factors including the mother's frame of mind and personality, it can be challenging to clearly prove the effectiveness of a given method. Epidural analgesia is widely used and effective in reducing labor pain [1]. There are, however, concerns that women, especially during their first baby delivery, may have weaker contractions and insufficient perception of contractions due to the use of narcotic analgesics. This may prolong labor and lead to a higher rate of instrumental delivery [2-6]. Although there is still debate over the aforementioned issues [7-9], the authors believe there is a need for augmentation of the natural labor force.

The manual application of pressure to the abdomen by a midwife during the second stage of labor (called fundal pressure) is a common practice to mechanically augment the natural secondary force (Figure 1). Kline-Kaye et al reported in 2002 that fundal pressure is used in up to 84% of all the deliveries in the U.S. [10]. Several authors have pointed out that the safety and efficacy of fundal pressure is not yet validated [11]. Fundal pressure increases the intrauterine pressure [12], but it may also increase the rate of perineal tears and bruises on the abdomen [13, 14].

The use of manually applied pressure to enhance secondary force goes back as far as the time of Hippocrates. However, the use of an automated inflatable belt allows the application of a consistent pressure to the abdomen, which can be safer than manually applied pressure. The results of clinical trials are promising; there were significant reductions in delivery time and the rate of instrumental deliveries [15, 16]. However, one clinical trial failed to demonstrate the effectiveness of the device [17]. In that trial, the device was applied an average of 26 minutes after the onset of the second stage labor, which may have adversely affected the study outcome.

In the present paper, we describe a fully automated system that applies pneumatic pressure to the mother's abdomen simultaneously with uterine contraction. The intrauterine pressure from the automated and manually applied secondary forces was measured and compared.

2. System Description

The product consists of three primary components: a microprocessor-based controller, a Tocodynamometer (Toco) contraction sensor, and a disposable inflatable belt (Figure 2).

Controller Description

The controller consists of a power supply, a display panel, an air pump, control valves, and printed circuit boards (Figure 3). 2 push buttons are provided on the front panel to start or pause the system. The front panel provides a visual indication of the system status. An audible alarm is activated if an error condition occurs or a switch button is pushed.

Toco Description

The Toco is attached to a separate elastic Toco belt that is wrapped around the mother, covering the area over the abdomen and uterus below the sternum. The Toco uses a strain-gauge based force sensor with an integrated amplifier (FS 03, Sensym USA). It senses the labor contraction and sends a signal to the controller over an electrical cable (Figure 4).

By analyzing the Toco signal, microprocessor firmware determines when a labor contraction has occurred, and inflates the belt by turning on the air pump. An on-off control scheme was implemented to maintain preset pressure (200mmHg) for a given duration of time (30 second).

The Toco signal that is processed by the controller is visualized in the LCD monitor, along with the current pressure of the belt. The controller has a RS232 port, allowing the output to be shown on a conventional fetal monitor.

Inflatable Belt Description

The belt is designed to cover a large part of the area over the abdomen and uterus beginning from the base of the sternum. The belt consists of a soft, biocompatible fabric cover that is in contact with the mother's skin with an inflatable bladder inside. The bladder is inflated by the air pump through a pneumatic hose connection so as to apply pressure to the patient's abdomen during second stage labor.

Safety Functions

The product has several safety features. The user interface has only two controls: "start" and "pause", each labeled accordingly. The absence of other controls minimizes the potential for misuse or confusion. There are redundant belt pressure sensors and air exhaust valves to minimize the possibility of malfunction. The system must have capability to depressurize the belt at any time, a primary safety requirement. A safety circuit opens the exhaust valve when the pressure exceeds 230 mmHg. A mechanical relief valve opens when the pressure is more than 250 mmHg.

The system has a latency period between each inflation. The controller is programmed to not pressurize the belt until at least 26 seconds have passed since the last inflation. This prevents continuous pressure in the event that the Toco were to malfunction.

3. Interuterine Pressure Measurement

Natural intrauterine pressure was measured in an IRB approved clinical protocol conducted by physicians (Shaofei Zhao,MD, JianQiu Yang, MD and Mingying Gai, MD) in the Department of OB/Gyn, Peking Union Medical College, Beijing China.

The controller is connected to an intrauterine pressure catheter (Intran Plus 400, Utah Medical Co.) to measure intrauterine pressure. The controller is calibrated to measure intrauterine pressure up to 189 mmHg (for comparison, a commercial fetal monitor measures only up to 100 mmHg). The catheter is inserted during the second stage when the amniotic membrane is ruptured and the cervix is fully dilated. The data obtained is transferred to a laptop computer through a RS-232 connector for analysis.

The study design involved 10 nulliparous women with uncomplicated pregnancies in which labor started spontaneously at term. All births were expected to be single deliveries with cephalic presentations. The intrauterine pressure was measured with and without supplementary belt pressure. The mothers were instructed to bear down during contractions whenever they felt the urge to push. To measure the intrauterine pressure increase associated exclusively with the application of belt pressure, the mothers were requested not to bear down.

4. Results of Intrauterine Pressure Measurement

The average maximum intrauterine pressures generated by each method are shown in Table 1 (All pressure values include a primary force component). Based on the results of the study, the following observations were made:

1. In two patients, the mother's bearing down alone produced a maximum intrauterine pressure above the monitor's upper detection limit (189 mmHg). The average maximum intrauterine pressure of the 10 women was 129 mmHg with a range of 60 to 172 mmHg.
2. Fundal massage (hand pushing) produced a maximum intrauterine pressure of up to 120 - 140 mmHg. The average maximum intrauterine pressure was 112 mmHg with a range of 104 to 120 mmHg.
3. The belt pressure (150 mmHg) generated a maximum intrauterine pressure of 80 - 110 mmHg. After baseline correction, the average maximum intrauterine pressure was 72 mmHg with a range of 59 to 87 mmHg.

The maximum intrauterine pressure produced by belt pressure was lower than that generated by maternal voluntary pushing or fundal massage. These results suggest that the device is safe.

The patterns of intrauterine pressure produced by various methods during labor are shown in Figure 5.

The secondary force produced by maternal voluntary pushing or fundal massage is generally not capable of generating a consistent force over the entire contraction period. Each of these methods of providing secondary force produces intermittent pressure (3-5 cycles of peaks and valleys) per contraction. In contrast, the labor assister produced a single consistent contraction profile that is similar to the primary force contraction with a slightly elevated intrauterine pressure. We believe that this type of force pattern is safer than the peak-and-valley patterns generated by other methods.

To support the claim that the force produced by the device during contractions is as effective as that by maternal voluntary pushing, we calculated the areas under the intrauterine pressure curve (AUC) by the following rules:

1. The AUC values were corrected for the baseline.
2. When the device was used, the AUC values were calculated for 30 seconds after the onset of contraction was detected.
3. When the device was not used, the AUC values were calculated for 30 seconds to yield the highest value.

The results of these calculations are described in Table 2. The difference between the maternal pushing (with voluntary contraction) and the no maternal pushing (only involuntary contraction) without any belt pressure (873 mmHg seconds) represents the AUC produced by voluntary maternal pushing. The device easily generates this amount of force with 100-150 mmHg belt pressures over 30 seconds. The authors believe that the use of the device alone is as effective as maternal voluntary pushing.

5. Preliminary Clinical Result

The complete reports of clinical studies conducted in China, Europe, and the United States, including the detailed protocol and statistical analysis, will be published elsewhere. Some of the results are briefly summarized as follows.

The results of clinical studies conducted for women who did not receive epidural analgesia showed that the

Labor Assister can reduce the incidence of instrument deliveries by 53% (11/108 patients, 10% vs. 25/114 patients, 22%) and the duration of second stage labor by 33%. There were no serious adverse events reported in these studies. To confirm the outcomes of the previous clinical trials [15-17], additional clinical tests are planned.

6. Discussion

The use of externally applied force to replace or enhance natural forces has been used in several therapies, including heart massage [18, 19] and massage machines for home use.

The Labor Assister provides a fully automated and controlled external pressure on the area over the mother's abdomen and uterus during second stage labor, resulting in increased intrauterine pressure. This demonstrates the advantages of the system compared with manually applied fundal pressure. The Labor Assister prevents the application of excessive pressure, reducing the likelihood of abdominal bruises and incidental trauma. Kline-Kaye and several other researchers expressed concern that the application of fundal pressure may lead to lawsuits over claims of trauma [10, 20]. Pan et al reported a rare case of uterine rupture resulting from external fundal pressure [14]. The Labor Assister can reduce or eliminate the potential for application of excessive pressure. The manual application of fundal pressure requires an experienced nurse. The automated system requires less skill and experience.

The pneumatic pressure of the belt is controlled in a rather simple manner. The Toco sensor determines the timing of the pressure, while the pressure and the duration are coded to be constant by the controller. Intelligent control of the pressure will significantly enhance the performance of the system without safety issues. As clinical data accumulates, the control scheme will be re-evaluated for improvement. The signal processing algorithm was tested in an empirical manner using the pressure and duration of the active inflation: false detection of the uterine contraction was less than 2%. Performance measures such as false detection rate will be published with additional clinical data.

The Labor Assister provides promising improvements in the clinical endpoints. The clinical benefit of manually applied fundal pressure, a common practice in the delivery room, has not been demonstrated in controlled clinical trials. The main benefits of the Labor Assister are its safety and the capacity to apply controlled pressure.

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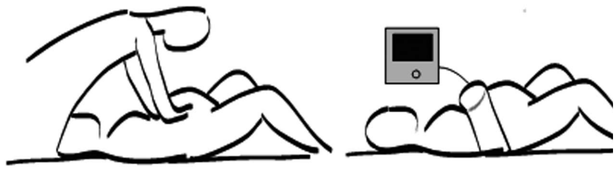

Fig. 1 An illustration of manual fundal massaging (left) and the proposed system (right)]

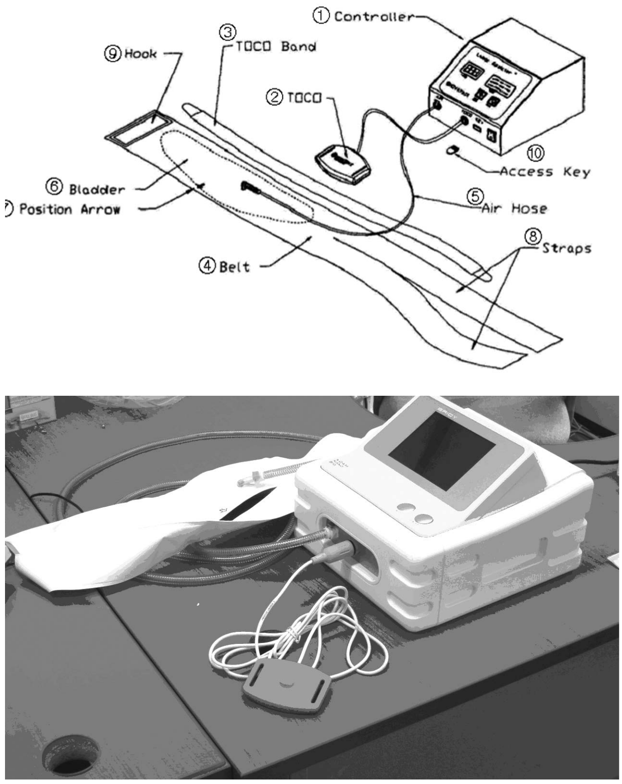

Fig. 2 (up) Diagram of the system (down) and photo of the whole system

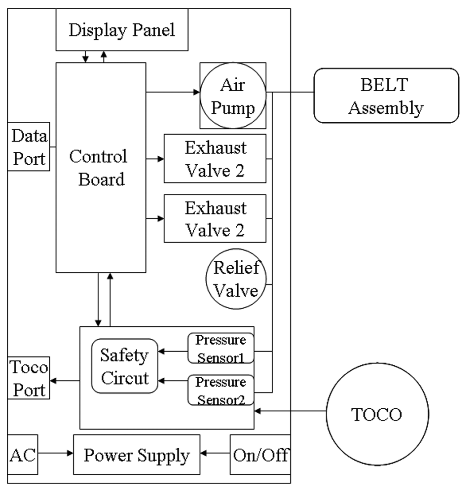

Fig. 3 Functional diagram of the Toco belt and controller

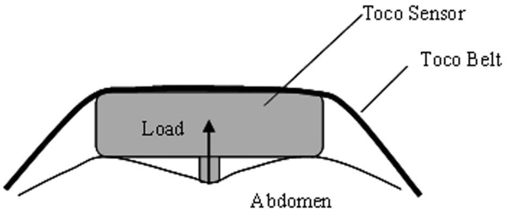

Fig. 4 The Toco sensor measures the repulsive load of the abdomen, which is related to the intrauterine pressure

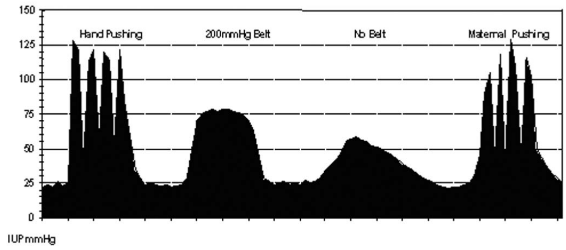

Fig. 5 Intrauterine pressure during hand pushing (manual fundal pressure), with inflatable belt, without belt, and with voluntary pushing, from left to right

Table 1. Intrauterine Pressure (IUP) Data Produced by Various Methods

Method	Average maximum IUP (mmHg)	Range (mmHg)
Maternal voluntary pushing	129 (±29)	60 - 172
Hand pushing	112 (±11)	104 - 120
Belt pressure at 150 mmHg	72 (±11)	59 - 87

Table 2. AUC Values at Various Belt Pressures with/without Maternal Voluntary Pushing (Average ±standard deviation)

Belt pressure	0 mmHg	50 mmHg	100 mmHg	150 mmHg
No maternal pushing_(mmHg sec)	1072 (±282)	1401 (±238)	1797 (±233)	1777 (±301)
Maternal pushing_(mmHg sec)	1945 (±537)	2314 (±454)	2654 (±490)	2740 (±511)