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(54) **Method for monitoring a childbirth process**

Verfahren zur Überwachung eines Geburtsprozesses

Procédé pour surveiller le déroulement d'un accouchement

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(73) Proprietor: **ObsteCare AB**
164 40 Kista (SE)

(72) Inventor: **Wiberg-Itzel, Eva**
182 39 Danderyd (SE)

(74) Representative: **Brann AB**
P.O. Box 3690
Drottninggatan 27
103 59 Stockholm (SE)

(56) References cited:
US-A- 5 377 673 US-B1- 6 409 680

- **LENNART NORDSTROM ET AL: "Fetal and Maternal lactate increase during active second stage of labour", BRITISH JOURNAL OF OBSTETRICS AND GYNAECOLOGY,, vol. 108, 1 March 2001 (2001-03-01), pages 263-268, XP002506982, ISSN: 0306-5456**
- **HENNER H ET AL: "Beitrag zur vergleichenden laktatbestimmung aus dem fruchtwasser bei normalem und pathologischem schawangershaftsverlauf [Contribution to comparative lactate determinations in amniotic fluid in normal and pathologic pregnancies]", GYNAEKOLOGISCHE RUNDSCHAU, S. KARGER AG, CH, vol. 17 Suppl 1, 1 January 1977 (1977-01-01), pages 113-115, XP008099385, ISSN: 0017-6001**

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Description

Technical Field

[0001] The present invention relates to a method for monitoring a childbirth process of a pregnant woman.

Background of the Invention

[0002] One problem in today's delivery methods is that women suffer from dystocya during labor. This could result in that the delivery does not progress as desired and that the labor is drawn out without a successful natural childbirth. The pregnant woman may become frustrated and it may be necessary to use methods such as, vacuum, forceps or caesarean to deliver the baby. The dystocya of the pregnant woman may also expose the fetus to injury and fatigue.

[0003] The lactate concentration in the blood of the fetus has been measured in the past to control that the fetus does not suffer from oxygen deficiency. However, the lactate concentration in the fetus does not indicate the condition of the pregnant woman. Same holds for the lactate concentration measured in the blood of the mother (see Nordström et al., British Journal of Obstetrics and Gynaecology, 2001, vol. 108, pp. 263-268) and in the amniotic fluid (see Henner et al., Gynäk. Rdsch. 17 (Suppl. 1), 1977, pp. 113-115).

[0004] There is a need to more effectively determine and control the condition of woman suffering from dystocya at an early stage to avoid unnecessary labor before using surgical and alternative childbirth methods.

Summary of the Invention

[0005] The method of the present invention, which is defined in independent claim 1, provides a solution to the above-outlined problems. More particularly, the method is for monitoring a childbirth process of a pregnant woman. In a first measuring step, a first lactate concentration of vaginal fluids is measured. In a comparison step, it is determined if the measured lactate concentration is greater than a predetermined lactate concentration value that indicates that amniotic fluid has passed from amnion of the pregnant woman and the membrane has ruptured. In a second measuring step, a second lactate concentration is measured. In a second comparison step, it is determined if the measured second lactate concentration is greater than a lactate threshold interval. Furthermore, in further aspects which are not in accordance with the present invention as defined by the claims, when the second lactate concentration is less than the lactate threshold interval the pregnant woman is stimulated in a stimulating step to give birth. When the second lactate concentration is greater than the lactate threshold interval and labor does not progress normally, the woman may be subjected to alternative childbirth options such as a surgical childbirth, to prevent unnecessary agonizing and drawn out efforts to give birth.

Brief Description of the Drawing

[0006] Fig. 1 is a schematic flow chart showing some of the steps of the method of the present invention, together with further aspects of a method which is not in accordance with the present invention as defined by the claims.

Detailed Description

[0007] With reference to Fig. 1, the method 10 of the present invention includes a measuring step 12 that measures a lactate concentration 15a in fluids, such as vaginal fluids, in connection with pregnancy to determine whether the amniotic fluids have passed or are in the process of being passed from the amnion. In general, the uterus muscle of pregnant women produces lactate so that the lactate concentration of the vaginal fluids may be measured to provide a measurement of the amount of lactate produced by the uterus muscle. Non-pregnant women often have no or very little lactate in the vaginal fluids.

[0008] If the lactate concentration 15a is higher than a predetermined lactate concentration 13, such as 4-5 mmol/l, more preferably higher than 4.5 mmol/l, as indicated in a comparison step 14 then it may be concluded that the membranes have ruptured and amniotic fluids likely have passed and that the childbirth labor is likely to start after a waiting period 16. It is to be understood that the 4-5 mmol/l is an illustrative example that applies to most women and that the invention is not limited to the values used in the examples.

[0009] If the lactate concentration is lower than 4.5 mmol/l then there is a high likelihood that the amniotic fluids are still contained within the amnion. The lactate concentration may again be measured in a measuring step 20 after a waiting period 18. It is again determined in the comparison step 14 whether the lactate concentration is more or less than 4.5 mmol/l. If the lactate concentration is again below 4.5 mmol/l, a second measuring may be conducted later and the measuring may be repeated at suitable time intervals until the lactate concentration exceeds 4.5 mmol/l or it is obvious that the amniotic fluids have passed.

[0010] As indicated above, if the lactate concentration measured in the measuring step 12 is above 4.5 mmol/l, the next step is to wait for about two days or so to see if the woman starts the labor by herself. In a determining step 22, it is determined whether the labor has started or not. If the labor has started and is progressing normally then the childbirth procedure 24 may proceed. If it is determined in the determining step 22 that the labor has not started or the labor is not progressing normally, a lactate concentration 15b is measured in a measuring step 26.

[0011] In a comparison step 28 it is then determined if

the lactate concentration 15b as measured in the measuring step 26 is within a lactate threshold interval 29 that may be about 8-10 mmol/l. If the lactate concentration as measured in the step 26 is not within the threshold interval 29, then it is determined in a comparison step 30 whether the lactate concentration is less than the threshold interval 29 or about 8 mmol/l. If the lactate concentration as measured in step 26 is greater than the threshold interval 29 then a waiting step 32, such as a couple of hours, may start to see if the labor progress normally. If labor does not progress normally, in a method not in accordance with the present invention as defined by the claims alternative childbirth options may be considered such as caesarean, forceps or the use of suction cups that are connected to vacuum to draw out the baby. An important feature of the present invention is that the monitoring of the lactate concentration may be used to predict whether the woman is likely to give a natural birth or not without forcing the pregnant woman to go through long and agonizing efforts to give birth. It is therefore possible to use alternative childbirth options at a relatively early stage. It is to be understood that the 8-10 mmol/l is an illustrative example that applies to most women and that the invention is not limited to the values used in the examples.

[0012] If the lactate concentration, as measured in step 26, is less than the threshold interval 29, then in a method not in accordance with the present invention as defined by the claims the woman may be stimulated with drugs or other aids to give birth in a stimulation step 34. In a determining step 36, it may be determined if the labor is progressing normally. If the labor is progressing normally the woman may proceed to give birth 38. If the labor is not progressing normally, the lactate concentration may again be measured in the measuring step 26 and the process continues in the comparison step 28, as described above.

[0013] If it is determined in the comparison step 28 that the lactate concentration, as measured in step 26, is at the threshold interval 29, such as between 8-10 mmol/l, then it is determined whether the labor is progressing normally in a determining step 40. If labor is progressing normally, the woman may proceed to give birth 42. In a method not in accordance with the present invention as defined by the claims, if labor is not progressing normally, the woman may be stimulated to give birth in the stimulation step 34 and the process continues to the determining step 36, as described above.

[0014] The various processing loops may continue until the woman either gives birth by herself or is subjected to alternative childbirth options (which are themselves not part of the method in accordance with the present invention). As indicated above, an important feature of the present invention is that the woman may be prevented from agonizing and long childbirth efforts before alternative childbirth options are used. Alternative childbirth options may be used at an earlier stage when the lactate concentration indicates that the uterus muscle is operating above the lactate threshold without resulting in a natural childbirth.

[0015] While the present invention has been described in accordance with preferred compositions and embodiments, it is to be understood that certain substitutions and alterations may be made thereto without departing from the scope of the following claims.

Claims

1. A method of monitoring a childbirth process of a pregnant woman, comprising:

   - measuring in a first measuring step (12) a lactate concentration (15a) of vaginal fluids;
   - comparing in a first comparison step (14) said measured lactate concentration (15a) to a predetermined lactate concentration (13);

   wherein said measured lactate concentration (15a) being higher than said predetermined lactate concentration (13) indicates that the membrane has ruptured and amniotic fluid has passed from an amnion of said woman.

2. The method according to claim 1 wherein, if said measured lactate concentration (15a) is lower than said predetermined lactate concentration (13), the method further comprises measuring the lactate concentration (15a) in a further measuring step (20) after a waiting period (18), and comparing in a further comparison step (14) said measured lactate concentration (15a) to the predetermined lactate concentration (13); and optionally repeating said steps at suitable time intervals until the measured lactate concentration (15a) exceeds the predetermined lactate concentration (13).

3. The method according to claim 1 wherein, if said measured lactate concentration (15a) exceeds said predetermined lactate concentration (13), the method further comprises determining, after a waiting period (16), in a determining step (22), whether labor has started and whether labor is progressing normally.

4. The method according to claim 3, comprising, if labor is not progressing normally:

   - measuring in a second measuring step (26) a second lactate concentration (15b) of vaginal fluids;
   - comparing in a second comparison step (28) said measured second lactate concentration (15b) to a lactate concentration threshold interval (29), to determine whether said measured second lactate concentration (15b) is within said

lactate concentration threshold interval (29).

5. The method according to claim 4 wherein, if said measured second lactate concentration (15b) is within said lactate concentration threshold interval (29), the method further comprises determining in a second determining step (40) whether labor is progressing normally.

Patentansprüche

1. Verfahren zum Überwachen eines Entbindungsprozesses einer schwangeren Frau, umfassend:

   - Messen, in einem ersten Messschritt (12), einer Laktatkonzentration (15a) von Vaginalfluiden;
   - Vergleichen, in einem ersten Vergleichsschritt (14), der gemessenen Laktatkonzentration (15a) mit einer vorbestimmten Laktatkonzentration (13);
   - wobei, wenn die gemessene Laktatkonzentration (15a) höher als die vorbestimmte Laktatkonzentration (13) ist, dies anzeigt, dass die Membran gerissen ist und Fruchtwasser aus einer Fruchtblase der Frau ausgetreten ist.

2. Verfahren nach Anspruch 1, wobei, wenn die gemessene Laktatkonzentration (15a) niedriger als die vorbestimmte Laktatkonzentration (13) ist, das Verfahren weiter ein Messen der Laktatkonzentration (15a) in einem weiteren Messschritt (20) nach einer Wartezeit (18) und ein Vergleichen der gemessenen Laktatkonzentration (15a) mit der vorbestimmten Laktatkonzentration (13) in einem weiteren Vergleichsschritt (14); und optional

   - ein Wiederholen der Schritte in geeigneten Zeitintervallen, bis die gemessene Laktatkonzentration (15a) die vorbestimmte Laktatkonzentration (13) übersteigt, umfasst.

3. Verfahren nach Anspruch 1, wobei, wenn die gemessene Laktatkonzentration (15a) die vorbestimmte Laktatkonzentration (13) übersteigt, das Verfahren weiter ein Bestimmen, nach einer Wartezeit (16), in einem Bestimmungsschritt (22), ob die Wehen begonnen haben und ob die Wehen normal voranschreiten, umfasst.

4. Verfahren nach Anspruch 3, umfassend, wenn die Wehen nicht normal voranschreiten:

   - Messen, in einem zweiten Messschritt (26), einer zweiten Laktatkonzentration (15b) von Vaginalfluiden;
   - Vergleichen, in einem zweiten Vergleichsschritt (28), der gemessenen zweiten Laktatkonzentration (15b) mit einem Laktatkonzentration-Schwellenintervall (29), um zu bestimmen, ob sich die gemessene zweite Laktatkonzentration (15b) innerhalb des Laktatkonzentration-Schwellenintervalls (29) befindet.

5. Verfahren nach Anspruch 4, wobei, wenn sich die gemessene zweite Laktatkonzentration (15b) innerhalb des Laktatkonzentration-Schwellenintervalls (29) befindet, das Verfahren weiter ein Bestimmen, in einem zweiten Bestimmungsschritt (40), ob die Wehen normal voranschreiten, umfasst.

Revendications

1. Procédé de surveillance d'un accouchement d'une femme enceinte, comprenant :

   - la mesure lors d'une première étape de mesure (12) d'une concentration de lactate (15a) de fluides vaginaux ;
   - la comparaison lors d'une première étape de comparaison (14) de ladite concentration de lactate mesurée (15a) à une concentration de lactate prédéterminée (13) ;

   dans lequel ladite concentration de lactate mesurée (15a) qui est supérieure à ladite concentration de lactate prédéterminée (13) indique que la membrane s'est rompu et que du liquide amniotique est passé depuis un amnios de ladite femme.

2. Procédé selon la revendication 1, dans lequel, si ladite concentration de lactate mesurée (15a) est inférieure à ladite concentration de lactate prédéterminée (13), le procédé comprend en outre la mesure d'une concentration de lactate (15a) lors d'une autre étape de mesure (20) après une période d'attente (18), et la comparaison lors d'une autre étape de comparaison (14) de ladite concentration de lactate mesurée (15a) à ladite concentration de lactate prédéterminée (13) ; et optionnellement la répétition desdites étapes à intervalles de temps appropriés jusqu'à ce que la concentration de lactate mesurée (15a) dépasse la concentration de lactate prédéterminée (13).

3. Procédé selon la revendication 1, dans lequel, si ladite concentration de lactate mesurée (15a) dépasse ladite concentration de lactate prédéterminée (13), le procédé comprend en outre le fait de déterminer, après une période d'attente (16), lors d'une étape de détermination (22), si le travail a commencé et si le travail se déroule normalement.

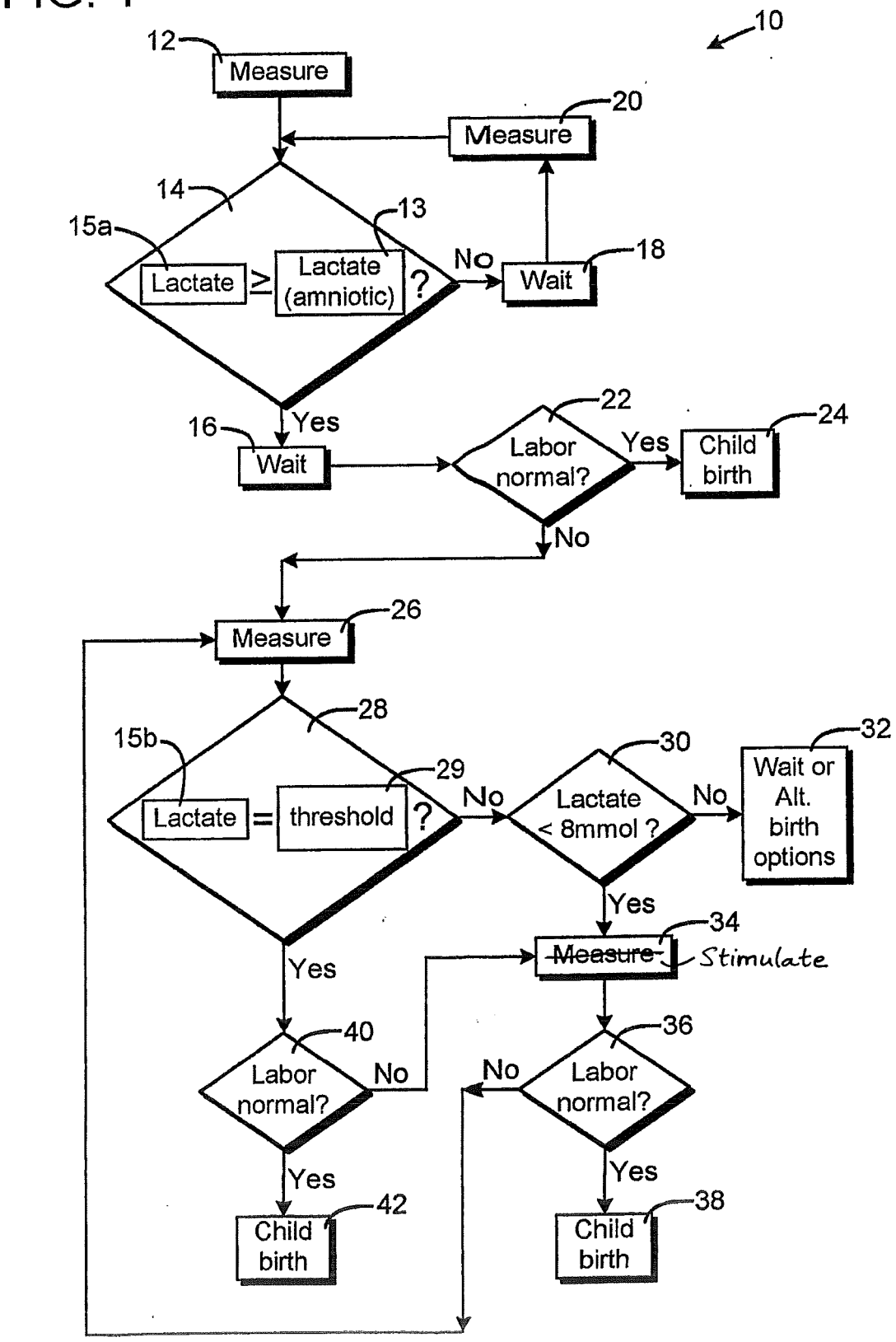
4. Procédé selon la revendication 3, comprenant, si le

travail ne se déroule pas normalement :

- la mesure lors d'une seconde étape de mesure (26) d'une seconde concentration de lactate (15b) de fluides vaginaux ;
- la comparaison lors d'une seconde étape de comparaison (28) de ladite seconde concentration de lactate mesurée (15b) à un intervalle de seuil de concentration de lactate (29), pour déterminer si ladite seconde concentration de lactate mesurée (15b) se trouve dans ledit intervalle de seuil de concentration de lactate (29).

5. Procédé selon la revendication 4 dans lequel, si ladite seconde concentration de lactate mesurée (15b) se trouve dans ledit intervalle de seuil de concentration de lactate (29), le procédé comprend en outre le fait de déterminer lors d'une seconde étape de détermination (40) si le travail se déroule normalement.

FIG. 1


10
12
Measure
20
Measure
14
15a
13
Lactate
≥
Lactate (amniotic)
?
No
Wait
18
16
Yes
Wait
22
Labor normal?
Yes
Child birth
24
No
26
Measure
28
15b
29
Lactate
=
threshold
?
No
30
Lactate < 8mmol ?
No
Wait or Alt. birth options
32
Yes
34
Measure
Stimulate
Yes
40
Labor normal?
No
No
36
Labor normal?
Yes
Yes
42
Child birth
38
Child birth

REFERENCES CITED IN THE DESCRIPTION

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Non-patent literature cited in the description

- **NORDSTRÖM et al.** *British Journal of Obstetrics and Gynaecology,* 2001, vol. 108, 263-268 **[0003]**
- **HENNER et al.** *Gynäk. Rdsch.,* 1977, vol. 17 (1), 113-115 **[0003]**

专利名称(译)	监测出生过程的程序		
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当前申请(专利权)人(译)	OBSTECARE AB		
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发明人	WIBERG-ITZEL, EVA		
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摘要(译)

该方法用于监测孕妇的分娩过程。 在测量步骤（12）中，测量阴道液的乳酸浓度（15a）。 在比较步骤（14）中，确定所测量的乳酸浓度是否大于预定的乳酸浓度（13），该预定的乳酸浓度指示羊水已经从孕妇的羊膜中流出。 在测量步骤（26）中，测量乳酸浓度（15b）。 在比较步骤（28）中，确定所测量的乳酸盐浓度（15b）是否大于乳酸盐阈值间隔（29）。 当乳酸盐浓度（15b）小于乳酸盐阈值间隔（29）时，在刺激步骤（34）中刺激孕妇分娩。

FIG. 1