Non-invasive hemodynamic measurements early in pregnancy
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Modelflow: a new method for noninvasive assessment of cardiac output in pregnant women

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Abstract

Objective: Estimation of cardiac output by continuous finger arterial pressure waveform analysis with Modelflow is a noninvasive technique for beat-to-beat hemodynamic assessment. The purpose of this study was to compare this method in pregnant women with the more commonly used Doppler echocardiography.

Study design: In 16 primigravid women, stroke volume was measured serially in first, second and third trimester and after pregnancy by the Modelflow method and by Doppler echocardiography. Aortic diameter and compliance were assessed serially by echocardiography and pulse wave velocity measurements.

Results: Aortic compliance was increased significantly in pregnancy compared to non pregnant values, but aortic diameter did not change. After adjustment for pregnancy-related changes in pulse wave velocity, blood pressure and heart rate, Modelflow stroke volume measurements gave comparable results to Doppler echocardiography during and after pregnancy. The observed variation was similar to reported comparisons of Doppler echocardiography with thermodilution.

Conclusion: After adjustment for pregnancy the Modelflow method is a useful research tool for assessment of stroke volume in pregnant women and offers the advantage of continuous measurement and convenience of application.
Introduction

Measurement of cardiovascular function is important for the understanding and treatment of hypertensive complications of pregnancy. Most studies on cardiovascular function in pregnancy use Doppler echocardiography, because this technique is non-invasive and considered sufficiently accurate. However, Doppler echocardiography is demanding technically, and the upward shift of the diaphragm late in pregnancy may interfere with the method. Continuous finger arterial pressure waveform registration by Portapres (TNO-TPD, Finapres Medical Systems, Amsterdam, the Netherlands) is a non-invasive technique for beat-to-beat hemodynamic assessment. This method is based on the volume-clamp method of Peñáz and the individual calibration technique (physiocal) of Wesseling et al. It has been established as a reliable tool for non-invasive beat-to-beat blood pressure signal recordings in nonpregnant and in pregnant women. Besides blood pressure, this technique allows estimation of stroke volume (SV) on a beat-to-beat basis by arterial waveform analysis. Modelflow could offer great opportunities for obstetric research on hemodynamics in physiologic and pathologic pregnancies. However, the method has never been validated in pregnant women. There are indications that the aorta characteristic elements, aorta diameter and aorta compliance, which are incorporated in the Modelflow method, change under influence of pregnancy. An increase of aorta compliance during pregnancy might cause an underestimation of SV.

We therefore compared the Modelflow method for SV assessment in pregnancy with the more commonly used Doppler echocardiography technique to see whether changes in aorta characteristics during pregnancy influence the Modelflow estimation of SV. At the same time, we measured aorta diameter and aorta compliance, because these parameters might be useful for the adjustment of Modelflow during pregnancy.

Methods

Subjects
Twenty-one healthy, normotensive primigravid women with a singleton pregnancy and a gestational age of < 12 weeks were selected at the outpatient clinic of our hospital. Gestational age was confirmed by crown-rump measurement during the first trimester. They had no medical history of cardiovascular disease, and no subject had vaso-active medication. All had a normal blood pressure at inclusion (systolic ≤120 mmHg; diastolic, ≤80 mmHg) that was measured by sphygmomanometer.

The Medical Ethical Committee of our hospital approved the study, and all participants gave informed consent.
Measurements
All women underwent identical study protocols. Data were collected serially at 4 times: end of first trimester (12-14 weeks), second trimester (21-23 weeks), third trimester (32-34 weeks), and approximately 5 months after delivery (16-26 weeks).
At each visit, data were acquired for the estimation of aortic characteristics and for SV estimation. Measurements were performed after a period of at least 10 minutes of rest and in a 30-degree left lateral tilt position to avoid vena cava compression. Participants were asked to refrain from caffeine and smoking on the day of study and were instructed not to move or speak during the procedure. All echocardiographic measurements were performed by an experienced cardio-sonographer, according to the recommendations of the American Society of Cardiology. Measurements were performed online with an ultrasound system (Philips / ATL HDI 3000; Eindhoven, The Netherlands) with a 3.0 MHz transducer and were recorded on videotape. Off-line, a second researcher reviewed all measurements.

Aortic characteristics
Aortic input impedance is reflected by aortic distensibility or compliance. The speed of the pressure pulse, generated by ventricular ejection, is determined by the elastic and geometric properties of the arterial wall and the blood density. Because blood is incompressible, the material properties of the arterial wall and its thickness, elasticity, and lumen diameter become the major determinants of pulse wave velocity (PWV). Measurement of PWV is a simple method for estimating aorta compliance. PWV can be calculated from the pulse transit time and the distance traveled by the pulse. For the estimation of PWV, pressure waves of the common carotid artery and the femoral artery were registered by applanation tonometry. Transducers were positioned simultaneously at the base of the neck and at the femoral fold. Because respiration influences the PWV, pulse waves were registered over a period of 60 seconds. After each procedure, the linear distance between the carotid and femoral site was measured with a marking gauge. The recorded arterial pulse signal was analyzed offline on a computer by dedicated software written in Delphi 4.0 (Velowaves; TNO, Amsterdam, The Netherlands; Figure 1). For each pulse wave, the upstroke was determined, and the time difference between carotid and femoral pulse waves was calculated. PWV was calculated from the average time difference of all recorded pulses and the distance that was measured. This distance was adjusted by subtraction of the distance between the supra-sternal notch to the carotic artery measurement site from the total distance between both measurement sites.
Aortic diameter was measured by echocardiography at the aortic sinus, the ascending aorta and the left ventricular outflow tract at systole and diastole of the cardiac cycle from images made in the parasternal long axis plane. Measurements were performed 3 times at each session. The average of 3 measurements was used for analysis.
Modelflow

Stroke volume

SV was estimated by 2 techniques: Doppler echocardiography and continuous finger arterial pulse wave registration.

With Doppler echocardiography, the velocity in the left ventricular outflow tract was measured in the apical 5-chamber view. The velocity integral in the left ventricular outflow tract was recorded, and the mean was calculated from 5 consecutive ejections. The SV was calculated by multiplication of the left ventricular outflow tract area by the time velocity integral. The cardiac output (CO) was obtained by multiplication of the SV with the heart rate (HR).

Continuous finger arterial pulse wave registration was performed by Portapres (TNO-TPD, Finapres Medical Systems, Amsterdam, the Netherlands). An appropriate size finger cuff was applied at the middle finger of the woman’s left hand, and the cuffed finger was kept at heart level during the procedure by a sling to avoid hydrostatic pressure influences. This inflatable cuff comprises an infrared sensor that is connected to a small box that is attached to the wrist that encloses a fast servo-controlled pressure system for continuous adjustment of cuff pressure according to changes in the output of the infrared sensor. Thereby, cuff pressure is related directly to arterial pulse pressure. The cuff and wrist-box are connected to a main unit that holds the air pump, electronics, and a
computer. Modelflow analyzed SV and CO over a period of 30 seconds of finger arterial pulse waves registration that was recorded simultaneously with the echocardiography measurements.

Left ventricular contraction causes inflow of blood into the arterial system, but this inflow is opposed by arterial counter pressure and aortic and peripheral arterial input impedance. The Modelflow method simulates this behavior. The computation of flow from pressure by Modelflow is based on the 3 major properties of the aorta and arterial system: aortic characteristic impedance \( (Z_0) \), a dynamic property of the aorta that impedes pulsatile outflow from the ventricle; windkessel or buffer compliance \( (C_w) \), the ability of the aorta and arterial system to store elastically the cardiac stroke output from the left ventricle; and peripheral resistance \( (R_p) \), the Poiseuille resistance of all vascular beds together. The value of total peripheral resistance in the model is the sum of \( Z_0 \) and \( R_p \). Given input pressure, aortic systolic inflow is determined principally by the time constant \( Z_0 C_w \). \( Z_0 \) and \( C_w \) can be calculated for any pressure if the aorta wall pressure and distension characteristics are known. These characteristics were estimated from 45 human aortas in vitro. Aortic wall distensibility was dependent on gender and age and can be calculated reliably with these parameters. However, maximum aorta area at the lower thoracic level had a scatter of approximately 20% in the in vitro study. This uncertainty affects reliability of the calculations and exact measurement could improve estimations. Aortic pressure is estimated for each heart beat form the integral of the finger arterial pressure wave. Flow, finally, is computed by simulation of the behavior of the model under the applied arterial pressure pulsation. The values for windkessel compliance and characteristic impedance, as a function of instantaneous pressure, are inserted in the model. Simulation is done digitally, and model computations are repeated for each new pressure sample that is taken. Left ventricular SV is computed by the integration of model flow during systole; CO is computed by multiplication of SV with instantaneous HR. The systolic duration and the heartbeat interval are derived from the pressure waveform. This approach was called the Modelflow method. SV estimation by this method has been investigated extensively in a variety of situations, although never during pregnancy. A measurement error of approximately 20% was described when compared to thermodilution. After calibration, however, the measurement error remained <10%. During the whole study protocol, blood pressure was recorded continuously by Portapres. Pressure registration was corrected for the pressure decay over the arm by the return to flow method. Blood pressure was analyzed by Beatscope (TNO, Amsterdam, The Netherlands). The pressure levels for each beat were recognized after digital low pass filtering of 24.5 Hz at 200 Hz sampling frequency. Before commencement of the procedure, blood pressure was measured with a standard calibrated aneroid sphygmomanometer.
Statistics
For each parameter, a 1-way repeated measures analysis of variance was used to compare data gathered at various periods. Correlations between HR and PWV and between mean arterial pressure and PWV were analyzed. If significant, 1-way repeated measures analysis of covariance, to compare PWV data gathered at various periods, was performed after correction for this parameter. Data that were obtained at different periods were compared by post-hoc analysis (Bonferroni). A probability value ≤ .05 was considered statistically significant. Relation between blood pressure and aortic diameter was analyzed from the difference between diastolic and systolic diameter.

The amount of agreement between both methods for SV measurement was analyzed as the ratio of the difference and the average of both measurements at each session, according to the method of Bland and Altman, 27 and made visual by a Bland-Altman plot. If a difference would be observed, we intended to calculate an algorithm for adjustment of Modelflow for pregnancy, assuming that Doppler echocardiography was independent of pregnancy. Nonlinear regression was performed with BMDP 9R (BMDP Statistical Software, Cork, Ireland) with systolic blood pressure, HR, PWV and a design parameter “pregnancy” (1=pregnant, 0=postpartum period) and a number of mathematic combinations of these parameters. Selection for the best subset was based on the lowest Mallow’s Cp, which accounts for number of cases and number of parameters.

All other statistical calculations were performed with SPSS software (version 12.02; SPSS Inc, Chicago, IL). We estimated that a study population of 16 women would enable the detection of a difference of 10% between the 2 methods of measurement of a parameter with a SD of 10% at alpha 0.05 and beta 0.8 with a 2-sided test.

Results

Twenty-one women were included, but 5 women did not complete all measurements. Four women resigned from participation after the first measurement and 1 woman was hospitalized for preterm uterus contractions.

Results of 16 women who completed all measurements were used for the analysis. Characteristics are presented in Table 1. The pregnancies were uneventful and all women were delivered at term of healthy babies with a birth weight of > 10th percentile.28

Data on aorta characteristics (PWV and aorta diameter) are presented in Table 2. PWV was significantly lower during pregnancy, when compared with the nonpregnant state 5 months after delivery. Within pregnancy, no significant change was observed between the 3 trimesters (Figure 2). HR was higher, and mean arterial pressure lower during pregnancy when compared to measurements at 5 months after delivery (Table 3). The difference between third trimester and postpartum measurements reached statistical significance. HR and blood pressure are related generally to PWV. In our data, only
mean arterial pressure had a significant inverse correlation with PWV (P= .046). After correction for mean arterial pressure, PWV was still significantly lower in all trimesters, when compared with postpartum values. Among trimesters, no statistically significant change was observed.
We did not observe statistically significant changes in diastolic or systolic aortic diameter during pregnancy. Measurement of aortic diameter five months postpartum was comparable to measurements during pregnancy.

Data on SV and CO that were measured by Doppler echocardiography and data that were analyzed by Modelflow are presented in Table 3.

For analysis of the agreement between both methods, the difference between the echo-Doppler and the Modelflow SV measurements was plotted against the average of both measurements (Bland-Altman plot) (Figure 3). For SV, the mean ratio of the difference and the average of echocardiography and Modelflow measurement was 0.082 ± 0.19 (SD) for the measurements during pregnancy and -0.082 ± 0.19 after delivery. The difference between pregnant and non-pregnant values was statistically significant (P=}

### Table 3 Measurements by echocardiography and Modelflow

<table>
<thead>
<tr>
<th>Variable</th>
<th>Trimester of gestation</th>
<th>Postpartum period</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First</td>
<td>Second</td>
<td>Third</td>
</tr>
<tr>
<td>Echocardiography</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SV (mL)</td>
<td>81 ± 12</td>
<td>80 ± 15</td>
<td>75 ± 16</td>
</tr>
<tr>
<td>HR (beats/min)</td>
<td>70 ± 10</td>
<td>76 ± 8</td>
<td>78 ± 10 †</td>
</tr>
<tr>
<td>CO (L/min)</td>
<td>5.6 ± 1.1</td>
<td>6.1 ± 1.2</td>
<td>5.7 ± 1.0</td>
</tr>
<tr>
<td>Modelflow</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SV (mL)</td>
<td>74 ± 21</td>
<td>77 ± 17</td>
<td>70 ± 14</td>
</tr>
<tr>
<td>HR (beats/min)</td>
<td>73 ± 9</td>
<td>76 ± 8</td>
<td>83 ± 9 †</td>
</tr>
<tr>
<td>CO (L/min)</td>
<td>5.3 ± 1.6</td>
<td>5.8 ± 1.3</td>
<td>5.7 ± 1.3</td>
</tr>
<tr>
<td>Total peripheral vascular resistance (μm)</td>
<td>0.96 ± 0.34</td>
<td>0.81 ± 0.24</td>
<td>0.81 ± 0.24</td>
</tr>
<tr>
<td>SV adjusted (mL)</td>
<td>81 ± 10</td>
<td>80 ± 8</td>
<td>76 ± 10</td>
</tr>
<tr>
<td>CO (L/min)</td>
<td>6.0 ± 1.1</td>
<td>6.1 ± 1.0</td>
<td>6.3 ± 1.1 †</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>112 ± 9</td>
<td>107 ± 9</td>
<td>100 ± 12 †</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>62 ± 7</td>
<td>58 ± 7</td>
<td>58 ± 7</td>
</tr>
<tr>
<td>Mean arterial pressure (mmHg)</td>
<td>79 ± 7</td>
<td>74 ± 6</td>
<td>72 ± 8 †</td>
</tr>
</tbody>
</table>

Data presented as mean ± SD
* P < .05 denotes that differences exist across the 4 periods of measurement.
† Statistically significant difference with postpartum measurement (post-hoc Bonferroni analysis)
and provides evidence of an underestimation of SV by Modelflow during pregnancy and overestimation after pregnancy. For CO, the mean ratio's were, respectively, 0.041 ± 0.19 and -0.078 ± 0.16, a statistically significant difference (P= .026). These ratios did not differ significantly between trimesters.

Modelflow measurements were adjusted for pregnancy by nonlinear regression analysis, with Doppler echocardiography as reference. The following algorithm was calculated:

\[
\text{Adjusted MF} = -264.53 + 5.951 \times \text{SBP} - 0.029932 \times \text{SBP}^2 + 0.00010725 \times \text{HR} \times \text{SBP} \times \text{MF} - 0.0328138 \times \text{MF}^2 \times (\text{HR} / \text{PWV} \times \text{SBP}) + 0.0018650 \times \text{MF}^{(\text{SBP}/\text{HR})} + 11.5868 \times \text{P},
\]

where MF is the Modelflow measurement, SBP is systolic blood pressure, HR is heart rate, PWV is pulse wave velocity, and P is 1 when pregnant and 0 when not. All parameters had statistical significance (2 sided analysis; P< .05) and Mallows’C<sup>p</sup> was 0.05.

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>Measurements</th>
<th>Method</th>
<th>SV change (%)</th>
<th>HR change (%)</th>
<th>CO change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robson et al&lt;sup&gt;39&lt;/sup&gt;</td>
<td>13</td>
<td>Serially, preconceptional and from 8 wk</td>
<td>Doppler ultrasonography</td>
<td>66 ➔ 84(27)</td>
<td>75 ➔ 87(16)</td>
<td>4.9 ➔ 7.2(48)</td>
</tr>
<tr>
<td>Mabie et al&lt;sup&gt;40&lt;/sup&gt;</td>
<td>18</td>
<td>Serially from 8-11 wk and postpartum period</td>
<td>Doppler ultrasonography</td>
<td>84 ➔ 99(18)</td>
<td>66 ➔ 87(32)</td>
<td>5.7 ➔ 8.7(52)</td>
</tr>
<tr>
<td>Duvekot et al&lt;sup&gt;37&lt;/sup&gt;</td>
<td>10</td>
<td>Serially from 5 wk and postpartum period</td>
<td>Doppler ultrasonography</td>
<td>73 ➔ 72(-1)</td>
<td>66 ➔ 87(32)</td>
<td>4.8 ➔ 6.5(35)</td>
</tr>
<tr>
<td>Lucini et al&lt;sup&gt;41&lt;/sup&gt;</td>
<td>14</td>
<td>Before 6 wk / late stage</td>
<td>Doppler ultrasonography</td>
<td>75 ➔ 77(3)</td>
<td>73 ➔ 84 (15)</td>
<td>5.5 ➔ 6.5(18)</td>
</tr>
<tr>
<td>Desai et al&lt;sup&gt;30&lt;/sup&gt;</td>
<td>35</td>
<td>Serially from 14 wk and postpartum period</td>
<td>Doppler ultrasonography</td>
<td>70 ➔ 80(14)</td>
<td>69 ➔ 81(17)</td>
<td>4.8 ➔ 6.4(35)</td>
</tr>
<tr>
<td>Rang et al (current study)</td>
<td>16</td>
<td>Serially from 12 wk and postpartum period</td>
<td>Doppler ultrasonography Modelflow</td>
<td>76 ➔ 81(7)</td>
<td>67 ➔ 78(16)</td>
<td>5.2 ➔ 6.1(17)</td>
</tr>
</tbody>
</table>

* Adjusted values according to description in the Results section.
Figure 4 shows a comparison of SV that was measured by Doppler echocardiography and by Modelflow after adjustment. A trend for lower Modelflow values at higher Doppler SV values was observed. The mean ratio of the difference and average of both measurements was $0.01 \pm 0.14$. CO that was measured by Doppler echocardiography and by Modelflow after adjustment is shown in Figure 5. With both techniques, the CO during pregnancy was approximately 18% higher than after pregnancy. This difference was not statistically significant (Table 3).

Comment

Our results indicate that, as expected, Modelflow underestimates SV in pregnant women. We observed that PWV was lower; therefore, aorta compliance was higher during pregnancy than in the nonpregnant state after delivery. However, values at the 3 measurement periods during pregnancy were similar. Our observations on the change in aortic compliance are in accordance with the observations of Poppas et al.\textsuperscript{14} and Slangen et al.\textsuperscript{15} Assuming that postpartum values were comparable with values before pregnancy, the decrease of PWV must have occurred early in pregnancy before 12 weeks of gestation. It is not known when this decrease of PWV commences and at which speed this change develops.

Literature regarding the change in aorta diameter during pregnancy is conflicting. Some studies confirmed our finding that aorta diameter did not change significantly during pregnancy.\textsuperscript{15,29} However, other studies described an increase of aorta diameter during pregnancy.\textsuperscript{14,16,30} Poppas et al.\textsuperscript{14} demonstrated a statistically significant difference between early pregnancy and late pregnancy. However, the absolute difference was only 5%, which is below the measurement error of echocardiography. Hart et al.\textsuperscript{16} observed an increase of the aortic cross area of > 30%, with a range between 15% in primiparous to 36% in multiparous women. Area was calculated by $\pi D^2/4$. When aorta diameter is recalculated from the data for primiparous women, which were presented in their article, the difference between postpartum and pregnant values was only 1.4 mm (7%).

The accuracy of CO measurement by Modelflow for further measurements in the same patient, has been demonstrated after calibration by Swan-Ganz catheter thermodilution.\textsuperscript{13,25,31} We did not calibrate our measurements with thermodilution; therefore, absolute measurement values may have a considerable error. However, CO was obtained longitudinally within the same patient; changes during pregnancy should be tracked with precision as long as the basic parameters of the algorithm do not change. Modelflow uses an estimation of descending aorta diameter and aorta distensibility for the calculation of SV from the finger arterial pulse wave registration. These values are applied from a built-in database with subject age and gender as input and based on data that are obtained from human aortas.\textsuperscript{24} Although we did not observe an increase in diameter of the ascending aorta, this cannot exclude a possible increase of lower thoracic part of the descending aorta. PWV and systolic blood pressure are both related to aorta compliance, and a difference between pregnancy and postpartum period was
observed. We entered these parameters for adjustment of Modelflow. Without adjustment, the average ratio between difference and average of both measurements for SV was 0.082 ± 0.19; after adjustment, this value was 0.010 ± 0.14, which accounted for a reduction of measurement error from approximately 40% to 30% (2 SD). Similar variations have been described for Doppler echocardiography when compared with thermodilution.32-34 One study measured CO simultaneously by thermodilution, arterial pulse contour, and Doppler echocardiography and reported a similar measurement error of 40-50% of the pulse contour and Doppler methods in comparison with thermodilution.35 Apparently both methods have a similar variation, which is substantiated by the results of this study.

Most data on CO in pregnancy describe an increase that varies by 18% – 50%.30;36-40 Table 4 summarizes the outcome of studies that serially measured HR, SV, and CO in normal pregnancy. The largest change occurred in early pregnancy, between 5 and 8 weeks of gestational age. 37;39 This increase initially is due to an increase in HR and subsequently by an increase in SV.37;38 Desai et al30, Robson et al39, and Mabie et al40 observed an increase in CO, partially due to an increase in SV; whereas the increase in CO observed by Duvekot et al37 and Lucini et al41 was based mainly on an increase in HR. We observed a 17% difference of CO by Doppler echocardiography and a 19% difference by adjusted Modelflow between pregnancy and postpartum measurements. This difference was in the lower range of the values presented by literature (Table 4). The increase was mainly due to an increase in HR and reached borderline statistical significance (P= .05).

All measurements were performed under stable conditions in a quiet environment after at least 10 minutes of rest. Because the Portapres was connected, we could observe blood pressure and HR continuously, which enabled us to observe the effect of resting before the start of the measurement procedure. The selection of patients and the possibility to obtain truly resting signals may have caused part of the difference between studies concerning CO.

Aorta characteristics (compliance and diameter) that were incorporated in Modelflow were constant during pregnancy. However, compliance was lower 5 months after pregnancy. After adjustment for pregnancy-related change of cardiovascular parameters, the measurement of CO by analysis of the finger arterial pulse wave by Modelflow gives results that are comparable with Doppler echocardiography during and after pregnancy, although a random variation of approximately 30% between both methods was observed, which is comparable with reported differences between Doppler echocardiography and thermodilution. Because of these measurement errors, neither Doppler echocardiography nor Modelflow is useful for routine clinical care, but both should be considered as useful research instruments. The advantage of Modelflow over Doppler echocardiography is the capability of continuous measurement, the reliability for longitudinal measurements, and the convenience of application.
Reference List


