Comparison between a newly developed PC-based Doppler umbilical artery waveform analyser and a commercial unit

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Objectives. To determine the accuracy of the resistance index (RI) of flow velocity waveforms of the umbilical artery measured using a newly developed PC-based continuous wave Doppler device (Umbiflow) with regard to systematic and random variations when compared with a commercial standard (Vasoflow).

Design. A cohort study.

Setting. The fetal evaluation clinic (FEC) at Tygerberg Hospital.

Subjects. Patients referred to the FEC at Tygerberg Hospital with suspected chronic placental insufficiency.

Outcome measures. The correlation coefficients indicating the strength of the relationship between the two devices and their agreement using the method of Bland and Altman.

Results. A total of 248 patients were studied. The mean RIs of the first Doppler assessment were 0.69 (standard deviation (SD) 0.11) and 0.67 (SD 0.11) using the Vasoflow and Umbiflow respectively. The Pearson's correlation coefficient comparing the RI of the first test was 0.85. The degree of agreement between the two methods was excellent, the mean differences being very small (< 0.024) with tight confidence intervals. One hundred and ninety-four patients (78.2%) of patients remained in the same percentile category with both the Vasoflow and Umbiflow.

Conclusions. The accuracy of the Umbiflow has been proved. A non-significant trend towards slightly lower values needs to be considered. This could be addressed by changing the percentile cut-off to slightly lower values.

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Umbilical artery Doppler flow velocimetry is essential in the clinical management of pregnancies where intra-uterine growth restriction (IUGR) is suspected.[1,2] It reduces the number of perinatal deaths and avoids unnecessary obstetric interventions. There is also a significant association between an increased resistance index (RI) and complications of placental insufficiency.[3]

The implementation of appropriate technologies with proven value and accuracy must be considered for use in developing countries. The proportion of women with pregnancy complications in these countries manifests in the profound difference in maternal mortality ratios and perinatal death rates when compared with developed countries.[4-7] Umbilical artery Doppler flow velocimetry has the potential to be of great value in the clinical management of pregnancies where IUGR is suspected. However, the more affordable continuous-wave Doppler wavefrom analysers developed initially were quickly replaced by pulsed-wave analysers that are incorporated into expensive ultrasound scanners. The benefit of non-invasive, safe and easy-to-use systems soon became too expensive for most health services in developing countries.

The Medical Research Council (MRC) Unit for Perinatal Mortality, the MRC and Centre for Scientific and Industrial Research (CSIR) worked together to develop a novel and affordable continuous-wave Doppler analyser (Umbiflow) for use with a standard personal computer (PC). The required software was developed and the Doppler probe housing the electronics was powered and connected via the USB port of the PC. The software is user-friendly and allows input of patient, fetal and neonatal data. The flow velocity waveforms are recorded on the computer screen. The RI, calculated from the waveform, is then plotted on an appropriate percentile graph against the estimated gestational age.

This study was conducted to determine the accuracy of the flow velocity waveforms of the umbilical artery as measured using the Umbiflow both with regard to systematic and random variations when compared with a commercial standard (Sonicaid Vasoflow 4, Oxford Instruments). The RI was used for all comparisons. Care was taken to include the gestational age range (24 - 40 weeks) and sufficient numbers of patients with abnormal values (≥ 95th percentile).

Patients and methods

A cohort study was conducted. Consecutive patients referred

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to the fetal evaluation clinic (FEC) at Tygerberg Hospital with suspected placental insufficiency were included in the study. Using Vasoflow and the Umbiflow alternately on each patient, a single observer (AMT) determined the RI using the best value as determined by auscultation followed by visualisation on a screen. Care was taken to do the measurement when the fetus was not moving, as reflected by constant velocity in the umbilical vein. Outcomes of the pregnancies were determined.

Patients with an RI < 75th percentile (category 1) were regarded as being at low risk for complications of placental insufficiency, and were not given fetal surveillance tests unless the clinical condition changed. Those with an RI ≥ 75 and < 95th percentile (category 2) required a repeat Doppler within 14 days, and those with RI ≥ 95th percentile (category 3) received more intensive fetal monitoring. When absent flow (category 4) was detected, patients were admitted to hospital for intensive fetal monitoring or delivery.

The strength of the relationship between the Vasoflow and the Umbiflow was determined by calculating correlation coefficients and the degree of agreement using the method of Bland and Altman.[8] A regression analysis was done on the scatter gram depicting the mean RI values on the x-axis and the differences on the y-axis to assess differences in the variances of smaller compared with larger mean values.[9] An assessment of the agreement or differences in category assignments (first assessment only), according to the percentile index, was made by calculating a Kappa index.

Results

A total of 248 patients were included in the study. Gestational age was confirmed by early ultrasound in 195 patients (78.6%). The most common reasons for referring patients for Doppler were poor symphysis-fundus (SF) growth (34.1%), previous pregnancy complications (24.5%), hypertension (19.7%) and pre-eclampsia (14.9%). The median gestational age at referral was 30 weeks, with a range of 21 - 40 weeks.

The mean RIs of the first Doppler assessment were 0.69 (standard deviation (SD) 0.11) and 0.67 (SD 0.11) using the Vasoflow and Umbiflow respectively. A second test was done on 59 patients (23.8%), and a third test on 13 patients later during the pregnancy because their initial and subsequent RIs were ≥ 75th percentile. In this second assessment the mean RIs were 0.69 (SD 0.10) and 0.66 (SD 0.10) and the RIs for the third test were 0.76 (SD 0.12) and 0.75 (SD 0.11) using the Vasoflow and Umbiflow respectively. The correlation coefficients comparing the RI as measured using the Vasoflow and Umbiflow (Table I) and the degree of agreement between the two methods, calculated according to the method of Bland and Altman,[8] are shown in Table II. Fig. 1 is a scattergram of the mean values of the first assessment using the two instruments (x-axis) and the differences between the two instruments (y-axis). The middle horizontal line is the mean difference and the other two horizontal lines 2 SDs above and below the mean difference. The correlation coefficient of a regression analysis assessing the possibility of a difference in the variances of the smaller compared with the larger mean values of the first assessment results on the scattergram is 0.12 (Fig. 1). The number of patients remaining in the same percentile category and those who shifted to another category are shown in Table III.

Table I. The correlation coefficients of the RI as measured with the Vasoflow and the Umbiflow

	1st test	2nd test	3rd test
Pearson	0.847	0.826	0.957
Spearman	0.789	0.731	0.797

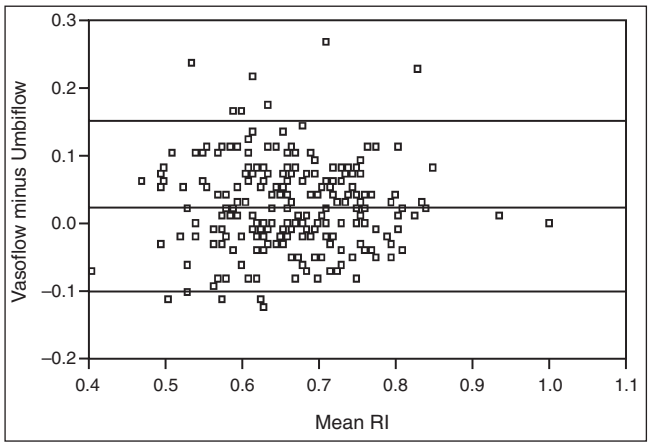

Fig. 1. A scattergram of the mean values of the first assessment using the two instruments, and the difference between the two instruments.

Table II. The mean differences and the distribution of these differences between the Vasoflow and the Umbiflow

	1st test	2nd test	3rd test
N	249	59	13
Mean	0.023	0.020	–0.005
SD	0.062	0.058	0.037
+2SD	0.147	0.136	0.066
–2SD	–0.100	–0.096	–0.077

Table III. Shifts in categories that occurred with the first assessment between the two instruments according to resistance category (*N* = 248)

		Umbiflow			
		1	2	3	4
Vasoflow	1	**131**	14	0	0
	2	36	**42**	1	0
	3	0	3	**11**	0
	4	0	0	0	**10**

Antenatal admission was necessary for 110 patients (44.3%) and complications occurred in 152 cases (61.3%). The median gestational age at delivery of patients with viable fetuses was 38 (27 - 46) weeks. Spontaneous onset of labour occurred in 129 patients (52.0%), induction of labour in 89 (35.9%), elective caesarean sections in 29 (11.7%) and 2 terminations of pregnancy were required. The overall caesarean section rate was 26.1%.

The mean birth weight of viable babies was 2 712 g (665 - 4 294 g), with 30.1% light for gestational age. There were 5 intra-uterine and 5 neonatal deaths (perinatal mortality rate 40.3/1 000).

Discussion

The study population met the stated objectives, i.e. it included patients across a wide range of gestational age, at high risk for placental insufficiency, pregnancy complications and poor perinatal outcome. A significant number of patients had abnormal RI values. A valid comparison between the Vasoflow and Umbiflow was therefore possible.

The mean RIs of the Vasoflow and Umbiflow differed by ≤ 0.03. A good correlation between the two instruments was demonstrated (Table II). The more important degree of agreement was excellent, with the mean differences being very small (< 0.024) with tight confidence intervals (Table II). Variability according to size of the smaller compared with larger mean values on the x-axis of the scattergram was very small (Fig. 1). The correlation coefficient of these values (0.12) deviates only very slightly from the horizontal line representing the mean difference on the scattergram. The correlation coefficient comparing the first measurements of the Vasoflow and Umbiflow of 0.8 (Table I) also confirms a small mean difference through the range of small and larger RI values.[9] The Kappa index of 0.7 indicates good reproducibility. However, very small differences may cause a shift on the percentile chart (Table III) that may exclude a patient from further fetal surveillance (i.e. to < 75th percentile). This would affect the 36 patients who fell into the < 75th percentile category with the Umbiflow but in the ≥ 75th but < 95 percentile category with the Vasoflow. If managed according to the Umbiflow measurements and our protocol they would have been excluded from further surveillance unless their clinical condition changed, e.g. development of pre-eclampsia in a patient who had only had poor SF growth. The appropriateness of the 75th percentile in our protocol needs further investigation and possible adjustment to a lower percentile. In addition 3 patients moved from the ≥ 95th percentile to the ≥ 75th but < 95th percentile. Our protocol requires non-stress tests twice weekly in the ≥ 95th percentile category whereas in the ≥ 75th but < 95th percentile category the Doppler is only repeated 2 weeks later with no additional surveillance. Patients moving up to a higher category would undergo unnecessary investigations; however this would be erring on the safe side of caution.

The accuracy of the Umbiflow has been proved. A non-significant trend towards slightly lower values needs to be considered. In our protocol this could be addressed by using the 70th percentile rather than the present 75th percentile as the threshold below which further investigations are not performed. The next step will be to conduct field trials to establish the value of the Umbiflow under field conditions at primary and secondary levels where more sophisticated Doppler equipment is unavailable.

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