

UMBIflow™ Mobile-connected doppler analyser for foetal health evaluation in low-resource settings

UMBIflow™ is a simple-to-use, cost-effective, mobile-connected, portable device for antenatal screening of placental function which is able to evaluate foetal health in low-resource settings without the need for specialists

BACKGROUND

Globally, the rate of stillbirths remains unacceptably high at 2.8 million stillbirths worldwide. The causal pathways for stillbirths often involve impaired placental function, either with foetal growth retardation or preterm labour, or both. In South Africa, two thirds of all stillbirths occur in the antenatal period and a large number of these occur in healthy women who had antenatal care as a low-risk pregnancy. At the same time, pregnant women with constitutionally small but healthy fetuses are being referred unnecessarily to higher level care for further investigation, which is more costly to both the patient and the public health sector. It is therefore important to be able to detect undiagnosed placental insufficiency at the primary health care level in otherwise healthy pregnancies, allowing intervention to ensure a good birth outcome, and to distinguish between a constitutionally small but healthy foetus and a pathologically small and therefore compromised foetus to ensure more effective and efficient decision making on specialist referrals.

TECHNOLOGY DESCRIPTION

The UMBIflow™ technology uses Doppler waveform analysis for reliable and cost effective antenatal screening. The technology evaluates blood flow in the umbilical artery of the foetus in the third trimester of pregnancy. From such a measurement, decisions can be made about the ability of the placenta to provide sufficient nutrients and oxygen in order to sustain the required foetal growth rate during this trimester. The ultrasonic Doppler probe connects to the USB port of a standard PC or laptop onto which is loaded the UMBIflow™ software. The system allows for a database facility, serial monitoring, plotting of results and “remote access” and “remote control” capabilities for real-time telemedicine. Captured data is automatically compared to the onboard proprietary clinical database information and a clinical assessment is suggested to the clinician or midwife.

VALUE PROPOSITION

UMBIflow™ is a simple-to-use, cost-effective, mobile-connected, portable device for antenatal screening of placental function by primary health care workers. The device is able to distinguish between naturally small fetuses with healthy placental function, which would have been referred to higher level care unnecessarily, and pathologically small fetuses from healthy, low-risk pregnant women, which need to be referred for intervention and thereby reducing the rate of stillbirth. The device can be used by primary healthcare workers with a wide range of skills levels, allowing for faster, low-cost diagnosis at primary health care level. Reduction of unnecessary referrals reduces the patient burden and costs at higher level care, as

well as patient stress; while identification of “at-risk” fetuses and subsequent intervention has been demonstrated to reduce stillbirth rates. As such it has application in low-, middle- and high-income countries.

CURRENT STATUS

Various clinical studies with the UMBIflow™ device have demonstrated:

- That the device works as well as / is equivalent to the gold standard (Theron et al., 2005).
- That screening of women with apparently small for gestational age fetuses can identify those that need intervention, thereby reducing unnecessary referrals (Mufenda et al., 2015).
- That the prevalence of abnormal UMBIflow readings in apparently “low-risk” pregnancies is 10x higher in certain districts in South Africa than those in high-income countries. The use of UMBIflow™ screening followed by the appropriate interventions in the study area reduced the stillbirths by 50% compared to the control group with no UMBIflow™ (Spencer et al., 2019).

Further studies, funded by the SAMRC and the WHO respectively, using UMBIflow™ in additional districts in South Africa, as well as in Rwanda, Ghana, Kenya and India, are underway to assess the prevalence of abnormal readings in those regions and the impact of using UMBIflow™ screening on the stillbirth rate. The SAMRC and CSIR are in discussions with potential commercial partners to manufacture and distribute the device.

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

The device and proprietary algorithms are protected as trade secrets and the software is protected by copyright.

- Spencer Nkosi, Jennifer Makin, Tsakane Hlongwane, Robert Pattinson. Screening and managing low risk pregnant population using continuous wave Doppler ultrasound in a low-income population: A cohort analytic study. S Afr Med J 2019; 109(5) 347-353.)
- Mufenda J, Gebhardt S, van Rooyen R, Theron GB. Introducing a mobile connected umbilical Doppler device (Umbiflow) into a primary care maternity setting: does this reduce unnecessary referrals to a specialised care? Results of a pilot study in Kraaifontein, South Africa. Plos One 2015; 10(11):e0142743. doi: 10.1371.
- Theron GB, Theron AM, Odendaal HJ, Bunn AE. Comparison between a newly developed PC-based Doppler umbilical artery waveform analyser and a commercial unit. S Afr Med J 2005; 95(1) 62-64.



UMBIflow™ Mobile-connected doppler analyser for foetal health evaluation in low-resource settings (continued)

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OPPORTUNITIES

The SAMRC and CSIR are seeking international partners to assist with market entry strategies into LMICs. Funding is also sought for a large multi-site randomized control trial on the device.

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