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SATTVA MEDTECH

Solving 300,000 Annual Intrapartum Deaths in India

An Unmet Need

Of the approximately 30 million pregnancies reported in India every year, 10 million mothers require extra monitoring during labor to detect complications. Maternal and child health indicators offer key insights into the state of the prenatal and antenatal care available and provided in a country. In India, due to the lack of effective monitoring during labor, there are close to 300,000 annual intrapartum deaths recorded due to undetected fetal distress and related conditions.

Often, during labor, the baby does not get enough oxygen supply and tries to compensate by erratically varying its heart rate. This is called fetal distress, and if not acted upon, may result in stillbirth.

The current technology to diagnose this condition requires skilled operators and is big and bulky. In countries like India, where the last mile delivery of health care services still remain a challenge, the need for developing small-scale infrastructure is critical. Medical devices that are less bulky, more mobile, affordable and less skill dependent are the need of the hour to ensure that health care services can reach the remote communities.

Sattva MedTech's device, the Fetal Lite, is designed to address this unmet need.

The Company

Sattva MedTech was conceptualized and founded in 2014 by Vibhav Joshi and Sumedh Kaulgud, young engineering students from BITS Pilani, Goa; with the aim to develop affordable medical devices designed to meet the needs of the Indian market.

The idea for their first product, a fetal monitoring device, was born during a visit home by Vibhav where his gynaecologist mother's experience with the expensive NST-CTG (Fetal Non-Stress-Test-Cardiotocography) machine was discussed. On undertaking further research through medical literature, interviewing doctors, immersions and field visits; the founders identified the need for an efficient, reliable and affordable fetal monitoring device which would work in low-resource settings as well.

The Fetal Lite

The NST-CTG, which is the current method, is an ultrasound-based measurement device that requires a high degree of skill dependency for operating the device and interpreting the results. Sattva MedTech's Fetal Lite, on the other hand, is an ECG-based fetal heart rate monitor that is more accurate and reliable than the NST-CTG. The Fetal Lite has been designed to overcome the drawbacks of the NST-CTG, such as skill dependency and inoperability in low-resource settings.

Since the Fetal Lite is based on the ECG, it travels throughout the abdomen and is not reliant on the technician's accuracy of the placement of the probe to look for the fetal heart rate. The probes can be placed around the mother's naval, for the device to detect the fetal heart rate. Additionally, the probe also has multiple sensors. The device also does not need to be attached to a continuous power source, making it ideal to be used in low-resource settings. The NST-CTG is bulky and fixed to a point, in comparison; the Fetal Lite weighs only 2 Kgs, including the sensor unit, display tablet, docking set and printer. The design is based on bio mimicry, and the placement does not need to be re-adjusted due to the mother's movement during labour. It is also equipped with automated marking of fetal heart rate baseline, dips, accelerations and decelerations – parameters which are critical in deciding risk to the baby. It also supports inbuilt remote monitoring and wireless report sharing capability over low bandwidth. The device retails at around INR 1.2 Lacs, a significant reduction in cost as compared to its counterpart, the NST-CTG.

Competitive Analysis

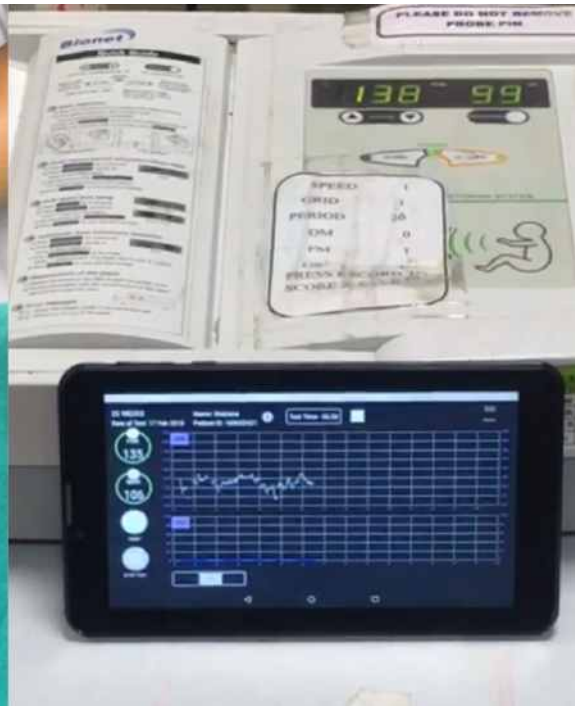
	Handheld Doppler	CTG	FSE & IUPC	Other f-ECG (GE, Mindchild)	Fetal Lite
Measures Fetal Heart Rate	Yes	Yes	Yes	Yes	Yes
Detects Uterine Contraction	No	Yes	Yes	Yes	Yes
Diagnostic Capability	No	Yes	Yes	Yes	Yes
Non-Invasive	Yes	Yes	No	Yes	Yes
Human Variability	High	High	High	Medium	Low
Twin Monitoring	No	Yes	No	No	Under Dev
Accuracy	Low	Medium	High	High	High
Ease of Use	High	Low	Low	Medium	High
Cost	Low	Medium	High	High	Medium

Ensuring Reliability

In 2015, Sattva MedTech conducted an ethical review board approved basic clinical evaluation study on more than 80 patients at St. John's Medical Hospital in Bengaluru. Following this, the device was further piloted at two more medical centers in Pune in 2017. The first was a comparative trial study (approved by an internal Institutional Ethics Committee) conducted involving 12 patients at Deenanath Mangeshkar Hospital and Research Center in Pune, where the reliability and accuracy of the Fetal Lite was assessed in comparison to the conventional Cardiotocography. The Fetal Lite, proved to be as accurate. The second was a comparative study conducted with 36 patients at another medical clinic in Pune, where the Fetal Lite could detect fetal distress in at least two cases that the conventional device had missed. After a series of pilots and device testing across 3 cities, Sattva MedTech's Fetal Lite has recorded a 98% detection accuracy rate.

The Fetal Lite has been well received by the medical community thus far, potentially paving the way for wider acceptance by medical institutions in the near future. A doctor, from a private hospital in Kochi, found that the device was able to detect contractions in a reliable manner. The wireless design also allowed for easy handling of the device, and the doctor was able to monitor the usage remotely, which was extremely convenient during busy work hours.

Clinical Evaluation



Simultaneous data collection from Fetal Lite and CTG
2 center IERB approved comparative
15 minutes of data collected per patient
Analysis methodology - Bland Altman Plots and the Positive Predictive Value (PPV)

Details of subjects in the study	
Total number of patients	36
Maternal age	24.82+/-3.22
Gestational age	38.77+/-1.53 weeks
Maternal weight	67.06+/-11.9
Gravity	2+/-1.045

STUDY RESULTS

- Positive Predictive Value - 98.86%
- Fetal Lite Vs CTG heart rate range - +/- 2bpm

Scalability and Sustainability

Very early on, Sattva MedTech raised a seed grant from BITS 75 Charitable Trust. In addition to the financial support, they also received the much-needed mentorship from the BITS Pilani network including the trustees of the BITS 75 trust, Mr. Vijay Chandru and Mr. Atul Sethi as well as alumni of the BITS Spark Angel Network.

In 2016, they were also awarded under the Millennium Alliance program with a grant amount of INR 58 Lacs; specifically focused on designing the prototype and conducting the pilot. The pilot served as a proof of concept for the company, which paved the way for a second round of funding from InnAccel of INR 4.1 Crore over 2014 – 2019 as well as a grant of INR 50 Lacs from GCE-India in 2018 to build up their team and further develop their device. Sattva has thus far raised INR 5.1 Crore in funding.

Since 2015, Sattva has been incubated at InnAccel, a leading medical technology focused accelerator turned company, based in Bangalore. More recently, Sattva MedTech and another company Coeo Labs have been included as subsidiaries under the larger umbrella of InAccel, opening up wider networks to them.

The Fetal Lite has gone through multiple iterations over the course of the time. The initial concept was a home care device, which a pregnant mother could use herself. However, on deeper interactions and research, the founders realised the safer and more reliable usage would be at hospitals or medical clinics. It was also decided to add a tablet along with the product that would strengthen wireless data collection and analysis.

While still in it's pilot stage, Sattva MedTech has successfully attained key clinical certifications, namely ISO 13485:2016 for Sattva MedTech, and CE Class 2A for Fetal Lite cementing the accuracy and reliability of the device.

The Indian MedTech market is currently dependent on bulky standard devices, which are expensive and thus not available in smaller health centers at the last mile. Sattva aims to market its products to not just health institutions, but also to smaller clinics. With a price point of around INR 1.2 Lacs, their first product “Fetal Lite” makes the cut, especially as compared to other standard devices from established international brands that are priced upwards of INR 5 Lacs. This price difference offers the Fetal Lite a competitive edge. While there are some other cheaper, locally produced fetal monitors in the market, the Fetal Lite has the added advantage of the backing of international programmes and regulatory compliance.

> The device assembly has been outsourced to a manufacturing firm in Mysore. This has been done so that the device meets manufacturing standards and use tests, while also keeping financial sustainability in mind. This allows Sattva to scale up the manufacturing process as and when the demand arises and to meet it.

The Fetal Lite was officially launched at the All India Conference for Obstetricians and Gynecologists in January 2018 in Bhubaneswar; where they received extremely positive feedback with over 300 representatives from different medical centers across the country signing up for the demonstration of the Fetal Lite. Till date, the device has been adopted and installed in 30 hospitals & maternity health clinics across Bangalore, Hyderabad, Pune, Lucknow and Mumbai; and benefitted over 300 women through the pilot testing and commercial usage.

With a set end-to-end development process, and a capable team, Sattva is now looking to scale-up their growth. To scale-up the product sales in India, they are looking to move ahead through a distributorship channel, since established networks can be more efficient to market the product, as against designing a sales strategy for a single product.

Moving forward, they are interested in creating an entire portfolio of devices for the unmet clinical needs of India and other low-resource geographies. To that end, they are actively looking to expand their team and test new ideas. They are also working towards building a pan-India sales team, licensing deals for ex-India markets and setting up large-scale (5000+ patients) pilots.

IMPACT

30
FETAL LITE INSTALLATIONS COMPLETED

300+
MOTHERS MONITORED

50%
REDUCTION IN NURSING TIME PER SCAN

6
FETAL DISTRESS CASES CAUGHT AND TREATED IN TIME