

United States Multicenter Clinical Usage Study of the STAN S21 Electronic Fetal Monitoring System.

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Objective

The fetal electrocardiogram system for electronic fetal monitoring (EFM) (STAN S21, Neoventa Medical, Moelndal, Sweden) has led to improved perinatal outcomes in other countries. We aimed to assess the ability of United States (US) obstetricians to use this system appropriately for intrapartum care.

Study design

A prospective nonrandomized trial was conducted in 6 sites. Enrollment required a singleton vertex fetus, >36 weeks' gestation, with indications for direct fetal monitoring during first stage of labor. Appropriate use was measured by negative predictive value (NPV) of nonintervention for fetuses with nonreassuring fetal heart rate (FHR) patterns, normal STAN readings, and normal neonatal outcomes with umbilical cord arterial pH >7.12; and percent agreement (PA) for intervention decisions with 3 STAN experts who conducted retrospective case reviews blinded to outcome.

Results

Five hundred and thirty patients were enrolled. An NPV of 95.2% was achieved while PA between investigators and STAN experts was 84%, and 90%, for intervention and nonintervention, respectively. No fetus with metabolic acidosis requiring intervention was missed by US clinicians.

Conclusion

US clinicians used the STAN system appropriately in a manner similar to that of experienced STAN users.

Key words: Intrapartum fetal monitoring; Fetal electrocardiogram