Comparison of the Manual Stimulation Test and the Nonstress Test: A Randomized Controlled Trial

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Objective: *To evaluate manual fetal stimulation (MST) through the maternal abdomen in comparison to standard nonstress test (NST) in terms of nonreactive rates and testing time.*
Material and Method: *Five hundred and forty high-risk singleton pregnancies at 28 gestational weeks or more were assigned to have either NST or MST using blocked randomization (270 each). All fetal heart rate (FHR) tracings were analyzed blindly using standard NST criteria by one perinatologist.*
Results: *The MST group provided a significantly higher reactive rate than that of the NST group, 98.9% and 84.4% respectively, $p < 0.001$. Mean testing time of the reactive results of the MST group was also significantly shorter than that of the NST group, 7.94 $\pm$ 6.27 min and 13.91 $\pm$ 9.58 min respectively, $p < 0.001$.*
Conclusion: *This is the first randomized controlled trial (RCT) to demonstrate the distinctive benefit of the simple and less expensive MST. MST significantly reduces the time to reactivity and increases the frequency of reactivity when compared to NST alone.*

Keywords: *Electronic fetal heart rate monitoring, Fetal surveillance, Fetal well being, Manual stimulation test, Nonstress test*

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Electronic fetal heart rate (FHR) monitoring has been used as an effective tool for evaluating fetal health for decades. The Nonstress test (NST) is a useful application of electronic FHR monitoring for predicting antepartum fetal well being in high-risk pregnancies. It provides high accuracy of identifying healthy fetuses without contraindication. However, fetal sleep state causes a long testing time and a high false positive rate. Different methods of stimulation have been tested extensively. Acoustic stimulation (AST) has been proved to benefit in reducing nonreactive tests and testing time[1,2]. It has been previously reported that glucose[3] and manual stimulation[4-6] were not useful in changing the sleep-awake state of the fetus.

The authors have noted, however, that there always was a fetal movement observed by both the patients and the examiners in response to a manual manipulation during abdominal examination with Leopold maneuver at one Antenatal Care Unit. A similar response was also observed by real-time ultrasound scanning at the Fetal Medicine Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University, which was contradictory to the old literature. Meta-analysis of previous published data also gave controversial results, i.e. the nonreactive rate of manual fetal manipulation was not different from that of the standard NST, nor vibrocoustic stimulation[7], while it was established that AST provided a lower nonreactive rate and a shorter testing time in comparison to the standard NST[1,2]. In the latter case, MST should have been comparable to either the standard NST or AST, not both. Therefore, it would be interesting to have a proper evaluation of the manual fetal stimulation, which is less expensive and harmless, in incorporating with NST in evaluation of fetal health testing. The aim of the present study was to conduct a prospective, randomized control trial to compare the efficacy of the manual stimulation test (MST) to the

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standard NST regarding the nonreactive rates and testing time.

Material and Method

High risk singleton pregnant women with the gestational age of 28 or more weeks who attended the Fetal Medicine Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University and needed fetal surveillance were counseled regarding the tests and their safety. Those who agreed to join the project signed the consent form that was approved by the Hospital Review Board. The patients were then assigned to have either NST or MST using blocked randomization, each of 270 tests. All tests were conducted at the Fetal Medicine Unit in the semi-Fowler position. Maternal blood pressure was recorded, the FHR was monitored using an external electronic FHR monitor, Corometrics Medical System 116 (Supreme Products Co. Ltd., Bangkok), Advance Medical System IM76 (Vidhayakom Co., Ltd., Bangkok), or Toitu MT-332 (RX Co., Ltd, Bangkok), and uterine contraction was monitored by an external tocodynamometer. In the MST group, the presenting part of the fetus was held through the maternal abdomen by the operator with one hand and the upper pole of the fetus with the other hand. After 3-min baseline recording of the FHR tracing, the fetus was then gently shaken left-and-right, up-and-down and forward-and-backward each procedure twice, making six manipulations. The procedure was repeated up to 3 times (4 times in total) if no qualifying acceleration was observed within 15 seconds. A new cycle of stimulation was carried out if no reactive criteria were fulfilled in 10 min. The same procedure was extended for another 20 min if no reactive criteria were achieved within 20 min for both MST and NST. All FHR tracings were read blindly by one independent perinatologist who did not know the clinical details of the procedures or patients.

The tests were interpreted as reactive when there were two or more FHR accelerations of at least 15 bpm lasting at least 15 seconds in any 20 min period. One prolonged FHR acceleration of at least 15 bpm lasting 2 or more min was also interpreted as reactive. The test was diagnosed as nonreactive when these criteria were not met within 40 min of monitoring and contraction stress test (CST), biophysical profile (BPP), Doppler velocity or delivery determination was conducted as the hospital standard practice guideline. As each fetal tracing was interpreted independently from each other, some patients might have the test more than once or might have both tests on different occasions. Maternal age, gestational age at the time of testing, indications for testing, demographic details of the patients, number of reactive tests and time used to achieve a reactive result were recorded and analyzed using Pearson Chi square, Fischer's exact and Student t-test. A p-value of less than 0.05 was considered statistically significant difference between the standard NST and MST group.

Results

Three hundred and eight high-risk singleton pregnant women were included for 540 individual FHR testings, 270 tests for each of the standard NST and MST. Maternal age of the NST and MST groups was not statistically different, 28.14 $\pm$ 7.32 (mean $\pm$ SD) and 28.08 $\pm$ 6.97 years, respectively. The mean gestational age of the two groups was not statistically different, 35.82 $\pm$ 19.58 weeks and 36.23 $\pm$ 19.47 weeks for NST and MST groups respectively. Other demographic details, including weight, height, blood pressure, fetal heart rate of both groups were also not statistically different. Indications for fetal testing including placental insufficiency/intrauterine growth restriction, decreased fetal movement, diabetes mellitus, nearly postterm/postterm, hypertension, and PROM were not statistically different between both groups (Table 1). The reactive rate of the MST group (98.9%) was statistically higher than that of the NST group (84.4%), (Fisher

Table 1. Indications for fetal surveillance of the standard nonstress test (NST) and the manual stimulation test (MST) groups

Indications	NST (n = 270)	MST (n = 270)
Placental insufficiency/ intrauterine growth restriction	159 (58.9%)	147 (54.4%)
Decreased fetal movement	45 (16.7%)	47 (17.4%)
Diabetes mellitus	29 (10.7%)	27 (10.0%)
Nearly postterm/postterm	16 (5.9%)	23 (8.5%)
Pregnancy induced hypertension	15 (5.6%)	20 (7.4%)
Chronic hypertension	4 (1.5%)	5 (1.9%)
PROM > 24 hours	2 (0.7%)	1 (0.4%)

Table 2. Results of fetal heart rate testing of the standard nonstress test (NST) and the manual stimulation test (MST) groups

Results	NST (n = 270)	MST (n = 270)	Fisher's exact test	p-value
Reactive	228 (84.4%)	267 (98.9%)		
Nonreactive	42 (15.6%)	3 (1.1%)	36.87	<0.001*

* Statistically significant

Exact test, p-value < 0.001) (Table 2). The mean testing time used to achieve a reactive result in the MST group (7.94 $\pm$ 6.27 min) was statistically shorter than that in the NST group (13.91 $\pm$ 9.58 min, Student T test, p-value < 0.001).

Discussion

A prospective, randomized, controlled trial evaluating the use of manual fetal stimulation through maternal abdomen in order to reduce nonreactive rate and shorten testing time of the NST was carried out. Although it had been long believed that fetal shaking provided no benefit to the NST[7], the present study was the first to exhibit the distinctive advantage of using simple, inexpensive simple manual stimulation. It statistically significant reduced the nonreactive rate of the NST by 93.0%, from 15.6% of the standard NST to 1.1% of the MST. Moreover, it also significantly shortened the testing time to achieve the reactive tests by 42.9%, from 13.91 $\pm$ 9.58 min of the standard NST to 7.94 $\pm$ 6.27 min of the MST.

Fetal testing with electronic FHR monitor has been accepted for surveillance of compromised fetuses for a long time. NST is a simple, safe, and reliable fetal surveillance method for predicting fetal health. Reactive test reassures that the fetus should remain in good health for one more week allowing pregnancy to continue to term. NST provides low false negative results, in other words reactive results are very reliable. However, NST gives false positive results as high as 20-80%, mostly due to fetal sleep-wake cycle. Nonreactive tests take longer testing time and require back-up tests, i.e. CST, BPP or Doppler velocity. Attempts have been made to wake the fetus in order to reduce testing time and nonreactive rate. It was established that AST is useful in reducing both nonreactive rate, and testing time[8]. However, acoustic stimulators are not standard equipment provided with the electronic FHR monitors and cost extra when needed. It has been reported that maternal glucose[9] did not have any effect on NST. Light stimulation can reduce testing time but the procedure is still not popular[10].

A systematic review concludes that there is insufficient data to support the use of MST[7]. One small, non-controlled study was conducted on 17 pregnant women, of which only three had repetitive stimulation protocol and concluded that FHR was not related to external stimuli[5]. Another small study performed on 10 compromised (nonreactive FHR) fetuses failed to show the benefit of fetal shaking[6]. One large randomized control trial including 790 patients that stimulated the fetus once every 20 min period found no difference of the NST results when simple manual manipulation was provided[4]. Therefore, prior to the present study there was still no systematic, randomized, controlled study to evaluate properly the use of MST. A previous study which reported MST as ineffective when incorporating with the standard NST only apply one or two manual stimulations on the fetus for the whole test[4]. The well-defined benefit outcome of the MST in the present study might be due to the repetitive manual stimulation protocol, which was several times more frequent thus more effective than other studies, and gave a recognizable fetal response.

The disadvantage of MST is that the variations in force intensity applied for the test can be difficult to standardize. The intensity of the manipulation could be varied among different examiners, whereas the intensity of acoustic stimulation in AST can be quantified and is more controllable. However, the studies of manual manipulation on FHR reactivity have given conflicting results, further studies with standardized protocol of the manipulation technique may be necessary.

Conclusion

The present study provides evidence supporting the benefit of the MST on the NST. The inexpensive and simple manual fetal stimulation through the maternal abdomen significantly reduced the nonreactive rate by 93.0%, and shortened the testing

time by 42.9% in comparison to the standard NST. The distinguished results of the present study from the literature might be due to the different methodology of this randomized, controlled study, and in particular the repetitive gentle manual stimulation protocol.

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เปรียบเทียบการทดสอบสุขภาพทารกในครรภ์ด้วยวิธีกระตุ้นทารกด้วยมือกับวิธี nonstress test: การทดลองควบคุมแบบสุ่ม

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วัตถุประสงค์*: เพื่อเปรียบเทียบประสิทธิภาพของการกระตุ้นทารกในครรภ์ด้วยมือ (manual stimulation; MST) กับการทดสอบสุขภาพมารกในครรภ์วิธีมาตรฐาน nonstress test (NST) ในแง่ของอัตราการให้ผล nonreactive และเวลาที่ใช้ในการทดสอบ*

วัสดุและวิธีการ*: ครรภ์เดี่ยวที่มีความเสี่ยงสูงและอายุครรภ์ 28 สัปดาห์ขึ้นไป ได้รับการแบ่งกลุ่มด้วยวิธีสุ่มแบบบล็อคให้ได้รับการทดสอบสุขภาพทารกในครรภ์ด้วยวิธี NST หรือ MST แถบบันทึกอัตราการเต้นของหัวใจทารก (FHR tracings) ได้รับการอ่านแปลผลตามเกณฑ์มาตรฐาน NST โดยแพทย์ด้านเวชศาสตร์มารดาและทารกเพียงท่านเดียว*

ผลการศึกษา*: จากการทดสอบทั้งหมด 540 การทดสอบ, กลุ่มละ 270 การทดสอบ พบว่า MST มีอัตรา reactive สูงกว่า NST อย่างมีนัยสำคัญ (98.9% และ 84.4% ตามลำดับ, $p < 0.001$) เวลาเฉลี่ยของการทดสอบในกลุ่ม MST สั้นกว่ากลุ่ม NST อย่างมีนัยสำคัญ (7.94 $\pm$ 6.27 นาที และ 13.91 $\pm$ 9.58 นาที ตามลำดับ, $p <0.001$)*

สรุป*: การศึกษานี้นับเป็นการศึกษาแบบสุ่มครั้งแรกที่แสดงให้เห็นว่า MST ซึ่งเป็นเทคนิคอย่างง่ายและราคาถูก มีประโยชน์ในแง่ของการช่วยลดอัตราผลการทดสอบ nonreactive และลดเวลาของการทดสอบลงเมื่อเทียบกับวิธี NST มาตรฐาน*