Prenatal Group B *Streptococcus* Test Using Real-time Polymerase Chain Reaction

To the Editor:

I read with great interest the article by Wei et al [1]. They used a real-time polymerase chain reaction (RT-PCR) technique for the detection of group B streptococci (GBS). Among 150 pregnant women, three were found to be positive with RT-PCR, and two of these were also found to be positive by standard culture techniques. The polymerase chain reaction (PCR) method provides an extremely sensitive test. The advantage of RT-PCR is its extreme sensitivity and a wide dynamic range. Evaluation of a test (such as the RT-PCR method) necessarily involves its comparison with a reference standard, and the "gold standard" in this case is the laboratory culture test. Any potential new test must be compared with the reference standard to minimize the chance of misdiagnosis. Positive predictive value (PPV) refers to the probability that a positive test correctly identifies an individual who actually has the disease. It is computed from two-by-two tables, i.e. true positives/(true positives + false positives). In the study of Wei et al, there were only two culture positives, and the RT-PCR results, therefore included two true positives and one false positive. The PPV of the RT-PCR method to detect GBS was thus 2/3 (66.7%).

The PCR assay is known to be more sensitive than the standard culture method. A previous report by Rallu et al [2] compared the sensitivity of antigen detection, PCR, and the standard culture method in 605 vaginorectal swab specimens from pregnant women. The three experimental assays were performed with the growth from the selective enrichment (LIM) broth (Todd-Hewitt broth with 15 μg/mL nalidixic acid and 10 μg/mL colistin) after overnight incubation. They included a GBS antigen detection assay (PathoDx) and two PCR assays (for *cfb* and *scpB*). The authors concluded that the *scpB* PCR assay was the most accurate (sensitivity, 99.6%; specificity, 100%), followed by the *cfb* PCR assay (sensitivity, 75.3%; specificity, 100%), the GBS antigen detection assay (sensitivity, 57.3%; specificity, 99.5%), and the standard culture assay (sensitivity, 42.3%; specificity, 100%). Wei et al used the IDI-Strep B test kit for GBS identification of the *cfb* gene. The sensitivity of the *cfb* PCR assay was, by comparison, 75.3% and 100% for the results of Rallu et al [2] and Wei et al [1], respectively. In another study evaluating the PCR detection rate, a total of 233 samples were analyzed [3]. Both the culture and PCR methods gave positive results in 59 patients and negative results in 157 patients. The culture method gave positive results in nine patients with negative PCR results, while culture results were negative in eight patients with positive PCR results. The sensitivity of the PCR assay was 86.8% and the specificity was 95.2%. The PPV was 88.1% and the negative predictive value was 94.6%. They concluded that although a rapid PCR assay may be useful for determining GBS status in the urgent intrapartum setting, the false-negative rate of RT-PCR of 13.2% should prohibit its use for standard GBS screening in the office [3]. It, therefore, seems unlikely that the sensitivity of the RT-PCR assay would have been 100% and the specificity 99.3% as claimed by the authors, if the sample size, especially the number of positive reference standard cultures, had been larger.

Secondly, repeat testing 4 weeks after initial negative results of GBS cultures was recommended by Wei et al. In time to come, the culture method should still be used as the standard and be the most reliable method. PCR-based rapid tests should only be used in women in labor if repeat testing is to be performed. In the future, PCR-based rapid tests may become the standard approach to management of women who present in labor with no screening culture results. However, these tests should not be used in place of standard culture tests until it is certain that the results from different laboratories and different tests are equally reliable.

Horng-Jyh Tsai, MD, PhD, FACOG
Department of Obstetrics and Gynecology
Kuang Tien General Hospital
117, Shatien Road, Shalu, Taiwan
E-mail: hjtsaics@yahoo.com.tw

References

1. Wei CF, She BC, Liang HS, et al. Prenatal Group B *Streptococcus* test using real-time polymerase chain reaction. *Taiwan J Obstet Gynecol* 2009;48:116–9.
2. Rallu F, Barriga P, Scrivo C, Martel-Laferrière V, Laferrière C. Sensitivities of antigen detection and PCR assays greatly increased compared to that of the standard culture method for screening for group B streptococcus carriage in pregnant women. *J Clin Microbiol* 2006;44:725–8.
3. Atkins KL, Atkinson RM, Shanks A, Parvin CA, Dunne WN, Gross G. Evaluation of polymerase chain reaction for group B streptococcus detection using an improved culture method. *Obstet Gynecol* 2006;108:488–91.