The value of the AmniSure® Test in the diagnosis of rupture of membranes

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Objective : The AmniSure□ Test is a rapid immunoassay strip test measuring the placental alpha microglobulin-1 (PAMG-1) in vaginal secretion. The purpose of this study was to determine the accuracy of the AmniSure□ Test for the diagnosis of rupture of membranes (ROM), in comparison with conventional methods.

Methods : 184 consecutive patients (gestational age between 11 and 42 weeks) who presented with signs or symptoms of ROM were evaluated by conventional methods and the AmniSure□ Test. The diagnosis of ROM (control method) required: 1) inspection of ongoing fluid leakage, or 2) positive results of at least two of the followings: visual pooling of fluid, positive Nitrazine test, and microscopic evidence of ferning. A clinical conclusive diagnosis of ROM was made after the patient delivered and the clinical record was reviewed. A comparative analysis of the control method and the AmniSure□ Test was performed and diagnostic indices of the AmniSure□ Test in the diagnosis of ROM were calculated.

Results : ROM was diagnosed in 76% (139/184) of cases using the control method and in 88% (161/184) using the AmniSure□ Test. After clinical conclusive diagnoses were made in 26 cases with discrepancies between methods, the diagnostic indices of the AmniSure□ Test in the identification of ROM were; a sensitivity of 99% (155/157), a specificity of 88% (21/24), a positive predictive value of 98% (155/158), and a negative predictive value of 91% (21/23). Compared with the Nitrazine test as well as the control method, the AmniSure□ Test showed better performance not only in the diagnosis of ROM but also in the prediction of delivery in patients with suspected ROM.

Conclusion : The AmniSure□ Test is a reliable method in the diagnosis of ROM.