

cervical effacement of more than 50% at the 32nd week of gestational week, more than 1 episode of mid-term abortion, hypersensitivity of the uterus, uterine mass, and poor obstetric history including premature ovarian failure and diabetes mellitus. Minor risk factors included fever during pregnancy, history of vaginal bleeding after 12 weeks of gestation, history of nephritis, smoking history (more than 10 cigarettes per day), history of mid-term abortion, and habitual abortion.

To prevent contamination of our samples by maternal blood and amniotic fluid, we excluded patients with premature rupture of membranes, placenta previa, and abruptio placentae, and patients with profuse vaginal bleeding.

Before each sampling, we informed the patient, and documented the patient data. A sterile speculum was used for visual examination of the cervix. A sample of the cervicovaginal secretion was collected with a sterile Dacron swab in the kit manufactured by Adenza Biochemical (Adenza Biochemical Corporation, Sunnyvale, CA, USA). The sterile Dacron swab was lightly rotated around the outside of the cervix. The swab was placed on the posterior fornix of the vagina. The swab was soaked by gently sweeping and twirling.

A fFN membrane immunoassay was used to measure fFN. This test employs a murine monoclonal anti-

body against a proprietary epitope of fetal fibronectin. The assay was performed according to the procedures provided by Adenza Biochemical.

Samples were defined as positive or negative depending on the results of the fFN immunoassay. Positive preterm labor was defined as patients who experienced preterm labor or labor pain requiring tocolytic therapy within 2 weeks after the fFN test. The criterion for requiring tocolysis therapy was uterine contractions at least once an hour. Negative preterm labor was defined as no labor pain within 2 weeks after the fFN test.

The statistics were expressed as sensitivity, specificity, positive predictive value and negative predictive value.

RESULTS

Thirty-four pregnant women with gestational ages ranging from 21 to 34 weeks were enrolled for an fFN test during routine prenatal visits. Forty-four samples were obtained. The ages of the patients ranged from 21 to 39 years.

Risk factors of the pregnant women in our study included multiple pregnancies (9), history of preterm labor (5), premature ovarian failure (1), hypersensitivity of the uterus (9), and poor obstetric history (2). Details were given in Table 1.

Table 1. Details of Risk Factors of Pregnant Women in Our Study

Risk factor	No. of patients
Multiple pregnancies	9 ^a
History of preterm labor	5
History of preterm labor, but labor at term	5
More than 1 episode of mid-term abortion	2
Hypersensitivity of the uterus: occasional uterine contractions	9
Diabetes mellitus	1
Premature ovarian failure	1
Fever during pregnancy combined with history of vaginal bleeding after 12 weeks of gestation	1
More than 2 episodes of early pregnancy loss combined with fever during pregnancy	1
Total	34

^a One of the women with multiple pregnancies went from triplets to twins after fetal reduction.