Comparison of Reliability of Tap Test and Shake Test for Determination of Fetal Lung Maturity

Bajracharya S

Department of Obs/Gyn, TUTH Teaching Hospital, Kathmandu, Nepal

Aims: To compare the reliability of tap test and shake test for determination of fetal lung maturity in pregnant women between 28 weeks and 36 completed week's gestation either with preterm prelabour rupture of membrane or preterm labour.

Methods: Amniotic fluid samples from vaginal pool were obtained from one hundred pregnant women who met the inclusion criteria. Both tap test and shake test were performed in each sample. All deliveries occurred within 72 hours of collection of amniotic fluid. The results of the tests were compared with the incidence of neonatal respiratory distress syndrome.

Results: Out of 100 tests performed, tap test predicted 17% as immature and 83% as mature and shake test predicted 51% as immature and 49% as mature. Among 100 newborns, 9 (9%) were found to be true immature as they developed respiratory distress syndrome. The sensitivity, specificity, predictive value for fetal lung immaturity and maturity by tap test was 88.9%, 90.1%, 47.1% and 98.8% respectively and the sensitivity, specificity, predictive value for fetal lung immaturity and maturity by shake test was 100%, 53.8%,17.6% and 100% respectively.

Conclusions: In view of very low specificity and predictive value for fetal lung immaturity by shake test compared to that by tap test and lower sensitivity of the tap test than the shake test, neither of the tests is reliable than the other and these two tests can not replace each other

Keywords: Fetal lung maturity, respiratory distress syndrome ,shake test, tap test.

INTRODUCTION

Preterm delivery has been a major concern for the patients, obstetricians as well as for pediatricians.[1] The state of maturity of the fetal lung is one of the major determinants of whether a prematurely born infant will survive without difficulty.[2]

Development of specialized alveolar cells (Type II pneumocytes) occurs during alveolar phase. Pneumocytes synthesize pulmonary surfactant and pack it into laminated storage granules called lamellar bodies which are swept into the amniotic fluid during fetal breathing movement. This makes it possible to assess the biochemical maturation of fetal lungs by studying the amniotic fluid composition. The consequence of immature lung is Respiratory Distress Syndrome (RDS). RDS is the primary cause in 50-70% of premature neonatal death and accounts for approximately 20% of neonatal deaths.[3]

The worldwide incidence of RDS is 1% of live births and 10 to 15% of live preterm births.[4]

The ideal test for fetal lung maturity should be rapid, inexpensive, and capable of being done at the patient's bedside with a high predictive value for both mature and immature results. No single test of amniotic fluid has yet been found to be exclusively secure, easily performed and completely relevant in the prediction of fetal lung maturity.[3,5,6]

The phospholipids profile, which includes the determination of phosphatidylglycerol and the lecithin/spingomyelin ratio, is the most accepted test of fetal lung maturity worldwide. It has a high sensitivity and predictive value for assessing fetal lung maturity but only a modest specificity and a low predictive value for assessing fetal lung immaturity. However, this test is costly, takes time and is not readily available outside normal working hours. [3,5,6]

CORRESPONDENCE

Dr. Surichhya Bajracharya
Department of Obstetrics and Gynaecology
Tribhuvan University Teaching Hospital
Phone: 9851049849
Email: sshrestha8@yahoo.com

So alternatively quick, simpler and inexpensive bedside tap test and shake test have been used in which pulmonary surfactant development correlates with the stability of the bubbles in amniotic fluid mixed with the respective diluents in a solution.

In places with limited facility of neonatal intensive care unit, ventilator and surfactant therapy, fetal lung maturity can be determined much before the delivery from vaginal pool of amniotic fluid by rapid bedside methods and make necessary arrangement for neonatal ventilator and surfactant therapy or refer the patients in places where such facility is available.

The amniotic fluid was tested by performing two different types of tests that is, tap test and shake test. The reliability of the tap test and shake test was tested by comparing the test results with the actual incidence of the neonatal respiratory distress syndrome which was regarded as the gold standard for the determination of fetal lung maturity in this study.

METHODS

This study was conducted in Labour room of Obstetrics and Gynecology Department of TUTH, Nepal from April 2008 to April 2009.

A hundred pregnant women between 28 weeks and 36 completed weeks of gestation either with preterm labour or preterm prelabour rupture of membrane were included in the study and pregnancy with jaundice, multifetal pregnancy, grossly blood stained amniotic fluid, grade 3 meconium stained amniotic fluid and deliveries which occurred after 72 hours of collection of the amniotic fluid specimen were excluded from the study.

Procedure of collection of amniotic fluid:

Pregnant women who were in preterm labour were followed till spontaneous rupture of membrane occurred or artificial rupture of membrane was done. To avoid contamination with blood and other vaginal secretion, the initial flow of amniotic fluid was not collected and 2ml of amniotic fluid thereafter was aspirated into a properly labeled clean and sterile syringe from the vaginal pool of amniotic fluid. If the amniotic fluid collected was light blood stained or contaminated with Grade 1 or Grade 2 meconium (see Annex for definition), the amniotic fluid was centrifuged for 5 minutes in a table top centrifuge at 400xg. Clear amniotic fluid or clear supernatant obtained following centrifugation of amniotic fluid was subjected to both tap test and shake test. If the tests could not be performed immediately after collection of amniotic fluid, the samples were refrigerated at 4 degree Celsius, however all samples were analyzed within 24hours of procuring.

Table 1. Comparison of tap test and shake test

Test	Outcome		Total	Sensi-tivity	Speci-ficity	Predictive values	
	RDS	No RDS				Immature	Mature
Tap							
Immatue	8	9	17				
Mature	1	82	83				
Total	9	91	100	88.9%	90.1%	47.1%	98.8%
Shake							
Immatue	9	42	51				
Mature	0	49	49				
Total	9	91	100	100.0%	53.8%	17.6%	100.0%

Procedure of Tap Test

The tap test was performed as described by Socol et al5 in 1984. 1ml of collected amniotic fluid was taken in the standard test tube (16x150mm). The amniotic fluid in the test tube was mixed with a drop of 6N hydrochloric acid to form an acidified amniotic fluid solution and approximately 1.5ml of diethyl ether was added to the acidified amniotic fluid solution. The test solution was agitated by briskly tapping the test tube three or four times with a finger to create an estimated 200 to 300 bubbles in the ether layer. The agitated testing solution was permitted to rest for an observational period of 5 minutes. In amniotic fluid from fetus with mature lung the bubbles rise quickly to the surface and break down. In amniotic fluid from fetus with immature lung the bubbles are stable or break down slowly. The cut off for fetal lung maturity was arbitrarily set at five bubbles. If no more than five bubbles persisted in the ether layer at 5 minutes, the test was considered positive or the fetal lung is mature. If five or more bubbles persisted in the ether layer at 5 minutes, the test was considered negative or the fetal lung is immature (Fig.1). The occasional bubbles, which were confined to the amniotic fluid layer and were not dispersed in the ether layer, were ignored.
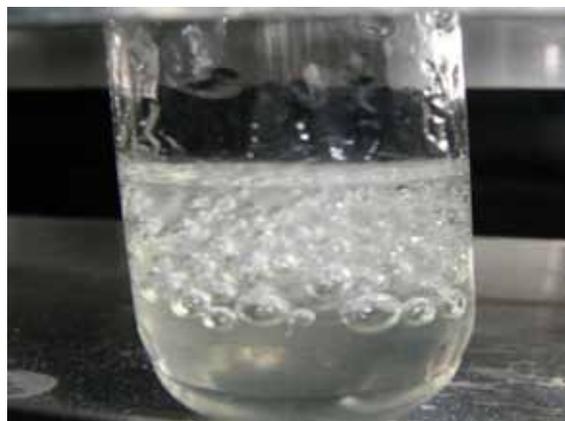

Figure 1. Immature tap test showing more than 5 bubbles

Procedure of Shake Test

The shake test was performed as described by Clements et al[8] in 1972. 1ml of collected amniotic fluid was taken in the standard test tube (12x100mm). 1ml of 95% ethanol (5ml deionized water plus 95ml absolute ethanol) was added into the test tube containing 1ml of undiluted amniotic fluid. The tube was shaken vigorously for 15 seconds and placed in upright rack for 15 minutes. Observation for a complete ring of bubbles at the meniscus after 15 minutes was done. The test was considered positive or the fetal lung is mature if it showed a complete ring of bubbles at the meniscus after 15 minutes (Fig.2). The test was considered negative or the fetal lung is immature if incomplete or no ring of bubbles at the meniscus was observed after 15 minutes.

Figure 2. Mature shake test showing ring of bubbles at the meniscus

If amniotic fluid collection and delivery interval was more than 72 hours, the cases were excluded from the study. The newborn was examined and estimated gestational age of the newborn was given based upon the standard clinical examination with the Expanded New Ballard Score. The best gestational age was determined by the best suitable of menstrual dates, ultrasonography and the Expanded New Ballard Score. The newborn was then followed for at least 72 hours following birth to rule out RDS.

Criteria for diagnosis of RDS in newborn

The diagnosis of RDS in newborn was made based on the clinical and radiological criteria. The clinical diagnosis of RDS was made with the presence of at least two of the following clinical signs manifesting within 6 hours after birth and persisted for 24 hours or more:[2,8,9]
• Respiratory rate > 60/min
• Expiratory grunting
• Chest retraction or cyanosis
The radiological diagnosis of RDS was made if features suggestive of RDS (hypo aeration, diffuse reticulogranular pattern with air bronchogram, ground glass appearance) were seen in Chest X-Ray taken 6 hours after birth.

The sensitivity, specificity, predictive value for fetal lung immaturity and maturity of the tap test and shake test were determined by comparing the results of these tests with the actual incidence of neonatal RDS.

RESULTS

Total of 100 cases were included in the study. Maximum number of pregnant women was between 34 to 36 weeks gestational age, which comprised of 75% of sample size.
All deliveries occurred within 72 hours of collection of amniotic. Among 100 newborns 9 (9%) developed RDS.
Among 9 newborns that developed RDS, 8 were correctly predicted immature by tap test and all 9 by shake test (sensitivity of tap test and shake test was 88.9% and 100% respectively).

Among 91 newborns that did not develop RDS, 82 were correctly predicted mature by tap test and 49 by shake test (specificity of tap test and shake test was 90.1% and 53.8% respectively).

Among 17 newborns that were predicted immature by tap test, only 8 developed RDS and among 51 newborns that were predicted immature by shake test, only 9 developed RDS. Therefore, predictive value for immature test results by tap test and shake test was 47.1% and 17.6% respectively.

Among 83 newborns that were predicted mature by tap test, 82 did not develop RDS and among 49 newborns that were predicted mature by shake test, none of them developed RDS. Therefore, predictive value for mature test results by tap test and shake test was 98.8% and 100% respectively.

DISCUSSION

The lower predictive value for the fetal lung immaturity for both the tap test and shake test the number of cases in this study is significantly skewed towards pregnant women with gestational age of 34 to 36 weeks where the incidence of RDS is comparatively small.

Comparison of tap test and shake test

Similar to other studies done by Guidozzi et al, 1991; Rodriguez-Macias KA, 1995 and Kucuk M, 1997, this study also reveals that the tap test has better specificity and predictive value for fetal lung immaturity than the shake test. However, unlike in other studies done by Guidozzi F et al, 1991; Rodriguez-Macias KA, 1995 and Kucuk M, 1998 where the tap test had better sensitivity and predictive value for fetal lung maturity compared to the shake test, this study had better sensitivity for shake test than for the tap test and comparable predictive value for fetal lung maturity between the two tests. [3,6,10]

The tap test is semi quantitative with arbitrary cut off for maturity and the shake test is also qualitative. The borderline results like 6 to 20 bubbles in the ether layer in tap test and incomplete ring of bubbles at the meniscus in the shake test were considered immature in this study. While Socol ML et al,5 who had encountered borderline results in previous 12 immature cases had mature result in duplicate. Therefore to decrease high false immature result, further study including the interpretation for these borderline results are required and it appears that optimal results may be obtained performing any borderline test in duplicate and reading on the second test if it indicates maturity.

CONCLUSIONS

Since RDS has high mortality rate it should be emphasized that high level of sensitivity of the test is critically important to ensure not to miss any immature case and the test should also have high specificity to decrease burden of false immature cases. In view of very low specificity and predictive value of fetal lung immaturity of shake test compared to that of tap test and lower sensitivity of the tap test than the shake test, neither of the tests is reliable than the other and these two tests can not replace each other.

REFERENCES

1. Goldenberg RL. The management of preterm labour. Obstet Gynecol 2002; 100(5): 1020-37.

2. McIntosh N, Helms P, Smyth R. Forfar and Arnel's Textbook of Pediatric. In:Halliday HL.Problems of the Newborn. Pulmonary disorders and Apnea.6thed.Churchil Livingston; 2003.250-56 Kucuk M. Tap test, shake test and phosphatidylglycerol in the assessment of fetal pulmonary maturity. Int J Gynecol Obstet. 1998;60:9-14.

3. Kucuk M. Tap test, shake test and phosphatidylglycerol in the assessment of fetal pulmonary maturity. Int J Gynecol Obstet. 1998;60:9-14.

4. Behrman RI, Kliegman RM, Jenson HB. Hyaline Membrane Disease (Respiratory Distress Syndrome). In: Nelson Textbook of Pediatric. 17th ed. China. Saunders Elsevier; 2004;575-82.

5. Socol ML, Sing E, Depp OR. The tap test: a rapid indicator of fetal pulmonary maturity. Am J Obstet Gynecol. 1984;148:445-50.

6. Guidozzi F, Gobetz L. The tap test a rapid bedside indicator of fetal lung maturity. Br J Obstet Gynecol. 1991;98:479-81.

7. Clements JA, Platzer AC, Tierney DF, Hobel CJ, Creasy RK, Margolis AJ. Assessment of the risk of the respiratory distress syndrome by a rapid test for surfactant in amniotic fluid. N Engl J Med. 1972;286:1077-81.

8. Teeratakulpisarn J, Taksaphan S, Pengsaa K, Wiangnon S, Kosuwon W. Prediction of Idiopathic Respiratory Distress Syndrome by the Stable Microbubble Test on Gastric Aspirate. Pediatric Pulmonology. 1998;25:383–89.

9. Greenough A, Roberton NRC. Acute respiratory disease in the newborn. Pulmonary disease of the newborn. Disorders of the Newborn. In:Janet M, Rennie, Roberton NRC. Textbook of Neonatology. 3rd ed. Edingburgh. Churchill Livingstone. 2000:481-607.

10. Rodriguez-Macias KA. A comparison of three tests for determining fetal pulmonary maturity. Int J Gynecol Obstet 1995;51:39-42.