



11-13⁺⁶ Weeks Scan Project

United States Newsletter

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Please come and visit our
Exhibit Booth at the

AIUM 2006

Annual Convention

Washington DC

March 24-26, 2006

Booth #511

- NT, Nasal Bone, and Tricuspid Accreditation, Software Information
- NT Reaccreditation
- Free Textbook
- Reprints of recent publications

WELCOME to the April 2006 issue of the FMF (USA) newsletter. In this issue you will find an article contributed by one of the leading researchers and proponents of first trimester screening in the United States, Dr. Eugene Pergament. In response to numerous inquiries, there is also an article pertaining to the current state of billing for first trimester ultrasound that includes nuchal translucency measurements. I hope you will enjoy these articles and take time to peruse the other features in this issue. On the last page is an updated list of Fetal Medicine Foundation first trimester courses.

Please stop by the Fetal Medicine Foundation exhibit booth (#511) at the AIUM Annual Convention In Washington DC for a free copy of the 11-13+6 Week Scan textbook as well as reprints of the latest FMF research articles.

Personal observations about first trimester screening

Eugene Pergament, M.D., Ph.D., FACMG

Professor, Obstetrics and Gynecology

Northwestern University Feingold School of Medicine

and President, Northwestern Reproductive Genetics, Inc.

Over the past five years, I have had the opportunity to participate in the introduction in the United States of first trimester screening for Down syndrome and trisomies 13 and 18. First, I was a contributor to the National Institutes of Health BUN (Biochemistry and Ultrasound Nuchal) multicenter trial on its efficacy. Secondly, I have served as a provider to several thousands of women each year of direct, face-to-face counseling, interpreting the implications and consequences of their screening results. In 2005, for example, over 2,500 women underwent first trimester screening at our facility, a simple testimony to the value placed by referring obstetricians on this non-invasive approach to monitoring fetal development early in pregnancy as well as its increasing acceptance by their patients as an integral part of their care during pregnancy. I would like to share with you some of my experiences and thoughts.....

First, nearly 45 percent of our patient population are women 35 years of age and older who never used our genetic services before. When these women were questioned, one finds that these are patients we as obstetrical geneticists never met before because they were not interested in any form of testing that incurred a direct risk to the fetus, specifically, invasive procedures such as first trimester chorionic villus sampling or midtrimester amniocentesis. These women either avoided any form of prenatal screening or testing or underwent second trimester screening with its attendant high false positive rate. After first trimester screening was introduced, many women 35 years of age and older quickly adopted this approach as a viable alternative to these previous choices. My responsibility has been to counsel them about the two properties of any screening test, particularly the implications and consequences of a false positive and of a false negative result. This also includes a discussion of the guidelines of the American College of Obstetrics and Gynecology using age as a determinant as to who is an appropriate candidate for diagnostic testing, that first trimester screening is designed to detect the more serious of chromosome abnormalities such as trisomies 13, 18, and 21, and that diagnostic testing would detect other chromosome abnormalities not identified by first trimester screening. This discussion is held with all women 35 years of age and older. In the course of our experience over the past five years, we also found that many women 35 years and older use first trimester screening as the basis for deciding whether to undergo diagnostic testing, emphasizing the paramount importance of such discussions. (cont. on pag. 2)

Personal observations (cont).

Eugene Pergament, M.D., PhD., FACMG

A second observation - one that hardly qualifies as new or startling - is that many pregnant women believe that there is possibly something terribly wrong with their pregnancy and that first trimester screening may be a better way to make such a determination. Here is the enormous value and contribution of first trimester screening, for it provides a way to document both visually through ultrasound and physiologically through chemistry that a pregnancy is developing normally. I refer to Table 1, page 72, of Kypros Nicolaides' newest version of 'The 11-13+6 Weeks Scan' which lists the estimated prevalence of delivery of a healthy baby with no major abnormalities as 97% if the nuchal translucency is <95th centile and as 93% if the nuchal translucency is increased but less than 3.5 mm. What I am explicitly addressing is the fact that for all-too-long the emphasis in prenatal diagnosis has been on searching for fetuses with anomalies with much less attention paid to the overwhelming majority of pregnant women who have normal pregnancies. Women understand, if counseled appropriately, that first trimester screening is not a guarantee of a normal child; for that matter, neither is such a guarantee offered after diagnostic testing. But what women need to see and hear is that their pregnancy is developing normally, based on the visual and biochemical documentation that first trimester screening offers in a quantitative fashion. This approach really gives fuller meaning to the notion that 'earlier is better' not just for the obstetrician but for the prospective parents as well. So, I have made a concerted effort to emphasize the role of nuchal measurements in reducing the likelihood of a chromosome abnormality, of a series of cardiac malformations and of a number of specific developmental and genomic syndromes. I recognize that this approach may well be controversial, and, yes, there have been a small number of women whose second trimester ultrasound has revealed structural anomalies not detected in the first trimester but without recriminations. All in all, from my perspective, personal to be sure, the greater good is being served by an approach emphasizing the likelihood of a normal pregnancy in the overwhelming majority of cases rather than focusing predominately on detection and false negative rates.

Finally, the question arises as to when we in the United States will stop using maternal age alone as the main criterion for diagnostic testing, as has already been recommended by the International Down Syndrome Society based in the United Kingdom. Will there be sufficient justification to offer diagnostic testing only if first trimester screening is performed first? On the other hand, there are a growing number of obstetricians who would like diagnostic testing by means of CVS or amniocentesis to be offered to all pregnant women regardless of age or indications. From my perspective, the risks of invasive testing are now fixed and defined, and, since non-invasive screening is preferred far and away by pregnant women, the focus should be on continuing to improve the content and accuracy of first trimester screening.

Evaluation of flow across the tricuspid valve in screening for trisomy 21

Cathy Downing RT RDMS RVT Jiri Sonek MD RDMS

Fetal Medicine Foundation, Maternal Fetal Medicine, Ultrasound, and Genetics Center, Dayton, OH

A number of studies have demonstrated that regurgitant flow across the tricuspid valve (TCV) is significantly more common in the presence of chromosomal defects.^(1,2) This is especially true early in pregnancy. Therefore, it is reasonable to expect that evaluation of blood flow across the tricuspid valve during ventricular systole could be useful in risk assessment of fetal aneuploidy at the 11-14 week scan. It has been shown that at this time in pregnancy the prevalence of TCV regurgitation in fetuses with trisomy 21 is about 74% whereas only 7% of chromosomally normal fetuses have this finding.⁽²⁾

The only practical way of evaluating cardiac function at the 11-14 week scan is pulsed-wave Doppler. This modality can also be used to assess blood flow across the TCV. The evaluation begins by obtaining an apical view of the four chamber heart. The ideal angle of insonation with respect to the longitudinal axis of the ventricular septum is 0° (i.e. the ventricular septum is positioned vertically on the image) but angles of up to 30° are acceptable. A relatively large (approx. 3mm) Doppler gate is placed over the tricuspid valve in order to be able to evaluate the blood flow in both directions. The biphasic forward flow across the valve is identified during the cardiac diastole and the atrial contraction. During the ventricular systole, however, there should be very little if any flow back across the closed TCV. Significant TCV regurgitation is diagnosed if reversed flow is noted and lasts for more than 50% of ventricular systole. Since the outflow tracts are in such a close proximity to the atrioventricular valves, it is not unusual to have their Doppler footprint superimposed on the region of the TCV. However, they are relatively easy to differentiate from TCV regurgitation because of the differences in their peak velocities and shapes of their waveforms. The details of the protocol to assess TCV flow can be found at www.fetalmedicine.com/usa.

Evaluation of flow across the tricuspid valve...(continued)

In order for any marker to be included in the combined screening (nuchal translucency measurement and maternal serum free β -hCG and PAPP-A, both adjusted for gestational age) at 11-13+6 weeks' gestation, it has to be sufficiently independent of these parameters to be of additional value. The prevalence of TCV regurgitation is known to decrease with increasing gestational age and increases with the degree of nuchal translucency thickening (delta NT) in a well described manner⁽²⁾. The levels of the biochemical markers have been shown to be independent of the presence or absence of TCV regurgitation⁽³⁾. Therefore, after the appropriate mathematical adjustment, this novel marker can be added to our armamentarium of early trimester markers. As with any of the other components of the screening program, it is imperative that sonographers receive the appropriate training and certification before this modality can be effectively utilized. This certification and quality assurance is now available through the Fetal Medicine Foundation.

The additional benefit of evaluating the flow across the TCV is that there is an association between an increased prevalence of cardiac defects and TCV regurgitation, irrespective of the presence or absence of aneuploidy. Therefore, if TCV regurgitation is noted and the fetal chromosomes prove to be normal, a more careful evaluation of the cardiac anatomy is always indicated.

The latest upgrade to the 11 to 13+6 First Trimester Screening Programme released in December of 2005 includes the adjustment of risk based on the finding of normal and abnormal tricuspid flow. The details of training, certification, and ongoing quality assurance are detailed on the Fetal Medicine Foundation web site at www.fetalmedicine.com/usa.

References

1. Huggon IC, DeFigueiredo DB, Allan LD. Tricuspid regurgitation in the diagnosis of chromosomal anomalies in the fetus at 11-14 weeks gestation. *Heart* 2003;89:1071-1073
2. Faiola S, Tsoi E, Huggon IC, Allan LD, Nicolaides KH. Likelihood ratio for trisomy 21 in fetuses with tricuspid regurgitation at the 11 to 13+6 week scan. *Ultrasound Obstet Gynecol* 2005;26:22-27
3. Falcon O, Auer M, Gerovassili A, Spencer K, Nicolaides KH. Screening for trisomy 21 by tricuspid regurgitation, nuchal translucency, and maternal serum free β -hCG and PAPP-A at 11+0 to 13+6 weeks. *Ultrasound Obstet Gynecol* 2006; 27: 151-155

Q&A about Billing for Nuchal Translucency in the First Trimester

Many ultrasound providers who are looking into setting up a first trimester screening program in their practices have asked for information about billing for nuchal translucency ultrasound scans. The issue of appropriate billing gains in importance as the popularity of this screening test increases. Our understanding is that there has been a great deal of effort to publish a new CPT code that will include reimbursement for the time and expertise necessary to perform nuchal translucency ultrasounds. The best guess we have is that this new code will be published in October 2006 and available for use in January 2007. As soon as we receive word, we will post this news on our website (www.fetalmedicine.com/usa). In the meanwhile, below are some of most frequently asked questions about billing along with some answers.

Question: NT/freeBeta/PAPP-A screening is recommended for all low and high risk patients (ACOG 2004). Are all patient ICD codes reimbursable?

Answer: Yes, 95% of all majors payers recognize general pregnancy related and ultrasound specific ICD codes.

Question: Which CPT codes might be used for the NT, nasal bone, or tricuspid flow assessments?

Answer: At this point, it is best to use the fetal/maternal ultrasound codes 76801, 76815, or 76999-22 U/S with documentation. A new NT CPT should be available in January 2007.

Question: If we are providing NT and an 11-13 week anomaly scan, would it be appropriate to bill a consult code?

Answer: Yes, but only at the request of the referring physician.

Upcoming Fetal Medicine Foundation United States Courses

Face-to-Face Courses

**Saturday April 1, 2006 in San Francisco CA * (6.75-8 CMEs possible)

**Saturday, May 20th in Dallas, TX * (6.75-8 CMEs possible)

**Saturday, June 3rd in Charlotte, NC * (6.75-8 CMEs possible)

**Saturday, July 15th in Cincinnati, OH * (6.75-8 CMEs possible)

**Saturday, August 5th in Seattle, WA *(6.75-8 CMEs possible)

**Contact Melissa Machtolff 1-800-277-4363 (MMachtolff@genecare.com)

or Carrie Spradley 1-800-277-4363 (CSpradley @genecare.com)

Website: www.genecare.com/35/id/Conferences

**Thursday April 20, 2006 in Las Vegas, NV * (7 CMEs possible)

**Saturday June 24, 2006 in New Haven CT * (7 CMEs possible)

**Saturday September 9 in Columbus OH * (7 CMEs possible)

**Saturday November 4 in Long Island NY **(7 CMEs possible)

** Contact Ulla Buchner-Howard 1-212-288-9793 (ubuchner@ubhInternational.com)

or Colleen Bobb 1-212-230-1426 (colleen@ubhinternational.com)

Website: www.ubhinternational.com/ultrasound.html

Online course:

***Online Fetal Medicine Foundation Course: http://www.mfmedicine.com/phys_train2.aspx

Naomi Greene email: naomihg@fetalmedicine.com John Lai email: John.Lai@mfmedicine.com

Frequently asked questions:

Question: I attended the theory course and completed my NT accreditation prior to the introduction of nasal bone and tricuspid valve assessments. Must I attend another one-day course to obtain these accreditations?

Answer: No, you do not have to attend another course. The guidelines for nasal bone and tricuspid valve assessments are available on our website (www.fetalmedicine.com/usa). They can be downloaded and reviewed. The accreditation protocols are also available on the web.

Question: What are the steps for maintaining my NT accreditation with the Fetal Medicine Foundation and what are the charges?

Answer: There are no charges for maintaining NT accreditation or for the nasal bone or tricuspid flow accreditation processes. To maintain accreditation the steps are: (1) Once per year each sonographer sends 5 still NT images chosen at random from the past year to Naomi Greene (address on front page or on the web), and (2) if you use the FMF software, you can export the data file and e-mail it to Naomi as an attachment or, if you do not use the FMF software, you may ask the lab that handles your first trimester screening to forward your data directly to Naomi.