American College of Cardiology
Position Statement

Doppler Echocardiography in the Human Fetus

[The following ACC position statement was adopted by the ACC Executive Committee on August 9, 1988. Reprints are available from: Educational Products Sales and Marketing; 9111 Old Georgetown Road; Bethesda, MD 20814; 800/257-4740.]

The delineation of fetal cardiac anatomy and the diagnosis of congenital heart disease in utero can be accomplished using high-resolution echocardiography. The application of Doppler techniques as an aspect of fetal echocardiography represents a clinical decision by the examining physician that appears to be indicated using the lowest possible power output (to the fetal thorax) yielding adequate results in the following situations in which Doppler flow observations have been shown to be of importance:

1. The interrogation of structurally abnormal fetal heart for valvular insufficiency and valvular stenosis or the verification of septation defects.

2. The interrogation of the functionally abnormal heart such as in fetal myocarditis and systolic ejection velocities.

3. The interrogation of atrioventricular valvular and semilunal flows for the evaluation of cardiac function related to arrhythmias.

The application of Doppler in these circumstances is documented as clinically established and nonexperimental by a substantial body of referenced literature. Such Doppler application in the second and third trimesters of pregnancy has not been documented to have any deleterious effects on the fetus.

The ACC Executive Committee also endorsed the attached position paper of the American Society of Echocardiography (ASE), "Doppler Echocardiography in the Human Fetus," (1) on August 9, 1988.

Doppler Echocardiography in the Human Fetus

[American Society of Echocardiography

Position Paper*]

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Fetal echocardiography has allowed prenatal diagnosis of heart disease to become a reality over the last decade. Recently, pulsed Doppler flow studies have been applied to the examination of the fetal cardiovascular system. In fetuses with dysrhythmias, complex structural heart malformations, nonimmune hydrops fetalis or mothers receiving nonsteroidal prostaglandin synthetase inhibitors, pulsed Doppler echocardiographic studies are clinically indicated. These studies involve noninvestigational tests that provide information of critical clinical import. These studies may occasionally require energy intensities that exceed the 510(k) limits. The physician should be held responsible for educating patients of the potential risks versus benefits of any imaging study they undergo, but appending potentially alarming labels to transducers, machines or cathode-ray tube displays can only serve to undermine the fabric of the physician-patient relationship without achieving the desired goal of protection of the patient. (J Am Soc Echo 1988;1:287-90.)

The 15 years that have elapsed since the original description of M-mode echocardiographic registration of fetal heart activity (2) have witnessed remarkable advances in the ability to diagnose heart disease in the human fetus. Fetal echocardiography has emerged as a tool that allows perinatologists and pediatric cardiologists to manage the conditions of fetuses with structural and functional heart disease.

Prenatal therapy of certain sustained heart dysrhythmias has proved to be lifesaving. The accurate identification of fetuses with severe structural heart disease has for the first time allowed the perinatal management team to plan treatment strategies antenatally. In the neonate with congenital heart disease that renders the child dependent on persistent patency of the ductus arteriosus to sustain pulmonary or systemic blood flow, advanced knowledge of the malformation has allowed timely lifesaving prostaglandin E therapy to be administered. Fetal echocardiography has therefore allowed prenatal diagnosis of heart disease to become a reality in 1988, approximately 25 years after ultrasonic examination of the human fetus became a reality.

The heart was the last organ to be subjected to systematic scrutiny prenatally, despite the fact that congenital heart diseases are the single most common lethal birth defects and are a major cause of neonatal morbidity resulting from birth defects. This relatively late development of prenatal cardiac diagnostic techniques can be attributed to the small size, complex anatomy and dynamic nature of the fetal heart. These properties necessitated the use of high-resolution real-tirne imagers. During the last several years pulsed Doppler flow studies have improved the diagnostic accuracy of postnatal echocardiography, and recently these studies also have been applied to the examination of the fetal cardiovascular system.

Recent studies (3-14) have demonstrated that pulsed Doppler fetal cardiovascular flow exarninations may provide information that is at once both complementary to real-time imaging and M-mode echocardiographic studies and unique. We maintain that in certain situations such studies have been demonstrated to be of essential value in the clinical assessment and management of fetuses with severe cardiovascular disease, that this information may be of great clinical importance for the provision of care to the fetus and neonate and that the information may be provided uniquely by pulsed Doppler examination. We believe further that in certain situations these studies are warranted, even if transducers that exceed the 510(k) guidelines must be employed to obtain imaging and flow information of minimal diagnostic quality. There are several situations in which these studies should no longer be considered investigational.

Perhaps the most frequent clinical application of pulsed Doppler techniques is for the analysis of fetal heart dysrhythmias (15-20). The information derived from these studies has been used to direct in utero therapy that has been lifesaving to many fetuses with sustained dysrhythmias and hydrops fetalis (15,16). A recent report (21) has also demonstrated that pulsed Doppler echocardiography may be a useful adjunct to M-mode and real-time echocardiography for rhythm analysis and monitoring of fetuses with bradycardia caused by atrioventricular block Such examinations have been demonstrated to provide unique information that may safely allow the mothers of such fetuses to avoid cesarean delivery.

Pulsed Doppler flow analysis may also provide critically important information in fetuses with structural or functional heart disease, in the absence of fetal heart dysrhythmias.

Recent studies (22,23) have demonstrated the value of structural screening examinations of the four fetal heart chambers. Four-chamber anatomy may be abnormal in the presence of a variety of heart defects that impart either increased or decreased flow through a given fetal heart chamber or blood vessel. Dilation of a given chamber may relate to obstruction to the inflow or outflow of the contralateral ventricle or to atrioventricular valve regurgitation of the ipsilateral valve. We believe therefore that ultrasound "screening" examinations of an "at-risk" population for congenital heart disease are medically indicated. Such screening examinations consist of two-dimensional and M-mode echocardiographic interrogation. Doppler examination should not be performed unless there is a specific indication to do so.

Pulsed Doppler technique has been used to characterize normal and abnormal intracardiac flows (24,25). Silverman et al. (26) demonstrated the use of these techniques to identify atrioventricular valve insufficiency in fetuses with nonimmune hydrops fetalis. This information may be critical for the rnanagement of this high-risk population of fetuses.

Recently, DeVore et al. (27) demonstrated that the newer, color flow mapping techniques may be used to complement real-time echocardiographic analysis of complex fetal congenital heart malformations. Pulsed Doppler echocardiography has proved to be important in the detection of potentially dangerous fetal ductal constriction in fetuses whose mothers receive prostaglandin

synthetase inhibitors (for example, indomethacin) for control of premature labor (28). Pulsed and color flow mapping Doppler studies may be used to detect normal foramen ovale blood flow (27) and to diagnose premature complete or partial closure of this essential fetal intracardiac communication in some fetuses with nonimmune hydrops fetalis.

We therefore maintain that in fetuses with complex heart dysrhythmias, complex structural heart malformations, nonimmune hydrops fetalis or mothers receiving nonsteroidal prostaglandin synthetase inhibitors, pulsed Doppler echocardiographic studies are clinically indicated, noninvestigational tests that provide information of critical clinical irnport.

We also maintain that although prudent use of ultrasound calls for the performance of studies under the tenet that ultrasound energy intensity and duration of exposure should be kept to a minimal level to obtain the clinically necessary information and that the ultrasound energy for these studies should be applied to avoid insonation of organs outside the fetal thorax and abdomen, these studies may occasionally require energy intensities that exceed the 510(k) limits. The physician should be held responsible for educating patients of the potential risks versus the benefits of any imging study they undergo, but appending potentially alarming labels to transducers, machines or cathode ray tube displays can only serve to undermine the fabric of the physician-patient relationship without achieving the desired goal of protection of the patient.

Years of research into the bioeffects of diagnostic ultrasound have suggested that ultrsound intensities that are attainable with commercially available equipment rnay potentially have bioeffects. Although any biohazard involves a bioeffect, not all bioeffects are hazards. At present it should be noted that there has been no documented harm from patient exposure to ultrasound (29,30) and that if there are any human effects, they must be so subtle or rare that epidemiologic studies to prove the null hypothesis would require many years and many thousands of patients.

Because we recognize that the safety of such studies has not been proved absolutely and may require follow-up studies of future generations of offspring, we believe that a search for untoward bioeffects should be ongoing in an orderly fashion and that investigators who perforrn such studies on pregnant women should be encouraged to perform follow-up studies on their offspring.

It should also be noted that the 510(k) guidelines are at best arbitrary and are based on performance characteristics of 1976 instrumentation with a 2 MHz transducer. The current instrumentation provides information of markedly different quality than the older equipment.

We are currently making no statement concerning the recent reports dealing with quantitative assessment of fetal cardiac output and the assessment of diastolic filling characteristics of the fetal ventricles. We have also not commented on the large body of information that has appeared in the obstetric literature concerning the evaluation of uteroplacental blood flow in normal and disease states (31-33). We believe, however, that until such studies have been proved satisfactorily to be safe and reliable that they should not be applied for routine screening of the human fetus.

We conclude, therefore, that prudent use of ultrasound places responsibility on the physician to weigh carefully the risk/benefit ratio of any diagnostic studies and to use minimal ultrasound exposures that allow clinically useful information to be obtained. We maintain that although routine Doppler echocardiographic screening of human fetuses cannot be advocated outside of a research setting, under an Institutional Review Board protocol there are a number of acceptable clinical indications for such studies: pulsed Doppler assessment of fetal heart dysrhythmias, complex structural fetal heart disease, cardiomyopathy, hydrops fetalis and mothers receiving prostaglandin synthetase inhibitors. The American Society of Echocardiography has reviewed these data and has voted to endorse the statement that in the above clinically indicated cases an echocardiographic Doppler study should not be considered investigational.

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