Opinion

The publishing of papers on first-trimester Doppler

This issue of the Journal contains two papers1,2 in which Doppler ultrasound was used in the first trimester of pregnancy. We must confess that we were in a deep quandary as to whether to proceed to publish them in Ultrasound in Obstetrics and Gynecology. This was not because they were of inferior quality. Both papers were well designed and addressed important aspects of early developmental physiology. Both studies had ethical review committee approval and were accepted by three of the Journal’s established reviewers. Our concern lay with the use of color and pulsed Doppler examination of the fetus in the early first trimester of a continuing pregnancy, because of theoretical risks to the developing fetus. We have previously published papers on the use of pulsed Doppler ultrasound at 11–14 weeks gestation1–3 because, at this time, fetal organogenesis is complete. The new studies involved using Doppler ultrasound as early as 6 weeks’ menstrual age and, up to the present time, there have been very few papers published on this subject at this early gestation. Francis Duck explains, in his excellent Editorial of June 19994, that a change in FDA policy in the early 1990s permitted the use of Doppler exposures, previously used for peripheral vascular work, in pregnancy, including the first trimester. To quote him directly, ‘no epidemiological or other evidence was then or is now available to support the assertion of safety at these high exposures’. Certain facts are indisputable. Transvaginal color and especially pulsed Doppler examination will create higher intensities than conventional B mode imaging; to quote Francis Duck again, ‘Doppler may have the capacity of thermally disturbing embryological development’. The main danger thus would appear to be that of heating and it could be argued that, as the fetal skeleton develops after the critical period of organogenesis, the main contribution of heating (i.e. bone) does not come into the equation.

Some reassurance may also be provided if equipment that displays safety indices such as TI and MI is used, as this at least provides evidence that attention has been paid to containing fetal exposure, while adoption of the ALARA principle does provide some evidence of user vigilance. Nonetheless, what we are left with at this moment in time is uncertainty, which is compounded by serious lack of experimental data on the in vivo effects on the fetus of color and pulsed Doppler ultrasound when performed transvaginally in the first trimester.

In view of this uncertainty, the question that faced us, as the Editors of a responsible medical journal, was, first, should we publish papers on the use of color and pulsed Doppler ultrasound performed transvaginally on continuing pregnancies during the period of fetal tissue differentiation and organogenesis (i.e. before 10 weeks’ gestation), and, second, if yes, what criteria should this Journal impose to ensure that each paper addresses safety concerns and the patients’ best interests.

We decided therefore to write to all members of the Editorial Board to ask for their opinion as to what policy the Journal should adopt as regards first-trimester Doppler studies. The response was very impressive with 31 members responding. Some wrote extensive personal opinions which, to some extent, reflected Francis Duck’s Editorial. Others outlined the problems but did not provide the sort of pragmatic policy statement that we were seeking.

In general, most of the members of the Board favored publication provided that certain safeguards were in place. Eric Jauniaux and Seth Granberg felt that, for the time being, first-trimester Doppler should only be performed for women requesting termination of pregnancy. This point was also raised by Lachlan de Crespigny, who believed that this group of patients should be the main focus for research; alternatively, he believed Doppler could be used if proven to be of clinical value. There are, we feel, deficiencies in both these arguments.

If, for example, the aim of a study was to determine whether first-trimester fetal circulatory parameters were predictive of pathology developing later in pregnancy, confining such studies to pregnancies planned for termination would be of no value. Limiting studies to circumstances where there is proven clinical value would virtually eliminate first-trimester Doppler studies, as there are few proven clinical indications at the present time. Asim Kurjak outlined some of the clinical situations where early color Doppler studies would be of value, such as measurement of spiral artery flow in patients with threatened miscarriage, subchorionic hematomas or trophoblastic disease, and the evaluation of umbilical artery and ductus venosus Doppler studies in the prediction of karyotype abnormalities. However, it could be argued that studies of spiral artery flow will not affect outcome, and Doppler studies to predict karyotype abnormality are optimally performed after 12 weeks’ gestation when fetal organogenesis is complete.

Having read and absorbed the comments of the Board, we have decided to formulate a policy which will be adopted by the Journal.

Journal policy on Doppler studies in the first trimester

The Journal will accept papers in which color and pulsed Doppler are used in the first trimester on continuing pregnancies only on the following basis:

(1) All equipment used must display the safety limits for TI and MI and these must be below the current FDA limits for safety.
Exposure times must be based on the ALARA principle. Maximum, minimum and mean exposure times used for the patient cohort must be given.

Obstetric (fetal) presets must be used where available.

Approval for the research must be given by a duly constituted legally authorized review committee or ethical review committee. In order to satisfy this Journal that the correct information has been provided to such a committee, the part of the application to this committee discussing the issue of safety of ultrasound in the first trimester must be submitted with the manuscript.

Informed patient consent must be obtained. In order to satisfy this Journal that full, unbiased information on potential bioeffects of ultrasound in the first trimester is provided to the patient and her partner, the patient information sheet must be submitted with the manuscript.

We hope that you, as readers, will approve of such measures and that they will be considered appropriate to protect the patients’ interests without preventing the publication of well-designed studies which could be of value in understanding early human development or improving clinical management of first-trimester disorders.

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On the next page we are publishing the Opinion of Frank Chervenak and Laurence McCullough, because it contains useful suggestions as to what information should be given to a patient and contains relevant information on ethical considerations when using first-trimester Doppler for research purposes.

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REFERENCES