

Against – 3D ultrasound in first and second trimester pregnancy – hype or helpful?

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“It is impossible to read through an imaging journal nowadays and turn a blind eye to the plethora of articles dealing with different aspects of three and four-dimensional ultrasound in our specialty”¹. This statement was made in 2007 and is concordant with my current literature review. Superficially, the message obtained from the mere volume of material could be that 3D ultrasound has a significant place in O&G imaging. The reality is that in the first and second trimesters of pregnancy 3D ultrasound is merely hype. This debate will not address gynaecological 3D imaging.

Technical advances

The concept that 3D ultrasound should be helpful is logical. Information obtained in volumes rather than slices and presentation in life-like images, could easily improve accuracy in spatial calculations, diagnosis and communication. However, it is now twenty years since the first publication of a system for the three-dimensional reconstruction of a fetus². Twenty years and we are still debating its usefulness. Surely that in itself supports, that in the main, we are dealing with hype. Initially the slow applicability in first and second trimester pregnancy could be excused due to technical hurdles. These included cumbersome transducer manipulation to acquire data and time-consuming off-line computer processing to produce meaningful displays. But, over the last five years, many advances in technology have been directly relevant to obstetric 3D use. “First, an increasingly fast acquisition speed, enabling quick sequences of fast moving organs such as the heart to be captured. Second, the increasing number of display modalities, making understanding and analysis of normal anatomy and pathology easier for clinicians”¹. It follows that this would account for the recent explosion in volume and diversity of publications relating to 3D ultrasound in pregnancy.

It is true, the obstetric community awaits a solution to the at least one major issue that besieges 2D imaging: operator dependence, suboptimal detection of abnormalities at screening and lack of evidence for improvement in perinatal outcomes. But, the irony of 3D imaging in first and second trimester pregnancy is that the main outcome from all this sophisticated research and development so far, is the ability to produce an instant surface rendered image of a fetal face at a routine 18 to 20 week scan or later – hype not helpful.

Limitations

Like any imaging technique, 3D in the first and second trimester of pregnancy has common problems that need to be acknowledged. These are itemised clearly in the review by Tarsa, *et al.*³. There is a learning curve with respect to data manipulation of stored volumes to obtain required infor-

mation. Not only the probe but also the fetus must remain stationary during image acquisition to avoid movement artifacts. This time period depends on volume size required. As 3D reconstruction depends on 2D image quality, a surface rendered image is only as good as the quality of the original 2D data. Avoiding structures that obstruct information in the area of interest requires knowledge in technical manipulation to avoid e.g. umbilical cord. For this reason 3D reconstruction in the presence of oligohydramnios is “nearly impossible”³. Artifacts that simulate pathology are common in 3D and can lead to misinterpretation of the study e.g. boundaries can lead to apparent defects such as a hole in the head or missing limbs. This is of particular concern in non-medical imaging use for social keepsake images. Limitations are not helpful to the use 3D ultrasound during the first and second trimester of pregnancy.

Current obstetric applications

In relation to diagnostic imaging, “currently, a minority of imaging specialists routinely utilise three-dimensional ultrasound technology”⁴. Two recent reviews conclude similarly on the topic of usefulness of 3D and 4D ultrasound in obstetrics having analysed 525 and 438 relevant articles respectively^{5,6}. Additional information is provided for the diagnosis of facial abnormalities, especially facial clefts, neural tube defects and skeletal abnormalities. In a specific review of the usefulness of 3D and 4D ultrasound in fetal facial evaluation, Kurjak, *et al.* concludes that the technique is presently used in conjunction with 2D imaging as a problem-solving modality, which adds extra time to the examination⁷. This evidence from experts in the field demonstrates that despite extensive published research 3D imaging in first and second trimester pregnancy is mainly hype.

Potential obstetric applications

“Prior to its acceptance into general clinical practice, a diagnostic modality such as 3D ultrasound must demonstrate a significantly increased predictive value in relation to currently accepted diagnostic tools”⁸. In 2000, Lawrence Platt made this statement. His editorial at this time addressed the problem that no randomized controlled trials of 2D versus 3D had been published. In addition, he pointed to inadequacies in the reported non-randomised comparative trials. In 2009, this situation appears unchanged. Additionally, my literature search did not find any studies addressing 3D use in the first and second trimester of pregnancy in non-tertiary centres of excellence or addressing its use by people without specific expertise in 3D ultrasound. Thus the available evidence to date is of limited generalisability and usefulness in an Australian obstetric population scanned mainly in a

local community setting. Again 3D ultrasound in the first and second trimester of pregnancy remains hype not helpful.

“Imaging technology for fetal diagnosis has rapidly evolved, but the clinical applicability of newer fetal imaging technology has not been defined”⁴. Volume acquisition is able to display 2D and reconstructed 3D images that display anatomical views that are not possible with 2D technology. The stage has been set for less skilled operators to be able to acquire data and create standardised images suitable for screening in the first and second trimester of pregnancy. This would revolutionise reliance on operator dependence universally and telemedicine in remote communities. Similarly, the reduced image acquisition time may be advantageous for both service providers and users in that there is potential for reduced work-related injury and length of appointments respectively. The ability to have multiple display modes should also enhance diagnosis, as should accurate volume measurement and 4D analysis to improve diagnosis of structural fetal heart malformations. Communication with prospective parents and with non-imaging clinicians also has the potential to benefit. In 2009 all the above applications remain unrealized, some awaiting further technical advances but many because the 3D research in the first and second trimester of pregnancy has not been focused on health outcomes.

In the USA in 2006, a workshop was held to address the advances made in fetal imaging technology and establish a research agenda⁴. The topics highlighted for 3D research included the development of standardised protocols for image acquisition, and an automated methodology to simplify image acquisition, manipulation and storage. The optimal 3D data set to represent fetal anatomy needs to be developed and a central volume data bank would be useful for storage. And once again the plea rang out for research to determine of the role of 3D ultrasound to improve the diagnosis of congenital abnormalities and pregnancy complications. Until this agenda is dealt with systematically by 3D researchers its use in the first and second trimester of pregnancy is hype not helpful.

Consumerism

“The commercialism and/or exploitation of pregnancy is a multi-million dollar business which has yet to fully explore the potential provided by fetal ultrasound examinations”. Trish Chudleigh’s comment is aptly prescient in her editorial in 1999⁹. Medison was the first company to produce integrated on-line 3D imaging in the Voluson 530 (Seoul, Korea). Most machines now have 3D/4D capability. Why? It is not improved screening for, or diagnosis of, fetal abnormalities in the first and second trimester of pregnancy and it is not automated image capture reducing time for examination or sonographers’ injury. It is consumer demand for a souvenir fetal ‘keepsake image’ which, generated by 3D, is much clearer and more realistic in appearance than with 2D.

In a survey conducted in 2006 in the USA, Simonsen, *et al.* reported that 9.3% of patients in their obstetric practice had an additional non-medical fetal scan in their current pregnancy¹⁰. These “shopping mall” imaging businesses have also opened up in Australia. Similarly, many medical ultrasound providers in Australia have expanded their businesses to include keepsake 3D imaging on the grounds that qualified personnel will provide a better informed, more accurate and safe service. However, there is no evidence-

base from which to counsel these women apart from the potential risk of bioeffects and the fact that fetal abnormalities can be missed whether 3D entertainment scans are done by trained or untrained personnel. The conclusions of a recent WHO systematic review stated that, “according to the available evidence, exposure to diagnostic ultrasonography during pregnancy appears to be safe”¹¹. So why is providing a 3D generated fetal image so controversial?

In Australia ASUM has a statement that use of diagnostic medical ultrasound equipment requires regulation such that its primary use is for the purpose of medical diagnosis¹². Recently in a collaborative project between ISUOG and WFUMB, a statement on the non-medical use of ultrasound takes a strong stand against the use of ultrasound without medical benefit¹³. So, is improved maternal bonding a medical benefit and what is the evidence that 3D ultrasound in the first and second trimester of pregnancy improves bonding? No randomized controlled trials have demonstrated a benefit to the fetus from maternal responses to 3D imaging and none have tested maternal responses with a validated psychological instrument^{14,15}. At best then, this justification for 3D ultrasound is tenuous. So then, is 3D keepsake imaging ethically justified because firstly, inconsistent policy on risks from bioeffects unnecessarily discriminates against harmless entertainment scanning and secondly, the medical profession should to satisfy women’s desire to enjoy their scans¹⁶? There is a fine line between medical care and consumerism. I believe that “keepsake imaging” as a reason for 3D usefulness is ethically unjustified as has been eloquently argued by Chervenak & McCullough who include in their arguments the economic conflict of interest by medical image providers and inappropriate interpretation of the role of medical cosmesis in that the fetus is not dissatisfied with its appearance but the mother may be and could even seek an abortion based on this information¹⁷. ASUM includes the trivialization of medical technology leading to erosion in the relationship between health providers and patients¹². They argue this will ultimately adversely affect maintenance of high standards of practice. But the main argument against the use of entertainment 3D should be the lack of standardised protocols to guide and monitor its use and the lack of appropriate dialogue between medical care providers and women using these services.

Conclusion

After twenty years, 3D in the first and second trimesters of pregnancy is a technology that is yet to realise its potential through improvement in either the practice of ultrasound or perinatal outcomes. It remains a research and development tool and should be acknowledged as such, with properly designed clinical trials used to evaluate its value-add to current 2D practice in screening, diagnosis and automated image acquisition. Furthermore, its credibility has been seriously undermined by its own successful marketing campaign promoting attractive fetal facial images which are now readily accessible from non-medical providers. 3D ultrasound in the first and second trimester of pregnancy is purely hype providing a platform to enable commercially lucrative “entertainment 3D” for consumers. This creates an ongoing conflict of interest for medical providers and exposure to non-standardised care and uncharted risks for pregnant women.



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