3D and 4D ultrasonography
– review of doubts and controversies

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Abstract
A constant progress in sonographic techniques and rapid evolution of 3D/4D techniques gave us a lot of advantages but made us also to ask and answer many important questions. We review and discuss such important topics like: marketing pressure, safety and law regulations, validity of 3D/4D US diagnostic and its impact on clinical route, 3D/4D and prenatal bonding/maternal anxiety, learning process, limitations of techniques and potential pitfalls of 3D/4D, imaging artifacts of medical instruments in 4D ultrasound-guided interventions. We point out the possible disadvantages and limitations of the method which become of a more and more clinical importance.

Key words: prenatal diagnostic, 3D/4D ultrasound, controversies

Abbreviations: 3D/4D US – three dimensional/four dimensional ultrasound, AIUM – American Institute of Ultrasound in Medicine, FDA – Food and Drug Administration, ANOVA – Analysis of Variance, STIC – Spatio-Temporal Image Correlation

Introduction
There is also no doubt that ultrasound has become one of the most powerful diagnostic tools in modern medicine. Ultrasonic imaging is one of the most frequently used imaging modalities today. A constant progress in sonographic techniques and rapid evolution of 3D/4D techniques gave us a lot of advantages and raised our hope to established more precise diagnosis then we ever did.

Growing number of ultrasound imaging exams and a fact that 3D/4D has become more widely used on a routine basis in either hospital departments or private practices made us to ask and answer many important questions.

We would like to review and discuss such important topics as:
• Marketing pressure
• Safety and law regulations
• Validity of 3D/4D US diagnostic and its impact on clinical route
• 3D/4D and prenatal bonding
• 3D/4D and maternal anxiety
• Learning process
• Potential pitfalls of 3D/4D
• Imaging artifacts of medical instruments in 4D ultrasound-guided interventions

Literature review and discussion
Marketing pressure
On TV, internet, newspapers one meets a lot of wonderful pictures of smiling, yawning babies. A lot of female fans heard that Tom Cruise purchased a 3-D ultrasound machine so that he could view the baby his wife, Katie Holmes, was carrying, whenever he wanted. Pressure on pregnant women is so high that who could resist? Manufacturers are pushing hard to win acceptance for a much more extensive 4D movie of the unborn infant, provided by “fetal portrait” studios in shopping malls.

All of them are captured on DVD using state-of-the-art ultrasound equipment depending on their financial status future mothers can choose between basic ultrasound video ($75) and deluxe package (incl. a 20-minute 4D video set to music and stored on DVD, a set of wallet photographs, and a set of larger photographs suitable for framing ($285) [1]. Clearly, there is money to be made at all levels of the ultrasound food chain and company 4D technology has been an area of surprising growth. Yet with the powerful technology has come a powerful controversy.

Safety
What is widespread opinion about safety of ultrasound examinations? “Extensive studies over 30 years
have found that ultrasound has not been shown to cause any harm to mother or baby. There has never been a harmful effect shown by the use of ultrasound. Many women have multiple ultrasounds during pregnancy with no negative effect on the baby. Thousands of studies have been conducted. Nothing has surfaced yet that indicates any harmful effects in the use of ultrasound on animals or on humans. That’s public opinion. Now if we come closer to physical knowledge how ultrasound impacts fetal tissue we realize that loud, heat and other effects seem to be important risk factors. For example although ultrasound itself does not produce audible noise, secondary vibrations can produce noises as loud as 100 decibels, causing fetuses to move. Tiny bubbles in tissue (a process known as cavitation), sheering forces within tissues, induced flows within fluids or creation of minute quantities of toxic chemicals are important but still poorly understood effects [2]. Of course because of ethical restrictions we do not have the direct study of ultrasound effects on humans. So animal models as well as data from populations of humans exposed to ultrasound in the past are used. One of important voices voting for safety of ultrasound were results of research which was conducted by Polish scientists. They observed actual temperature obtained from an adult human brain during ultrasound exposure and did not noticed any temperature increase. Conclusion was that human brain enjoys better cooling capacities than the brains of smaller mammals [3]. But what is fetus if not a very small mammal? Most authors underline that only one effect, a higher rate of left-handedness among boys exposed to neonatal ultrasound, has been observed in at least two separate studies. Nevertheless left-handedness is statistically linked to many cognitive and developmental problems ranging from learning difficulties to autism and epilepsy [4, 5]. The increase in left-handedness associated with neonatal ultrasound exposure could be the result of subtle brain damage causing people who ought genetically to be right-handed to become left-handed [6]. We cannot forget that most findings were based on health data from children whose mothers were scanned in the late 1970s and early 1980s. But by the mid-1990s, average exposure levels had risen significantly. „...time-averaged values of intensity in the most common ultrasound scanning mode are now up to 1000 times greater than those reported in the 1970s...” [7]. If we carefully review that statement it is to be clear that scientists need to repeat the left-handedness studies, as well as studies of other possible effects, on this younger, more intensively exposed population. The facts are that to date, such follow-up studies have not been done. On October 2004, Pasko Rakic, Chairman of the Neurobiology Department at Yale University said „...we have observed disruption of normal migration of cells in the brains of fetal mice following exposure to ultrasound...” [8]. In humans, such disruption is known to be caused by certain viruses, mutations, and drugs, and it is linked to a range of disorders including autism and learning disabilities.

Law regulations

The AIUM strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes. The use of either two-dimensional (2D) or three-dimensional (3D) ultrasound to only view the fetus, obtain a picture of the fetus, or determine the fetal gender without a medical indication is inappropriate and contrary to responsible medical practice [7]. Persons who promote, sell or lease ultrasound equipment for making “keepsake” fetal videos should know that FDA views this as an unapproved use of a medical device. In addition, those who subject individuals to ultrasound exposure using a diagnostic ultrasound device (a prescription device) without a physician’s order may be in violation of state or local laws or regulations regarding use of a prescription medical [9].

The validity of 3D US diagnostic and its impact on clinical route

Michailidis and co-authors scanned one hundred and fifty-nine pregnant women at 12-13 weeks gestation. A survey of the fetal anatomy was obtained by 2-D ultrasound. Subsequently, two volumes of the whole fetus were acquired using 3D ultrasound. A complete anatomical survey was achieved in 93.7% of the cases with 2D ultrasound as compared to 80.5% of the cases with 3D volume acquisition. In conclusion they pointed out that while 3D ultrasound can be a useful addition to clinical practice, 2D ultrasound remains the best way to examine fetal anatomy in the first trimester [10]. Scharf et al. examined 433 pregnant women with 2D and 3D ultrasound. 3D visualization in healthy fetuses was reported to be inferior in quality to 2D visualization of the internal organs, extremities, face, and heart. A clear 3D view of the gender was possible for 7.9% of the fetuses compared to a 95% visualization rate with 2D sonography. In case of fetuses with malformations 3D imaging provided a slightly better description of the congenital defect in only one case and this did not result in a different therapeutic approach. Authors stated that 3D imaging can be useful for specific malformations under the condition that these examinations would be perfor-
The total number of defects detected was 1012. Comparing the 2D and 3D techniques, 3D ultrasonography proved advantageous in 60.8% of the defects, which was related to the favorable demonstration of targeted areas in different views (e.g., multiplanar, surface). In 42 of the 1012 malformations (4.2%), a defect was accurately identified or verified with 3D ultrasound only. According to the investigators, 3D US used as an adjunct to 2D US allowed for a better assessment of the severity of fetal defects. In conclusions authors underline that 3D sono-
graphy is not a competitive, but complementary techni-
que to 2D ultrasound [12]. Goncalves with co-workers scanned 99 fetuses. Initially examinations were done by 3D/4D volume ultrasound. After establishing an initial diagnostic impression by 3D/4D ultrasound, a blinded independent examiner performed a 2D ultrasound examination. Information provided by 3D/4D ultrasound examinations was found to be consistent with results of 2D ultrasonography in 90% of cases. The authors concluded that the evaluation of fetal anatomy and diagnosis of congenital anomalies are possible using 3D/4D volume datasets alone. Nevertheless one must notice that a total of six anomalies were missed by 3D/4D when compared to 2D ultrasonography [13]. Jani and colleagues compared a prediction of postnatal survival in isolated diaphragmatic hernia by prenatal 2D versus 3D sonographic assessment of the contra lateral lung was assessed. The survival rate was 59.6% (28 of 47). There were significant associations between O/E LHR trace and O/E LHR diameters, and between each O/E LHR and O/E volume, but multiple regression analysis demonstrated that significant prediction of survival was provided only by O/E LHR trace and intrathoracic herniation of the liver. Their conclusion was that in diaphragnatic hernia prenatal prediction of postnatal outcome is better by 2D measurement of LHR trace than it is by 3D measurement of lung volume [14]. A Hayes review of the evidence found that overall the studies suggest that compared with conventional 2D ultrasound. There is no doubt that 3D sonography can provide additional and more specific diagnostic information on high risk and normal fetuses in the second trimester. However, there was insufficient evidence to conclude that 3D or 4D ultrasound can replace the 2D technique for obstetrical examinations. Also, none of the studies identified examined the impact of 3D and/or 4D ultrasound on clinical outcomes and appropriate clinical roles for the technology have not been established [15]. Discussing the problem of 4D and prenatal bonding we still have more questions than simple answers. The phenomenon of maternal–fetal attachment develops gradually throughout pregnancy and peaks in the few weeks after the birth of the child. It is now widely accepted that the early routine scans at 12 and 20 weeks are the main factors involved in initiating this bonding process, although, disappointingly, ultrasound has not been shown to intensify this process in the third trimester. Furthermore, it has not yet been demonstrated that ultrasound can make a positive impact on pregnant women with sub-optimal prenatal attachment [16]. Sedgmen’s group tried to explore the impact of timing and type of ultrasound exposure on maternal-fetal attachment and maternal health behavior during pregnancy. Maternal–fetal attachment increased after both 2D and 3D ultrasound exposure and the effect was moderated by the timing of exposure, with women receiving their first ultrasound examination at around 12 weeks showing the greatest change. Surprisingly there was no significant difference in the pattern of change for 2D compared with 3D ultrasound exposure, and no effect of ultrasound exposure on maternal perception of the fetus. They concluded that ultrasound generally has a positive impact on maternal–fetal attachment, particularly in the first trimester. However in their opinion 3D ultrasound did not offer enhanced benefits [17]. Lapaire conducted prospective randomized pilot study among low risk women with singleton fetuses in the second and third trimester (sixty patients were included). Dependent on the randomization pattern, US was commenced either with 2D US or 3D US and the effects were recorded with standardized questionnaires. Although the quality of 2D US, assessed by the examiner, was superior to 3D US, maternal recognition was higher with 3D US. With 2D US, nulliparous patients had significantly more difficulties visualizing the fetus, than multiparous. However, the maternal preference of 3D US had no significant impact on maternal-fetal bonding.

Authors realize that the three-dimensional images may facilitate recognition of the fetus. This finding may be a reason not to consider 3D ultrasound for routine scanning [18]. A similar conclusion was presented by Rustico and colleagues. Their results indicated that the addition of 4D ultrasound does not significantly change the perception that women have of their baby nor their
anteral emotional attachment compared with conventional 2D ultrasound [19]. A very important question is if there are any connection between 4D and maternal anxiety. Leung and co-workers in their randomized study tested the hypothesis that the use of 2D with 3D/4D ultrasonography can reduce anxiety to a greater extent in women at risk of having a fetus with congenital abnormalities than the use of 2D ultrasonography alone. Repeated measures ANOVA (analysis of variance) also showed that there was no significant interaction effect between groups and time of assessment on the state anxiety scores. About 80% of women reported a better understanding that their baby was normal after viewing 3D rather than 2D images. Their results suggest that the addition of 3D/4D ultrasound does not cause a significant reduction in maternal anxiety in pregnancies at risk of fetal abnormalities compared with conventional 2D ultrasound alone [20]. Stuart Campbell does realize that problem of 4D and prenatal bonding is still not examined enough. A lot of work ought to be done, for example future studies should be randomized, should involve an assessment of 4D ultrasound in the third trimester, should assess whether giving parents a video consolidates the experience, should target the cohort of women who are sub-optimal bonders and should assess the impact of the scan on tangible health-behavior benefits [16].

Learning process

3D/4D ultrasound is a novel and different technique. For the beginners it seems to be essential to get teaching sessions supervised by most experienced colleagues. The learning process is gradual, one should get and improve new skills step by step. Important question is what learning curve of 3/4D US for experts in conventional 2D ultrasound looks like. To explore that problem Azumendi with co-workers did an overall of 1000 randomized selected routine prenatal scans. Scans were performed by nine experts in 2D US with different levels of expertise in 3D/4D technique. The highest quality scores were obtained by the most experienced group, with no differences observed in maternal satisfaction. It seems that 3/4D scan has some technological limitations despite expert knowledge [21].

Time

3D/4D is a very important part of tertiary detailed ultrasound scan. Usually 2D is performed first. Then 3D volumes are acquired for storage followed by the 4D examination. What does take time according to authors’ opinion is the interrogation of the stored 3D volumes after they have been acquired. They point out that in most units it will generally be done at the end of the day, either on the machine itself or, if available, on a computing workstation. At this stage of technology evolution, the time investment in this phase can be considerable. Authors underline that any theoretical benefit that 3D may reduce sonographer scanning time remains firmly in the future. 3 and 4D does not have a part in a busy screening practice at present [22].

Limitations of the technique and potential pitfalls

As every method 3D/4 technique has its limitations. Rapid fetal or maternal movements may be a source of artifacts and poor visualization. However it could be more or less overcome by sonographer’s patience.

In case of inadequate amniotic fluid volume the proper acquisition may be more problematic and could be not solved properly. These problems are especially clearly seen in 3D/4D echocardiography. In STIC acquisition its’ quality will affect all further stages of post-processing and evaluation.

The original angle of isonation at which a scan was performed will impact on the quality of all the planes acquired. It is important to achieve an optimal beginning 2D plane before starting 3D or 4D acquisition. Shadowing artifacts pose a particular problem for 3D/4D ultrasound. However, they may be present within the acquired volume block. It is imperative to review suspected defects with repeated 2D and 3D scanning to confirm their presence in additional scanning planes [23]. 3D rendering creates virtual images. That application of some algorithms designed to smooth the image can lead to loss of data from the original scan therefore 3D rendering should always be used in conjunction with the A-frame 2D image for comparison.

Rotation of the volume with Doppler directional flow information can mislead the operator. If the directions are reversed, flow data can be misinterpreted.

The operator must confirm any suspected pathological flow patterns by confirming the original direction of scanning [24].

As 3D/4D ultrasound imaging becomes more often used in guided interventions knowledge of potential artifacts caused by medical instruments during such procedures seems to be essential. Surgical instruments generate imaging artifacts, which can obfuscate their location, orientation, and geometry and obscure nearby tissue. The purpose of the study was to identify and describe the types of artifacts which could be produced by metallic instruments during interventions guided by 3D/4D ultra-
sound imaging. Authors point out that instrument artifacts in real-time 3D ultrasound images can be more confusing than those from the same instruments imaged in 2 dimensions. Artifacts could be diminished by using mitigation techniques, including careful selection of probe and incision locations, as well as by instrument modification [25].

Conclusion

There is no doubt that three and four dimensional techniques are the most promising and encouraging in modern sonographic diagnostic. However contemporary 2D ultrasound is of such high quality that it may have hindered balanced appreciation of 3 and 4D ultrasound potential.

The state-of-art 3D/4D ultrasound equipment remains still very expensive. We must remember that novel 3/4D imaging technique requires considerable expertise and can only be achieved from excellent basic 2D skills. Finally also in our opinion 3/4D have a place in the armamentarium of a tertiary referral unit, but not yet in routine screening and should be rather used as complementary techniques to conventional 2D ultrasound [22].

References


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