

'Misplaced faith' in the 20-week morphology scan



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In Australia, the 20-week morphology scan is available and recommended for all women as part of routine obstetric management. Medicare statistics from 2004 to 2006 indicate that 75 per cent of women accessed this service through the Medicare Benefits Schedule (MBS) at a cost of \$17 to \$19 million per year.¹⁻⁴

Actual rate of uptake and cost is likely to be much higher as many morphology scans are not acknowledged by the MBS for various reasons, including gestational age exceeding 22 weeks, hence categorised as a 'growth scan'; scanned in the public sector with no direct MBS billing; or scanned but ineligible for MBS rebates. This data supports the morphology scan as a well-accepted test, but is this popularity and cost to the Australian community justified?

Definition and purpose

To optimise visualisation, this scan is ideally performed from 18 to 22 weeks gestation. As a routine screening test, the morphology scan aims to provide the woman and her obstetric care provider 'with as much information as possible about the pregnancy in the safest and most cost-effective manner.'⁵ Traditionally, the morphology scan is used by health professionals as a single scan in pregnancy to assess gestational age, detect fetal structural anomalies, locate the placenta and diagnose multiple births in the belief that this is useful information. However, with the increasing rate of first trimester dating scans and the increasing use of nuchal translucency scans for first trimester aneuploidy screening, its role in the assessment of gestational age and diagnosis of twins is being superseded. As leaders in obstetric care, it is our responsibility to understand and inform women of the evidence-based health outcomes associated with this scan performed in its current context.

Benefits

When compared with selective ultrasound, routine ultrasound screening before 24 weeks gestation is associated with significantly less inductions of labour for apparent post-term pregnancy (OR 0.61, 95% CI 0.52 to 0.72), less undiagnosed twins at 20 weeks (OR 0.12, 95% CI 0.03 to 0.56) and more terminations of pregnancy for fetal abnormality (OR 3.19, 95% CI 1.54 to 6.60).⁶

This *Cochrane* systematic review provides high-level evidence that a routine screening ultrasound in the second trimester before 24 weeks enables better gestational age assessment, earlier detection of multiples and improved detection of fetal anomalies, resulting in more planned termination of pregnancy for affected fetuses. However, this meta-analysis was first published in 1998 and has remained unchanged, being last assessed as up-to-date in 2001.

In the contemporary context of a prior dating ultrasound or nuchal translucency ultrasound, gestational age assessment and detection of multiples has been attained more accurately than is possible at

the 20-week morphology scan. Thus detection of fetal anomalies is the only efficacious outcome remaining, as perinatal mortality is not altered and 'there is no good quality evidence on long-term outcomes for women and their children'.⁷

Accuracy

Ascertaining the accuracy of the 20-week morphology scan is complex. Firstly, what aspects of the scan should be considered given that the purpose of the scan as stated by the Australasian Society for Ultrasound in Medicine (ASUM) is to 'provide as much information as possible about the pregnancy'.⁵ There is the accuracy of gestational age assessment; accuracy in diagnosis of multiples; accuracy of placental location; and accuracy of detection of structural malformations, as all are relevant. For the purpose of this discussion, I will limit accuracy to the detection of structural abnormalities, as this remains the unique feature of this scan that is supported by high-level evidence.

With all screening tests, the accuracy depends on the number of false positive and negative results generated when the test is applied in a setting similar to one's own situation. The Eurofetus study was designed to assess the accuracy of routine ultrasound in the antenatal detection of malformations in an unselected population.⁸ This prospective study in 61 European obstetric units included 230,750 women whose fetuses had 4615 (two per cent) malformations detected after postnatal follow-up.

Overall, 44 per cent of malformed fetuses were detected before 24 weeks gestation. Limiting this detection to fetuses with severe malformations, therefore, 'lethal abnormalities or those that were incurable and likely to incur marked handicap or those requiring major surgical intervention', the sensitivity was 55 per cent. This means that 45 per cent of severe malformations were not detected by the 20-week morphology scan. In addition, if all the pregnancies in the study are considered, there were 492 false alarms or false positive diagnoses for malformation and 2022 false negative diagnoses.

It is also important to acknowledge that this study was exclusively performed in level two hospitals with qualified personnel and high quality equipment. It is therefore not a population-based study but an institution-based study and therefore not necessarily reproducible in an Australian setting.

Limitations

Detection rates of fetal malformations at the 20-week morphology scan are limited by a number of factors, including pregnancy-specific (for example, gestational age); maternal (for example, obesity); organ-specific (for example, central nervous system

[CNS] versus congenital heart disease [CHD]); level of training (for example, tertiary versus non-tertiary); and quality of equipment. However, not all of these factors have been studied systematically.

The Radius study highlighted that the level of expertise is paramount in optimising detection rates by obtaining significantly different sensitivities in tertiary and non-tertiary settings (RR 2.7, 95% CI 1.3 to 5.8).⁹ This study also demonstrated the relevance of gestational age with higher rates of detection if later gestational ages are included (cases: controls 35%: 11%, RR 3.1, 95% CI 2.0 to 5.1) compared with less than 24 weeks gestation, therefore, the 20-week morphology scan (cases: controls 17%: 5%, RR 3.4, 95% CI 1.6 to 7.1).⁹ This probably reflects the increasing size of organs examined, the evolution of some malformations (for example, gastrointestinal disorders which become detectable in late pregnancy due to the development of fluid-filled masses), and late onset conditions causing deformation, such as hydrocephalus due to intracranial haemorrhage.

As an example of organ-specific differences and variations between countries with different policies, detection of neural tube defects ranged from 62 per cent to 97 per cent and detection of CHD from zero to 64 per cent in the Euroscan study.¹⁰ This was a population-based routine ultrasound detection study using retrospective analysis of congenital malformation registries in 12 European countries where 8126 malformed fetuses and babies were diagnosed in 709,030 consecutive births. Eurofetus documented a similar trend with 88.3 per cent of CNS malformations detected but only 38.8 per cent CHD.⁸ In addition to organ system discrepancies, detection rates differ in specific anomalies in a particular organ system. A population-based study in Victoria, Australia, demonstrated that the highest antenatal detection of 84.6 per cent was for hypoplastic left heart syndrome compared with the lowest of 17.0 per cent for transposition of the great arteries.

As well as detection rates (sensitivity) for malformations, the accuracy of the ultrasound screening test (positive and negative predictive values) will depend on the prevalence of malformation in the community and of each anomaly specifically. This is influenced by ethnic group, genetics, environment, diet, chronic disease and maternal age to mention a few.

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Harm

There is potential to cause harm with any screening test. False positive results may lead to anxiety and unnecessary further testing which may be invasive, risking continuation of the pregnancy. False negative results are not known until some later time, may have devastating consequences for the child and family depending on the severity of the congenital abnormality and are a common reason for litigation in Australia. False negatives are the particular issue with routine screening ultrasound and although increased detection is desirable, it is not always realistic. Informing and educating pregnant women about the benefits, accuracy and limitations may avoid unnecessary harm. It is important for women to understand that this scan is not a screening test for aneuploidy and is therefore not an alternative to the nuchal translucency scan. The National Institute for Health and Clinical Excellence (NICE) guidelines in

the United Kingdom recommend in relation to screening for fetal anomalies ‘at the first contact with a healthcare professional, women should be given information about the purpose and implications of the anomaly scan, enabling them to make an informed choice as to whether or not to have the scan’.⁷

Women’s perceptions and expectations

Women are commonly unquestioning about their morphology scan and accept it as a routine service which gives them an opportunity to visualise their baby and obtain a picture, as well as provide reassurance and a means to determine gender.¹² It is therefore not surprising that when a problem is encountered, the response is often that of anxiety and shock.¹³ ‘Such a trade-off between a large number of reassured, negatively tested subjects against the small number of distressed, positively tested subjects is endemic to all screening programs and not only during pregnancy.’¹²

Women may not fully understand information on the accuracy of the morphology scan as a screening test, especially as this may be covered in a cursory manner by the referring clinician. Similarly, they can be unprepared for uncertainty in results and do find it difficult to put variations of normality into perspective. These issues can induce anxiety and confusion, even if further monitoring and intervention may resolve the situation. A qualitative study to determine women’s responses to the detection at her 20-week morphology scan of the minor structural variant, the isolated choroid plexus cyst, determined that the majority of women (88 per cent) will experience intense negative emotions and anxiety despite having had low-risk aneuploidy screening.¹⁴

It is maybe unfortunate that a clinical examination, which has the potential to affect women’s emotions positively, has not capitalised on studying these effects systematically. In the domain of reassurance, none of the trials comparing screening ultrasound with no or selective ultrasound use has studied the psychological effects on parents. Neither has high-level evidence been achieved for the effect of routine ultrasound on maternal behavioural change that may improve health outcomes, such as a reduction in smoking.^{7,13}

Doctor’s perceptions and expectations

Most obstetricians have accepted the 20-week morphology scan as part of routine antenatal care. Standards of information provided to the pregnant woman prior to this test vary considerably. Written information is available and RANZCOG has relevant brochures.¹⁵ To assist in achieving the desired standard of care, the Australian Department of Health and Ageing, in conjunction with RANZCOG and other learned bodies, have developed *Guidelines for the Use of Ultrasound in the Management of Obstetric Conditions*, protocols for counselling, referring, examining and reporting the routine 20-week morphology scan.¹⁶ This document will provide obstetricians with tools to assess the level of expertise of the healthcare providers they use to provide this service. It is important that deviations from normal are referred early for tertiary-level assessment and interpretation, as this scan is a major cause for litigation in obstetrics. There is high-level evidence of improved detection rates of malformation with the appropriate level of expertise.⁹

Restoring ‘faith’ in the 20-week morphology scan

The purpose of the 20-week morphology scan in contemporary practice is to identify fetal anomalies. RCOG categorises congenital anomalies into one of four groups: lethal; possible survival and long-term morbidity; anomalies amenable to intrauterine therapy; and anomalies associated with possible short-term or intermediate morbidity. Ultrasound cannot reassure women that their baby is normal as many anomalies are missed.⁷ Despite not improving

outcomes, this scan does enable the pregnant woman and her partner to be counselled appropriately and exercise management choice to optimise care according to category of anomaly and their preferences. The choice encompasses termination of pregnancy, preparation for palliative care, disability or treatment with delivery or intrauterine therapy organised in a setting with the correct specialist services if necessary.

In Australia, optimising screening outcomes by utilising systematic referral patterns from low to high-level expertise is desirable. Consideration should be given to economic rationalisation by developing organised triaging pathways.

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