Ultrasound diagnosis of miscarriage: new guidelines to prevent harm

At the recent ISUOG meeting in Los Angeles, there was great debate about the current cut-offs we use to define miscarriage using transvaginal ultrasound. In particular, the guidelines used by both the RCOG and ASUM are not conservative enough and may lead to false positive diagnosis of miscarriage.

In routine practice, when there is a suspicion of a non-viable pregnancy, we rely on the measurements of the CRL and gestational sac to make the diagnosis. The current guidelines state that:

- If the crown rump length (CRL) is > 6 mm and there is no embryonic cardiac activity, this is defined as a missed miscarriage, or
- If the mean gestational sac diameter is > 20 mm and there is no yolk sac or embryonic pole, this is defined as an empty sac miscarriage, or
- If at the follow up scan after at least one week, there is still no embryonic cardiac activity or the gestational sac remains empty, then a diagnosis of non-viability can be made.

In four studies, recently published in *Ultrasound in Obstetrics and Gynecology*, based at Imperial College London, UK, Queen Mary, University of London, UK, and the Katholieke Universiteit Leuven, Belgium, researchers found that these aforementioned current definitions used to diagnose miscarriage could lead to an incorrect diagnosis.

A systematic review by Jeve, *et al.* concluded that the data behind the current guidelines is based on old studies and unreliable evidence.

Two studies by Abdallah, *et al.* also published in the November issue of *Ultrasound in Obstetrics and Gynecology,* suggest that in some cases these ultrasonographic cut-off values to define miscarriage cannot be relied upon. When there is doubt about the diagnosis of miscarriage, current guidelines suggest the woman should be rescanned seven to 10 days later to re-measure the gestational sac. If the gestational sac does not grow, it is assumed that a miscarriage has occurred.

However, gestational sac and embryonic growth are not useful as criteria to define miscarriage, and the authors found that perfectly healthy pregnancies may show no measurable growth over this period of time.

Anecdotally, I have heard reference to a case in which a transvaginal scan was performed in a woman who was 6 weeks and 3 days gestation in her second pregnancy. The gestational sac was empty and the mean gestational sac diameter was 15.3 mm. As per current guidelines, an interval ultrasound was scheduled in seven days. At the rescan the gestational sac was still empty and the mean gestational sac diameter was now 24.3 mm. Based upon the RCOG and ASUM guidelines dated 7th September 2011, there was a diagnosis of an empty sac miscarriage. Her obstetrician was on holidays and upon his return (four weeks later), before booking the D&C, he performed a bedside ultrasound and found a viable embryo!

The final study, by Pexsters, *et al.*, also published in November's issue of *Ultrasound in Obstetrics and Gynecology,* revealed that there is up to a 20% variation in the size of gestational sacs reported when different clinicians measure the same pregnancies on transvaginal ultrasound. If the first measurement over-estimated the gestational sac size and the second measurement some days later underestimated it, then it would be easy to incorrectly conclude that no growth had occurred. These errors could lead to a false positive diagnosis of miscarriage being made in some women.

Soon after these papers were published, the RCOG released a press release stating that the guidelines for the diagnosis of miscarriage are not conservative enough. The recommendation which has been temporarily endorsed by the RCOG states that:

- If the crown rump length (CRL) is > 7 mm and there is no embryonic cardiac activity, this is defined as a missed miscarriage, or
- If the mean gestational sac diameter is > 25 mm and there is no yolk sac or embryonic pole, this is defined as an empty sac miscarriage.

In light of these findings ASUM has initiated a press release which suggests that practitioners exercise caution, highlighting the importance of transvaginal confirmation of early pregnancy failure.

The challenge now is to prospectively validate new ultrasound cut-offs. On the basis of these recent publications, there is no doubt of the need to review the current RCOG and ASUM definitions used to diagnose miscarriage to incorporate these new data.

Assoc Prof George Condous, Editor

ASUM Press Release

ASUM would like to draw your attention to recent research conducted by the University of London and the Katholieke Universiteit Leuven, Belgium, published in the November 2011 issue of *Ultrasound in Obstetrics and Gynaecology*.

The studies suggest that given inter-observer variability in ultrasound measurements and the significant variation in early embryonic growth, a more conservative approach to the diagnosis of early pregnancy loss is warranted.

The recommendation which has been temporarily endorsed by the RCOG suggests a mean sac diameter (MSD) cut off > 25 mm and a crown rump length (CRL) cut off > 7 mm be introduced to minimise the risk of a false positive diagnosis of miscarriage.

While this research awaits confirmation from other centres ASUM suggests interim caution and highlights the importance of transvaginal confirmation of early pregnancy failure.

It should also be noted that many other factors are used when assessing early pregnancy failure, including the presence of a yolk sac, shape of the gestation sac, position within the uterine cavity or cervix, progress from a previous scan and correlation with known gestational age especially in IVF pregnancies.

Fergus Scott, ASUM President
Simon Meagher, Policy and Standards Chair