UPDATES IN EARLY FIRST TRIMESTER GUIDELINES

Kalesha Hack, MD, FRCP(C)
Division of Women’s Imaging
Sunnybrook Health Sciences Center

DISCLOSURE

• I have no financial conflicts of interest to disclose

OVERVIEW

• Indications for early T1 ultrasound
• Terminology of early pregnancy
• New US criteria for assessing viability
• New approach to discriminatory B-hcg level
• How to apply new criteria in clinical practice

INDICATIONS FOR T1 US

• Confirm viable IUP
• Accurate pregnancy dating
• Assess for multiple gestation
• Assess nuchal translucency
• Screening for gross major anomalies

CHALLENGE OF EARLY PREGNANCY US

• Coupled with the fact that women are presenting earlier than they ever did for confirmatory ultrasound
• Significant potential to do harm if misdiagnose early pregnancy loss or ectopic pregnancy in setting of a viable intrauterine pregnancy
ECTOPIC OR INTRAUTERINE

DOUBLE SAC SIGN

- 2 concentric rings around GS:
  - Decidua capsularis
  - Decidua basalis
- First described 1982 as means to exclude EP
- Sign present in 33/44 patients with IUP and in no patients with EP

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INTRADECIDUAL SIGN

• Fluid collection in eccentric location on one side of intrauterine cavity
• Described in 1986
• Seen in 92% of IUP

HOW OFTEN ARE THESE SIGNS PRESENT

A. 50%
B. 75%
C. 80%
D. >90%

A lot less than we thought!

PRESENCE OF DDS AND IDS

• Parvey et al, 1996
  • DDS present in 53% of IUP without yolk sac or embryo
• Laing et al, 1997
  • IDS present in 34% of IUP and absent or indeterminate in >60%
• Doubilet and Benson, 2013
  • Interobserver agreement for DDS κ = 0.24
  • Interobserver agreement for IDS κ = 0.23
  • 75% of cases had neither sign present

UPDATE #1

• Better ultrasound technology
• Signs of early pregnancy detectable before DDS or IDS reliably seen
• Confirmatory signs of IUP (ie. Yolk sac and embryo) often seen before DDS and IDS
• These signs of historical value but no longer clinically relevant to exclude ectopic pregnancy
CASE 1: AM I PREGNANT?

- 31 year old G1P0 presents to ED with "spotting"
- LMP 4-5 weeks ago
- How do you proceed?

WHAT IS MOST LIKELY DIAGNOSIS?

- Early IUP
- Doublet and Benson, *First do no harm… to early pregnancies*
  - Low likelihood of ectopic pregnancy (2%)
  - Low incidence of 'pseudogestational sac' in ectopic pregnancy (10%)
  - 99.5% that a round or oval intrauterine fluid collection with a positive pregnancy test is an early IUP

UPDATE #2

- Any round or ovoid fluid collection in a woman with a positive pregnancy test is most likely a gestational sac
- Careful interrogation of adnexa should be performed to exclude ectopic pregnancy
- In absence of adnexal mass, presume early IUP and recommend follow up

NEW TERMINOLOGY (UPDATE #3)

- Viable = can result in a live birth
- Nonviable = cannot result in live birth
- IUP of unknown viability = intrauterine GS but no heartbeat
- Pregnancy of unknown location (PUL) = positive B-hcg but no IUP or ectopic demonstrated at TVUS
- Early pregnancy loss = replace miscarriage, spontaneous abortion to describe nonviable IUP

CONCEPT OF THRESHOLD LEVELS

- Need to have some cut-off to determine viable vs nonviable
- False positive rate must be zero to prevent harm to potentially viable pregnancy
- In that past, variability in cut-off values for MSD at which yolk sac or embryo should be seen
- Several studies investigating FP rates at previous cutoffs
ABDALLAH ET AL

- Using cut-off MSD of 16 mm – FP rate 4.4%
- Using cut-off MSD of 20 mm – FP rate of 0.5%
- No FP using MSD >21 mm

PEXSTERS ET AL 2011

- Interobserver variability for MSD +/- 18.78%
- Interobserver variability for CRL +/- 14.64%
- Also demonstrated intraobserver variability
- SIGNIFICANCE OF RESULTS:
  - For MSD 20 mm – another observer between 16.8-24.5mm
  - For CRL 6 mm – another observer between 5.4-6.7 mm

“NEW RULES” FOR NONVIABILITY

- Findings diagnostic of pregnancy failure:
  - CRL > 7 mm with no heartbeat
  - MSD > 25 mm with no embryo
  - No embryo with heartbeat ≥ 2 weeks after scan showing GS with no YS
  - No embryo with heartbeat ≥ 11 days after scan showing GS with YS

UPDATE #4

“NEW RULES” FOR NONVIABILITY

- Findings diagnostic of pregnancy failure:
  - CRL > 7 mm with no heartbeat
  - MSD > 25 mm with no embryo
  - No embryo with heartbeat ≥ 2 weeks after scan showing GS with no YS
  - No embryo with heartbeat ≥ 11 days after scan showing GS with YS

UPDATE #5: SUSPICIOUS

Table 1. Guidelines for Transvaginal Ultrasonographic Diagnosis of Pregnancy Failure in a Woman with an Intact Gestation (Pregnancy of Incomplete Vaginal Delivery)

<table>
<thead>
<tr>
<th>Findings diagnostic of pregnancy failure</th>
<th>Findings suggestive, but not diagnostic of pregnancy failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRL &gt; 7 mm with no heartbeat</td>
<td>CRL &gt; 7 mm without heartbeat</td>
</tr>
<tr>
<td>MSD &gt; 25 mm with no embryo</td>
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</tr>
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<td>No embryo with heartbeat ≥ 2 weeks after scan showing GS with no YS</td>
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</tr>
<tr>
<td>No embryo with heartbeat ≥ 11 days after scan showing GS with YS</td>
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</tr>
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</table>

*Criteria are from the Society of Radiologists in Ultrasound Multispecialty Consensus Conference on Early First Trimester Diagnosis of Nonviability and Viability of a Viable Intact Pregnancy, October 2016.*
CASE 2

ENLARGED YOLK SAC

- Finding suspicious for but NOT DIAGNOSTIC of early pregnancy loss
- Recommendation: Follow up

CASE 3

- 38 year old female
- Rule out ectopic pregnancy

CASE 3

- Diagnosis?
- First-trimester oligohydramnios
  - Difference between CRL and MSD < 5mm
- Recommendation: F/U

FOLLOW UP ON CASE 3
CASE 4: WHERE IS MY PREGNANCY?

- 37 year old female
- LMP uncertain
- B-hcg 1500
- Presents with pain
- Rule out ectopic pregnancy

CASE 4

- Diagnosis?
  - Pregnancy of unknown location
- Recommendation:
  - Follow-up scan if patient hemodynamically stable

CASE 4 FOLLOW UP

DISCRIMINATORY B-HCG LEVEL

- Discriminatory value:
  - Level of B-hcg above which ALL normal IUP should be seen sonographically
- Where is this threshold?

DISCRIMINATORY B-HCG LEVEL

- Nyberg et al, 1987
  - 1800 mIU/ml
- Doubilet and Benson, 2011
  - 4.5% of cases with NO VISIBLE INTRAUTERINE FLUID and B-hcg >2000 mIU/ml resulted in IUP with embryonic cardiac activity
- Connolly et al, 2013
  - Suggested cut-off level of 3510 mIU/ml
UPDATE #6

- In pregnancy of unknown location and B-hcg >2000:
  - 65% IUP
  - 35% Ectopic pregnancy
  - 2% Viable IUP
- Recommendation: F/U if hemodynamically stable

CASE 5

- 37 year old G2P1 with positive B-hcg and LMP 6 weeks ago
- Presents with pelvic pain
- How do you proceed?

ECTOPIC PREGNANCY

- 4 categories of adnexal findings in EP:
  - Embryo with a heartbeat *100%
  - Mass with a yolk sac and no ECA *100%
  - Mass with central anechoic area with a hyperechoic ring *95%
  - Any mass, other than a simple cyst or an intraovarian lesion *92%

AN UNUSUAL PRESENTATION

ULTRASOUND AFTER CT

Ruptured ectopic pregnancy at OR
CASE 6: I'M PREGNANT, RIGHT?

- 28 year old female in ED with pelvic pain and positive bHCG
- Outside scan showing IUP

HETEROTOPIC PREGNANCY

- Coinciding intrauterine and ectopic pregnancy
- Thought to be exceedingly rare
- Incidence in spontaneous pregnancies 1/8000 to 1/30,000
- Don’t forget to ask about history of assisted fertility
- Incidence up to 1/100 in this population

SUMMARY OF KEY POINTS

- DDS and IDS not reliable to distinguish IUP and EP
- ANY curved fluid collection in women with positive B-hCG is an IUP until proven otherwise
- Inter- and Intra-observer variability exists in MSD and CRL measurements
- New transvaginal criteria for viability to eliminate FP for nonviability

SUMMARY OF KEY POINTS

- Findings diagnostic of early pregnancy loss:
  - CRL >7 mm with no heartbeat
  - MSD > 25 mm with no yolk sac or embryo
  - Failure of YS after >14 days showing GS
  - Absence of embryo with heartbeat >11 days after YS

SUMMARY OF KEY POINTS

- New category of findings “suspicious” but not diagnostic of early pregnancy loss
- When in doubt?
  - Recommend follow-up ultrasound
  - Suggested time for follow up 7-10 days