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Determining a Threshold for Defining Oligohydramnios in a Low-Risk Population at Term

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Abstract:
Objective: To determine if a certain low level of amniotic fluid incidentally found in low risk term pregnancies is predictive of adverse perinatal outcome.

Study Design: Prospective cohort study of patients at 37-40 weeks gestation during 2004-2008 at the Hospital of the University of Pennsylvania (n=195) and Lehigh Valley Health Network (n=113).

Inclusion criteria: Women with medical or obstetric complications, known oligohydramnios prior to 37 weeks’ gestation, size equal to dates on clinical exam, nulliparous and multiparous patients.

Exclusion criteria: Delivery mode, intrapartum complications and neonatal resuscitation were similar by AFI levels. Delivery mode, intrapartum complications and neonatal resuscitation were similar by AFI levels. Amniotic fluid volume was measured sonographically by research nurses. An amniotic fluid index was calculated by the AFI (4-quadrant technique). The AFI was repeated weekly until 40 weeks gestation if the patient was delivered before that time.

Clinicians were blinded to the AFI levels. Any AFI less than 1 cm was disclosed to the clinicians for further management. AFI levels less than 5 cm were revealed to the clinicians if the patient was exactly 40 weeks gestation at the time of ultrasound.

Primary outcomes: Neonates who experienced a positive FVI were determined by the clinician. Neonatal outcome, assessed by the Fetal Vulnerability Index (FVI), was a positive FVI.

Post-enrollment exclusion criteria included pregnancies diagnosed with severe oligohydramnios (AFI < 1 cm) or polyhydramnios after the ultrasound. If the amniotic fluid index was less than 5 cm, a biophysical profile was performed. The patient was to be excluded from enrollment if the biophysical profile was less than 6/8. AFI remained blinded if the score was 6/8.

The amniotic fluid volume was measured sonographically by research nurses. An amniotic fluid index was calculated by the AFI (4-quadrant technique). The AFI was repeated weekly until 40 weeks gestation if the patient was delivered before that time.

Clinicians were blinded to the AFI levels. Any AFI less than 1 cm was disclosed to the clinicians for further management. AFI levels less than 5 cm were revealed to the clinicians if the patient was exactly 40 weeks gestation at the time of ultrasound.

Results: 308 patients met criteria for study analysis. Mean gestational age on admission was 39.8 weeks (range 37.2-41.6 weeks). Mean AFI measured closest to delivery was 11.4 (± 3.5 cm). 2% (n=6) had AFI’s < 5 cm before delivery; 16.5% (n=48) had AFI’s < 8 cm before delivery. 7.8% (n=30) of deliveries delivered a neonate with a +FVI. There were no fetal or neonatal deaths.

Last AFI level was 10.2 (± 3.4 cm) among pregnancies with a positive FVI vs. 11.5 (± 3.5 cm) among those with a negative FVI. An AFI < 8 cm increased the risk of a +FVI by almost 3-fold (risk ratio 2.70 [95% CI 1.2, 6.0]; p=0.01). Using an AFI cutoff of < 8 cm, the area under the receiver operating characteristic curve was 0.59, with a sensitivity of 33.3% and a specificity of 85.8%.

Conclusions: In our prospective cohort study, an AFI cutoff < 8 cm was associated with an increased number of +FVI outcomes yet was not a strong predictor of a positive FVI. Our data suggest that the incidental finding of low amniotic fluid, in otherwise uncomplicated low-risk patients, may not be an indication for immediate intervention. Larger prospective studies are needed to further evaluate this question.

Materials and Methods:
A prospective cohort study was performed by recruiting patients attending prenatal clinic between 37 and 40 weeks’ gestation.

Inclusion criteria:
- women with a singleton intrauterine pregnancy
- multiple pregnancies and multifetal gestations
- unsatisfactory preload
- documented adequate prenatal care with well-established dates
- intact membranes

Exclusion criteria:
- multiple gestations
- a patient with a gestational age at less than 37 weeks’ or greater than 40 1/7 weeks’ gestation
- known oligohydramnios prior to 37 weeks’ gestation
- women with medical or obstetric complications
- feositis with congenital anomalies and/or intrauterine growth restriction
- diagnosis of ruptured membranes, placental abruption or pre-eclampsia at enrollment

Post-enrollment exclusion criteria included pregnancies diagnosed with severe oligohydramnios (AFI < 1 cm) or polyhydramnios after the ultrasound. If the amniotic fluid index was less than 5 cm, a biophysical profile was performed. The patient was to be excluded from enrollment if the biophysical profile was less than 6/8. AFI remained blinded if the score was 6/8.

The amniotic fluid volume was measured sonographically by research nurses. An amniotic fluid index was calculated by the AFI (4-quadrant technique). The AFI was repeated weekly until 40 weeks gestation if the patient was delivered before that time.

Clinicians were blinded to the AFI levels. Any AFI less than 1 cm was disclosed to the clinicians for further management. AFI levels less than 5 cm were revealed to the clinicians if the patient was exactly 40 weeks gestation at the time of ultrasound.

Primary outcomes:
- neonatal outcome, assessed by the Fetal Vulnerability Index (FVI). A positive FVI was defined in a previous study but modified for our study as the presence of one or more of these factors:
  - five minute Apgar ≤ 3
  - umbilical cord pH ≤ 7
  - intrapartum fetal death
  - neonatal death
  - neonatal seizures
  - intervention in the absence of meconium

- neonatal ICU admission for greater than 24 hours

Neonatal experience characteristics were represented only once in the outcome analyses.

Since our aim was to select a threshold for an AFI in predicting a positive fetal vulnerability index (FVI), we desired a test with a sensitivity of 80%. We estimated that 10% of women deliver a neonate with a +FVI. Basing our sample size on the half width of the 95% confidence interval around the sensitivity estimate, we calculated that we need to perform ultrasounds on 620 women, 62 of which should have a positive FVI. Following our operating characteristic (ROC) curves we were able to determine if there is a threshold at which an AFI is predictive of a positive FVI. In patients with more than one AFI level, we used the level closest to delivery.

Results: 308 patients met criteria for study analysis. Table 1 describes the patient population. Table 2 describes the outcome and admission characteristics.

Table 1: Patient Population (n=308)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (±SD)</th>
<th>Median (±IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age</td>
<td>39.8 weeks (± 0.8 weeks)</td>
<td>39.8 weeks</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td>62 (20.3%)</td>
<td>62 (20.3%)</td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>62 (20.3%)</td>
<td>62 (20.3%)</td>
</tr>
<tr>
<td>Birthweight</td>
<td>3.4 kg (± 0.7 kg)</td>
<td>3.4 kg</td>
</tr>
<tr>
<td>Apgar at 1 minute</td>
<td>7.8 (± 1.2)</td>
<td>7.8</td>
</tr>
<tr>
<td>Apgar at 5 minutes</td>
<td>9.5 (± 0.8)</td>
<td>9.5</td>
</tr>
<tr>
<td>Neonatal seizures</td>
<td>2.4%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>0.65%</td>
<td>0.65%</td>
</tr>
<tr>
<td>Neonatal ICU admission</td>
<td>20.3%</td>
<td>20.3%</td>
</tr>
</tbody>
</table>

Table 2: Secondary Outcomes by AFI level

<table>
<thead>
<tr>
<th>AFI level</th>
<th>Number of patients (n=260)</th>
<th>Number of positive FVI outcomes (number of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 8 cm</td>
<td>208 (80.6%)</td>
<td>5.9% (15.6)</td>
</tr>
<tr>
<td>≥ 8 cm</td>
<td>52 (20.4%)</td>
<td>1.4% (14.3)</td>
</tr>
</tbody>
</table>

Conclusions: In our prospective cohort study, an AFI cutoff < 8 cm was associated with an increased number of +FVI outcomes yet was not a strong predictor of a positive FVI. Our data suggest that the incidental finding of low amniotic fluid, in otherwise uncomplicated low-risk patients, may not be an indication for immediate intervention particularly in the setting of a low Bishop score. Larger prospective studies are needed to further evaluate this question.