# Practice Management Guidelines for the Diagnosis and Management of Injury in the Pregnant Patient: the EAST Practice Management Guidelines Work Group

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## Diagnosis and Management of Injury in the Pregnant Patient: <u>A Practice Management Guideline</u> 6/2005

#### I. STATEMENT OF THE PROBLEM

Trauma during pregnancy has presented very unique challenges over the centuries. From the first report of Ambrose Pare of a gunshot wound to the uterus in the 1600's to the present, there have existed controversies and inconsistencies in diagnosis, management, prognostics and outcome. Anxiety is heightened by the addition of another, smaller patient. Trauma affects 7% of all pregnancies and requires admission in 4 out of 1000 pregnancies. The incidence increases with advancing gestational age. Just over half of trauma during pregnancy occurs in the third trimester. Motor vehicle crashes comprise 50% of these traumas, and falls and assaults account for 22% each. These data are considered an underestimates as many injured pregnant patients are not seen at trauma centers. Trauma during pregnancy is the leading cause of non-obstetric death and has an overall 6-7% maternal mortality. Fetal mortality has been quoted as high as 61% in major trauma and 80% if maternal shock is present.<sup>58</sup> The anatomy and physiology of pregnancy make diagnosis and treatment difficult.

#### **II. PROCESS**

An initial computerized search was undertaken using Medline with citations published between the years 1966 and 2003. Search words included "pregnancy", "radiography" and the MesH term for trauma, "Wounds and Injuries". Papers were limited to human and English language. Over 1,600 papers were screened. In addition, bibliographies of book chapters and reviews were examined for any additional references. No time limit was imposed on the literature in order to acquire adequate data. Due to concerns about the availability of literature concerning these areas, studies were not excluded initially based on number of subjects. Isolated case reports were excluded. A total of 76 references are contained in the evidentiary table. Two position statements were also included. The references were reviewed by a trauma surgeon or obstetrician and classified according to the following standards. Data from each article was extracted using a data extraction form and placed in a table. Conclusions of each article were critiqued and a determination made regarding consistency of the conclusion and data

Criteria for achieving a specific classification and the number of articles for each class are shown below:

Class I: Prospective randomized controlled trials. (0 studies)

**Class II:** Clinical studies in which data was collected prospectively and retrospective analyses that were based on clearly reliable data. Types of studies so classified include observational studies, cohort studies, prevalence studies and case control studies. (18 studies)

**Class III:** Studies based on retrospectively collected data, i.e. clinical series, database or registry review, large series of case reviews and expert opinion. (**58 studies, expert opinions and position statements**)

#### **III. RECOMMENDATIONS**

#### A. Level 1

a. There are no Level 1 standards.

#### B. Level 2

- a. All pregnant women > 20 weeks' gestation who suffer trauma should have cardiotocographic monitoring for a minimum of 6 hours. Monitoring should be continued and further evaluation should be carried out if uterine contractions, a nonreassuring fetal heart rate pattern, vaginal bleeding, significant uterine tenderness or irritability, serious maternal injury or rupture of the amniotic membranes is present.
- b. Kleihauer-Betke analysis should be performed in all pregnant patients > 12 weeks' gestation.

#### C. Level 3

- a. The best initial treatment for the fetus is the provision of optimum resuscitation of the mother and the early assessment of the fetus.
- b. All female patients of childbearing age with significant trauma should have a  $\beta$ -HCG performed and be shielded for X-rays whenever possible.
- c. Concern about possible effects of high-dose ionizing radiation exposure should not prevent medically indicated maternal diagnostic X-ray procedures from being performed. During pregnancy, other imaging procedures not associated with ionizing radiation should be considered instead of X-rays when possible.
- d. Exposure to less than 5 rad has not been associated with an increase in fetal anomalies or pregnancy loss and is herein deemed to be safe at any point during the entirety of gestation.
- e. Ultrasonography and MRI are not associated with known adverse fetal effects. However, until more information is available, MRI is not recommended for use in the first trimester.
- f. Consultation with a radiologist should be considered for purposes of calculating estimated fetal dose when multiple diagnostic X-rays are performed.
- g. Perimortem Cesarean section should be considered in any moribund pregnant woman of  $\geq 24$  weeks gestation.
- Delivery in perimortem cesarean sections must occur within 20 minutes of maternal death but should ideally start within 4 minutes of the maternal arrest. Fetal neurological outcome is related to delivery time after maternal death.
- i. Consider keeping the pregnant patient tilted left side down 15 degrees to keep the pregnant uterus off the vena cava and prevent supine hypotension syndrome.

j. Obstetric consult should be considered in all cases of injury in pregnant patients.

#### **IV. SCIENTIFIC FOUNDATION**

Pregnancy is considered a triage criterion for transport to trauma center by the American College of Surgeons Committee on Trauma. Despite this respect given to the care of the injured pregnant patient, the literature is very limited and comprised of mostly class III studies. There are few multicenter studies and many of the other studies are inadequately powered.

The Level 2 guidelines were based predominantly on class II studies. The class II study by Pearlman, et al. indicates monitoring should begin at 20 weeks gestation.<sup>54</sup> The duration of fetal monitoring has been the subject of debate. Early studies indicating that abruptio placenta, the main obstetric cause of fetal demise, can occur up to 48 hours post-injury led to recommendations for this duration of monitoring.<sup>1, 24</sup> Recommended minimum times of post-trauma monitoring quoted in the literature vary from of 2 to 6 hours in the absence of signs, symptoms or monitoring abnormalities. <sup>5, 16, 19, 32,73, 75</sup> None of these times, however, have been validated by large, prospective studies. Therefore, we suggest adopting the most conservative estimate of 6 hours while recommending this topic be further investigated by our and other multi-institutional trials groups.

Two Class II studies and one class III study conclude that Kleihauer-Betke testing should be routinely performed in whom blunt uterine trauma is suspected. <sup>47, 54, 57</sup> One study showed an increased incidence of abruptio placenta in those with a positive test.<sup>54</sup> In the latest class III study, the Kleihauer –Betke test was a predictor of preterm labor. <sup>47</sup> As per ACOG recommendations, the main utility of the test is to restrict Rh immune globulin use to those who need it and to detect the few patients for whom that quantity is insufficient. <sup>4</sup> Another option is to administer Rh immune globulin to all unsensitized Rh-negative pregnant patients who have suspected blunt uterine trauma. Then, one would guide additional dosing by the Kleihauer –Betke test results. There is a 72-hour window after

fetomaternal hemorrhage within which Rh immune globulin can be administered to provide protection from alloimmunization. The appropriate dose is 300 mcg per 30 ml of fetomaternal hemorrhage.

The first Level III recommendation is based on expert opinion. Advanced Trauma Life Support teaches that "the best initial treatment for the fetus is the provision of optimum resuscitation of the mother and the early assessment of the fetus." The most common cause of fetal demise is maternal demise.

Routine  $\beta$ -HCG testing appears to make sense in our present medico- legal environment. One class II paper recommends routine  $\beta$ -HCG testing due to "incidental pregnancy".<sup>12</sup> Many of our patients arrive without the ability to communicate, with testing being especially important in this group.

As for recommendations c through f, data regarding diagnostic radiation exposure is particularly lacking. Much of the data comes from atomic bomb blasts or large series in cancer registries. Many of these studies have inherent bias making useful conclusions impossible. No study to date has shown any increase in teratogenicity above baseline at fetal exposures below 10 rad or 100 mGy to the fetus. Growth restriction, microcephaly and mental retardation can occur with high dose radiation, well above that used in medical imaging.<sup>13, 50, 51</sup> The fetus is most at risk for central nervous system effects from 8 -15 weeks and the threshold appears to be at least 20 to 40 rad.<sup>50, 51</sup> The American College of Obstetricians and Gynecologists (ACOG) has published recommendations for diagnostic imaging during pregnancy.<sup>5</sup> They state that 5 rad or 50 mGy exposure *to the* fetus is not associated with any increased risk of fetal loss or birth defects. The reference cited for this dose and statement was a paper concerning counseling of pregnant patients on radiation exposure. There is, however, class III data from our literature search which supports this number.<sup>49</sup> There is no mention regarding leukemia incidence.

Several Class II and III studies have suggested variable increased risk of childhood leukemia above baseline with "low level radiation". <sup>15, 28, 32, 34, 55, 67, 69, 74, 76</sup> There are three class II and III references which show no significant increase in risk. <sup>44, 45, 60</sup> Agreeing with the former studies, the National Radiation Protection

Board of Britain has adopted a 6% per 100 rad excess absolute risk coefficient for childhood cancer or 1 in 17,000. Data from the Oxford Survey of Childhood Cancers and Japanese survivors of the atomic bombings reported in May 2003 estimate an 8% per 100 rad increased risk of childhood cancers. <sup>74</sup> This is equivalent to an excess absolute risk of childhood cancer of from 0.00006 to 0.00008 for each mGy. For comparison, the baseline age-adjusted cancer rate as reported for children age 0-19 in 2001 by the Surveillance, Epidemiology and End Results (SEER) Program of the National Cancer Institute was 4.2 per 100,000 or 0.0042%. Most X-rays are a fraction of a mGy or rad. The authors admit these figures are based on mathematical models and dosimetry estimates that are subject to various uncertainties.

Fetal dose without shielding is 30% of that to the mother. Therefore, a policy of limiting testing to those studies that would influence maternal (and thereby fetal) outcome should reduce the fetal risk. Mandatory shielding of the fetus for all but pelvic and lumbar spine films/CT scans should be performed. Plain x-rays and CT scans have traditionally been liberally employed in other patients. Particularly in the pregnant patient, tests should be ordered judiciously and redundancy should be eliminated. For instance, a pelvic x-ray may not be necessary if the patient would still require an abdominopelvic CT scan regardless. ACOG recommends in their 2004 Guidelines that consultation with a radiologist or radiation specialist should be considered for purposes of calculating estimated fetal dose when multiple diagnostic X-rays are performed.<sup>5</sup> This seems prudent especially when approaching 5 - 10 rad. Sample doses of typical radiographic studies in trauma patients are given in Appendix 1.

Emergency cesarean section should be differentiated from perimortem cesarean section. Emergency cesarean section may be undertaken for many reasons, including fetal distress, premature rupture of membranes, etc. Perimortem cesarean section refers to that which is performed at the time of maternal death. The 1996 paper on emergency cesarean section by Morris, et al. demonstrates the utility of this intervention but only one case in this study was perimortem.<sup>46</sup> Two class III papers as well as ACOG support consideration of

perimortem cesarean section with gestational age at least 24 weeks.<sup>4,37,40</sup> The survival and neurological outcome are related to time between maternal death and delivery. Perimortem cesarean section should be ideally started within 4 minutes of maternal arrest , but this recommendation is based on isolated case reports.<sup>4</sup> Review of the literature shows that most survivors were delivered within 5 minutes, but one was delivered greater than 20 minutes after maternal arrest.<sup>37</sup> Emergency cesarean section is potentially an option for fetuses of at least 24 weeks gestation with fetal heart tones and may be indicated for fetal or maternal distress per the article by Morris, et al. It should be ensured that saving the fetus will not adversely affect the maternal outcome. The indication for perimortem cesarean section is a little less clear when times reach 10 to 15 minutes.

Prevention of supine hypotension syndrome is well-documented in many sources, including Advanced Trauma Life Support. The pregnant patient should be tilted 15 degrees on her left side to keep the pregnant uterus off the vena cava to prevent this syndrome.

Routine obstetric consult in the injured pregnant patient is strongly recommended although there is no specific literature on this topic.<sup>4</sup>

Independent predictors of fetal mortality and morbidity remain unclear in context of the available literature. Among the maternal factors cited in the literature are Injury Severity Score (ISS), Revised Trauma Score (rTS), hypotension, heart rate, Glasgow Coma Score (GCS), pH, pO2, serum bicarbonate and abdominal AIS. Obstetrical factors include vaginal bleeding, uterine tenderness, contractions, fetal heart rate and fetal monitoring findings. Conflicting data regarding the above is presented in 15 class II/III papers making indications for their use to determine fetal outcome unclear. <sup>3, 8, 9, 18, 22, 23, 25, 27, 32</sup>, 36, 38, 56, 63, 64, 70

#### V. FUTURE INVESTIGATIONS

Clearly, given the relatively small number of gravid trauma patients, a multi-center trial is necessary to clarify some of these issues. However, prospective, randomized trials to answer many of these questions would be

unethical. Trauma database review with prospective follow-up might provide clarity to many of these issues raised here.

A review of diagnostic studies performed in all pregnant trauma patients in EAST participating institutions over the last 5 or 10 years followed by a prospective phone follow-up at five year intervals to determine presence or absence of childhood cancers could raise enough data to rival that of the studies used in our guideline review. Dose estimates could be calculated from radiographic studies done and correlated with the incidence of childhood cancers.

Questions concerning the Kleihauer-Betke test and monitoring could be answered in part from data that already exists with a chart review of outcomes across EAST participating institutions. A pregnancy trauma score could be modeled on such data with the predictors cited above and prospectively applied in a multi-institutional fashion. We are in a unique position as a premier trauma organization with large membership to be able to comment on all of these issues in a more definitive fashion than ever before. We encourage our colleagues in the Multi-Institutional Trials Committee to take up some of these issues in the near future.

Examination type	Estimated fetal dose per
	exam (rad)
Plain films	
Cervical spine	0.002
Chest (two view)	0.00007
Pelvis	0.040
Thoracic spine	0.009
Lumbosacral spine	0.359
CT scans (10 mm slices)	
Head	< 0.050
Chest	< 0.100
Abdomen	2.60

### Appendix 1: Estimated Fetal Exposure for Various Radiographic Studies

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