Office Management of Early Pregnancy Loss (EPL)

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• Paid expert witness for Bayer

Objectives

• Identify key components required to confirm the EPL diagnosis
• Discuss the range of treatment options for EPL
  – Expectant management
  – Medical management with misoprostol/mifepristone
  – Surgical evacuation in the office
• Discuss clinical considerations when determining treatment plan
• Identify available resources to support practices implementing office management options
• Describe tools and techniques used in office-based procedures
  – “hands on” practice with pelvic models.
Good Resource!

PRACTICE BULLETIN
CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN- GYNECOLOGISTS

Early Pregnancy Loss
Each pregnancy loss is an area for investigation and evaluation. Early pregnancy loss, or miscarriage, is encountered commonly in clinical practice. Obstetricians and gynecologists should understand the use of various diagnostic tools to differentiate between viable and nonviable pregnancies and offer the full range of therapeutic options to patients, including expectant, medical, and surgical management. The purpose of this Practice Bulletin is to review diagnostic approaches and describe options for the management of early pregnancy loss.

Early Pregnancy Loss: Definition

- Nonviable, intrauterine pregnancy
  - Empty gestational sac
  - Gestational sac with embryo or fetus without heart beat
  - Within first 12 6/7 weeks gestation
- Early pregnancy loss (EPL) is one preferred terminology
  - No consensus on terminology

EPL: Diagnosis

- Symptoms of EPL (bleeding/cramping) also occur in normal pregnancy and ectopic pregnancy
- Consequences of treatment before certain diagnosis are serious
  - Interrupt normal pregnancy
  - Birth defects
  - Rupture of unrecognized ectopic
EPL: Diagnosis

• Medical/surgical history
• Physical examination
• Beta hCG levels
• Ultrasound

A single Beta hCG or ultrasound examination may not be sufficient

EPL Diagnosis: Ultrasound

• First reported in 1990s when transvaginal ultrasound became available
  – CRL 5mm without cardiac activity
  – Empty gestational sac measuring 16mm
• More recent studies suggested that more conservative cut offs may be appropriate
  • Using 5mm cut off resulted in 8.3% false positive rate (Abdullah 2011)

Ultrasound Guidelines*

(Society of Radiologists in Ultrasound Multispecialty Consensus)

Findings Diagnostic of Early Pregnancy Loss*
- Crown-rump length of 7 mm or greater and no heartbeat
- Mean sac diameter of 25 mm or greater and no embryo
- Absence of embryo with heartbeat 2 weeks or more after a scan that showed a gestational sac without a yolk sac
- Absence of embryo with heartbeat 11 days or more after a scan that showed a gestational sac with a yolk sac

*Guidelines for Transvaginal Ultrasonographic Diagnosis of Early Pregnancy Loss
Ultrasound Guidelines*

(Society of Radiologists in Ultrasound Multispecialty Consensus)

- Crown-rump length of less than 7 mm and no heartbeat
- Mean sac diameter of 16-24 mm and no embryo
- Absence of embryo with heartbeat 7-13 days after an ultrasound scan that showed a gestational sac without a yolk sac
- Absence of embryo with heartbeat 7-10 days after an ultrasound scan that showed a gestational sac with a yolk sac
- Absence of embryo for 6 weeks or longer after last menstrual period
- Empty amnion (membrane seen adjacent to yolk sac, with no visible embryos)
- Enlarged yolk sac (greater than 7 mm)
- Small gestational sac in relation to the size of the embryo (less than 5 mm difference between mean sac diameter and crown-rump length)

*Guidelines for Transvaginal Ultrasonographic Diagnosis of Early Pregnancy Loss

Ultrasound Guidelines: Criticism

- These guidelines use stricter cut offs than the studies on which they are based
- There were very few cases at or near the boundaries.
- The basis for the time between ultrasounds (14 days) was unclear

EPL Diagnosis

- Use other clinical factors when interpreting ultrasound findings
- Consider the woman’s wishes in treatment planning
  - Fear of passing tissue at home
  - Possible need for unscheduled procedure
  - Woman’s willingness to postpone intervention until 100% certain
EPL: Treatment Options

COMMONLY

• Surgical treatment in operating room
• Expectant Management

How did this treatment pattern evolve?

• Pregnancy losses presented with bleeding and/or infection
  – Some were actually illegal or self-induced abortions
• Urgent uterine evacuations for bleeding/infection common
  – Procedures done mainly in an operating room

Contemporary Context

• EPL presents earlier
  – Sensitive pregnancy tests
  – Widespread availability of ultrasound
• Often asymptomatic
  – No urgent symptoms (bleeding, infection)
• Most patients can safely be offered a range of treatment options
EPL: Treatment Options

- Surgical treatment in operating room
- Expectant Management
- Medical treatment with misoprostol
- Surgical treatment in an office setting

Expectant Management

- Generally should be limited to gestations in the first trimester
- With adequate time up to 80% successful
- May be more effective in symptomatic women with incomplete expulsion (vs. asymptomatic women)

Expectant Management: Patient Education

- Patient education
  - Bleeding may be moderate to heavy
  - May need surgical intervention
  - Cramping – consider offering pain management
  - Provide contact for women with concerns
Expectant Management: Follow-up

- Documenting completion
  - Follow-up USN should focus on absence of gestation NOT endometrial stripe measurement
  - Other follow-up options: serial beta hCGs, phone calls

EPL: Medical Management

- Option for women who want more predictability but not surgery
- Usually done with misoprostol (prostaglandin E1)
- Misoprostol reliably reduces need for surgery by 60%
- Shortens time to completion over expectant

EPL: Medical Management

- 800 vs 400 micrograms of misoprostol
  - Higher dose may shorten interval and reduce need for second dose
  - Higher dose may have more side effects
- Vaginal vs. oral vs. sublingual
  - Vaginal or sublingual more effective than oral
## EPL: Sample protocol

- Patient education
- Consider pain medications
- Initial dose 800 micrograms misoprostol vaginally
  - Second dose no earlier than 3 hours and typically within 7 days if no response
  - 71% success after 1 dose
  - 84% success if second dose is administered as needed

## EPL: Medical Management

- Rh(D)-immune globulin for Rh(D) negative women within 72 hours of first misoprostol dose
- Follow-up to document complete passage
  - Ultrasound in 7-14 days
  - Serial beta hCG or patient reported symptoms also option if USN not available
- If misoprostol treatment fails options include expectant or surgery

## EPL: Medical Management

- Confirm EPF!!
  - Does not treat ectopic and may increase risk of rupture
- Insufficient evidence to support the routine addition of mifepristone
- Misoprostol does not clearly increase success among women with incomplete pregnancy loss over expectant management
## Non-surgical Options

<table>
<thead>
<tr>
<th>Expectant Management</th>
<th>Medical Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Watchful waiting</td>
<td>• Misoprostol</td>
</tr>
<tr>
<td>• Successful 25-80%</td>
<td>• 85% successful in 1 week</td>
</tr>
<tr>
<td>- depends on how long you wait</td>
<td>• Faster than expectant</td>
</tr>
<tr>
<td>• Small risk of needing urgent surgical (D&amp;C)</td>
<td>• Small risk of needing urgent surgical (D&amp;C)</td>
</tr>
<tr>
<td>• Typically takes weeks</td>
<td>• Typically takes 1-2 weeks</td>
</tr>
</tbody>
</table>

## Surgical Evacuation

- Traditional treatment
  - Preferred with hemodynamic instability, or signs of infection
  - Maybe preferred in women with comorbidities such as significant anemia, bleeding disorders, or cardiovascular disease
- Can be done in operating room or office
- Offers more predictable completion
- Suction curettage – NOT sharp curettage

## EPL Treatment: Surgical Location

<table>
<thead>
<tr>
<th>Operating room</th>
<th>Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Full range of anesthesia choice</td>
<td>• Anesthesia typically per facility regulations</td>
</tr>
<tr>
<td>• Successful 97%</td>
<td>• Successful 97%</td>
</tr>
<tr>
<td>• Infection rate 1-2%</td>
<td>• Infection rate 1-2%</td>
</tr>
<tr>
<td>• Retained tissue 2-3%</td>
<td>• Retained tissue 2-3%</td>
</tr>
<tr>
<td>• Treatment complete the day of surgery</td>
<td>• Treatment complete the day of surgery</td>
</tr>
<tr>
<td></td>
<td>• Not appropriate for urgent evacuations or women with certain co-morbidities</td>
</tr>
</tbody>
</table>
Surgical Location: Complications

- Surgical complications are similar
  - Hemorrhage 2-3%
  - Infection 1-2%
  - Perforation (1/1000)
  - Intruterine adhesions (rare?)
- But anesthesia-related risks may differ
  - Increased risk of hemorrhage
  - Increased risk we are more aggressive?

Antibiotic Prophylaxis

- Single perioperative dose of doxycycline is recommended (ACOG)
  - 200mg doxycycline 1 hour prior
  - Based on studies among women undergoing suction curettage for induced abortion
  - Antibiotics are not recommended in women undergoing surgical evacuation for incomplete pregnancy loss

Office uterine evacuation with manual vacuum aspiration (MVA)
Sample Procedure

- Review patient medical and surgical hx
  - BMI cut off, comfort with pelvic exam
- Patient consent
- Pain meds, antibiotics prior to procedure
  - Is the patient appropriate for office IV sedation?
- Prep cervix, paracervical block

Sample Procedure

- Cervical dilation according to gestation age (7 weeks = 7mm cannula)
- Aspirate uterine contents
- Assess for hemostasis and uterine tone
- Examine for gestational tissue
  - Confirm gestational tissue removed

Tissue Inspection

- MVA is helpful when examining very early pregnancies

MacIsaac 2000; Edwards 1997
Introducing Office Uterine Evacuation Service

- Our main barriers
  - Perception that office procedure was unsafe/cruel
  - Nursing with limited procedural experience
  - Staffing
  - Belief that patients would not accept it

Introducing Office Uterine Evacuations Service

- Staff and faculty education and training
- Involved diverse individuals to champion the change
- Partnered with midwives and family medicine to streamline referrals
- Operating room procedure still offered

Non-urgent Procedures for Early Pregnancy Loss 2001-2002
Office Uterine Evacuation

- About 50% of patients undergoing uterine evacuation for EPF do so in the clinic
- Patient satisfaction is high
  - Supportive environment
  - Nursing
  - Partner/support person
  - Preoperative counseling key
- 2 patients have been transferred to the OR for bleeding in 10 years

Pain Management Options

- Initially only offered oral medications and paracervical block
- Added option for IV sedation
  - Now 2/3 of patients opt for IV sedation

Comparative reimbursement of office versus OR-based uterine evacuations (2004)

<table>
<thead>
<tr>
<th></th>
<th>Office MVA (n=46)</th>
<th>OR (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (S.D.)</td>
<td>Mean (S.D.)</td>
</tr>
<tr>
<td>Obstetrician/Gynecologist Reimbursement</td>
<td>$550 ($288)</td>
<td>$512 ($245)</td>
</tr>
<tr>
<td>Facility Reimbursement</td>
<td>$7082 ($247)</td>
<td>$2718 ($817)*</td>
</tr>
<tr>
<td>Other Reimbursement</td>
<td>$0 ($0)</td>
<td>$139 ($1158)*</td>
</tr>
<tr>
<td>Total Reimbursement</td>
<td>$1626 ($361)</td>
<td>$3375 ($898)*</td>
</tr>
</tbody>
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*p<0.01
Choosing Management for Early Pregnancy Loss

• Patient preferences
  – anesthesia preferences
• Is ectopic possible?
• Medical risk factors
  – Comorbidities, symptoms, obesity, prior cs or vaginal delivery
• Patient comfort with pelvic exams

Patient Preferences

• Strong treatment preferences (Wieringa-de-Waard 2002; Dalton 2007)
• Individual preferences are diverse
  – Avoid surgery (Molnar et al 2000; Dalton 2007)
  – Avoid general anesthesia (Clark 2002;Hemlin 2001; Dalton 2007)
  – Desired to be treated quickly (Dalton 2007)

Summary

• Several safe treatment options for first trimester pregnancy failure
  – Differ mainly in process
  – Surgical and non-surgical approaches
• No approach is clearly superior
  • Often women’s preferences can drive treatment choice
Good Resource!

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