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Standardizing early aspiration abortion complication definitions and tracking:

Testing an evidence-based framework

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Background

National patient safety tracking frameworks for identifying procedural complications (for non-abortion procedures) define adverse events by diagnoses (ICD codes), treatments (CPT codes) and outcomes which include uniform definitional criteria. Published data on first-trimester aspiration abortion-related complication diagnoses and treatments range from 1.3% to 4.4% (+/- 1%) are based on data from nine peer-reviewed papers with a combined sample size of 180,710 aspiration abortion procedures published between 1990-2009.[1-8]

Wide variation exists across these nine studies in 1) the confounding of immediate and delayed abortion complications; 2) the definition of major and minor complications;[5] 3) the definition of the complication type; 4) the criteria for treatment of post-abortion pain/bleeding symptoms distinct from hemorrhage or hematometra; 5) the use of "reaspiration" as a diagnosis and a treatment; 6) the lack of diagnostic criteria that includes etiology or confirmatory data to support a particular diagnosis; and 8) lack of specificity in describing patient outcomes.

Purpose of study

The purpose of this study was to develop and evaluate a standardized method of assessing immediate and delayed abortion-related complications based on national patient safety methods for non-abortion procedures.

Methods

We are evaluating a systematic method for defining and tracking early aspiration abortion (<14 weeks) incidents as part of a larger IRB-approved study of early aspiration abortion provision outcomes. We evaluated a minimum dataset and standardized coding methods developed by expert clinician consensus and quality improvement experts reflecting ten patient diagnoses (abortion-related and non-abortion related), treatments (type/location) and outcomes for monitoring both abortion complications and non-abortion related incidents.

This methodology reflects a national model of adverse event reporting elements for monitoring immediate and delayed incidents associated with abortion procedures and includes post-abortion patient tracking methods (e.g., patient calls or visits and outside provider reports). Between 2007-2010, this standardized diagnosis, treatment and outcome process was used to report incidents by 107 abortion clinicians performing first-trimester aspiration abortion procedures on 7,423 patients.

Results

Major findings from this empirically tested model:

- Differentiation of incidents by incident type:
  - Abortion-related complications include cases where there is a confirmed diagnosis of incomplete abortion, failed abortion, hemorrhage/excessive bleeding, hematometra, infection, cervical injury, uterine perforation, symptomatic intrauterine material (SIM), anesthesia-related complication, or an "other" diagnosis determined by the study's safety monitoring board to be abortion-related (Rate = 1.3%, n=96).
  - Non-abortion-related incidents include concurrent medical problems which are diagnosed and/or treated at the time of the abortion procedure (e.g., ectopic or molar pregnancy, pre-existing medical condition, infection present at the time of the procedure, and bleeding or hemorrhage secondary to anemia or uterine abnormality) (Rate = 0.3%, n=20).
  - System incidents include cases in which a patient self refers to a hospital but does not receive an abortion-related diagnosis or treatment (e.g. observation only) (Rate = 0.1%, n=7).
- Specification of the timing of the abortion-related complication:
  - Immediate: incident occurs during the procedure, or while the patient is recovering (0.2%, n=16 immediate complications).
  - Delayed: incident occurs after the patient leaves the clinic and up to 4 weeks after the procedure (1.1%, n=80 delayed, confirmed complications).
- Specification of the definition of major abortion-related complication: Defined as those "complications requiring abortion-related surgeries, transfusion or hospitalization." None have occurred.
- Standardized complication diagnoses with etiology and confirmatory criteria for
  - incomplete abortion, failed abortion, hemorrhage and hematometra;
  - post-abortion pain/bleeding symptoms (SIM) distinct from hemorrhage or hematometra;
- Improved precision and specificity in the estimation of abortion-related complication diagnoses.
  - The most frequently reported complications were SIM (post-abortion pain/bleeding that did not meet the criteria for hemorrhage, 0.4%, n=29), hematometra (0.2%, n=12) and incomplete abortion (0.3%, n=22).
- Clarification of reaspiration as a treatment for incomplete abortion, SIM (patient or provider preference), or hematometra.

Early abortion diagnoses/treatments/outcomes (encountered vs. published rates)

Outcome	No.	Rate	Published
Aspiration abortion complications by diagnosis			
Successful, uncomplicated	7,327	98.7%	95.9–99.1[3,4,7]
Incomplete abortion	22	0.3%	0.2–4.4%[1,2,4,5,7-9]
Failed abortion (cont pg)	11	0.1%	0.4–2.3%[2,4-7]
Infection	10	0.1%	0.1–2.6%[2-4,6-8]
Post-abortal hematometra	12	0.2%	0.1–2.2%[1,2,7]
Uterine perforation	2	0.0%	0.2–0.7%[1-4]
Cervical injury	1	0.0%	0.0–1.1%[1-8]
Symptomatic intra-uterine material (SIM)	29	0.4%	NA
Hemorrhage >150 cc	1	0.0%	0.1–0.4%[1-3,7]
Anesthesia-related	0	0.0%	0.0– 0.1%[4,8]
Missed ectopic pregnancy	0	0.0%	0.0–0.3%[7]
Other diagnoses	8	0.1%	N/A
Other diagnoses (not directly related to abortion)			
Diagnosed ectopic pregnancy	6	0.0%	0.03–0.33%[10]
Diagnosed molar pregnancy	4	0.0%	0.01–0.04%[11,12]
Uterine abnormality	2	0.0%	NA
Other diagnosis	8	0.1%	NA
Treatments for abortion-related diagnoses/complications			
Reaspiration	57	0.8%	2 to 4.7%[1,6]
Repeat abortion	9	0.1%	0.036–2.3%[6,7]
Medications (non IV)	43	0.6%	NA
IV medications	1	0.0%	0.3 to 4.4%
Hospital or ER transfer	0	0.0%	0.07–0.1%[1]
Surgical treatment	0	0.0%	0.0–0.1%
Outcomes for abortion-related diagnoses/complications			
Diagnosis resolved	93	98.7%	NA
Unable to complete abortion	1	0.0%	0.87%[7]
Adverse outcome	0	0.0%	NA
Unknown outcome	2	0.0%	NA

Conclusion

With improved precision and specificity in defining abortion-related incidents by diagnosis, treatment and outcomes, all complication rates associated with early aspiration abortion procedures performed were lower than published rates[1-8]. This systematic framework for defining and tracking abortion complications across the continuum of care will allow evidence-based comparisons with national clinical effectiveness assessment standards for other common, low-risk, outpatient procedures and can be used in all settings including primary care sites.

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