

Research Article

Pre-operative pregnancy testing (POPT) and the undiagnosed pregnancy rate in an elective gynaecology surgery population

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Abstract

Background: Surgery in a female with an undiagnosed pregnancy has recognized teratogenic and disruptive embryo/fetal risks. What is the incidence of an undiagnosed pregnancy in females undergoing elective surgery in an urban hospital?

Methods: A retrospective quality assessment audit of a hospital based patient information system from November 2013– January 2015; **Setting:** Elective gynaecological operation locations in 5 urban hospitals; **Population:** Female gynaecological surgical population; **Process:** A population of females undergoing elective gynaecological surgery with an established pre-operative 'point of care' urinary pregnancy testing process was used to identify the 'at risk' undiagnosed pregnancy rate.

Results: The undiagnosed pregnancy rate in this elective gynaecology population was 33 positive tests in a population of 5477 females (0.60%). The estimated cost per undiagnosed pregnancy identified was \$3568 (Can).

Discussion: The audit cohort and literature review summary identified 45 undiagnosed pregnancies in 10,531 females tested (0.42%) or 1 in 235 female surgeries.

Conclusion: A literature summary of pre-operative or pre-ionizing imaging pregnancy testing reported undiagnosed pregnancies in 45 of 10,531 females (0.42%) or 1 in 235. Urinary based pre-operative pregnancy testing should be considered in all potentially fertile females, aged 12–55, having pelvic ionizing radiation imaging or elective or semi-urgent cardiac, gynaecological, colo-rectal, pelvic fracture or urological surgery (ies) (without an absolute contraindication of hysterectomy).

Introduction

Pre-Operative Pregnancy Testing (POPT) for females undergoing elective/semi-urgent surgery has been recommended but there is limited incidence of undiagnosed pregnancy information or practice/process for implementation of pregnancy testing demonstrated in the literature. The risk of pregnancy loss or damage is not well documented for human cohorts. True informed consent is required, but unlikely to be occurring, for this clinical scenario.

The Alberta Institute for Health Economics in 2007 recommended 'a consensus development conference involving a group of 12–18 experts in the field be convened to answer, amongst other things, the benefits and potential harms of routine preoperative testing in Alberta'[1]. This recommended conference has not occurred.

The POPT process has been a standard of care for elective gynaecologic surgery patients in Calgary, Alberta since June 2002. This was initially introduced in single Calgary based hospital gynaecology daycare following an incident and case review of gynaecologic hysterectomy surgery in an unrecognized pregnant woman. This POPT practice is established in 5 operative/gynaecologic based hospital locations in Calgary.

This clinical research audit was undertaken to determine the number of undiagnosed pregnancies prior to elective gynaecological surgery using a nursing directed 'point of care' urinary pregnancy

testing process. This quality assessment audit was completed as part of the data required to inform whether the development and implementation of a provincial practise standard related to POPT was appropriate.

Methods

An anonymous (no patient identifiers) and retrospective audit of pre-operative gynaecology pregnancy test results using the Sunrise Clinical Manager (SCM) search application was completed. The routine practice of pre-operative 'point of care' urinary pregnancy testing was audited using the SCM information system from November 2013 - January 2015 in a female gynaecological population. Five clinical hospital sites with multiple site based pre-operative testing locations were reviewed as this pre-operative testing is a standardized nursing delegated and directed practice. There was limited follow-up on the pregnancy outcome or management as this quality improvement

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audit was restricted to the pre-operative pregnancy testing question (pregnancy test positive yes or no) only.

The protocol for POPT uses the Calgary Health Region Pregnancy Testing (Point of Care, Pre-operative for Obstetrics and Gynaecology Policy and Procedure process that was established in June 2002) and the Calgary Health Region Surgical Pre-Operative Check List (revised version 05/2005). The Check List has an area in Section D. Patient Preparation Section with pregnancy test completed yes/no (Section A. Health Record; Section B. Communication with OR; Section C. Personal Property removal; Section E. Actions/Reminders/Comments)

The Point of Care urinary pregnancy testing device is the 'QuickVue[®]' (Quidel Corporation San Diego, CA USA). This one step pregnancy test device (urine/serum) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG). In normal pregnancy, the hCG can be detected in urine as early as 7-10 days after conception (before a missed menstrual period is identified by the patient). Device detects the presence of hCG in urine at the sensitivity of 25 mIU/ml (normally in pregnancy, the hCG exceeds 100 mIU/ml by the first missed menstrual period). Urine testing method protocol has both the test device and the urine specimen at room temperature (15-30 degree C) prior to testing. Three drops of urine are placed in the device specimen well and results are read at 3 minutes for urine (5 minutes for serum) as positive, negative, and invalid. The pregnancy test result is recorded on the Surgical Pre-operative Check List Section D and/or on the Alberta Surgical Safety Checklist (ASSCL) and in SCM.

POPT Quality Assurance is provided through a cooperative process between QuickVue[®] and AHS POPT Gynaecology hospital based services. Multiple urine test samples are provided by the QuickVue[®] and then the AHS 'point of care' testing results are returned to QuickVue[®] for validation twice yearly.

Results

Total number of female gynaecological patients screened (November 2013 – January 2015) was 5477 from the 5 AHS Calgary Zone hospital sites with 33 positive pregnancy tests (true positives). No false positive results were reported or identified by provider or patient reporting. The false negative rate was not evaluated.

The unsuspected or undiagnosed pregnancy rate in pre-operative women having elective gynaecological surgery in the Alberta Health Services Calgary Zone was 0.60% (0.006)

The estimated cost per undiagnosed pregnancy identified was \$3568 (\$Can) using equipment/device at \$1.50 per test and RN nursing time at \$20 per test (20 minutes @ \$60 per hour).

Discussion

The UK NICE consensus based guidelines [2] suggested that when considering the statement of 'pre-operative pregnancy testing should be carried out in female patients of reproductive ages':

- They were UNCERTAIN with a history of the Last Menstrual Period (LMP) or females who say it is not possible for her to be pregnant
- They were APPROPRIATE for females who say it is possible that she may be pregnant and that informed consent should be obtained.

Watts *et al.* [3] reported on their current Western Australia practice and opinion on POPT and found that 'the majority of senior clinical

staff surveyed supported routine pre-operative testing (77% of MD's and 75% of Nurses) and 89% of respondents supported the need for National or Australian State-wide guidelines.

Wong and Wingfield [4], using an Irish postal questionnaire, reported that advice on adequate contraception or avoidance of pregnancy prior to elective surgical procedures is only done by 35% of gynaecologists. Urinary HCG is still the standard test used in most units to exclude pregnancy.

Grisby *et al.* [5] reported results from an adolescent population using a cross-sectional study. They surveyed 51 American Society of Pediatric Otolaryngology members and 108 American Pediatric Surgical Association members about how often (always, sometimes, never) they asked adolescent females (age 12-18 years) about substance use, pregnancy, and assent for surgery. Physicians vary in how they involve adolescents in the decision making process for surgery and in how they approach drug, alcohol, tobacco, and pregnancy issues in this adolescent female population. Pregnancy testing and screening for adolescent substance use are not standardized among peri-operative adolescent healthcare providers.

Herr *et al.* [6] reported that prospective pregnancy testing was undertaken upon arrival in the radiology department, prior to HSG imaging (which is recommended at 8-12 days from day 1 of menstrual bleeding). The urine pregnancy test results were reviewed retrospectively; 1/410 (0.2%) of women presenting for HSG were found to have an unsuspected early pregnancy which was detected with a point-of-care urine pregnancy test. Cost of urinary pregnancy test was \$1.25 per test (ClearviewhCG COMBO II test kit; \$50 for 40 tests).

Abdallah [7] commented in a Letter to the Editor about teen pregnancy testing (related to an earlier 1995 paper Manley *et al.* [8]). Preoperative pregnancy testing in ambulatory surgery: incidence and impact of positive results). He indicated that on further review the topic, there is lack of consensus with a number of issues of concern: teratogenic and abortive effects on the human of the more commonly used anaesthetics may be equivocal, anaesthesia and surgery may expose the fetus to potentially peri-operative procedures; a positive pregnancy test usually results in cancellation or postponement of an elective surgical procedure; ethical responsibility and balance between risk and benefit are important factors in the anaesthesiologist's decision-making of administering anaesthesia for an elective surgery in 'high risk' patients when pregnancy testing is not consented; and practice guidelines and medico-legal implications are not well established.

Kahn *et al.* [9] reported on a one year experience of pregnancy testing in an elective orthopaedic surgical daycare process. There were 2588 women scheduled for surgery with 5 positive urinary hCG tests. There were 4 true positive pregnancies (3 intra-uterine; 1 ectopic) and 1 false positive pregnancy test. The calculated cost of screening for an unrecognized pregnancy was \$3273 (US) for each true positive result. This cost is consistent with the estimated cost per undiagnosed pregnancy in the present study.

Manley *et al.* [8] reported on a prospective 1 year study testing urine or serum hCG, in all women of child bearing potential (defined as menstruating women without prior hysterectomy or tubal ligation) prior to ambulatory non-obstetrical surgery and identified 7/2056 (0.3%) women with an unrecognized pregnancy. All patients elected to cancel or postpone the proposed surgical procedure.

Table 1 summarizes the present audit cohort and three other 'undiagnosed pregnancy' population studies with an overall estimated

Table 1. Audit Cohort and Literature Summation.

Source	Population tested	# of Pregnancies	Pregnancy Incidence
Manley <i>et al.</i> [9]	Non obstetrical 2056	7	0.34%
Kahn <i>et al.</i> [8]	Orthopaedic 2588	4	0.15%
Herr <i>et al.</i> [6]	Pre HSG 410	1	0.24%
Calgary (2015)	Gynaecology 5477	33	0.60%
Total	10,531	45	0.42%

rate for an undiagnosed pregnancy of 0.42% or 1 in 235 elective surgeries or uterine imaging procedures.

The informed consent process involves consideration of both, the surgical risk of the maternal hemodynamic and bleeding risks based on the anatomic location and type of surgery and the anaesthetic risk of anaesthesia type/systemic pharmaceutical /anaesthetic agent risks. Certain types of surgery, with regional/local blocks and with no surgical risk for the abdominal or pelvic fields, could be reasonably excluded from POPT process.

Ing *et al.* [10] have recently reviewed the risks of anaesthesia to the fetus as part of a larger comparative analysis related to neuro-developmental effects of early childhood anaesthesia exposure. Fetal teratology issues were reviewed including the teratology factors, teratology mechanisms, and the determinants of trans-placental drug transfer. Elective surgery in the first trimester of pregnancy should best be avoided when possible as it cannot be assumed there is no teratogenic anaesthetic effect. They state that 'it behooves the surgeon and the anaesthesiologist to establish the presence or absence of pregnancy before proceeding with surgery'. The choice of anaesthetic should be limited to those with a strong background of success. If the surgery is unavoidable, nitrous oxide should be avoided during the first trimester. Whenever possible, regional anaesthesia should be considered with spinal anaesthesia offering the lowest drug transfer for the degree of anaesthesia achieved. Hypotension, aorto-caval compression, maternal hypoxia and acidosis need to be avoided or treated promptly if present during the surgery. There has been no association with teratogenic effects in humans from reasonable levels of local anaesthetics and recent animal studies tend to confirm the human observations.

A first trimester anaesthesia exposure review [11] reports that while the literature reports no increase in congenital anomalies at birth in women exposed to anaesthesia during pregnancy, first trimester anaesthesia exposure does increase the risk of spontaneous abortion and lower birth weight. The rationale is those obstetrical outcomes are secondary to the surgical manipulation and the medical condition that requires the surgery rather than the exposure to anaesthesia.

The Institute for Clinical Improvement [12] has a published Perioperative Protocol that recommends a pre-operative pregnancy test if the patient is of child-bearing age, is sexually active and has a history suggestive of a possible pregnancy (delayed menstruation) or patient is concerned about possible pregnancy or the possibility of pregnancy is uncertain.

The anatomical location for the surgery and the possibility of hemodynamic effects on uterine and/or placental blood flow need to be considered. Disruptive congenital anomalies in the embryo can occur from systemically administered compounds/medications/agents, ionizing radiation, and prolonged episodes of uterine/placental hypotension.

Verbal questioning of the patient has been reported to be an acceptable screening test for pregnancy prior to surgery or radiological

imaging [13] but the reliability of this approach is questionable. Patient age will impact the reliability of the patient answer to the question 'could you be pregnant' based on their age, contraception use, sexuality, and menstrual frequency.

At the time of the office based surgical assessment, booking of the surgery, and the anticipated waiting period, the female patient should be advised to protect herself against becoming pregnant, if sexually active, with regular periods, and an intact uterus. The fertility or infertility of the male partner should not be a consideration related to the previous recommendation. The patient should be advised that pre-operative testing may be requested depending on the surgical location and peri-operative protocol [12].

Elective or semi-urgent surgeries in women, that may have a pelvic/uterine hemodynamic risk, would include (but are not limited to) cardiac, gynaecology, colo-rectal, pelvic fracture, and urology. The informed consent and implementation process for POPT could be limited to females undergoing the elective/semi-urgent surgeries as listed above.

The other high risk group for an undiagnosed pregnancy in a surgery setting is the adolescent females (age 12-18). This female age group of 12-18 has ethical and age of consent issues that add to the complexity of the POPT process.

Point of care urinary pregnancy testing references are included but are not the focus of this report [14-18].

Conclusions

1. While many jurisdictions and services have indicated that pre-operative surgical POPT guidelines need to be developed and implemented, these practices have not been widely initiated.
2. Due to the possibility of teratogenic effects to a related to anaesthesia as well as risks associated with particular surgeries, particular strategies should be considered when treating women of childbearing age.
3. Where surgical and/or anaesthesia risks are present, women of childbearing age should be counselled to avoid pregnancy pre-operatively. On the date of surgery, pregnancy status should be confirmed by questioning these patients. In cases where pregnancy status is in any doubt, point of care testing should be considered/offered/undertaken.
4. Pregnancy rate (literature and local) in the pre-op gynaecology/non-obstetric/imaging procedure populations is 0.42% or 1 in 235.
5. Undiagnosed pregnancies in the first trimester ranging from 4-10 weeks after LMP are likely to be identified with adolescent and peri-menopausal females at the greatest risk.
6. Anaesthetic, imaging exposure, surgical location and uterine hemodynamic risks are variable and depend on the elective or semi-urgent surgery that is planned (intra-uterine access/pelvic surgery would carry the highest risk to an undiagnosed pregnancy; with anaesthesia agents and ionizing radiation as primary or secondary risks based on the anticipated surgery). Where evidence of risk-benefit is weak, clinical judgement and informed patient preference should be used to guide care.
7. Embryonic/fetal risk exposure will range from no demonstrable impact (dependent on the timing and length of follow-

up and type of screening test initiated) to a live born with congenital disruption/deformation anomalies or to a pregnancy loss/miscarriage.

8. The 'true' risk/cost benefit for surgery with an associated undiagnosed pregnancy is difficult to estimate.

9. The most conservative guideline for urinary based POPT is for women aged 12-55 years who are undergoing pelvic ionizing radiation imaging or elective or semi-urgent cardiac, gynaecologic, colo-rectal, pelvic fracture, and urologic surgery(ies).

10. No published Provincial or National Policies for POPT in Canada were identified by the review process.

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There are no Copyright or Permission concerns.

References

1. IHE Report Routine Pre-Operative Tests- Are They Necessary? (2007) Institute of Health Economics Alberta Canada.
2. NHS National Institute for Clinical Excellence (2003) Preoperative Tests: The use of routine preoperative tests for elective surgery: Evidence, Methods, and Guidance. National Collaborating Centre for Acute Care pp 71 (Pregnancy Testing).
3. Watts JC, Wong SZ, Faithfull TJ, Wylde K, McGurgan PM (2014) Looking for the second patient: current practice and opinion on pre-operative pregnancy testing in Western Australia. *Aust N Z J Obstet Gynaecol* 54: 20-25. [[Crossref](#)]
4. Wong LF, Wingfield M (2013) Pre-operative testing for pregnancy in Dublin day surgery units. *Ir J Med Sci* 182: 231-235. [[Crossref](#)]
5. Grisby S, Miller M, Dunn JC, Patel S, Elashoff D, et al. (2013) Variations in pre-operative management of adolescents undergoing elective surgery. *Int J Pediatr Otorhinolaryngol* 77: 770-775. [[Crossref](#)]
6. Herr K, Moreno CC, Fantz C, Mittal PK, Small WC, et al. (2013) Rate of detection of unsuspected pregnancies after implementation of mandatory point-of-care urine pregnancy testing prior to hysterosalpingography. *J Am Coll Radiol* 10: 533-537. [[Crossref](#)]
7. Abdallah C. (2011) Teen Pregnancy Testing: risk documentation versus Cancellation? Letter to the Editor. *J Pediatr Adolesc Gynecol* 24, e45
8. Manley S, de Kelaita G, Joseph NJ, Salem MR, Heyman HJ (1995) Preoperative pregnancy testing in ambulatory surgery. Incidence and impact of positive results. *Anesthesiology* 83: 690-693. [[Crossref](#)]
9. Kahn RL, Stanton MA, Tong-Ngork S, Liguori GA, Edmonds CR, et al. (2008) One-year experience with day-of-surgery pregnancy testing before elective orthopedic procedures. *Anesth Analg* 106: 1127-1131. [[Crossref](#)]
10. Ing CH, DiMaggio CJ, Malacova E, Whitehouse AJ, Hegarty MK, et al. (2014) Comparative analysis of outcome measures used in examining neurodevelopmental effects of early childhood anesthesia exposure. *Anesthesiology* 120: 1319-1332. [[Crossref](#)]
11. Allaert SE, Carlier SP, Weyne LP, Vertommen DJ, Dutré PE, et al. (2007) First trimester anesthesia exposure and fetal outcome. A review. *Acta Anaesthesiol Belg* 58: 119-123. [[Crossref](#)]
12. Card R, Sawyer M, Degnan B (2014) Perioperative Protocol Institute for Clinical Systems Improvement 5thEdn.
13. Minnerop MH, Garra G, Chohan JK, Troxell RM, Singer AJ (2011) Patient history and physician suspicion accurately exclude pregnancy. *Am J Emerg Med* 29: 212-215. [[Crossref](#)]
14. Cervinski MA, Lockwood CM, Ferguson AM, Odem RR, Stenman UH, et al. (2009) Qualitative point-of-care and over-the-counter urine hCG devices differentially detect the hCG variants of early pregnancy. *Clin Chim Acta* 406: 81-85. [[Crossref](#)]
15. O'Kane MJ, McManus P, McGowan N, Lynch PL (2011) Quality error rates in point-of-care testing. *Clin Chem* 57: 1267-1271. [[Crossref](#)]
16. Fromm C1, Likourezos A, Haines L, Khan AN, Williams J, et al. (2012) Substituting whole blood for urine in a bedside pregnancy test. *J Emerg Med* 43: 478-482. [[Crossref](#)]
17. Cole LA (2012) ThehCG assay or pregnancy test. *ClinChem Lab Med* 50: 617-630. [[Crossref](#)]
18. Greene D, Schmidt RL, Kamer SM, Grenache DG, Hoke C, et al. (2013) Limitations in qualitative point of care hCG tests for detecting early pregnancy. *Clin Chim Acta* 415: 317-321. [[Crossref](#)]