Date	11/13/2019
Title	Clinical Utility of Postoperative Hemoglobin Testing Following Vaginal Hysterectomy and Reconstruction for Symptomatic Pelvic Organ Prolapse
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Introduction:

- Obtaining a complete blood count (CBC) on post-operative day (POD) 1 to assess postoperative hemoglobin levels is routine practice at our institution after pelvic reconstructive surgery.
- There is minimal data supporting this practice. Multiple studies throughout the gynecology literature suggest that this is not a necessary or cost effective strategy to assess for postoperative anemia. [2,6,9,11]
- Most patients who require blood transfusion or reoperation for bleeding will show clinical signs of anemia. [2, 6, 7, 11] It is necessary to consider the entire clinical picture before initiating blood transfusion for postoperative anemia. [1]
- Although the individual cost of each lab test is low, the cumulative cost of these tests is substantial. [2,9]
- The procedure of choice for prolapse repair by Cincinnati Urogynecology Associates, TriHealth Inc. is a vaginal hysterectomy (TVH) with concurrent apical, anterior, and posterior compartment native tissue repairs as indicated. A review of the literature failed to identify any studies that have looked specifically at the utility of postoperative CBC after vaginal hysterectomy with prolapse repairs.

Purpose of Study

- To determine if checking a routine CBC results in clinically relevant changes to patient care in women undergoing pelvic reconstructive surgery with vaginal hysterectomy for treatment of pelvic organ prolapse.

Hypothesis or Research Question:

- We hypothesize that there is minimal utility in the routine collection of POD1 CBC in patients undergoing TVH during vaginal prolapse repairs.
- We also hypothesize that the overall blood transfusion rate of our pelvic reconstructive patients is low, and that a more selective approach to CBC collection would be appropriate.

Background:

Surgeons commonly check a CBC on patients after major gynecologic surgery. This is done to evaluate for postoperative anemia and to provide surgeon reassurance prior to discharging a patient home. There are more than 200,000 inpatient operative procedures completed for pelvic organ prolapse annually in the United States. [5] Studies quote rates from, 87-99.6% of patients having a CBC drawn on POD1 and up to 1/3 of these patients requiring some intervention based on these results. [6,7,11] Further evaluations of abnormal lab results may be additional blood work or more invasive procedures such as imaging tests or reoperation.

In recent years, multiple studies have shown that routine preoperative lab testing is not ubiquitously indicated for women undergoing gynecologic and urologic surgery. Thirty day outcomes do not change regardless of lab collection prior to surgery. [3] The American Society of Anesthesia recommends against routine preoperative lab testing in the absence of clinical indications. [14] Even with these recommendations, up to 40% of women receive un-indicated preoperative lab testing prior to urologic procedures. [13] Similar to lab testing in the preoperative period, despite the high rate surgeons ordering postoperative labs, the clinical utility of a POD1 CBC has been called into question.

Throughout the gynecology literature, studies have identified multiple risk factors for a larger drop in hemoglobin on POD1 including hysterectomy at the time of pelvic surgery, midurethral sling placement at the time of prolapse repair, lower BMI, and the amount of IVF received in the OR. [2, 11] These findings were corroborated by additional studies, which also identified preoperative anemia, history of coagulopathy, and African American or Hispanic ethnicity as risk factors for postop blood transfusion. [4,8,10,12] Although these patient and surgical characteristics have been identified as risk factors for postoperative anemia and transfusion, one study noted based on their data, that if they restricted CBC collection to patients with at 2 or more signs of anemia on POD1, 90% of their sample would not have required testing. [7] Other studies have corroborated that almost all patients that ultimately require blood transfusion will show clinical signs of anemia. [2, 6, 11]

Within our Division, the surgical procedure of choice to treat pelvic organ prolapse is a total vaginal hysterectomy with concurrent vaginal native tissue prolapse repairs. As standard practice, patients are kept overnight in the hospital for observation and a CBC is collected the morning on POD1. Studies in the gynecology literature have looked at the utility of routine CBC on patients after elective gynecologic surgery in general, total laparoscopic hysterectomy, minimally invasive sacrocolpopexy with or without concurrent hysterectomy, but none have looked specifically at our patient population having a vaginal hysterectomy with vaginal prolapse repairs. [2, 6, 7, 10]

Our goal is to show that routine collection of a CBC on POD1 in asymptomatic patients after vaginal hysterectomy with prolapse repair is unnecessary. If this is found, we could stop routine CBC collection which is a bothersome procedure for many patients and an added expense contributing to high health care costs.

Research Plan:

Study Design: Retrospective chart review

Setting of Study: TriHealth Epic platform at one of the various clinical locations.

Participants: All patients who underwent a total vaginal hysterectomy with concurrent vaginal native tissue prolapse repairs performed by one of four fellowship trained urogynecologists at TriHealth between 10/1/2014 and 10/1/2019. The patients will be identified by CPT codes in the EPIC electronic medical record.

Inclusion Criteria:

Total vaginal hysterectomy with or without bilateral salpingectomy/oophorectomy (CPT 58260, 58262, 58263, 58270, 58290, 58291, 58292, 58294)

At least one of the following vaginal native tissue prolapse repairs

Apical repair with uterosacral ligament suspension (CPT 57283)

Apical repair with sacrospinous ligament fixation (CPT 57282)

Anterior repair (CPT 57240, 57260, 57284, 57285, 57250)

Posterior repair (CPT 45560, 56800, 56810, 57200, 57210, 57250)

Age >18

Surgery by one of four fellowship trained urogynecologists at TriHealth

Exclusion Criteria:

Concomitant surgical procedure by a second surgeon

Malignancy identified at the time of surgery or active malignancy

Cases converted to open hysterectomy or prolapse repairs

Prolapse repair completed robotically

Prolapse repair completed with mesh

Known coagulopathy

Patient on long term preoperative anticoagulant medication (Arixtra, Coumadin, Eliquis, Heparin, Lovenox, Pradaxa, Savaysa, Xarelto)

Sample Size:

Similar retrospective studies included between 629-1105 patients in their chart review. [2, 6, 7, 11] Based on the number of vaginal hysterectomies performed by our department annually, we anticipate five years of data collection will provide a comparable study size for this review. Our anticipated sample size will be approximately 800 patients.

Data Collection: Please see attached data collection sheet

- Charts of all patients having a total vaginal hysterectomy by one of our four fellowship trained urogynecologists during the study time frame will be identified and analyzed for inclusion and exclusion criteria.
- All charts meeting inclusion criteria will be included in the analysis.
- Each chart will be reviewed and the following variables collected for analysis:
    - Type(s) of prolapse repair(s)
    - Additional procedure for urinary incontinence at the same time as hysterectomy and prolapse repair – yes/no
    - Preoperative CBC collected within 30 days of surgery – yes/no
    - Preoperative hemoglobin
    - CBC collected the morning of POD1 – yes/no
    - POD1 hemoglobin
    - Change in hemoglobin from preoperative to postoperative collection
    - Change in hemoglobin level ≥2 – yes/no
    - Postoperative hemoglobin ≤10 – yes/no
    - More than one postoperative hemoglobin obtained – yes/no
    - Patient with objective signs of anemia (*persistent hemodynamic changes: pulse >100 beats per minute, blood pressure <90/60)* – yes/no
    - Patient with subjective signs of anemia (*dizziness, lightheadedness, weakness, pale, cool, diaphoretic)* – yes/no
    - Blood transfusion – yes/no
    - Estimated blood loss
    - IVF volume received intraoperatively
    - Length of surgery (in minutes)
    - Prophylactic heparin given preoperatively – yes/no
    - General demographic data including: name, DOB, age, race, BMI, medical comorbidities, parity, smoking history, menopausal status
    - Preoperative aspirin use – yes/no
    - Preoperative antiplatelet medication use (i.e.: Brilinta, Effient, Plavix) – yes/no
    - Stage of pelvic organ prolapse at preoperative appointment
    - Prior abdominal or pelvic surgery – yes/no
    - Patient readmitted within 30 days of surgery – yes/no

- Patient seen in emergency department within 30 days of surgery – yes/no
- Length of hospital stay (in days)
- Delay in discharge due to CBC results – yes/no

Intervention or experimental aspect of the study:

- No intervention will occur as part of this study.
- There are no potential risks to the study population by any aspect of this study.

Statistical Analysis:

Demographic data will be described using frequency (percentage) for categorical variables and mean (standard deviation) or median (min, max) for continuous variables. The percentage of subjects with hemoglobin less than 10 g/dL at POD1 will be evaluated as well as the percentage of subjects with signs of anemia. Pearson product moment correlation coefficient will be employed to measure the association between postoperative hemoglobin level and perioperative variables such as age, BMI, blood loss, or length of surgery. The mean hemoglobin change from pre- to postoperative measurement in symptomatic subjects will be compared with that of asymptomatic subjects using Student's t-test. Multiple linear regression will be used to investigate risk factors impacting mean decrease in hemoglobin. On the other hand, multiple logistic regression will be used to investigate factors associated with the presence of signs of anemia.

Ethical Considerations:

Informed Consent:

- Informed consent will not be required given the retrospective chart review design of this study.

Privacy Information:

- Extensive effort will be made to ensure and maintain participant confidentiality. All identifying information will be maintained in a secure area at all times. All communication between staff members regarding participant data will occur via the Subject ID number only. However, identifying information will be retained in the original/source documents.
- The Excel spreadsheet will be stored on a password protected, encrypted TriHealth computer for ten years following study closure, and then purged.

Cost/Budget:

- This study will incur no cost to the institution, the participants, or the investigators.

Estimated Period of Time to Complete Study	
When will study begin?	Winter 2019
Protocol Development Completed	2 weeks
Admin Review Time	2 weeks
IRB Approval	3 weeks
Data Collection	4 weeks
Data Analysis	2 weeks
Presentation Development (if applicable)	2 weeks
Manuscript Development (if applicable)	4 weeks
Journal Submission Process (if applicable)	4 weeks
Study Closure	2 weeks

When and how will results be disseminated?

- The results will be disseminated by way of an oral or poster presentation at a national meeting and with publication in a high-impact journal.

References:

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4.) Grathwohl KW, Bruns BJ, Ohno AK, et al. Does hemodilution exist? Effects of saline infusion on hematologic parameters in euvolemic subjects. South Med J. 1996 Jan; 89(1): 51-5.
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7.) Lavelle ES, Giugale L, Sears S, et al. Clinical utility of hemoglobin testing after minimally invasive sacrocolpopexy. Female Pelvic Med Reconstr Surg. 2018 Jan/Feb; 24(1): 17-20.
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13.) Pandya LK, McLaughlin EM, Hudson CO, et al. Utility of preoperative laboratory testing in women undergoing suburethral sling. Female Pelvic Med Reconstr Surg. 2019 Mar/Apr; 25(2): 99-104.
14.) Practice Advisory for Preanesthesia Evaluation: An Updated Report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation. Anesthesiology. 2012;116(3):522-538.