



## Association between hypoalbuminemia and surgical site infection in vulvar cancers



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### HIGHLIGHTS

- Hypoalbuminemia rate in vulvar cancer is similar to other gynecologic malignancies.
- Hypoalbuminemia is associated with major wound complication in vulvar cancer.
- Albumin should be assessed to accurately counsel patients about postoperative risk.

### ARTICLE INFO

#### Article history:

Received 8 May 2016

Received in revised form 26 June 2016

Accepted 29 June 2016

Available online 6 July 2016

#### Keywords:

Albumin

Vulvar

Wound

Postoperative

Infection

Readmission

### ABSTRACT

**Objective.** To determine if preoperative hypoalbuminemia is associated with postoperative wound complications among patients with vulvar cancer.

**Methods.** The National Surgical Quality Improvement Program database was queried for cases of vulvar cancer undergoing vulvectomy with or without lymphadenectomy (LND) from 2008 to 2013. Primary outcome was major wound complication. Secondary outcome was minor wound complication. Hypoalbuminemia was defined as albumin < 3.5 g/dL. Descriptive statistics and multivariable logistic regression were used for analysis.

**Results.** Of 777 vulvar cancer patients, 514 (66.2%) had vulvar surgery alone and 263 (30.3%) had a LND. Median age was 66 (range 20–90) and median BMI was 28.9 kg/m<sup>2</sup> (range 14.3–65.5). The incidence of wound complication was 10.4% (81/777) with 48 minor and 39 major complications. There was no difference in major wound complications when a LND was performed ( $p = 1.0$ ). Preoperative albumin was recorded in 429 patients (55.2%). Patients with hypoalbuminemia were more likely to have a major wound complication (OR 2.9 95% CI 1.1–7.3,  $p = 0.02$ ), even after adjusting for BMI, age, preoperative hematocrit, and diabetes (aOR 2.7 95% CI 1.1–7.1,  $p = 0.04$ ). In bivariable analysis, age, diabetes, and BMI were not associated with wound complication. Patients with a wound infection had 10 times the odds of being readmitted within 30 days (OR 9.5, 95% CI 4.9–18.4,  $p < 0.01$ ).

**Conclusions.** Low preoperative albumin is associated with major postoperative wound complications in women undergoing surgery for vulvar cancer. When obtaining informed consent, patients with low albumin should be counseled regarding higher risks of postoperative wound complication.

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### 1. Introduction

Vulvar cancer is a rare, but potentially devastating malignancy. The incidence of vulvar cancer has increased over the last 30 years [1]. Vulvar disease is frequently diagnosed at an early stage where primary surgery, consisting of vulvectomy with or without inguinal

lymphadenectomy, is the treatment of choice. Surgical therapy, however, has a high rate of wound complications with up to one third of patients experiencing wound breakdown, cellulitis, and lymphedema when an inguinal lymphadenectomy is performed, and as many as half of patients experiencing wound infection with vulvectomy [2,3].

Recognition and modification of risk factors for wound infection in this population may provide opportunities to improve outcomes after surgery. Vulvar cancer is most commonly diagnosed in postmenopausal women who frequently have other medical co-morbidities that may affect wound healing. Diabetes, obesity, and smoking have all been found to be associated with wound infection, although not consistently [2,4,5].

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Additional targets are needed to modify surgical outcomes for this high-risk population.

Biomarkers associated with wound prognosis have been studied in cancer and post-operative patients. It has been observed that albumin, as a marker for protein-deficiency and oncotic pressure homeostasis, predicts wound healing in patients undergoing surgery [6–9]. In patients with gynecologic malignancies pre-operative albumin below 3.5 g/dL was found to increase the odds of a postoperative wound complication 4-fold when compared to patients with a normal pre-operative serum albumin level [10]. Other studies have found that low albumin predicts post-operative complications, poor prognosis, and mortality [11–13]. The impact of low albumin in patients undergoing vulvar cancer procedures has not been evaluated in regards to wound complications or their sequelae. The objective of this study was to determine the association between preoperative hypoalbuminemia and postoperative wound complications in women undergoing surgery for vulvar cancer.

## 2. Methods

### 2.1. Data sources and patient population

All patients with a diagnosis of vulvar cancer who had a vulvectomy with or without lymphadenectomy from 2008 to 2013 were identified from the National Surgical Quality Improvement Program (NSQIP) database. Procedural terminology codes (CPT) codes and International Classification of Diseases, Ninth Revision (ICD-9) codes were used to identify patients. NSQIP is a nationally recognized quality initiative that collects prospective clinical data on surgical outcomes. NSQIP data are collected by a trained surgical clinical reviewer who records data directly from the medical record. Patient outcomes are tracked for 30 days after surgery to capture complications that occur post-discharge. Readmission data became available in 2011; therefore, results regarding readmissions reflect data collected from 2011 to 2013 only. Reason for admission was made available only in 2012, and therefore was not included in this investigation. The University of North Carolina reviewed this study and declared it exempt from formal review as it does not constitute human subjects research.

### 2.2. Data collection and statistical analysis

The primary outcome was major wound complication defined as deep surgical site infection (SSI), organ space SSI, wound dehiscence, or graft/flap failure. The secondary outcome was minor wound complication defined as superficial SSI. Our exposure was hypoalbuminemia, which was defined as albumin < 3.5 g/dL. This cutoff has been previously demonstrated to be associated with clinically significant changes in the incidence of wound infection [11–13]. Covariates elicited from the NSQIP database included age, BMI, smoking status, preoperative creatinine, preoperative hematocrit (HCT), preoperative white blood cell (WBC), steroid use, preoperative transfusion > 4 units of red blood cells, number of RBC units transfused intraoperatively, Charlson Comorbidity Index, and presence of diabetes, cardiovascular disease, or hypertension. Data regarding total work relative value unit (WRVU) and operative time were collected and analyzed as surrogates for surgical complexity. Covariates for the multivariable model were selected based on published risk factors for vulvar wound complication [2–5,14].

Postoperative factors associated with major and minor wound complications were also examined in relationship to hypoalbuminemia using bivariable tests. Hospital readmission, defined as any readmission within 30 days of surgery, as well as sepsis and septic shock, defined by the NSQIP participant use file were examined as possible sequelae of postoperative wound infection [15]. The association between wound infection and readmission was measured with a rate ratio.

Descriptive statistics were used to describe continuous data and discrete data. For univariate analysis, two-tailed t tests, Fisher exact and Chi

Square tests were applied. Multivariable logistic regression was used to adjust for covariates. Complete case analysis for the exposure, outcomes and all listed covariates was performed. For variables with >5% missing data, a logistic regression model was performed to determine if there were significant associations between that variable being missing and the outcome, exposure and other covariates. A p-value of <0.05 was considered statistically significant. All analyses were performed using SPSS version 20.0 (IBM Corp, Armonk, NY).

## 3. Results

Seven hundred seventy-seven surgical patients with vulvar cancer were identified; 514 (66.2%) underwent vulvar surgery alone and 263 (30.3%) had a lymph node dissection. The median age was 66.0 years (range 20–90) and more than half (54%) of the population was older than age 65. The median BMI was 28.9 kg/m<sup>2</sup> (range 14.3–65.5). More than a third of the population (43.1%) had at least class I obesity with a BMI > 30 and 11% of the population had class III obesity with a BMI > 40. The overall wound complication rate was 10.4% (81/777). There were 48 minor and 39 major complications; 6 (0.8%) patients had both a major and minor complication.

Preoperative albumin was recorded in 429 patients (55.2%). Fifty-five (12.8%) patients were hypoalbuminemic with a level < 3.5 g/dL. Data was missing for <5% of the sample for all examined covariates. However, the exposure, albumin, was missing for 348 (44%) patients. To address this, we performed a logistic regression model including all examined covariates and found no association between missing albumin level and any covariates. There was also no association between missing albumin level and our primary or secondary outcomes (major or minor wound complication).

Patients with hypoalbuminemia were more likely to experience a major wound complication (OR 2.9, 95% CI 1.1–7.3,  $p = 0.03$ ). Longer operative time was associated with major wound complications with a mean time of 203 min  $\pm$  170 for patients with a major wound complication versus 125 min  $\pm$  115 in those without a major wound complication ( $p \leq 0.001$ ). Additionally, total work relative value unit (WRVU) was associated with increased major wound complications with a higher mean WRVU of 41 in those with major wound complications versus 26 in those without ( $p \leq 0.01$ ). There was no difference in major wound complications between patients who underwent an inguinal lymph node dissection and those who did not ( $p = 1.0$ ). The associations between preoperative factors and major wound complications are summarized in Table 1.

Preoperative hypoalbuminemia was not associated with increased risk for minor wound complications ( $p = 0.40$ ). Inguinal lymphadenectomy was also not associated with an increased incidence of minor wound infection ( $p = 0.16$ ). Preoperative hematocrit (HCT) of <38% was associated with increased minor wound complications (OR 2.13, 95% CI 1.1–4.0,  $p = 0.01$ ). No other preoperative factors such as age > 65 years, BMI, preoperative creatinine, preoperative white blood cell count, cardiac comorbidities, diabetes, smoking status, Charlson Comorbidity Index, or steroid use were found to be associated with major or minor wound infection. Intraoperative red blood cell (RBC) transfusion was not associated with an increased risk of major or minor wound complications, regardless of number of RBC units given ( $p = 0.3$  and 0.4, respectively). Associations between preoperative factors and minor wound complications, the secondary outcome, are summarized in Table 2.

In a multivariable logistic regression model adjusting for BMI, age, preoperative hematocrit, diabetes and total WRVU, the relationship between hypoalbuminemia and major wound complication persisted (aOR 2.7 95% CI 1.1–7.0,  $p = 0.05$ ). The total number of postoperative sepsis occurrences in our population was 11 (1.4%) and 4 (0.5%) patients were diagnosed with septic shock. Of these 15 patients, there was no association between hypoalbuminemia or LND and major post-operative wound infection ( $p = 0.66$  and 0.78 respectively).

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