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Case series

Adverse post-operative outcomes in Jehovah's witnesses with gynecologic cancer within 30 days of surgery: A single institution review of 36 cases☆

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ABSTRACT

Rates of blood transfusion are reported as high as 32% in women undergoing major gynecologic cancer surgery. Therefore, care of the gynecologic oncology patient who refuses blood products, such as Jehovah's witnesses, can pose a unique challenge. The objective of this study was to determine rate of adverse post-operative outcomes within 30 days of surgery in Jehovah's witnesses with gynecologic cancer. This was a retrospective cohort study of Jehovah's witnesses undergoing laparotomy or minimally invasive surgery (MIS) for gynecologic cancer at a single institution. Data for post-adverse complications within 30 days of surgery were recorded. In total, 36 patients were included with a median age of 58.5 years (32–85 years). The majority had endometrial adenocarcinoma (n = 23; 63.9%) or epithelial ovarian, fallopian tube or peritoneal cancer (EOC) (n = 8; 22.2%). 61.1% (n = 22) of patients underwent laparotomy and 38.9% (n = 14) had MIS procedures. 31.8% of laparotomies (n = 7) were terminated prematurely due to surgeon concern for ongoing blood loss. In patients with advanced stage EOC, the rate of suboptimal cytoreduction (> 1 cm) was 50%. In the laparotomy cohort, there were four (18.2%) ICU admissions and two (9.1%) mortalities. The time to adjuvant chemotherapy or radiation was 45.5 days (31–64) for laparotomy compared to 35.0 days (12–64) for MIS. While the majority of patients (97.2%) were unwilling to accept packed red blood cells, over one third (38.9%) were agreeable to autologous blood transfusion. Additionally, five (13.9%) patients were accepting of fresh frozen plasma, six (16.7%) patients were agreeable to cryoprecipitate and seven (19.4%) patients were willing to accept platelet transfusions. There is a high rate of postoperative adverse outcomes among Jehovah's witnesses undergoing laparotomy for gynecologic malignancy compared. Acceptance of blood products is low among Jehovah's witnesses, even in the setting of major oncologic surgery.

1. Introduction

Over 80,000 women are diagnosed with gynecologic cancer annually in the United States (U.S. Cancer Statistics Working Group, 2015). For most gynecologic malignancies, the initial treatment consists of surgery and may be followed by adjuvant chemotherapy, radiation therapy or a combination of both. Primary cytoreductive surgeries for gynecologic malignancies can be associated with significant post-operative morbidity (Chen and Bochner, 1985) Severe anemia has been identified as a predictor of adverse outcome in the peri-operative period, with mortality exceeding 30% in patients with hemoglobin of < 5 g/dL (Carson et al., 2002). Transfusion of blood products is often a necessary intervention with a rate of transfusion reported as high as 32% during the post-operative period among women undergoing major gynecologic cancer surgery (Doo et al., 2016). There are a number of situations in which a patient may refuse blood transfusions, with the most well known involving Christians known as Jehovah's witnesses with over 8 million members world-wide. While devout Jehovah's Witnesses will not accept transfusions of any component of whole blood, others will consider acceptance of blood sub-fractions including albumin and clotting factors as well as autologous donation. Care of the surgical patient who refuses blood products can pose a unique challenge.

While there have been several case reports of patients with gynecologic cancer or complex gynecologic issues undergoing successful bloodless surgery and several reviews focusing on bloodless surgery in these women, there is little data for rates of adverse short-term perioperative outcomes, ability to obtain complete cytoreduction and time to

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initiation of adjuvant chemotherapy in a cohort of Jehovah's witnesses undergoing surgery for gynecologic cancer (Nagarsheth and Sasan, 2009; Nagarsheth et al., 2007). Determining the rates of adverse post-operative outcomes in this population of patients will be helpful for pre-operative surgical planning and patient counseling.

The objective of this study was to identify the incidence of adverse post-operative outcomes including ICU stay, readmission and mortality within 30 days of surgery for Jehovah's witnesses undergoing major laparotomy and minimally invasive surgery for gynecologic cancer.

2. Materials and methods

A retrospective cohort study was performed at a single tertiary care academic health care institution after Institutional Review Board approval for the study was obtained. Patients with a diagnosis of any gynecologic malignancy (cancer of the cervix, uterus, vagina, vulva, ovary, fallopian tube or peritoneum) (ICD-9, 158, 179, 180, 182, 183, 184) who reported their religion as a Jehovah's Witness (V62.6) were identified from the electronic medical record using ICD-9 codes from 2004 to 2015. Patients were included if they underwent surgery for treatment of their cancer, which included both laparotomy and minimally invasive surgery (MIS, including both laparoscopy and robotic assisted procedures). No vulvar or vaginal surgeries were performed in this patient sample. Patients who did not undergo surgery were excluded.

Data was extracted from the electronic medical record for demographic, oncologic and surgical characteristics of patients. Data collection for patient demographics included age at the time of surgery, ASA (American Society of Anesthesiologists) classification and Charlston co-morbidity index. Data was collected for oncologic variables including site of cancer, histology, stage of disease and whether neoadjuvant or adjuvant chemotherapy was received. Operative variables that were collected included pre-operative and post-operative hematologic parameters, operative time, surgical procedures performed, estimated blood loss (milliliters) and extent of cytoreduction (complete, optimal < 1 cm, suboptimal). Operative time was defined as time from skin incision to closure. Intra-operative complications were defined as injury to bowel, bladder, ureters or major vascular structures. Each operative report was reviewed for notation that the surgery was terminated due to concern for ongoing or potential blood loss given patient's refusal of blood loss. Data was collected for adverse postoperative outcomes including readmission, ICU stay, mortality and surgical site infection within 30 days of surgery.

At our institution, all patients who refuse blood products complete a document attesting their refusal to some or all blood components including packed red blood cells, cryoprecipitate, albumin, whole blood, which is scanned into the electronic medical record. This form was reviewed for all patients to verify their refusal or acceptance of blood products, as well as their refusal or acceptance to use autologous blood transfer methods. Descriptive statistics were performed. Statistical analysis was performed using JMP software 12.2.0.

3. Results

In total, 36 women were identified as Jehovah's witnesses who underwent surgery for gynecologic malignancy. Table 1 includes the baseline demographic data for women included in the study. Median age at the time of surgery was 58.5 years old. Pre-operative median ASA score was 3.0 and median Charleston Comorbidity Index was 6.0. Median pre-operative hemoglobin and hematocrit were 12.8 (5.4–15.5) mg/dL and 38.6 (19.6–45.6) mg/dL, respectively. No patient's received hematopoietic growth factors pre- or post-operatively.

Of the 23 patients (63.6%) with endometrial adenocarcinoma, nine (39.1%) were Stage IA, eight were Stage IB (34.7%), one was Stage IIIA (4.8%), one was stage IIIB (4.8%), two were stage IIIC1 (9.5%) and two were Stage IVA (9.5%). Six patients (16.7%) had ovarian adenocarcinoma with one had Stage IIC disease (16.7%), two had IIIC disease (33.3%), one had IIIB disease (16.7%) and one (16.7%) with stage IVB disease. Futhermore, two patients (5.6%) had adenocarcinoma of the cervix (Stage 1A2, 1B1), one (2.8%) had adenocarcinoma of the fallopian tube (Stage IA), one (2.8%) had uterine carcinosarcoma (Stage IV), one (2.8%) had uterine leiomyosarcoma (Stage IV), one (2.8%) had uterine papillary serous carcinoma (Stage IIIC) and one (2.8%) had primary peritoneal adenocarcinoma (Stage IIIC). Two patients (5.6%) with advanced ovarian carcinoma received neoadjuvant chemotherapy.

Table 1
Demographic, clinical and treatment characteristics of Jehovah's witnesses undergoing surgery for gynecologic malignancy.

Factor		Total ($N = 36$)
Age, y		58.5 (32–85)
ASA score		3.0 (2.0–4.0)
Charlston comorbidity index		6.0 (2.0–9.0)
Pre-operative hemoglobin (mg/dL)		12.8 (5.4–15.5)
Pre-operative hematocrit (mg/dL)		38.6 (19.6–45.6)
Neoadjuvant chemotherapy		2 (5.5)
Histology and site		
Cervix	Adenocarcinoma	2 (5.5)
Ovarian, Fallopian Tube, Peritoneal	Adenocarcinoma	8 (22.2)
Uterus	Adenocarcinoma	23 (63.9)
	Leiomyosarcoma	1 (2.8)
	Carcinosarcoma	1 (2.8)
	High grade serous	1 (2.8)
Extent of Surgery		
Laparotomy		22 (61.1)
Minimally Invasive Surgery		14 (38.9)
Procedures		
Hysterectomy +/− BSO		34 (94.4)
Small bowel resection		4 (11.1)
Large bowel resection		4 (11.1)
Ileostomy/colostomy		2 (5.5)
Pelvic lymphadenectomy		11 (30.6)
Para-aortic lymphadenectomy		7 (19.4)

Statistics presented as Median (range) or N (column %).
ASA, American Society of Anesthesiologists; BSO, bilateral salpingo-oophorectomy.

22 patients (61.1%) underwent laparotomy and 14 (38.9%) had minimally invasive surgery (MIS). Postoperative outcomes of Jehovah's witnesses who underwent surgery for gynecologic cancer are described in Table 2. For those undergoing MIS procedures, the median pre-operative hemoglobin and hematocrit were 13.3 (11.5–15.5) mg/dL and 40.2 (34.8–45.6) mg/dL, respectively and median post-operative hemoglobin and hematocrit were 11.7 (9.5–13.6) mg/dL and 34.2 (30.6–41.1) mg/dL, respectively. For those undergoing who underwent laparotomy, the median pre-operative hemoglobin and hematocrit were 12.4 (5.4–14.6) mg/dL and 37.9 (19.6–44.5) mg/dL, respectively and median post-operative hemoglobin and hematocrit were 8.9 (3.4–13.3) mg/dL and 27.9 (11.0–42.2) mg/dL, respectively.

In the patients who underwent laparotomy, in 31.8% ($n = 7$) of the cases there was notation in the operative report by the surgeon that the procedure was stopped prematurely due to current bleeding or high risk of hemorrhage if surgery was continued. Among all patients included with advanced stage EOC, the rate of suboptimal cytoreduction (> 1 cm residual disease) was 50.0%. Median length of stay was 7 days in those undergoing laparotomy vs. 1 day for MIS. Median EBL was 250.0cm^3 (25–4300) for laparotomy vs. 75.0cm^3 (10 − 200) for MIS. Among those who underwent laparotomy, there were four (18.2%) ICU admissions and two (9.1%) deaths occurred within 30 days. No hemodilution techniques were utilized in any patient undergoing surgery.

Table 3 displays additional peri-operative details of the patients with ICU admissions and mortalities. Of the four patients who were admitted to the ICU post-operatively, two of them were noted to be anemic at the time of surgery with one of these surgeries performed in an emergent fashion due to a complication of their malignancy. Among

Table 2
Postoperative outcomes of Jehovah's witnesses undergoing surgery for gynecologic cancer.

Variable		Laparotomy (N = 22)	MIS (N = 14)
Cancer Site and Stage			
Cervix	Stage I/II	2 (9.1)	0 (0.0)
	Stage III/IV	0 (0.0)	0 (0.0)
Ovarian, Fallopian Tube, Peritoneal	Stage I/II	2 (9.1)	0 (0.0)
	Stage III/IV	7 (31.8)	0 (0.0)
Uterus	Stage I/II	4 (18.2)	13 (92.9)
	Stage III/IV	7 (31.8)	1 (7.1)
Length of hospital stay (days)		7 (1 − 20)	1 (1–4)
Estimated blood loss (mL)		250 (25–4300)	75 (10–200)
Preoperative Hemoglobin (mg/dL)		12.4 (5.4–14.6)	13.3 (11.5–15.5)
Preoperative Hematocrit (mg/dL)		37.9 (19.6–44.5)	40.2 (34.8–45.6)
Postoperative Hemoglobin (mg/dL)		8.9 (3.4–13.3)	11.7 (9.5–13.6)
Postoperative Hematocrit (mg/dL)		27.9 (11.0–42.2)	34.2 (30.6–41.1)
Operating time (min)		214 (91–349)	137 (100–264)
Early termination of procedure due to hemorrhage		7 (33.3)	0 (0)
Postoperative complications within 30 days		9 (40.9)	3 (21.4)
Death		2 (9.1)	0 (0.0)
Reoperation		1 (4.5)	0 (0.0)
ICU admission		4 (18.2)	0 (0.0)
Readmission		0 (0.0)	0 (0.0)
Urinary Tract Infection		0 (0.0)	1 (7.1)
Myocardial infarction		1 (4.5)	0 (0.0)
Abdominal abscess		1 (4.5)	1 (7.1)
Cellulitis		0 (0.0)	1 (7.1)
Time to adjuvant treatment (days)		45.5 (31–64)	35 (12–64)

Statistics presented as Median (range) or N (column %).
MIS, minimally invasive surgery; ICU, intensive care unit.

the two mortalities, one patient was severely anemic (hemoglobin 5.4 mg/dL) and underwent emergency surgery due to a bowel perforation which was a complication of their malignancy without significant surgical blood loss. Neither of these patients were referred to a blood management specialist or received intravenous iron replacement. There were no ICU admissions or patient deaths within the MIS group. Additional postoperative complications among those having laparotomy included intra-abdominal abscess (4.5%), myocardial infarction (4.5%) and surgical site infection (4.5%). Time to adjuvant chemotherapy or radiation was 45.5 days (31–64) vs. 35 days (12–64) for MIS.

On review of the blood acceptance form for each patient (Table 4), 32 patients (97.2%) were not willing to accept transfusion of packed red blood cells. One patient was willing to accept blood transfusion in the case of life threatening anemia and she was received transfusion of packed red blood cells intra-operatively due to emergent hemorrhage. Five (13.9%) of patients reported acceptance of fresh frozen plasma and six (16.7%) patients were agreeable to administration of cryoprecipitate. Seven (19.4%) patients were willing to accept transfusion of platelets. 14 patients (38.9%) reported acceptance of autologous blood transfer methods at the time of their surgery. No patients in the study received erythropoietin (0%).

Table 4
Acceptance of blood products among Jehovah's Witnesses undergoing surgery for gynecologic cancer.

Blood Product	N = 36
Packed red blood cells	1 (2.8)
Cryoprecipitate	6 (16.7)
Fresh frozen plasma	5 (13.9)
Platelets	7 (19.4)
Autologous blood transfusion	14 (38.9)

Statistics presented as N (column %).

4. Discussion

In this single-institution study of 36 Jehovah's witnesses, those undergoing laparotomy for gynecologic malignancy had high rates of postoperative adverse outcomes including ICU admission and death

Table 3
Detailed information for Jehovah's Witnesses with Gynecologic Cancer with unplanned ICU admission or mortality within 30 days after surgery.

Age (yr)	Diagnosis	Adverse outcome	Pre-operative Hgb/Hct (mg/dL)	Post-operative Hgb/Hct (mg/dL)	Procedure	EBL (cc)	Charlson index
60	Stage IV LMS	Unplanned ICU admission, Mortality	5.4/19.6	5.1/16.0	Exploratory laparotomy, loop ileostomy due to bowel perforation	100	6.0
62	Stage IIIB Mucinous AdenoCA of the Ovary	Unplanned ICU admission, Mortality	12.3/40.3	3.4/11.0	Exploratory laparotomy, BSO, removal of Pelvic Mass	2000	8.0
75	Stage IIIV Serous CA of the Ovary	Unplanned ICU admission	9.7/31.7	6.1/19.6	Exploratory laparotomy, en bloc resection of ileum, sigmoid colon, rectum and removal of pelvic tumors	1500	6.0
54	Stage IIIB Endometrial Endometrioid AdenoCA, FIGO grade 3	Unplanned ICU admission, blood transfusion	12.4/37.3	7.6/21.4	TAH, BSO, Resection of Sigmoid Colon, Terminal Ileum, Hemicolectomy, Omentectomy, Incisional Hernia repair	4300	9.0

LMS, leiomyosarcoma; adenoCA, adenocarcinoma; ICU, intensive care unit; Hgb, hemoglobin; Hct, hematocrit, EBL, estimated blood loss; TAH, total abdominal hysterectomy; BSO, bilateral salpingo-oophorectomy.

compared to those who underwent MIS. The benefits of MIS among women with cervical and uterine cancers have been well documented, with both laparoscopic and robotic approaches associated with reduction in surgical blood loss and blood transfusion when compared to open procedures (Chan et al., 2015; Bogani et al., 2014; Ditto et al., 2016). In an analysis of the Nationwide Inpatient Sample database by Chan et al., patients with endometrial cancer undergoing conventional or robotic laparoscopic hysterectomy had a significantly lower rate of blood transfusion compared to those having open surgery (Chan et al., 2015). Similarly, Bogani et al. reported a lower rate of both operative blood loss and rate of blood transfusion in patients undergoing minimally invasive radical hysterectomy compared to open radical hysterectomy for early stage cervical cancer (Bogani et al., 2014). There is growing evidence supporting a possible role of laparoscopic staging in early stage epithelial ovarian cancer. In a retrospective case control study by Ditto et al. of 100 matched patients with predominantly stage I/II disease, laparoscopic staging was associated with significant reduction quantity of blood loss and the rate of blood transfusion (Ditto et al., 2016). Given the overall lower rate of significant post-operative morbidity, need for blood transfusion and surgical blood loss, Jehovah's witnesses with gynecologic cancer may benefit from MIS when feasible.

The rate of mortality and ICU admission after cytoreductive surgery in this study is significant. Among the four patients who were admitted to the ICU post-operatively, three of them had laparotomies that were complicated by an estimated blood loss of greater or equal to 1500 cm^3. In addition, two of them were noted to be anemic at the time of surgery with one of these surgeries performed in an emergent fashion due to a complication of their malignancy. Our findings suggest that where possible, referral to a blood management service may be considered to optimize their hematologic parameters prior to surgery.

The standard treatment for advanced EOC is a combination of cytoreductive surgery followed by adjuvant treatment with platinum and taxane based chemotherapy. However, neoadjuvant chemotherapy (NACT), which has been shown to reduce perioperative morbidity and mortality and increase likelihood of complete resection at the time of surgery, is an acceptable alterative (Onda et al., 2016; Vergote et al., 2010). In the European Organization for the Research and Treatment of Cancer (EORTC) 55,971 trial that randomized patients with advanced stage EOC to initial therapy with primary debulking surgery or neoadjuvant chemotherapy (NACT), there was a lower rate of complications including hemorrhage in the NACT arm at the time of interval debulking surgery (IDS) (Vergote et al., 2010). Similar findings were reported in the Japanese Clinical Oncology Study Group (JCOG) 0602 study, which randomized patients with advanced EOC to upfront debulking surgery followed by adjuvant chemotherapy versus IDS following NACT (Onda et al., 2016). Patients who received NACT followed by IDS had significantly lower rates of transfusion of blood products and surgical blood loss during their treatment (Vergote et al., 2010). In light of the proven reduction in surgical blood loss and lower rate of blood transfusion in those who receive NACT, NACT followed by IDS may be considered as more appropriate initial appropriate to patients with advanced EOC who are Jehovah's witnesses. Furthermore, in this study, 50% of patients undergoing cytoreductive surgery for advanced ovarian cancer had suboptimal disease resection. Patients should be counseled that refusal to accept blood products at the time of surgery may impact final cytoreductive status and, therefore, overall prognosis.

In the study population, the acceptance of blood products was low even when faced with major oncologic surgery. These findings are consistent with previously published findings in patients with gynecologic malignancy (Nagarsheth et al., 2014). In a retrospective analysis by Nagarsheth et al., no gynecologic oncology patients identifying as Jehovah's witnesses agreed to accept transfusions of whole blood, red cells, white cells, platelets, or plasma under any circumstance. Among the patients included in this analysis, the rate of acceptance for packed red blood cell transfusion was very low. However, the reported acceptance of fresh frozen plasma, cryoprecipitate and platelets was higher. Furthermore, in our study population, 39% were willing to accept autologous blood transfer technologies at the time of their surgery. Prior studies in Jehovah's witness patients with gynecologic malignancy have demonstrated that acceptance of autologous blood transfer technologies is high (Connor et al., 1995). While never definitively demonstrated, concern that autologous blood transfusion will lead to dissemination of malignant cells has limited this practice (Futamura et al., 2005). However, studies across all surgical disciplines, including gynecologic oncology, have shown minimal risk of propagation of malignant cells leading to metastatic disease and worsening of survival outcomes (Connor et al., 1995; Mirhashemi et al., 1999). In a study of 40 patients who identified as Jehovahs's witnesses undergoing radical hysterectomy for locally advanced cervical carcinoma who accepted autologous blood transfusion, Connor et al., found no disseminated disease and only one pelvic recurrence at a mean follow up of 24 months (Connor et al., 1995). Further studies are needed to further understand the long-term oncologic outcomes from autologous blood transfusion among patients undergoing major surgery for gynecologic malignancy.

A limitation of this study is the inherent biases related to its retrospective design and small sample size. Patients were identified from the electronic medical record using diagnosis codes entered by providers during outpatient or inpatient encounters and inclusion of patients in this study is contingent on accurate coding within the medical record. Therefore, it is possible that there are Jehovah's witnesses treated for gynecologic malignancies at our institution who were not included in the study. Furthermore, the authors were unable to determine reasons for acceptance of blood products by Jehovah's witnesses and potential for regret among patients. Despite these limitations, this study is the first that reports specifically on short-term adverse post-operative outcomes for laparotomy compared to MIS in patients with gynecologic cancer. Patients should be counseled that refusal of blood products when undergoing major oncologic surgery may be associated with significant morbidity and mortality and may delay further adjuvant treatment.

In conclusion, in this series of Jehovah's witnesses who refused blood transfusion, laparotomy for gynecologic malignancy was associated with high rates of postoperative adverse outcomes including ICU stay and mortality when compared to minimally invasive surgeries, with a longer time to adjuvant therapy initiation. Neoadjuvant chemotherapy or MIS may be preferred in this patient population. While acceptance of packed red blood cell transfusion is low among Jehovah's witnesses, even in the setting of major oncologic surgery, it is higher for cryopreciptate, platelet and fresh frozen plasma administration. These data are important for patient counseling and treatment planning.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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