



Perioperative adverse events in women undergoing rectovaginal fistula repair in the United States

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Contributions: (I) Conception and design: All authors; (II) Administrative support: All authors; (III) Provision of study materials or patients: OH Chang, CE Bretschneider; (IV) Collection and assembly of data: OH Chang, CE Bretschneider; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Background: The objective of this study is to determine the incidence of adverse events associated with rectovaginal fistula (RVF) repair surgery and compare the incidence of adverse events by route of surgery.

Methods: This was a retrospective population-based cohort study. We used data from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database from January 2013 until December 2016. Patients were identified by their Current Procedure Terminology codes for RVF repair. We excluded patients with diagnosis codes related to infectious, ischemic, malignancy, inflammatory bowel disease and colostomy-related causes. The database was queried for preoperative and demographic data, operative characteristics and postoperative data.

Results: There were 752 RVF cases that met inclusion criteria. Of these cases, 64.0% (483/752) were repaired by the vaginal and transanal approach and 35.8% (269/752) were repaired by the abdominal approach. The overall incidence of complications was 13% (98/752). The abdominal approach was associated with a higher incidence of postoperative complications (23% *vs.* 7.5%, $P < 0.001$) and a higher readmission rate (12.6% *vs.* 6.2%, $P = 0.006$) when compared to the vaginal and transanal approach. Multivariable logistic regression analysis was performed looking at our primary outcome controlling for age, race, preoperative hematocrit and American Society of Anesthesiologists (ASA) class. After adjustment, fistula repairs by the abdominal approach had significantly higher odds of developing a postoperative complication [adjOR: 2.88 (CI: 1.79–4.73)].

Conclusions: In this cohort of patients with RVFs, the incidence of postoperative complications was 13%. The abdominal approach to the RVF repair was associated with higher odds of postoperative complications.

Keywords: Rectovaginal fistula (RVF); adverse events; perioperative complications; obstetric anal sphincter injuries (OASIS); National Surgical Quality Improvement Program (NSQIP)

Received: 18 April 2020; Accepted: 22 January 2021; Published: 25 June 2021.

doi: 10.21037/gpm-20-38

View this article at: <http://dx.doi.org/10.21037/gpm-20-38>

Introduction

A rectovaginal fistula (RVF) is an abnormal formation of an epithelialized tract between the rectum and vagina (1,2). In the United States, between 1979 and 2006, a total of 81,735 women underwent surgical repair of a RVF (3).

There are different approaches to the repair of the RVF. In patients who develop a fistula as a result of an obstetric complication, conservative management with regular sitz baths for 3–6 months, along with stool bulking and perineal care may be sufficient (4). In patients who require further intervention, a local approach may be taken with the use of

a seton, plug, or glue. If surgical repair is necessary, it can be repaired vaginally or transanally. In some cases a muscle graft is necessary, while an abdominal approach may be required in more complicated cases (5).

In the developed world, the most common causes of RVFs include obstetric complications, inflammation, infection and cancer (4,6-8). Patients with RVFs of non-obstetric causes had nearly four-fold increased risk of repair failure (9). In a large multi-center retrospective cohort study of 342 patients with a RVF, 42% were related to obstetric trauma. In this cohort, 82% of patients were initially managed with a surgical repair. Most patients underwent either a transvaginal or transanal approach, with 59% of patients undergoing a simple fistulectomy and 23% requiring a transphincteric repair. Eight-percent of patients underwent an abdominal procedure (6). The approach to RVF repair is often determined by the location and size of the RVF along with the condition of the surrounding tissues (7).

While many studies have assessed outcomes following RVF repair (6,10-12), few have focused on adverse events related to the surgery itself. Even fewer have looked at adverse events related to route of RVF repair, and this information can be helpful for surgical planning and patient counseling. Therefore, the objective of this study is to determine the incidence of adverse events associated with RVF repair surgery and compare the incidence of adverse events by routes of surgery. We present the following article in accordance with the STROBE reporting checklist (available at <https://gpm.amegroups.com/article/view/10.21037/gpm-20-38/rc>).

Methods

This was a retrospective population-based cohort study. We used data from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database from January 2013 until December 2016. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was considered exempt by the Cleveland Clinic Institutional Review Board (IRB) since this study was an analysis of a publicly-available and de-identified database, and informed consent was waived. We included women who were 18 years or older. Patients were identified by their CPT codes for RVF repair (57300—closure of RVF; vaginal or transanal approach; 57305—closure of RVF; abdominal approach; 57308—closure of RVF; transperineal approach, with perineal body reconstruction, with or without levator plication) during the

time period. Primary surgical procedures were categorized as abdominal, vaginal or transanal or transperineal.

Prior attempts at fistula repair is associated with poor wound healing (13,14) and inflammatory bowel disease is associated with a higher failure rate with breakdowns occurring at a median of 20 days (8,14). The cause of RVF affects surgical outcomes (5,9); therefore, we wanted to exclude patients with diagnoses that are inherently more likely to result in a postoperative complication independent of the surgery performed. We excluded patients undergoing RVF repairs, identified by patients with ICD-9 codes related to infectious, ischemic, malignancy, inflammatory bowel disease and colostomy-related causes. Similarly, we excluded patients who underwent placement of a concomitant skin or tissue flap at the time of RVF repair (e.g., gracilis transposition muscle flap), as this procedure is usually reserved for recurrent RVFs and inherently has a higher rate of morbidity (4,11,15). Two investigators reviewed the remaining patients' ICD-9 codes and excluded those with diagnoses inconsistent with a RVF repair.

The NSQIP is a validated, risk-adjusted and outcomes-based program to measure the quality of surgical care (16). There are more than 600 hospitals participating in NSQIP, representing 49 out of 50 states in the United States. Each participating hospital submits preoperative through 30-day postoperative data on randomly assigned patients by trained surgical clinical reviewers. Data quality is maintained by standardized training of all reviewers, and each site is led by surgeon champions. Intermittent interrater audits are performed at participating sites. More than 150 perioperative variables are entered online in a HIPAA-compliant and secure web platform. The database uses Current Procedural Terminology (CPT) codes and the International Classification of Diseases, 9th Revision (ICD-9) Clinical Modification codes to report on all procedures.

Once our cohort was identified, the database was queried for preoperative and demographic data such as age, body mass index (BMI), race, major medical comorbidity (MMC) and American Society of Anesthesiologists (ASA) class. We defined a MMC as a composite of any of the following medical conditions: congestive heart failure, ascites, renal failure, dialysis-dependent, disseminated cancer, steroid use, weight loss, diabetes, bleeding disorder, hypertension requiring medications, and >10% of total body weight loss in the past 6 months. Operative time for cases, length of stay, specialty of the primary surgeon, 30-day postoperative events, readmission, and reoperation data were collected. The primary outcome was the presence or absence of

an adverse event as defined by the NSQIP data set. This included blood transfusion intraoperatively or within 72 hours of surgery, venous thromboembolic disease, pneumonia, reintubation, renal insufficiency or failure, sepsis or septic shock, wound dehiscence, myocardial infarction or cardiac arrest, cerebral vascular accident, urinary tract infection, and deep or organ space infection. Blood transfusion was defined as at least 1 unit of packed or whole red blood cells given from the start of surgery up to 72 hours post-operatively. Our secondary outcomes included readmission and reoperation rates.

Statistical analysis

This was a descriptive study and standard statistical analyses were performed. Categorical data were presented as % (n/N) and continuous data were presented as mean \pm standard deviation or median (range). Comparisons between groups were done using the Student *t*-test and Mann-Whitney test for continuous variables and the χ^2 and Fisher exact tests for categorical variables. Univariable and multivariable logistic regression models were fit to evaluate factors associated with postoperative morbidity while adjusting for potential confounders. A P value of <0.05 was considered statistically significant. All data was analyzed with R 3.4.1.

Results

There were 752 RVF cases that met our inclusion criteria. Of these cases, 64.2% (483/752) were repaired by the vaginal and transanal approach and 35.8% (269/752) were repaired by the abdominal approach. No cases were identified under CPT code 57308—closure of the RVF via the transperineal approach. Our final comparative groups were patients who underwent RVF repair via the vaginal approach or the transanal approach versus those who underwent an abdominal approach.

Table 1 displays patient characteristics by route of surgery. Most patients were white [75.3% (566/752)] and there were more Hispanic patients in the vaginal and transanal group than the abdominal group [8.7% (42/483) vs. 3.7% (10/269), $P=0.03$]. Patients in the vaginal and transanal group were significantly younger (32.1 vs. 45.7 years old, $P\leq 0.001$). More patients with RVF repaired by the vaginal and transanal approaches were ASA class II [55.1% (266/483) vs. 39% (105/269)] while more patients with RVF repaired by the abdominal approach were ASA class III [54.6% (147/269) vs. 32.7% (158/483), $P\leq 0.001$]. Both groups were

more often cared for by general surgeons than gynecologists or plastic surgeons, but patients undergoing RVF repair by the abdominal route of surgery were almost exclusively cared for by general surgeons [98.0% (263/269)]. More patients in the abdominal group had a MMC compared to the vaginal and transanal group (67.3% vs. 42.7%, $P\leq 0.001$).

Perioperative characteristics and postoperative complications by mode of surgical approach are described in Table 2. The overall incidence of complications was 13% (98/752). The abdominal approach was associated with a higher incidence of postoperative complications (23.0% vs. 7.5%, $P<0.001$) and a higher readmission rate (12.6% vs. 6.2%, $P=0.006$) when compared to the vaginal and transanal approach. RVF repairs by the abdominal route had longer operation times [244.5 vs. 114.6 min, $P<0.001$] and longer length of hospital stay [6 vs. 1 day(s), $P<0.001$].

We performed univariable logistic regression analysis looking at independent predictors of postoperative complications. In this analysis, an abdominal approach to the repair of RVF has 3.7 times the odds of developing a postoperative complication when compared to the vaginal and transanal approach [OR: 3.72 (CI: 2.40–5.84)]. ASA class III, ASA class IV and presence of a MMC were also associated with a higher likelihood of an adverse event occurring [OR: 7.03 (CI: 2.11–43.66), OR: 14.54 (CI: 3.1–105.7), OR: 2.51 (CI: 1.60–4.03), respectively].

Multivariable logistic regression analysis was performed looking at our primary outcome controlling for age, race, preoperative hematocrit and ASA class. After adjustment, ASA class III and class IV continued to be independent predictors of postoperative complications [adjOR: 4.85 (CI: 1.32–31.58), adjOR: 9.14 (CI: 1.76–71.19), respectively]. Fistula repairs by the abdominal approach had significantly greater odds of developing a postoperative complication when compared to the vaginal and transanal approach [adjOR: 2.88 (CI: 1.79–4.73)]. We also found that the following racial groups were associated with higher odds of experiencing a postoperative complication [OR: 3.48 (CI: 1.05–10.03)]: Asian, American Indian, Alaska native, Native Hawaiian and Pacific Islander.

Discussion

In this large cross-sectional population-based cohort study, we found that incidence of complications after a RVF repair was 13%. Women with a RVF repair by the abdominal approach had nearly 3 times the odds to develop an adverse event, when compared to those with surgery via the vaginal

Table 1 Patient characteristics by route of surgery

Variable	All patients (n=752)	Vaginal or transanal approach (n=483)	Abdominal approach (n=269)	P value
Race				0.34
White	566 (75.3)	356 (73.7)	210 (78.1)	
Black or African American	87 (11.6)	61 (12.6)	26 (9.7)	
Other/not reported	77 (10.2)	49 (10.1)	28 (10.4)	
Asian, American Indian or Alaska Native, Native Hawaiian or Pacific Islander	22 (2.9)	17 (0.4)	5 (1.9)	
Hispanic ethnicity	52 (6.9)	42 (8.7)	10 (3.7)	0.03
Age (years)	36.9 (16.5)	32.1 (15.5)	45.7 (14.4)	<0.001
BMI	29.9 (7.4)	30.2 (7.8)	29.4 (6.6)	0.17
Surgical specialty				
General surgery	641 (85.2)	378 (78.3)	263 (97.8)	<0.001
Gynecology	94 (12.5)	91 (18.8)	3 (1.1)	
Plastic surgery	12 (1.6)	11 (2.3)	1 (0.4)	
Urology	5 (0.7)	3 (0.6)	2 (0.7)	
ASA class				<0.001
Class I	56 (7.4)	51 (10.6)	5 (1.9)	
Class II	371 (49.3)	266 (55.1)	105 (39.0)	
Class III	305 (40.6)	158 (32.7)	147 (54.6)	
Class IV	20 (2.7)	8 (1.7)	12 (4.5)	
MMC*	387 (51.5)	206 (42.7)	181 (67.3)	<0.001
Smoker	146 (19.4)	92 (19.0)	54 (20.1)	0.73
Pre-operative hematocrit (%)	38.1 (4.6)	38.2 (4.5)	37.8 (4.7)	0.24

Data is presented as n (%) or mean (SD), unless otherwise specified. *, MMC is a composite of the following medical conditions: congestive heart failure, ascites, renal failure, dialysis dependent, disseminated cancer, steroid use, weight loss, diabetes, bleeding disorder, hypertension requiring medications, and >10% of total body weight loss in the past 6 months. BMI, body mass index; ASA, American Society of Anesthesiologists; MMC, major medical comorbidity.

and transanal approach. Patients with RVF repaired with a vaginal and transanal approach had shorter operation times, shorter length of hospital stay and lower incidence of readmission.

The 13% complication rate from our cohort mirrors the current literature. In a retrospective study of 125 patients who underwent fistula repair between 1998 and 2008, the reported complication rate was 11.4% (17). In another study, 22.4% of patients undergoing RVF surgery had an Accordion grade two or greater complication, and 7.5% had an Accordion grade three or greater complication (5).

Our results also suggest that the transvaginal and

endorectal approaches were associated with a lower incidence of complications, need for readmission, operating time and length of hospital stay. While patients in the abdominal group were more likely to have a medical comorbidity and higher ASA class, once controlled for, we were able to show that this route of surgery remained associated with a higher incidence of complications. Similar findings have been shown in studies looking at the incidence of adverse events by route of hysterectomy (18). Patients who underwent an abdominal hysterectomy had longer length of stay, more wound complications and more febrile episodes (18). An abdominal approach to surgery requires

Table 2 Perioperative characteristics and post-operative complications of RVF repair surgery by mode of surgical approach

Variable	All patients (n=752)	Vaginal or transanal approach (n=483)	Abdominal approach (n=269)	P value
Total operation time (min)	161.1 (123.3)	114.6 (99.5)	244.5 (118.0)	<0.001
Length of total hospital stay (days), median [IQR]	3 [0–6]	1 [0–3]	6 [4–8]	<0.001
Unplanned reoperation	43 (5.7)	25 (5.2)	18 (6.7)	0.39
Postoperative complications	98 (13.0)	36 (7.5)	62 (23.0)	<0.001
Superficial incisional surgical site infection	2 (0.3)	2 (0.4)	0 (0.0)	
Deep incisional surgical site infection	2 (0.3)	1 (0.2)	1 (0.4)	
Organ/space surgical site infection	7 (0.9)	2 (0.4)	5 (1.9)	
Wound disruption	18 (2.4)	12 (2.5)	6 (2.2)	
Pulmonary embolism	0 (0.0)	0 (0.0)	0 (0.0)	
Urinary tract infection	5 (0.7)	2 (0.4)	3 (1.1)	
Cerebral vascular accident/stroke with neurologic deficit	1 (0.1)	0 (0.0)	1 (0.4)	
Cardiac arrest	2 (0.3)	0 (0.0)	2 (0.7)	
Myocardial infarction	4 (0.5)	1 (0.2)	3 (1.1)	
Blood transfusions*	59 (7.8)	19 (3.9)	40 (14.9)	
Deep venous thrombosis/thrombophlebitis	5 (0.7)	2 (0.4)	3 (1.1)	
Readmission	64 (8.5)	30 (6.2)	34 (12.6)	0.006

Data is presented as n (%) or mean (SD), unless otherwise specified. *, defined as “at least 1 unit of packed or whole red blood cells given from the surgical start time up to and including 72 hours postoperatively”. RVF, rectovaginal fistula.

a larger incision, resulting in increased pain, and longer period of convalescence.

In our study, Asians, American Indians, Alaska natives, Native Hawaiians and Pacific Islanders had 3.5 times higher odds of having a postoperative complication after RVF surgery compared to the other ethnic groups captured in the database. One explanation is that Asian women are 50% to 130% more likely to experience obstetric anal sphincter injuries (OASIS) (19-21). OASIS result from trauma to the external anal sphincter, internal anal sphincter or anal epithelium at the time of delivery (22). With an OASIS, the risk of the development of a RVF increases by 2.1-fold (23). This may be an area of potential research interest looking at whether Asian patients' increased incidence of adverse events after RVF repair is associated with the higher likelihood of OASIS.

In this cohort of patients with RVF, the majority were cared for by general surgeons, including colorectal surgeons. A multi-center retrospective cohort study by Oakley *et al.* demonstrated that 87% of their institutional RVFs were

repaired by urogynecologists, with a success rate of more than 80% following primary surgical closure (6). In another study staffed by one urogynecologist, the success rate following obstetric-related RVF repair was 88.7% (9). Review of the literature reveals similar success rates following primary closure of RVF from obstetric causes when they are surgically repaired by colorectal surgeons (17). Regardless of the surgeons' specialty, it seems that in the hands of experienced surgeons, there is high success rates following primary closure of RVF in the minimally-invasive fashion, and patients should be counseled about these favorable outcomes.

The major strength of our study is that it utilizes a large national database that includes surgical procedures performed by different surgical specialties and by different routes, which allowed us to compare the incidence of complications between the routes of surgery.

The biggest limitation of our study is associated with the use of the NSQIP database. Incomplete data is inherent to large databases; for example, in this study, 45% of the RVFs were not associated with an ICD-9 diagnosis. A priori,

we made the assumption that after applying our exclusion criteria, these cases were mostly from obstetric-related causes, as this is the most common cause of RVF in the developed world. The database only captures outcomes up to 30 days after the procedure and there may be variations in the levels of care provided across hospitals, which may contribute to the level of adverse events. Additionally, we were also not able to subtype the ethnicities of our cohort for our analysis which may limit generalizability. In addition, individual patient characteristics such as the size of the fistula or the location of the fistula could not be clearly delineated which may have contributed to surgeon choice in mode of surgery, which also could have biased our results.

In this study, the incidence of complications associated with any RVF repair was 13%. The abdominal approach to the RVF repair was associated with a higher incidence of postoperative complications. Whenever possible, a transvaginal or transanal approach to RVF repair should be taken to mitigate the risk of associated complications.

Acknowledgments

The authors would like to thank Dr. David Sheyn for assisting with the formulation of the study objective.

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://gpm.amegroups.com/article/view/10.21037/gpm-20-38/rc>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://gpm.amegroups.com/article/view/10.21037/gpm-20-38/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was considered exempt by the Cleveland Clinic Institutional Review Board (IRB) since this study was an analysis of a publicly-available and de-identified database, and informed consent was waived.

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doi: 10.21037/gpm-20-38

Cite this article as: Chang OH, Bretschneider CE, Ferrando CA. Perioperative adverse events in women undergoing rectovaginal fistula repair in the United States. *Gynecol Pelvic Med* 2021;4:12.