ORIGINAL RESEARCH ARTICLE

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Rates of severe complications in patients undergoing colorectal surgery for deep endometriosis—a retrospective multicenter observational study

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Abbreviations: DE, deep endometriosis.

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Abstract

Introduction: Surgical experience and hospital procedure volumes have been associated with the risk of severe complications in expert centers for endometriosis in France. However, little is known about other certified units in Central European countries.

Material and methods: This retrospective observational study included 937 women who underwent surgery for colorectal endometriosis between January 2018 and January 2020 in 19 participating expert centers for endometriosis. All women underwent complete excision of colorectal endometriosis by rectal shaving, discoid or segmental resection. Postoperative severe complications were defined as grades III–IV of the Clavien–Dindo classification system including anastomotic leakage, fistula, pelvic abscess and hematoma. Surgical outcomes of centers performing less than 40 (group 1), 40–59 (group 2) and ≥60 procedures (group 3) over a period of 2 years were compared.

Results: The overall complication rate of grade III and IV complications was 5.1% (48/937), with rates of anastomotic leakage, fistula formation, abscess and hemorrhage in segmental resection, discoid resection and rectal shaving, respectively, as follows: anastomotic leakage 3.6% (14/387), 1.4% (3/222), 0.6% (2/328); fistula formation 1.6% (6/387), 0.5% (1/222), 0.9%; (3/328); abscess 0.5% (2/387), 0% (0/222) and 0.6% (2/328); hemorrhage 2.1% (8/387), 0.9% (2/222) and 1.5% (5/328). Higher overall complication rates were observed for segmental resection (30/387, 7.8%) than for discoid (6/222, 2.7%, P = 0.015) or shaving procedures (12/328, 3.7%, P = 0.089). No significant correlation was observed between the number of procedures performed and overall complication rates ($r_{\text{Spearman}} = -0.115$; P = 0.639) with a high variability of complications in low-volume centers (group 1). However, an intergroup comparison revealed a significantly lower overall severe complication rate in group 3 than in group 2 (2.9% vs 6.9%; P = 0.017) without significant differences between other groups. **Conclusions:** A high variability in complication rates does exist in centers with a low volume of activity. Major complications may decrease with an increase in the volume

KEYWORDS

colorectal endometriosis, endometriosis, endoscopic surgery, laparoscopy, surgical techniques

of activity but this effect cannot be generally applied to all institutions and settings.

1 | INTRODUCTION

Deep endometriosis (DE) affecting the intestines can be observed in up to 12% of patients with endometriosis.^{1,2} Surgical therapy of DE is considered the treatment of choice in patients not responding to medical or assisted reproductive technology therapies, organ dysfunction and/or clinically relevant bowel stenosis.^{3,4} For this, various techniques for surgical resection of colorectal endometriosis have been proposed depending on the degree of infiltration and stenosis including shaving, discoid and segmental resection.^{5,6} However, extensive and radical surgical interventions for DE entail the risk of major complications and sequelae such as hemorrhage, anastomotic

Key message

Major complications related to surgical resection of colorectal endometriosis may decrease with an increase in the volume of activity but this effect cannot be generally applied to all institutions and settings.

leakage, rectovaginal fistula formation and postoperative voiding dysfunction.^{2,7} Several authors have tried to elucidate a possible association between surgical techniques and the prevalence of major

surgical complications.^{6,8} Although the data are conflicting and evidence from large randomized controlled trials is sparse due to the methodological difficulties in designing such studies, a recently published systematic review suggest a slightly lower risk of anastomotic leakage and fistula formation following rectal shaving when compared with discoid or segmental resection for colorectal DE.⁸ However, apart from the fact that rectal shaving may not be suitable for all women with colorectal DE due to extensive infiltration and/or multifocal disease, other factors such as anastomotic height, vaginal involvement and surgical experience and caseload have been correlated with the occurrence of major complications.^{2,7,9,10} For example, Bendifallah et al. examined the correlation of surgeon and hospital caseloads of colorectal DE and the prevalence of major complications suggesting a critical optimal cut-off of at least 20 procedures per center per year as a determining factor of surgical morbidity,¹⁰ which is in line with recommendations for the surgical treatment of advanced ovarian cancer.¹¹ This has stimulated the ongoing process of establishing and certifying centers of excellence for treatment of extensive DE in Germany, Austria, the Czech Republic, Romania, Hungary and Switzerland primarily initiated by the Stiftung Endometrioseforschung following defined criteria and recommended caseloads for certain degrees of excellence and certification.¹² Hence, the aim of the present study was to evaluate the prevalence of major complications in certified tertiary referral centers for endometriosis and to examine a possible association between hospital caseload and the occurrence of grade III-IV complications following surgery for colorectal DE.

2 | MATERIAL AND METHODS

The present study included patients undergoing surgical resection of colorectal endometriosis in public and private healthcare facilities in Germany, Switzerland, Czech Republic and Austria, from January 1, 2018 to December 31, 2019. Patients with serosal endometriosis, concomitant malignancies or women with ongoing medical treatment potentially increasing complication risks such as anticoagulation or immunosuppression were excluded from the analysis. All heads of tertiary referral centers for endometriosis according to Stiftung Endometriosforschung guidelines in Germany, Austria and Switzerland were invited to include their patients and outcomes in this work. All participating units were provided with a 12-item questionnaire including information on the number of patients operated, involvement and number of colorectal surgeons per center, preoperative use of laxatives and/or antibiotics, use of intraoperative tests to evaluate patency of colorectal anastomosis, localization of colorectal DE, surgical procedure performed, and the presence and type of intraoperative and postoperative complications following the Clavien-Dindo complication categories: grade III, defined by the requirement for surgical, endoscopic or radiologic intervention; grade IV, defined as life-threatening and including central nervous system complications requiring intermediate care or intensive unit care; and grade V, defined by death.¹³ Information on grade I and grade

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II complications was not collected since data on these complications were not documented continuously in all patients included in this analysis. Definitions of complications were as follows: hemorrhage was defined as postoperative blood loss leading to a hematoma needing surgical, endoscopic or radiological intervention. Leakage was defined as a defect of the intestinal wall at the anastomotic site leading to a communication between the intra- and extraluminal compartments.¹⁴ Similarly, fistula was defined as an abnormal opening or passage between two epithelial surfaces such as ureters and peritoneum or rectum and vagina. Pelvic abscess was defined as a collection of infected fluid in the pelvis. In accordance with the literature,⁵ rectal shaving was defined as removal of colorectal DE layer-by-layer until healthy, underlying tissue was visualized. Discoid excision included full-thickness excision of the infiltrated portion of the bowel wall with the resultant defect stapled or sutured, whereas segmental resection was defined as complete resection of an affected bowel segment with subsequent reanastomosis.

2.1 | Procedure outcomes and statistical analysis

Based on the number of colorectal surgeries performed over a 2-year period per center, three subgroups were formed, as suggested in the literature,¹⁰ including centers carrying out <40 (group 1), 40–59 (group 2) and \geq 6 (group 3) colorectal surgeries over 2 years. Statistical analyses included the Kruskal–Wallis test and the Mann–Whitney test for parametric and nonparametric continuous variables. Associations between volume activity per 2 years and complication rates were evaluated using Spearman rank correlation. Values of P < 0.05 were considered significantly different. Data were managed with SPSS 27 statistical software (IBM).

2.2 | Ethical approval

The work was approved by the local institutional review board of Hospital St. John of God, Vienna, Austria, Reference Number: BBGyn050917 on September 5, 2017.

3 | RESULTS

3.1 | Characteristics of patients and hospitals

The present study involved 19 centers including 937 colorectal procedures for DE, which were retrospectively analyzed over the study period. Eight centers performed less than 40 procedures (group 1), six performed 40–59 (group 2) and five centers \geq 60 (group 3) colorectal interventions over a 2-year observation period. The number of patients with colorectal DE managed in participating centers varied from 8 to 191 over a period of 2 years. All centers involved colorectal surgeons for full-thickness colorectal surgeries (discoid resection, segmental resection). The number of gynecological surgeons per



center varied from one to seven, with a median and mean of 3 and 3.3, respectively. The number of general, ie colorectal surgeons, involved varied from one to four, with a median and mean of 2 and 2.3. When asked about the quality and practicability of interdisciplinary work, ie involvement of general surgeons (low, intermediate and high/optimal), all units stated that their collaboration with general surgeons was optimal. All centers performed air leak tests and/or dye test and/or rectoscopy to evaluate the safety of bowel anastomosis. Seventeen of 19 units (89.5%) used single-shot antibiotics, all units applied presurgical laxatives and 2/19 (10.5%) used selective decontamination of the digestive tract with oral aminoglycosides given 24 hours prior to surgery. Characteristics of the patients included in the study are listed in Table 1.

3.2 | Complication rates and associated procedures

The overall complication rate of grade III and IV complications was 5.1% (48/937), with no recorded grade V complication (Table 2), including anastomotic leakage (19/937, 2.0%), rectovaginal and/ or ureteral fistula formation (10/937, 1.0%), pelvic abscess (4/937, 0.4%) and hematoma (15/937, 0.1%). The rate of protective ileostomies was 46/937 (4.9%), with conversions from laparoscopy to laparotomy in 17/937 cases (1.9%). The rates of surgical techniques for resection of colorectal endometriosis applied in participating centers showed a wide range and were as follows: rectal shaving 3.8% (1/26) 67.1% (55/82); discoid resection 0% (0/26) 81.7% (157/192); segmental resection 5.2% (1/19) 55.2% (37/67).

The distribution of surgical methods in the centers according to caseload was as follows: rectal shaving was performed in groups 1, 2 and 3 in 67/328 (20.5%), 103/328 (31.4%) and 158/328 (48.1%), with severe complications in 3/67 (4.5%), 7/103 (6.8%) and 2/158 (1.3%) without statistically significant differences between groups

(P = 0.178), respectively. Discoid resection was performed in 13/222 (5.9%), 30/222 (13.5%) and 179/222 (80.6%) in groups 1, 2 and 3, respectively. Complication rates were 0/13 (0%), 0/30 (0%) and 6/179 (3.4%) in groups 1, 2 and 3 with statistically significant differences in group 3 compared with the other groups (P = 0.009). Segmental resection was performed in groups 1, 2 and 3 in 110/387 (28.4%), 141/387 (36.4%) and 136/387 (35.2%) cases, with complications respectively in groups in 12/110 (10.9%), 12/141 (8.5%) and 6/136 (4.4%) lacking statistical significance (P = 0.59). Complications associated with the respective surgical techniques are listed in Table 2. As shown, overall rates of grade III-IV complications were higher for segmental resection (30/387, 7.8%, P = 0.013) than for discoid (6/222, 2.7%, P = 0.015) or shaving procedures (12/328, 3.7%, P = 0.089). No significant differences were observed between discoid and shaving procedures (P = 0.465). The overall rate of postoperative voiding dysfunction was 3.3% (31/937; shaving group 1.8%, discoid resection 0.9%, segmental resection 5.9%) with statistically significant differences regarding the surgical approach (segmental resection vs discoid resection cases: 5.9% vs 0.9%, P = 0.043). No significant differences in rates of voiding dysfunction were observed regarding volume activity (group 1, 3.1%; group 2, 5.5%; group 3, 2.1%; P = 0.43).

Table 3 presents complication rates according to the volume of activity per center over 2 years in groups 1–3. We were unable to verify significant differences in overall and type-specific complication rates between centers with <40 procedures, centers performing 40–59 and ≥60 colorectal interventions over a 2-year observation period. Distributions of overall and type-specific complications in the three groups are shown in Figures 1–3, respectively, Figure 4 shows the distribution of overall complication rates in relation to the number of procedures performed over a period of 2 years. No significant correlation was observed between the number of procedures performed and the overall complication rate ($r_{Spearman} = -0.115$; P = 0.639).

Patient characteristics Pa	tient number, ($n = 937$) %
Localization of deep endometriosis	
Rectum 75	7 80.7%
Rectum and sigmoid colon 8	7 9.3%
Sigmoid only, cecum, small bowel 9	3 9.9%
Urinary bladder 9	5 10.1%
Ureters 11	3 12.0%
Vagina/RVS 14	2 15.5%
Surgical approach	
Laparoscopy 89	1 95.0%
Laparotomy 2	9 3.1%
Conversion 1	7 1.9%
Type of surgery for colorectal deep endometriosis	
Shaving 32	8 35.0%
Discoid resection 22	2 23.7%
Segmental resection 38	7 41.3%

TABLE 1Patient characteristics andsurgical approach

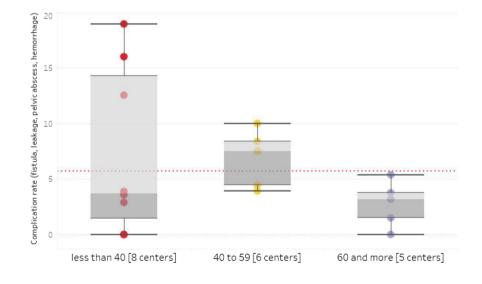
TABLE 2Type of complicationaccording to surgical procedure

Procedures (n)		Overall complication rate	Leakage	Fistula	Pelvic abscess	Hemorrhage
Shaving	328	3.7% (12/328)	2/328	3/328	2/328	5/328
Discoid	222	2.7% (6/222)	3/222	1/222	0/222	2/222
Segmental	387	7.8% (30/387)	14/387	6/387	2/387	8/387
Total	937	5.1% (48/937)	19/937	10/937	4/937	15/937

TABLE 3 Complication rates of 937 interventions for colorectal deep endometriosis according to the volume activity per center/2 years

	Volume of activity/2	2 years				
Complication rates	<40 (8 centers) n = 190	40–59 (6 centers) n = 274	≥60 (5 centers) n = 473	Chi ² [<i>df</i> = 2]	P [2-tailed]	Total
Leakage	4.21% (8/190)	2.19% (6/274)	1.06% (5/473)	2.54	0.281	2.03% (19/937)
Fistula	2.11% (4/190)	1.46% (4/274)	0.42% (2/473)	0.01	0.993	1.07% (10/937)
Hemorrhage	1.58% (3/190)	2.19% (6/274)	1.27% (6/473)	1.82	0.403	1.60% (15/937)
Pelvic abscess	0% (0/190)	1.09% (3/274)	0.21% (1/473)	3.00	0.223	0.43% (4/937)
Total	7.89% (15/190)	6.93% (19/274)	2.96% (14/473)	3.97	0.138	5.12% (48/937)

FIGURE 1 Overall complication rate according to the volume of activity per center/2 years. The red dotted line depicts the overall complication rate according to the current literature.⁸



In a subgroup analysis, we then compared group 1 with groups 2 and 3, as well as group 2 with group 3. Significantly lower overall complications rates were observed when comparing group 3 with group 2 (2.9%, 14/473 vs 6.9%, 19/274; P = 0.017), with no significant values for type-specific complications such as anastomotic leakage (P = 0.251), fistula (P = 0.833), hemorrhage (P = 0.350) or pelvic abscess (P = 0.486). No significant differences were observed in other group comparisons.

4 | DISCUSSION

The present work is the first of its kind to evaluate complication rates and their correlation with surgical case volume in centers for endometriosis in Austria, Germany, Switzerland and the Czech Republic as members of EuroEndoCert-certified hospitals. In line with previous reports on possible major complications linked with colorectal surgeries for DE, we observed an overall complication rate of 5.1%, which is slightly lower than reported for endometriosis centers in France (7.6%)¹⁰ and in line with data from a recently published meta-analysis listing 5.7% major complications when performing rectal surgery for DE.⁸ Furthermore, and in line with Bafort et al.,¹⁵ we observed differences depending on the surgical technique, with segmental resection techniques conferring significantly higher rates of grade III–IV complications of 7.8% compared with discoid resection (2.7%). A statistical trend was also observed for rectal shaving (3.7%). Data from a meta-analysis by Bendifallah et al.⁸ evaluated differences in surgical outcomes of segmental resection, discoid and rectal shaving for DE observing rates of 9.9%, 9.7% and 2.2%, suggesting rectal shaving to be associated less with complications compared with discoid



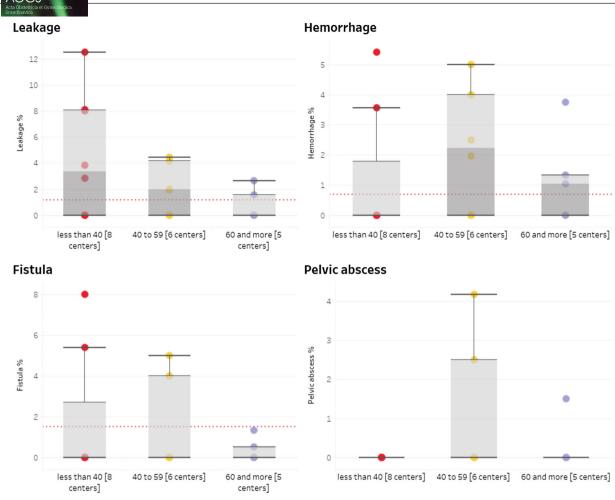


FIGURE 2 Type-specific complication rate according to the volume of activity per center/2 years. The red dotted line depicts the overall complication rate according to the current literature.⁸

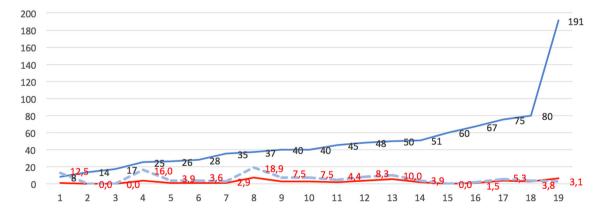


FIGURE 3 Overview of total number of procedures/2 years of respective centers (blue line) and number of complications (blue dotted line) and complication rate (red line). The y-axis depicts number of procedures/2 years and the x-axis depicts the number of respective centers (1–19).

or segmental resection; no significant differences were observed between segmental and discoid techniques. Our observations do not fully support this, since we did observe statistically significantly higher overall complication rates for segmental resection when compared with discoid, but not shaving techniques, where only a trend towards lower complication rates was noted. Segmental resection

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resulted in higher leakage and fistula rates (3.6% and 1.6%) compared with discoid resection (1.4% and 0.5%); there were no significant differences for shaving (0.6%, 0.9%). It should be noted that not all patients are suitable for rectal shaving, especially in cases of extensive and/or multifocal disease. In addition, rates of recurrence have been shown to be higher in patients undergoing rectal shaving.⁶

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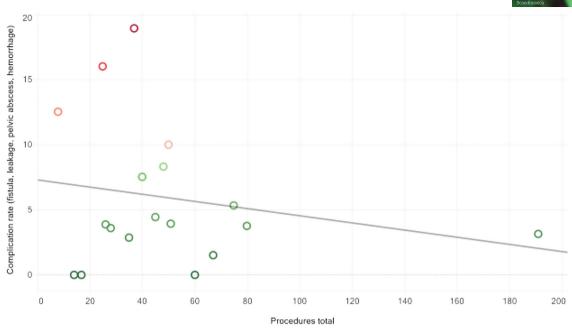


FIGURE 4 Scatterplot depicting the relation between the number of procedures/2 years and the overall complication rate

Several factors have been shown to contribute to an increase of complication rates when performing colorectal surgery for DE, such as height of anastomosis, comorbidities and vaginal opening.^{2,6,9} Surgical experience reflected by caseloads and volume activity per vear in centers for endometriosis has also been demonstrated to influence the risk of complications.¹⁰ In a French retrospective multicenter study of 56 hospital facilities performing colorectal surgery for DE including 1135 cases. Bendifallah et al. observed that when performing a multivariate analysis of factors such as volume of activity per center and per year, the type of structure and the mean number of procedures per year and per surgeon, only the volume of activity per center per year was independently and significantly correlated to complication outcome, with rates of 10% of severe complications with a volume of activity <20 cases per year compared with 6.5% in centers with a higher caseload.¹⁰ However, these data must be interpreted with caution. First and foremost, the complication rates did not increase in a linear manner in respective centers with a lower volume of activity. For example, centers with 10-19 procedures/year exhibited lower rates of leakage and fistula (0% and 1.7%) compared with centers with more than 20 or more than 40 colorectal surgeries/year (0.6% and 0.9%, and 2.7% and 2.8%).¹⁰ Furthermore, surgical experience has been shown to decrease complication rates in univariate analysis, with surgeons managing fewer than seven cases per year being significantly more likely to have complications (7.95%) compared with those with a higher activity (6.97%), which may additionally influence these results.

The results of the present work basically support the observation that an increase in caseloads per center confers a decrease in complication rates. We observed significantly lower overall complication rates in centers managing \geq 60 cases/2 years than units managing 40–59 cases/2 years.

However, some limitations have to be discussed. First, we were unable to observe a linear regression of overall and type-specific complication rates with increasing surgical numbers. For example, and in line with Bendifallah et al.,¹⁰ a high variation in complication rates was observed in centers managing <40 cases/2 years (Figure 4). Secondly, surgical experience has to be taken into account as a limiting factor. Although we did not evaluate the caseload per vear per surgeon due to the regular involvement of experienced general colorectal surgeons in all units, one may assume that small centers performing <40 colorectal surgeries for DE over 2 years with low complication rates may compensate low caseloads by involving colorectal surgeons with a large caseload of colorectal surgeries/ year for other indications, thereby increasing surgical safety. Thirdly, the present study only provides a retrospective snapshot of a limited number of 19 centers in Central Europe and may not fully reflect the true and overall incidence of severe complications in these countries. The retrospective nature of the study and the results would need to be confirmed by larger prospective data. Finally, one may raise the question of whether units known as well-established tertiary referral centers and therefore performing a great volume of surgery, will also have a more complex workload such as extensive parametrial and low and deep infiltrating rectovaginal disease compared with low-volume centers. If so, this would tend to equalize complication rates.

5 | CONCLUSION

The present work is the first to evaluate overall complication rates and their correlation with volume activity in centers for endometriosis in Austria, Germany, Switzerland and the Czech Republic. Surgical morbidity appears to decrease with an increase in volume activity. However, in the light of other factors such as a high variability and heterogeneity of surgical procedures and surgeons involved, these observations may not be generally applicable. Larger and further studies are clearly needed to better define quality criteria for tertiary referral centers.

AUTHORS' CONTRIBUTION

GH: study design, execution and analysis. BS: statistical analysis. MS: coordination of participating units. All other co-authors: data and patient recruitment. All authors approved the final manuscript.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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