

Impact of hospital and surgeon case volume on morbidity in colorectal endometriosis management: a plea to define criteria for expert centers

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Abstract

Summary of background data National and international guidelines recommend referring patients with severe forms of endometriosis to expert centers. However, there is a lack of clear criteria to define an expert center. We examined the roles of surgeon and hospital procedure volumes as determinants of morbidity in deep infiltrating endometriosis of the rectum and sigmoid colon (DIERS).

Methods We conducted a French retrospective multicenter study of hospital facilities performing colorectal surgery for DIERS in 2015. The primary end point was to analyze the relation between case volume and the incidence of complications. We estimated the optimal cut-off (OCO) determined by a minimal p-value approach.

Results The study included 56 hospital facilities and collected data of 1135 cases of surgical management of colorectal endometriosis. The mean and median number of

procedures per year and per surgeon were 9.17 and 5.58, respectively. The overall rate of grade III–V complication was 7.6% (82/1135). One grade V complication occurred. The rates of rectovaginal fistula, anastomotic leakage, pelvic abscess, and ureteral fistula were: 2.7% (31/1135), 0.79% (9/1135), 3.4% (39/1135), and 0.70% (8/1135), respectively. An OCO of 20 procedures per center and per year ($p < 0.001$) was defined. The OCO per surgeon and per year varied between seven ($p = 0.007$) and 13 procedures ($p = 0.03$). In a multivariate analysis, we found that only the volume of activity was independently correlated to complication outcomes ($p = 0.0013$).

Conclusion Our results contribute to providing objective morbidity data to determine criteria for defining expert centers for colorectal surgery for endometriosis.

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Endometriosis is a well-known gynecological disorder defined by the presence of endometrial glands and stroma outside the uterus. It affects from 10 to 15% of women of reproductive age and is a source of pain and infertility [1, 2]. Colorectal endometriosis is recognized as one of the most severe forms of deep infiltrating endometriosis (DIE) [3–5]. Its exact incidence remains unknown but is thought to range between 5 and 12% of patients with endometriosis [1].

Due to the limited efficacy of medical treatment, colorectal surgery is often performed to relieve the symptoms of DIE of the rectum and sigmoid colon (DIERS) and enhance fertility [6–9]. However, surgical colorectal resection is a major procedure exposing the patient to the risk of severe complications [5, 10–12]. Previous retrospective studies [5, 11, 13–15], a randomized study [16] and meta-analyses [8, 11], have reported a relatively high incidence of complications including rectovaginal fistulae, anastomotic leakage, pelvic abscess, and voiding dysfunction depending on the route and the type of surgery. Consequently, both national and international guidelines recommend that patients with severe forms of DIE, such as colorectal endometriosis, be referred to an expert center [2, 9, 17, 18]. However, in contrast to gynecologic oncology, no clear criteria have been published to define expert centers for DIERS.

For ovarian cancer, quality criteria for expert centers have been demonstrated to be associated with both an increased survival and decreased morbidity mainly based on sufficient hospital and surgical volumes [19–21]. Bristow et al. demonstrated that hospitals treating ≥ 20 cases/year and surgeons treating ≥ 10 cases/year are more likely to administer standard recommended treatment with an independent survival benefit [21].

Therefore, the aim of the present study was to evaluate the impact of surgeon and hospital procedure volumes as determinants of morbidity in cases of colorectal surgery for DIERS. We performed a French multicenter analysis of DIERS surgical procedures involving 1135 patients managed in 56 facilities (33 universities, four general public hospitals and 19 private facilities) in 2015 [22]. We sought to determine whether high-volume providers (i.e., hospitals and surgeons) achieved better outcomes for their patients than low-volume providers.

Methods

The present data pooled a series of patients managed for DIERS in 56 public and private healthcare facilities in France, from January 1st to December 31st 2015. DIERS

was defined as infiltration of the digestive wall including muscular, submucosal or mucosal layers (patients presenting with only involvement of serosa were excluded) [3]. To involve the largest number of healthcare facilities in France, all heads of department of gynecology and obstetrics in university hospitals in France, as well as all surgeons known for managing patients with DIERS were invited to participate in the study according to the previously published research protocol [23]. A list of surgeons, gynecologists and general surgeons, which we called the FRIENDS (French coloRectal Infiltrating ENDometriosis Study) group, was constituted over three consecutive weeks. One surgeon was identified as correspondent for each facility.

All surgeons were sent a 43-item questionnaire concerning data on their facility, the number of surgeons involved in the management of DIERS, the number of patients managed for DIERS during the period study, localizations of nodules on digestive tract and associated localizations of deep endometriosis, surgical route, surgical procedures performed, and postoperative complications. Data were collective and not individual (subjects were represented by the facilities). A dictionary in French listing the definition of each item was sent to each surgeon to ensure standardized inclusion criteria [22]. All the surgeons were sent a glossary defining each item to avoid any confusion about the inclusion criteria. The completed questionnaires were sent to the clinical researcher of the CIRENDO database (Rouen University Hospital) who compiled a collective database managed by the second author (H.R.).

Outcomes after colorectal surgery for DIERS

Patient complications were assessed at hospital discharge and at the 1-month postoperative visit, and classified according to the Clavien-Dindo classification [24]. We focused on the following complication categories: grade III, defined by the requirement of 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. Exhaustive evaluation of grade I and grade II complications were not always available.

Procedure volume

Hospitals were ranked by volume according to the total number of procedures performed from January 1, 2015 to December 31, 2015. We used an analogous approach to ascertain surgeon-specific procedure volume. Surgeons were ranked according to their total volume for DIERS procedures performed.

We estimated the optimal cut-off (OCO) to correlate both complication outcomes and the volume of activity per center

and the surgeon-specific procedure volume per year. The OCO was determined by a minimal p -value approach. This involved dichotomizing the OCO into dummy variables with a cut-off every unit of its range of values. The cut-off with the lowest p -value was chosen as the OCO for this variable [25].

Statistical analysis

Other statistical analyses included the Student's t -test and the Mann–Whitney test for parametric and nonparametric continuous variables, respectively, and the W^2 or Fisher's exact test, as appropriate, for categorical variables. Values of $p < 0.05$ were considered to denote significant differences. Data were managed with an Excel database (Microsoft, Redmond, WA, USA) and analyzed using R 2.15 software, available online.

Results

Characteristics of the survey population

The study involved 56 healthcare facilities; 33 university hospitals, 4 general hospitals, and 19 private hospitals. They were located in the 13 regions of France. The number of patients managed per facility varied from 1 to 121. Nine facilities reported more than 40 procedures (7 university hospitals and 2 private hospitals), 12 facilities reported between 20 and 39 procedures (7 university hospitals, 2 general hospitals and 3 private hospitals), 9 facilities reported 10 to 19 procedures (5 university hospitals and 4 private hospitals), and 26 facilities reported less than 10 procedures (14 university hospitals, 2 general hospitals and 10 private hospitals), in 2015. The number of patients managed in any one center varied from 1 to 121. The mean and median number per center were 20.6 and 11, respectively. The number of surgeons per center varied from 1 to 10. The mean and median number of interventions per year and per surgeon were 9.17 and 5.58, respectively.

Deep endometriosis infiltrated the rectum in 645 patients (56.8%), both the rectum and the sigmoid colon in 412 patients (36.3%) and the sigmoid colon in 78 cases (6.9%). The bladder was also involved in 102 patients (9.1%). Concomitant vagina endometriosis was noted in 374 patients (33.1%). Deep shaving or partial thickness excision was performed in 546 patients (48.1%), segmental colorectal resection in 459 patients (40.4%), full thickness disc excision in 83 patients (7.3%) and sigmoid colon resection in 73 patients (6.4%). Protective defunctioning stoma (PDS) was performed in 217 patients (19.1%) mainly in patients requiring concomitant colorectal and vaginal resection or hysterectomy and patients

requiring segmental colorectal resection without information whether this was performed for low rectal resection. Associated 185 resection of the cecum with or without the small bowel was 186 recorded in 77 patients (6.8%). Surgical multidisciplinary teams involving a gynecologic and a general surgeon performed the procedures in 489 patients (43.1%) while the remaining cases were managed by a gynecologic surgeon with expertise in DIE. Characteristics of the study population and database are reported in Table 1.

Complication analysis

Complication rates according to the surgical procedure

The overall rate of severe grade III–IV complications in the whole population was 7.6% (82/1135). There was one death (grade V complication). The overall rates of rectovaginal fistula, anastomotic leakage, pelvic abscess, and ureteral fistula were: 2.7% (31/1135), 0.79% (9/1135), 3.4% (39/1135), and 0.70% (8/1135), respectively. According to the type of the surgery, the rate of rectovaginal fistula, 4.57% (21/459), 1.28% (7/546), 3.6% (3/83) were in case of colorectal resection, shaving, and disc excision on the rectum, respectively. The complementary rate of specific complications according to the type of surgery is provided in Table 2.

Table 1 Characteristics of the survey population

Characteristics	Number of patients treated <i>n</i> = 1135
Deep endometriosis location	
Rectum only	645 (56.8%)
Rectum and the sigmoid colon	412 (36.3%)
Sigmoid only	78 (6.9%)
Associated location	
Caecum	75 (6.6%)
Small bowel	53 (4.7%)
Bladder	102 (9.1%)
Stenosis of ureters	152 (13.4%)
Concomitant vaginal involvement	374 (33.1%)
Surgical route	
Laparoscopic procedure	933 (82.2%)
Robotic assisted-laparoscopy	110 (9.7%)
Open surgery	92 (8.1%)
Surgery	
Segmental colorectal resection	459 (40.1%)
Deep shaving or partial thickness excision	546 (48.1%)
Full thickness disc excision	83 (7.3%)

Table 2 Complication rates according to the surgical procedure

Complication rates	Type of surgery		
	Colorectal resection	Shaving	Disc excision on the rectum
Overall	6.53% (30/459)	1.28% (7/546)	3.6% (3/83)
Rectovaginal fistula	4.57% (21/459)	1.28% (7/546)	3.6% (3/83)
Anastomotic leakage	1.96% (9/459)	0% (0/546)	0% (0/83)

Complication rates according to the volume of activity per center/per year

Based on the number of procedures per year and per center, we defined five subgroups. Table 3 summarizes the distribution of complication types and rates according to the volume of activity ($p < 0.001$).

Correlation between the volume of activity per center/per year and complications

The definition of an OCO denoting the strongest correlation between volume of activity per center/per year and complication outcomes selected with a p-value approach is summarized in Fig. 1.

The ensuing OCO was > 20 procedures per center and per year ($p < 0.001$). We compared the overall complication rate according to this cut-off: centers with a volume of activity < 20 cases per year were more likely to have complications [$n = 35$; 10% (22/220)] than those with a higher activity [$n = 21$ centers; 6.5% (60/915)], ($p < 0.001$).

Correlation between surgeon-specific procedure volume and complications

The definition of an OCO denoting the strongest correlation between volume activity per surgeon and per year and

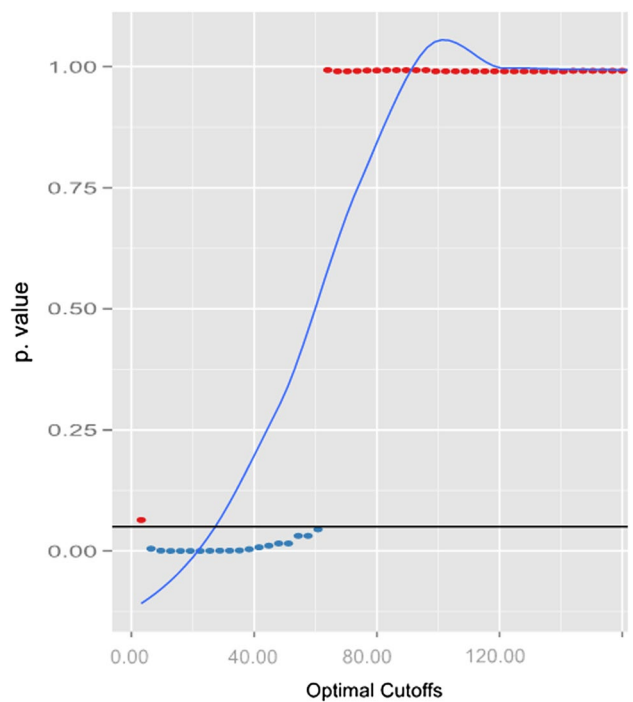


Fig. 1 Optimal cut-off distribution for correlation between volume of activity per center and complications

complication outcomes selected with a p-value approach is summarized in Fig. 2.

The OCO defined varied between 7 and 13 procedures per surgeon and per year ($p = 0.007$ and $p = 0.03$, respectively). Surgeons managing fewer than seven cases per year were more likely to have complications (7.95%, (23/289)) compared with those with a higher activity [6.97% (59/846)], $p < 0.001$. Similar results were observed with the upper cut-off value of 13 procedures per surgeon per year ($p = 0.006$).

e) Complication rates according to type of center

For the year 2015, 9 centers reported managing ≥ 40 patients (7 university hospitals and 2 private clinics), 12

Table 3 Complication rates according to the volume activity per center/per year

Complication rates	Volume of activity (number of procedures per center and per year)				
	Less than 10	Between 10 et 19	Between 20 et 29	Between 30 et 39	Over 40
	26 centers	9 centers	8 centers	5 centers	8 centers
Overall	11.88% (12/101)	8.40% (10/119)	5.15% (10/194)	7.73% (14/181)	6.66% (36/540)
Rectovaginal fistula	4.95% (5/101)	1.68% (2/119)	2.06% (4/194)	2.76% (5/181)	2.77% (15/540)
Anastomotic leakage	1.98% (2/101)	0% (0/119)	0.51% (1/194)	0.55% (1/181)	0.92% (5/540)
Pelvic abscess	1.98% (2/101)	3.36% (4/119)	2.57% (5/194)	4.97% (9/181)	3.51% (19/540)
Fistula of ureter	0% (0/101)	0.84% (1/119)	1.03% (2/194)	2.20% (4/181)	0.18% (1/540)

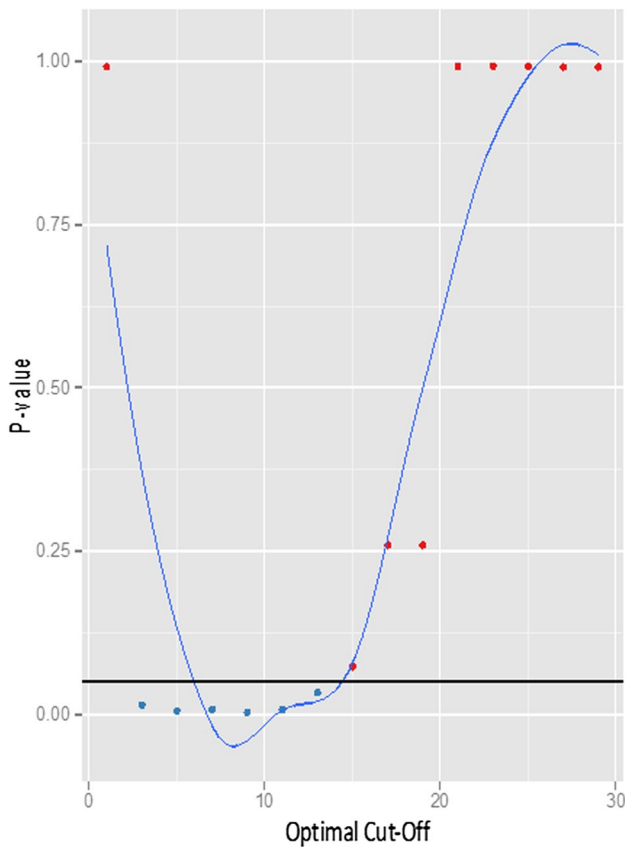


Fig. 2 Optimal cut-off distribution for correlation between surgeon-specific procedure volume and complications

centers from 20 to 39 patients (7 universities, 2 public non-university and 3 private facilities), 9 centers from 10 to 19 cases (5 university and 4 private facilities), while 26 centers managed fewer than 10 cases (14 university, 2 public non-university and 10 private facilities). Four university centers reported more than 60 cases, with one of these managing more than 100 patients. Table 4 summarizes the distribution of complications according to hospital structure.

Multivariate analysis to determine grade III–IV complications risk factors

In a multivariate analysis (Table 5) including the volume of activity per center and per year, the type of structure and the mean number of procedures per year and per surgeon, we found that only the volume of activity was independently correlated to complication outcome ($p = 0.0013$).

Discussion

This study provides the first quantitative evidence of the correlation between hospital DIERS surgical case volume and postoperative morbidity. The concentration of certain procedures in high-volume hospitals is increasingly being presented as a means of improving the quality of care. However, until now, no study has verified the link between volume of activity and quality of the care in France for colorectal surgery in the context of endometriosis. The present study confirms that colorectal surgery for endometriosis is a major procedure exposing patients to a relatively high risk of severe complications. Moreover, the incidence of postoperative complications is significantly dependent on both the hospital and the surgeon’s volume of activity whatever the type of surgery or type of hospital facility.

This study, involving 56 hospital facilities and including more than 1000 cases of DIERS procedures over a 1-year period, is one of the largest series to be reported. The most important finding is the relatively high incidence of severe complications, reaching up 7.6% (82/1135), including one case of a grade V complication (death). The most frequent complications were rectovaginal fistula (2.7%) and pelvic abscess (3.4%). This incidence of rectovaginal fistulae is in agreement with the meta-analysis of Meuleman et al. involving 49 series from specialized centers and reporting 2.7% of rectovaginal fistulae after segmental colorectal resection [11]. As previously mentioned [5, 10, 14, 26, 27], this complication occurs mainly in patients requiring a partial colectomy. However, the rate of pelvic abscess in our study was ten times higher than that reported in the meta-analysis

Table 4 Distribution of complication rate and type according to hospital structure

Complications rates	Structure type		
	University hospital 33 centers	General hospital 4 centers	Private hospital 19 centers
Overall	7.46% (60/804)	12% (6/50)	5.69% (16/281)
Rectovaginal fistula	2.98% (24/804)	4% (2/50)	1.77% (5/281)
Anastomotic leakage	0.87% (7/804)	0% (0/50)	0.71% (2/281)
Pelvic abscess	4.10% (33/804)	2% (1/50)	1.77% (5/281)
Fistula of ureters	0.62% (5/804)	2% (1/50)	0.71% (2/281)

Table 5 Multivariate analysis to determine complication risk factors

Covariates	OR 95% CI	<i>p</i>
Structure type		
General hospital	Reference	
University hospital	0.08 (0.003, 2.45)	
Private hospital	0.09 (0.003, 2.79)	0.2873
Number of procedure per surgeon/per year		
< 8	Reference	
≥ 8	4.24 (0.53, 33.56)	0.1625
Number of procedure per centers/per year		
< 20	Reference	
≥ 20	8.36 (0.96, 72.61)	0.0499
PDS		
Yes	Reference	
No	3.61 (0.85, 15.19)	0.0705
Multidisciplinary team		
Yes	Reference	
No	2.20 (0.21, 22.75)	0.4983

(3.4 vs. 0.34%) [10]. When considering complication rates according to the type of surgery, segmental resection was correlated with higher rates of severe complications than mixed surgery including rectal shaving and discoid resection. These data are in agreement with those of Meuleman et al. showing that the incidence of rectovaginal fistulae was 0.7% after mixed surgery compared to 2.7% after segmental resection [11]. Thus, the apparent discrepancy concerning the rate of pelvis abscess can be partly explained by the exclusion in the present study of patients requiring superficial shaving corresponding to the excision of rectal serosa without true involvement of the muscularis and not requiring bowel suture while Meuleman et al.'s meta-analysis included patients who underwent superficial rectal shaving (serosal excision). Moreover, our data are in agreement with those of the ENDORE randomized trial comparing segmental resection to rectal shaving or discoid resection with similar complication rates according to the types of colorectal surgery [28].

Another striking finding of the current study is the relation between the volume of hospital cases and the incidence of severe grade III–IV complications. The overall complication rate decreased for hospital facilities as the number of procedures performed per year increased. When considering rectovaginal fistulae, which is the most severe postoperative complication often imposing a second operation, we found the lowest rate in hospital facilities performing more than 40 procedures per year. This finding supports that concentrating DIERS procedures in high-volume hospitals is a means of improving the quality of care.

When considering volume activity per year and per center, a threshold of 20 was associated with the lowest morbidity ($p < 0.001$). Moreover, it is important to note that the median volume of cases per surgeon and per year was only five. As for the hospital volume, the number of cases per surgeon appeared as a determinant factor of morbidity, with the optimal threshold value defined as being between, over or equal to 7–13 procedures per year and per surgeon (Fig. 2). Our data reflect findings in gynecology oncology, such as for ovarian cancer, which show that the complication rate depends on both hospital and surgeon volumes [27, 29]. Recently, a threshold of 20 interventions per year per center and a threshold of 10 surgeries per year per surgeon appeared the best criteria to decrease morbidity [27, 29]. However, the applicability of these oncological criteria to a benign disorder raises some issues especially in determining criteria for expert centers. First, endometriosis is a frequent disorder with an incidence higher than that observed for gynecologic cancers as it is thought to affect 10% of women in the reproductive period. These rules out centralizing all cases in a limited number of centers [3]. However, the incidence of bowel endometriosis is estimated between 5 and 12% in patients with endometriosis which means that these patients could be referred to an expert center. Second, although colorectal endometriosis is one of the most severe forms of the disease, no consensus exists on which types of DIE lesions justify referring a patient to an expert center. Indeed, bladder, ureteral, and parametrial endometriosis without colorectal involvement can also be the source of severe complications such as ureteral fistulae or voiding dysfunction. Third, in contrast to oncology, not evaluable immediately after surgery, other criteria of quality of care have to be taken into account such as quality of life, symptoms, and especially fertility [2, 6, 9]. Indeed, for patients with symptomatic colorectal endometriosis who wish to conceive, the main issue is striking the balance between surgery and Assisted Reproductive Therapy (ART) [30–33]. For this specific topic, in addition to the volume of cases, a multidisciplinary team discussion with the possibility of input from an ART team is crucial for determining an expert center.

Some limitations of the present study have to be underlined. First, although the present work collected a high number of colorectal surgical procedures, we do not know the percentage this represents of total procedures performed in France in 2015 and hence, the true incidence of postoperative complications after colorectal surgery for endometriosis. Moreover, we can suppose that some facilities with low volumes of activity did not participate in the study potentially contributing to underestimating the overall complication rate. Second, the retrospective nature of the study is also a potential bias. Third, although we defined a clear threshold value for the number of cases per structure, the threshold per surgeon/per year is highly variable probably due to

high procedure heterogeneity between centers and also in each structure. Further studies are thus necessary to define a clear volume of procedures per center and per surgeon in the future.

Fourth, although we attempt to provide a quantitative evidence of the correlation between hospital DIERS surgical case volume and postoperative morbidity by on collective data, our results must be analyzed with caution, in particular, due to the lack of individual analysis. Fifth, the rate of rectovaginal fistula seemed to vary according to the use of PDS in the literature, underlining the lack of consensus about the systematic indications for PDS in patients with endometriosis requiring colorectal resection [11, 27, 34]. In the current results, our data must be analyzed with caution, due to the impossibility to weight the thresholds according to this parameter. However, in the multivariate analysis, the PDS was not associated with a significant decrease in the complication risk. Finally, we focused on the rate of high-grade complications and did not take into account the incidence of grade I–II complications. However, in a recent prospective study of colorectal surgery, Meuleman et al. underlined that the incidence of low-grade complications was similar to that of high-grade complications [35, 36].

In conclusion, our results contribute to providing objective morbidity data based on hospital and surgeon case volumes to determine criteria for defining expert centers in colorectal surgery for endometriosis [35, 36]. Further studies are required to better define additional structural and indicator criteria for expert centers. Indeed, endometriosis is a multidimensional pathology that cannot be restricted to the evaluation of surgical complication rates but should also consider quality of life, long-term evaluation of morbidity, recurrence rates, and especially fertility outcomes.

Finally, expert centers should be able to evaluate long-term complications through clinical trials and by maintaining a prospective database. Clear identification of expert centers, as in oncology, should facilitate involvement in prospective studies hence improving global health care quality.

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Compliance with ethical standards

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