

# Natural Orifice Transluminal Endoscopic Surgery (NOTES) for colon resections—analysis of the first 139 patients of the German NOTES Registry (GNR)

Dirk R. Bulian · Norbert Runkel · Jens Burghardt · Wolfram Lamade · Michael Butters · Markus Utech · Klaus-Peter Thon · Rolf Lefering · Markus M. Heiss · Heinz J. Buhr · Kai S. Lehmann

Accepted: 23 April 2014 / Published online: 7 May 2014  
© Springer-Verlag Berlin Heidelberg 2014

## Abstract

**Background** The German NOTES registry (GNR) is the largest published database for natural orifice transluminal endoscopic surgery (NOTES) worldwide. Although transvaginal cholecystectomy is the most frequent procedure in the GNR, the number of colorectal resections is increasing. The objective of this study was to analyze the first 139 colonic procedures of the GNR.

**Methods** All colonic procedures from the GNR were analyzed regarding patient- and therapy-related parameters. A multivariate analysis was conducted for transvaginal sigmoid resections regarding procedural time, hospital stay, conversion rate, and rate of complications.

**Results** From October 2008 to January 2013, 139 colon NOTES procedures (12 male, 127 female) were registered. Main diagnoses were sigmoid diverticulitis (85.6 %), colon carcinoma (9.4 %), and ulcerative colitis (3.6 %). Sigmoid resections (87.1 %), proctocolectomies (3.6 %), right-sided resections (2.9 %), left-sided resections (3.6 %), segmental resections (2.2 %), and 1 ileocecal resection (0.7 %) were performed. All procedures were conducted in transvaginal (87.8 %) or transrectal (12.2 %) hybrid technique, with a median of 3 percutaneous trocars. Conversions to laparoscopic technique were necessary in 3.6 % (none to conventional technique). Intraoperative complications were recorded in 2.9 % and postoperative complications in 12.2 %. The

---

Presented in part to the 130th National Congress of the German Association of Surgery, Munich, Germany, May 2013.

---

D. R. Bulian (✉) · M. M. Heiss  
Department of Abdominal, Vascular and Transplant Surgery,  
Cologne-Merheim Medical Center, Witten/Herdecke University,  
Ostmerheimer Strasse 200, 51109 Cologne, Germany  
e-mail: buliand@kliniken-koeln.de

N. Runkel  
Department of Surgery, Schwarzwald-Baar-Klinikum,  
Villingen-Schwenningen, Germany

J. Burghardt  
Department of Surgery, Evangelisch-Freikirchliches Krankenhaus  
Rüdersdorf, Rüdersdorf, Germany

W. Lamade  
Department of General, Visceral and Minimal Invasive Surgery,  
HELIOS Spital Überlingen, Überlingen, Germany

M. Butters  
Department of General and Visceral Surgery, Krankenhaus  
Bietigheim, Bietigheim-Bissingen, Germany

M. Utech  
Department of General and Visceral Surgery, Klinikum Vest,  
Knappschafts-Krankenhaus, Recklinghausen, Germany

K.-P. Thon  
Department of General and Visceral Surgery, Robert-Bosch Hospital,  
Stuttgart, Germany

R. Lefering  
Institute for Research in Operative Medicine, Witten/Herdecke  
University, Cologne, Germany

H. J. Buhr  
German Society for General and Visceral Surgery, Berlin, Germany

K. S. Lehmann  
Department of General, Visceral and Vascular Surgery, Charité  
University Medical Center Berlin, Campus Benjamin Franklin,  
Berlin, Germany

institutional case number in transvaginal sigmoid resections correlated negatively with procedural time ( $p=0.041$ ) and the number of percutaneous trocars ( $p=0.002$ ).

**Conclusion** The analysis of the first 139 colon NOTES operations of the GNR shows the feasibility of colon operations in hybrid technique, especially for transvaginal sigmoid resection as the most frequent procedure.

**Keywords** Colon · Transvaginal/transrectal · Diverticulitis · NOTES · Natural orifice transluminal endoscopic surgery · Registry

## Introduction

After transvaginal natural orifice transluminal endoscopic surgery (NOTES) cholecystectomy was published by several groups in 2007[1–4]; NOTES procedures were increasingly performed in Germany. An analysis of a series of 20 transvaginal hybrid NOTES cholecystectomies was published in 2008 [5]. In order to ensure a transparent introduction as well as responsible further development of this new technique, the German Society for General and Visceral Surgery (DGAV) established the German NOTES registry (GNR) as a voluntary, structured data acquisition. The GNR has been accessible as an internet-based database since March 2008. All German hospitals were asked to document their NOTES procedures in the GNR. Further details on the GNR have been published before [6]. So far, the GNR is the largest published registry for NOTES [6–8]. In the meantime, 2,906 NOTES procedures have been documented in the GNR. Initially, transvaginal cholecystectomies made up almost all registered procedures. In due course, an increasing number of procedures used transrectal and transgastric access, and more complex procedures like colon resections were performed using the NOTES technique as documented in the GNR. The aim of this study was to give an overview of the colon procedures that have been registered in the GNR so far and to analyze the applied techniques.

## Methods

The GNR is a prospective, pseudonymized, and voluntary online database. NOTES was defined in the GNR as a surgical operation, which is performed by using one or more natural orifices for instrument manipulation or endoscope access. Additional transcutaneous trocars can be used. Among others, the following parameters are acquired: patient-based parameters like sex, age, height, weight, and ASA classification; therapy-based parameters like the pathology determining the procedure (acute

sigmoid diverticulitis/elective procedure after former sigmoid diverticulitis/colon adenoma/colon carcinoma/Crohn's disease/ulcerative colitis/other), the performed procedure (sigmoid resection/colon segment resection/left hemicolectomy (including extended)/transverse colon resection/right hemicolectomy (including extended)/colectomy/proctocolectomy/other), month and year of the procedure, type of NOTES access (transvaginal/transgastric/transrectal/transvesical/transesophageal and combinations), hybrid technique (none/abdominal wall + transvaginal/abdominal wall + transgastric/abdominal wall + transrectal/abdominal wall + transvesical/other), type of closure of the NOTES access (direct suture/laparoscopic suture/endoscopic clip/endoscopic suture device/endoscopic stapler/other), type of endoscope (flexible endoscope/rigid endoscope/flexible + rigid endoscope/other), number of percutaneous trocars, procedural time, specialty of the operator (surgeon/gastroenterologist/other), possible specialty of additional operators, use of a Foley catheter, questions concerning conversion, intraoperative and postoperative complications, mortality, and hospital stay. The Clavien-Dindo classification was used in order to assess the severity of postoperative complications [9, 10]. Additionally, all items could be annotated with details and comments in free text.

Conversions: a conversion to traditional laparoscopic technique was defined as abdominal wall incision for specimen retrieval after the NOTES access had been established, and the remaining procedure was performed laparoscopically. The number of percutaneous trocars was irrelevant for this definition. Cases, where the NOTES access was planned but not initiated, e.g., due to adhesions, were defined as “NOTES planned, but not performed” and were not used for this analysis. A conversion to a conventional procedure was defined as abdominal wall incision and continuing of the procedure with conventional instruments.

In October 2008, the first colon procedure was recorded in the GNR. For this study, we analyzed all colon procedures, which were entered until January 31st, 2013. All data for each individual case were reviewed with the operating surgeon, and missing or inconsistent data were completed or revised according to the patients' medical files.

Since all procedures were performed using either transvaginal or transrectal access, these two access routes were compared and analyzed for differences in gender distribution, age, ASA score, BMI, closure of the NOTES access, number of percutaneous trocars, conversion rate, complication rate, procedural time, and length of hospital stay.

Since the entire collective depicts a very heterogeneous group, a regression analysis for all cases would be unreasonable. Therefore, single procedures which made up more than 25 % of all procedures were planned for a multivariate analysis.

This was the case only for transvaginal sigmoid resection in our data. The influence of patient-related (age, gender, BMI, ASA score) and center-related variables (high vs. low volume, order of procedures) was analyzed for the outcome parameters procedural time, hospital stay, conversions, and complications.

Hospitals were divided into high volume centers (>18 procedures during the study period) and low volume centers ( $\leq 18$  procedures) for a case volume analysis of transvaginal sigmoid resections. The threshold of 18 procedures corresponded to the upper quartile.

Data processing and statistical analysis were done with IBM SPSS Statistics Version 21. Since normal distribution could not be assumed for continuous variables, the median (minimum–maximum) was calculated. Ordinal and nominal variables are presented in absolute counts and percentages. Patient-related parameters like age, body mass index (BMI; kg/m<sup>2</sup>), and ASA score were tested for significant differences depending on patients' gender. The Fisher's exact test was used for comparisons between groups of nominal variables. The Mann–Whitney *U* test was used for comparisons between two independent groups for continuous variables. Ordinal parameters were analyzed with the chi-square test for trend.  $P < 0.05$  was considered statistically significant.

## Results

### Demographic data

One hundred and thirty-nine patients, 12 male and 127 female, with colon NOTES operations were registered. The median number of trocars was 3; median procedural time was 137 min (Table 1).

There was no substantial difference between male and female patients for age (62 vs. 60 years) and BMI (23.5 vs. 25.7 kg/m<sup>2</sup>). The ASA classification for male patients was lower than that for female patients. According to the WHO classification, 3.6 % of all patients were underweight (BMI < 18.5 kg/m<sup>2</sup>), 43.2 % were of normal weight (BMI 18.5–24.99 kg/m<sup>2</sup>), 31.7 % overweight (BMI 25.0–29.99 kg/m<sup>2</sup>), and 21.6 % obese (BMI  $\geq 30$  kg/m<sup>2</sup>).

### Therapy details

Perioperative details for all patients and for surgical access are depicted in Table 1; details on the specific operations are provided in Table 2. Procedures and underlying pathologies are shown in Table 3. The transvaginal and transrectal groups included a heterogeneous group of procedures. The different

**Table 1** Patient characteristics and perioperative details for all patients and depending on surgical access

	All patients ( <i>n</i> =139)	Access	
		Transvaginal ( <i>n</i> =122)	Transrectal ( <i>n</i> =17)
Age—years	61.0 (22–86)	60.5 (30–86)	61.0 (22–76)
BMI—kg/m <sup>2</sup>	25.5 (16–47)	26.0 (16–47)	23.5 (18–34)
Percutaneous trocars— <i>n</i>	3.0 (1–5)	3.0 (1–5)	3.0 (1–4)
Length of surgery—min	137 (55–752)	131 (55–752)	205 (87–600)
Length of stay—days	8.0 (2–99)	8.0 (2–28)	11.0 (5–99)
Female gender	91.4 (127)	100 (122)	29.4 (5)
ASA			
1	15.8 (22)	13.1 (16)	35.3 (6)
2	62.6 (87)	63.1 (77)	58.8 (10)
3	13.7 (19)	14.8 (18)	5.9 (1)
n.a.	7.9 (11)	9.0 (11)	0 (0)
Closure of NOTES access			
Direct suture	86.3 (120)	98.4 (120)	0 (0)
Laparoscopic suture	2.9 (4)	0 (0)	23.5 (4)
Endoscopic stapler	9.4 (13)	0 (0)	76.5 (13)
Other technique	1.4 (2)	1.6 (2)	0 (0)
Conversion			
No	96.4 (134)	95.9 (117)	100 (17)
Yes, to laparoscopy	3.6 (5)	4.1 (5)	0 (0)
Yes, to conventional surgery	0 (0)	0 (0)	0 (0)
Intraoperative complications	2.9 (4)	3.3 (4)	0 (0)
Postoperative complications	12.2 (17)	12.3 (15)	11.8 (2)

Values are expressed as median (minimum–maximum) for continuous variables and percent (number) for categorical variables  
n.a. not available

**Table 2** Patient characteristics and perioperative details depending on the type of operation

	Transvaginal sigmoid resection (n=106)	Transrectal sigmoid resection (n=15)	Transvaginal left hemicolectomy (+extended) (n=5)	Transvaginal right hemicolectomy (+extended) (n=4)	Transvaginal colon segment resection (n=3)	Transvaginal proctocolectomy (n=3)	Transrectal proctocolectomy (n=2)	Transvaginal ileocecal resection (n=1)
Age—years	61.0 (35–86)	61.0 (30–76)	71.0 (51–79)	63.5 (55–77)	47.0 (33–69)	46.0 (30–51)	28.5 (22–35)	57.0
BMI—kg/m <sup>2</sup>	26.2 (16–47)	24.4 (18–34)	25.5 (23–32)	26.0 (22–33)	23.4 (19–30)	29.1 (23–35)	18.5 (18–19)	18.6
Percutaneous trocars—n	3.0 (1–5)	3.0 (1–4)	3.0 (3–4)	3.0 (3–3)	3.0 (2–4)	4.0 (3–4)	1.5 (1–2)	2.0
Length of surgery—min	127 (55–430)	149 (87–510)	149 (97–221)	183 (127–222)	79 (70–140)	600 (600–752)	551.5 (503–600)	234
Length of stay—days	7.0 (2–28)	10.0 (5–23)	12.0 (5–23)	11.5 (6–13)	11.0 (5–20)	12.0 (11–13)	55.0 (11–99)	8.0
Female gender	100 (106)	33.3 (5)	100 (5)	100 (4)	100 (3)	100 (3)	0 (0)	100 (1)
ASA								
1	13.2 (14)	26.7 (4)	0 (0)	25 (1)	0 (0)	33.3 (1)	100 (2)	0 (0)
2	63.2 (67)	66.7 (10)	80.0 (4)	25 (1)	100 (3)	66.7 (2)	0 (0)	0 (0)
3	13.2 (14)	6.7 (1)	20.0 (1)	50 (2)	0 (0)	0 (0)	0 (0)	100 (1)
n.a.	10.4 (11)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Closure of NOTES access								
Direct suture	98.1 (104)	0 (0)	100 (5)	100 (4)	100 (3)	100 (3)	0 (0)	100 (1)
Laparoscopic suture	0.0 (0)	26.7 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Endoscopic stapler	0.0 (0)	73.3 (11)	0 (0)	0 (0)	0 (0)	0 (0)	100 (2)	0 (0)
Other technique	1.9 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Conversion								
No	96.2 (102)	100 (15)	100 (5)	100 (4)	100 (3)	100 (3)	100 (2)	0 (0)
Yes, to laparoscopy	3.8 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	100 (1)
Yes, to conventional surgery	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Intraoperative complications	3.8 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Postoperative complications	12.3 (13)	13.3 (2)	20.0 (1)	25 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Values are expressed as median (minimum–maximum) for continuous variables and percent (number) for categorical variables

n.a. not available

**Table 3** Details of colonic resections

	Transvaginal (n=122)	Transrectal (n=17)	All (n=139)
Type of resection			
Sigmoid resection	86.9 (106)	88.2 (15)	87.1 (121)
Colon segment resection	2.5 (3)	0 (0)	2.2 (3)
Left hemicolectomy (+extended)	4.1 (5)	0 (0)	3.6 (5)
Right hemicolectomy (+extended)	3.3 (4)	0 (0)	2.9 (4)
Proctocolectomy	2.5 (3)	11.8 (2)	3.6 (5)
Ileocecal resection	0.8 (1)	0 (0)	0.7 (1)
Pathology			
Acute sigmoid diverticulitis	21.3 (26)	11.8 (2)	20.1 (28)
Other sigmoid diverticular disease <sup>a</sup>	66.4 (81)	58.8 (10)	65.5 (91)
Colon carcinoma	9.0 (11)	11.8 (2)	9.4 (13)
Ulcerative colitis	2.5 (3)	11.8 (2)	3.6 (5)
Other colon pathology	0.8 (1)	5.9 (1)	1.4 (2)

Values are expressed as percent (number)

<sup>a</sup> Including a complicated sigmoid diverticulitis in the past (e.g., covered perforation, stenosis, etc.)

procedural times between transvaginal sigmoid resections and proctocolectomies (127 vs. 600 min;  $p<0.001$ ) serves as an example.

Of the procedures, 87.8 % used the transvaginal technique, 12.2 % a transrectal approach. All procedures were performed in hybrid technique using additional percutaneous trocars (Table 4). In 89.3 % of all procedures, a urinary catheter was used.

Apart from two procedures which used a flexible endoscope, a rigid endoscope was used for most cases (98.6 %, in two cases with an additional flexible endoscope).

All procedures were performed by surgeons, in five cases (3.6 %) with the assistance of a gynecologist. The access site in most transvaginal NOTES was closed with sutures under direct vision (98.4 %). Laparoscopic sutures (23.5 %) or endoscopic staplers (76.5 %) were used in transrectal NOTES procedures (Table 1).

**Table 4** Number of percutaneous trocars for colon NOTES

No. of trocars	Transvaginal (n=122)	Transrectal (n=17)	All (n=139)
1	1.6 (2)	11.8 (2)	2.9 (4)
2	2.5 (3)	23.5 (4)	5.0 (7)
3	56.6 (69)	47.1 (8)	55.4 (77)
4	33.6 (41)	17.6 (3)	31.7 (44)
5	5.7 (7)	0 (0)	5.0 (7)

Values are expressed as percent (number)

$p=0.001$  (chi-square test for trend)

### Conversions and complications

A conversion to laparoscopy was performed in 4.1 % of the transvaginal procedures and in none of the transrectal procedures (Table 1). A conversion to open surgery did not occur in any procedure. There were five conversions to traditional laparoscopic technique: In three cases, it was impossible to retrieve the specimen through the NOTES access. In one case, there was a need to redo the primarily intraabdominally performed linear stapling anastomosis due to uncertainty of the adequacy of the blood supply. In another case, the stapler anvil had to be reinserted and fixed through a Pfannenstiel incision.

Intraoperative complications occurred in 2.9 % of all operations (none in transrectal NOTES). Postoperative complications were found in 12.3 % of transvaginal NOTES and in 11.8 % of transrectal procedures (Table 1).

The four intraoperative complications were one splenic injury, two second-look resections of the afferent colon due to a compromised blood supply or venous congestion, and one injury of the serosa by the stapler anvil.

Among the 17 postoperative complications were 5 anastomotic leakages (3.5 %); 4 intraabdominal infections (2.8 %); 1 secondary vaginal bleeding without a need for reoperation (0.7 %); 2 anastomotic bleedings, which were successfully clipped endoscopically (1.4 %); 3 other surgical complications (small bowel leakage, internal herniation, and trocar hernia; 2.1 %); and 2 non-surgical complications (deep venous thrombosis and postoperative collapse; 1.2 %). The small bowel leakage was most likely due to intraoperative hyperthermic damage and necessitated revisional surgery including small bowel segment resection.

**Table 5** Clavien-Dindo classification of postoperative complications

	Transvaginal (n=122)	Transrectal (n=17)	All (n=139)
No complication	87.7 (107)	88.2 (15)	87.8 (122)
Grade I	0.8 (1)	0 (0)	0.7 (1)
Grade II	0.8 (1)	0 (0)	0.7 (1)
Grade III	9.8 (12)	11.8 (2)	10.1 (14)
Grade IV	0.8 (1)	0 (0)	0.7 (1)
Grade V	0 (0)	0 (0)	0 (0)

Values are expressed as percent (number)

*Grade I* any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions; *Grade II* requiring pharmacological treatment; *Grade III* requiring surgical, endoscopic, or radiological intervention; *Grade IV* life-threatening complication requiring IC/ICU-management; *Grade V* death of a patient

$p=0.998$  (chi-square test for trend)

Table 5 summarizes the postoperative complications according to the Clavien-Dindo classification. Most complications lead to a surgical, endoscopic, or radiological intervention (Clavien-Dindo grade III). The Mortality was 0 %.

#### Institutional case volume analysis for transvaginal sigmoid resections

A case volume analysis and a multivariate analysis were performed for transvaginal sigmoid resections, as these accounted for more than 25 % of all colon NOTES procedures. Data from nine hospitals were analyzed. The median case number was 11 (1–55). Following the criteria mentioned above, seven low volume centers ( $\leq 18$  NOTES procedures: 1, 1, 2, 3, 11, 11, 18 cases; median 3) and two high volume centers ( $>18$  NOTES procedures: 37, 55 cases; median 46) were analyzed. Low volume centers performed 31, and high volume centers performed 75 transvaginal sigmoid resections (Table 6). High volume centers used significantly less trocars ( $p<0.001$ ), and procedural time was 20 min shorter ( $p=0.021$ ). However, conversions, intraoperative complications,

**Table 6** Case volume analysis for transvaginal sigmoid NOTES

	7 low volume centers (31 patients)	2 high volume centers (75 patients)	P value
Age—years	62.0 (37–77)	61.0 (35–86)	0.774
BMI—kg/m <sup>2</sup>	26.7 (21–33)	25.5 (16–47)	0.220
Percutaneous trocars—n	4.0 (1–5)	3.0 (1–5)	<0.001
Length of surgery—min	140.0 (85–430)	120.0 (55–262)	0.021
Length of stay—days	7.0 (2–28)	7.5 (5–27)	0.597
Conversion (to laparoscopy)	6.5 (2)	2.7 (2)	0.334
Intraoperative complications	0 (0)	5.3 (4)	0.245
Postoperative complications	9.7 (3)	13.3 (10)	0.436

Values are expressed as median (minimum–maximum) for continuous variables and percent (number) for categorical variables

and postoperative complications were not significantly different.

#### Multivariate analysis for transvaginal sigmoid resections

All data exclusively concerning the 106 transvaginal sigmoid resections are depicted in Table 2. The multivariate analysis of these data for conversion rate, complication rate, procedural time, number of percutaneous trocars, and hospital stay is shown in Table 7. Age, institutional case volume, and ASA score did not significantly influence the conversion rate. BMI had no significant impact on the conversion rate, either.

A strong effect of the ASA score (odds ratio 80.956) was seen for intraoperative complications, but this was without significance ( $p=0.074$ ). Procedural time significantly influenced the postoperative complication rate ( $p=0.013$ ), however, with a slight effect only (odds ratio 1.018). Intraoperative complications had no significant influence on the postoperative complication rate.

Institutional case volume had a significant influence on procedural time, with shorter times for higher volume centers. A similar influence of case volume was found for the number of trocars that were used.

Postoperative complications prolonged the hospital stay significantly ( $p=0.003$ ). High volume centers had a non-significant tendency for a shorter hospital stay ( $p=0.056$ ).

## Discussion

The DGAV (German Society for General and Visceral Surgery) established the GNR in March 2008 to quickly close the natural gap of lacking evidence for NOTES as a new surgical technique. Furthermore, apart from the first single center results, multicenter experiences, and the introduction into clinical practice, an early detection of possibly arising problems was aspired.

Pure NOTES procedures are feasible, and some approaches, for example, for cholecystectomy and appendectomy, have

**Table 7** Multivariate analysis of predictors in transvaginal sigmoid NOTES

Binary variables	Odds ratio (95 % CI)	<i>P</i> value
Conversions		
Age	0.99 (0.90–1.08)	0.750
BMI	0.88 (0.65–1.20)	0.420
Institutional case volume	0.95 (0.89–1.01)	0.084
ASA	8.1 (0.77–86.2)	0.082
Intraoperative complications		
Age	0.90 (0.80–1.02)	0.098
BMI	0.77 (0.55–1.08)	0.133
Institutional case volume	1.08 (0.96–1.23)	0.213
ASA	81 (0.65–10,042)	0.074
Length of operation	1.01 (0.99–1.03)	0.262
Postoperative complications		
Age	0.98 (0.92–1.05)	0.600
BMI	0.96 (0.83–1.10)	0.537
Institutional case volume	1.04 (0.99–1.10)	0.122
ASA	1.84 (0.34–10.10)	0.482
Length of operation	1.02 (1.00–1.03)	0.013
Intraoperative complications	0.80 (0.04–15.21)	0.881
Continuous variables		
	Estimate (95 % CI)	<i>P</i> value
Length of operation		
Age	−0.59 (−1.60 to 0.41)	0.243
BMI	−0.37 (−2.56 to 1.83)	0.742
Institutional case volume	−0.65 (−1.28 to −0.03)	0.041
ASA	5.5 (−18.4 to 29.4)	0.649
No. of percutaneous trocars		
Age	0.01 (−0.01 to 0.02)	0.277
BMI	0.00 (−0.02 to 0.03)	0.751
Institutional case volume	−0.01 (−0.02 to −0.01)	0.002
ASA	−0.18 (−0.48 to 0.12)	0.237
Length of stay		
Age	0.02 (−0.09 to 0.13)	0.716
BMI	0.02 (−0.22 to 0.26)	0.872
Institutional case volume	−0.06 (−0.13 to 0.00)	0.056
ASA	2.30 (−0.26 to 4.85)	0.078
Postoperative complications	5.5 (1.88–9.1)	0.003

Institutional case volume denotes the total number of NOTES procedures that was performed by the reporting institution. Multivariate logistic regression for binary variables, linear regression for continuous variables

been published [11, 12]. However, the more complex the procedure, the more difficult the technical execution of a pure NOTES procedure without percutaneous trocars, regardless of the access route [13–15]. Our analysis of the colon procedures from the GNR showed that only hybrid procedures were performed, using either a transvaginal or a transrectal access and one or more percutaneous trocars. All types of colon resections, even restorative proctocolectomies, were registered. The most frequent procedure was the transvaginal sigmoid resection.

Conversion and complication rates in the GNR seem comparable to or even lower than those of laparoscopic colon surgery [16, 17]. However, patients for NOTES procedures usually depict a highly selected group and are not directly comparable to the general patient population. Median hospital stay was 8 days. However, the different organization of the German health care system, which generally includes longer hospital stays when compared to other countries, must be taken into consideration.

To better judge the effect of the centers' NOTES experience on operative outcome, low volume centers were compared to high volume centers. Considerable advantages of centers with more experience became apparent, one of them being shorter procedural time. However, complication rates were not significantly different, which lets us conclude that centers with less experience perform this technique safely.

The multivariate analysis confirmed the impact of experience. The conversion rate, as well as the rate of intraoperative and postoperative complications, was not significantly depending on experience in the multivariate analysis, either. Among other factors, selected patients and experienced surgeons certainly accounted for these results. Anyhow, these data indicate that colon NOTES procedures can be performed safely.

There are some limitations to our investigation. At first, it is difficult to assess the completeness of the data as the analysis is based on a voluntary registry, and reporting is not mandatory in Germany. However, the German NOTES community is still small and is well organized with several yearly conventions. To the authors' knowledge, all hospitals which perform colon NOTES are participating in the GNR. Every individual data set in the registry was reviewed with the operating surgeons, and missing or inconsistent data were completed in order to assure a high data quality. Another limitation is the heterogeneity of the procedures, which were registered. Thereby, a wide variety of hybrid NOTES techniques exist. Procedures vary not only in the number of percutaneous trocars and the NOTES access but also in the usage of the latter. Another limitation is the heterogeneity of colon procedures in the GNR. Only limited statements can be made about operative details (e.g., specimen extraction, dissection, stapling). The GNR so far cannot differentiate between a NOTES procedure with minimal laparoscopic assistance and a laparoscopic resection with natural orifice specimen extraction (NOSE). This problem will be addressed with the next registry update.

The NOTES access can be used not only for specimen retrieval but also for the access of dissecting instruments. Curved retractors as well as additional trocars have been applied through transvaginal access routes [18–22]. For right-sided resections, the anastomosis is regularly created

by intraabdominal stapling technique [20, 23, 24], while for left-sided resections, different techniques exist. On the one hand, the specimen can be retrieved through the NOTES access, and the anastomosis can be created using transanal double-stapling technique [25–28]. On the other hand, the specimen can be pulled out either through the transvaginal or the transrectal access, then be resected extracorporeally, followed by open insertion and fixation of the anvil for the double-stapling anastomosis [21, 29, 30]. The latter bears the danger of injury to the blood supply of the oral stump with fatal consequences to anastomotic healing, as shown by Tarantino et al. [30]. However, the NOTES access limits the maximum size of the specimen to be retrieved. Accordingly, problems in retrieving the sigmoid colon through the transvaginal access were the reason for conversion to a laparoscopic procedure with an abdominal retrieval incision in three out of five cases in our analysis.

## Conclusion

In Germany, colonic NOTES procedures are performed using either transvaginal or transrectal access in hybrid technique. Morbidity is comparable to the conventional technique, and there is no mortality so far. Transrectal access as a gender-independent approach requires less percutaneous trocars, but a longer procedural time than the transvaginal technique. The most common colonic NOTES procedure is the transvaginal hybrid NOTES sigmoid resection. The technique can be performed safely in low volume centers. After appropriate patient selection, the introduction of the NOTES technique therefore seems to be possible without an increased complication rate. NOTES techniques differ widely between centers. Therefore, techniques need to be standardized before conducting large controlled trials to confirm an advantage not only of the hybrid NOTES technique as such but also of one of the possible access routes.

**Acknowledgments** The authors thank the DGAV (German Society for General and Visceral Surgery) for providing the technical resources for the German NOTES registry. The authors also thank Jurgen Knuth for help with the preparation of the manuscript.

The following German sites and investigators were also involved in the German NOTES Registry: T. Böttger, Department of General, Visceral and Vascular Surgery, Euromedclinic Fürth, Fürth, Germany; U. Pohlen, Department of General, Visceral and Vascular Surgery, Klinikum Offenburg, Offenburg, Germany; B. Schneider, Department of General and Visceral Surgery, St. Marien-Hospital, Bonn, Germany.

**Disclosures** Drs. Dirk Rolf Bulian, Wolfram Lamadé, Jens Burghardt, Norbert Runkel, Michael Butters, Markus Utech, Klaus-Peter Thon, Rolf Lefering, Markus Maria Heiss, Heinz J. Buhr, and Kai S. Lehmann have no conflicts of interest or financial ties to disclose.

## References

- Zornig C, Emmermann A, von Waldenfels HA, Mofid H (2007) Laparoscopic cholecystectomy without visible scar: combined transvaginal and transumbilical approach. *Endoscopy* 39(10):913–915
- Marescaux J, Dallemagne B, Perretta S, Wattiez A, Mutter D, Coumaros D (2007) Surgery without scars: report of transluminal cholecystectomy in a human being. *Arch Surg* 142(9):823–826. doi:10.1001/archsurg.142.9.823, discussion 826–827
- Bessler M, Stevens PD, Milone L, Parikh M, Fowler D (2007) Transvaginal laparoscopically assisted endoscopic cholecystectomy: a hybrid approach to natural orifice surgery. *Gastrointest Endosc* 66(6):1243–1245. doi:10.1016/j.gie.2007.08.017
- Dolz C, Noguera JF, Martin A, Vilella A, Cuadrado A (2007) Transvaginal cholecystectomy (NOTES) combined with minilaparoscopy. *Rev Esp Enferm Dig* 99(12):698–702
- Zornig C, Mofid H, Emmermann A, Alm M, von Waldenfels HA, Felixmuller C (2008) Scarless cholecystectomy with combined transvaginal and transumbilical approach in a series of 20 patients. *Surg Endosc* 22(6):1427–1429. doi:10.1007/s00464-008-9891-2
- Lehmann KS, Ritz JP, Wibmer A, Gellert K, Zornig C, Burghardt J, Busing M, Runkel N, Kohlhaw K, Albrecht R, Kirchner TG, Arlt G, Mall JW, Butters M, Bulian DR, Bretschneider J, Holmer C, Buhr HJ (2010) The German registry for natural orifice transluminal endoscopic surgery: report of the first 551 patients. *Ann Surg* 252(2):263–270. doi:10.1097/SLA.0b013e3181e6240f
- Arezzo A, Zornig C, Mofid H, Fuchs KH, Breithaupt W, Noguera J, Kaehler G, Magdeburg R, Perretta S, Dallemagne B, Marescaux J, Copaescu C, Graur F, Szasz A, Forgione A, Pugliese R, Buess G, Bhattacharjee HK, Navarra G, Godina M, Shishin K, Morino M (2013) The EURO-NOTES clinical registry for natural orifice transluminal endoscopic surgery: a 2-year activity report. *Surg Endosc* 27(9):3073–3084. doi:10.1007/s00464-013-2908-5
- Zorron R, Palanivelu C, Galvao Neto MP, Ramos A, Salinas G, Burghardt J, DeCarli L, Henrique Sousa L, Forgione A, Pugliese R, Branco AJ, Balashanmugan TS, Boza C, Corcione F, D'Avila Avila F, Arturo Gomez N, Galvao Ribeiro PA, Martins S, Filgueiras M, Gellert K, Wood Branco A, Kondo W, Inacio Sanseverino J, de Sousa JA, Saavedra L, Ramirez E, Campos J, Sivakumar K, Rajan PS, Jategaonkar PA, Ranagajan M, Parthasarathi R, Senthilnathan P, Prasad M, Cucurullo D, Muller V (2010) International multicenter trial on clinical natural orifice surgery–NOTES IMTN study: preliminary results of 362 patients. *Surg Innov* 17(2):142–158. doi:10.1177/1553350610370968
- Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240(2):205–213
- Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, de Santibanes E, Pekolj J, Slankamenac K, Bassi C, Graf R, Vonlanthen R, Padbury R, Cameron JL, Makuuchi M (2009) The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg* 250(2):187–196. doi:10.1097/SLA.0b013e3181b13ca2
- Solomon D, Lentz R, Duffy AJ, Bell RL, Roberts KE (2012) Female sexual function after pure transvaginal appendectomy: a cohort study. *J Gastrointest Surg* 16(1):183–186. doi:10.1007/s11605-011-1706-4, discussion 186–187
- Bessler M, Gumbs AA, Milone L, Evanko JC, Stevens P, Fowler D (2010) Video. Pure natural orifice transluminal endoscopic surgery (NOTES) cholecystectomy. *Surg Endosc* 24(9):2316–2317. doi:10.1007/s00464-010-0918-0
- Bernhardt J, Kohler P, Rieber F, Diederich M, Schneider-Koriath S, Steffen H, Ludwig K, Lamade W (2012) Pure NOTES sigmoid resection in an animal survival model. *Endoscopy* 44(3):265–269. doi:10.1055/s-0031-1291546



14. Alba Mesa F, Amaya Cortijo A, Romero Fernandez JM, Komorowski AL, Sanchez Hurtado MA, Sanchez Margallo FM (2012) Totally transvaginal resection of the descending colon in an experimental model. *Surg Endosc* 26(3):877–881. doi:10.1007/s00464-011-1919-3
15. Rieder E, Spaun GO, Khajanchee YS, Martinec DV, Arnold BN, Smith Sehdev AE, Swanstrom LL, Whiteford MH (2011) A natural orifice transrectal approach for oncologic resection of the rectosigmoid: an experimental study and comparison with conventional laparoscopy. *Surg Endosc* 25(10):3357–3363. doi:10.1007/s00464-011-1726-x
16. Neudecker J, Klein F, Bittner R, Carus T, Stroux A, Schwenk W, Trialists LI (2009) Short-term outcomes from a prospective randomized trial comparing laparoscopic and open surgery for colorectal cancer. *Br J Surg* 96(12):1458–1467. doi:10.1002/bjs.6782
17. Klarenbeek BR, Veenhof AA, Bergamaschi R, van der Peet DL, van den Broek WT, de Lange ES, Bemelman WA, Heres P, Lacy AM, Engel AF, Cuesta MA (2009) Laparoscopic sigmoid resection for diverticulitis decreases major morbidity rates: a randomized control trial: short-term results of the Sigma Trial. *Ann Surg* 249(1):39–44. doi:10.1097/SLA.0b013e31818e416a
18. Lamade W, Hochberger J, Ulmer C, Matthes K, Thon KP (2010) Triluminal hybrid NOS as a novel approach for colonic resection with colorectal anastomosis. *Surg Innov* 17(1):28–35. doi:10.1177/1553350609359920
19. Lamade W, Ulmer C, Hochberger J, Matthes K, Friedrich C, Thon KP (2010) Triluminal hybrid-NOS proctocolectomy. *Surg Innov* 17(2):164–169. doi:10.1177/1553350610365702
20. Burghardt J, Federlein M, Muller V, Benhidjeb T, Elling D, Gellert K (2008) Minimal invasive transvaginal right hemicolectomy: report of the first complex NOS (natural orifice surgery) bowels operation using a hybrid approach. *Zentralbl Chir* 133(6):574–576. doi:10.1055/s-2008-1076992
21. Torres RA, Orban RD, Tocaimaza L, Vallejos Pereira G, Arevalo JR (2012) Transvaginal specimen extraction after laparoscopic colectomy. *World J Surg* 36(7):1699–1702. doi:10.1007/s00268-012-1528-x
22. Fu T, Liu B, Zhang L, Wen Y (2005) Outcome of transvaginal excision of large rectal adenomas. *Int J Color Dis* 20(4):334–337. doi:10.1007/s00384-004-0691-4
23. Cheung TP, Cheung HY, Ng LW, Chung CC, Li MK (2012) Hybrid NOTES colectomy for right-sided colonic tumors. *Asian J Endosc Surg* 5(1):46–49. doi:10.1111/j.1758-5910.2011.00106.x
24. McKenzie S, Baek JH, Wakabayashi M, Garcia-Aguilar J, Pigazzi A (2010) Totally laparoscopic right colectomy with transvaginal specimen extraction: the authors' initial institutional experience. *Surg Endosc* 24(8):2048–2052. doi:10.1007/s00464-009-0870-z
25. Fuchs KH, Breithaupt W, Varga G, Schulz T, Reinisch A, Josipovic N (2013) Transanal hybrid colon resection: from laparoscopy to NOTES. *Surg Endosc* 27(3):746–752. doi:10.1007/s00464-012-2534-7
26. Akamatsu H, Omori T, Oyama T, Tori M, Ueshima S, Nakahara M, Abe T, Nishida T (2009) Totally laparoscopic sigmoid colectomy: a simple and safe technique for intracorporeal anastomosis. *Surg Endosc* 23(11):2605–2609. doi:10.1007/s00464-009-0406-6
27. Leroy J, Diana M, Wall J, Costantino F, D'Agostino J, Marescaux J (2011) Laparo-endoscopic single-site (LESS) with transanal natural orifice specimen extraction (NOSE) sigmoidectomy: a new step before pure colorectal natural orifices transluminal endoscopic surgery (NOTES(R)). *J Gastrointest Surg* 15(8):1488–1492. doi:10.1007/s11605-011-1557-z
28. Awad ZT (2012) Laparoscopic subtotal colectomy with transrectal extraction of the colon and ileorectal anastomosis. *Surg Endosc* 26(3):869–871. doi:10.1007/s00464-011-1926-4
29. Alba Mesa F, Amaya Cortijo A, Romero Fernandez JM, Komorowski AL, Sanchez Hurtado MA, Fernandez Ortega E, Sanchez Margallo FM (2012) Transvaginal sigmoid cancer resection: first case with 12 months of follow-up—technique description. *J Laparoendosc Adv Surg Tech A* 22(6):587–590. doi:10.1089/lap.2011.0469
30. Tarantino I, Linke GR, Lange J, Siercks I, Warschkow R, Zerz A (2011) Transvaginal rigid-hybrid natural orifice transluminal endoscopic surgery technique for anterior resection treatment of diverticulitis: a feasibility study. *Surg Endosc* 25(9):3034–3042. doi:10.1007/s00464-011-1666-5