

# vNOTES hysterectomy reduces laparotomy conversion rates in class III obesity – a retrospective comparative study

## vNOTES hysterektomie snižuje míru laparotomie u obezity III. stupně – retrospektivní srovnávací studie

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**Summary: Objective:** This study aims to compare the outcomes of laparoscopic hysterectomy (LH) and vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) hysterectomy (vNH) in obese patients undergoing the procedure for benign gynaecological indications, with results classified according to obesity class (class I, II, and III). **Materials and methods:** We retrospectively reviewed the data of patients with a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> who underwent either LH or vNH for benign indications at a tertiary teaching and research hospital between January 2020 and December 2024. **Results:** A total of 134 patients (70 LH, 64 vNH) were included in this single-centre study. The median operative time was significantly longer in the vNH group (205 min vs. 178 min;  $P < 0.01$ ). Overall, major complication rates were similar between the two groups. The most striking finding of the study was that in patients with class III obesity (BMI  $\geq 40$  kg/m<sup>2</sup>), the vNOTES approach significantly reduced the conversion rate to laparotomy compared to laparoscopy (0 vs. 23.5%;  $P = 0.035$ ). **Conclusion:** Our study demonstrates that the most significant advantage of vNOTES surgery in obese patients undergoing benign hysterectomy is the reduction in the conversion rate to laparotomy, particularly within the class III obesity group. vNOTES statistically eliminated the risk of conversion to laparotomy compared to laparoscopy in patients with class III obesity (OR 0.08; 95% CI 0.00–0.91;  $P = 0.035$ ). These findings underscore the importance of risk stratification based on patient BMI when selecting a minimally invasive surgical approach for obese patients.

**Key words:** morbid obesity – natural orifice surgery – surgical complications – conversion rate – patient selection

**Souhrn: Cíl:** Tato studie si klade za cíl porovnat výsledky laparoskopické hysterektomie (LH) a hysterektomie vNOTES (vaginální transluminální endoskopická chirurgie s přirozeným otvorem) (vNH) u obézních pacientek podstupujících zákrok z benigních gynekologických indikací, přičemž výsledky byly stratifikovány podle třídy obezity (třída I, II a III). **Materiály a metody:** Retrospektivně jsme zhodnotili data pacientek s indexem tělesné hmotnosti (BMI)  $\geq 30$  kg/m<sup>2</sup>, které podstoupily buď LH, nebo vNH z benigních indikací v terciární fakultní a výzkumné nemocnici v období od ledna 2020 do prosince 2024. **Výsledky:** Do této monocentrické studie bylo zahrnuto celkem 134 pacientek (70 LH, 64 vNH). Medián operační doby byl ve skupině vNH významně delší (205 min vs. 178 min;  $p < 0,01$ ). Celkově byla míra závažných komplikací v obou skupinách podobná. Nejvýraznějším zjištěním studie bylo, že u pacientek s obezitou třídy III (BMI  $\geq 40$  kg/m<sup>2</sup>) přístup vNOTES významně snížil míru konverze k laparotomii ve srovnání s laparoskopií (0 vs. 23,5 %;  $p = 0,035$ ). **Závěr:** Naše studie ukazuje, že nejvýznamnější výhodou operace vNOTES u obézních pacientek podstupujících benigní hysterektomii je snížení míry konverze k laparotomii, zejména ve skupině s obezitou třídy III. Metoda vNOTES statisticky eliminovala riziko konverze k laparotomii ve srovnání s laparoskopií u pacientek s obezitou třídy III (OR 0,08; 95% CI 0,00–0,91;  $p = 0,035$ ). Tato zjištění podtrhují důležitost stratifikace rizika na základě BMI pacienta při výběru minimálně invazivního chirurgického přístupu u obézních pacientů.

**Klíčová slova:** morbidní obezita – chirurgie přirozeného otvoru – chirurgické komplikace – míra konverze – výběr pacienta

### Introduction

Obesity is a growing global health concern affecting women of reproductive age, with a steadily increasing prevalence [1].

In gynecological surgery, obesity presents a range of challenges, including increased comorbidities, anesthetic difficulties, and surgical site complications [2].

A thickened abdominal wall and increased visceral fat, in particular, can impair surgical visualization and instrument manipulation, leading to longer operative

times and increased blood loss. This significantly elevates the risk of postoperative complications such as surgical site infection, wound dehiscence, and venous thromboembolism (VTE) [3].

To overcome these challenges, minimally invasive surgery (MIS) has become the standard of care in gynecologic surgery, as it is associated with lower morbidity compared to laparotomy [4]. In obese patients, MIS reduces wound complications through smaller incisions and facilitates a faster recovery. However, the question of which MIS technique – conventional laparoscopic hysterectomy (LH) or vNOTES (vaginal Natural Orifice Transluminal Endoscopic Surgery) hysterectomy – is superior for the obese population remains a subject of debate.

As an alternative to these technical challenges, vNOTES hysterectomy has gained popularity. By offering the advantage of no abdominal incisions (scarless surgery), vNOTES holds potential benefits for obese patients, who are at a high risk for wound complications. It aims to overcome the limitations of traditional vaginal hysterectomy by providing endoscopic vision while eliminating the difficulties associated with a thick abdominal wall and trocar placement seen in laparoscopy. Conversely, vNH has its own unique challenges. The literature indicates that the vNOTES technique has a steep learning curve, and surgical success, especially in difficult cases, is closely linked to the surgeon's experience with the technique. The current literature has not demonstrated a consistent and clear superiority of one approach over the other regarding major complications [5].

However, a significant limitation of existing studies is their tendency to treat obesity as a single, homogeneous group, overlooking the differential impact of obesity classes (class I, II, III) on surgical outcomes. The risk profile of obesity exhibits a "dose-response" relationship that changes as the body mass index (BMI) increases. Class I (BMI 30–34.9), class II (BMI 35–39.9), and

class III (BMI  $\geq 40$ ) obesity carry different risk levels and can affect surgical outcomes differently. The primary hypothesis of this study is that the vNOTES approach will significantly reduce the conversion rate to laparotomy compared to conventional laparoscopy, particularly in patients with class III obesity, where the technical difficulties of abdominal MIS are most pronounced. The aim of this study is to compare LH and vNH approaches in obese patients undergoing hysterectomy for benign indications, stratifying the results by obesity class, to investigate which patient group may benefit most from which approach.

## Materials and methods

### Study design and population

This retrospective cohort study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. Ethical approval was obtained from our institution's ethics committee (Decision No: HRÜ/2024/11-7, Date: 15. 1. 2024). Using our hospital's electronic health record system, we identified patients aged 18 years and older who underwent total laparoscopic hysterectomy (LH) or vNOTES hysterectomy (vNH) for benign gynecological indications between January 2020 and December 2024. Only patients with a BMI  $\geq 30$  kg/m<sup>2</sup> who did not meet the exclusion criteria were included. Patients with suspected malignancy, known severe pelvic adhesions based on prior imaging or surgical history, or contraindications to minimally invasive surgery (e.g., severe cardiopulmonary disease) were excluded. Due to the retrospective design, selection bias based on surgeon preference and unmeasured confounding factors are potential limitations, which are addressed in the Discussion section.

### Surgical technique and standardisation

Both surgical approaches were performed according to our institution's

standard protocols using the same laparoscopy tower (Karl Storz, Germany). In the LH procedure, a 10-mm umbilical trocar for the camera and two or three 5-mm ancillary trocars in the lower quadrants were standard. A standard CO<sub>2</sub> pneumoperitoneum was established at a pressure of 12–15 mmHg. A 3-port technique was used in 21 patients, and a 4-port technique was used in 49 patients in the LH group. For the vNH procedure, a posterior colpotomy was performed under direct vision using a specific transvaginal access platform, the V-PORT (GePOINT, Inc.), and a 10-mm 30° laparoscope was introduced. The VCare® uterine manipulator was used in the LH group. Ligasure™ (Medtronic) bipolar vessel sealing devices were predominantly used for the dissection of uterine vessels and ligaments. The vaginal cuff was closed in a continuous fashion using delayed absorbable sutures in both groups after hemostasis was achieved. All patients received standard antibiotic prophylaxis with 2 g intravenous Cefazolin 30–60 minutes before the surgical incision.

### Data collection

All data were extracted from electronic and pathology patient records using a structured data collection form. The variables collected were:

- **Demographic and clinical data** – age, BMI, obesity class according to the World Health Organization classification (class I: 30–34.9, class II: 35–39.9, class III:  $\geq 40$  kg/m<sup>2</sup>), Charlson Comorbidity Index, and history of prior abdominal surgery (yes/no).
- **Surgical and pathology data** – surgical approach (LH or vNH), operative time (minutes from the first incision to the completion of skin closure for LH or vaginal cuff closure for vNH), estimated blood loss (EBL, mL; calculated by subtracting the irrigation fluid used from the volume in the suction canister), conversion to laparotomy and reason for conversion, postoperative uterine

weight (grams) from the pathology report, and experience level of the operating surgeon (defined as 'experienced' if they had performed > 50 cases of the respective technique (LH or vNH). This 50-case threshold is based on previous studies indicating the vNOTES learning curve reaches a competency plateau after 40–60 cases [5,6].

• **Postoperative data** – length of hospital stay (days), postoperative complications within 30 days (graded according to the Clavien-Dindo classification), blood transfusion, reoperation, and readmission within 30 days. Surgical site infection (SSI) was defined according to the U.S. Centers for Disease Control and Prevention (CDC) criteria and recorded separately as abdominal port site and vaginal cuff infections. Venous thromboembolism (VTE). Major complications (Clavien-Dindo  $\geq$  III) were defined as conditions requiring reoperation, organ injury, or admission to the intensive care unit. Vaginal cuff infection was defined according to CDC criteria as erythematous purulent discharge requiring antibiotic therapy [7].

### Outcome variables

The primary outcome was the composite rate of major postoperative complications (Clavien-Dindo class III–IV) within 30 days. Secondary outcomes included operative time, EBL, conversion rate to laparotomy, length of hospital stay, and rates of specific complications (SSI, VTE, reoperation, readmission). For binary outcomes found to be significant, the absolute risk reduction (ARR) and the number needed to treat (NNT) to prevent one event were also calculated.

### Statistical analysis

Statistical analyses were performed using SPSS Version 25.0 (IBM Corp., Armonk, NY). Missing data, which accounted for less than 5% for all variables, were managed using a complete-case analysis method. There was no missing data for the primary outcomes of

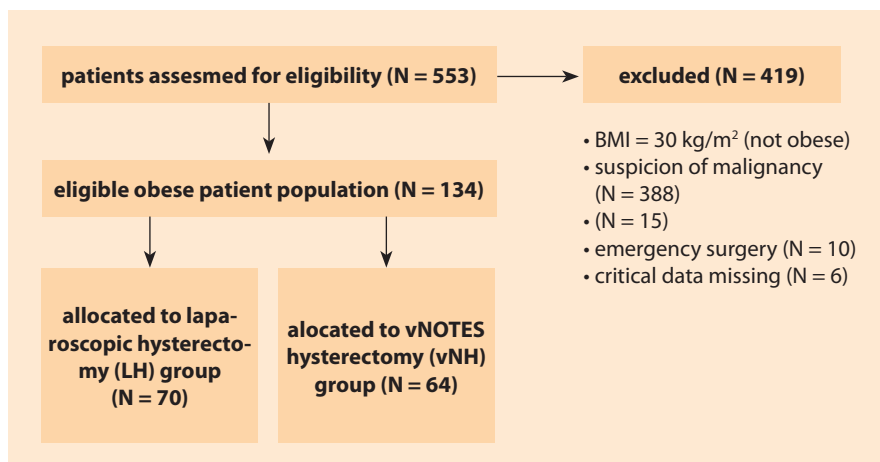


Fig. 1. Flow diagram of the patient selection process.

Obr. 1. Vývojový diagram procesu výběru pacienta.

conversion to laparotomy and major complications. The chi-square or Fisher's exact test was used for categorical variables, and after checking for normal distribution with the Shapiro-Wilk test, the Student's T-test or Mann-Whitney U-test was used for continuous variables as appropriate. A P-value < 0.05 was considered statistically significant for all analyses. To control for the confounding effect of potential adhesions, a pre-defined sensitivity analysis was performed by excluding patients with a history of prior abdominal surgery. A post-hoc power analysis for our primary outcome, conducted using G\*Power (v3.1), showed that the study's power to detect the 23.5% absolute risk reduction observed in the class III obese subgroup was over 90% ( $\alpha = 0.05$ ; two-tailed).

### Results

During the study period, 553 patients were assessed, and after excluding those who met the exclusion criteria, a total of 134 patients (70 LH, 64 vNH) were included in the study (Fig. 1). The demographic and clinical characteristics of the included patients are summarized in Tab. 1. There were no statistically significant differences between the two groups in terms of age, comorbidity burden, mean BMI, uterine weight, or history of prior abdominal surgery.

The proportion of experienced surgeons tended to be higher in the vNH group, but this difference did not reach statistical significance ( $P = 0.32$ ).

Intraoperative outcomes are shown in Tab. 2. The median operative time in the vNH group was significantly longer than in the LH group (205 vs. 178 min;  $P < 0.01$ ). There was no significant difference in median EBL between the groups ( $P = 0.09$ ). While the overall conversion rates to laparotomy were similar (5.7 vs. 3.1%;  $P = 0.48$ ), in the class III obesity subgroup, the conversion rate was significantly higher in the LH group compared to the vNH group (23.5 vs. 0%;  $P = 0.035$ ). This corresponds to an absolute risk reduction of 23.5%, and the number needed to treat (NNT) to prevent one conversion to laparotomy was calculated as 4. The primary reason for conversion in the laparoscopic group was poor visualization/technical difficulty, whereas in the vNOTES group, it was dense adhesions.

Postoperative outcomes are summarized in Tab. 3. There were no significant differences between the groups regarding median length of hospital stay, major complication rate (Clavien-Dindo  $\geq$  III), or rates of VTE, reoperation, and readmission. The overall rates of surgical site infection were similar between the two groups. As expected, abdominal port

**Tab. 1. Baseline demographic and clinical characteristics of the patients.**

Tab. 1. Základní demografické a klinické charakteristiky pacientů.

Characteristic	Laparoscopic hysterectomy (N = 70)	vNOTES hysterectomy (N = 64)	P-value
age (years, mean $\pm$ SD)	48.7 $\pm$ 10.5	49.3 $\pm$ 9.5	0.71
BMI (kg/m <sup>2</sup> , mean $\pm$ SD)	36.8 $\pm$ 5.9	37.9 $\pm$ 6.0	0.25
obesity class, N (%)			0.81
class I (30–34.9)	29 (41.4)	24 (37.5)	
class II (35–39.9)	24 (34.3)	22 (34.4)	
class III ( $\geq$ 40)	17 (24.3)	18 (28.1)	
Charlson comorbidity index (median, IQR)	2 (1–3)	2 (1–4)	0.18
uterine weight (g, mean $\pm$ SD)	288 $\pm$ 112	275 $\pm$ 108	0.46
prior abdominal surgery, N (%)	22 (31.4)	17 (26.6)	0.54
experienced surgeon rate, N (%)	59 (84.3)	58 (90.6)	0.32

Data are presented as mean  $\pm$  standard deviation (SD), N (%), or median (IQR). P-values were calculated using the Student's T-test for normally distributed continuous variables, the Mann-Whitney U-test for non-normally distributed continuous variables, and the Chi-square or Fisher's exact test for categorical variables.

BMI – body mass index, IQR – interquartile range, SD – standard deviation

**Tab. 2. Comparison of intraoperative outcomes.**

Tab. 2. Porovnání intraoperačních výsledků.

Outcome	Laparoscopic hysterectomy (N = 70)	vNOTES hysterectomy (N = 64)	P-value
operative time (min, median (IQR))	178 (150–210)	205 (180–245)	< 0.01
estimated blood loss (mL, median (IQR))	125 (75–200)	150 (100–250)	0.09
conversion to laparotomy, N (%)	4 (5.7)	2 (3.1)	0.48
conversion in class III obesity, N/N (%)	4/17 (23.5)	0/18 (0)	0.035

Data are presented as median (IQR) or N (%). P-values were calculated using the Mann-Whitney U-test or Fisher's exact test. Statistically significant ( $P < 0.05$ ).

IQR – interquartile range, N/N – number of events per total number of patients in subgroup

**Tab. 3. Comparison of postoperative outcomes.**

Tab. 3. Porovnání pooperačních výsledků.

Outcome	Laparoscopic hysterectomy (N = 70)	vNOTES hysterectomy (N = 64)	P-value
length of hospital stay (days, median (IQR))	2 (1–3)	2 (1–3)	0.90
major complication (CD $\geq$ III), N (%)	5 (7.1)	4 (6.3)	0.85
surgical site infection (total), N (%)	11 (15.7)	10 (15.6)	0.99
abdominal port site infection	5 (7.1)	0	
vaginal cuff infection	6 (8.6)	10 (15.6)	0.08
VTE, N (%)	1 (1.4)	0 (0.0)	0.48
reoperation, N (%)	2 (2.9)	1 (1.6)	0.64
readmission, N (%)	6 (8.6)	5 (7.8)	0.87

Data are presented as median (IQR) or N (%). P-values were calculated using the Mann-Whitney U-test or Fisher's exact test. CD – Clavien-Dindo classification of surgical complications, IQR – interquartile range, VTE – venous thromboembolism

site infections were observed only in the LH group. While the rates of vaginal cuff infection were numerically higher in the vNH group, the difference was not statistically significant ( $P = 0.08$ ).

### Sensitivity analysis results

In the sensitivity analysis performed to exclude the potential impact of prior abdominal surgery, only 95 patients with no surgical history (48 LH, 47 vNH) were examined. In this more homogeneous subgroup, the conversion rate to laparotomy in class III obese patients was still higher in the LH group (25%) compared to the vNH group (0%). However, due to the very small sample size of this subgroup, the difference did not reach statistical significance ( $P = 0.22$ ). Nevertheless, the preservation of the clinical trend toward a reduction in this subgroup supports our main findings.

In the multivariate logistic regression analysis for major complications, class III obesity (OR 2.1; 95% CI 1.3–3.4;  $P = 0.003$ ) and conversion to laparotomy (OR 4.5; 95% CI 2.8–7.2;  $P < 0.001$ ) were identified as independent risk factors for major morbidity. Surgical approach (LH vs. vNH) was not found to be an independent risk factor for major morbidity (OR 1.1; 95% CI 0.6–2.0;  $P = 0.75$ ).

### Discussion

This retrospective cohort study examined the outcomes of surgical approaches in obese women undergoing hysterectomy for benign indications, stratified by obesity class. The most striking finding of our study is the dramatic difference in the conversion rate to laparotomy. While the rate was 23.5% for laparoscopic hysterectomy (LH) in patients with class III obesity, it was 0% in the vNOTES hysterectomy (vNH) group (OR: 0.08; 95% CI 0.00–0.91). This finding is particularly significant when compared to literature data; a meta-analysis by Luo et al. reported an average conversion rate of 6% for LH in the general

population, and a systematic review by Blikkendaal et al. for patients with  $BMI \geq 35 \text{ kg/m}^2$  reported a pooled rate of 10.6% [3,4]. Our findings show that the vNOTES approach provided an absolute risk reduction of 23.5% in this specific patient group, which means that the additional morbidity and cost associated with one laparotomy could be prevented for every four patients treated (NNT = 4). This supports the high technical success rate of vNOTES in the challenging obese population, consistent with the series by Bouchez et al. [8]. However, our study distinguishes itself by stratifying obesity and showing this effect is most pronounced in the class III group, a methodological approach whose importance is underscored by studies like Hurni et al. Hurni's group found a non-linear conversion risk for vNOTES across obesity classes (0% in class I; 11.1% in class II; and 7.7% in class III), revealing that treating obesity as a single category can mask the true risk profile [9–12].

The underlying mechanism for this success is based on fundamental differences in surgical technique. One of the main reasons for conversion to laparotomy in class III obesity is the difficulty in establishing a safe pneumoperitoneum and placing trocars due to a thickened abdominal wall. Failures in Veress needle or optical trocar entry can lead directly to laparotomy. vNOTES bypasses these steps entirely by starting the surgery via the vaginal route. Furthermore, the 'fulcrum effect' and restricted manipulation created by long instruments in a thick abdominal wall during laparoscopy are not present in vNOTES. This facilitates dissection, especially in the deep pelvis, reducing causes of conversion such as bleeding and poor visualization. This finding supports the hypothesis that vNOTES enables the successful completion of MIS in this patient group by avoiding the difficulties of abdominal trocar entry and limited instrument manipulation.

Regarding secondary outcomes, the operative time was significantly longer in the vNOTES group, which is consistent with the literature and may be related to the technique's learning curve [10]. The IDEAL framework, describing surgical innovation development, emphasizes a structured experience process for such techniques [11]. However, in our multivariate analysis, operative time was not an independent risk factor for major complications. Therefore, the clinical relevance of the 27-minute mean difference may be less important when weighed against the reduced risk of laparotomy conversion vNOTES provides. Additionally, it is noteworthy that we did not find a significant reduction in overall wound infection rates with the vNOTES approach, despite its elimination of abdominal incisions. This can be explained by the similar risk of vaginal cuff infection in both approaches [10]. The numerically higher rates of vaginal cuff infection in the vNH group may encourage investigation into additional prophylactic measures for this procedure.

Clinically, our findings offer surgeons a more nuanced perspective. For patients with class I and II obesity, laparoscopy remains an excellent option, given the shorter operative time and widespread experience. However, in patients with class III obesity, considering the high morbidity risk associated with conversion to laparotomy, the vNOTES approach should be considered a valuable alternative to reduce this risk, especially in centers with vNOTES experience.

This study has significant limitations. Its retrospective design carries a risk of selection bias based on surgeon preference, though our sensitivity analysis including only patients with no prior abdominal surgery showed our main finding remained unchanged. As a single-center study, our results' generalizability may be limited. Surgeon experience is another critical potential confounding factor. As the vNOTES

technique is newer at our institution, it may have been preferred for patients perceived to have lower risk. The experience level of our surgeons likely played a significant role in the 0% conversion success, which emphasizes that structured training is indispensable. The literature supports this, with studies like Charles et al. demonstrating a learning curve of approximately 53 cases for vNOTES, and conflicting results from other studies being largely attributable to this effect [5,10]. Finally, our sample size may be susceptible to a Type II error for rare secondary outcomes, our 30-day follow-up is insufficient for long-term complications, and the lack of data on patient-reported outcomes (PROs) and cost-effectiveness limits the scope of our findings.

Although this study focused on clinical outcomes, a holistic evaluation requires examining cost-effectiveness and PROs. Initial studies suggest vNOTES may offer potential cost advantages compared to conventional laparoscopy [13]. Future research should conduct comprehensive economic analyses including indirect costs and also focus on PROs. Metrics such as postoperative pain, recovery speed, sexual function, and quality of life are critical to understanding a technique's true value [14]. Supporting our findings with larger-scale,

prospective, randomized controlled trials in these areas will more clearly define the place of vNOTES in gynecologic surgery.

### Conclusion

This study reveals that in the obese patient population undergoing hysterectomy for benign reasons, vNOTES surgery significantly reduces the rate of conversion to laparotomy, particularly in the class III obesity group. In centers where surgical expertise is available, vNOTES should be considered the preferred minimally invasive approach for patients with class III obesity to mitigate the high risks associated with conversion to laparotomy. This personalized approach has the potential to improve surgical outcomes in the highest-risk patient group. Multi-center prospective studies are needed to enhance the generalizability of these findings.

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**Dedication:** This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Harran University (Date: 15.01.2024 / No: HRÜ/2024/11-7).

**Dedikace:** Tato studie byla provedena v souladu se zásadami Helsinské deklarace. Schválení udělila Etická komise Harranské univerzity (datum: 15.01.2024 / č.: HRÜ/2024/11-7).

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