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COMPARATIVE ANALYSIS OF THE EFFECTIVENESS OF LAPAROSCOPIC ORGAN-PRESERVING TREATMENT OF DEEP ENDOMETRIOSIS USING THE STANDARDIZED METHOD AND THE TRADITIONAL METHOD

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Deep endometriosis is the most aggressive type of endometriosis with deep tissue infiltration, leading to disruption of the anatomy and functionality of vital organs and a decrease in the quality of life.

The aim of the study. To conduct a comparative analysis of intraoperative and postoperative indicators of organ-preserving surgical treatment of women with deep endometriosis accompanied by pain syndrome, using a standardized technique and a traditional laparoscopic method.

Materials and methods. A comparative study was conducted, involving 309 patients of reproductive age with pain syndrome, who underwent surgery for deep endometriosis. The main group (I clinical) consisted of 210 patients who were operated on using the standardized method proposed by us. The comparison group (II clinical) consisted of 99 patients who were operated on using the traditional laparoscopic method.

Results. Improvement of intraoperative parameters was obtained in the main group, in particular, a reduction in the duration of the operation (122.32 ± 2.61 min in the main group and 148.44 ± 3.05 min in the control group, $p < 0.001$), reduction in blood loss (136.13 ± 2.41 ml in the main group and 174.43 ± 3.23 ml in the control group, $p < 0.001$); early postoperative indicators, namely, a decrease in the duration of hospital stay (in the main group 4.17 ± 0.1 days and in the control group 5.42 ± 0.16 days, $p < 0.001$); reduction of Clavien-Dindo class I complications (cases of postoperative intestinal paresis decreased by 4.9 times, the number of cases of urination dysfunction – by 4.2 times). In both group, no difference was found in Clavien-Dindo class II, III and IV complications. A significant reduction in pain scores was obtained 6 month after surgery in both groups, with no significant difference between the groups.

Conclusions. The use of a standardized surgical intervention algorithm helps improve some intraoperative and early postoperative indicators of surgical treatment of deep endometriosis.

Keywords: deep endometriosis, surgical treatment, laparoscopic surgery, pain syndrome, #Enzian.

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ПОРІВНЯЛЬНИЙ АНАЛІЗ ЕФЕКТИВНОСТІ ЛАПАРОСКОПІЧНОГО ОРГАНОЗБЕРІГАЮЧОГО ЛІКУВАННЯ ГЛИБОКОГО ЕНДОМЕТРІОЗУ ЗА СТАНДАРТИЗОВАНОЮ МЕТОДИКОЮ ТА КЛАСИЧНИМ МЕТОДОМ

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Проведено порівняльне дослідження, у яке включено 309 пацієнток репродуктивного віку з больовим синдромом, прооперованих з приводу глибокого ендометріозу. Отримано покращення інтраопераційних показників в основній групі, зокрема зменшення тривалості операції (122,32 ± 2,61 хв в основній групі та 148,44 ± 3,05 хв – у контрольній, $p < 0,001$), зменшення об'єму крововтрати (136,13 ± 2,41 мл в основній групі та 174,43 ± 3,23 мл – у контрольній, $p < 0,001$); ранніх післяопераційних показників, а саме зменшення тривалості перебування в стаціонарі (в основній групі 4,17 ± 0,1 дн. та в контрольній – 5,42 ± 0,16 дн., $p < 0,001$); зменшення ускладнень I класу за Clavien-Dindo (випадки післяопераційного парезу кишківника зменшились у 4,9 раза, кількість випадків лихоманки – у 3,2 раза, кількість випадків дисфункції сечовипускання – у 4,2 раза). В обох групах не отримано різниці в ускладненнях класу II, III, IV за Clavien-Dindo. Отримано суттєве зниження показників больового синдрому через 6 місяців після операції в обох групах, без достовірної різниці між групами.

Ключові слова: глибокий ендометріоз, хірургічне лікування, лапароскопічна хірургія, больовий синдром, #Enzian.

Introduction. Deep endometriosis is the most difficult to treat endometriotic formation [1–4]. It can be treated with medication, but most patients require surgical excision to relieve symptoms and improve quality of life [5–7]. To date, surgical excision of deep endometriosis is the only cytoreductive approach with promising results in alleviating symptoms, including pain [4, 6]. In addition, surgical intervention becomes inevitable in case of organ dysfunction [3, 7]. The main principles of surgical removal of endometriosis are the performance of adhesiolysis, uncomplicated resection of visualized endometrioid lesions,

aimed at restoring normal pelvic anatomy [3, 4]. However, there are no clear, regulated recommendations for the surgical treatment of DE in the world. We have developed a standardized technique for laparoscopic treatment of deep endometriosis, which includes step-by-step instructions for surgical intervention [8]. This study conducted a comparative analysis of the effectiveness of surgical treatment of patients with deep endometriosis accompanied by pain syndrome using a standardized technique and a traditional laparoscopic method.

The aim of the study. To conduct a comparative analysis of intraoperative and postoperative indicators of organ-preserving surgical treatment of women with deep endometriosis accompanied by pain syndrome, using a standardized technique and a traditional laparoscopic method.

Materials and methods. A single-center comparative study was performed at the Gynecological Department of the Multidisciplinary Medical Center of Odesa National Medical University, which included 309 women of reproductive age with deep endometriosis associated with pain syndrome. The patients were divided into two groups. Group I of patients, the main group, included 210 women who participated in a prospective study and were operated on using a standardized technique developed by us using 7 consecutive steps [8]. The second group, the comparison, consisted of 99 women who had previously undergone traditional laparoscopic surgery and were analyzed retrospectively. The study met the established standards of the Declaration of Helsinki and was approved by the local ethics committee of the Odesa National Medical University on November 14, 2022. All women consented to the processing of personal data. All patients underwent a comprehensive preoperative examination, which included a collection of complaints (manifestations and severity of pain syndrome), taking anamnesis (general, obstetric and gynecological), gynecological examination (with speculum and bimanual examination), laboratory (assessment of CA-125 level, according to indications), instrumental examination (transvaginal ultrasound was performed on all patients, MRI, ultrasound of the kidney and bladder, colonoscopy, cystoscopy, according to indications). Examination of patients before surgery was carried out in accordance with modern international guidelines [1, 4, 5, 9]. Transvaginal sonography and MRI results are described according to the IDEA 2016 Consensus [10]. For preoperative classification of endometriosis, the #Enzian 2021 classification was used, based on TVS and MRI data [11]. The severity of pain syndrome, namely chronic pelvic pain, dysmenorrhea, dyspareunia, dyschezia, and dysuria, was assessed using a visual analog scale (VAS) (from 0 to 10, from no pain (0) to severe (10)) [12]. In the study, we compared intraoperative, early postoperative and long-term outcomes.

Postoperative complications that occurred within 30 days after surgery were described according to the Clavien-Dindo classification [13]. Data were analyzed using R software (a language and environment for statistical computing). Data distribution was tested for normality using the Shapiro-Wilk test. Data were presented as mean ± standard error of the mean. Groups were compared using unpaired t-test or one-way analysis of variance (ANOVA) followed by a posteriori analysis using Tukey's test. Categorical data were compared using the chi-square ($\chi 2$) test (Pearson's agreement test with Yates' continuity correction where appropriate). In all cases of analysis, the critical significance level was taken to be 0.05 [14].

Results and discussion. All patients (n = 309) were operated on laparoscopically, there were no conversions to laparotomy. The operations were performed by a single surgeon who has experience in performing such interventions. As needed, multidisciplinary teams were created (involving a urologist and/or colorectal surgeon). In terms of clinical and anamnestic characteristics, the patients in both groups were homogeneous, as shown in Table 1.

All patients suffered from pain syndrome. This is the main inclusion criterion. The distribution of women in both groups according to the characteristics of the pain syndrome before surgery was comparable (Table 2).

As can be seen from Table 3, the distribution of patients in both groups according to the surgical procedures performed was homogeneous (Table 3).

The results of using the proposed standardized technique in patients of group I showed significant

Table 1

Clinical and anamnestic characteristics of patients in both groups (n = 309)

Indicator	Main group (I)		Control group (II)		p
Number, abs.	210		99		
Age (in years)	31.32 ± 0.31		31.99 ± 0.52		p = 0.252
Height (cm)	164.61 ± 0.16		165.96 ± 0.39		p < 0.001
Body weight (kg)	61.35 ± 0.39		62.25 ± 0.69		p = 0.218
BMI (kg/m2)	22.6 ± 0.11		22.54 ± 0.17		p = 0.75
Parity, abs/ %	Abs.	%	Abs.	%	
0	124	59.2	52	52.5	p = 0.847
1	78	37.4	39	38.6	
2	7	3.4	9	8.9	
Previous hormone therapy for DE	54	26.7	21	21.2	p = 0.472
Previous surgeries for DE	15	7.3	8	8.1	p = 0.951
CA-125, U/ml.	81.6 (±5.8)		69.0 (±3.2)		p < 0.001
Infertility	108	51.3	48	48.5	p = 0.718
Associated diseases	78	37.1	34	34.34	p = 0.726

Table 2

Preoperative distribution of patients by type of pain syndrome in both groups (n = 309), VAS scores, points.

Indicator	Абс.	%	Абс.	%	p
Chronic pelvic pain	128	61.2	58	58.3	
	4.87 ± 0.28		5.1 ± 0.23		p = 0.648
Dysmenorrhea	208	99.3	96	97	
	8.46 ± 0.12		8.51 ± 0.22		p = 0.834
Dyspareunia	193	92	90	91.5	
	7.42 ± 0.18		7.47 ± 0.26		p = 0.863
Dysuria	44	21	15	15.2	
	1.2 ± 0.17		1.1 ± 0.27		p = 0.75
Dyschezia	51	24.5	21	21.2	
	1,8 ± 0,23		1,3 ± 0,26		p = 0.16

Table 3

Distribution of patients in both study groups according to surgical procedures performed (n = 309)

Surgical manipulation	Main group (I)		Control group (II)		P
	Абс.	%	Абс.	%	
Laparoscopy	210	100	99	100	
Revision of the abdominal cavity and pelvic organs	210	100	99	100	
Adhesiolysis	199	95.1	91	91.9	p = 0.367
Ovariopexy	145	69	61	61.6	p = 0.245
Ovarian surgery	131	62.4	64	64.6	p = 0.796
Enucleation of ovarian cyst	119	91.2	86	86.9	p = 0.297
Ovarian cyst ablation	8	5.8	7	7.07	p = 0.834
Ovarian resection	3	2.3	4	4.04	p = 0.655
Oophorectomy	1	0.7	2	2.02	p = 0.503
Ablation of peritoneal endometriosis foci	51	24.3	28	28.3	p = 0.541
Focal excision of peritoneal end. f.	101	48.1	57	57.6	p = 0.152
Partial peritonectomy	89	42.4	50	50.5	p = 0.224
Complete peritonectomy	35	16.7	22	22.2	p = 0.309
Removal of deep endometriosis lesions (according to #Enzian): Compartment A	128	61	54	54.5	p = 0.345
Compartment B	152	72.4	63	63.7	p = 0.154
Ureterolysis	57	27.1	24	24.2	p = 0.687
Ureteral resection with anastomosis	4	2	2	2.02	p = 1
Ureter reimplantation	1	0.5	1	1.01	p = 1
Bladder shaving	17	8	6	6.06	p = 0.687
Bladder resection	5	2.4	2	2.02	p = 1
Rectal shaving	68	32.4	34	34.3	p = 0.832
Rectal resection	13	6.2	5	5.05	p = 0.889
Sigmoid colon resection	5	2.38	3	3.03	p = 1
Appendectomy	3	1.43	1	1.01	p = 1

advantages compared to the traditional method of surgical treatment of DE in women of group II. The duration of surgery was identified as a risk factor for postoperative complications in our study. It could be argued that complex surgical procedures with significant adhesiolysis and bowel resection require longer operative time; however, this was demonstrated as an independent factor in multivariate analysis. We observed that the duration of the operation correlated with the amount of blood loss and the duration of hospitalization and primarily depended on the complexity of the operation. The duration of surgical intervention in our study was reduced due to the use of a standardized technique, a step-by-step surgical algorithm (Table 4).

The average duration of hospital stay in the main group was shorter than in the comparison group and was 4,17 ± 0,1 days (95% ДІ 3.97–4.37), in the comparison group – 5.42 ± 0.16 days (95% ДІ 5.12–5.73), p < 0.001.

Pain scores significantly decreased 6 months after surgery in both groups, but no significant difference was found between the groups (Table 5). In our series, dysmenorrhea was the most common symptom, regardless of the location of endometriosis, however, it

Table 4

Comparative characteristics of intraoperative indicators in both groups

Intraoperative indicators	Main group (I)		Control group (II)		p
Duration of operation, minutes	122.32 ± 2.61		148.44 ± 3.05		p < 0.001
Blood loss, ml	136.13 ± 2.41		174.43 ± 3.23		p < 0.001
Injury to organs and structures	Abs.	%	Abs.	%	
	1	0.5	3	3.03	p = 0.189
Other complications	–	–	–	–	
Laparotomic conversions	–	–	–	–	

should be noted that most patients had more than one symptom, therefore, such patients required safe radical excision of endometriosis foci. The intensity of chronic pelvic pain decreased by 2 times, dysmenorrhea – by 4 times, dyspareunia – by 3.3 times, dyschezia – by 3 times, and dysuria – by 3 times in both study groups. There was no statistically significant difference between the groups (Table 5). Similar encouraging results have been obtained in similar studies [16, 17]. This once again emphasizes the value of surgical treatment of symptomatic deep endometriosis, even if these operations are very complex.

Using the standardized methodology, we obtained a small number of complications of Clavien-Dindo class I–II – 11.59% and Clavien-Dindo class III–IV – 0.5% (Table 6), these results are consistent with the results of similar interventions in specialized centers [16, 17].

We think that surgery for deep endometriosis needs standardization to objectify such treatment and improve treatment outcomes. Our center has developed a standardization of surgical laparoscopic treatment of deep endometriosis by creating an algorithm for surgical intervention, which includes 7 sequential steps to improve surgical treatment of DE [8], which is based on the analysis of deep endometriosis subtypes, variants and the frequency of their combination. These results were published in a previous retrospective study [15]. First, simpler steps are performed. This makes it easier to perform the subsequent more complex stages of the operation. Given the presence of painful symptoms, one should strive for complete removal of endometrioid lesions. The first steps are aimed at facilitating subsequent surgical procedures.

Our standardization of surgical treatment of DE includes the following steps: 1) revision of the abdominal cavity and pelvic organs, 2) visceral adhesiolysis and "second-look" revision, 3) ovarian surgery (oophoropexy and/or treatment of endometriomas), 4) lateral, central, posterior partial or total peritonectomy and removal of DE foci of this localization (in compartments A and B according to #Enzian 2021), 5) surgical manipulations on hollow organs, 6) hemostasis and checking the integrity of structures and organs, 7) evacuation of macropreparations [10].

Table 5

Pain syndrome indicators according to the VAS scale in both groups of patients 6 months after surgery (n = 309), points

Indicator	Main group (I)	Control group (II)	p
Chronic pelvic pain	2.41 ± 0.21	1.91 ± 0.23	P = 0.14
Dysmenorrhea	2.08 ± 0.12	2.4 ± 0.1	p = 0.141
Dyspareunia	2.22 ± 0.23	2.26 ± 0.31	p = 0.914
Dysuria	0.4 ± 0.12	0.25 ± 0.1	p = 0.44
Dyschezia	0.6 ± 0.14	0.39 ± 0.13	p = 0.351

Table 6

Comparative characteristics of postoperative complications according to Clavien-Dindo (n = 309)

Grade	Type of complication	Main group (I)		Control group (II)		p
		Абс.	%	Абс.	%	
I	Postoperative intestinal paresis	3	1.43	7	7.07	p = 0.023
	Fever	10	4.7	15	15.15	p = 0.068
	Urinary tract infection	5	2.6	8	8.08	p = 0.194
	Urinary dysfunction	3	1.43	6	6.06	p = 0.058
II	Pelvic hematoma	2	0.95	4	4.04	p = 0.814
	Pelvic abscess	1	0.48	2	2.02	p = 0.503
III, IV	Rectal bleeding	–	–	1	1.01	p = 0.7
	Intestinal anastomosis failure	–	–	–	–	
	Anastomotic stenosis	1	0.5	–	–	p = 1
	Rectovaginal fistula	–	–	–	–	
	Vesicovaginal fistula	–	–	–	–	

Surgical treatment of deep endometriosis does not always require the use of all seven steps. It depends on the subtype and extent of endometrioid lesions in each individual patient. Surgery for deep endometriosis is a very difficult task and can have serious consequences for the patient, therefore, in our opinion, there should be an algorithm for surgical intervention that the surgeon will follow. This will facilitate the work of the surgeon himself, structure the surgical intervention, and make such intervention more complete and radical. In our methodology for standardizing the surgical treatment of deep endometriosis, we apply all generally accepted techniques for the surgical treatment of endometriosis, which are fully consistent with the review of current literature. The novelty of our research is the creation of a step-by-step algorithm for surgical intervention, avoiding chaos during the operation. [4, 5, 7, 8]. Certainly, a standardized technique must be adapted to each specific patient.

Our results demonstrate that structuring and standardization of surgical treatment of deep endometriosis, contribute to improving treatment outcomes for patients with deep endometriosis. There is no doubt that the course of the intra- and postoperative period directly depends, among other factors, on the surgical technique used, the level of surgical technique, and the conditions of performance. The standardization of surgical laparoscopic treatment of deep endometriosis proposed by us allows reliably reduce the duration of surgical intervention by 1.2 times ($p < 0,001$), reduce intraoperative blood loss by 1.3 times ($p < 0,001$), reduce the length of hospital stay by 1.3 times ($p < 0,001$), reduce the incidence of Clavien-Dindo class I complications, in particular, cases of postoperative intestinal paresis decreased by 4.9 times ($p = 0,023$), the number of cases of urinary dysfunction decreased by 4.2 times ($p=0,058$) in the main group compared to the control group.

Conclusions. Thus, these results demonstrate that our method for standardizing surgical laparoscopic treatment of deep endometriosis, is an improved surgical procedure that helps optimize the stages of the operation, greatly facilitating the surgeon's work, has better clinical results, helps reduce the duration of the operation, as well as reducing blood loss and some complications, and the length of hospital stay. Regarding the improvement of long-term outcomes – pain syndrome and disease recurrence – more research is needed. Since there is no consensus and standard recommendations for the treatment of DE, our study aims to provide a structured framework for such treatment.

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