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Predictive risk factors of vaginal cuff infection and vaginal cuff dehiscence in Egyptian female patients undergoing total laparoscopic hysterectomy for benign gynecological conditions

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ABSTRACT

Objective. A reported complication after total laparoscopic hysterectomy (TLH) is vaginal cuff infection (VCI) that needs readmission, antibiotic therapy and worsen post-operative quality of life in patients**.** Another bad complication of TLH is occurrence of vaginal cuff dehiscence (VCD), which is the separation of sutured vaginal incision.
Identification of possible risk factors of VCI and VCD after TLH could help in reducing such annoying complications of patients and health care system. Aim of the study was the assessment of prevalence, preoperative, operative and post-operative risk factors of VCI and VCD after performing TLH for treatment of benign pathological uterine conditions in Egyptian patients.
Patients and Methods. This is a prospective cohort study and included 200 females with clinical and radiological evidence of benign pathological conditions in the uterus that underwent TLH. We followed-up all patients for 6 weeks post-operatively by performing full gynaecological examination in addition to transvaginal sonography then followed up by telephone to assess occurrence of VCI or VCD.
Results. 14 of the 200 included patients (7%) were diagnosed with VCI and 8 of the 200 included patients developed VCD (4%) during the 30 days after TLH.
There is statistically significant relation between occurrence of vaginal cuff infection and specimen weight, high CRP, vaginal cuff haematoma, complications, suturing technique ($p < 0.001$); and between occurrence of vaginal cuff dehiscence and specimen weight (lower with dehiscence) and vaginal cuff haematoma (associated with dehiscence) ($p < 0.001$).
Conclusions. High post-operative CRP level and occurrence of postoperative vaginal cuff haematoma without sufficient prophylactic antibiotic therapy were significant risk factors of VCI while smaller uterine size is a predictor risk factor of VCD.

INTRODUCTION

Hysterectomy which is considered the commonest performed gynaecological surgical intervention is mostly an elective procedure which is performed due to benign pathological uterine conditions [1]. Recently there was a gradual shift from performing abdominal and vaginal hysterectomy to total laparoscopic hysterectomy (TLH) which has many advantages over other open procedures as minimization of post-operative morbidity and pain in addition to rabid recovery and short period of hospitalization [2].

A reported complication after TLH is vaginal cuff infection (VCI) that needs readmission and antibiotic therapy. VCI after TLH worsen post-operative quality of life in patients [3].

Another bad complication of TLH is occurrence of vaginal cuff dehiscence (VCD), which is the separation of sutured vaginal incision [4]. VCD is a relatively rare complication which happens after TLH more than abdominal and vaginal hysterectomy, but occurrence of abdominal or pelvic organs evisceration through the vagina could lead to bowel injury, necrosis, peritonitis and sepsis which are serious sequences that mostly need additional surgical interventions [5, 6].

There are some studied general predictors of VCI and VCD after TLH as pelvic floor defects, electrosurgery, previous radiation therapy, and early postoperative sexual intercourse, but detailed data on operative and post-operative predictors of VCI and VCD after TLH are not sufficiently studied [7]. Identification of possible risk factors of VCI and VCD after TLH could help in reducing such annoying complications of patients and health care system [8].

Aim of the present work was assessment of prevalence, preoperative, operative and post-operative risk factors of VCI and VCD after performing TLH for treatment of benign pathological uterine conditions in Egyptian patients.

PATIENTS AND METHODS

We conducted the following prospective cohort study. We have an approval for performing the study from institutional review board of Faculty of Medicine Zagazig University.

A written informed consent was taken from all included patients to perform the study.

Inclusion criteria

All females with clinical and radiological evidence of benign pathological conditions in the uterus that underwent TLH in the period from January 01, 2015, and December 31, 2020, at Zagazig University Hospital.

Exclusion criteria

Patients underwent abdominal or vaginal hysterectomy, patients diagnosed with malignant gynaecological tumours, patients with lost follow-up or patients who refused to be included in the study.

Methodology

Admission to hospital was done 1 day before surgery where full medical history was acquired: full gynaecological examination, radiological evaluation and basic laboratory tests were done to them. Antibiotic therapy and low molecular weight heparin were given to all patients. All performed surgical procedures were done by using a uterine manipulator.

We closed the vaginal vault with single-layer laparoscopic sutures using Vicryl 1-CT-1 and intra-corporeal knots technique.

We followed up all patients for 6 weeks post-operatively by performing full gynaecological examination in addition to transvaginal sonography then followed up by telephone to assess occurrence of VCI or VCD.

Measurements of pre-operative, operative and post-operative findings

We collected preoperative information as patients demographics, comorbid conditions, laboratory results within the 90 days before performed surgery, surgical data, method of specimens retrieval, performed surgical techniques, intraoperative complications, postoperative laboratory values on POD2, pathological results of retrieved specimens, 30-day postoperative complications which might occurred before VCI or VCD as vaginal bleeding which might need reoperation and occurrence of vaginal cuff haematoma.

Measurements of VCI and VCD incidence and related parameters

VCI was defined if occur within 30 days from performed TLH and it presented as fever, presence of

purulent vaginal discharge, occurrence of pelvic, abdominal and low back pain. We diagnosed VCI depending on vital signs, physical findings, blood tests, findings during gynaecological examination and trans-vaginal ultrasound in addition to computed tomography in some cases.

We defined VCD as full-thickness vaginal cuff separation at its anterior or posterior edges with or without evisceration of the bowel.

VCD was categorized as complete in cases with separation of the entire length of the vaginal vault while it was categorized as partial in cases with affection of only part of the incision [1].

Repair of diagnosed cases with VCD was performed laparoscopically after complete inspection of the abdominal cavity for presence of haematoma, abscess, or bowel injury, then irrigation and excision of necrotic tissue was done followed by re-suturing with Vicryl 1-CT-1 using single-knot technique. In cases diagnosed with minimal dehiscence without clinical or sonographic suspicion of haematoma, abscess, or injury of the bowel we performed the vaginal repair using single-knot sutures.

Statistical analysis

Sample size was calculated by a specialized biostatistician according to rate of patients' admission in out institution.

Data were reported as median for continuous variables and as number (%) for categorical variables. For detection of predictive risk factors for VCI and VCD during the 30 days after TLH, we performed univariate analyses, and multivariable logistic regression, and estimated odds ratios (OR) and 95% confidence intervals (CI). For comparison between variable in included patients we used the chi-square test or Fisher's exact test for categorical variables and the Mann-Whitney U test for continuous variables. All tests were two-sided, with P-value set at less than 0.05 is considered significant. Confidence (CI) interval was 90-95%.

RESULTS

The clinical and demographic data of included patients are detailed in **Table 1**.

Table 1. *Correlations between demographic, clinical data and both VCD and VCI among the studied patients.*

Parameter	Total n = 200	VCD		P-value	VCI		P-value
		Absent n = 192 (%)	Present n = 8 (%)		Absent n = 192 (%)	Present n = 8 (%)	
Age (Mean ± SD)	44.7±5.66	44.63±5.67	46.5±5.4	0.361∞	44.59 ± 5.69	46.21 ± 5.15	0.302∞
BMI (Mean ± SD)	22.52±1.31	22.53±1.32	22.19±1.0	0.464∞	22.54 ± 1.33	22.25 ± 0.91	0.424∞
Parity							
P0	10 (5)	9 (90)	1 (10)		8 (80)	2 (20)	
P1	40 (20)	38 (95)	2 (5)		37 (92.5)	3 (7.5)	
P2	40 (20)	39 (97.5)	1 (2.5)		38 (95)	2 (5)	0.491¥
P3	60 (30)	58 (96.7)	2 (3.3)	0.55¥	57 (95)	3 (5)	
P4-7	50 (25)	48 (96)	2 (4)		46 (92)	4 (8)	
Mode							
CS	120 (60)	116 (96.7)	4 (3.3)	0.556¥	112 (93.3)	8 (6.7)	0.821¥
VD	80 (40)	76 (95)	4 (5)		74 (92.5)	6 (7.5)	
Previous operation							
No	120 (60)	115 (95.8)	5 (4.2)	> 0.999¥	111 (92.5)	9 (7.5)	0.734¥
Yes	80 (40)	77 (96.2)	3 (3.8)		75 (93.8)	5 (16.2)	
TLH							
Without BSO	100 (50)	96 (96)	4 (4)	> 0.999¥	92 (92)	8 (8)	0.579¥
BSO	100 (50)	96 (96)	4 (4)		94 (94)	6 (6)	
Indications							
Adnexal mass	20 (10)	20 (100)	0 (0)		19 (95)	1 (5)	
AUB	106 (53)	103 (97.2)	3 (2.8)		102 (96.2)	4 (3.8)	
AUB+fibroid	32 (16)	30 (93.8)	2 (6.2)		28 (87.5)	4 (12.5)	
Fibroid	22 (11)	20 (90.9)	2 (9.1)	0.974¥	20 (90.9)	2 (9.1)	0.571¥
Infection	12 (6)	12 (100)	0 (0)		11 (91.7)	1 (8.3)	
Unexplained pain	8 (4)	7 (87.5)	1 (12.5)		6 (75)	2 (25)	

¥Chi square test; ∞independent sample t-test.

The median patient age was 45.0 years (ranged from 42.0-50.0 years), median body mass index was 23.4 (ranged from 19.4-26.4) kg/m^2.

14 of the 200 included patients (7%) were diagnosed with VCI and 8 of the 200 included patients developed VCD (4%) during the 30 days after TLH. The median time of onset of VCI was 7th POD (range from 5-9), and the median time of onset of VCD was 12 days (range 1-30 days).

7 of the infected patients (50%) were found to have mixed polymicrobial infection.

Patients with VCD presented with vaginal bleeding or discharge (n = 3), abdominal pain (n = 3), and vaginal pressure (n = 2).

Five patients with VCD required laparoscopic re-operation, and vaginal closure via single-knot was performed in 3 patients with minor dehiscence.

There is statistically non-significant relation between occurrence of both vaginal cuff infection and dehiscence and either age, BMI, parity, mode, history of previous operation, TLH or indication of surgery (**Table 1**).

There is statistically non-significant relation between occurrence of vaginal cuff infection and dehiscence and pathological analysis of ovarian, endometrial, myometrial or cervical specimen (**Table 2**).

Associations between pre, intra, and postoperative factors and the development of VCI

There is statistically significant relation between occurrence of vaginal cuff infection and specimen weight (lower with infection), operative bleeding (higher with infection), CRP (higher with infec-

Table 2. *Correlations between pathological data and both VCD and VCI among the studied patients.*

Parameter	Total n = 200	VCD		P-value¥	VCI		P-value¥
		Absent n = 192 (%)	Present n = 8 (%)		Absent n = 192 (%)	Present n = 8 (%)	
Pathology							
Atrophic	12 (6)	12 (100)	0 (0)		12 (100)	0 (0)	
Disordered proliferative	16 (18)	16 (100)	0 (0)		16 (100)	0 (0)	
EH	32 (16)	30 (93.8)	2 (6.2)		30 (93.8)	2 (6.2)	
End polyp	52 (26)	50 (96.2)	2 (3.8)		50 (96.2)	2 (3.8)	
Endometritis	24 (12)	24 (100)	0 (0)		22 (91.7)	2 (8.3)	
Hormonal effect	16 (8)	16 (100)	0 (0)		15 (93.8)	1 (6.2)	
PCO	8 (4)	8 (100)	0 (0)	0.986	7 (100)	1 (0)	0.81
Proliferative	20 (10)	18 (90)	2 (10)		16 (80)	4 (20)	
Secretory	20 (10)	18 (90)	2 (10)		18 (90)	2 (10)	
Myometrial pathology							
Adenomyosis	36 (18)	34 (94.4)	2 (0)		35 (97.2)	1 (1.8)	
Fibroid	68 (34)	66 (94.1)	2 (5.9)		61 (89.7)	7 (10.3)	
Fibroid+adenomyosis	36 (18)	35 (97.2)	1 (2.8)		34 (94.4)	2 (5.6)	
Myometritis	44 (22)	43 (97.7)	1 (2.3)	0.417	43 (97.7)	1 (2.3)	0.129
Normal	16 (8)	14 (87.5)	2 (12.5)		13 (81.3)	3 (18.7)	
Cervical pathology							
Cervicitis	104 (52)	100 (96.2)	4 (3.8)		94 (90.4)	10 (9.6)	
Fibroid	40 (20)	40 (100)	0 (0)	0.22	40 (100)	0 (0)	0.16
Normal	56 (28)	52 (92.9)	4 (7.1)		52 (92.9)	4 (7.1)	
Ovarian findings							
Endometriosis	20 (10)	20 (100)	0 (0)		19 (95)	1 (5)	
Functional cyst	52 (26)	52 (100)	0 (0)		50 (96.2)	2 (3.8)	
Mucinous	18 (9)	18 (100)	0 (0)		17 (94.4)	1 (5.6)	
Normal	48 (24)	44 (91.7)	4 (8.3)		44 (91.7)	4 (8.3)	0.987
Serous	46 (23)	44 (95.7)	2 (4.3)	0.07	42 (91.3)	4 (8.7)	
Teratoma	16 (8)	14 (87.5)	2 (12.5)		14 (87.5)	2 (12.5)	
Ovarian HSO	n = 100	n = 96	n = 4		n = 94	n = 6	
Endometriosis	12	12 (100)	0 (0)		12 (100)	0 (0)	
Fibroma	6	5 (83.3)	1 (16.7)		5 (83.3)	1 (16.7)	
Functional cyst	22	21 (95.5)	1 (4.5)		21 (95.5)	1 (4.5)	
Mucinous cyst	8	7 (87.5)	1 (12.5)		7 (87.5)	1 (12.5)	
Normal histology	14	13 (92.6)	1 (7.4)		10 (85.7)	4(28.6)	
Oophoritis	10	10 (100)	0 (0)	0.543	10 (100)	0 (0)	0.163
Serous cystadenoma	20	20 (100)	0 (0)		20 (100)	0 (0)	
Teratoma	8	7 (87.5)	1 (12.5)		6 (87.5)	1 (12.5)	

¥Chi square test.

tion), vaginal cuff haematoma (associated with infection), complications (associated with infection), suturing technique (running suture was associated with infection) ($p < 0.001$) (**Table 3**).

Binary logistic backward regression of risk factors associated with vaginal cuff infection

Intraoperative bleeding, presence of vaginal cuff haematoma, and running suture non-significantly increased risk by 1.044, 1.792 and 1.099 folds, respectively, while low CRP decrease specimen weight and absence of postoperative complications were protective factors against VCI (**Table 4**).

Associations between various factors in the pre, intra, and postoperative periods and the development of VCD

There is statistically non-significant relation between occurrence of vaginal cuff dehiscence and either intraoperative bleeding, operative time or suturing technique.
There is statistically significant relation between occurrence of vaginal cuff dehiscence and specimen weight (lower with dehiscence), CRP (dehiscence associated with CRP), vaginal cuff haematoma (associated with dehiscence), and complications (associated with dehiscence) ($p < 0.001$, 90-95%CI).

Table 3. *Correlations between operative data and both VCD and VCI among the studied patients.*

Parameter	Total n = 200	VCD		P-value	VCI		P-value
		Absent n = 192 (%)	Present n = 8 (%)		Absent n = 192(%)	Present n = 8 (%)	
Specimen weight (Mean ± SD)	214.63 ± 30.39	220.79 ± 44.6	67.75 ± 19.75	**< 0.001*∞**	221.03 ± 44.07	130.14 ± 85.63	**0.002*∞**
Intraoperative bleeding (Mean ± SD)	64.9 ± 30.39	65.1 ± 30.94	60.0 ± 10.69	0.643∞	63.44 ± 29.68	84.29 ± 34.13	**0.013*∞**
Operative time (Mean ± SD)	155.5 ± 56.22	155.26 ± 56.49	161.25 ± 52.22	0.769∞	155.48 ± 57.33	155.71 ± 40.14	0.988∞
CRP (Mean ± SD)	2.06 ± 0.96	1.97 ± 0.87	4.13 ± 0.35	**< 0.001*∞**	1.85 ± 0.57	4.79 ± 0.89	**< 0.001*∞**
Hospitalization (Mean ± SD)	9.43 ± 3.48	9.41 ± 3.45	10.0 ± 4.41	0.638∞	9.4 ± 3.41	9.86 ± 4.47	0.712∞
Vaginal cuff haematoma							
Absent	186 (93)	185 (99.5)	1 (0.5)		181 (97.3)	5 (2.7)	
Present	14 (7)	7 (50)	7 (50)	**< 0.001*¥**	5 (37.5)	9 (62.5)	**< 0.001*¥**
Complications							
Absent	181 (90.5)	179 (98.9)	2 (1.1)	**< 0.001*¥**	175 (96.7)	6 (3.3)	**< 0.001*¥**
Present	19 (9.5)	13 (68.4)	6 (31.6)		11 (57.9)	8 (42.1)	
Suturing techniques							
Single knot	167 (83.5)	162 (97)	5 (3)	0.128¥	161 (96.4)	6 (3.6)	**< 0.001*¥**
Running suture	33 (16.5)	30 (90.9)	3 (9.1)		25 (75.8)	8 (24.2)	

¥Chi square test; ∞ independent sample t-test; *P-value < 0.05 is statistically significant.

Table 4. *Binary logistic backward regression of risk factors associated with vaginal cuff infection.*

	AOR	95%CI		P-value
		Lower	Upper	
Specimen weight	.981	0.952	1.010	0.981
Postoperative vaginal cuff haematoma (present)	1.792	0.079	40.875	1.792
Postoperative complications absent	0.000	0.000	.	0.000
Low CRP	0.000	0.000	.	0.000
Running sutures	1.099	0.030	40.301	1.099
Intraoperative bleeding	1.044	0.988	1.104	1.044

AOR: adjusted odds ratio; CI: confidence interval.

Table 5 *Binary logistic backward regression of risk factors associated with vaginal cuff dehiscence.*

	β	AOR	95%CI	P-value
Vaginal cuff haematoma (absent)	-32.809	0	0-	0.981
Specimen weight	-1.337	0.263	0-	0.996
Complications	-18.647	0	0-	0.999
CRP	-11.952	0	0-	0.999

AOR: adjusted odds ratio; CI: confidence interval.

There is statistically non-significant relation between occurrence of vaginal cuff infection and either operative time or hospitalization (**Table 3**).

Binary logistic backward regression of risk factors associated with vaginal cuff dehiscence

Absence of vaginal cuff haematoma, increase specimen weight, low CRP and absence of postoperative complications were protective factors against vaginal dehiscence (**Table 5**).

DISCUSSION

In our study we showed that rate of VCI after TLH was about 7% and VCD was 4% which is slightly higher than previous findings. Tsuzuki *et al*. [8] showed that the rate of 30-day VCI was 4.6%, which is higher than that reported in previous studies.
Previously rate of VCI after TLH was found to be about 3.5% [9].
Our study similar to previous reports tried to identify main risk factors of VCI after TLH.
Previous reports showed that smoking was the main predictive risk factor for VCI [8], as it leads to ischemia and delayed healing of the vaginal wound healing that leads to higher rate of any surgical site infection (SSI) [10]. Tsuzuki *et al*. [8] showed that patients must stop smoking at least 30 days before any elective surgery. As the rate of smoking in our cohort was very low so we cannot consider it as a risk factor for development of VCI.
Regarding intraoperative predictive factors of VCI Tsuzuki *et al*. [8] detected an association between Seprafilm use and occurrence of postoperative VCI.
It was found that Seprafilm is formed of two anionic polysaccharides, sodium hyaluronate, and chemically modified carboxy-methylcellulose. It was transformed into a gel after placing it in the peritoneum, it is reabsorbed after 7 days from occurrence of normal tissue repair and subsidence of the inflammatory cascade [11]. So Seprafilm has the advantage of reducing rate of postoperative adhesions. Although it has many advantages, it was reported to increase risk of intraabdominal infections, abscess formation and anastomotic leaks [12]. It might lead to fluid collection, and even sterile peritonitis [13].
As we did not assess the association between Seprafilm and VCI which is not used in Egypt, and due to few included patients in whom Seprafilm was used in study of Tsuzuki *et al.* [8], further studies are needed to confirm associations between Seprafilm use and the occurrence of VCI after TLH.
We found that the most significant predictive risk factors of VCI in the postoperative period is the level of CRP on POD2 and occurrence of postoperative haematoma, similar to results of Tsuzuki *et al*. [8] and Tormena *et al*. [14].
We showed that presence of postoperative haematomas after TLH was related to occurrence of VCI, so maintaining adequate haemostasis, handling of tissues gently, removal of any haematoma and using prophylactic pre-operative antibiotic is important in preventing VCI [15]. Taking prophylactic antibiotic was essential prophylactic factor against VCI occurrence.
We showed that operative time was not considered a predictive risk factor of VCI after TLH in our study which was similar to results of Tsuzuki *et al*. [8].
But in other studies, longer operative time was considered a risk factor for surgical site infections [10, 16, 17].
We found that VCI was polymicrobial as opening of the vagina during surgery in TLH allow vaginal content of endogenous polymicrobial (aerobic and anaerobic) flora to ascend from the vagina and endocervix to the site of operation, in addition to the skin microorganisms which are aerobic gram-positive cocci. So, the pathogens sources in VCI are polymicrobial [17, 18].
In the current report we found a rate of 4% for VCD, which is in line with vaginal cuff dehiscence rates described by previous reports 0.64-5.4% [1].

We identified predictive risk factors for occurrence of VCD which are occurrence of VCI and low uterine weight. We are the first study to detect such association between VCI and VCD.
Previous studies showed that low surgeon laparoscopic expertise and low uterine weight were identified as risk factors for VCD [1, 5].
Rettermaier *et al*. [5] found a VCD incidence rate of 0.75% which was lower than most performed studies in this issue. These discrepancies were due to differences in their performed procedures as they performed two-thirds of their cases via robotic-assisted laparoscopic hysterectomies that has lower VCD rates than for TLH [19, 20].
Rettenmaier *et al*., [5] and Karacan *et al*. [21] used barbed sutures for closure of vaginal vault in most cases and found no occurrence of VCD after this approach and they showed that using Vicryl sutures was considered a predictive risk factor for VCD.
In studies comparing between VCD incidences in various approaches of hysterectomy they found that rate of VCD was higher in TLH than detected rates in abdominal and vaginal hysterectomies. This is because laparoscopic closure of vaginal cuff during TLH was the main predictive risk factor for VCD [7].
Surgeon's laparoscopic experience in addition to performed surgical technique particularly laparoscopic suturing which needs advanced training has major roles in prediction surgical outcomes and rates of complication [22].
Additionally, we identified small uterine size as a predictive factor for VCD which was similar to results of Radosa *et al*. [1] who identified an inverse association between weight of the uterus and VCD incidence.
Radosa *et al.* [1] explained that using a small uterine-manipulator portio cap (32 mm) for patients having small uteri lead to higher rates of VCD in this group.
First, the small cap could not fully enclose the cervix that leads to opening of the vaginal vault above vaginal fornix level, leaving cervical tissue in the vaginal vault which leads to necrosis and a higher rate of VCD. The second explanation is that patients who have smaller uterine size has smaller vaginal-tissue resection, which harbours the danger of greater thermal vaginal injury.
It is recommended in those patients to give a special attention to selection and placement of the uterine-manipulator cap to allow a full enclosure of the uterine portio after application of uterine-manipulator.
Regarding prevention of intrauterine adhesions, most reports assessed values of hyaluronic acid gel, with or without insertion of a copper intrauterine device, and were found to be effective in preventing adhesions [23]. We used gel foam to prevent adhesions.

Strengthens of the study

Our study has many strength points: first we have chosen an important point of research which is VCI and VCD in TLH as incidence of laparoscopic surgeries increased. Second, we included a relatively large number of patients. The study was a prospective one which avoids bias of retrospective studies performed in previous retrospective studies. Additionally, our patients received standardized and similar management strategies in our hospital.

Limitations of the study

Our study reflected the experience of only a single hospital, which might not be generalizable to other institutions and settings. Another limitation is the sample size. Although our sample was not small, the rareness of VCI and VCD makes its statistical correlation with risk factors difficult.

CONCLUSIONS

In a population of women who underwent TLH for benign indications, we found that VCI and VCD occur at a median incidence of 7% and 4% of included patients, respectively.
We concluded that high postoperative CRP level and occurrence of postoperative vaginal cuff haematoma without sufficient prophylactic antibiotic therapy were significant risk factors of VCI while smaller uterine size is a predictor risk factor of VCD.

Clinical applications and recommendations

Our study aims to minimizing VCI and VCD risks and added to current knowledge about VCI and VCD in laparoscopic hysterectomy, but we recommend future large scale prospective studies that are better to be multicentre and included large number of patients to highlight results and apply them.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

All authors contributed equally to this work.

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None.

Study registration

The study was registered in institutional review board (number Zag.Gyn. A.2020).

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

Ethical approval was obtained from the Local Ethic Committee of Faculty of Medicine of Zagazig University.

Informed consent

Written informed consent was obtained from included patients.

Data sharing

Data are available under reasonable request to the corresponding author.

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