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Incidence and Risk Factors of Venous Thromboembolism in Patients Undergoing Surgery for Gynecologic Malignancies

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ABSTRACT

Introduction: A potentially fatal complication of gynecological cancer surgery is venous thromboembolism (VTE). Low-molecular-weight heparin prophylaxis does not reduce the risk of VTE. This research determined the incidence of VTE and to identify the risk factors in patients having surgery for gynecological malignancy with extended dual prophylaxis.

Methods: In this retrospective cohort study, all patients with gynecological cancer undergone surgery at the Division of Gynecologic Oncology of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine were identified between January 2008 and April 2018. Age, body mass index (BMI), menopausal status, comorbidities, the primary site of the neoplasm in gynecology, surgical details, and operative time, the need for intensive care unit admission, perioperative complications, the patient's smoking habits, the diagnosis of VTE, and follow-up assessments up to one month after surgery were among the data collected.

Results: With a 2.4% incidence rate, 29 of 1,201 analyzed patients experienced postoperative VTE events. BMI >30, operation duration >180 min, paraaortic and/or pelvic lymphadenectomy, neoadjuvant chemotherapy, smoking, and chronic renal failure were revealed to be significant variables [odds ratio (OR): 5.357; 95% confidence interval (CI): 1.833-15.654; p=0.002; OR: 5.698; 95% CI: 1.971-16.474; p=0.001; OR: 0.252; 95% CI: 0.068-0.933; p=0.039; OR: 0.002; 95% CI: 0.001-0.025; p=0.001; OR: 0.217; 95% CI: 0.082-0.577; p=0.002; OR: 0.033; 95% CI: 0.003-0.379; p=0.006, respectively].

Conclusion: We suggest that every patient undergoing gynecological oncology surgery should have preoperative pharmacological and postoperative extended dual prophylaxis to achieve the lowest incidence of VTE in this group.

Keywords: Pulmonary embolism, venous thromboembolism, gynecological cancer, postoperative care, deep vein thrombosis

Introduction

The incidence of malignant tumors has risen dramatically recently. Gynecological cancers are common and frequently necessitate radical surgery; in 2020, it is estimated to be 604,127 new cases of cervical cancer, 417,359 new cases of endometrial cancer, and 313,959 new cases of ovarian cancer (1).

Gynecological cancer operations can result in a deadly complication called venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE) (2). In patients with gynecologic malignancy, the incidence of postoperative DVT was as high as 37.9% without VTE prophylaxis (2-5). Within 30 days of diagnosis, approximately 12% of VTE patients die (6). Consequently, perioperative VTE prophylaxis is of utmost importance.

There was no universal standard for VTE thromboprophylaxis. There are various therapies and procedures for reducing the risk of postoperative VTE: Mechanical prophylaxis, preoperative or postoperative pharmacologic prophylaxis, and dual pharmacologic and mechanical prophylaxis for an extended duration (7,8). After gynecological cancer surgery, there is an exceptionally high risk of VT, this is true even when low-molecular-weight heparin (LMWH) prophylaxis is used (9,10). Guidelines recommend dual prophylaxis for patients with a high risk of getting postoperative VTE (7, 8). There was a need for further studies regarding

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the selection of cancer patients for thromboprophylaxis. Several studies comparing prophylaxis techniques for VTE incidence have concluded that extended dual prophylaxis is effective (2-4,6,9,11-12). To the best of our knowledge, no research on VTE in gynecological cancer patients getting extended dual prophylaxis has yet been conducted in Turkey.

This current research estimated the incidence of VT and identify risk factors for VTE in patients undergoing surgery for gynecological cancer and receiving extended dual prophylaxis.

Methods

This retrospective cohort analysis included all consecutive patients who had undergone gynecological cancer surgery at Division of Gynecologic Oncology of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine between January 2008 and April 2018. The clinical Research Ethics Committee of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine approved the study in accordance with the Declaration of Helsinki (approval number: A-51, date: 08.05.2018). The collected data consisted of age, body mass index (BMI), menopausal status, comorbidities, the primary gynecologic site of the tumor, surgical details (open/laparoscopy, upper abdominal surgery, pelvic and paraaortic lymphadenectomy, inguinal lymphadenectomy), the need for intensive care unit, and postoperative complications (surgical site infection, wound dehiscence, fistula formation, sepsis, acute renal failure, cardiac arrest, DVT and PE, smoking, and follow-up evaluations until one month after surgery. Since 2008, our division has been used extended dual prophylaxis. All patients received combined thromboprophylaxis with compression anti-embolic stock, initiated at the induction of anesthesia, and LMWH (1 mg/kg/day, maximum: 100 mg), which began 12 h before surgery and 8 h after surgery and continued until hospital discharge. All surgical patients received 28 days of extended prophylaxis consisting of stocks and LMWH. All patients provided their written informed consent.

The inclusion criteria included patients who had gynecologic cancer surgery. Patients lacking data and those who did not receive extended double thromboprophylaxis were excluded, as were pregnant patients and those receiving preoperative prophylaxis and anticoagulation therapies.

The primary objective of the study was the occurrence of VTE, defined as DVT or PE or both, confirmed by imaging [a positive duplex ultrasound, venogram, or computed tomography (CT) scan for DVT, and a positive CT examination, pulmonary arteriogram, or CT angiogram for PE] within 30 days of surgery.

The paper was created under the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) standard (10).

Statistical Analysis

SPSS 18.0 for Windows was used to make a statistical study (SPSS Inc., Chicago, IL, USA). The descriptive statistics of the data used mean, standard deviation (SD), median, minimum, maximum, frequency, and ratio values. Using the Kolmogorov-Smirnov test, the distribution of the factors was assessed. The chi-square test was used for categorical variables, and regularly distributed continuous variables, and the Student's t-test was applied. The link between VTE and variables was analyzed using the Sperman correlation method. Additionally, logistic regression analyses were carried out to find the potential predictors of VTE onset. We evaluated the model's structure with and without each factor to avoid multi-collinearity. To control for any confounding effects, we used correlation tests with regression variables. The results were presented as odds ratios (ORs) with 95% confidence intervals (95% CI). The p-value of all tests was calculated as two-tailed with a 95% CI and significance at <0.05.

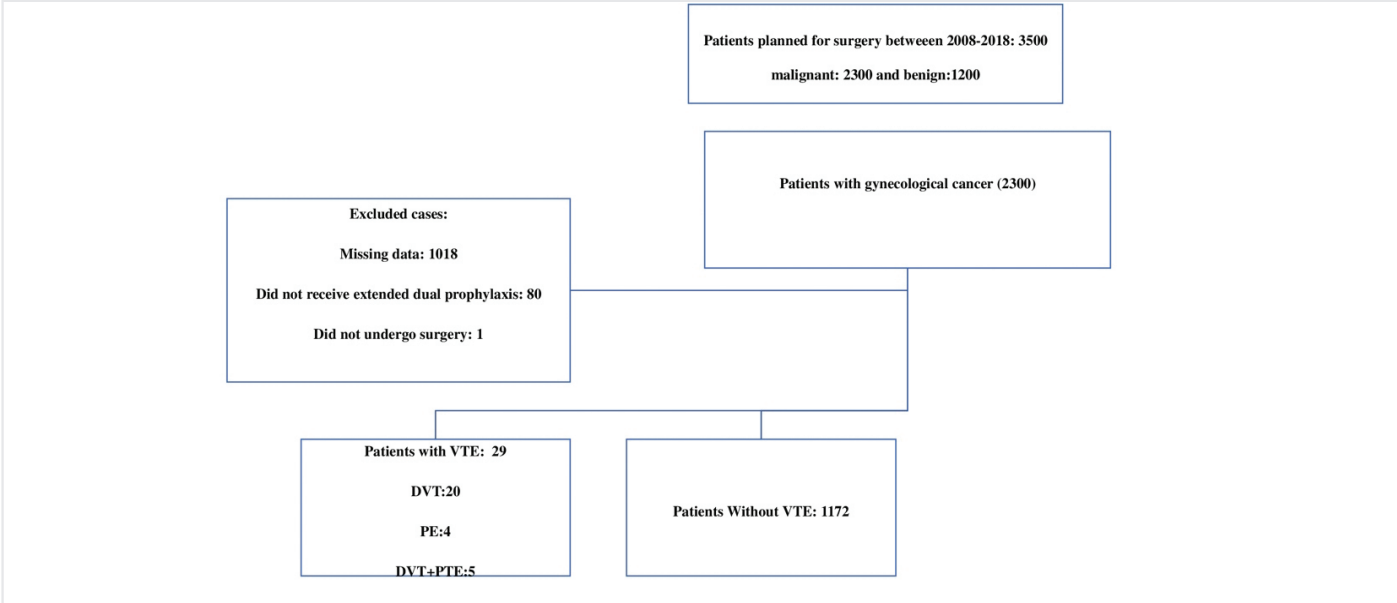

Figure 1. Flowchart diagram of the study
VTE: Venous thromboembolism, DVT: Deep venous thromboembolism, PE: Pulmonary embolism

Table 1. Patient demographic features

Variable	VTE group, (n=29) (DVT: 20.69.0%, PTE: 413.8%)	Non-VTE group, (n=1172)	Total, (n=1201)	p
Age, years	56.76±12.29	54.20±13.92	54.26±13.88 (13-92)	0.327
BMI, kg/m^2	**38.02±20.12**	28.85±7.62	29.04±8.25 (15.22-132.33)	0.021*
>25	**25 (86.2%)**	744 (63.5%)	769 (64.0%)	0.011*
>30	**19 (65.5%)**	424 (36.2%)	443(36.9%)	0.001*
Smoking	**16 (55.2%)**	224 (19.1 %)	240 (20.0%)	0.001*
Prior VTE history	**2 (6.9%)**	3 (0.3%)	5 (0.4%)	0.001*
Neoadjuvant chemotherapy	**7 (20.1%)**	1 (0.1%)	7	0.001*
The type of gynecological cancer	1 (3.4%)	28 (2.4%)	29 (2.4%)	0.848
Vulvar	3 (10.3%)	191 (16.3%)	194 (16.2 %)	
Cervix/vagina uterine	11 (37.9%)	479 (40.9%)	490 (40.8%)	
The ovary gestational	14 (48.3%)	470 (40.1%)	484 (40.3 %)	
Trophoblastic neoplasm	0	4 (0.3%)	4 (0.3%)	
Type of surgery laparoscopic open	6 (20.7%) 23 (79.3%)	179 (15.3%) 993(84.7%)	185 (15.4%) 1016 (84.6 %)	0.425
Duration of surgery, min	171.38±68.63	116.48±48.77	117.81±50.02 (30-420)	0.001*
Hospitalization duration, days	10.93±5.33	9.29±6.74	9.33±6.72 (1-95)	0.194

VTE: Venous thromboembolism, DVT: Deep venous thromboembolism, PE: Pulmonary embolism

Results

Postoperatively, 29 (DVT=20, PE=4, DVT + PE=5) of the 1,201 patients analyzed experienced VTE (DVT: 20, PTE: 4, DVT + PE: 5), for an incidence rate of 2.4%. Figure 1 shows a flowchart for the study. We divided the patients who underwent analysis into two groups: Group 1 is the VTE group, and Group 2 does not have VTE. The patients were evaluated in Tables 1, 2. The population characteristics are outlined in Table 1. The mean age was 54.26 (SD:13.8), and the mean BMI was 29.04 (SD: 15.22). We found no significant differences between the groups concerning age and type of gynecological cancer (vulvar: 2.4%, cervix-vagina: 16.2%, uterine=40.8%, ovary: 40.3%, gestational trophoblastic neoplasm: 0.3%), type of surgery (open: 84.6%, laparoscopic: 15.4%); but BMI (38.02+20.12, P= 0.021), smoking (55.2%, p=0.001), prior VTE (6.9%, p=0.001), neoadjuvant chemotherapy (NACT) (20.1%, p=0.001), and operation duration (171.38+68.63, p=0.001) differed in the VTE group statistically significant.

In Table 2, the characteristics of patients with VTE are summarized. 27 of 29 patients had VTE in the first week and 2 in the third week. In Table 3, comorbidities and surgery modalities between the groups were analyzed. Atrial fibrillation (17.2%, p=0.001), congestive heart failure (13.8%, p=0.003), prior VTE history (6.9%, p=0.001), and chronic renal failure (10.3%, p=0.001) were higher in the VTE group. Operation duration >180 min (44.8%, p=0.001), paraaortic lymphadenectomy (44.8%, p=0.042), and total lymphadenectomy (79.3%, p=0.019), postoperative intensive care unit monitorization (27.6%, p=0.001), sepsis (20.7%, p=0.001), postoperative wound infection (20.7%, p=0.001), and postoperative renal failure (13.8%, p=0.001) were found high in the VTE group.

We conducted a logistic regression analysis to determine the variables that might be potential risk factors for VTE (Table 4). The variables found to be significant included BMI >30 (OR: 5,357; 95% CI: 1,833 to 15,654; p=0.002), operation period >180-minute (OR: 5,698; 95% CI: 1,971 to 16,474; p=0.001), Paraaortic and pelvic lymphadenectomy (OR: 0.252; 95% CI: 0.068 to 0.933; p=0.039), NACT (OR: 0.002; 95% CI:0.001 to 0.025; p=0.001), smoking (OR: 0.217; 95% CI: 0.082 to 0.577; p=0.002), and chronic renal failure (OR: 0.033; 95% CI: 0.003 to 0.379; p=0.006).

Discussion

VTE is the second major factor for mortality in women with gynecologic cancer who received surgery. DVT risk and PE prevalence were calculated to be 17-40% and 1-26%, respectively, in this population of women. International guidelines, including those from the ACCP5 and ASCO, recommend combined mechanical and pharmacological thromboprophylaxis for most cancer patients undergoing abdominal and pelvic surgery (7,8). In a study, Corr et al. (9) used the Caprini Risk Assessment Model to give each patient a Caprini score to clarify the operation's complexity. Seventy-six percent of benign and 96.3% of malignant patients were categorized as high risk and were administered extended dual prophylaxis. Their investigation showed that extended dual prophylaxis significantly decreased the VTE rate from 6.7% to 2.7% (9). Additionally, a meta-analysis of 16 trials demonstrated that preoperative pharmacologic thromboprophylaxis reduces the risk of VTE in the perioperative phase for major gynecologic oncology surgery by about 40% when combined with mechanical prophylaxis (intra-operative and postoperative sequential compression devices) (11). In this study, independently of the Caprini Risk Assessment Model, all cancer patients

Table 2. Patient with VTE characteristics

Patients	Age	Weight	BMI (kg/m²)	Primary malignancy site	Open/ laparoscopic	Operation duration (minute)	Lymphadenectomy	Neoadjuvant chemotherapy	Other primary malignancy	Smoking	Chronic renal failure	Hospitalization (day)	Postoperative diagnosis time of the VTE event (day)
1	63	138	52	The ovary	Open	210	No	No	No	No	No	12	1st day
2	49	74	29	Uterus	Open	110	Yes	No	No	No	No	6	2nd day
3	38	120	41	Uterus	Laparoscopy	155	Yes	No	No	No	No	15	1st day
4	59	100	40	Uterus	Laparoscopy	120	Yes	No	No	No	No	7	2nd day
5	60	94	39	Uterus	Laparoscopy	120	Yes	No	No	No	No	8	2nd day
6	49	93	33	The ovary	Open	120	Yes	No	No	No	No	3	5th day
7	51	102	35	Cervix	Open	300	No	No	No	No	No	15	2nd day
8	53	63	26	The ovary	Open	180	No	Yes	No	No	No	18	3rd day
9	49	78	34	Uterus	Open	55	Yes	No	No	No	No	10	2nd day
10	49	90	35	Cervix	Open	120	Yes	No	No	No	Yes	5	1st day
11	56	170	80	Uterus	Laparoscopy	170	Yes	No	No	No	No	13	1st day
12	63	85	30	The ovary	Open	180	Yes	Yes	No	No	No	20	3rd day
13	61	65	27	The ovary	Open	280	Yes	Yes	No	No	No	12	2nd day
14	75	60	23	The ovary	Laparoscopy	170	Yes	Yes	No	Yes	No	7	1st day
15	85	51	20	The ovary	Open	180	No	No	No	Yes	No	7	1st day
16	70	104	39	Uterus	Open	180	Yes	No	No	Yes	No	8	1st day
17	51	107	44	Uterus	Open	120	Yes	No	No	Yes	No	6	2nd day
18	28	80	30	The ovary	Open	240	Yes	No	No	Yes	No	6	14th day
19	42	98	45	Cervix	Open	200	Yes	No	No	Yes	No	8	3rd day
20	63	55	21	The ovary	Open	160	Yes	Yes	No	Yes	No	12	2nd day
21	58	56	20	Uterus	Open	160	Yes	No	Yes	Yes	No	6	1st day
22	38	74	28	The ovary	Open	160	Yes	No	No	Yes	No	13	2nd day
23	63	119	52	The ovary	Open	240	Yes	Yes	No	Yes	No	7	1st day
24	73	64	26	The ovary	Open	120	No	Yes	No	Yes	Yes	8	1st day
25	73	89	35	Uterus	Open	250	Yes	No	No	Yes	No	7	18th day
26	66	65	25	The vulva	Open	360	No	No	Yes	Yes	Yes	21	2nd day
27	52	85	31	The ovary	Open	180	Yes	No	No	Yes	No	17	3rd day
28	57	160	62	The ovary	Open	120	Yes	Yes	No	Yes	No	22	5th day
29	52	98	39	Uterus	Laparoscopy	90	Yes	No	Yes	Yes	No	18	1st day

VTE: Venous thromboembolism, BMI: Body mass index

Table 3. Comorbidities and surgery modalities

Variable	VTE group, (n=29)	Non-VTE group, (n=1172)	Total	p
Comorbidities				
None	15 (51.7%)	649 (55.4%)	664 (55.3%)	0.919
1	9 (31.0%)	328 (28.0%)	337 (28.1%)	
≥2	5 (17.2%)	195 (16.6%)	200 (16.7%)	
Hypertension	10 (34.5%)	367 (31.3%)	377 (31.4%)	0.690
Diabetes	4 (13.8%)	129 (11.0%)	133 (11.1%)	0.553
Coronary artery disease	8 (27.6%)	92 (7.8%)	100 (8.3%)	0.002*
Atrial fibrillation	5 (17.2%)	16 (1.4%)	21 (1.7%)	0.001*
Congestive heart failure	4 (13.8%)	23 (2.0%)	27 (2.2%)	0.003*
Hipothroidism	2 (6.9 %)	64 (5.5%)	66 (5.5%)	0.481
Prior VTE history	2 (6.9%)	3 (0.3%)	5 (0.4%)	0.001*
Chronic renal failure	3 (10.3%)	3 (0.3%)	6 (0.5%)	0.001*
Operation duration, >180 minutes	13 (44.8%)	156 (13.3%)	169 (14.1%)	0.001*
Pelvic lymphadenectomy	15 (51.7%)	668 (57.0%)	683 (56.9%)	0.571
Paraaortic lymphadenectomy	13 (44.8%)	329 (28.1%)	339 (28.2%)	0.042*
Pelvic + paraaortic lymphadenectomy	23(79.3%)	674 (57.5%)	697 (58.0%)	0.019*
Type of surgery				
Laparoscopic	6 (20.7%)	179 (15.3%)	185 (15.45%)	0.425
Open	23 (79.3%)	993 (84.7%)	1,016 (84.6%)	
Intensive care unit yes	8 (27.6%)	58 (4.9%)	66 (5.5 %)	0.001*
Sepsis yes	6 (20.7%)	9 (0.8%)	15 (1.2%)	0.001*
Postoperative wound infection	6 (20.7%)	14 (1.2%)	20 (1.7 %)	0.001*
Postoperative renal failure	4 (13.8 %)	6 (0.5 %)	10 (0.8 %)	0.001*

VTE: Venous thromboembolism

Table 4. Logistic regression analysis of predictive factors of VTE

Risk factors for VTE	Sperman's correlations (r;p)	Logistic regression analysis	
		OR (95% CI)	p-value
BMI >30	0.001; 0.093	5,357 (1,833-15,654)	0.002*
Operation duration, >180 minutes	0.001; 0.139	5,698 (1,971-16,474)	0.001*
Lymphadenectomy	0.019; 0.068	0.252 (0.068-0.933)	0.039*
Neoadjuvant chemotherapy	0.001; 0.415	0.002 (0.001-0.025)	0.001*
Intensive care unit	0.001; 0.152	0.851 (0.851-0.168)	0.845
Smoking	0.001; 0.138	0.217 (0.082- 0.577)	0.002*
Chronic renal failure	0.001; 0.220	0.033 (0.003-0.379)	0.006*
Prior VTE	0.001; 0.158	0.086 (0.002-3.261)	0.186
Coronary artery disease	0.001; 0.110	0.479 (0.118-1.947)	0.304
Atrial fibrillation	0.001; 0.186	0.119 (0.011-1.258)	0.077
Chronic heart failure	0.001; 0.123	0.873 (0.058-13.230)	0.922

VTE: Venous thromboembolism, BMI: Body mass index

received preoperative LMWH and extended dual thromboprophylaxis, and the incidence of VTE was 2.4%.

Race, age, BMI, ascites, comorbidities, major complications, operating hours, upper abdominal surgery, NACT, ovarian cancer, and lymphadenectomy were all recently found to be risk factors for VTE in patients undergoing laparotomy for gynecological cancers with extended prophylaxis (4). The duration of an operation, disseminated disease, and ovarian cancer were found to be independent risk factors (4). Similarly, we found that chronic renal failure, smoking, lymphadenectomy, NACT, a BMI greater than 30, and operations lasting more than 180 min are all predictors of VTE. Smoking and other primary cancers were among the different risk variables we identified.

The incidence of VTE in gynecologic cancer patients undergoing laparoscopy ranges from 0.5% to 1.2% on average (13). According to Bouchard-Fortier et al. study, only two of 352 individuals receiving laparoscopy for gynecologic cancer without VTE prophylaxis (anticoagulation or compression devices) experienced VTE (14). However, a recent retrospective study found that 11.55% of 355 patients who received gynecological laparoscopic surgery experienced postoperative DVT. This research identified age, hypertension, D-dimer level, surgery duration, intraoperative pneumoperitoneum, and length of hospital stay as significant risk variables (15). We were unable to establish a link between the form of surgery (open versus laparoscopic) and VTE. In this study, 185 patients received dual extended prophylaxis and underwent laparoscopic surgery at a rate of 15.4%. Six (3.2%) were diagnosed with VTE. Five of the six individuals had a BMI greater than 39. Each patient should be evaluated individually because, despite having undergone a laparoscopy, they may still be at risk for VTE for other reasons.

Study Limitations

The study's strengths include its big sample size from a single center where the same gynecologic oncology surgeons worked throughout the research and surgical procedures were standardized. A hospital-based retrospective cohort from a prominent referral hospital in the most populous city is a limitation of this study.

Conclusion

Morbid obesity, prolonged surgery duration, lymphadenectomy, neoadjuvant chemotherapy, smoking, and chronic renal failure were independently associated with the risk of postoperative VTE in patients getting extended dual thromboprophylaxis for gynecological cancer surgery. To obtain the lowest possible incidence of VTE in this population, we propose that all patients undergoing gynecological oncology surgery receive preoperative pharmacologic and postoperative extended dual prophylaxis.

Ethics Committee Approval: The Clinical Research Ethics Committee of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine approved the study in accordance with the Declaration of Helsinki (approval number: A-51, date: 08.05.2018).

Informed Consent: Written informed consent was obtained from all the subjects.

Peer-review: Externally peer-reviewed.

Authorship Contributions: Surgical and Medical Practices - H.T., İ.K., U.A., K.H.C., T.B., M.A., F.D.; Concept - H.T., İ.K., F.D.; Design - H.T., İ.K., T.B., M.A., F.D.; Data Collection or Processing - U.A., K.H.C.; Analysis or Interpretation - H.T., U.A., K.H.C., F.D.; Literature Search - H.T., U.A., K.H.C.; Writing - H.T., İ.K., T.B., M.A., F.D.

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