



· 论 著 ·

早期卵巢癌（I C~II A）患者腹主动脉旁淋巴结清扫术对预后影响的临床分析

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【摘要】 背景与目的: 卵巢癌是妇科恶性肿瘤中死亡率最高的恶性肿瘤。对于早期卵巢癌患者来说, 系统性腹主动脉旁淋巴结清扫术可以为病理学分期提供准确的信息, 但是能否改善患者预后一直是个有争议的问题。探讨腹主动脉旁淋巴结清扫术对早期卵巢癌患者预后的影响。方法: 回顾性收集复旦大学附属肿瘤医院妇瘤科2001年—2019年的246例早期卵巢癌 [国际妇产科联盟 (International Federation of Gynecology and Obstetrics, FIGO) 分期 I C~II A期] 患者的临床资料, 根据患者是否进行系统性淋巴结清扫, 将患者分为病理学分期组和临床分期组, 采用Kaplan-Meier法计算生存率, 对数秩检验进行生存分析, 并进行了多因素分析来探讨可能影响预后的相关因素。同时, 采用 t 检验比较病理学分期组和临床分期组的平均手术时间、平均住院时间及术中出血量, 以探讨腹主动脉旁淋巴结清扫术的应用对患者术后并发症的影响。结果: 两组患者的基本临床特征差异无统计学意义, 病理学分期组的3、5、10年总生存率分别为91.87%、80.77%和45.45%, 临床分期组的3、5、10年总生存率分别为90.91%、81.43%和42.86% ($P>0.05$)。病理学分期组的平均总生存期为151个月, 临床分期组为165个月, 两组间的差异无统计学意义 ($P=0.184$)。临床分期组的中位无进展生存期为122个月, 病理学分期组的中位无进展生存期为88个月, 两组的无进展生存期差异无统计学意义 ($P=0.194$)。所有患者术后均接受了以铂类药物为基础的辅助化疗, 其中使用卡铂+紫杉醇方案化疗6个疗程的患者最多 (103/246, 41.87%), 化疗疗程的中位数为6。随访中, 共有85例发生了复发转移, 其中发生在盆腔及腹腔的转移最多, 有78例 (78/85, 91.76%); 此外, 病理学分期组中有2例 (2/47, 4.26%)、临床分期组中有3例 (3/38, 7.89%) 发生了腹膜后淋巴结转移, 两组间差异无统计学意义。而病理学分期组的平均手术时间明显长于临床分期组 ($P<0.01$), 且病理学分期组的平均住院时间也明显长于临床分期组 ($P=0.016$)。病理学分期组有4例发生术后并发症 (4/123, 3.25%), 而临床分期组仅有1例发生了术后并发症 (1/123, 0.81%)。多因素分析显示, FIGO分期是总生存期的独立预测因子, 肿瘤的组织学分级是无进展生存期和总生存期的独立预测因子, 而淋巴结清扫术与无进展生存期及总生存期均无关。结论: 系统性腹主动脉旁淋巴结清扫对早期卵巢癌患者的预后没有改善, 相反延长了手术时间, 增加了手术风险。

【关键词】 卵巢癌; 淋巴结清扫; 预后

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Potential role of lymphadenectomy in patients with ovarian cancer (I C~II A): a retrospective trial LEI Yajie^{1#}, GAO Yi^{2#}, WANG Zhijie², CHENG Xi^{1, 3}, YANG Yufei¹, ZHOU Hongyu¹, CHEN Lihua³, CHEN Yixin¹, LI Haoran¹, LI Ziting¹, WU Xiaohua¹ (1. Department of Gynecological Oncology, Fudan University Shanghai Cancer Center, Department of Oncology, Shanghai Medical College, Fudan University, Shanghai 200032, China; 2. Shanghai Eighth People's Hospital, Shanghai 200235, China; 3. Department of Gynecological Oncology, Minhang Branch of Fudan University Shanghai Cancer Center, Shanghai 200240, China;)

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[Abstract] Background and purpose: Ovarian cancer is the most common cause of death in gynecological malignancy. For patients in the early stage, the value of lymphadenectomy remains a question. This study demonstrated the relationship between lymphadenectomy and the progression-free survival outcomes of patients with early stage ovarian cancer. **Methods:** The information of 246 patients with International Federation of Gynecology and Obstetrics (FIGO) stage I C- II A ovarian cancer treated from 2001 to 2019 was collected from Fudan University Shanghai Cancer Center. The patients were divided into two groups according to the type of surgery, the pathological staging group ($n=123$) and the clinical staging group ($n=123$). And survival analysis was performed to evaluate the prognosis of patients. Multivariable regression analysis was conducted to explore the association between overall survival (OS) or progression-free survival and other variables. Meanwhile, t -test was used to compare the average operative duration, average hospitalization and the average blood loss between the pathological staging group and the clinical staging group, to explore the effect of lymphadenectomy on postoperative complications. **Results:** There was no significant difference in the clinical characteristics between the two groups. The 3-year, 5-year and 10-year OS rates were 91.78%, 80.77% and 45.45% in pathological staging group, and were 90.91%, 81.43% and 42.86% in the clinical staging group, respectively. Kaplan-Meier method and log-rank test demonstrated that there was no significant difference in progression-free survival ($P=0.194$) and OS ($P=0.184$) between these two groups. All patients received platinum-based adjuvant chemotherapy. The patients who received CBP+taxol for 6 courses were the most (103/246, 41.87%), and the median course of chemotherapy was 6. A total of 85 patients developed recurrent metastasis, and 78 (78/85, 91.76%) of them had metastasis in the pelvic and peritoneal cavity. During the follow-up of the patients in the pathological staging group, we found two patients with retroperitoneal lymph node metastasis while there were 3 patients in clinical staging group. Furthermore, the median operating time was longer in the pathological staging group than in clinical staging group ($P<0.001$). And the mean time of hospitalization was also significantly longer in the pathological staging group than in clinical staging group ($P=0.016$). Four patients in the pathological staging group developed postoperative complications (4/123, 3.25%), whereas only one patient in the clinical staging group developed postoperative complications (1/123, 0.81%). In the multivariate analysis model, we found that the FIGO stage was an independent predictive factor for OS, while the grade of tumor was an independent prognostic factor for both progression-free survival and OS. Lymphadenectomy was not associated with progression-free survival and OS. **Conclusion:** The use of lymphadenectomy did not improve the prognosis of patients. Moreover, it may increase the risk of postoperative complications due to its prolonged operating time.

[Key words] Ovarian cancer; Lymphadenectomy; Prognosis

卵巢癌高居女性生殖道恶性肿瘤死亡率的首位^[1-3]。在早期卵巢癌的治疗中,初次手术发挥着至关重要的作用^[4]。在长期的临床实践中,关于早期卵巢癌的手术范围是否需要在子宫、卵巢、大网膜切除的基础上做系统性腹主动脉旁淋巴结清扫一直是一个有争议的问题^[5-7]。近年来,Harter等^[8]报道了一项关于晚期卵巢癌的前瞻性随机对照试验,其结果显示,进行系统性淋巴结清扫的患者尽管发现并切除了更多的淋巴结转移病灶,然而与未清扫的患者比较生存差异并无统计学意义。不仅如此,进行了淋巴结清扫的患者发生并发症的比例明显升高。因此,本研究拟通过回顾性临床资料分析,初步探讨术后均接受了辅助化疗的国际妇产科联盟(International Federation of Gynecology and Obstetrics, FIGO)分期 I C~II A 的早期卵巢癌手术患者,通过术前的影像学检查和术中探查是否有可疑的腹膜后淋

巴结转移,判定系统性腹主动脉旁淋巴结清扫手术的临床价值。

1 资料和方法

1.1 一般资料

本研究回顾性收集了2001年3月—2019年9月在复旦大学附属肿瘤医院就诊的卵巢癌患者7 005例,其中分期为FIGO(2014年修订版)^[9]

I C~II A 的患者共276例,排除术后未接受辅助化疗的患者4例,为了平衡两组患者的临床特征排除26例,最终246例患者纳入分析病例。根据患者初次手术中是否接受腹膜后淋巴结切除术分为两组:一组为术式中包括腹主动脉旁淋巴结清扫术的病理学分期组123例;另一组为术中未行淋巴结清扫术的临床分期组123例,包括根据术前影像学检查未提示腹膜后淋巴结转移,和(或)术中探查腹膜后淋巴结未及可疑肿大淋巴结的患者。患

者纳入排除的流程见图1。病理学分期组中同时排除了清扫术后病理升级的患者。其中, FIGO分期为I c期: 肿瘤局限在一侧或双侧卵巢/输卵管且术

中发生肿瘤包膜破裂, 或腹水/腹腔洗液中发现有恶性肿瘤细胞; FIGO分期为II a期: 肿瘤侵犯盆腔, 但局限于子宫/输卵管/卵巢。

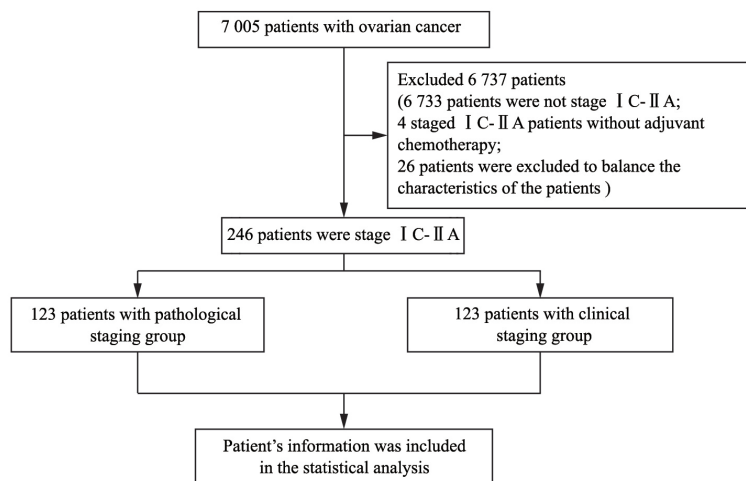


图1 患者的入排流程图

Fig. 1 Patient flow chart

All patients had a definite pathological diagnosis of primary ovarian cancer and had no other treatment before surgery. All patients were diagnosed with primary ovarian cancer of FIGO stage I C to II A. According to the collected clinical information (the type of the surgery), the patients were divided into two groups, 123 patients in the pathological staging group and 123 patients in the clinical staging group

1.2 观察指标

年龄、分期、CA125水平、手术方式、手术时间、术中出血量、住院时间、病理学类型、组织学分级、术后辅助治疗、并发症、复发转移部位、随访时患者的生存情况。

1.3 随访

通过电话及门诊复查相结合的方式对患者进行随访, 了解患者的生存情况。以患者手术日期作为观察生存率的时间起点, 随访截至2020年9月或患者死亡, 全部患者的随访时间为1~195个月(中位随访时间40个月)。

1.4 统计学处理

采用SPSS 25.0的统计软件进行统计学分析, 采用Kaplan-Meier法计算生存率, 对数秩检验(log-rank test)进行单因素分析, 多因素分析采用Cox回归模型。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 患者的基本信息

纳入研究的246例FIGO I C~II A期卵巢癌

患者的基本信息见表1。病理学分期组和临床分期组的中位年龄分别为49和52岁; 病理学分期组患者FIGO分期为I C期的占78.9%, II A期占21.1%, 而临床分期组中I C期占76.4%, II A期占23.6%; 两组患者在手术结束后的随访期内出现复发转移的比率分别为38.2%和30.9%。

表1 246例早期卵巢癌患者的临床资料

Tab. 1 Clinicopathological characteristics of 246 early-stage ovarian cancer patients

Characteristics	Pathological staging group (n=123)	Clinical staging group (n=123)	P value
Median age/year	49 (12-67)	52 (15-72)	0.612
Differentiation n(%)			0.670
Low	39 (31.7)	38 (30.9)	
Moderate	54 (43.9)	49 (39.8)	
High	30 (24.4)	36 (29.3)	
Pathological type n(%)			0.724
Epithelial	105 (85.4)	103 (83.7)	
Non-epithelial	18 (14.6)	20 (16.3)	
FIGO stage n(%)			0.646
I C	97 (78.9)	94 (76.4)	
II A	26 (21.1)	29 (23.6)	
Metastasis after surgery	47 (38.2)	38 (30.9)	0.228

在发生复发转移的85例患者中，有78例（78/85，91.76%）患者发生了盆腔及腹腔转移，其中发生在盆腔有53例（53/78，67.95%），其次为消化道4例（4/78，5.13%），在行淋巴结清扫的病理学分期组，有2例（2/47，4.26%）发生腹膜后淋巴结转移，而在未行淋巴结清扫的临床分期组中，有3例（3/38，7.89%）发生腹膜后淋巴结转移，且此3例患者均发生腹主动脉旁淋巴结转移；另有7例（7/85，8.24%）患者发生了远处转移，包括3例肺转移，2例骨转移，1例胸膜转移和1例颅内转移。

纳入研究的所有患者术后均接受了以铂类药物为基础的辅助化疗，在208例上皮性卵巢癌患者中，11例患者接受了以顺铂为基础的化疗方案，192例患者接受以卡铂为基础的化疗方案，5例患者接受以洛铂或奥沙利铂为基础的化疗方案；在所有的化疗方案中，使用卡铂+紫杉醇方案化疗6个疗程的患者数量最多，共103例（103/208，49.5%）其次是卡铂+紫杉醇方案化疗4个疗程的患者共21例（21/208，10.1%）。非上皮性卵巢癌患者共38例，其病理学类型主要为生殖细胞瘤，28例患者（28/38，73.7%）接受了

博来霉素+依托泊苷+顺铂的化疗方案，5例患者（5/38，13.2%）接受了博来霉素+长春新碱+顺铂的化疗方案，另有3例患者（3/38，7.9%）接受了卡铂+紫杉醇的化疗方案。化疗疗程的中位数为6（3~8）。

总体而言，两组患者的年龄（ $P=0.612$ ）、组织学分级（ $P=0.670$ ），病理学分型（ $P=0.724$ ）、FIGO分期（ $P=0.646$ ）及术后复发转移情况（ $P=0.228$ ）差异均无统计学意义。

2.2 生存分析

病理学分期组的3、5、10年总生存率分别为91.87%、80.77%和45.45%，临床分期组的3、5、10年总生存率分别为90.91%、81.43%和42.86%。病理学分期组的中位无进展生存期为88（95% CI: 64.4~111.6）个月，临床分期组的中位无进展生存期为122（95% CI: 61.1~182.9）个月，两组的无进展生存期差异无统计学意义（ $P=0.194$ ，图2A）。病理学分期组的平均总生存期为151（95% CI: 136.8~165.2）个月，临床分期组的平均总生存期为165.3（95% CI: 146.2~184.4）个月，两组差异无统计学意义（ $P=0.184$ ，图2B），因分析结果两组患者均未达到中位总生存期，因此采用平均总生存期进行分析。

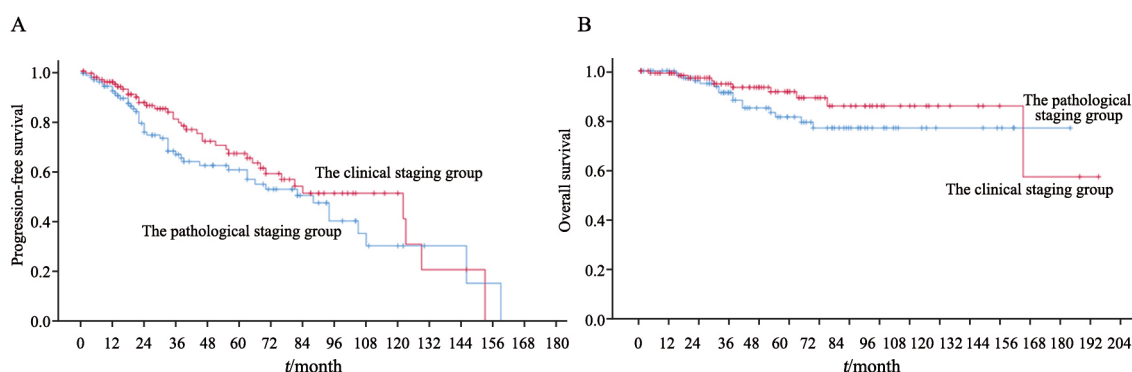


图2 病理学分期组与临床分期组无进展生存期及总生存期的比较

Fig. 2 Comparison of progression-free survival and overall survival between pathological staging group and clinical staging group

A: Progression-free survival according to the pathological staging group or the clinical staging group ($P=0.194$). B: Overall survival according to the pathological staging group or the clinical staging group ($P=0.184$)

2.3 多因素分析

多变量的回归分析总结见表2。统计学分析结果显示，FIGO分期为I C、II A与无进展生存期无关（ $P=0.126$ ，HR=1.839，95% CI: 0.84~4.01），但它是总生存期的独立预测因子（ $P=0.009$ ，

HR=1.877，95% CI: 1.17~3.02）。肿瘤的组织学分级对于无进展生存期（ $P<0.001$ ，HR=2.881，95% CI: 1.70~4.89）和总生存期（ $P=0.014$ ，HR=1.415，95% CI: 1.07~1.87）都是独立预测因子。淋巴结清扫术与无进展生存期（ $P=0.716$ ，

HR=1.142, 95% CI: 0.56~2.33) 及总生存期 ($P=0.116$, HR=1.395, 95% CI: 0.92~2.11) 均无关。除此之外, 我们还发现病理学分期组与临床分期组的平均手术时间分别为115.1和75.4 min, 病理学分期组的平均手术时间明显长于临床分期组 ($P<0.001$); 病理学分期组与临床分期组的平均住院时间分别为6.66和5.40 d,

病理学分期组的平均住院时间长于临床分期组 ($P=0.016$); 两组的术中出血量差异无统计学意义 ($P=0.664$)。病理学分期组有4例患者 (4/123, 3.25%) 发生术后并发症, 包括1例术后肠梗阻和3例术后感染; 而临床分期组仅有1例患者 (1/123, 0.81%) 发生术后并发症, 为术后出血 (表3)。

表2 早期卵巢癌患者的无进展生存率与总生存率的多因素分析

Tab. 2 Multivariate analysis of PFS and OS

Item	PFS			OS		
	<i>P</i> value	HR	95% CI	<i>P</i> value	HR	95% CI
Group	0.716	1.142	0.56-2.33	0.116	1.395	0.92-2.11
FIGO stage (I C-II A)	0.126	1.839	0.84-4.01	0.009	1.877	1.17-3.02
Grade	0.000	2.881	1.70-4.89	0.014	1.415	1.07-1.87
Histology	0.281	0.886	0.71-1.10	0.124	0.892	0.77-1.03

PFS: Progression-free survival; OS: Overall survival

表3 病理学分期组与临床分期组术中情况及术后并发症的比较

Tab. 3 Comparison of intraoperative and postoperative complications between the pathological staging group and the clinical staging group

Item	Pathological staging group	Clinical staging group	<i>P</i> value
The average operative duration <i>t</i> /min	115.10	75.40	0.001
The average blood loss <i>V</i> /mL	234.80	215.80	0.664
The mean time of hospitalization <i>t</i> /d	6.66	5.40	0.016
The postoperative complications <i>n</i> (%)	4 (3.25)	1 (0.81)	0.184

3 讨 论

尽管系统性腹主动脉旁淋巴结清扫术是准确判断淋巴结是否转移, 从而进行TNM分期的重要手段, 但是否能够改善患者的预后是一个非常值得探讨的问题。在本研究中, 我们发现腹主动脉旁淋巴结清扫并不能提高I C~II A期卵巢癌患者的生存率, 接受淋巴结清扫术的患者其无进展生存期与未接受淋巴结清扫术的患者无明显差异。不仅如此, 腹主动脉旁淋巴结清扫术延长了手术时间和住院时间, 增加了手术并发症发生率^[10]。我们推测, 对于没有临床影像学 and 术中探查可疑淋巴结转移从而未接受腹主动脉旁淋巴结清扫的临床分期组患者, 即使有少部分存在镜下转移的淋巴结, 也可能通过术后的辅助化疗被消除, 从而使得两组间的无进展生存期差异无统计学意义。随着近年来影像学检查方法如PET/CT等的广泛运用, 可以更好地帮助医师诊断术

前淋巴结转移, 从而为患者精准地选择恰当的手术方式, 避免不必要的腹主动脉旁淋巴结清扫可能带来的一系列并发症, 如淋巴瘘、大血管损伤导致的大出血、淋巴囊肿伴感染、下肢水肿等。

既往有研究显示系统性腹主动脉旁淋巴结清扫术与早期卵巢癌患者的预后相关^[11-13]。John等^[14]报道了一项纳入6 000多例患者的回顾性分析, 认为淋巴结清扫术使FIGO分期为I期的患者的5年生存率从87.0%提高到92.6% ($P<0.001$), 但此回顾性数据库分析混杂因素较多, 缺乏患者后续治疗方案等详细资料。Chan等^[15]也报道了在1988—1992年、1993—1997年和1998—2001年共3个时间段内, 卵巢癌患者的总生存率呈逐渐上升趋势 (86.1%、87.2%和88.8%, $P=0.076$), 虽然随着时间推移, 淋巴结切除术的使用增加, 但在接受淋巴结切除术分期的患者中, 3个时期的生存率没有改善 (93.2%、93.5%和93.1%; $P=0.978$);

但淋巴结清扫术仍是影响患者预后的独立危险因素。

与此相反,一些研究也报道了淋巴结清扫术与患者的预后并无相关性。Zhou等^[16]的研究结果提示,淋巴结清扫术可能提高早期卵巢癌患者的总生存率,但与无进展生存期无关。Maggioni等^[17]进行的一项随机研究的结果则显示,在FIGO I~II期的卵巢癌患者中,系统性淋巴结清扫术与患者的总生存期和无进展生存期均无关,并且淋巴结清扫组的中位手术时间更长($P=0.001$),需要输血的患者更多($P=0.012$)。

对于晚期的卵巢癌,Harter等^[8]的多中心前瞻性随机对照临床试验结果已证实了系统性淋巴结清扫不能改善患者预后,相反严重并发症的比例明显升高($P=0.01$)。我们认为可能与辅助治疗可以最大程度地消灭镜下癌灶有关。

本研究中,尽管两组患者的基本临床特征差异无统计学意义,且患者均进行了术后辅助化疗,但仍然可能有其他潜在的偏倚因素影响患者的生存期。因此,为了明确早期卵巢癌患者能否从淋巴结清扫术中获益,仍然需要进一步的前瞻性随机对照临床试验加以证实。

综上所述,本研究认为系统性淋巴结清扫术不仅不能延长早期卵巢癌患者的无进展生存期,还会增加患者并发症的发生率。因此,对于IC~IIA的早期卵巢癌的患者,如果术前无影像学提示有淋巴结可疑转移,且术中探查无可疑肿大淋巴结,可以不进行系统性腹主动脉旁淋巴结清扫。但此结论仍需要前瞻性临床试验来验证。

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