대한방사선종양학회지 2008;26(1):1~9

Management of Regional Lymph Nodes in Localized Vulvar Carcinoma

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Purpose: To evaluate the impact of postoperative radiotherapy on loco-regional failure in patients with vulvar carcinoma and to determine the treatment strategy for inguinal lymph nodes.
Materials and Methods: Sixty-six patients who received treatment for primary vulvar carcinoma at Seoul National University Hospital, from October 1979 through June 2004, were retrospectively analyzed. Sixteen patients were excluded from the analysis due to the following reasons: distant metastases in two patients; palliative intent for six patients; previous radiotherapy given to the pelvis in three patients; follow-up loss after surgery for four patient; insufficient medical records for one patient. Of 50 eligible patients, 35 were treated with surgery alone (S), ten were treated with surgery followed by radiotherapy (S+RT), and five were treated with radiotherapy alone.
Results: The 5-year overall survival (OS) and disease-free survival (DFS) rates of all patients were 91% and 78%, respectively. Twelve patients (26%) experienced treatment failures and the sites of initial failure were as follows: a primary site in eight patients; regional lymph nodes in three patients; the lung in one patient. Although risk factors for failure were more common in the S+RT group than the S group of patients ($p < 0.05$), the DFS rates were similar for the two groups (5-year DFS rates, 78% vs. 83%, $p=0.66$). The incidences of occult lymph node metastases was 10%. Ten of 31 patients with clinically negative lymph nodes did not received inguinal lymph node dissection, but no patient experienced regional failure.
Conclusion: Postoperative radiotherapy may have a potential benefit for patients with risk factors for failure. The omission of inguinal dissection or elective radiotherapy to the inguinal lymph nodes may be considered in low-risk patients with clinically negative lymph nodes.

Key Words: Vulvar cancer, Lymph node, Radiotherapy, Surgery

Introduction

Vulvar carcinoma is a malignancy of elderly women with a mean age of approximately 70 years old at the time of diagnosis. The incidence of vulvar carcinoma is below 2 per 100,000 women per year in industrialized countries, and approximately 75% of the cases are squamous cell carcinomas according to population-based studies.[1)]

Submitted November 26, 2007, accepted January 15, 2008
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The traditional standard treatment of vulvar carcinoma has been a radical vulvectomy with bilateral inguinal lymph node dissection.[2)] The results of treatment in early stage vulvar carcinoma were excellent, with high rates of local control in the primary site and very low rates of failure in the inguinal areas.[3,4)] However, in patients that were treated with surgery alone, local failure rates range from 10% to 70%, depending on stage.[5,6)] Additionally, radical surgery (especially including inguinal lymph node dissection) is associated with high rates of complications such as wound breakdown, cellulites, and lymphedema.[7~10)] The most frequent sites of failure after radical vulvectomy are the vulva and the inguinal areas.[5,6,11~13)]

Surgico-pathological studies undertaken by the Gynecologic Oncology Group (GOG) have confirmed the importance of the

inguinal lymph node status as predictor for survival.[14] Homesley, *et al.* have demonstrated that postoperative radiotherapy to the pelvis and inguinal lymph node prevents regional failure and thereby improves survival in node-positive patients that have undergone bilateral inguinal lymph node dissection.[15] However, there is still controversy on how to manage the inguinal areas in patients with clinically negative lymph nodes.

The purpose of this study was to evaluate the impact of postoperative radiotherapy on loco-regional failure and to determine a treatment strategy for inguinal lymph nodes in patients with vulvar carcinoma in a single institution experienced over a period of 25 years.

Materials and Methods

1. Patients

The medical records of 66 patients who received a first treatment for primary vulvar carcinoma at Seoul National University Hospital from October 1979 through June 2004 were reviewed retrospectively. Sixteen patients were excluded from the analysis due to the following reasons: distant metastasis in 2 patients palliative intent in 6 patients previous radiotherapy to the pelvis because of cervical cancer in 3 patients, follow-up loss after surgery in 4 patients, and an insufficient medical record in one patient. The remaining 50 patients were included in the study.

Clinical and pathological characteristics of the analyzed patients are summarized in Table 1 and Table 2, respectively. The median age of patients at the time of initial treatment was 60 years (range; 26～89). Histologically, 39 (78%) patients had squamous cell carcinoma. Thirty-seven (74%) tumors were well lateralized, and 40 tumors (80%) were no more than 3 cm in diameter. All tumors were staged according to the 2002 6th American Joint Committee for Cancer Staging,[16] and 30 tumors (60%) were staged clinical T1 and 31 tumors (62%) were staged clinical N0.

Table 1. Clinical Characteristics (n=50)

Characteristic	No. (%)
Age (year)	Median 61 (range; 27～89)
Direction of primary tumor	
Both	13 (26)
Right	19 (38)
Left	18 (36)
Histology	
Squamous cell carcinoma	39 (78)
Adenocarcinoma	5 (10)
Verrucous carcinoma	1 (2)
Basal cell carcinoma	4 (8)
Warty carcinoma	1 (2)
Size	
≤3 cm	40 (80)
>3 cm	10 (20)
Clinical T stage*	
T1	30 (60)
T2	19 (38)
T3	1 (2)
Clinical N stage*	
N0	31 (62)
N1	15 (30)
N2	4 (8)
Treatment	
Surgery alone	35 (70)
Surgery followed by radiotherapy	10 (20)
Radiotherapy alone	5 (10)

*American Joint Committee for Cancer Staging 6th ed.

2. Treatment

Thirty-five (70%) patients were treated with surgery alone, 10 (20%) with surgery followed by postoperative radiotherapy, and 5 (10%) with radiotherapy alone, after an initial biopsy.

Table 2. Pathological Characteristics of the Patients Treated with Surgery (n=50)

Characteristic	No. (%)
Depth of invasion	
≤1 cm	13 (29)
>1 cm	4 (9)
Not available	28 (62)
Differentiation	
Well differentiated	23 (51)
Moderately differentiated	3 (7)
Poorly differentiated	1 (2)
Not available	18 (40)
Resection margin	
Negative	36 (80)
Close (≤8 mm)	2 (4)
Positive	5 (11)
Not available	2 (4)
Pathologic N stage	
NX	9 (28)
N0	27 (54)
N1	7 (14)
N2	2 (4)

As surgery for the primary site, 31 patients (62%) were treated with a radical vulvectomy, 4 patients (9%) with a simple vulvectomy, one patient (2%) with a hemivulvectomy, 3 patients (7%) with wide local excision, and 5 patients (11%) with local excision. One patient (2%) had no surgery for the primary lesion and had only left inguinal lymph node dissection for metastasis of unknown origin (MUO). As surgery for a regional lymph node, 31 patients (69%) were treated with bilateral inguinal lymph node dissection, 5 patients (11%) with ipsilateral inguinal lymph node dissection, and 9 patients (20%) with no lymph node dissection. Eighteen of 19 patients with a clinically positive lymph node had inguinal lymph node dissection and 9 had a pathologically positive lymph node.

Radiotherapy was delivered with 60-Co or 4～15 MV photon to the vulva, bilateral inguinal and pelvic lymph nodes. A parallel-opposed field was mainly used to treat the pelvis and vulva while the inguinal lymph node was covered only by an anterior extended field (whole pelvis and bilateral inguinal lymph node in 11 patients, lower pelvis and bilateral inguinal lymph node in 3 patients and a bilateral inguinal lymph node alone in one patient). Ten of 15 patients also received 6～12 MeV electron (except for one patient who was treated with 4 MV photon) boost radiotherapy to increase the dose to the vulva or to an inguinal lymph node. Referral for postoperative radiotherapy was at the discretion of the surgeons. Indications for postoperative radiotherapy were as follows: (a) positive resection margin after surgery (2 patients); (b) pathological positive inguinal lymph node (6 patients); (c) prophylactic inguinal nodal irradiation (2 patients). The median radiation doses given were as follows: 66.4 Gy (range: 50.75～70.2) to involved site and 50.4 Gy (range: 44.0～50.75) to inguinal lymph node for radiotherapy alone; 50.4 Gy (range: 16.2～64.8) to tumor bed and 50.0 Gy (range: 16.2～50.4) to inguinal lymph node for surgery followed by postoperative radiotherapy. The median duration of radiotherapy was 49 days (range: 11～72). In patients who received postoperative radiotherapy, the median time from surgery to the start of radiotherapy was 48 days (range, 34～101 days). Three patients had incomplete radiotherapy due to the following reasons: severe desquamation in 1 patient; death from neutropeniain 1 patient; and patient's refusal in 1 patient. These 3 patients were excluded from analysis about survival analysis and patterns of failure Of the 15 patients who received radiotherapy, 5 (33%) received concurrent chemotherapy. Of these patients, two received radiotherapy alone and three received surgery followed by postoperative radiotherapy as local treatment modality. The chemotherapeutic agents were 5-fluorouracil and cisplatin.

3. Follow-up and statistical analysis

The data were analyzed with a closeout (study censor) date of 8 April 2007. For 47patients, the median duration of follow-up from the date of initial treatment was 64 months (range; 7～254 months). OS and DFS rates at 5-years were calculated using the Kaplan-Meier method and differences were compared using log-rank tests. Fisher's exact test was used to compare the distribution of various clinical and pathological characteristics. All calculations were performed using the SPSS 12.0.1 for Windows (SPSS Inc. Chicago, IL USA) statistical software package. A level of 0.05 was considered statistically significant.

Results

1. Compliance

Forty-seven (94%) of the analyzed patients received all of the planned treatment. In 10 patients who were treated with surgery followed by postoperative radiotherapy, three patients discontinued treatment. One patient died of neutropenia during the concurrent chemotherapy at 3 months after the initial treatment and the other patients refused further treatment.

2. Survival outcome

OS rates at 5 and 10-years of 47 patients were 91% and 81%, respectively (Fig. 1). By univariate analysis, primary tumor size was a significant prognostic factor for OS ($p < 0.01$). In patients with a large tumor (>3 cm), the 5 year OS rates were 78% in contrast to 94% for those with a small tumor (≤3 cm). Age, postoperative radiotherapy, resection margin status, clinical T-stage, lymph node involvement, depth of invasion, and histological differentiation were not significant (Table 3). By multivariate analysis, primary tumor size ($p < 0.01$) was the only significant prognostic factor for OS (Table 4).

DFS rates at 5 and 10 years of 47 patients were 78% and

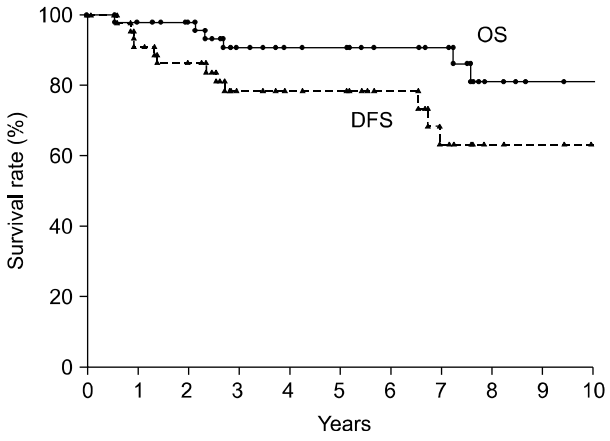

Fig. 1. Overall and disease-free survival of 47 analyzed patients. OS: overall survival, DFS: disease-free survival.

Table 3. Prognostic Factors of Vulvar Carcinoma: Univariate Analysis (n=47)

Variables	Overall survival rates		Disease-free survival rates	
	5-years (%)	p-value	5-years (%)	p-value
Age		0.24		0.13
≤60 years	96		72	
>60 years	84		86	
Tumor size		<0.01		0.53
≤3 cm	94		82	
>3 cm	78		65	
Clinical T-stage		0.42		0.02
T1	92		91	
T2, T3	87		64	
Lymph node involvement		0.48		0.19
Yes	83		50	
No	96		86	
Resection margin		0.65		0.25
Positive	100		75	
Negative	94		79	
Depth of invasion		0.40		<0.01
≤1 cm	90		91	
>1 cm	67		25	
Differentiation		0.29		0.67
W/D*	87		71	
M/D†, P/D‡	100		75	
Postoperative radiotherapy		0.30		0.66
No	97		78	
Yes	86		83	

*well differentiated, †moderately differentiated, ‡poorly differentiated

63%, respectively (Fig. 1). By univariate analysis, clinical T-stage and depth of invasion were significant prognostic factors for DFS ($p<0.05$) (Table 3). By multivariate analysis, lymph node involvement was the only significant prognostic factor for DFS (p=0.05) (Table 4).

3. Postoperative radiotherapy

The number of patients with a pathologically positive lymph node were 3 (9%) in the S group and 3 (43%) in the S+RT group, respectively. ($p<0.05$ by chi-square test). The number of patients with a positive resection margin were 2 (6%) and 2 (29%), in the two groups, respectively ($p<0.05$ by chi-square test) (Table 5). However, OS (97% vs. 86%, p=0.30) and DFS (78% vs. 83%, p=0.66) rates at 5 years were similar for the two treatment groups (Fig. 2). Three patients who received incomplete radiotherapy were excluded

Table 4. Prognostic Factors of Vulvar Carcinoma: Multivariate Analysis (n=47)

Variables	p-value	
	Overall survival	Disease-free survival
Age	0.42	0.07
Tumor size	<0.01	0.61
Clinical T-stage	0.90	0.07
Lymph node involvement	–	0.05
Resection margin	–	0.68
Postoperative radiotherapy	–	0.85

Table 5. Lymph Node and Resection Margin: Surgery vs. Surgery Followed by Radiotherapy

Prognostic factor	Treatment	
	S* (n=35)	S+RT† (n=7)
Lymph node		
Positive	3	3
Negative	28	2
Not available	4	2
p-value (by chi-square test)	<0.05	
Resection margin		
Positive	2	2
Negative	32	4
Not available	1	1
p-value (by chi-square test)	<0.05	

*surgery alone, †surgery followed by radiotherapy

from this analysis.

4. Patterns of failure

The patterns of failure are detailed in Table 6. Total twelve patients (26%) experienced treatment failure, and the sites of initial failure were as follows: a primary site in 8 patients (17%), a regional lymph node in 3 patients (6%) and the lung in one patient (2%). One of three patients with regional failure had pathologically positive lymph nodes. This patient was treated with ipsilateral lymph node dissection alone. Nine of 12 patients with failure had salvage treatment. Five patients (4 in S group and 1 in S+RT group) were treated with surgery and radiotherapy, 3 (2 in S group and 1 in radiotherapy alone group) with radiotherapy alone, and one (1 in S group) with surgery alone. Salvage treatment was successful for 7 patients. Four of 7 patients with successful salvage treatment are alive without evidence of disease, 2 died of distant metastasis, and one had second salvage treatment for local recurrence.

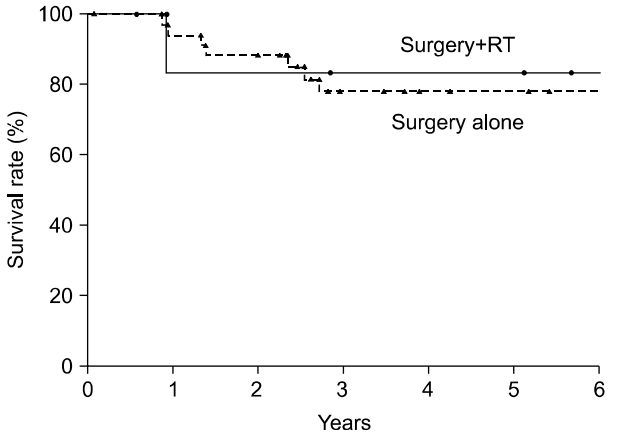

Fig. 2. Disease-free survival according to the treatment modality.

Table 6. Patterns of Overall Failure

Failure	Treatment (%)		
	S* (n=35)	S+RT† (n=7)	RT‡ (n=5)
Local	3 (9)	1 (14)	1 (20)
Local+regional	1 (3)	0 (0)	0 (0)
Local+distant	2 (6)	0 (0)	0 (0)
Regional	3 (9)	0 (0)	0 (0)
Regional+distant	0 (0)	0 (0)	0 (0)
Distant	0 (0)	1 (14)	0 (0)
No failure	26 (74)	5 (72)	4 (80)

*surgery alone, †surgery followed by radiotherapy, ‡radiotherapy alone

5. Patients with clinically negative inguinal lymph nodes

Thirty-one patients (62%) had clinically negative lymph nodes (Table 7). Twenty-one patients (T1N0 in 13, T2N0 in 8) received inguinal lymph node dissection and 10 patients (T1N0 in 8, T2N0 in 2) received no lymph node dissection. In each group, the DFSrates at 5 years were 85% and 86%, respectively (p=0.889) (Fig. 3). Only 2 (10%) of 21 patients had occult inguinal lymph nodemetastasis on radical vulvectomy and bilateral inguinal lymph node dissection. One patient had a clinical T1N0 tumor and was alive with no evidence of disease at the last follow-up. The other patient had a clinical T2N0 tumor and developed local failure and distant metastasis (to the bone). Five (16%) of 31 patients with clinically negative lymph nodes experienced local failure, but no patient experienced regional failure.

6. Complications

As for surgery-related complications, a wound problem such as wound breakdown, seroma, and cellulitis was developed in

Table 7. Characteristics of Patients with a Clinically Negative Inguinal Lymph Node

Characteristic	Inguinal lymph node dissection	
	Yes (n=21)	No (n=10)
Stage		
T1N0	13 (62)	8 (80)
T2N0	8 (38)	2 (20)
Treatment modality		
Surgery alone	20 (95)	6 (60)
Surgery followed by radiotherapy	1 (5)	2 (20)
Radiotherapy alone	0 (0)	2 (20)
Pathological lymph node		
Yes	2 (10)	0 (0)
No	19 (91)	0 (0)
Not available	0 (0)	10 (100)
Patterns of failure		
Local	3 (14)	1 (10)
Regional	0 (0)	0 (0)
Local+distant	1 (5)	0 (0)

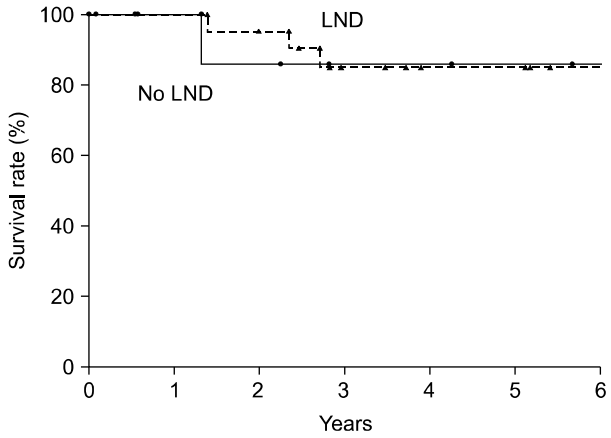

Fig. 3. Disease-free survival of patients with a clinically negative lymph node. LND: lymph node dissection.

21 (58%) of 36 patients who were treated with vulvectomy and 4 (44%) of 9 patients with local excision, respectively. According to the surgical procedure performed for excision of an inguinal lymph node, a wound problem developed in 21 (68%) of 31 patients who were treated with bilateral inguinal lymph node dissection. The wound problem developed in two (40%) of 5 patients who were treated with with ipsilateral inguinal lymph node dissection, and 2 (22%) of 9 patients who were treated with with no inguinal lymph dissection, respectively (p=0.02). According topostoperative radiotherapy, 20 (57%) of 35 patients in S group and 5 (50%) of 10 patients in S+RT group experienced a wound problem (p=0.17 by chi-square test).

In 25 patients with a wound problem, the treatments for wound care were as follows: debridement in 5 patients skin graft in 6 patients a flap in 2 patients a graft and flap in one patient a long-term dressing in 3 patients; treatment was not available in 8 patients.

Generally, radiotherapy was well tolerated. Four (27%) of 15 patients experienced a NCI-CTC Grade III acute skin reaction. NCI-CTC Grade III acute lymphedema occurred in only one patient (7%) that was treated with surgery followed by postoperative radiotherapy. There were no radiotherapy-related late complications.

Discussion and Conclusion

In 1986, Homesley *et al.* demonstrated that radiotherapy can prevent inguinal lymph node recurrence and can thereby improve survival in node-positive patients who had undergone bilateral inguinal lymph node dissection (75% vs. 56%, p <0.05).[15] However, the survival advantage was limited to those patients with a clinically evident inguinal lymph node or more than one pathologically positive inguinal lymph node. In our study, the presence of a positive lymph node (43% vs. 9%, $p<0.05$) or resection margin (29% vs. 6%, $p<0.05$) was significantly more likely in patients that were treated with surgery followed by radiotherapy than in patients that were treated with surgery alone ($p<0.05$). The 5-year DFS rates was similar for the two treatment groups (78% vs. 83%, p=0.66). In patients treated with surgery followed by postoperative radiotherapy, only one patient experienced locoregional failure. Our results suggest that postoperative radiotherapy may be beneficial to patients with a positive lymph node or resection margin, but a small sample size precludes any definitive conclusion.

Currently, most patients with vulvar carcinoma do not show spread to an inguinal lymph node at the time of first treatment. However, these lymph nodes are the first sites of lymphatic spread and must be taken into consideration in formulating the treatment strategy of each patient. Cancer failure in an untreated inguinal lymph node has been associated with a high probability of fatal outcome, regardless of the salvage therapies used.[3,13,17] In a prospective GOG study, the involvement of inguinal lymph nodes was rated as clinically negative in 477 (81%) of 588 analyzed cases.[14] Of the clinically negative lymph nodes, 24% were affected by a tumor as demonstrated by histopathological analysis. This study showed that clinical examination of the lymph node status results in an underestimation of the tumor stage in nearly one-fourth of all patients. Hacker *et al.* reported that the occult inguinal lymph node metastasis rates were 11% and 25% in T1 and T2, respectively.[3] In our study, only two patients (10%) had occult inguinal lymph node metastasis; this result was comparable with findings of previous studies.[3,14,18,19]

Radical surgery is associated with a high rate of complications such as wound problems and lymphedema. In GOG protocol #36, 27% of patients who were treated with radical surgery suffered some degree of chronic lymphedema, and 49% of patients experienced a wound problem.[7] Podratz *et al.* have reported that in patients that were treated with

bilateral inguinal lymph node dissection, 69% experienced lymphedema, 17% had seromas, and 85% had significant impairment of wound healing secondary to wound separation, infection and necrosis.[8] Morely *et al.* described lymphedema as "frequent" and reported a 50% wound problem rate.[9] These complications have been associated primarily with inguinal lymph node dissection. Patients who undergo vulvectomy without inguinal lymph node dissection are known to experience fewer complications and shorter hospital stays.[9,10] The high rate of complications becomes more difficult to accept when one notes that 70～80% of patients have a negative inguinal lymph node. In our study, the incidence of wound problem was also more common in patients that were treated with inguinal lymph node dissection than those that did not undertake inguinal lymph node dissection. Considering the impressive complications of the inguinal lymph node dissection procedure, we presume that omission of inguinal lymph node dissection may be considered for low-risk patients with clinically negative lymph nodes.

Alternatively, omission of inguinal lymph node dissection in patients with very small cancers with limited invasion, or elective radiotherapy to the inguinal lymph node may be options. In our study, 10 of the 31 patients with clinically negative lymph node didn't inguinal lymph node dissection. Four patients had radiotherapy to inguinal lymphnode and 6 patients had no further treatment. But none of these patients experienced regional failure. In 1992, Stehman *et al.* reported GOG study 88. Five out of 27 patients (18.5%) who received primary inguinal radiotherapy developed inguinal lymph node failure, which is an unacceptably high failure rate.[10] However, criticisms can be made of the radiotherapy dose, dose distribution, and techniques. The maximum dose was prescribed at3 cm in this study. The depth beneath the skin of the deep femoral nodes is between 4.5 and 6.1 cm to McCall *et al.*[20]. It is likely, therefore, that deep nodes were relatively under-treated. Petereit *et al.* reported that good local control and survival after elective radiotherapy was seen, and it was concluded that elective radiotherapy might be a viable alternative to utilize in place of inguinal lymph node dissection, with the advantage of less acute and delayed complications as compared with surgery.[21] In 2003, Katz *et al.* also showed that radiotherapy alone or in combination with inguinal lymph node dissection is highly effective in preventing inguinal lymph node failure, and is associated with a low risk of major late complications.[22]

This study has some limitations such as the small patient number and heterogeneity of treatment. However, despite the presence of risk factors for failure, there was no significant difference in OS and DFS when surgery followed by postoperative radiotherapy was compared with surgery alone. Postoperative radiotherapy may have a potential benefit to patients with risk factors (lymph node involvement, positive resection margin) for failure. The omission of an inguinal lymph node dissection or elective radiotherapy to inguinal lymph node may be considered in low-risk patients with a clinically negative lymph node and small sized primary tumor. In addition, well-designed, prospective studies using modern surgical and radiation technique are needed to determine which patients are most likely to benefit from initial inguinal lymph node dissection vs. radiotherapy.

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국문초록

국소 외음부 암에서 영역 림프절의 치료

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목 적: 외음부 암환자에서 국소영역 치료실패에 대한 수술 후 방사선치료의 영향을 평가하고 임상적으로 림프절이 전이가 없는 환자들에서 서혜부 림프절에 대한 치료방침을 결정해 보고자 하였다.

대상 및 방법: 1979년 10월부터 2004년 6월까지 서울대학교병원에서 일차성 외음부 암으로 치료를 받은 환자 66명에 대해 후향적 분석을 시행하였다. 이들 중에서 원격전이가 있는 2명, 고식적 목적으로 치료를 받은 6명, 이전에 골반부위 방사선 치료의 병력이 있는 3명, 추적관찰이 탈락된 4명, 의무기록이 불충분한 1명을 포함하여 16명의 환자들은 이번 분석에서 제외되었다. 50 명 중에 수술만 받은 환자가 35명, 수술과 방사선 치료를 받은 환자가 10명, 방사선 치료만을 받은 환자가 5명이었다.

결 과: 5년 전체 생존율과 무병 생존율은 각각 91%, 78%였다. 12명(26%)에서 치료 실패를 보였으며, 국소 실패가 8명, 영역림프절 전이가 3명, 원격 전이가 1명이었다. 수술과 방사선치료를 같이 받은 환자들이 수술만을 받은 환자들보다 위험요인을 더 많이 가지고 있었지만, 무병 생존율은 두 집단에서 통계적으로 유의한 차이를 보이지 않았다(5년 무병 생존율 78% vs. 83%, p=0.66). 잠재성 림프절 전이의 빈도는 10%였다. 임상적으로 림프절 전이가 없었던 31명의 환자들 중에서 10명은 서혜부 림프절 절제술을 받지 않았지만, 이들 중에서 영역림프절 전이를 경험한 사람은 아무도 없었다.

결 론: 치료실패의 위험요인을 가진 외음부 암자들에게 수술 후 방사선 치료는 잠재적인 이점을 가지고 있다. 임상적으로 림프절 전이가 없는 위험도가 낮은 환자들에게는 서혜부 림프절 절제술을 하지 않는 것이나 서혜부 림프절에 대해 예방적 방사선치료를 하는 것에 대해서 고려해 볼 수 있겠다.

핵심용어: 외음부암, 림프절, 방사선치료, 수술