Prognostic role of inguinal lymphadenectomy in vulvar squamous carcinoma: younger and older patients should be equally treated. A prospective study and literature review

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HIGHLIGHTS
• Prognostic role of nodal status in very elderly patients also.
• Number of positive nodes and of lymphnodes removed impact survival.
• Literature review about variable associated to nodal status and lymphadenectomy.

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Nodal status
Prognosis
Survival
Very elderly patients

ABSTRACT
Objective. This study analyzed the prognostic significance of nodal involvement in vulvar squamous carcinoma and its correlation with other prognostic factors, focusing the research on comparison between <75 and ≥75 years old patients.

Methods. We prospectively enrolled patients with >1-mm-deep stromal invasion, Ib–III stage vulvar cancer. Patients underwent unilateral or bilateral inguinal lymphadenectomy, according to tumor localization.

Results. In total, 131 patients met inclusion criteria; 93 (71%) underwent bilateral and 38 (29%) unilateral lymphadenectomy with 36 (27%) of them presenting nodal disease. At Kaplan–Meier analysis factors associated to prognosis were nodal status (in very elderly patients also) and number of resected nodes both in bilateral and unilateral lymphadenectomy groups. In univariate analysis, covariates associated with survival included age, in terms of overall survival (OS) but not with disease free-survival (DFS) and disease-specific survival (DSS), grading, nodal status, the presence of bilateral nodal metatases, the number of resected nodes in both unilateral, in terms of OS and DSS but not of DFS and bilateral lymphadenectomy and the number of metastatic nodes. In multivariate analysis covariates associated with survival were age, the number of positive nodes and the number of resected nodes in bilateral lymphadenectomy.

Conclusions. Results confirm the prognostic role of nodal status in very elderly patients also. Although DSS in older patients resulted worse, lymphadenectomy is not associated with more complications, suggesting its importance in older patients too. Furthermore, the resection of less than 15 lymph nodes in bilateral lymphadenectomy seems to have a negative impact on survival.

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1. Introduction

Vulvar cancer represents 4% of all female gynecologic malignancies with 4580 estimated new cases and 1030 deaths in USA in 2014 [1]. Most of vulvar carcinomas are squamous cell carcinomas (SCC).

This tumor predominantly occurs in elderly women; 54% of patients with the diagnosis of vulvar carcinoma are 70 years or older; no more than 15% are younger than 50 years [2,3].
Until 1980, the standard treatment of vulvar cancer consisted of en bloc radical vulvectomy and bilateral dissection of the upper and deep groin lymph nodes, even if associated with high morbidity rates. From that time on, surgeons began to implement a less invasive surgery, trying to ensure better aesthetic results with the development of different techniques without compromising cancer-related outcome.

These surgical innovations have led to lower morbidity and complication rates while the local recurrence rate has remained unchanged.

Lymph-nodal spread represents one of the most important prognostic factors for vulvar carcinoma, such as FIGO staging system revised the classification in 2009, including all cases with nodal involvement in all stage (irrespective of tumor diameter) [4].

Lymph-nodal status is strictly related to other parameters such as tumor size, depth of stromal invasion, histological grade, and lymph vascular space involvement [5–12]. Generally, lateralizing lesions (> 1 cm beyond the midline) drain to the ipsilateral superficial inguinal lymph nodes, whereas midline lesions can drain to either side [9].

Therefore, the indication to inguino-femoral lymphadenectomy is limited to patients with more than 1 mm of stromal invasion and contralateral inguinal lymphadenectomy could be safely omitted for lateral tumors when ipsilateral lymph nodes are negative [13].

Furthermore, in an effort to reduce the almost inevitable inguinal dehiscence, other variations were proposed regarding groin lymphadenectomy technique.

Some authors have recommended either the use of sentinel node sampling [14] or superficial nodal dissection with saphenous vein preservation [15].

Due to the lack of established long-term oncologic outcomes as well as experience with sentinel node procedures in most centers, this approach remains experimental.

On the other hand, patients undergoing superficial inguinal node dissections have been reported to have a slight but significant increase in the rate of inguinal recurrences compared to those having a complete groin dissection [4,16].

In this prospective study we reported our experience about lymphadenectomy in vulvar squamous carcinoma, evaluating characteristics of lymph-nodal involvement in this tumor, its prognostic role and its possible correlation with other prognostic factors. Moreover we analyzed the role of nodal status in patients older than 75 years, usually defined as very elderly population [17].

2. Materials and methods

We prospectively enrolled patients affected by invasive SCC of the vulva who were amenable to radical surgery comprehensive of inguinal lymphadenectomy. Patients were afferent to “Campus Biomedico” University of Rome and “Sapienza” University of Rome and were recruited from 1998 to 2012. The study protocol was approved by the ethical committee. Written informed consent was obtained from all patients. Eligibility criteria were as follows: histologically documented squamous vulvar carcinoma with >1-mm-deep stromal invasion; stages Ib–III, according to the International Federation of Gynecology and Obstetrics (FIGO) new classification (all patients treated before 2009 were restaged according to the new criteria), performance status 0–1, age 18–80, no history of major surgery or radiotherapy to the pelvis, no previous chemotherapy or hormonal therapy for vulvar carcinoma, no concomitant malignancies.

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patients (N+). On the contrary, 95 patients (73%) had negative nodes (N−). Since scientific evidences showed that vulvar cancer is a chemo-sensitive tumor and that adjuvant chemotherapy could be a valid choice for the treatment of nodal disease with acceptable toxicity [12], patients with metastatic nodes were treated with 4 cycles of cisplatin (100 mg/m²). All patients completed the treatment that overall was well-tolerated with 5 out of 36 (14%) patients suffering from grade 4 neutropenia. Such as it concerns the possible association between nodal status and characteristics of patients, there was no statistically significant difference in age between patients with nodal metastases and patients without nodal metastases: the median age were 70.5 and 72 (p = NS) respectively. Histologically, 99 patients (76%) had G1–G2 disease and 32 (24%) had G3 disease. In N− group 80 patients (84%) had G1–G2 disease whereas 15 (16%) had G3 tumor; in N+ group 19 patients (53%) had G1–G2 tumor whereas 17 patients (47%) had G3 tumor (p = 0.007). We did not analyze possible correlations between stage and nodal involvement, considering that new FIGO staging system classifies only nodal metastatic disease as stage III. In total, 5-year OS and DFS were 69% and 44% respectively.

OS was higher in patients affected by G1–G2 disease than in patients affected by G3 disease (p = 0.001) and also in patients affected by stages I–II disease than in patients affected by stage III disease (p = 0.005). Consequently, patients with N+ disease had both worst DFS and OS (p < 0.0001 and <0.0001 respectively): 5-year OS of patients N− was 86%, whereas 5-year OS of patients N+ was 36%. Survival curves according to nodal status are reported in Fig. 1. Furthermore, we compared survivals between patients with negative nodes and patients with positive nodes older than 75 years, observing that DFS and OS are significantly better in N− disease also in this group of patients (p < 0.0001 and <0.0001 respectively).

Since very elderly patients tend to have more co-morbidities resulting in a shorter life expectancy, in order to confirm these data, we also analyzed DSS obtaining the same results (p < 0.0001). Fig. 2 reports DSS according to nodal status in very elderly patients. Regarding the number of resected nodes, we observed that removing ≥15 nodes at bilateral lymphadenectomy improves both DFS and OS (p < 0.0001 and <0.0001 respectively).

This occurred also when unilateral lymphadenectomy was carried out: the resection of ≥10 lymph nodes correlated with better DFS and OS (p = 0.04 and 0.006 respectively).

Fig. 3 reports both OS according to the number of resected nodes in bilateral and unilateral lymphadenectomy. Moreover we tried to confirm if the number of positive nodes significantly correlates with survival. We did not find any statistical correlation between the number of positive lymph nodes and survival (p = NS), using the Kaplan–Meier method and log-rank test. However, in univariate analysis, covariates associated with survival included age (with OS but not with DFS and DSS), grading, nodal status, the presence of bilateral nodal metastases, the number of resected nodes in both unilateral (even if with OS and

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (range)</td>
<td>69.5 years (48–66)</td>
</tr>
<tr>
<td>≥ 75 years (%)</td>
<td>79 (60%)</td>
</tr>
<tr>
<td>&lt; 75 years (%)</td>
<td>52 (40%)</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
</tr>
<tr>
<td>• Radical vulvectomy</td>
<td>66 (50%)</td>
</tr>
<tr>
<td>• Hemivulvectomy</td>
<td>57 (44%)</td>
</tr>
<tr>
<td>• Local wedge excision</td>
<td>8 (6%)</td>
</tr>
<tr>
<td>Inguinal Lymphadenectomy</td>
<td></td>
</tr>
<tr>
<td>• Bilateral</td>
<td>93 (71%)</td>
</tr>
<tr>
<td>• Unilateral</td>
<td>38 (29%)</td>
</tr>
<tr>
<td>Median tumor size (mm)</td>
<td>40 (7–70)</td>
</tr>
<tr>
<td>Depth of invasion (mm)</td>
<td>4 (0.8–20)</td>
</tr>
<tr>
<td>Number of resected lymph nodes</td>
<td></td>
</tr>
<tr>
<td>• Total</td>
<td>18 (4–43)</td>
</tr>
<tr>
<td>• Bilateral lympadenectomy</td>
<td>23 (10–43)</td>
</tr>
<tr>
<td>• Unilateral lymphadenectomy</td>
<td>11 (4–19)</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
</tr>
<tr>
<td>• Stage I</td>
<td>51 (39%)</td>
</tr>
<tr>
<td>• Stage II</td>
<td>44 (34%)</td>
</tr>
<tr>
<td>• Stage III</td>
<td>36 (27%)</td>
</tr>
<tr>
<td>Grading</td>
<td></td>
</tr>
<tr>
<td>• G1</td>
<td>30 (23%)</td>
</tr>
<tr>
<td>• G2</td>
<td>69 (53%)</td>
</tr>
<tr>
<td>• G3</td>
<td>32 (24%)</td>
</tr>
<tr>
<td>Nodal status</td>
<td></td>
</tr>
<tr>
<td>• N+</td>
<td>36 (27%)</td>
</tr>
<tr>
<td>• N−</td>
<td>95 (73%)</td>
</tr>
</tbody>
</table>

**Table 1**

Clinical, surgical and pathological characteristics.

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DSS but not with DFS) and bilateral lymphadenectomy and the number of metastatic nodes (with particularly higher HR when the number of positive nodes was major than 3).

In multivariate analysis covariates mainly associated with OS, DFS and DSS were age, the number of positive nodes (particularly when \( N \geq 3 \)) and the number of resected nodes in bilateral lymphadenectomy. Results of univariate and multivariate analysis are reported in Table 2.

4. Discussion

In this prospective study we confirmed that nodal status represents a very important prognostic factor in very elderly patients also.

Moreover we demonstrated, according to other studies [18–21], that the number of removed lymph nodes impacts both DFS and OS.

Results were similar in bilateral and unilateral lymphadenectomies leading to conclude that when bilateral lymphadenectomy is carried out, more than 15 nodes should be removed, and in unilateral nodal dissection the number of resected nodes should be at least 10.

On the contrary, the number of metastatic nodes did not have a statistical significance in terms of survival at Kaplan–Meier evaluation, even if it showed a statistically significant correlation with OS, DFS and DSS both at univariate and multivariate analysis.

We hypothesized that it happened for the more complete representation of the sample of patients through the Cox proportional hazards model.

Up to now nodal status represents one of the most important prognostic factors for vulvar carcinoma [5]. However, there are no data in the international literature suggesting its importance also in patients older than 75 years. As previously defined, demographers consider the “older population” to be over 55 years of age. Within this group they distinguish the “elderly” (from 65 until 74 years) from the “very elderly” (over 75 years) [17].

In the present study the lymphadenectomy was carried out in very elderly patients also, showing that in these patients it seems to be feasible with no higher complication rates than in younger patients. Therefore, as concerns surgical complications following lymphadenectomy, we reported a complication rate of 33%, similar to those reported in the international literature [22–35,15]. Most common complications were wound breakdown and lymphedema. As previously reported, complication rates were similar between patients older than 75 years and those younger. Moreover, the nodal status represents a very important prognostic factor, in terms of DSS also, in very elderly patients such as in patients younger than 75 years. Analyzing the impact of nodal status on survival of very elderly patients, the presence of negative nodes at lymphadenectomy resulted in better OS, DFS and overall in DSS. At univariate analysis the age seems related to OS only, showing a higher hazard ratio in patients older than 75 years (1.0 vs 1.82; CI 1.02–3.24, \( p = 0.04 \)).

However, at multivariate analysis those patients seem to have a worse survival also in terms of DFS and DSS, even if in DSS, the difference is lower (\( p = 0.001 \) vs 0.007).

These data suggest the importance of obtaining a complete lymph nodal dissection with resection of both superficial and deep lymph nodes in older patients too.

Nevertheless, the worse DSS obtained at multivariate analysis leads to better investigate the role of nodal status and the meaning of a radical inguinal lymphadenectomy in these patients. Regarding the number of resected nodes, different studies established that the number of removed lymph nodes represents an important prognostic factor in vulvar cancer [18–21].

Le T et al. [18] established that the number of removed lymph nodes is an important prognostic factor in vulvar cancer and the authors arbitrarily proposed a cut-off value of at least 10 nodes in total to define optimal bilateral inguino-femoral lymphadenectomy.

Another study published by Courtney-Brooks M et al. [19] analyzed the impact of lymph nodal count on survival of 1030 patients with vulvar cancer and negative nodes.

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The authors concluded that the resection of more than 10 nodes correlated significantly with better DSS and OS in former stage III node-negative vulvar cancer patients.

However, in this study the stratification of patients was carried out using old FIGO staging system in which stage III included tumors of any size with adjacent spread to the lower urethra, vagina or anus. Gadducci A et al. reported the same results with a higher cut-off value of lymph-node removal, demonstrating that among patients any size with adjacent spread to the lower urethra, vagina or anus.

Consecutively, Baiocchi G et al. [20] showed that the number of lymph nodes removed is a prognostic factor but only in those patients with unilateral lesions and homolateral negative lymph nodes. It probably happens because the removal of an adequate number of lymph nodes results in a worse prognosis, mainly when the number of positive nodes was higher than three. It probably happened because Cox proportional hazards multivariate analysis the number of metastatic nodes resulted in a significant impact with better DSS and OS in former stage III node-negative vulvar cancer patients.

Nevertheless, in our trial all patients underwent the resection of more than 10 nodes when a bilateral lymphadenectomy had been carried out, was less than 10; so we need a cut-off value higher than 10 in order to obtain statistically significant results. Thus we chose the number of 15 nodes as cut-off of resected nodes that can be used to define an optimal bilateral lymphadenectomy, obtaining impressive differences in terms of HR, according to the results obtained by Gadducci A et al. [8].

The number of lymph nodes removed seems to be prognostic also when a unilateral lymphadenectomy was carried out in those patients with unilateral lesions and homolateral negative lymph nodes. It probably happens because the removal of an adequate number of lymph nodes may provide a better staging and eliminate the possibility of underestimated metastases. We furthermore observed that the number of metastatic nodes did not represent a prognostic factor at Kaplan–Meier analysis, leading to hypothesize that when an extensive lymphadenectomy is carried out, eventually followed by appropriate adjuvant treatment, the number of positive nodes does not represent a factor able to modify the prognosis. However, at both univariate and multivariate analysis the number of metastatic nodes resulted in a worse prognosis, mainly when the number of positive nodes was higher than three. It probably happened because at Cox proportional hazards analysis.
model the sample analyzed was more representative and numerous, including patients with negative nodes; the hazard ratio showed a significant increase in OS, DFS and DSS resulting in the worsening of prognosis between patients with negative nodes and patients with different numbers of metastatic nodes. The influence of the number of metastatic nodes on DSS remains controversial with some studies showing lack of association and others showing a direct association[5,8,13]. Moreover, based on these data, it is clear that the correct cut-off in order to define an optimal lymphadenectomy should still be defined[42]. Table 3 reports a literature review about inguinal lymphadenectomy in patients affected by vulvar carcinoma with any of the most important prognostic correlations about nodal status. Further prospective studies are needed to better characterize optimal inguinal lymphadenectomy in squamous vulvar carcinoma, with particular attention to its role in very elderly patients.

References


Table 3

5-year OS in vulvar cancer patients related to number of positive nodes.

<table>
<thead>
<tr>
<th>Author</th>
<th>Study design</th>
<th>Pts (n)</th>
<th>Type of lymphadenectomy</th>
<th>Resected nodes (n)</th>
<th>5 year OS</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hacker, 1983 [7]</td>
<td>Retrospective</td>
<td>131</td>
<td>Bilateral (113 pts) &amp; unilateral (18 pts)</td>
<td>NA</td>
<td>96%</td>
<td>NA</td>
</tr>
<tr>
<td>Paladini, 1994 [36]</td>
<td>Retrospective</td>
<td>75</td>
<td>Bilateral (68 pts) &amp; unilateral (7 pts)</td>
<td>NA</td>
<td>90%</td>
<td>NA</td>
</tr>
<tr>
<td>Van der Velden, 1995 [37]</td>
<td>Retrospective</td>
<td>71</td>
<td>Bilateral &amp; unilateral</td>
<td>NA</td>
<td>75.2%</td>
<td>NA</td>
</tr>
<tr>
<td>Raspagliesi, 2006 [38]</td>
<td>Retrospective</td>
<td>110</td>
<td>Bilateral &amp; unilateral</td>
<td>10 (6–14)</td>
<td>76%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Le T, 2007 [18]</td>
<td>Retrospective</td>
<td>58</td>
<td>Bilateral</td>
<td>14 (NA)</td>
<td>68%</td>
<td>NS</td>
</tr>
<tr>
<td>Tabbaa, 2012 [39]</td>
<td>Retrospective</td>
<td>468</td>
<td>Bilateral</td>
<td>NA</td>
<td>58%</td>
<td>0.021</td>
</tr>
<tr>
<td>Woelber, 2012 [40]</td>
<td>Prospective</td>
<td>49</td>
<td>NA</td>
<td>2 – 3 N+</td>
<td>68%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Courtney-Brooks 2012 [19]</td>
<td>Retrospective</td>
<td>1030</td>
<td>NA</td>
<td>No. of resected nodes &gt; 10 is prognostic (but only in st III)</td>
<td>91%</td>
<td>0.03</td>
</tr>
<tr>
<td>Gadducci A 2012 [8]</td>
<td>Retrospective</td>
<td>87</td>
<td>Bilateral</td>
<td>15</td>
<td>68%</td>
<td>NS</td>
</tr>
<tr>
<td>Baiocchi, 2013 [20]</td>
<td>Retrospective</td>
<td>234</td>
<td>Bilateral</td>
<td>22.5</td>
<td>55%</td>
<td>NS</td>
</tr>
<tr>
<td>Van Beekhuizen 2014 [21]</td>
<td>Retrospective</td>
<td>134</td>
<td>Bilateral &amp; unilateral</td>
<td>9.8</td>
<td>52%</td>
<td>NS</td>
</tr>
<tr>
<td>Bogani 2014 [41]</td>
<td>Retrospective</td>
<td>101</td>
<td>NA</td>
<td>14 (St I)</td>
<td>55%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Our experience</td>
<td>Prospective</td>
<td>131</td>
<td>Bilateral (93 pts) &amp; unilateral (38 pts)</td>
<td>23 (10–43) &amp; 12 (4–19)</td>
<td>86%</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

N, nodes; NA, not available; pts, patients; NS, not significant; BL, bilateral lymphadenectomy; UL, unilateral lymphadenectomy.

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