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Research Article

Vulvar Cancer. Surgery Results in 151 Patients

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Abstract

Objective: The present study is a review of our experience of the surgical options for vulvar cancer using The International Federation of Gynecology and Obstetrics (FIGO) classification.

Materials and Methods: The records of 151 patients treated with surgery for vulvar cancer with or without adjuvance in a lapse of 34 years, were retrospective reviewed in the Department of Gynecology Oncology at the General Hospital of Mexico. Data were analyzed using the Program Epi Info version 7.2.

Results: Patients were divided into groups, those with pre-invasion or minimal invasion disease were resolved with local excision or simple vulvectomy n = 24 (15.8%). Patients with invasive cancer were treated with conservative surgery with or without unilateral lymph node dissection n = 16 (14.5%); radical vulvectomy with inguino femoral lymphadenectomy n = 94 (62.2%) (47 block surgeries and 47 with separate incision); ultra-radical surgery n = 11 (7.2%) (6 abdomino-perineal resections and 5 pelvic exenterations).

127 Patients had follow - up and 62 of them had a disease-free survival rate of 30 months (48.8%). The overall survival in pre-invasion or minimal invasion disease were 91.3% (21/23), in Stage IB-II 75.5% (37/49), in Stage III 31.7% (13/41) (p = 0.00007) and in Stage IVA 21.4% (3/14).

Conclusion: Although a more individualized and less radical treatment is suggested, in this series only 14.5% of patients, could be resolved with conservative surgery. In addition, the lymph node status was the most important prognostic factor for survival.

Keywords: *Vulvar Cancer; Surgery*

Background

Vulvar cancer is a rare neoplasm that predominates in older women. It is the fourth most common gynecologic cancer and contains 3-5% of all malignancies of the female genital tract [1-3]. In 2018, 6,190 new cases of vulvar cancer (5.6% of gynecologic cancers) and 1,200 cancer deaths are projected in the United States [4].

In Mexico, the General Directorate of Epidemiology of the Ministry of Health estimated a frequency of 625 cases between 2004 and 2006, which represented 1.4% of malignant neoplasms of the female genital tract [5]. In the Oncology Service of the General Hospital of Mexico, in 2010 and in 2011, 22 cases were diagnosed, which constituted 2% of all gynecological malignancies diagnosed at this institution [6].

The traditional treatment was radical surgery in block, which consisted of vulvectomy with inguinofemoral lymphadenectomy, accompanied by high morbidity and mortality. But in recent decades, this has decreased due to a better understanding of its natural history and the tendency to individualize its management, in function of the patient stage and the location of the lesions, close to the development of modern radiotherapy equipment and new chemotherapy drugs [1-3,7,8].

Early lesions of less than 2 cm with stromal invasion of up to 1 mm (stage IA, FIGO) [3] are currently treated with local excisions with 1 - 2 cm margins, avoiding dissection of inguinofemoral lymph nodes. Sentinel lymph node biopsy has been incorporated for lesions between 2 and 4 cm with stromal invasion > 1 mm and without clinical or imaging lymph node metastases, in which the depth margin must reach the urogenital fascia. (Stage IB, FIGO) [1-3,8-11].

In lesions limited to the vulva, (Stage IB FIGO) [3] preserve the vulvar tissue as possible in local excisions or radical vulvectomies, carrying out unilateral or bilateral inguinofemoral lymph node dissection by separate incisions when the lesion measures more than 4 cm or is in the midline [8-10]. This same management with partial resections of the urethra, anus or perineum, is considered for those cases in which such invasion is demonstrated. (FIGO Stage II) [3].

Locoregionally advanced lesions are considered those in which the presence of metastatic nodes, and/or invasion of the lower third of urethra, lower third of the vagina or anus, is demonstrated with a histopathological study (Stages III and IVA) [3].

Surgical treatment for patients with cancers limited to the vulva with inguinofemoral nodes that are considered operable includes radical local excision or radical vulvectomy with bilateral inguinofemoral lymphadenectomy using separate incisions [1,2,8,10]. Patients not candidates for surgery or with even more advanced lesions, with ulcerated metastases or invasion of the bladder or rectum, require concomitant chemoradiotherapy as primary management [2,3,7,10,12].

In this publication, an Institutional experience in the surgical treatment of vulvar cancer is shown through the review of 151 cases treated in three different periods, using for analysis the current surgical classification of the International Federation of Gynecology and Obstetrics (FIGO) [3]. The surgical procedures performed by clinical stage are reviewed, with the respective results and conclusions are obtained in this regard.

Material and Methods

Retrospective study of patients with vulvar cancer treated in the Oncology Service of Mexico General Hospital during 34 years, divided in three periods between 1967 - 1986, 2001 - 2011 and 2012 - 2016. Of the record of 219 patients with malignant neoplasms of the vulva 151 received some type of surgical treatment in the aforementioned period.

The cases were classified according to the current Classification of the International Federation of Gynecology and Obstetrics [3]: VIN: Vulvar intraepithelial neoplasia (VIN 2 and VIN 3). Stage IA: Lesions of 2 cm or less with stromal invasion up to 1 mm without nodal metastasis; Stage IB: Lesions > 2 cm with stromal invasion > 1 mm confined to the vulva or perineum without nodal metastasis. Stage II: Tumor of any size with extension to the lower third of the urethra, lower third of vagina, or anus without metastatic inguinofemoral nodes. Stage III: Tumor with inguinofemoral lymph node metastases demonstrated by histopathological studies of surgical specimens. Stage IVA: Tumor invading the upper urethra and/or vaginal mucosa, bladder mucosa, rectal mucosa or fixed to pelvic bone 3. For this review, stages I and II were considered early lesions and III and IVA advanced stages [1,10,12].

The non-invasive lesions were managed conservatively with local excisions or simple vulvectomies; invasive neoplasms were operated on an individual basis, although in the first period most patients were treated with radical vulvectomy plus inguinofemoral lymphadenectomy in block, and pelvic lymph node dissection in the presence of metastasis in the Cloquet's node [13] (Figure 1 and 2).

Figure 1: *Radical vulvectomy with inguinofemoral nodal dissection in a single block.*

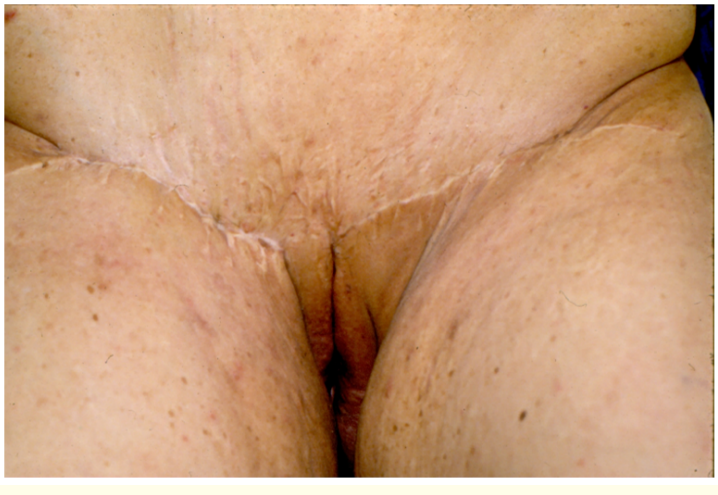

Figure 2: *Surgical scar in a patient with radical surgery in a single block.*

Lesions in clinical stage IB up to 4 cm were managed electively with radical local excisions that included margins of 1 to 2 cm on the surface, up to the fascia in depth and unilateral inguinofemoral lymphadenectomy (Figure 3 and 4). With clinically metastatic nodes, radical vulvectomy plus bilateral inguinofemoral lymphadenectomy (radical surgery) was performed in a single block during the first period of the study; and through separate incisions in the second and third periods. In the last years, patients with lesions < 4 cm without lymph node metastases underwent sentinel lymph node biopsy [1-3,8-11]. Larger lesions with or without metastases were managed with radical vulvectomy plus bilateral inguinofemoral lymphadenectomy through separate incisions. From 2001 to 2011, the approach was carried out through incisions parallel to the crural arch and from 2012 to 2016, through incisions in Italic S (Figure 5). The distal invasion of the urethra required resection of this third, displacing a flap from the anterior wall of the vagina to integrated a new meatus through points from mucosa to mucosa [13].

Figure 3: *Conservative surgical treatment (wide radical local excision).*

Figure 4: *Unilateral inguinofemoral lymph node dissection. Incision in Italic S.*

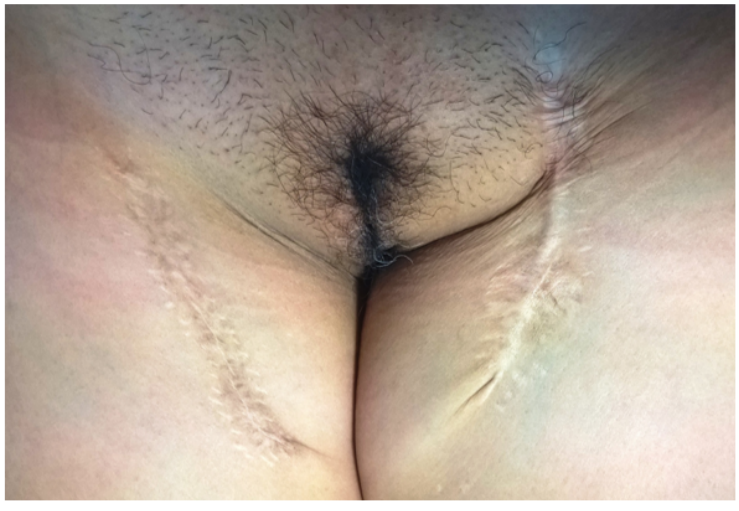

Figure 5: *Bilateral inguinofemoral nodal dissection with separate incisions.*

In this series, we preform ultraradical surgeries by means of pelvic exenterations or abdominoperineal resections plus vulvectomy and deferred inguinofemoral lymphadenectomy, in patients with proximal invasion of the urethra, the mucosa of the bladder or the rectum (Figure 6).

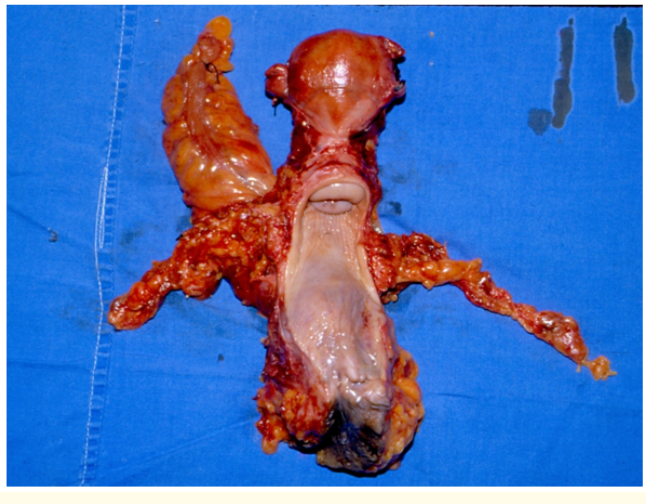

Figure 6: *Abdominal perineal resection with continuous vulvectomy.*

To the patients with lymph node metastases in the definitive histopathological study, adjuvant radiotherapy was administered to the primary lesion, to groins and to the pelvic nodes in an average dose of 50 GY. Patients with tumor recurrences eligible for surgery were submit to radical local re-excisions with or without lymphadenectomy, or radical vulvectomies with lymph node dissection. Patients not eligible for surgery received radiation therapy with or without concomitant chemotherapy with platinum-based agents.

The results obtained were subjected to statistical analysis with Chi2 tests and Fisher's exact test when one of the cells had an expected value of less than 5, with 95% confidence intervals. The Epi info Program version 7.2 was used. Confidence values of less than 95% were considered without statistical significance (N.S.).

Results

Of the record of 151 patients with vulvar cancer who received surgical treatment during the analyzed period, 67 (44.3%) belonged to the first period form 1967 - 1986 and 84 (55.6%) to the second on of 2001 - 2016.

Clinical and pathological aspects

The clinical and pathological characteristics of the entire group were selected in table 1. The youngest patient was 31 years old and the oldest 99, with an average age of 66 years. The 60.9% of the patients showed an age greater than 60 years. In the first group,15 patients reported being 50 years or younger (22.3%) and 16 in the second and third one (19.0%) (p = 0.762, N.S). Likewise, 6 of the first group (8.9%) and 17 of the second and third (20.2%) were 80 years of age and older (p = 0.09, N.S). The clinical stage III was the most common with 38.4% (Table 1).

Variable	Number of patients	Percentage
Age in years*		
31 - 40	9	5.9
41 - 50	22	14.5
51 - 60	28	18.5
61 - 70	37	24.5
71 - 80	32	21.1
81 and over	23	15.2
Total	151	99.7
Histological types		
Epidermoid	141	93.3
Adenocarcinomas	10	6.6
Total	151	99.9
Clinico-pathological stages		
VIN 2 - 3	13	8.6
IA	11	7.2
IB-II	53	35.0
III	58	38.4
IVA	16	10.5
Total	151	99.7

Table 1: *Clinical pathological aspects.*

**Minor: 31 years, Major: 99, Average: 66 years.*

Surgical treatment

Twenty four cases of VIN 2 - 3 and stage IA vulvar cancer resolved with wide local excisions (WLE) or simple vulvectomies (15.8%). Sixteen patients with stage IB vulvar cancer were treated with radical local excisions as the treatment of choice. Five sentinel lymph node (SNB) biopsies were performed, which were reported negative in all patients avoiding lymph node dissection, and in 8 the surgery was

completed with unilateral inguinofemoral lymphadenectomy. Derived surgery plus radiotherapy was performed in 6 patients with stage IVA and radical and ultraradical surgeries were performed in the remaining 69.5% (105 patients). Radical and ultra-radical surgeries were carried out (Table 2). It should be mentioned that 47 radical surgeries of the first period were resolved with in block resections: radical vulvectomy plus inguinofemoral lymphadenectomy (72.3%) plus pelvic lymph node dissection (27.6%) (Figure 1 and 2). In the 47 remaining radical surgeries belonging to the second and third period, the specimens were obtained through separate incisions (Figure 5).

Surgery	Number of patients	Percentage
Simple vulvectomy	14	9.2
WLE	10	6.6
Radical local excisions**	8	5.3
Radical local excisions plus inguinofemoral lymphadenectomy	8	5.3
Radical vulvectomy plus inguinofemoral lymphadenectomy	81	53.6
Vulvectomy plus inguinofemoral and pelvic lymphadenectomy	13	8.6
Radical vulvectomy plus abdominoperineal resection	6	3.9
Radical vulvectomy plus pelvic exenteration	5	3.3
Colostomy	6	3.9
Total	151	99.7

Table 2: *Surgical procedures performed.*

**WLE: Wide local excision. **5 cases with Sentinel Node Biopsy.*

In 11 of the cases, the surgeries were ultra-radical and consisted of 6 abdominoperineal resections with vulvectomy (Figure 6). Five in stage IVA and one in stage IIB with progression to the rectum after radiotherapy; and 5 pelvic exenterations plus continuous vulvectomy in stage IVA patients.

When establishing a correlation between the clinical diagnosis of lymph node metastasis and the pathology reports on 211 lymph node dissections performed, we found an error of 29.8% in the diagnoses: 24.1% of false positives versus 5.6% of false negatives (Table 3).

Correlation	Number	Percentage
No diagnostic error	148	70.1
Diagnostic error	63	29.8
False positives	51	24.1
False negatives	12	5.6

Table 3: *Clinical pathological correlation in 211 lymph node dissections.*

Morbidity and mortality

Cases managed with conservative surgeries had no morbidity. Of the patients resolved with radical vulvectomy plus lymph node dissection 61/94 (64.8%) developed complications during the first 30 days postoperatively (early complications), with necrosis of dissected flaps being the most common (47.8%) (Table 4 and 5).

The comparative study of the morbidity of radical surgery in the different periods analyzed showed a decrease of 80.8% for the period in which the surgeries were performed in bloc to 48.9% through separate incisions ($p = 0.001$). The lymphadenectomies with the lowest morbidity were those performed during 2012 - 2016 through incisions in Italic S (Table 6).

Evolution	1967 - 1986*		2001 - 2011**		2012 - 2016**	
	Number	%	Number	%	Number	%
Without morbidity	9	19.1	16	47	9	69.2
With morbidity +	(a) 38	80.8	(b) 19	52.9	(c) 4	30.7
Total	47	99.9	34	99.9	13	99.9

Table 4: *Radical vulvectomy morbidity with lymphadenectomy in different periods.*
+61/ 94 cases: 64.5%.
**Block surgeries. **Surgeries with separate incisions.*
(a) vs.(b+c):p = 0.001. (a) vs.(b):p = 0.019. (b)vs.(c):p = 0.19,N.S.

Complication	Number of patients	Percentage
Flap necrosis	45	47.8
Wound infection	40	42.5
Pulmonary embolisms	3	3.1
Thrombophlebitis	2	2.1
Gastrointestinal bleeding	2	2.1
Pneumonia	1	1.0

Table 5: *Vulvectomy complications with lymphadenectomy in 94 patients.*

Period	Number of patients	Percentage
(a) 1967-1986	33/47*	70.2
(b) 2001-2011	10/34	29.4
(c) 2012-2016	2/13	15.3
Total	45/94	47.8

Table 6: *Flap necrosis of the lymphadenectomies in different periods.*
**13 patients (27.6%) with inguinofemoral and pelvic lymphadenectomies.*
(a)vs.(b):p = 0.0006. (a)vs.(c):p = 0.001 (b)vs.(c):p = 0.464.

In this review, 20 late complications of radical vulvectomy with lymph node dissection were reported (21.7%); 16 patients with lymphedema (17.0%) and 4 (4.2%) with urinary incontinence.

Only 7/105 patients who underwent radical or ultra-radical surgery (6.6%) died of postoperative complications. The figure includes 4/94 radical vulvectomies with lymphadenectomy (4.2%) and 3/11 (27.2%) of those treated with ultra-radical surgeries: 1/6 abdominal perineal resections plus vulvectomy (16.6%) and 2/5 pelvic exenterations plus vulvectomy (40%). Radical surgery deaths were recorded in the 1967 - 1986 series.

Treatment results

A follow-up of 12 to 60 months was obtained with an average of 30 in 127 patients, of whom 62 (48.8%) were alive and without evidence of disease and 65 (51.1%) died of cancer or with tumor activity. Twenty-four patients (15.8%) abandoned their controls without evidence of disease during the first consecutive months of treatment and were not considered for the final results.

They evolved without evidence of disease 46/59 (83%) patients with early invasive lesions (Stages I and II) and 16/55 (29.0%) with advanced lesions (Stages III and IVA). As shown in table 7, a follow-up without tumor activity was obtained for the aforementioned period in 75.5% of Stages IB-II, in 31.7% of Stages III (p = 0.00007) and in 21.4% of Stage IVA.

Clinical and surgical stages	Disease free survival*	
	Number of patients	Percentage
VIN: 2 - 3	12/13	92.3
IA	9/10	90.0
IB-II. (a)	37/49	75.5
III. (b)	13/41	31.7
IVA. (c)	3/14	21.4
Total	62/127**	48.8

Table 7: *Vulvar cancer results of treatments.*

**30 average months.*

(a) vs. (b): p = 0.00007 (b) vs. (c):p = 0.7342.

***24 patients (15.8%) abandoned their treatment without disease.*

Only in 3/11 (27.2%) patients treated with ultra radical surgeries was a follow-up obtained without evidence of disease during the mentioned period; this included 2/6 (33.3%) abdominal perineal resections plus vulvectomy and 1/5 (27.2%) pelvic exenterations.

Tumor recurrences

Tumor recurrences were observed in 61/127 patients (48.0%) and occurred between 10 and 53 months after treatment, with an average of 13 months. Of this, 27 were local (44.0%); 28 locoregional and pelvic (45.9%) and 6 (9.8%) remotely: 2 to the lung and 4 to the para-aortic region.

Additional treatment was required in 46 patients (75.4%): 23 radical local resections (21.7%); 10 radical vulvectomies with lymphadenectomy (16.3%) and 13 (28.2%) radiotherapy with or without chemotherapy. The control of the disease was obtained only in 11 cases (23.9%) with local, locoregional and pelvic recurrences. The figure included 5/23 radical local excision (21.7%); 3/10 radical vulvectomies with lymphadenectomy (30%) and 3/9 with radiotherapy (33.3%).

Discussion

The treatment of invasive vulvar cancer represents a real challenge for the oncologist because in most cases the disease occurs in elderly women, many of them with comorbidities, which requires individualizing their treatment based on a better knowledge of the natural history of the disease and on the fact that radical surgery is the therapy of choice, even when it involves high operative morbidity and mortality [1-3,7,9].

In recent decades an increase in the disease has been reported in patients younger than 50 years attributable to infection by the Human Papillomavirus as a causative agent (Neoplasia Type 1) [1-3,14] in the analysis of this casuistry. The increase was not reflected when comparing the number of cases in patients of 50 years or less in two different periods. However, if it is to be noted that in recent years the number of patients older than 80 years has increased by 11.3% (p: 0.091, N.S.) which made the choice of treatment even more difficult for these cases.

The current FIGO classification for vulvar cancer is surgical, this has allowed dividing the disease into Early Disease (Stage IB and II) and Locally Advanced Disease (Stage III and IVA), which has therapeutic and prognostic implications [1-3,15].

Although in this series the pre-invasive lesions with minimal stromal invasion (VIN 2 - 3 and stage IA) were resolved with local excisions or by simple vulvectomies with very satisfactory results, the management of more advanced lesions with or without node metastases is a real problem.

Conservative surgeries (radical local excisions) was performed in 16 cases of invasive neoplasm with or without node metastases (14.5%), 5 of them with SNB and 8 with unilateral lymphadenectomy, procedures actually accepted for injuries of lateral location and preferably less than 4 cm [1-3,8-11,14].

In this regard, it is worth noting that the decision to perform conservative surgeries in invasive vulvar cancer must be carried out with good clinical judgment, since elderly patients usually carry out local inflammatory processes that mask areas of multicentricity of the lesions, with risk for local recurrences, which justifies that only 16 patients in this series (14.5% of early invasive lesions) were candidates for this management.

In the second half of the last century, the management of invasive lesions established in the Service was radical vulvectomy with lymphadenectomy using a single incision, obtaining the specimens in block with high morbidity and mortality, as the results of the first series of the study shows. Due to the high morbidity of the surgeries reported by various authors, the block approach has been abandoned and in its place for a lesion > 4 cm, central, or with suspicion of lymph node metastasis, surgeries are performed using 3 separate incisions [1,2,8,10,16].

The radical surgery in the present century has less morbidity because in our institution we perform groin incisions in Italic S. Pelvic lymph node dissections, performed in 8.6% of the patients in this series, are currently only indicated for highly selected cases with easily accessible metastases altogether with inguinofemoral lymphadenectomy [3,9,10]. Stage III patients with Non-resectable metastases are candidates for elective radiation therapy plus chemotherapy, with the subsequently debulking surgeries according to responses [2,3,10,15].

Adjuvant radiotherapy in patients with lymph node metastases is the therapy of choice for these cases with the aim of reducing locoregional tumor recurrences [1,3,7,10,15]. Unfortunately, its use increases the risk of late complications such as lymphedema of the extremities reported by up to 30% [7,10,17]. This complication was present in 17% of our patients as well.

In this series, 11 patients were candidates for ultra-radical surgeries with vulvectomy and deferral of lymphadenectomy. Ten cases as primary treatment and one more as salvage surgery after radiation therapy. The operative mortality was 27.2% and the disease free survival (DFS) was 27.2%. Although the indication to carry out these procedures is still in force, the selection of candidates must be carried out very carefully, due to their high morbidity and mortality and poor quality of life that they provide to their survivors [1,2,10,15]. The concomitant chemoradiotherapy using platinum drugs is an option for patients without complete responses and the procedure of choice for Stages IVA and some IVB with pelvic metastases [1-3,7,10,16,18].

The clinical pathological correlation in the 211 lymph node dissections in this series showed 29.8% errors in the diagnosis of metastases. In 51 cases (24.1%) these were not corroborated in surgical specimens, and in 12 (5.6%) metastases were not suspected by clinicians.

Although the tumor size is an indication for the lymph node approach, the dimensions of the primary lesions do not influence the involvement of the regional nodes, so the current classification of the disease includes lymph node metastases as advanced lesions (Stage III) and lesions limited to the vulva and the proximity of the vagina, urethra or anus as early lesions (Stages IB and II), regardless of their size [3,10].

Sixty-one patients in this series (48.0%) developed tumor recurrences on an average of 13 months after treatment, and the most common site was regional or to the pelvis in 45.9%. Six patients (9.8%) evolved distant dissemination, 4 to the para-aortic region and 2 to the

lung. Only 11 cases with local and/or locoregional and pelvic recurrences (23.9%) were managed to become patients with DFS: 8 with new surgeries and 3 with radiotherapy. Given the greater tendency to individualize the management of this neoplasm and to try to be more conservative in surgeries, the risk for locoregional recurrences whose presentation commonly occurs within the first two years has been increased and can be resolved with the new surgical procedures [3,12,17].

In this review, 62/127 patients (48.8%) had DFS in a period of 30 months, this includes 21/23 (91%) patients with preinvasive lesions and invasion less than 1 mm; 37/49 (75.5%) of Stages IB2 and II, 13/41 (31.7%) of stages III and 3/14 (21.4%) of stages IVA (p = 0.00007).

The most important prognostic factor for patients who are candidates for radical surgery is the presence or absence of lymph node metastases in surgical specimens. Without lymph node metastases, the 5-year survival rate was 70 - 90% (Stages I and II), with lymph node metastases between 25 - 50%, (Stages III and IVA) and for patients with distant metastases was less than 20% (Stages IVB) [10,12,17].

Conclusion

In this series the average age was 66 years. When comparing the periods 1967 - 1986 vs. those of 2001 - 2016, no differences were found in terms of the number of patients younger than 50 years, but there was an increase of 11.1% for those older than 80 years in the period 2001 - 2016 (p = 0762).

The predominant surgical stage was III with 58 patients (38.4%). Twenty-four patients (15.8%) had preinvasive lesions or minimally invasive lesions (VIN 2 - 3 and stage IA); 53 (41.7%) with early invasive cancers (Stages IB-I) and 74 (58.2%) with advanced invasive cancers (Stage III and IVA).

Only in 16 patients with invasive cancers (14.5%), conservative surgeries of the primary lesion were carried out with or without unilateral lymph node dissections.

Radical vulvectomies with lymph node dissections were performed in 94 patients, in 13 (13.8%) the pelvic nodes were included. In the first period the specimens were extracted in a single block and in the rest through separate incisions.

In 11 patients (8.6%) the condition was resolved with ultra-radical surgeries: 6 abdominoperineal resections and 5 pelvic exenterations.

The clinical pathological correlation in the 211 lymph node dissections performed showed an error in the diagnosis of metastasis of 29.8%: 24.1% of false positives and 5.6% of false negatives. Of the patients summit to radical surgeries 61/94 cases (64.5%) developed postoperative complications. Flap necrosis was the most common with 47.8%. These decreased from 70.2% in the first series, to 29.4% and to 15.3% in the second and third series respectively (p = 0.0006 and 0.001). The S Italic incision to address the groins was the one with the lowest morbidity.

Sixty-one patients (48.0%) developed tumor recurrences, of which 46 (75.4%) received treatment. Only in 11 (23.9%) it was possible to obtain new control of the disease, with new surgeries or with radiotherapy.

Follow-up was obtained in 127 patients, of whom 62 (48.8%) evolved 30 months on average without evidence of disease. The figure includes 21/23 (91.3%) of preinvasive and early invasive lesions (VIN 2.3 and stage IA); 37/49 (75.5%) of invasive lesions in Stages IB-II; 13/41 (31.7%) of Stages III (p = 0.00007) and 3/14 (21.4%) of Stage IVA.

Although the trend is to individualize the surgical treatment of invasive cancer of the vulva in order to reduce the morbidity of radical surgery, in this series only 14.5% resolved with conservative surgery. The presence of lymph node metastases was the most unfavorable prognostic factor.

Conflict of Interest

The authors express that there is no conflict of interest for the publication of this article.

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