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Cervical Cancer: Epidemiological, Clinical and Therapeutic Aspects Experience of the Mohamed VI Center for Cancer Treatment

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ABSTRACT

Introduction: Cervical cancer is the second most common gynaecological cancer after breast cancer in low-middle income countries, particularly Morocco. Worldwide, cervical cancer is the 4th most frequently diagnosed cancer and the 4th leading cause of cancer-related death in women. Its pathogenesis is linked to HPV infection. Improved hygiene and living conditions, and the organization of FCV screening, could reduce the incidence and mortality of this neoplasm. HPV vaccination and screening remain the two mainstays of cervical cancer prevention.

Aim of the study: The aim of our work is to study the epidemiological, clinical, paraclinical, therapeutic and evolutionary profile of cervical cancer at the Mohamed VI Center for Cancer Treatment.

Material and methods: This is a descriptive retrospective study, spread over a six-year period from December 31, 2016 to, January 1, 2010, including all patients diagnosed with cervical cancer and initially managed at the Mohamed VI Center for Cancer Treatment.

Results: A total of 168 cases meeting the inclusion criteria were collected. The age group most affected was between 51 and 60. The age of onset of sexual activity was before 18 in 23.8% of cases. Multiparity was noted in 73.82% of cases. 48.8% of patients were using oral contraception. Repeated genital infections were found in 41.07% of patients, the majority of whom were inadequately treated and monitored. Genital bleeding was the main reason for consultation in 89.25% of cases. The mean tumor size was 5 cm, with extremes of 2 and 10 cm. Squamous cell carcinoma predominated with a percentage of 87.5%. Patients were classified according to F.I.G.O 2009 criteria, and stage IIB was most frequently found, with a percentage of 64.2% (108 patients). The most commonly used protocol was concomitant radio- chemotherapy (CRT) followed by brachytherapy in 51.2% of patients. Outcome was specified for 112 patients. It showed locoregional recurrence in 16 patients, lymph node metastases in 2 patients, 1 case of bone metastasis and 1 case of liver metastasis. In our study, estimates of overall survival, progression-free survival and relapse-free survival at 5 years were 71%, 63.2% and 78% respectively. Survival by
F.I.G.O. stage was 86%, 78%, 56% and 9% respectively for stages I, II, III and IV.

Conclusion: Cervical cancer remains a major public health problem, especially in low and middle income countries where it is a major cause of death. Major advances in diagnosis and treatment occurred in the management of cervical cancer but we still need to step up our screening efforts and extend them to the entire population in order to make impacting breakthroughs.

INTRODUCTION

Cervical cancer, although on the decline in most developed countries in recent years, ranks 4th in terms of frequency and cause of death from cancer in women worldwide, with around 604,000 new cases and 342,000 deaths in 2020(1). In emerging countries, notably Morocco, cervical cancer remains a major public health problem. It is the 2nd most common cancer in women after breast cancer (1). It is currently well established that the human papillomavirus (HPV) is the main pathogenic agent of cervical cancer. Other sexual and non-sexual factors act as cofactors in the progression of HPV infection to cervical cancer (2). Cervical cancer starts by a pre-cancerous phase that can last several years before clinical symptoms appear, making

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it an important area for prevention through testing, and thus a preventable disease. Regular testing with cervico-vaginal smears enables precancerous lesions to be detected and treated at an early stage. In industrialized countries, advances in diagnosis and treatment, coupled with the introduction of an appropriate policy of systematic screening, have led to a sharp reduction in mortality and morbidity, with only 15% of cervical cancers occurring, and a decline of 4% per year (3).

HPV vaccination is complementary and synergistic with testing, making it a standard for primary prevention of this cancer. Indeed, vaccines could be the most effective weapons against the spread of this disease in developing countries. The therapeutic challenge of the last ten years has been to reduce mortality and improve patients' quality of life.

The aim of our study is not only to discuss the epidemiological, clinical and anatomopathological profile of cervical cancers in our series, but also to identify the different therapeutic modalities instituted. These results will then be compared with those published in the litterature.

MATERIEL AND METHODS

Our study is a retrospective descriptive analysis of 168 patients with cervical cancer treated at the Mohamed VI Center for Cancer Treatment, over a total period of 06 years from December 31, 2016 to January 1, 2010. All patients diagnosed with cervical cancer and initially treated at the Mohamed VI Center for Cancer Treatment were included in our study, whether or not they underwent medical or surgical treatment. We extracted the necessary information from the electronic patient file of the "ENOVA" information system, which enabled us to retrace the history of consultations, hospital admissions, various paraclinical explorations and therapeutic management. Statistical analysis of our study was performed using SPSS version 22.0 (Statistical Package for the Social Sciences). The method used to calculate survival was Kaplan-Mayer.

RESULTS

Epidemiological Profile

Age was specified in all our patients (168 cases). The extreme ages ranged from 31 to 81, with an average of 56. The age group most affected was between 51 and 60 years old, corresponding to 38% of cases (Table 1). 77% of patients were from urban areas and 23% from rural areas. The proportion of our sample who had early sexual relations before the age of 18 was 23.80%. This notion was specified with reference to the age of 1st marriage. Concerning the multiplicity of sexual partners, in our Moroccan context, this notion corresponded to the number of marriages, although marital status alone is not sufficient to determine sexual activity. It was found in 3 patients, representing 1.8% of cases, with 2 patients married on 2 occasions and one patient on 3 occasions.

Table 1: Summary of patients Characteristics

Patient's characteristics N (%)	
Total patients	168
Age (years) Range Most affected	 31 – 81 51 – 60

Parity	
None	11 (6.54%)
≤ 3 parity	33 (19.64%)
≥ 4 parity	124 (73.82%)
Repeated genital infections	
Yes	69 (41.07%)
No	46 (27.38%)
Symptoms	
Spontaneous bleeding	140 (83.3%)
Leucorrhoea	66 (39.23%)
Pelvic pain	47 (28%)
Urinary tract symptoms	5 (2.98%)
Digestive symptoms	3 (1.80%)
Tumor's characteristics	
Size	
Range	2 – 10 cm
Median	5 cm
< 4 cm	64 (38%)
> 4 cm	104 62%
Macroscopic aspect	
Exophytic lesion	77 (45.8%)
Ulcerative lesion	15 (9%)
Exophytic + Ulcerative	55 (32.7%)
Infiltrative	21 (12.5%)
Vaginal extend	
Fornix invasion	27 (16.1%)
Upper 1/3 of vagina	65 (38.7%)
Upper 2/3 of the vagina	33 (19.6%)
Lower 1/3 of vagina	10 (6%)
Parametrium extend	120 (71.42%)
Internal 2/3	87 (51.78%)
Entirely infiltrated	21 (12.5%)
Inguinal lymph nodes extend	7 (4.16%)
Histology	
Squamous cell carcinoma	147 (87.50%)
Adenocarcinoma	19 (11.30%)
Muco-epidermoid	1 (0.6%)
Papillar carcinoma	1 (0.6%)
Degree of differentiation	
Well differentiated	38%
Moderately differentiated	36%
Poorly differentiated	26%
Assessment of the disease extension	
Pelvic MRI	82 (48.8%)
Abdominal and pelvic CT scan	74 (44.04%)
PET-CT (18 FDG)	5 (3%)
Staging (FIGO 2009)	

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Stage Ia	0
Stage Ib (Ib2)	9 (5.4%)
Stage IIa	21 (12.5%)
Stage IIb	108 (64.2%)
Stage IIIa	9 (5.4%)
Stage IIIb	12 (7.1%)
Stage IVa	9 (5.4%)
Stage IVb	0
Treatment Modalities	
Surgery	77 (45.8%)
External Beam radiation therapy (EBRT)	
Exclusive EBRT + concomitant chemotherapy	91 (54.2%)
Preoperative EBRT + concomitant chemotherapy	16 (9.5%)
Adjuvant EBRT + concomitant chemotherapy	61 (36.3%)
Brachytherapy (HDR)	
Utero-vaginal	135 (80.35%)
Vaginal	16 (9.52%)
Chemotherapy	
Neo adjuvant	5 (3%)
Concomitant	163 (97%)
Treatment sequences	
Surgery first followed EBRT + concomitant chemotherapy + vaginal brachytherapy	16 (9.5%)
EBRT + concomitant chemotherapy + utero-vaginal brachytherapy followed by Surgery	49 (29.16%)
EBRT + concomitant chemotherapy followed by Surgery	12 (7.4%)
EBRT + concomitant chemotherapy + utero-vaginal brachytherapy +/- parametrial boost	86 (51.2%)
Exclusive EBRT + concomitant chemotherapy without brachytherapy	5 (3%)

The majority of our patients, 124 cases (73.82%), were multiparous (≥ 4 parities). In our study, 82 patients (48.80%) adopted oral contraception. The intrauterine device was used in only 20 patients (11.90%). 15 patients (8.9%) had received no contraception at all. Active smoking was found in only 3 patients, representing 1.8% of our series and passive smoking was found in only 3 patients, corresponding to 1.8% of our series. Almost 71% of our sample, came from a low socio-economic background.

Clinical Study

The main reason for consultation was spontaneous menstrual bleeding, reported in 140 patients, equivalent to 83.3% of cases, followed by purulent leucorrhoea and pelvic pain, found in 39.23% and 28% of our patients respectively. Induced menstrual bleeding was reported by 10 patients, corresponding to 5.95% of our series. Dyspareunia was found in 3 patients (1.80%). Urinary signs were noted in 5 cases (2.98%), and digestive signs in only 3 cases (1.80%).

A complete gynecological examination, including perineal examination, pelvic touching and speculum examination, enabled macroscopic appearance, tumor size and locoregional extension to be determined, and biopsies to be taken.

The mean tumor size was 5 cm, with extremes of 2 and 10 cm. Tumors smaller than 4 cm made up 38% of our series. Tumors > 4 cm accounted for 62% of our series. The tumor was mostly exophytic (cauliflower aspect) on speculum inspection in 77 patients, i.e. 45.8% of our series.

Palpation of the vaginal walls during vaginal touch revealed invasion in 80.4% of cases, with:

- Invasion of the vaginal fornix in 27 patients (16.1% of cases).
- Involvement of the upper 1/3 of vagina in 65 patients, equivalent to 38.7%.
- Involvement of the upper 2/3 of the vagina in 33 patients, representing
- 19.6%.
- Involvement of the lower 1/3 of vagina in 10 patients (6%).

The vaginal examination revealed parametrium's infiltration in 120 patients. The internal 2/3 of the parametrium was affected in 87 patients and the entire width of the parametrium was invaded in 21 cases, the clinical examination found fixed parameters in 12 patients. Parameters were free in 37 patients. The status of the parameter's infiltration was not specified for 11 patients.

Anatomopathological Study

All our patients underwent a cervical biopsy. The predominant histological type was squamous cell carcinoma (SCC) at 87.50%.

The degree of differentiation was distributed as follows:

- 38% were well-differentiated
- 36% were moderately differentiated
- 26% were poorly differentiated

Adenocarcinoma was found in 11.30% of our series' patients. some histological types were found less frequently, including one case of mucoepidermoid carcinoma and one case of papillary carcinoma.

Evaluation of the Disease Spread

Magnetic resonance imaging (MRI) was performed on 82 patients, i.e. 48.80% of cases. This enabled assessment of the locoregional extension of the cervical tumor, and revealed:

- Parametrial infiltration in 51 patients (62.20%).
- Pathological lymph nodes in 16 cases (19.51%), of which 12.20% were pelvic and 7.31% lombo-aortic.
- Vaginal extension in 13 patients (15.90%).
- Bladder extension in 5 cases (6.1%).
- Rectal extension in 3 patients (3.65%).

Abdominopelvic CT was performed in 74 patients (44.04%), and revealed pelvic adenopathy in 19% of cases, lumbo-aortic adenopathy in 9.45% and ureterohydronephrosis in 8 patients (10.81%). i.e. 10.81% of cases.

In our series, FDG-PET-CT was performed in only 5 patients (3%), and no distant secondary lesions were found.

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Classification

Staging was based on the 7th edition of the classification of the International Federation of Gynecology and Obstetrics (F.I.G.O. 2009).

- Stage IIB was most frequently found in our series, with a percentage of 64.2%, i.e. 108 patients.
- Stage IIA in 21 patients (12.5%)
- Stage IIIB in 12 patients (7.1%).

Therapeutic Management

Surgery:

Surgery was performed in 77 patients, equivalent to 45.8% of cases in our series, of whom only 16 patients (9.5%) underwent first-line surgery. Enlarged adeno-colpo-hysterectomy (ACHE) was the most frequently performed procedure, in 67.5% of cases. Total hysterectomy was performed in 20 patients, i.e. 26% of our patients. Total hysterectomy combined with pelvic curage was performed in 5 patients representing 6.5% of cases.

Anatomopathological Findings:

Tumor size of less than 4cm accounted for 62.50% of cases. Resection margins were tumoral in 17.64% of cases. In the 49 patients who received concomitant radio-chemotherapy and utero-vaginal brachytherapy followed by surgery, 61.3% of the operative parts were completely sterilized (pathological complete response pCR), compared with 38.7% who still had residual tumor, ranging in size from a few microscopic sites to a macroscopic residue of 1.5 cm. Only 12 resection specimens showed parametrial invasion, i.e. 22.64% of cases, and 16 cases showed vascular emboli, i.e. a percentage of 20.77%.

Pelvic lymph node dissection was performed in 56 patients, with an average of 15 nodes removed. Locoregional lymph node involvement was identified in 9 patients (16.07%).

External Beam Radiotherapy:

External pelvic radiotherapy to the tumor or the tumor's bed and lymph node drainage chains was delivered to all our patients with curative intent, using three modalities:

- Exclusive concomitant radiochemotherapy (CRT) in 91 patients (54.2%).
- Preoperative concomitant radiochemotherapy in 16 patients (9.5% of cases).
- Adjuvant (Postoperative) concomitant radiochemotherapy in 61 patients (36.3%).

55.35% of cases received the dose of 50 Gy in 25 fractions of 2 Gy, 29.76% received the dose of 46 Gy in 23 fractions of 2 Gy and 13.09% of cases had 45 Gy in 25 fractions of 1.8 Gy. However, the dose of 60 Gy in 30 fractions of 2 Gy was used in only 3 patients (1.8%). Additional irradiation on the parameters was carried out in the case of invasion after RCC and utero-vaginal brachytherapy in 12 patients, representing 7.14% of cases.

High Dose Rate Brachytherapy:

89% of patients underwent a brachytherapy treatment. It was a high-dose-rate endocavitary brachytherapy. Uterovaginal brachytherapy was used in 135 patients (80% of cases), delivered in 4 fractions of 7 Gy, 2 fractions per day, at least 6 hours apart, with a 1-week interval between the first 2 and last 2 sessions, in 78 patients (57.7% of cases). Vaginal

Brachytherapy (after surgery) was performed in 11% of cases and was usually delivered in 2 fractions of 5 Gy, 2 fractions a day, at least 6 hours apart, in 10 patients (62.5% of patients).

Chemotherapy:

163 patients (97%) had Concomitant chemotherapy. The drug used was cisplatin (CDDP) at a dose of 40mg/m2 in the majority of patients for an average of 4 courses concomitantly with radiotherapy. Neoadjuvant chemotherapy was mainly used in cases of lumbo-aortic adenopathy. Carried out in only 5 patients (3% of cases), the average number of courses was 3, and the protocol used was Cisplatin-5-Fluorouracil (CDDP-5FU). Palliative chemotherapy was not used in any of our patients, given the absence of metastatic cases in our case series.

Treatment Modalities:

Most of our patients were in locally advanced stages, and received concomitant radiochemotherapy (CCT) in several modalities:

- 9.5% of cases underwent surgery first followed by concomitant radio-chemotherapy and vaginal brachytherapy.
- The patients treated by surgery after concomitant radio-chemotherapy and brachytherapy represented 29.16% of patients.
- Patients who underwent concomitant radio-chemotherapy followed by surgery accounted for 7.14% of patients.
- 51.2% of cases were treated with concomitant radio-chemotherapy + brachytherapy +/- parametrial complement.
- 3% of patients received exclusive concomitant radio-chemotherapy without brachytherapy.
- 3% of patients received neoadjuvant chemotherapy.

Therapeutic Complications

Post-operative complications:

These were observed in 7.8% of cases, and were mainly represented by wall infection in 4 patients. There was also one case of acute urine retention with hematic urine and one case of vesico-vaginal fistula.

Post-radiation Complications:

Found in 31% of cases. Acute toxicities such as radiation-induced mucositis was reported in 20 patients; 6% of cases described cystitis and 3% had rectitis and 3% of patients suffered from vulvovaginitis. 11.3% of patients developed late toxicities such as vaginal synechia. Urinary fistula occurred in 4 cases and only one patient had a Rectal fistula.

Chemotherapy Associated Toxicities

Found in 22% of patients.

- 14.9% of cases had hematological toxicities, 10.7% presented anemia, 4.2% developed neutropenia. Thrombocytopenia was not observed in any case.
- Renal complications such as renal failure occurred in 2 patients (1.1%).
- Digestive toxicities such as vomiting and diarrhoea in 6% of patients.
  Evolution and monitoring

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Post-treatment Monitoring and Survival Indicators

112 patients attended follow-up regularly up to 5 years after the end of treatment, representing 67% of the patients treated. Monitoring took place every 3 months for 2 years, every 6 months for 3 years and then once a year. It was based essentially on questioning, clinical examination and a paraclinical work-up consisting of abdomino-pelvic ultrasound or abdomino-pelvic CT scan and/or pelvic MRI in case of suspicion of loco-regional recurrence, and other examinations in case of call signs. Of the 112 patients who regularly attended follow-up consultations:

- Complete remission occurred in 74.1% of cases
- 17.9% had a recurrence:
  - 16 cases had a locoregional recurrence.
  - 2 cases of cervical lymph node metastases.
  - 1 case of bone metastasis.
  - 1 case of liver metastasis.
- Therapeutic failure due to tumor progression in 9 patients (8%).

Overall survival of our patients at 5 years was 71% (Figure 1). Progression-free survival at 5 years in our case series is estimated at 63.2% (Figure 2).

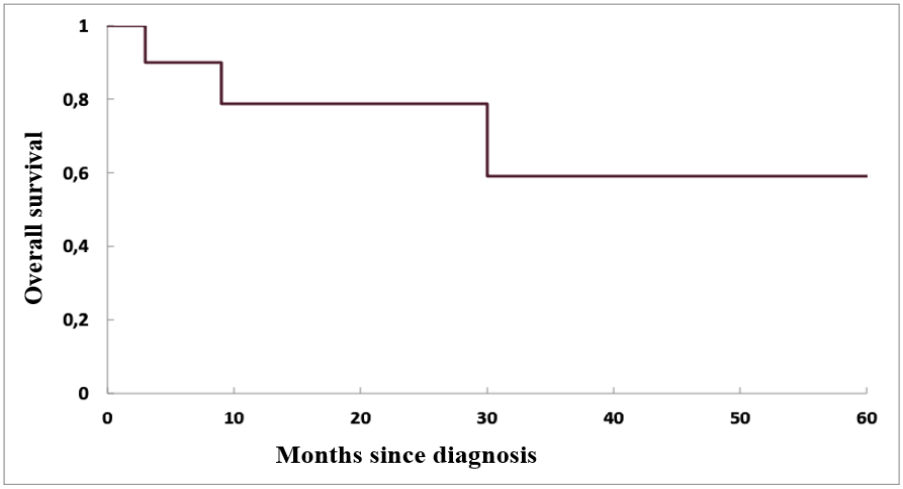

Figure 1: Overall survival (OS) at 5 years in our study

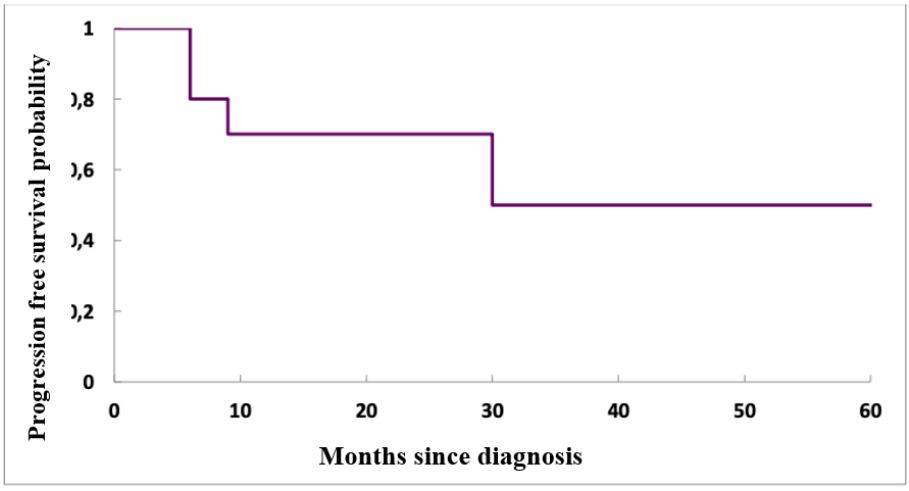

Figure 2: Progression free survival (PFS) at 5 years in our study

In our patients, local relapse-free survival at 5 years was 78% (Figure 3). We note in our case series that survival rate and tumor stage are inversely proportional. The more advanced the stage, the lower the survival rate. The probability of survival is 86%, 78%, 56% and 9% for stages I, II, III and IV respectively (Figure 4).

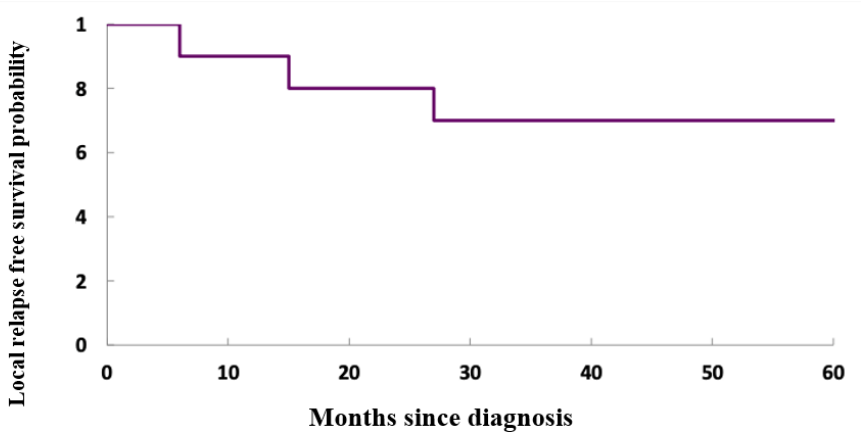

Figure 3: Local relapse free survival (LRFS) at 5 years in our study

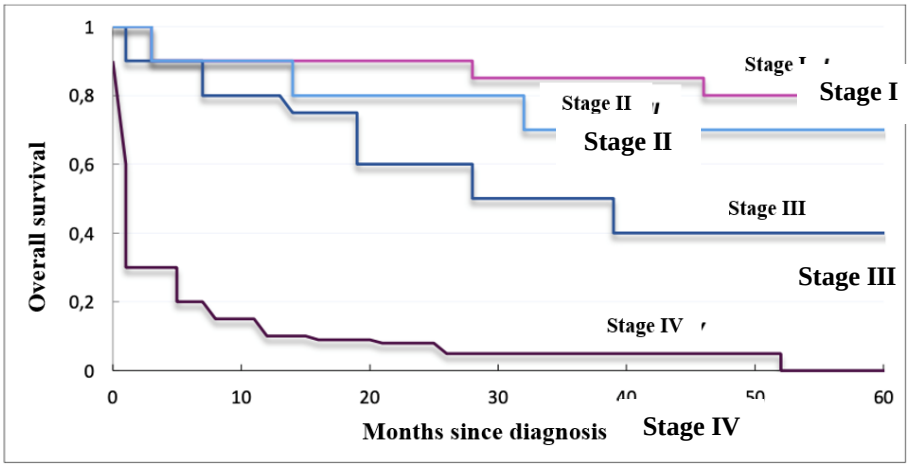

Figure 4: Overall survival (OS) at 5 years according to the stage (FIGO) in our study

DISCUSSION

Cervical cancer still represents a major public health problem in low-income countries. Based on recent findings in 2020, there were an estimated 604 127 cervical cancer cases and 341 831 deaths (4). Human papillomavirus (HPV) plays a major role and remains the main risk factor. It should be noted that the entire treatment strategy is based on the staging established from the International Federation of Gynecology and Obstetrics (Figo) of 2009, which was modified in 2018.

The management of cervical cancer has undergone numerous diagnostic and therapeutic evolutions. The clinician's aim will always be to optimize the therapeutic strategy, ensuring both locoregional and distant control by eradicating metastatic disease, while at the same time improving recurrence-free survival and avoiding excessive morbidity that would severely impair patients' quality of life. For this approach to be successful, close collaboration between surgeon and radiation oncologist is essential.

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Dursun and Al. established a timeline describing the evolution of the radical hysterectomy (5) that was first described in 1895. Nowadays, surgery is the standard treatment for early-stage cervical cancer in the first instance: The surgical procedure would consist of a more or less enlarged colpohysterectomy combined with a surgical lymph node work-up (6,7). In an Italian randomized trial, Landoni and Al. compared surgery versus radiotherapy in early stages of cervical cancer and showed that disease free-survival and overall survival for both groups were the same (8), however, A multi-institutional japanese survey of the quality of life demonstrated that surgery should be the primary choice regarding quality-of-life issues, ovarian failure, and the usual consequences of radiotherapy (9). In certain cases, pre-operatory brachytherapy may be an option. This combination had been evaluated in rare studies, but still had demonstrated low rate of early and late complications without compromising local control and overall survival (9-10-11). In a french study that compared the two different therapeutic strategies for early stages has shown that the debate remains open for patients with an IB1 tumors, for whom the combination of pre-operatory brachytherapy and surgery is possible (12), especially since 25 to 40% of IB stages will require an adjuvant treatment due to some risk factors identified on the hysterectomy pathology specimen (13). In our study, 36.3% of patients underwent post-operative radiochemotherapy, since it was demonstrated that this combination is the best way to improve the progression-free and the overall survival in case of pejorative risk factors such as positive pelvic lymph nodes, positive margins, or microscopic involvement of parameters (14-15).

Concurrent chemoradiotherapy followed by brachytherapy is the standard of care for locally advanced cervical cancer (16-17). The radiotherapy consists of a total dose of 45 to 46 Gy, to the pelvis. para-aortic lymph nodes may be included if positive at primary lymph node staging. An external radiotherapy boost will be performed to macroscopic lymph nodes. The radiation therapy is combined to 5 cycles of weekly cisplatin. In a systematic review on the basis of 13 trials, there was 6% improvement in 5-year survival with chemoradiotherapy and 8% improvement in 5-year disease free survival (18). Chemoradiotherapy reduced local and distant recurrence (19).

Brachytherapy is an integral part of the treatment of patients with locally advanced cervical cancer. It has been shown that brachytherapy decreases the incidence of local relapses and improves the survival (20-21). In a recent cross-sectional study that assessed Moroccan brachytherapy practices, it has been established that brachytherapy remains essential for the management of locally advanced cervical cancer with a well-defined international guideline ensuring the treatment quality (22).

Several studies have evaluated neoadjuvant chemotherapy without any positive outcomes (23-24), until the INTERLACE phase III trial that challenged induction chemotherapy followed by chemoradiation with significantly positive results combining improvement of both overall and progression free survival for locally advancer cervical cancer suggesting that neoadjuvant chemotherapy should be a new standard of care (25).

In the other hand, many investigators tried to evaluate the benefit of adjuvant chemotherapy (26). OUTBACK, a randomized trial found no benefit in OS or DFS (27). Then, there was a shift towards immune checkpoint inhibitors with The CALLA trial evaluating the benefit of adding

Durvalumab during and after chemoradiotherapy with no good results either (28). The benefit has finally been confirmed by the recently presented KEYNOTE-A18 study that found a 2-year DFS benefit of concurrent and adjuvant pembrolizumab (29). Other ongoing trials will try to improve outcomes of locally advanced cervical by suggesting maintenance therapy by dostarlimab (30) or the potential benefit of monoclonal antibodies (31).

FURTHER PERSPECTIVES AND CONCLUSION

Studies may lead to the identification of high-risk patterns for locoregional relapse. Genomic profiling studies investigated PIK3CA, STK11and PTEN signaling pathways (32). This signaling pathways were altered in more than 70 per cent of cervical cancers thereby representing potential targets (33). Further research into these subtypes may lead to better risk stratification and targeted therapies.

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