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SYSTEMATIC REVIEW

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Vaginal wall smooth muscle tumors: a systematic review of literature and a case report of vaginal STUMP

Fabio Francesco Ciancio[1], Giulio Insalaco[1], Sara Forte[2], Claudia Randazzo[1], Federica Grasso[1], Giuseppina Trombetta[1], Michele Dello Spedale Venti[3], Piergiuseppe Colombo[4], Simone Millan[1], Marianna Gulisano[5], Marco Palumbo[5], Gaetano Valenti[1,*]

[1]Unit of Gynaecologic Oncology, Humanitas Hospital, 95045 Catania, Italy
[2]University of Montreal, Montréal, QC H1A 0A1, Canada
[3]Department of Pathology, Humanitas Hospital, 95045 Catania, Italy
[4]Department of Pathology, IRCCS Humanitas Research Hospital, Humanitas University, 20089 Milan, Italy
[5]Department of General Surgery and Medical Surgical Specialties, University of Catania, 95123 Catania, Italy

***Correspondence**
valenti.gaetano@humanitascatania.it
(Gaetano Valenti)

Abstract

Background: Despite Smooth Muscle Tumors (SMTs) being the most common mesenchymal neoplasms of the vagina and vulva, they are rare entities. Among these, to date, only three cases of vaginal SMT of Uncertain Malignant Potential have been reported in the literature. **Methods**: According to the PRISMA statement, research was conducted on PubMed, Scopus, ScienceDirect and Cochrane Library from 2000 to January 2024 for vaginal leiomyomas and from inception to January 2024 for leiomyosarcoma and smooth muscle tumors of uncertain malignant potential (STUMP). All women with histological diagnoses of vaginal SMTs were included in the analysis. Women with a diagnosis of metastasis of SMTs at the vagina arising from other districts and para-urethral leiomyomas were excluded. **Results**: Of the 888 articles eligible for title screening, 104 met the inclusion criteria and were included. A total of 163 women were included, 78 were affected by vaginal leiomyoma, 82 by vaginal leiomyosarcoma, and 3 by vaginal STUMP. **Conclusions**: Vaginal STUMP is a rare entity, and no data is retrievable for statistical analysis. Pathologists experts in the gynaecological field, specific immunohistochemistry panels, and wide excision with free resection of margins are strongly recommended to properly recognize and radically remove the neoplasm and reduce the local recurrence threat. **The PROSPERO Registration**: CRD42023393514.

Keywords

Vaginal smooth muscle tumors; Vaginal smooth muscle tumor of uncertain potential; Vaginal wide excision

1. Background

Despite Smooth Muscle Tumors (SMTs) being the most common mesenchymal neoplasms of the vagina and vulva, they are rare entities [1]. Among these, most of them are vaginal leiomyomas. Vaginal leiomyomas are benign, occur mainly in premenopausal women, and can be asymptomatic or paucisymptomatic. Complete surgical removal is curative and has an excellent prognosis. On the other hand, leiomyosarcomas is rarer and usually develops in premenopausal to postmenopausal women (mean, 53 years) and might also be linked to a history of pelvic irradiation [2]. Vaginal SMTs arising at extra-uterine sites present the same morphologic features as their uterine counterparts [1, 3–5]. However, due to the rarity of vaginal SMT, proper stratification criteria were claimed to better predict the malignant potential of these entities. Nowadays, the World Health Organization (WHO) uterine SMTs criteria are considered the most accurate system and are recommended [6]. According to the latest WHO 2020 Classification of Tumors of Female Reproductive Organs, in the section on uterine corpus SMTs, vaginal leiomyosarcoma is claimed when at least 2 of 3 of the following features are present: (1) moderate to severe cytologic atypia, (2) >10 mitotic figures/10 high power fields (HPFs), and (3) tumors cell necrosis. Smooth-Muscle Tumors of Uncertain Malignant Potential (STUMP) are currently used to define SMTs groups with features that preclude an unequivocal diagnosis of leiomyosarcoma but do not fulfill the criteria for leiomyoma or its variants [7]. Uterine STUMPs are relatively rare, and their frequency varies around 0.01% of all uterine lesions presumptively removed as leiomyomas. Mostly discovered in women during the fertile period, they could recur and metastasize [5, 8, 9]. Conceptually, as happens for uterine SMTs, STUMP might arise from the vaginal district. However, it occurs even more rarely, and eventually only three cases of vaginal STUMP were reported in the literature [10, 11]. Due to the scanty evidence retrievable in the literature, we report a systematic review of SMTs of vaginal walls strengthened by a case report of vaginal STUMP to address the impossibility to perform dedicated sub-analyses. The aim is to provide as much information as possible to face this rare entity, starting from data retrievable from other vaginal SMTs. Thus, this

systematic review is aimed to assess the features of vaginal SMT, with a particular emphasis on vaginal STUMP, focusing on diagnostic appearance, surgical and medical management, follow-up management, and outcome.

2. Methods

2.1 Study design, eligibility and exclusion criteria of included studies

This was a case report with a systematic review of the literature on vaginal wall STUMPs. The review was written following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12]. The review protocol was registered in PROSPERO prior to carrying out the literature search (registration number: CRD42023393514).

We used the PICO criteria to frame the P—Population, I—Intervention, C—Comparison, O—Outcome(s), T—Timing and S—Study type. In particularly:

Inclusion: All women with a histological diagnosis of vaginal Smooth Muscle Tumor (SMTs).

Exclusion: Women with a diagnosis of metastasis of SMTs at the vagina arising from other districts including para-urethral leiomyomas; Women with a concomitant or previous diagnosis of other SMTs or gynaecology tumors.

Intervention: Women who undergo surgical removal of vaginal SMT, including STUMP.

Comparators: Patients in whom vaginal STUMP occurred compared with those with a diagnosis of other extra-uterine vaginal SMT.

Study design: Observational studies (randomized control trials, retrospective and prospective studies, case-control series, and case control studies) are included. Reviews, letters to the editor, and congress abstracts are excluded.

Language: Only studies written in English are included.

Aims: to assess the features of vaginal SMT, with a particular emphasis on vaginal STUMP, with respect to diagnostic appearance, surgical and medical management, follow-up management and outcome.

2.2 Search strategy

A systematic search of the literature was conducted in Research is conducted on PubMed, Scopus, ScienceDirect and the Cochrane Library from 2000 to January 2024 for vaginal leiomyomas and from inception to January 2024 for leiomyosarcoma and STUMP. A combination of the following search terms is used: “Smooth muscle tumor of uncertain potential” OR “STUMP”; OR “Smooth muscle tumor” OR “SMTs”, “leiomyomas” OR “leiomyosarcoma” AND “vaginal”.

2.3 Study selection, data extraction and data synthesis

Three reviewers were involved to accomplish the screening, quality assessment and data extraction processes. Two authors independently checked the titles and abstracts of the studies obtained by the search. They obtained the text of eligible studies and assessed studies for inclusion. Two other authors performed a manual search of reference lists in order not to miss relevant or recent publications. Any disagreement between them on the eligibility of studies was resolved through discussion with a third author. Two authors extracted data regarding study features (symptoms, surgery, histology report, follow-up) and population characteristics (age, parity, concomitant pathologies). Two additional authors checked the data extraction.

We used a standardized, pre-specified format for data extraction. We extracted descriptive characteristics of the studies including year of publication, number of cases, patient features (age, symptoms, position and size of the lesions) surgery and histological features. These data are shown in **Supplementary Table 1** divided into leiomyomas, leiomyosarcomas and Vaginal STUMPs subgroups.

2.4 Bias and quality assessment

The checklist “Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)” [12] for reporting observational study-based reviews and randomized controlled trials (RCTs) was used. Two authors independently assessed the methodological quality of studies reporting vaginal STUMP. The “methodological quality and synthesis of case series and case reports” toll was used for bias risk assessment. Eight items, categorized into four domains (selection, ascertainment, causality and reporting), converged in a rating system scoring from 0 (indicating the highest presence of bias) to 8 (indicating the lowest presence of bias), were used to screen the risk of bias in the included studies (**Supplementary Table 2**).

3. Results

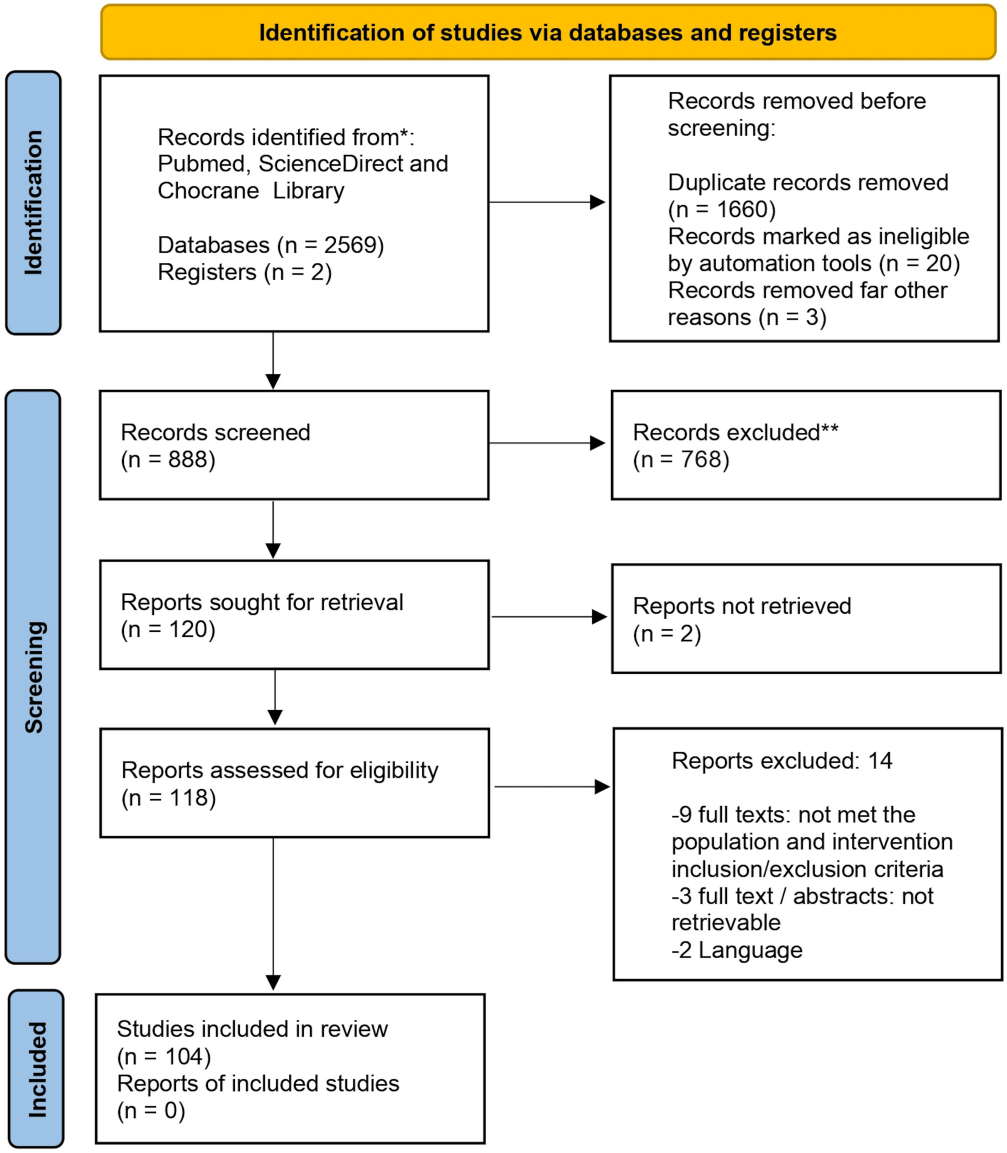
3.1 Study screening and selection process

The search strategy provided a total of 2571 articles. After removing duplicates, 888 articles were eligible for title screening. After title screening, 120 were initially eligible. Of these, 14 studies were subsequently excluded after the examination of the abstract and full text: 9 due to population and intervention inclusion/exclusion criteria, 2 due to language and 3 because only the abstract was retrieved. Finally, 104 articles met the inclusion criteria and were included (Fig. 1).

A total of 163 women were included, 78 were affected by vaginal leiomyoma, 82 by vaginal leiomyosarcoma, and 3 by vaginal STUMP (**Supplementary Table 1**).

3.2 Characteristic of included studies

The average age values were not retrievable for a total of six patients included in two articles [10, 13]. The average age of the 83 patients in the population affected by vaginal leiomyoma was 41 years old. It was provided for 81 patients with vaginal leiomyosarcoma, and the weighted average age of this group was 46 years old. There are three patients who suffered from vaginal STUMP, one patient was 71 years old, and the other two were 33 and 38 years old, respectively (average age 47 years old). The description of the symptoms was not retrievable for six patients in two articles [10, 14] for the vaginal leiomyoma population, and it was reported for



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

FIGURE 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

70 patients. The most frequent symptoms were a feeling of vaginal mass reported in 33 patients (47%), vaginal bleeding declared by 18 patients (25%), dyspareunia for 18 patients (25%), chronic pelvic pain for 14 patients (20%), and urinary disorders in 14 patients (20%); vaginal leiomyoma was asymptomatic in 8 patients (11%). Among vaginal leiomyosarcoma cases, the description of the symptoms was not available for 26 patients included in seven articles [10, 13, 15–19]; Symptoms were described for 56 patients. In this group, 24 patients (42%) suffered from vaginal bleeding, 12 patients (21%) from chronic pelvic pain, 3 patients (5%) from dyspareunia, and 4 patients (7%) from urinary disorders; for 8 patients (14%) a sensation of vaginal mass was declared without any other symptoms. Symptoms were not reported for the three patients with vaginal STUMP. Concerning the characteristics of the tumor mass we collected the size and the location. In the vaginal leiomyoma population, the size of the tumor was not retrievable for 5 patients included in 4 articles [10, 20–22] and it was reported for 71 patients. In this group of patients, the maximum size of the mass was 20 cm. For patients suffering from vaginal leiomyosarcoma the size of the tumor was not available for 26 patients included in 8 articles [13, 17–19, 23–26] and available for 56 patients. In this group of patients, the maximum size of the tumor was 20 cm. The size was available only for 1 patient in two who had vaginal STUMP and in this case, the maximum length of the tumor was 4.2

cm. The leiomyoma was retrieved in the anterior wall in 45 cases (59%). The posterior wall was involved in 7 patients (9%), the left vaginal wall in 9 patients. Vaginal leiomyoma positioning was not retrievable in 6 patients in two articles [10, 27]. The involvement of the left vaginal wall was reported in 8 cases (11%) and the right wall vaginal wall in 6 (7%) patients. Laterality was not specified in 4 cases (5%) [28–30]. Vaginal cuff was reported as site of lesion in one case [31]. The location of the vaginal leiomyosarcoma was not available in 8 articles [10, 13, 17, 19, 25, 32–34]. Vaginal leiomyosarcoma occupied the anterior wall of the vagina in 13 (15%) patients, the posterior vaginal wall in 19 (23%) patients; the right vaginal wall was involved in 8 patients (9%), whereas the left in 10 (12%) cases. Laterality was not specified in 11 cases (13%) [13–35] and vaginal cuff was reported as site of lesion in one case [35]. The position of the mass was not available for the three patients who suffered from vaginal STUMP.

Treatment and outcome: all patients with vaginal leiomyoma received surgical treatment. 66 of them (86%) received wide excision of the lesion by vaginal approach, 2 patients (2.6%) by vaginal natural orifice transluminal endoscopic surgery (vNOTES) methods [31–36], in one case (1.3%), by laparoscopy approach [37] and in 10 (13%) cases, a laparotomic hysterectomy followed the removal of the vaginal lesion [27, 38–46]. Patients with the diagnosis of vaginal leiomyosarcoma received different types of treatments. In specifics, 28 (34%) instances involved surgery alone; 3 (3.6%) cases involved chemotherapy alone [35, 47]; 12 (14%) cases involved surgery followed by adjuvant chemotherapy [23, 35, 47–52]; and 5 (6%) cases involved neoadjuvant chemotherapy followed by surgery [26, 53–56]. The preferred course of treatment in 14 cases (17%) was surgery followed by radiotherapy, while in 8 cases (9%), it was surgery followed by chemo-radiotherapy. Chemoradiotherapy was chosen in 3 cases (3.6%) [35, 47], radiotherapy as the only treatment was chosen in 6 cases (7.3%) [13, 26, 47]. Surgery for recurrence was performed in 4 cases [32, 48, 57, 58]. The type of treatment was not available in detail for the two patients, three with vaginal STUMP, but a surgical treatment seems to be the most probable treatment received by them. The treatment was certainly available for one patient, and it consisted of a surgical vaginal Wilde excision. The follow-up period was not retrievable for 55 (72%) patients with vaginal leiomyoma. However, no recurrence was reported for any patients in this group.

Concerning leiomyosarcoma, follow-up average time was 38.4 months; information was unavailable for 19 (23%) patients. Local recurrence occurred in 17 (20%) patients, distant metastasis was reported in 6 cases (7%) [10, 23, 48, 54, 59, 60] (2 lung metastasis and one thyroid metastasis). Dead of patients (DOP) was reported in 18 cases (21%) with an average time of 45.8 months. In the group of patients affected by vaginal STUMP, two patients (the youngest, aged 33 and 38) had a recurrence of the disease: the first one had positive margins at the first surgery and developed a local recurrence as STUMP in the cervix after 19 months. The margins were negative at the second removal, and no further follow-up was available for her. The second one had a recurrence after 1.13 months, and she was free of disease after 35 months. The oldest patient in the group (71 years old) died of the disease after 56 months, no more information was available for this patient [61–112].

3.3 Case report

Informed consent was obtained before data collection. A statement of consent to the use of anonymous data for research and publication purposes was also obtained. On June 2022, a 43-year-old woman was referred to our Gynecologic Oncology Department due to vaginal discharges and discomfort during intercourse for an anterior wall vaginal mass. She had a regular obstetric history, parity 4004 of them all spontaneous deliveries, and no previous gynecological symptoms or relevant family history were recorded. Furthermore, her clinical history was not remarkable. At the gynecological examination, a swelling mass was noted at the upper vaginal sidewall. This was a soft, painless mass not fixed in the surrounding layers that arose behind the regular vaginal mucosa and closer to the urethra. A transvaginal ultrasound showed a mildly vascularized mass of 4 cm in vaginal wall and rule out any uterine mass suspicious to be a leiomyomas like lesion. with regular margins, embedded between vaginal and vesical space, strictly related to the urethra. The uterus, including the cervix and adnexa, were regular. To rule out the urological origin of the lesion, a urethral-cystoscopy was performed, showing no endoluminal lesions both in the vesical and urethral mucosa. Thus, a punch transvaginal biopsy was done, documenting the presence of a vaginal leiomyoma. In September 2022, a transvaginal-wide excision of the entire mass was performed Histologic examination described macroscopically a grey-yellow soft tissue without a clear capsule; microscopically fragments of spindle cell neoplasm of myogenic nature with areas of severe cytological atypia, a mitotic count up to 7–8 × 10 HPF with atypical mitosis, and the absence of tumor necrosis (Fig. 2a). Neoplastic cells showed immunoreactivity for Estrogen Receptor (Fig. 2b), Smooth Muscle Actin (Fig. 2c), Caldesmon (Fig. 2d), Desmin (Fig. 2e), Vimentin and Progesteron Receptors; they were negative for the human melanoma black (HMB45), melanoma antigen recognized by T cells (MART1) and CathepsinK. The proliferation index, determined with Ki67 immunostaining, was about 10%. Morphological and immunophenotypical features placed a differential diagnosis between a smooth muscle tumor of uncertain malignant potential and a well-differentiated leiomyosarcoma. The margins of the lesion were positive. A second opinion was required at one of the international referral centers for soft tissue tumors, confirming the diagnosis of a vaginal smooth muscle tumor with uncertain malignant potential (STUMP). The case was raised at the multidisciplinary tumor board (MDT) of our institution, which agreed to further imaging investigations with a thoracic and abdomen computed tomography (CT-scan) and pelvic MRI that were negative. A complementary hysterectomy was ruled out due to the patient's age and negative imaging results. Follow-up with a gynecological evaluation and transvaginal ultrasound scan was scheduled every 3–4 months for one year. Follow-up was negative for up to six months, then a swelling mass

suspicious of recurrence was noted again at the upper vaginal sidewall during the gynecological examination. A pelvic MRI was further performed, highlighting the presence of an irregular mass with high cellularity, arising from the anterior vaginal wall, compressing the vaginal lumen measuring 18 × 13 mm. with intermediate signal at T1-weighted sequences and Hyperintense at T2-weighted sequences. Cystoscopy was negative for intraluminal lesions and a total body CT scan was also negative for repetitive lesions. On April 2023, a further vaginal wider excision of the lesion was performed, confirming the presence of a spindle cell neoplasm of myogenic nature with morphological and immunophenotypical characteristics referable to the lesion already removed (Fig. 2f). Follow-up with gynecological evaluation and transvaginal ultrasound scan was scheduled every 3–4 months for one year, and pelvic MRI at 4 months was rescheduled according to MDT decision. At 10 months, no recurrence was detected both at transvaginal ultrasound and pelvic MRI.

4. Discussion

Extrauterine SMTs, including vaginal SMTs, are rare entities with unclear biology and clinical courses [5]. In our review, we analysed a total of 161 women, of whom 76 were affected by vaginal leiomyoma (excluding para-urethral leiomyomas), 82 by vaginal leiomyosarcomas, and 3 by vaginal STUMP. Symptoms cannot steer the diagnosis. Vaginal leiomyomas occur both in premenopausal and postmenopausal women (mean, 41 years old), and despite the main symptoms being bleeding, dyspareunia, chronic pelvic pain, and urinary disorders, they can be entirely asymptomatic. Leiomyosarcomas usually develop later (average age 46 years old), and symptoms almost overlap the benign counterpart, despite asymptomatic arising being less common. Bearing in mind that uterine STUMPs are considered diagnostically and clinically challenged, vaginal STUMP place physicians in an unknown field. First of all, a differential diagnosis between a primary vaginal tumor and a metastasis from the uterine level must be carried out. Transvaginal ultrasound, MRI and CT scan could help rule out the concomitant presence of a uterine lesion. If it is present, after the diagnosis of vaginal STUMP and according to fertility desire and age, a hysterectomy should be considered to assess the origin of the tumor. In the 2014 edition of WHO Female Genital Tumor Nomenclature, risk stratification criteria for uterine SMTs have also been extended for these entities [1]. Thus, since no specific criteria exist for the diagnosis of vaginal STUMPs, uterine ones are broadly accepted. It is not accidental that uterine SMTs remain a benchmark for these diseases. They share the same clinical presentation (metrorrhagia and pelvic pain), clinical and paraclinical investigation, and histological and immunohistochemical evaluation. The therapeutic approach for uterine STUMP relies on the same principle of surgical removal of the entire lesion (hysterectomy), leaving the lesion intact to rule out the risk of recurrence or implantation. excepting rare cases, it also shares indolent behaviour with prolonged survival [113]. In the literature, vaginal STUMPs are reported to be spindled with mild to moderate cytologic atypia, 7–11 mitotic figures/10 HPFs that lacked atypical division forms; foci of necrosis. At immunohistochemistry (IHC), they show reactivity for Desmin

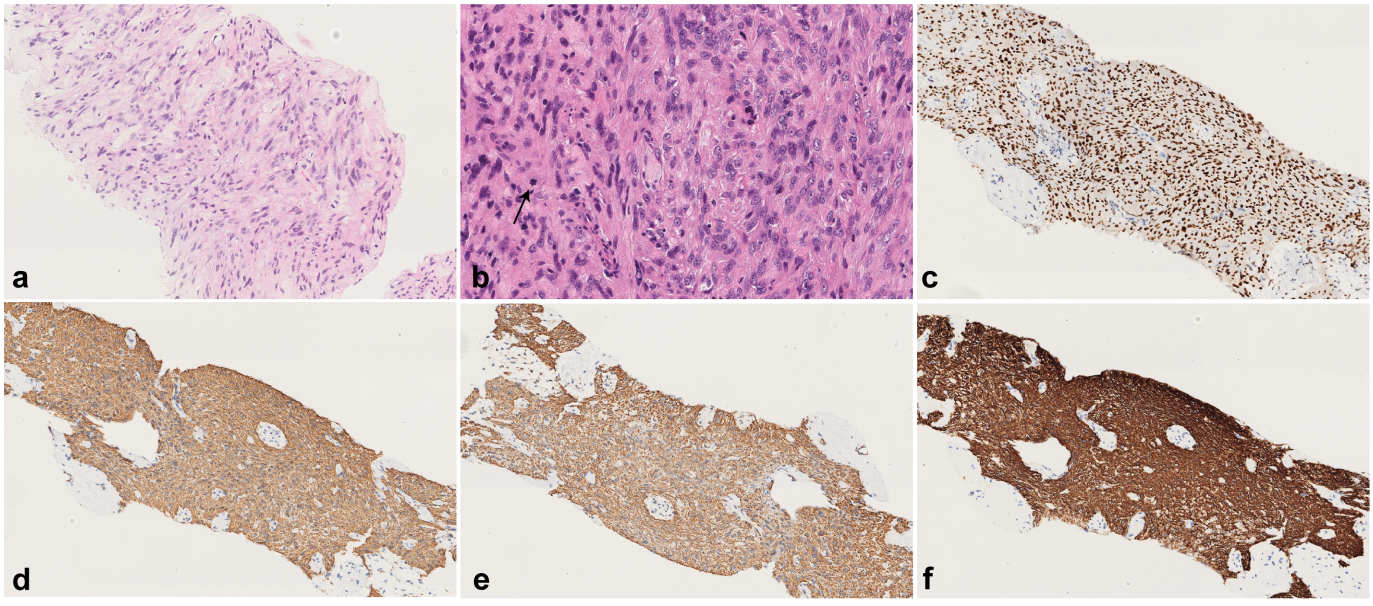


FIGURE 2. Histologic images of vaginal STUMP and its relapse. (a) Hematoxylin-Eosin image of one of the fragments of a spindle cell lesion, with moderate cytologic atipya (100× magnification); (b) Hematoxylin-Eosin image of the relapsed lesion with a spindle cell lesion, with moderate-severe cytologic atipya, arrow shows an atypical mitosis (200× magnification); (c) immunohistochemical staining for Estrogen Receptor of the first vaginal STUMP, showing diffuse positivity (100× magnification); (d) immunohistochemical staining for Smooth Muscle Actin of the first vaginal STUMP, showing diffuse positivity (100× magnification); (e) immunohistochemical staining for Caldesmon of the first vaginal STUMP, showing diffuse positivity (100× magnification); (f) immunohistochemical staining for Desmin of the first vaginal STUMP, showing strong and diffuse positivity (100× magnification).

and h-Caldesmon, and they are negative for S100 protein since one of the differential diagnoses that must be ruled out is melanoma. Loss of alpha thalassemia with mental retardation (ATRX gene) or the Death-associated protein 6 (DAXX) expression is also reported. Other molecular variants, such as p53 aberrant expression or p16INK4A overexpression, are not reported [11]. This aspect is also in line with the similarity of uterine STUMPs with positive expression of p53 varies between 0–42.3% [113]. In our institution, we reported a case of vaginal STUMP histologically characterized as spindle cell neoplasm of myogenic nature with areas of severe cytological atypia, a mitotic count up to 7–8 × 10 HPF with atypical mitosis, and the absence of tumor necrosis (Fig. 2a,b). Neoplastic cells showed immunoreactivity for Estrogen Receptor (Fig. 2c), Smooth Muscle Actin (Fig. 2d), Caldesmon (Fig. 2e), Desmin (Fig. 2f), Vimentin and Progesteron Receptors; they were negative for HMB45, MART1 and CathepsinK. The proliferation index, determined with Ki67 immunostaining, was about 10%. Remarkably It was removed vaginally with positive margins of resection, and a local recurrence occurred six months later. A second vaginal wider resection with free surgical margins was performed, and no further recurrence was reported in 24 months of follow-up. In the literature, vaginal access is the only documented approach and was also used in our case. The free margin of excision seems to be a prognostic factor for local recurrence [9]. Among vaginal STUMPs, 3/4 had a local recurrence of the disease. In two cases, including ours, positive margins at the first surgery were reported and correlated to recurrence. Therefore, any solid vaginal mass should be treated excisionally, requiring a wide local excision to ensure negative margins. Molecular features appear to have an impact on recurrences as well, suggesting that IHC may have both diagnostic and prognostic utility. According to studies by Slatter *et al*. [11] IHC and FISH may be helpful in the differential diagnosis procedure as well as in post-operative care for the molecular diagnosis and prognosis of uterine STUMPs and early-stage leiomyosarcoma. A poor prognosis in uterine STUMP has mostly been connected to the mutant expression of ATRX (athalassemia/mental retardation syndrome X-linked) and DAXX (death-domain-associated protein), which are proteins involved in the remodeling of chromatin structure. Despite a similar conclusion that might not be claimed for vaginal STUMPs due to the scarce numbers for statistical analysis of survival, the loss of ATRX or DAXX expression was present both in the case of death and the local recurrence of vaginal STUMP. As a result, after complete free-margin eradication of the disease, follow-up becomes critical in vaginal STUMP management. No statistical data can be retrieved for Follow-up management (timing and diagnostic tools), but since local recurrence must be ruled out in the first months, we suggest a gynecological evaluation and transvaginal ultrasound scan every 3–4 months for the first year and a pelvic MRI at 4–6 months, then an annual evaluation. It is important to closely monitor patients with vaginal STUMP to detect any signs of local recurrence early on. Regular gynecological evaluations and imaging studies can help in the timely detection and management of any potential recurrence. This approach allows for early detection of any potential recurrence and ensures timely intervention if needed. Additionally, close monitoring in the initial post-treatment period can provide valuable insights into the long-term prognosis of patients with vaginal STUMP. To date, this is the first systematic review of primitive vaginal SMTs with a focus on an extreme entity such as vaginal STUMP. The main limitations of our review are related to the design of original studies (all case reports or series) and to the lack of report consistency. However, this analysis might be helpful for comparing different treatment approaches, shedding light on a rare tumor where no sufficient data is retrievable for standardized management. Because of that, another main limitation of this study is the lack of statistical analysis of outcomes, including disease-free survival and overall survival, in relation to the patient's characteristics, type of surgery, and molecular variabilities. The lack of statistical analysis hinders the ability to draw definitive conclusions about the effectiveness of different treatments.

5. Conclusions

Vaginal STUMP is a rare entity, and no data is retrievable for statistical analysis. Considering our report the prevalence of vaginal STUMP among all vaginal SMTs are to properly recognize and radically remove the neoplasm reducing the risk of local recurrence, specific immunohistochemistry panels, and wide excision with free resection of margins are strongly recommended. Transvaginal ultrasound and MRI are advocated to rule out the persistence or recurrence of the disease during the follow-up. These imaging techniques can help ensure timely detection and treatment, if necessary.

AVAILABILITY OF DATA AND MATERIALS

All relevant data are within the manuscript and its **Supplementary material**.

AUTHOR CONTRIBUTIONS

FFC and GV—performed protocol/project development, conceptualization, design, quality assurance. GI and SF—performed data collection, extraction and quality supervision. CR, FG, GT, SM, MG and MP—performed data analysis. MDSV and PC—performed pathological features analysis and imaging descriptions. GV—performed Manuscript writing, editing and final manuscript write-up. All authors contributed to the study conception and design.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was in accordance with the Helsinki Declaration, conforms to the consensus-based Clinical Case Reporting Guideline Development (http://www.equator-network.org/) the Committee on Publication Ethics (COPE) guidelines (http://publicationethics.org/). No Institutional Review Board (IRB) approval was required for this study. The institutional Patient's consent for the use of the data for scientific purposes was obtained before data collection.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Gaetano Valenti is serving as one of the Editorial Board members of this journal. We declare that Gaetano Valenti had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to TM.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.ejgo.net/files/article/1879407867319992320/attachment/Supplementary%20material.docx.

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