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Creatsas Vaginoplasty in Patients After Pelvic Chemoradiation in Cervical Cancer: A Preliminary Study

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1. Abstract

1.1. Objective: The main objective of this study was to assess the impact of the Creatsas vaginoplasty on the improvement in the sexual life of patients with cervical cancer who have received chemo radiotherapy and have sexual dysfunction measured by The Female Sexual Function index.

1.2. Methods: The design was an observational prospective individual cohort study between January 2018 - December 2019 of Patients Report Outcomes (PRO) using The Female Sexual Function Index. A total of 12 patients were evaluated.

1.3. Results: Among all patients, the global scores of The Female Sexual Function Index questionnaire improved after surgery except for one patient. No patients had post-operative complications.

1.4. Conclusion: This preliminary study suggests that the Creatsas procedure improves the sexual life of cervical cancer patients with vaginal stenosis who have received chemo radiotherapy as the first treatment.

2. Introduction

Chemo radiotherapy followed by brachytherapy is the standard treatment in locally advanced cervical cancer patients [1], providing up to 66% of overall survival rate [2]. Therefore, the evaluation of the long-term toxicity of this treatment is crucial. After radiotherapy, 11% of the patients with cervical cancer have reductions in vaginal diameter and 66% in vaginal length [3]. One of the most common side effects after pelvic radiation therapy is vaginal stenosis, which is defined as an abnormal tightening and shortening of the vagina due to the formation of fibrosis after pelvic radiation [4].

As more patients survive their cancer, new investigations to improve their quality of life are critical. Sexual health is an essential component of humans, being affected and decreased due to chemo and radiotherapy [5]. Female sexual dysfunction is complex; even when an immediate structural cause of dysfunction is clear and solved, emotional and hormonal disorders could co-exist and make vaginal penetration unpleasant [6]. However, gynecologic oncologists may identify this and offer the best method of treatment.

Reconstructive surgery can be an option to improve the sexual function of these patients [7]. The use of the Creatsas modification of Williams vaginoplasty [8], previously published [9], represents a simple surgical technique, which may boost the patient's sex life [10]. However, there is a lack of well-established criteria to evaluate the sexual dimension on the quality of life of these patients in the literature. The Female Sexual Function Index is a 19-item questionnaire, that has been developed as a brief, multidimensional self-report instrument for assessing the key dimensions of sexual function in women [11]. This questionnaire has been validated on clinically diagnosed samples of women with female sexual arousal disorder, female orgasmic disorder, and hypoactive sexual desire disorder.

In this preliminary approach, our study analyzed the cervical cancer patients with vaginal stenosis and a pathologic total score in the Female Sexual Function Index after receiving chemo radiotherapy. All of them were performed a Creatsas vaginoplasty technique to improve their quality of life tested by the Female Sexual Function Index questionnaire during the follow-up [12].

3. Material and Methods

This was a study endorsed by the Department of Gynecologic Oncology in Hospital Universitarioy Politécnico La Fe and conducted after obtaining the Institutional Review Board approval.

3.1. Study Design

This was an observational prospective individual cohort study of patients reported outcomes with cervical cancer who received chemo radiotherapy and underwent the Creatsas procedure between December 2018- December 2019. This timeframe allowed at least 1 year of follow-up. The outcomes were evaluated through The Female Sexual Function Index [11]. Additionally, to examine sexual function in culturally diverse populations there are translated versions of the questionnaire; we used the Spanish version [13].

3.2. Objective

The primary endpoint of this study was to evaluate the impact of the Creatsas vaginoplasty on the improvement in the sexual life of patients with cervical cancer who have received chemo radiotherapy and have sexual dysfunction measured by The Female Sexual Index.

3.3. Procedure

The Female Sexual Function Index has been used for assessing the key dimensions of sexual function in women [11], including sexual desire, arousal, lubrication, orgasm, pain, and satisfaction.

The Female Sexual Function Index was developed in the year 2000, comprised by 19 items in total organized in 6 different domains (desire, arousal, lubrication, orgasm, satisfaction, and pain), and the estimated time to complete all 6 domains was 5-10 min. (Supplemental 1). The questionnaire was administered to patients by study coordinators in person at baseline (before surgery) and each follow-up appointment after surgery (4 weeks, 6, and 12 months after surgery). The questionnaire at 4 weeks postoperative aimed to assess the early vaginal recovery. Moreover, the vaginal length during the subsequent appointments verifies the maintenance of the vaginal length. The 19 items use a 5-point Likert scale ranging from 15 with higher scores indicating greater levels of sexual functioning on the respective item. To score the measure, the sum of each domain score is first multiplied by a domain factor ratio (0.6 for desire; 0.3 for arousal; 0.3 for lubrication; 0.4 for orgasm; 0.4 for satisfaction; and 0.4 for pain) to place all domain totals on a more comparable scale, and then subsequently summed to derive a total FSFI score [11]. Changes in Female Sexual Function Index scores over the course of treatment assessed the effect of the surgery on patients' sexual functioning.

Under general anesthesia, a symmetrical U-shaped vulvar incision was made, starting from 4cm lateral to the external urethral meatus and lateral to the labia majora. The perineal subcutaneous tissue was mobilized dorsally, and the inner skin margins were sutured from below upwards in an interrupted fashion, keeping the knots towards the inside (2–0 absorbable suture) in order to create a vaginal pouch. The perineal muscles and subcutaneous fat were closed with simple interrupted sutures. Finally, the lateral skin margins were sutured from below upwards in an interrupted fashion with polyglactinic suture (Figure 1).

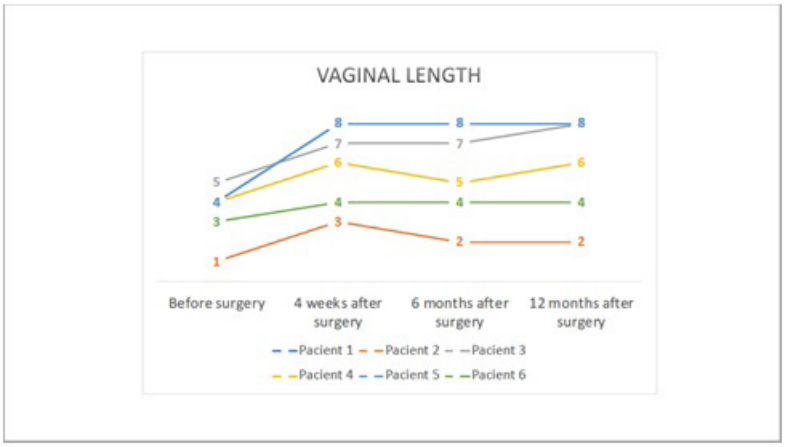

Figure 1: Vaginal length evolution. We can see 5 lines in the graphic because patient number 1 and number 5 have the same vaginal length before and during the follow-up period.

3.4. Cohort Selection and Study Variables

Eligible patients were women aged 18 years or older with carcinoma of the cervix who received concurrent chemo radiotherapy, with total dose of 45 to 50 Gy (1.8 Gy per fraction) and cisplatin (weekly 40 mg/m2) , with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, and International Federation of Gynecology and Obstetrics (FIGO) 2018 stage more than IB1 disease, more than 2 years of recurrence-free survival who was sexually active and expressed dispareunia and accomplished radiation-induced vaginal stenosis, defined as vaginal narrowing or

shortening interfering with the use of tampons, sexual activity or physical examination using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 in reproductive (and breast disorders) section: vaginal stricture-grade3 [3, 14].

Included patients were evaluated by the standard physical examination including a speculum pelvic exam. The length of the vagina was measured from the vaginal dome to the introitus with a flexible plastic rule and a vaginal manual examination before the surgery and each appointment after the surgery. Patients were included in the study if the total score of the Female Sexual Function Index was less or equal than 26.55, that defines a sexual disorder. Patients were excluded if they had a history of pelvic or abdominal radiotherapy before the diagnosis of cervical cancer and if they have not been sexually active after the 4-week reference period, to avoid the erroneous use of the zero categories for ensuring against zero scores being added into the calculation of Female Sexual Function Index domain and total scores. Moreover, patients were excluded if their total score of the Female Sexual Function Index was more than 26.55, because they did not have an objective sexual disorder. Postoperative complications were measured as any postoperative complication (≥ grade III Clavien-Dindo classification) that occurred within 30 days after surgery.

3.5. Statistical Analysis

Data was summarized using the mean (standard deviation) in the case of numerical variables, and by absolute and relative frequencies in the case of categorical variables. To assess the effect of the surgery overtime on 6 dimensions and total score in The Female Sexual Function Index, a Bayesian ordinal regression model was performed. Given the longitudinal nature of the study and the non-independence of the observations, an independent term for each sample was included in the models. Furthermore, as the effect of time was not expected to be linear, time was included in the model as a monotonic effect. Given the limitation in sample size, the focus has been given to the partial effect plots and their 95% credibility intervals. All statistical analyses were performed using R (version 4.0) and the BRMS packages (version 2.12) and R packages clickR (version 0.4.47) [15-17].

In accordance with the journal's guidelines, we will provide our data for the reproducibility of this study in other centers if such is requested.

4. Results

4.1. Study Population

A total of 12 patients were evaluated, 6 patients were excluded because 4 rejected the surgery and 2 did not meet the inclusion criteria. Among the 6 included patients the Creatsas technique was performed between December 2018, and December 2019. The demographic characteristics are summarized. The median age was 42.5 years (IQR 38-48.5), and the median body mass index was 21.85 kg/m^2 (IQR 19.5-25.1) before surgery. The median pre-surgery vaginal length was 4cm (3.25-4) and post-surgery was 8.5 cm (IQR 5.75-9) (Figure 2).

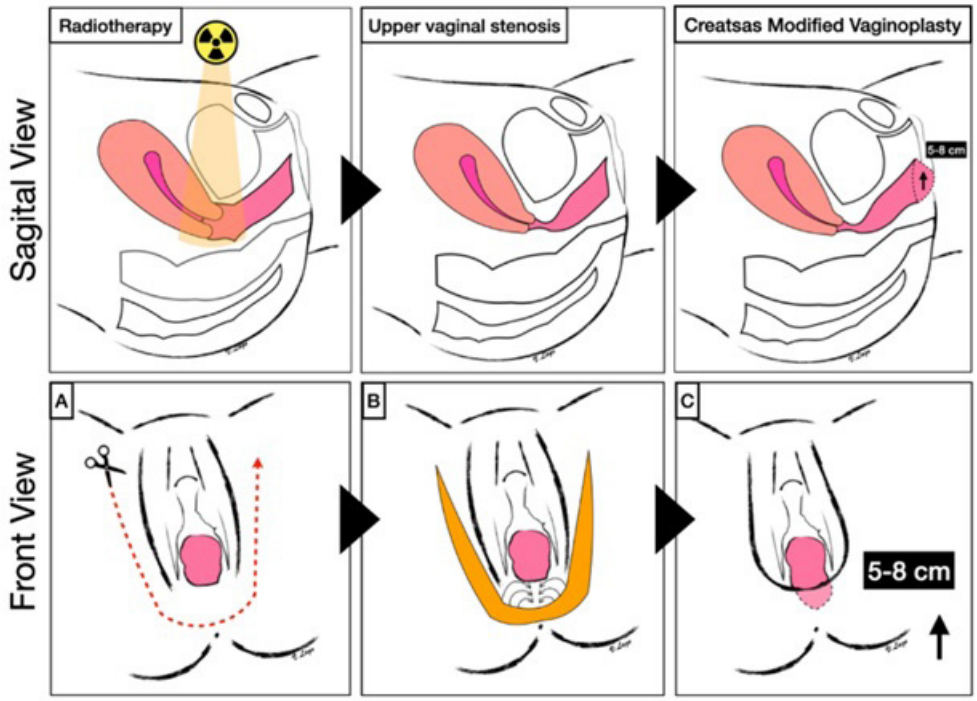

Figure 2: Sequential pictures showing in the sagittal view the upper vaginal stenosis and the vaginal pouch creation after the surgery, and in the front view the technique and final result after the Creatsas surgery

4.2. Subgroup Analysis

No patients had sexual relations 4 weeks after the surgery, thus we were not able to assess the early postoperative vaginal recovery. The median of the desire before the surgery was 2.1 (1.35, 3.3) after 6 months was 3.9 (3.6, 4.65) and after 12 months 4.2 (3.6, 5.7). Therefore, the desire was increased after the surgery and during the subsequents months of follow-up period (OR = 1.34 CI95% [1.117; 1.642]). The median of the excitation before the surgery was 3.75 (2.25, 4.12), after 6 months was 4.95 (4.58, 5.33) and, after 12 months 4.95 (4.35, 5.78). The excitation was increased after the surgery and remained stable after 12 months (OR = 1.30 CI 95% [1.087; 1.582]). The median of the lubrication before the surgery was 3.6 (3.08, 4.12), after 6 months was 3.6 (3.37, 3.82) and, after 12 months 3.6 (3.37, 3.82). Despite the same median of the lubrication score was reported during follow up, the OR was increased after the surgery during the follow-up (OR = 1.14 CI 95% [0.97; 1.338]) among all patients except one (number 2). However, patient number 2 had an increased global score. The median of the orgasm score before the surgery was 3.8 (3.3, 4), after 6 months was 4.4 (4.4, 4.7) and, after 12 months 4.6 (4.4, 4.8). So, the orgasm score was gradually increased after the surgery (OR = 1.40 CI 95% [1.163; 1.747]). The median of the satisfaction before the surgery was 4.2 (3, 4.8), after 6 months was 5 (3.9, 5.5) and, after 12 months 5.4 (4.9, 5.6). Therefore, the satisfaction increased after the surgery (OR = 1.323 CI 95% [1.116; 1.589]) (Figure 3) However, the median of the global score before the surgery was 22.95(19.18, 24.92), after 6 months was 26.95 (24.95, 27.23) and, after 12 months 24.5 (23.18, 26.42). The global score had increased after the surgery (OR = 1.27 CI 95% [1.087; 1.499]) (Figure 4).

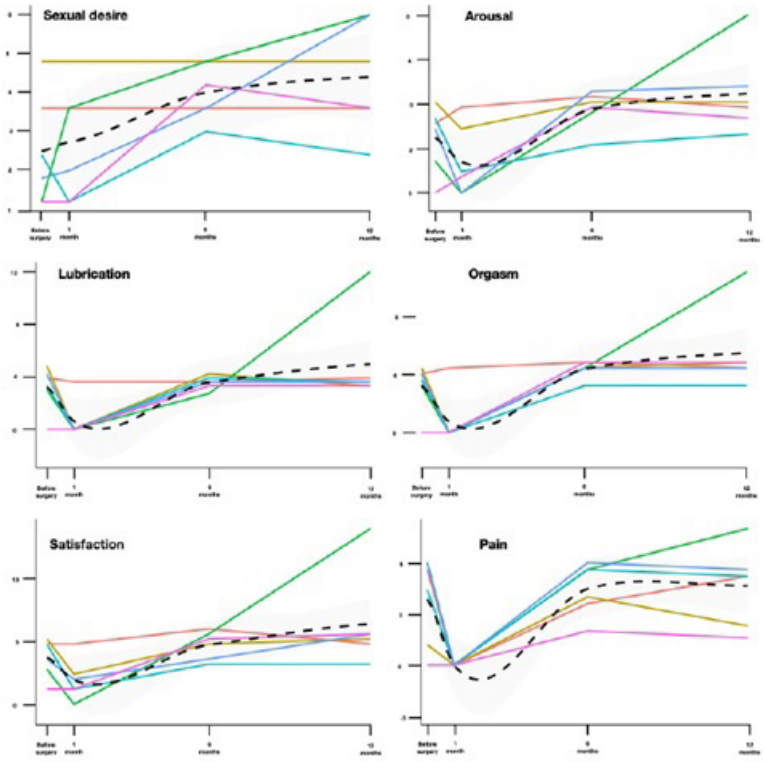

Figure 3: These graphics show the evolution before and after the surgery in the 6 different domains (desire, arousal, lubrication, orgasm, satisfaction, and pain) of The Female Sexual Function Index.

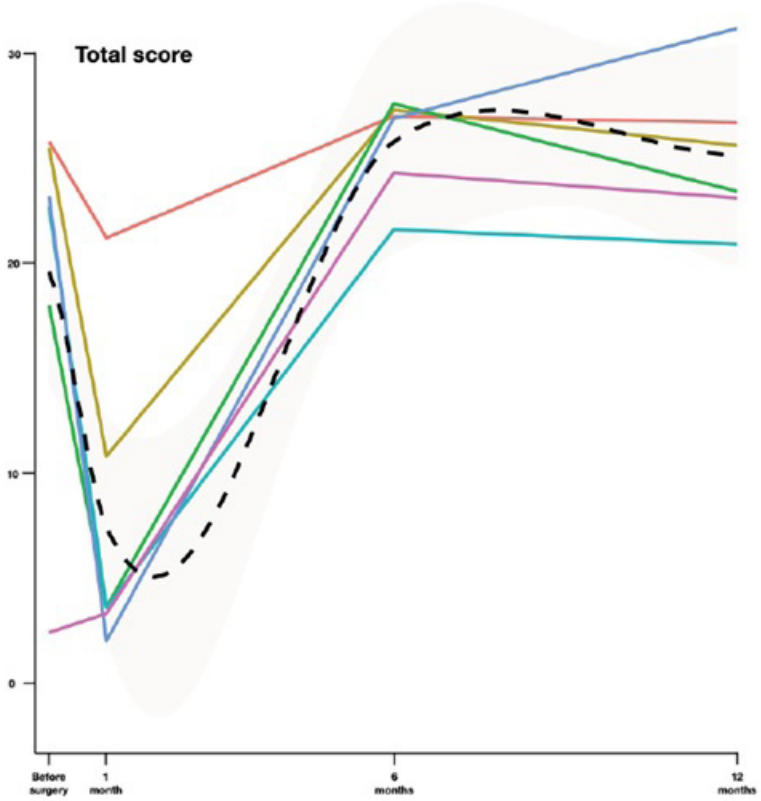

Figure 4: This graphic shows the improvement of the total score of The Female Sexual Function Index in the 6 analyzed patients.

5. Discussion

The present study suggests that patients with vaginal stenosis and sexual dysfunction after receiving chemo radiotherapy who underwent the Creatsas surgery presented a higher global score in the Female Sexual Function Index. After 12 months of follow-up, all the domains showed better scores than before the surgery.

Currently, quality of life is the main objective in oncology patients. Sexual health is an integral understudied component across the lifespan of humans. Cancer survivors who experience sexual morbidity are at an increased risk of distress and poor well-being.

A major barrier to the development of clinical research in this area was the absence of well-defined endpoints and outcomes, which in turn reflects the lack of interest regarding an early diagnostic for assessing and treating female sexual dysfunction over the years. However, quality of life and the study of women's sexual function in oncologic patients have increased over the past 20 years. The Female Sexual Function Index has become the most widely used screening tool and outcome measure of female sexual function in the literature [18].

Among all patients, the global scores of the Female Sexual Function Index questionary improved after surgery except for one patient, number 4, who decreased her global score although the desire was stable, and lubrication improved after the surgery.

The Creatsas surgery is a technically easy and safe perineal procedure with a low cost because patients do not require hospitalization. There are many vaginal reconstructive procedures described in the literature, such as labial, skin, or myocutaneous flaps. Most of the literature related to vaginal reconstruction is described after exenterative surgeries or congenital abnormalities but not after chemoradiotherapy treatment [8, 19]. The idea of using a bowel segment for vaginal reconstruction rise since 1892. In a long-term assessment, 85% of the patients who performed sigmoid vaginal reconstruction developed a vaginal stenosis [20]. Moreover, all these techniques have been evaluated in patients who performed surgery as primary treatment. It is well studied how radiotherapy alters the quality of tissues [21] that makes these procedures technically more complex with higher inherent morbidity and complications than the Creatsas surgery. This procedure is a pelvic reconstruction with any possibility of vaginal stenosis for overcoming the drawbacks of other vaginal reconstruction options.

Despite the good results and the simplicity of the procedure, no patients restore her sexual function before 4 weeks after surgery. This shows once again the complexity of women sexuality.

Considering the widespread diffusion of female sexual dysfunction among gynecologic cancer patients and the improvement in their prognosis, it undoubtedly looms the need for proactive countermeasures to maximize the sexual dimension of well-being and the quality of life of these patients without increasing morbidity. The Creatsas surgery is a great option without major post-operative complications that meet the need of these patients with cervical cancer who received chemo radiotherapy.

The main strength of our study is the current prospective series of well-selected cases focused only on patients who received chemo radiotherapy without surgery. The cohort individual design let us know a reliable control of the sexual improvement of each patient. In order to decrease the risk of bias, we only analyze patients after 6 months and 12 months of the surgery to demonstrate its effect after the patients start with sexual relations, 4 weeks after surgery. Moreover, we assess the global sexual health, including anatomical but also psychological components of the sexual evaluation based on patients reported outcomes defined as a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else.

Our study has several limitations; above all, the inherent bias of a small sample of the study and the fact that there is only one center that contributed to include patients. We did not use a reliable tool to assess the aesthetic outcome. It is a subjective measure and patients used to assess aesthetic outcome differently than professionals. However, all patients have a high score in sexual desire domain, that it is very related to a positive self-image (Figure 5).

In conclusion, this preliminary study suggests that the Creatsas procedure improves the sexual life of cervical cancer patients with vaginal stenosis who have received chemo radiotherapy as the first treatment.

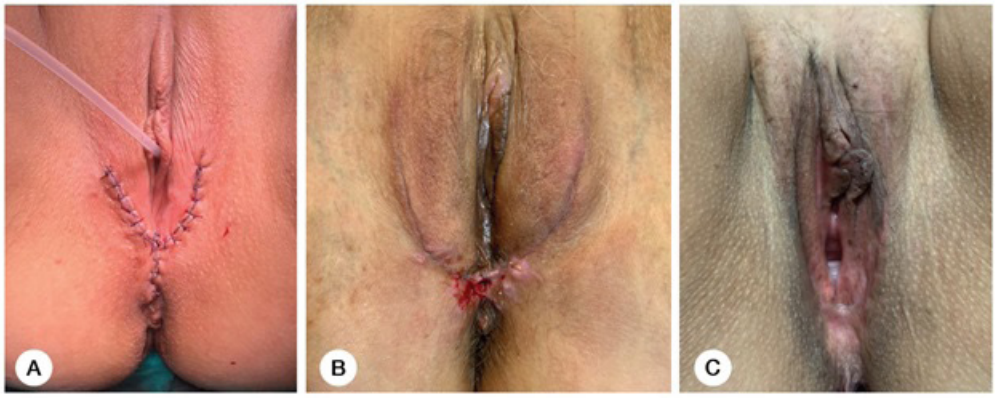

Figure 5: Chronological evolution of the vulvar scar in patient number 4 during the follow-up (4 weeks, 6 months and 12 months after surgery from top to the bottom pictures).

6. Acknowledgements

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