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Research Article

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The Use of Transdermal Carboxytherapy in the Postoperative Evolution of Gynecological Oncological Surgeries of the Vulva

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ABSTRACT

Introduction: A vulvectomy, a surgical procedure often performed to treat vulvar cancer, involves the removal of tissue from the vulva. While this surgery can be life-saving, it also carries the potential for various side effects that can affect patients both physically and emotionally. Significant sequela in women with a history of vulvar cancer, exacerbated by surgical and radiotherapy treatments that compromise the anatomy and function of the lower genital tract. Hormonal therapeutic options are often limited in this population due to oncologic risks, emphasizing the need for safe and effective alternatives. In this context, transdermal carbon dioxide (CO_2)-releasing gels have demonstrated beneficial effects on microcirculation, tissue oxygenation, and cellular regeneration, offering an innovative non-hormonal strategy for managing vulvovaginal symptoms in cancer survivors.

Objective: To evaluate the progression of vulvoperineal symptoms in patients with a history of vulvar cancer undergoing regenerative therapy.

Materials: Five patients underwent a surgical procedure and radiotherapy. They performed regenerative treatment using a combination of transdermal gels that release CO_2.

Methods: Regenerative treatment was applied, and 15 symptoms were evaluated at baseline, after 6 weeks, and 3 months.

Results: The mean total symptom burden decreased from 14.4 at baseline to 10.0 at 6 weeks, and to 0.8 at 3 months (94.4% reduction). Although paired comparisons did not reach statistical significance ($p=0.0625$), effect size measures (ARR and RRR) indicated clinically meaningful improvement in most symptoms.

Conclusion: The regenerative protocol produced marked and sustained clinical improvement in signs and symptoms in patients with a history of vulvar cancer. Studies with larger sample sizes are warranted to confirm statistical significance.

Keywords: Fibrosis Post OP, Carbon Dioxide-Releasing Transdermal Gel, Regenerative Therapies, Vulvar Cancer Survivors

Introduction

We present a study in patients operated on for vulvar cancer and subsequent radiotherapy, where transdermal carboxytherapy is used, and we evaluate the evolution in the quick recovery of patients.

Vulvar cancer is an unusual gynecological malignancy primarily concerning postmenopausal women, accounting for only 4% of gynecological malignancies. The most effective strategy to reduce vulvar cancer incidence is the appropriate treatment of

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predisposing lesions associated with its development. While vulvar cancer may be asymptomatic, most women present with vulvar pruritus or pain or have noticed a lump or ulcer. Consequently, any suspicious vulvar lesion should be biopsied. The most common subtype is squamous cell carcinoma. Treatment of vulvar cancer depends primarily on histology and surgical staging. Treatment is predominantly surgical, particularly for squamous cell carcinoma, although concurrent chemoradiation is an efficient complementary treatment, particularly for advanced tumors [1].

A vulvectomy, a surgical procedure often performed to treat vulvar cancer, involves the removal of tissue from the vulva. While this surgery can be lifesaving, it also carries the potential for various side effects that can affect patients both physically and emotionally. The nature and severity of these side effects depend on factors such as the extent of tissue removal, whether lymph nodes are removed, and individual healing responses. Understanding these common side effects is crucial for patients and healthcare providers to manage expectations, provide appropriate care, and support recovery effectively [2].

High-grade squamous intraepithelial lesions (HSIL). Multiple treatment modalities exist for the management of HSIL, but minimal excision with 5-mm margins and 4-mm depth is the most common. Excision has the benefit of eliminating invasion histologically, but the lack of conservation of vulvar skin results in psychosexual morbidity [3].

Patients who have undergone vulvectomy with or without the addition of therapies such as brachioplasty or radiotherapy experience pain and discomfort in the postoperative period that is exacerbated by the subsequent development of postoperative fibrosis [4].

Based on our experience with a combination of gels that enable CO_2 production to treat vulvar atrophy and varicose ulcers, we propose using this gel after completing radiotherapy and surgery [5].

The treatment of the post-vulvectomy scar should be divided into different stages, with radiotherapy noted to increase the fibrotic reaction in the operated and treated area.

Vulvar Wound Care Post-Vulvectomy:

"Fibrosis is defined by the overgrowth, hardening, and/or scarring of various tissues and is attributed to excess deposition of extracellular matrix components, including collagen. Fibrosis results from chronic inflammatory reactions induced by a variety of stimuli, including persistent infections, autoimmune reactions, allergic responses, chemical insults, radiation, and tissue injury" [6].

1. Background & Importance

- Vulvectomy, often executed for vulvar cancer or severe dysplasia, results in complex wounds requiring specialized care [7].
- Gynecological post-care rules play a critical role in **postoperative wound management, infection prevention, and patient education** [8].

2. Wound Care Protocols

- **Aseptic technique** is essential during dressing changes to prevent contamination.
- Use of **non-adherent dressings** to minimize trauma during removal.
- **Moist wound healing** principles are recommended to promote epithelialization.

3. Pain & Comfort Management

- Pain is often significant due to the sensitivity of the vulvar region.
- The surgeon will give the correct indication for adequate analgesia
- Positioning strategies (e.g., side-lying) can reduce pressure and discomfort.

4. Psychosocial Support

- Vulvectomy can impact body image, sexual identity, and emotional well-being [9].
- Empathetic support and facilitate referrals to counseling or sexual health services.

5. Watching for Complications

- Watch for signs of **infection, hematoma, dehiscence, or delayed healing.**
- Early identification and appreciation of the surgical team are crucial.

6. Education & Discharge Planning

- Teach patients how to perform gentle hygiene and dressing changes at home.
- Provide written instructions and contact information for follow-up care.

Fibrosis After Vulvectomy: Mechanisms & Clinical Implications

1. Pathophysiology of Fibrosis [10]

- **Fibrosis** is the result of excessive extracellular matrix (ECM) deposition during wound healing.
- In vulvectomy, especially radical procedures, **tissue trauma, inflammation, and impaired lymphatic drainage** can promote fibrotic remodeling.
- **Chronic inflammation,** infection, or poor wound care may exacerbate fibroblast activation and collagen deposition.
- **The use of brachytherapy and radiotherapy increased postoperative fibrosis.**

2. Clinical Manifestations

- **Scar contracture** or thickened plaques in the vulvar region.
- **Reduced elasticity** and discomfort during movement or sexual activity.
- **Sensory changes** due to nerve entrapment in fibrotic tissue.
- May contribute to **chronic pain syndromes** or **vulvodynia-like symptoms**.

3. Risk Factors

- Radical vulvectomy with wide margins.
- Delayed wound healing or wound dehiscence.
- Prior radiation therapy or lymphadenectomy.
- Coexisting conditions like **diabetes** or **autoimmune disorders**.

4. Management Strategies
- **Early wound care for optimization** to reduce inflammation.
- Use of **silicone gel sheets** or **pressure garments** to modulate scar formation.
- **Physical therapy** for pelvic floor and soft tissue mobilization.
- In severe cases, **surgical scar revision** or **reconstructive flap procedures** may be considered.

The side effects post-op and radiotherapy significantly impact quality of life, particularly in women with a history of cancer, where hormonal therapy is often contraindicated [11].

Regenerative therapies have emerged as a promising alternative, with early evidence supporting the use of PRP, autologous exosomes, and mesenchymal stem cells [12]. However, systematic evidence in this specific population is scarce. This prospective pilot study aims to evaluate symptom progression in patients with a history of vulvar cancer treated with a regenerative protocol.

Material and Methods

In a group of patients, we have used transdermal carboxytherapy in the immediate postoperative period and in other cases after radiotherapy.

A total of 5 **patients** with a history of cancer and a diagnosis of GSM were included. Demographic data (age, weight, height) and **15 vulvoperineal symptoms** were recorded.
- Symptoms were evaluated at three time points: baseline, 6 weeks, and 3 months, using a structured questionnaire.
- Symptom prevalence was calculated at each time point, along with improvement rates (patients who changed from *yes to no*).
- Absolute (ARR) and relative risk reductions (RRR) were estimated.
- Paired **McNemar** tests were applied for each symptom, and the **Wilcoxon test** for the total symptom burden [12].
- Statistical analysis was performed using **Python and Excel**.

CO_2 Lift/V® Application Technique [14]

1. Patient preparation
- Complete medical history and exclusion of active vaginal infections, premalignant lesions, or tumor recurrence.
- Explain the procedure and obtain informed consent.
- Position the patient in gynecological lithotomy, ensuring privacy and comfort.

2. Vulvovaginal area preparation
- Cleanse with sterile saline solution or a non-irritating cleanser.
- Dry with sterile gauze without friction.

3. Product preparation
- The CO_2 Lift/V® system consists of two packets (precursor and activator).
- Mix both components in a sterile container until a homogeneous emulsion is obtained.
- Load the mixture into a sterile application cannula.

4. Application technique
- Apply a uniform layer to the labia majora, labia minora, vulvar vestibule, and external clitoral area.
- Gently insert the cannula and deposit the gel along the vaginal wall, distributing it evenly (3-4 g).
- Allow the gel to act for **45-60 minutes** for progressive CO_2 release and absorption.
- The patient remains at rest during the application period.

5. Product removal
- Remove the gel with a disposable spatula or sterile gauze.
- Wash with warm water or physiological solution until the area is spotless.

6. Therapeutic regimen
- **Initial protocol:** 2 applications per week for 4-6 weeks.
- **Maintenance:** 1 monthly application depending on symptoms and clinical response.
- Reassess at 6-8 weeks using validated scales (e.g., Vaginal Health Index).

7. Safety measures
- Avoid use in patients with open lesions, active infections, or unexplained genital bleeding.
- Contraindicated during active radiotherapy or in cases of oncologic recurrence.
- Record any adverse events (irritation, pruritus, transient burning).

Results

Wilcoxon tests yielded p-values of 0.0625 for baseline vs. 6 weeks and baseline vs. 3 months. No single symptom reached significance in McNemar's test ($p<0.05$), but effect sizes demonstrated clinically meaningful reductions, particularly in dryness, burning, and vulvar irritation.

The present pilot study explored the use of **CO_2 Lift/V®,** a transdermal carbon dioxide-releasing gel, in women with a history of vulvar cancer and fibrosis side effects. This population is particularly challenging, as conventional **hormone replacement therapy is often contraindicated** due to oncologic concerns. Our findings suggest that CO_2 Lift/V® may represent **a safe and effective non-hormonal alternative** for symptom relief.

Previous reports have highlighted the role of regenerative therapies such as PRP, autologous exosomes, and mesenchymal stem cells in vulvovaginal rejuvenation and GSM management. However, evidence remains limited and heterogeneous, especially in cancer survivors. To our knowledge, this is the **first structured clinical report on CO_2 Lift/V® in this subgroup,** providing preliminary data on feasibility, safety, and symptom evolution.

In our series, patients **reported progressive improvements in vulvovaginal dryness, burning, pruritus, and dyspareunia after** 6 weeks and 3 months of treatment. Importantly, no severe adverse events were documented, supporting the safety profile of this therapy. The mechanism of action is likely related to **enhanced microcirculation, tissue oxygenation, and stimulation of fibroblast activity**, resulting in improved mucosal hydration and elasticity.

Discussion

The optimum follow-up schedule for vulval cancer remains unknown. Follow-up visits provide a considerable opportunity to address the long-term physical and psychological impact of vulvar cancer and its treatment.

What he does know is that the postoperative course will be simpler with a partial or total vulvectomy than with extended surgeries that require skin grafts.

Among the side effects of the operation have been observed

Numbness, tingling, or nerve pain

- Nerve damage can cause numbness, tingling, "electric shock" sensations, or altered temperature sensations in the vulva, groin, or legs1.

Scarring and vaginal narrowing

- Scar tissue may make the vaginal opening tighter, causing pain with penetration12.
- sexual function
- Pain during intercourse, reduced pleasure, or difficulty reaching orgasm—especially if the clitoris was removed or nerves were affected12.
- Emotional impact on body image and intimacy is also common.

Changes in urination

- The urine stream may change direction if tissue around the urethra is removed.

Approach to specialist support services, such as lymphedema clinics and psychosexual counseling, can improve the quality of life for survivors of this disease [15].

When post-surgical radiotherapy is necessary, symptoms and signs increase. Postoperative radiotherapy significantly increases the risk and severity of fibrosis in the vulvar region and groin.

Radiotherapy induces progressive fibrosis in irradiated tissues

Pelvic radiotherapy causes:

- Cellular damage and reactive inflammation
- Microvascular injury and ischemia
- Stem cell depletion
- Progressive collagen deposition and tissue stiffening

These mechanisms lead to progressive tissue fibrosis, stenosis, and atrophy in pelvic organs and soft tissues [16].

From an oncological perspective, follow-up aims to assess treatment effect and to prevent and early detect subsequent tumors.

The present pilot study explored the use of CO_2 Lift/V®, a transdermal carbon dioxide-releasing gel, in women with a history of cancer and GSM. This population is particularly challenging, as conventional hormone replacement therapy is often contraindicated due to oncologic concerns. Our findings suggest that CO_2 Lift/V® may represent a safe and effective non-hormonal alternative for symptom relief [17].

To our knowledge, this is the first structured clinical report on CO_2 Lift/V® in this subgroup, providing preliminary data on feasibility, safety, and symptom evolution.

Regenerative medicine is today considered the newest and most promising pillar of global health, based on its clinical applications that promote and stimulate the body's own repair mechanisms.

At the start, Carboxytherapy involves the therapeutic use of carbon dioxide (CO_2) in its gaseous state via subcutaneous injection [18].

When administered subcutaneously, CO_2 immediately diffuses into the cutaneous and muscular microcirculatory systems.

At the vascular level, CO_2 increases vascular tone and induces active microcirculatory vasodilatation—CO_2-induced vasodilatation results from its direct action on smooth arteriolar muscle cells [19].

CO_2 promotes Bohr's effect, where the affinity of hemoglobin for oxygen decreases due to an increase in carbon dioxide, which means that extra oxygen is supplied to tissues that need it the most. (The Bohr effect refers to the shift in the oxygen dissociation curve caused by changes in the concentration of carbon dioxide)

After hemoglobin binds oxygen in the lungs due to high oxygen concentrations, the Bohr effect facilitates its release in tissues, particularly those most in need of oxygen, resulting in higher tissue oxygenation and, therefore, angiogenesis [14].

There is subsequent stimulation of fibroblasts, resulting in improved ECM quality. (extracellular matrix)

CO_2 pharmacodynamics support the bio-stimulation effect and can be used alone to aid the regeneration process or as a basis for combining with other procedures to synergize additional treatments.

Transdermal Carboxytherapy is the use of CO_2 through the skin's superficial layer [20].

CO_2LIFTV® kit contains two gels (gel one, magnesium carbonate, and gel two, gluconolactone); when mixed and applied to the Vulvovaginal area, it promotes the penetration of carbon dioxide through the skin's superficial layer, increasing oxygenation (Bohr effect) and angiogenesis, helping to reduce symptoms in postmenopausal women as part of "Genitourinary Syndrome of Menopause."

CO_2 promotes tissue oxygenation through the Bohr effect and is thus thought to contribute to regeneration in the vulvovaginal area of postmenopausal women experiencing GSM symptoms [21]. Significant improvements in patient symptoms have been observed after use, especially concerning dryness, pain during intercourse (dyspareunia), burning, and itching. Sakai et al. reported that transcutaneous CO_2 was beneficial for therapeutic purposes by increasing blood flow and microcirculation, as evaluated by laser Doppler, and by intensifying tcpO2 in ischemic tissues, thus providing evidence of the Bohr effect in vivo [22]. Leibaschoff and co-workers used video capillaroscopy to assess the impact of a CO_2 transdermal gel. They found that microcirculation improves, as observed after subcutaneous CO_2 injection.

Based on the pharmacological properties of the transdermal CO_2 CO_2Lift already studied, and its therapeutic action on atrophic tissue as well as its regenerative capacity in diabetic ulcers, we decided to implement this therapeutic protocol together with the oncology group to see the evolution of patients operated on for vulvectomies and who evolved with pain and fibrosis in the operated and treated area.

We decided to implement this cosmeceutical therapy based on previous studies, knowledge of the pathophysiology of postoperative fibrosis, and the scant attention these treatments received for the patient's recovery. Although the sample is small, the results are essential and will open the door for other women suffering from post-operative symptoms.

Patients reported progressive improvements in vulvovaginal dryness, burning, pruritus, and dyspareunia after 6 weeks and 3 months of treatment. Importantly, no severe adverse events were documented, supporting the safety profile of this therapy. The mechanism of action is likely related to enhanced microcirculation, tissue oxygenation, and stimulation of fibroblast activity.

Despite these promising results, limitations must be acknowledged. The small sample size (n=5) and short follow-up period restrict generalizability. Additionally, outcomes were primarily symptom-based, without histological or biomarker confirmation. Future studies should include larger cohorts, longer-term follow-up, and validated scales such as the Vaginal Health Index (VHI) to corroborate these findings.

Conclusions

- CO_2Lift/V® demonstrated significant symptom improvement in women after surgical treatment of vulvar cancer, where hormonal therapies are not an option.
- The treatment was well tolerated, with no adverse effects reported.
- These results support CO_2 Lift/V® as a novel, non-hormonal, regenerative approach for oncologic patients.
- Further research in multicenter, randomized controlled trials is warranted to confirm efficacy, establish standardized protocols, and evaluate long-term outcomes.

Table 1: Global Study Summary

Metric	Value
Patients (n)	5
Unique symptoms evaluated (n)	15
Mean symptoms at baseline	14.4
Mean symptoms at 6 weeks	10.0
Mean symptoms at 3 months	0.8
Wilcoxon p (Baseline vs. 6 weeks)	0.0625
Wilcoxon p (Baseline vs. 3 months)	0.0625

Table 2: Symptom Prevalence and Effect Measures

Symptom	Baseline Prevalence (%)	6 Weeks (%)	3 Months (%)	MR 6w (pp)	RRR 6w (%)	ARR 3m (pp)	RRR 3m (%)
Do your symptoms affect your desire for intimacy?	100	80	0	20	20	100	100
Do your symptoms affect your desire to socialize?	100	60	0	40	40	100	100
Pain during sexual activity	100	60	0	40	40	100	100
Bleeding during sexual activity	100	20	0	80	80	100	100
Vaginal dryness during sex	100	60	0	40	40	100	100
Vulvar itching	100	40	0	60	60	100	100
Vulvar burning/stinging	100	80	0	20	20	100	100
Embarrassment due to symptoms	100	100	0	0	0	100	100
Difficulty showing affection	100	80	0	20	20	100	100
Concern about symptoms	100	100	0	0	0	100	100
Vulvar irritation	100	60	0	40	40	100	100
Vaginal/vulvar discharge	100	80	0	20	20	100	100
Vulvar dryness	100	80	0	20	20	100	100
Unpleasant odor	40	0	0	40	100	40	100
Frustration due to symptoms	100	100	80	0	0	20	20

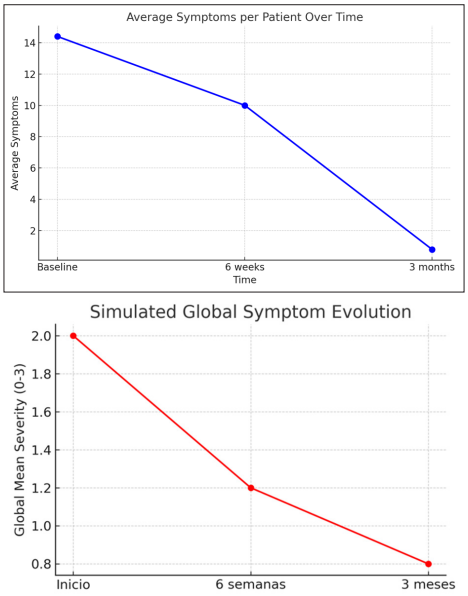
Table 3: Data Completeness by Symptom
(Values represent number of patients reporting each symptom at each time point.)

Symptom	Baseline	6 Weeks	3 Months
All listed symptoms	5	5	5

Surgical and Radiotherapy Characteristics of the Study Population

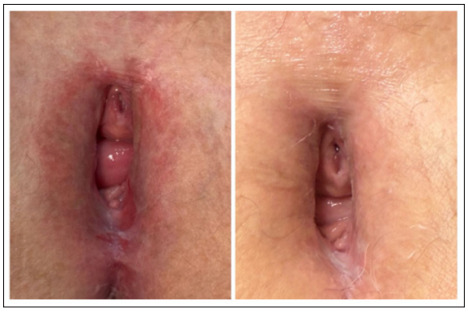
Surgical procedures and radiotherapy exposure are reported as approximations based on standard oncologic practice, as complete historical oncologic records were not available for all patients. This reflects real-world treatment patterns in vulvar cancer management.

Patient	Surgical Procedure	Clinical Rationale	Estimated Radiotherapy Exposure
Patient 1	Partial radical vulvectomy	Localized disease with resectable margins	External beam radiotherapy, ~25-30 sessions
Patient 2	Radical vulvectomy	Extensive local tumor involvement	External beam radiotherapy, ~30-35 sessions
Patient 3	Partial vulvectomy	Localized disease with anatomical preservation	Adjuvant radiotherapy, ~25-30 sessions
Patient 4	Radical vulvectomy with inguinal lymphadenectomy	Locally advanced disease	Pelvic and inguinal radiotherapy, ~30-35 sessions
Patient 5	Partial radical vulvectomy	Intermediate-stage tumor requiring adjuvant treatment	External beam radiotherapy, ~25-30 sessions

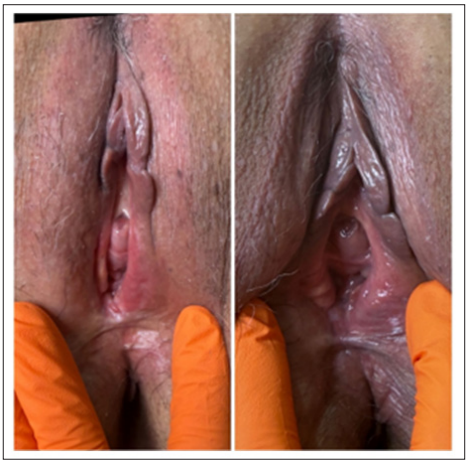


Symptom Burden Over Time: Progressive reduction in mean symptom scores per patient at baseline, 6 weeks, and 3 months.

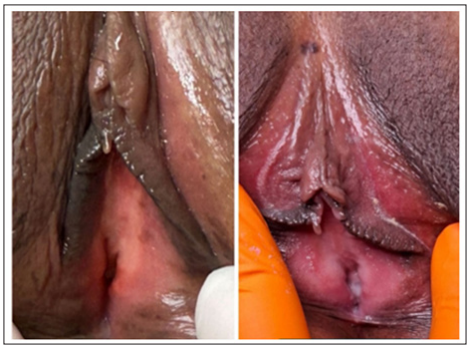
Case Images



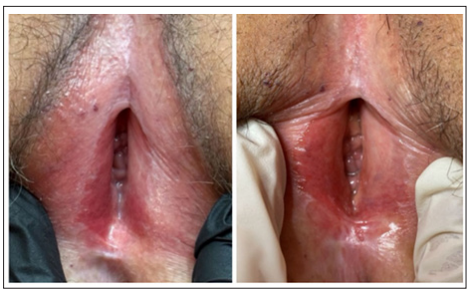
Patient 1: 70-year-old female, history of vulvar cancer, radical total vulvectomy, inguinofemoral lymphadenectomy, tumor-free for 5 years.



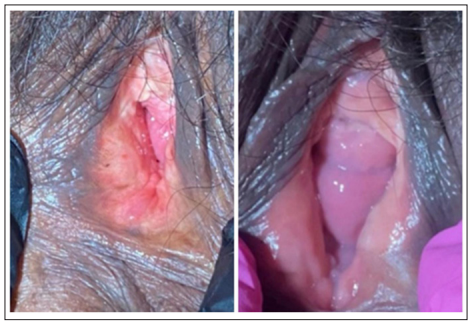
Patient 2: 71-year-old female, wide local excision, 33 radiotherapy sessions, tumor-free for 2 years.



Patient 3: 52-year-old female, wide local excision, 28 radiotherapy sessions, tumor-free for 4 years.



Patient 4: 69-year-old female, wide local excision, 31 radiotherapy sessions, tumor-free for 6 years.



Patient 5: 84-year-old female, wide local excision, 28 radiotherapy sessions, recurrence after 4 years, additional 22 radiotherapy sessions, tumor-free for 12 years.

Note: All patients participating in the study signed the corresponding informed consent, and the study was carried out at the Oncology Center

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