

Kidney Cancer, Dental Assistance and Health Judicialization: A Case Report

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Abstract: *The right to health must be guaranteed by the State and is part of the fundamental principles of the Unified Health System (SUS). PCLB, 60 years old, white, married, ex-smoker, ex-alcoholic, diagnosed with metastatic renal cell carcinoma, referred to the Oncology Center of the Oswaldo Cruz University Hospital of the University of Pernambuco (CEON / HUOC / UPE) for treatment with multi-professional assistance, including dental assistance and the use of oral laser therapy to minimize the side effects of cancer treatment. Treated with tyrosine kinase inhibitors (TKIs) Sutent® (sunitinib maleate 50 mg/day), and with disease progression, Votrient® (Pazopanib hydrochloride 800 g/day). Subsequently, treatment with an immuno-oncological agent (IO) Nivolumab (10mg/ml intravenous). These medications were dispensed to the patient through a judicial process with the public defender. Due to the slowness and fragility of the system, there were intervals of discontinuity of the current treatments and reduction of their quality of life. After three years of therapeutic attempts, PCLB presented a systemic worsening of the disease and appearance of brain metastases, which led to death. The creation of positive structural reforms in SUS is necessary for the realization of the right to health.*

Keywords: Judicial role, Kidney neoplasms, Laser therapy, Dental care.

1. Introduction

The Unified Health System (SUS), created by the Brazilian Federal Constitution of 1988, has as its fundamental principle the guarantee of the right to health based on universality, completeness, and equity [1],[2]. Despite advances in the development of the SUS, citizens began to seek the guarantee of the right to health, especially concerning access to medicines, through the judiciary. This phenomenon has been called "health judicialization", and has grown exponentially in the last two decades, affecting even patients undergoing treatment for cancer control [3]-[5].

Cancer is a public health problem and is considered the second leading cause of death in Brazil. According to the National Cancer Institute José Alencar Gomes da Silva (INCA), the estimates for the biennium 2018-2019 presented

about 600 thousand new cases of cancer in Brazil, for each year. Among the most frequent cancers, except for non-melanoma skin, are those of the prostate, lung, intestine, stomach and oral cavity for the men group and in the women, breast, intestine, cervix, lung, and thyroid [6].

Despite advances in medicine and technologies in the oncology area, surgical resection, radiotherapy, and chemotherapy remain the main therapeutic modalities against the disease. However, although they may be often effective in treating, these therapeutic modalities (unimodal or multimodal) can cause significant morbidity with direct and indirect effects on structures of the oral cavity such as mucositis, xerostomia, osteoradionecrosis, and oral infections [7]-[10].

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Patients on oncologic and oncohematological treatment usually present oral manifestations as a consequence of intense immunosuppression due to antineoplastic therapy. A multidisciplinary approach is essential for patients undergoing oncological treatment, as can be seen in this case report.

Renal cell carcinoma (RCC) is the most common type of kidney cancer [11]. During their natural clinical course, they remain asymptomatic and not palpable until they are detected late. With this, most diagnoses are performed at an advanced or metastatic stage [12].

The Therapeutic Diagnostic Guideline of the RCC of the Ministry of Health [12] recommends radical nephrectomy as the initial treatment for metastatic disease, except for patients who do not present clinical conditions for surgical procedure. Already in patients with metastatic disease unresectable, the therapeutic proposal is based on chemotherapeutic and more often immunotherapy [13].

This paper aims to describe a case of metastatic RCC and the search for drug therapy through the process of judicialization. The participant signed the Term of Free and Informed Consent, consenting to the disclosure of the case for academic purposes.

2. Case Report

In the case reported below, the participant signed the Free and Informed Consent Term (CAAE: 07264818.7.0000.5207).

PCLB, 60 years old, white color, married, ex-smoker, ex-alcoholic, from Recife-PE, went to an Emergency Care Unit with a bleeding complaint while urinating. Initially treated as a urinary tract infection, he went to the General Hospital of Areias after complementary exams found an expansive process in the right kidney. He underwent nephrectomy in April 2016, with removal of the right kidney and segment of ureter, whose anatomopathological report (AP: 100.951) was conclusive for renal cell carcinoma, stage IV, presenting tumor metastases affecting liver and lung.

He was referred to the Oncology Center of the Oswaldo Cruz University Hospital of the University of Pernambuco (CEON/HUOC/UPE) for conducting antineoplastic treatment. Initially, the medical team proposed the VEGF inhibitory agent Sutent® (sunitinib maleate - 50 mg/day), which started in August 2016, through a judicial process with the public defenders.

After the first cycle of treatment, with good tolerance, the patient could not acquire medication for continuity of treatment, with a delay of 90 days for the beginning of the subsequent treatment cycle, which occurred in January 2017. At the time, a new medical report was provided for medication request for a lawsuit.

Considering the oral condition, PCLB sought the dental service of the Oncology Center of the University Hospital

Oswaldo Cruz of the University of Pernambuco – CEON-ODONTO/HUOC/UPE, in Recife - PE, with complaint of dysphagia and oral ulcers related to the use of the drug Sunitinib.

In the initial anamnesis, the user reported that after initiation of oral chemotherapy medication, remained about 20 days with feeding only of liquid and pasty consistency due to oral ulcers and pain in the oral cavity, and also reported not having performed any specific oral care.

Clinical intraoral examination revealed unsatisfactory oral hygiene, white tongue, use of upper removable total dentures, and lower removable partial denture on implant, and it was also observed ulcerated lesions on the floor and lower gingival edge (Figure 1) with oral mucositis grade III (World Health Organization classification - WHO) [14].

The Standard Operational Protocol on Oral Care was established (POP - Oral), adapted by VIDAL, AKL (2012) [15], being prescribed use of a dental brush with small head and soft bristles, non-abrasive toothpaste, mouthwash with sodium bicarbonate solution (8/8h), mouthwash with chlorhexidine digluconate 0.12% (12/12h), and mouthwash with nystatin oral solution (100.000 IU) four times a day.

After signing the Consent Term, was started at Low-Level Laser Therapy (LLLT) (MMO Optics device), in the visible red spectrum (660nm), with fixed power of 100mW and energy density of 2 J / cm². The Low-Power Laser was used as a punctual type on the lesions (treatment) and scanning in the regions without lesions (preventive) until all areas of the oral cavity were examined, being performed three times a week. At each consultation/care, the Visual Analog Scale (VAS) was applied before laser therapy. In the first care, PCLB reported grade 8 on the pain scale (VAS), the early stage of the patient (Figure 1), and managed to reach the absence of painful symptomatology, identified as grade 0, after the third session of LLLT (Figure 2). As PCLB continued to use oral chemotherapy on alternate days, he was monitored weekly in CEON-ODONTO / HUOC / UPE. It should be noted that PCLB was lucid, conscious, oriented, very collaborative and valued oral care.



Figure 1: Clinical aspect of oral mucositis, Grade III [14], ulcerated lesions on the floor and lower gingival border, VAS: Grade 8.



Figure 2: Clinical aspect of the oral mucosa, after 3rd session of Laser therapy, VA: Grade 0.

In January 2018, PCLB presented a new systemic progression of disease with numerical and volumetric increase of pulmonary nodules bilaterally, besides a volumetric increase of the mediastinal lymph nodes, need to change the treatment line for Votrient® (Pazopanib hydrochloride 800 g/day), also an angiogenesis inhibitor. The new medication was started in June 2018, three months after judicial request. PCLB remained assisted by dentistry in use of POP-Oral, and LLLT [15], without oral complaint.

Two cycles of Votrient® were concluded, with good tolerance, but the patient presented radiological progression of the disease. PCLB developed severe depression and antidepressant medication (escitalopram oxalate 10mg / day) was started.

The medical course was to opt for the third line of treatment with immunomodulator Nivolumab (intravenous 10mg/ml). After four months without any specific therapeutic line awaiting judicial authorization, PCLB begins treatment with Nivolumab, released through a judicial process.

In April 2019, PCLB attended the consultation with a lethargic state, reporting frequent headache, in addition to left humerus fracture due to the fall caused by difficulty in walking. Magnetic resonance imaging of the skull with contrast was requested, whose images showed multiple metastatic brain nodules that compromised the supra and infratentorial compartments. In addition to a voluminous, expansive, solid process, completely filling the left nasal cavity. At that time PCLB, still under dental care - use of POP-Oral[15] and without oral complaint.

PCLB was admitted to the hospital in the CEON / HUOC Ward, in June 2019, with an important decrease in his general condition, as a therapeutic measure, exclusive use of palliative care, use of systemic corticosteroids, and dental care were included. PCLB died after three days of hospital admission.

3. Discussion

Metastatic renal cell carcinoma is one of the solid tumors most resistant to chemotherapy [12]. Agents such as sunitinib, pazopanib and sorafenib, which target the vascular endothelial growth factor pathway, are the first-line standard therapy for advanced disease. Moreover, they were the first antiangiogenic agents approved in Brazil for the treatment of these patients [16].

The promotion of oral health and dental follow-up in the multidisciplinary oncology team helps to minimize and/or control the risk of the sequelae of cancer treatment. These sequelae include mucositis and infections that may hinder or prevent continuity of treatment, negatively impacting patient's quality of life [7],[8],[17].

Recent studies have shown the efficacy of LLLT for prevention and treatment of oral complications, as a result of its anti-inflammatory, biomodulator and tissue repair potential, as demonstrated in this case report [18]-[21]. Oral mucositis, in addition to being one of the most frequent complications in patients undergoing cancer treatment, is considered the most common cause of oral pain in these patients [7],[15]. This pain can reach significant levels and compromise their nutrition and quality of life, such as grade 8 of pain, on the VAS scale, initially reported by the patient.

The LLLT has been used as a form of prevention and treatment of oral mucositis and has obtained positive responses from a clinical and functional point of view [7],[8],[15],[17]-[21]. This can be observed in this article when the patient after the third session of the LLLT declared absence of painful symptomatology, identified as grade 0, in the VAS pain ladder.

Sunitinib is an oral chemotherapeutic agent formed by a small molecule with an inhibitory effect on multiple receptor tyrosine kinases, being considered as the first line of choice of treatment for metastatic renal cancer. About the adverse effects of drug administration, a toxicity of treatment affecting about 50% of patients in the literature is reported. The most common side effects observed are hypertension, thrombocytopenia, mucositis, hand-foot syndrome, diarrhea, and weakness. The percentage of oral mucositis in this group of patients may range from 1-5% [22]. Therefore, it is necessary to keep the patient under care and follow-up of the oncological dentistry service.

The LLLT has been studied and practiced both as a therapeutic and preventive form for oral mucositis. Studies demonstrate [7],[8],[15],[17]-[21], that its use reduces the severity of the degree of mucositis and also, oral pain, as reported in this article, providing pain relief, inflammation control, maintenance of mucosal integrity, improved tissue repair, and improved patient comfort.

Recently developed immunotherapies have better overall survival and better tolerance for various types of tumors. The Nivolumab, immunoglobulin G4 monoclonal antibody,

demonstrated durable antitumor activity in patients with previously treated metastatic RCC [23].

These medications are registered by ANVISA (National Agency of Sanitary Surveillance) and released for use in Brazil, however, are not part of the National List of Essential Medicines (RENAME), besides being medications of high cost, inaccessible to the Hospital because it does not have standardization in the subsystem APAC (Authorization of Procedure of High Cost) by SUS [13]. Because it is the best treatment proposal for the case and given the patient's socioeconomic conditions, the process of health judicialization began.

Many dilemmas permeate the question of judicialization, one of them is the exorbitant amount necessary to guarantee the demands that are processed in the Judiciary [24],[25]. These non-programmed expenditures increase access to health inequities due to the redirection of their resources [26].

On the other hand, the 1988 Constitution guarantees health as a universal right, giving the State the obligation to provide the citizen with adequate and sufficient services for the maintenance of life [5],[27]-[29]. From this knowledge, PCLB began the search for their rights through the judiciary, but experienced the stress of the process and the discontinuity of its treatment, causing reduction of time and quality of life.

Judicial actions are a consequence of the maturation in the organization of society on the one hand, and, on the other, of deficiencies in public administration [25]. The weakness of the states in guaranteeing the fundamental rights of their citizens and the limited financial resources were pointed out as important causes of judicialization of access to medicines [30].

In order to avoid new processes, the incorporation of medicines into the public network must be better understood, improved and streamlined. In addition, improving resource management and accessing medicines are positive structural reforms needed to change this framework [30].

In 2018 CONITEC (National Commission for the Incorporation of Technologies) issued unfavorable preliminary recommendations for the inclusion of Sunitinib and Pazopanib medications in SUS [16]. However, recently, the Ministry of Health finally decided, after a new analysis of CONITEC, with a favorable opinion, for the incorporation of the medicines. The effects of this new decision have not yet been experienced.

4. Conclusion

The judicialization of health is an emerging phenomenon and generated by the difficulty of the Public Power in offering therapies and inputs to SUS users. Every citizen has the right to health, broadly, with adequate multiprofessional assistance and control of diseases such as cancer. Therefore, deciding which patient to grant a therapeutic possibility goes beyond the duties of the magistrate. The creation of positive

structural reforms in the SUS is necessary for the realization of the right to health and life guaranteed mainly by the Brazilian constitution.

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