ORIGINAL ARTICLE

The Impact of a Follow-up Nursing Consultation in Lung Cancer Patients Receiving Immunotherapy

O Impacto de uma Consulta de Enfermagem de Seguimento em Doentes com Cancro do Pulmão em Tratamento com Imunoterapia

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https://doi.org/10.82582/thorac.17

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Declaração de Contribuição/ Contributorship Statement:

CA e RC: Conceptualização, redação do artigo e aprovação da versão final a ser publicada.

CA and RC: Conceptualization, manuscript writing and approval of the final version to be published.

Aprovação Final/ Final Approval: Todos os autores leram e aprovam a versão final do manuscrito/ All authors have read and approved the final version of the manuscript.

Received/Recebido: December 11th, 2024

Accepted/Aceite: December 12th, 2025

Published Online/Publicado Online: December 31st, 2025

Published/Publicado: December 31st, 2025

ABSTRACT

The use of immune checkpoint inhibition (ICI) has revolutionized cancer treatment. However, these medications are associated with significant and potentially debilitating immune-related adverse events or even life-threatening. It is important for the health team, and particularly the nurse team, to recognize and manage toxicities early in order to limit severe toxicity and to enhance the patient's quality of life. The goal was to identify health gains from implementing a nursing consultation to patients with lung cancer treated with checkpoint inhibitors.

Observational, longitudinal, prospective and exploratory study initiated November 1st, 2019, until December 31st, 2020, at the Portuguese Cancer Institute (IPOLFG) in Lisbon.

This study included 41 men and 23 women, ranging from 31 to 90 years old (averaging 63 years of age) and ECOG PS: 1.

A total of 32.8% of patients experienced at least one adverse event (AE). Of the reported adverse events, 29.7% occurred with pembrolizumab administration and 52.9% with nivolumab. The average of the AE showing up, happens after C2.

The study shows the nurses' critical need and role for appropriately engaging with, educating, assessing and managing lung cancer patients under immunotherapy. All patients benefited from the creation of this consultation. Even patients who did not experience adverse events reported a need for advice from the nursing team.

RESUMO

A administração de inibidores do checkpoint Imunitário revolucionou o tratamento do cancro. No entanto, estas terapêuticas têm um espectro de toxicidade único e amplo – referido como EAir – podendo potencialmente afectar todos os órgãos e sistemas desde graus ligeiros a graves ou mesmo life threatening. Torna-se fundamental para a equipa multidisciplinar, e particularmente, para a equipa de enfermagem, antecipar e detectar precocemente a toxicidade imuno-relacionada de forma a limitar o seu agravamento ou toxicidade severa com o intuito de melhorar a qualidade de vida dos doentes.

O estudo teve como objectivo identificar os ganhos em saúde da implementação de uma consulta de enfermagem ao doente com Cancro do Pulmão submetido a imunoterapia. Estudo observacional, longitudinal, prospectivo e exploratório iniciado em 1 de Novembro de 2019 no IPO de Lisboa até 31 de dezembro de 2020.

Este estudo incluiu 41 homens e 23 mulheres, com idades compreendidas entre os 31 e 90 anos (média de idades 63,9) e PS: 1.

Dos doentes, 32,8% teve pelo menos, 1 EA. Dos EA 29,7% surgiram com a administração de pembrolizumab e 52,9% com o Nivolumab. A média de aparecimento dos EA acontece após C2.

São evidentes os benefícios e vantagens da implementação da consulta de enfermagem de follow up, uma vez que o enfermeiro desenvolve um papel fundamental de Educador, bem como de Implementador de cuidados, Conselheiro e Consultor, papéis esses que têm como principal objetivo a redução de idas ao hospital da área de residência, a identificação precoce da toxicidade imuno-mediada, a gestão e controlo de sintomas, o empowerment da pessoa de forma manter níveis saudáveis de vida, evitar complicações e a manutenção da adesão ao regime terapêutico. Todos os doentes beneficiaram da criação desta consulta. Mesmo os doentes que não tiveram qualquer registo de EA do tratamento sentiram e houve necessidade de aconselhamentos por parte da equipa.

Keywords:
Immune Checkpoint Inhibitors; Immunotherapy/adverse effects; Lung Neoplasms/drug therapy; Lung Neoplasms/nursing; Referral and Consultation

Palavras-chave:
Encaminhamento e Consulta; Imunoterapia/efeitos adversos; Inibidores de Checkpoint Imunológico; Neoplasias do Pulmão/enfermagem; Neoplasias do Pulmão/tratamento farmacológico

INTRODUCTION

Historically, advanced non-small cell lung cancer (NSCLC) has been a complex disease and research has pursued new approaches to give more patients the chance at a longer life.[1]

Systemic cancer treatment is improving thanks to the continuing technological and scientific developments as new kinds of drugs have emerged.[2-5]

Immunotherapy with checkpoint inhibitors created a paradigm change, with lasting and effective responses in several types of cancer, including lung cancer. Currently, the five-year survival rate has gone from 5.4% to 31.9% for the advanced non-small cell lung cancer treated with IO.[2]

Due to its mechanism for activation and proliferation of lymphocytes T in the immune tumoral response, they have a unique and wide toxicity spectrum — referred as AEir— it may potentially affect all organs and systems from slight degrees to grave or even life-threatening, sometimes with hospitalizations, therefore, abandonment is a possibility. Support and vigilance by health care is foremost important and nurse plays a pivotal role in it.[3-5]

The AEir arising from the administration of immune checkpoint inhibitors (ICI), namely the CTLA-4 (anticytotoxic T-lymphocyte–associated antigen-4) and PD-1 (programmed cell death protein 1)/PD-L1 (programmed cell death-ligand protein 1) inhibitors, are different in their presentation, beginning and duration compared to chemo. Studies point that, usually, the immune-mediated adverse reactions start in the first few weeks to months after treatment, as their appearance is more frequent in the first three months after the beginning of the IO.[6-9]

Dermatological, gastrointestinal, endocrine and liver systems are the most frequently affected.[6-9]

The international guidelines of the ESMO clinical practice recommend specific algorithms to carry out the evaluation, specific management and treatment of immune-mediated toxicity. The ICI interruption or discontinuation must be adequately weighed, i.e., the ICI may continue to be administered in light to moderate cases, but if it is found that the injuries become more serious and/or persistent, the interruption of the ICI's should be considered.[10,11]

In this sense, the incidence of complications arising from the administration of immunotherapy forces a new demand for nurses, inserted in collective and professional social responsibility, promoting alternatives to resolve these challenges.

According to the Cancer Nursing Education Framework developed by the European Society for Oncology Nursing, oncological nursing is the science that focuses on the treatment of cancer, safety and support of the person during all phases of the oncological disease. Oncological Nurses must be at the forefront of the service to the Person, with knowledge of treatment and their AE and competences in early identification of toxicity, management and monitoring any change caused or experienced by the patient and educating the patient/family to limit their severe worsening/toxicity, promote quality of life and security and reduce social and economic costs.[12]

Most AE related to treatment, and immunotherapy is no exception, are experienced at home. It is therefore of extreme importance to instruct the person/caretaker to continuous surveillance of the side effects of immunotherapy, early toxicity tracking and its management. The lack of self-care due to the side effects of the treatment it is often due to the lack of information. Providing information about the side effects and how to deal with them could trigger an early action of self-care, with identification of potential dangers from the patient and therefore a greater probability of producing the relief of symptoms and this would be advantageous.[13]

As Henderson (2007) says, it is the need to estimate the needs, immediate and long term, and plan the physical care, emotional support and re-education, which makes nursing a service of the utmost importance.[14]

Nursing consultation (NC) emerges from the need to apply more effective methods to develop the patient's trust and motivation for their self-care potential. The nurse must assess the need for education and knowledge of the persons in treatment, in order to participate in decision-making processes, know how to control their disease and the symptoms associated with treatment and know how to handle the experience of having cancer.[15]

Faced with the exposed and after reflection and identification of gaps (the non-existence of a continuous monitoring of these patients by nursing), the nursing team, to minimize this problem, understood the need to develop strategies for improving nursing care depending on the Quality Standards of Nursing Care of the Nurses' Association.

The NC follow-up (FU) program was developed, implemented and under the coordination of the Nurses of the pneumology service and the chemotherapy day unit hospital, it is carried out during the treatment, including:

- First face-to-face nurse consultation, before treatment, in which data will be gathered and an analysis and assessment of the overall state and susceptibility of the person to the immune-mediated toxicity. Subsequently, the role of immunotherapy in cancer treatment and its toxicity and safety profile is taught; phone number of the nursing team is given as well as written information on EA.

Also, in this appointment, we apply the European Organization for the Research and Treatment of Cancer Quality of Life (EORTC QLQ-C30) Questionnaire - formal authorization was requested to the author for its application and promptly requested and granted - Dyspnea (Medical Research Council) and Psychologic Distress scales;

- Subsequent, weekly telephone consultations, to anticipate and identify EA and to enable managing the symptoms from the comfort of home.
- Unscheduled SOS consultations.

This study aims to identify health gains from implementing a nursing consultation to patients with Lung Cancer treated with checkpoint inhibitors at the Portuguese Cancer Institute (IPOLFG) in Lisbon, Portugal.

MATERIAL AND METHODS

Longitudinal, prospective and exploratory study with patients with Lung Cancer from November 1st, 2019, until December 31st, 2020, at the Portuguese Cancer Institute (IPOLFG) in Lisbon. Patients were selected with age ≥ 18 years at the time of the diagnosis with non-small cell lung cancer histology and who received ICI on an outpatient basis and/or hospitalization regimen at the IPOLFG EPE.

Clinicopathologic variables were collected: gender, age, Eastern Cooperative Oncology Group (ECOG) performance status; Fatigue Assessment (FAS), autoimmune disease pre-existing, ICI received, major comorbidities (0/>1comorbidities).

Exclusion criteria were:

- Initiation of immunotherapy at another health facility
- Administration of only 1 immunotherapy cycle
- Refusal to participate in the study

Informed consent for participation in the project was assured by the FU.

To recover this data for the psychometric evaluation, the computer applications EXCEL and SPSS version 24 were used.

Were performed:

- 196 scheduled phone consultations
- 24 unscheduled phone consultations
- 13 unsuccessful phone consultations
- 99 in-person scheduled consultations
- 4 in-person unscheduled consultations

According to protocol, the therapeutic plan includes:

- Symptomatic control. To achieve these strategies, tools such as Common Terminology Criteria for Adverse Events (CTCAE version 5) and ESMO Clinical Practice Guidelines for management of toxicities from immunotherapy were used.
- Directing to the physician's assistant wherever the situation so requires (according to the unit's algorithm);
- Psychosocial and spiritual approaches;
- Practical needs of the patient-family duo, taking into consideration their preferences, values, beliefs and objectives.

In order to evaluate the project patients were encouraged to carry out a questionnaire on satisfaction with the nursing care, adherence to the recommendations provided and what they would do if the consultation did not exist.

RESULTS

The data were gathered between November 1st, 2019, and December 31st, 2020.

This study included 41 men and 23 women, ranging from 31 to 90 years old (averaging 63 years of age) and ECOG PS: 1. The baseline characteristics of patients are broken down in Table 1 and Fig. 1:

Table 1 Baseline characteristics of patients

Median Age, years	63 (31-90)
Gender, n	
Men	41
Women	23
ICI, n	Patients
Pembrolizumab	**40**
· 200 mg 3/3 or 4/4 weeks	24
· 400 mg 6/6 weeks	16
Durvalumab 1500 mg 2/2 weeks	**5**
Nivolumab	**19**
· 240 mg 2/2 weeks	2
· 480 mg 4/4 weeks	17
FAS	
Normal (10-21)	38
Fatigue (22-34)	21
Fatigue extreme (≥35)	5
Autoimmune disease	**8**
Sjogren syndrome	1
Hashimoto's disease	1
Hypothyroidism	4
Psoriasis	1
Rheumatoid arthritis	1
Other Diseases	**8**
HCV	1
Atopic dermatitis	2
Coagulopathy	2
Systemic sclerosis	1
Most prevalent co-morbidities (Metabolic, Cardiovascular, Respiratory Diseases, Anxiety/Depression, Osteoarthritis)	
0	23 (35.9%)
1	17 (26.6%)
> 1	24 (37.5%)

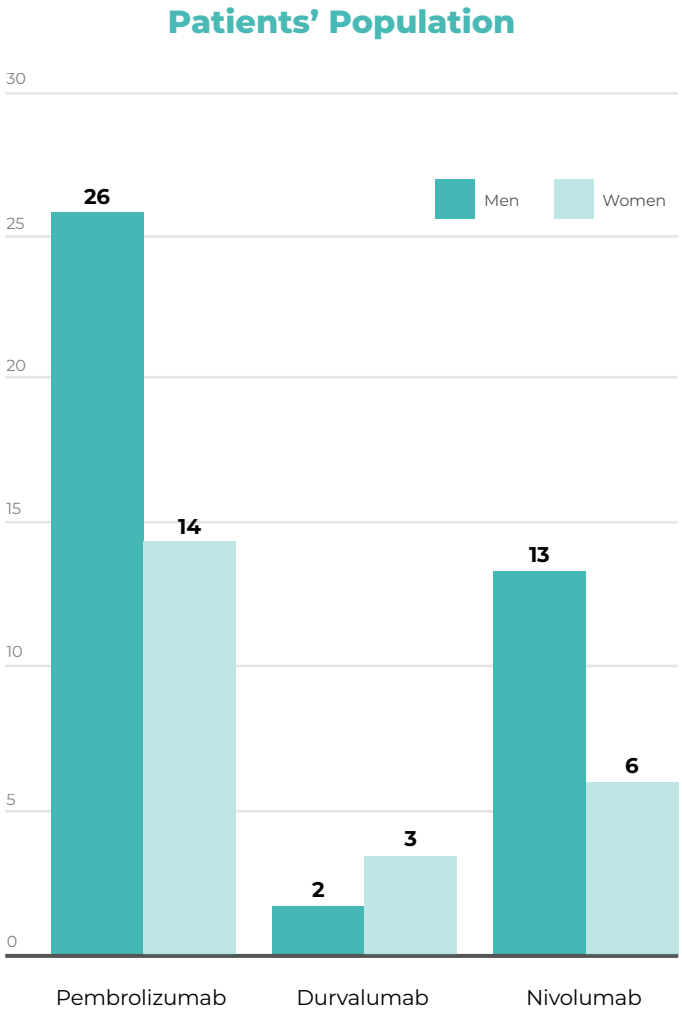

Figure 1 ICI's distribution by gender

Cardiovascular diseases (57.8%) were the most prevalent co-morbidity, followed by metabolic diseases (46.9%), respiratory pathology (28.1%), anxiety/depression (9.6%) and others (17.2%).

As far as the previous oncological treatments are concerned: 17 of the patients were submitted to chemotherapy exclusively, 16 to chemo-radiotherapy, 4 to radiotherapy and 1 patient already had had previous immunotherapy.

Forty patients had absolutely no AE. Three patients up to the date of completion of this work, also remain without having AE (they did C1). In three patients, immunotoxicity is being equated: 1 pulmonary, 1 liver (patient with liver metastatic prior to IO) and 1 skeletal muscle (patient with AR: symptoms worsen).

Twenty-one patients had the following AE as it is summarized in Fig. 2 and in Table 2.

Table 2 Incidence of AEir

	Total (n=64)
Patients with at least 1 AE, n (%)	21 (32.8%)
Arthritis G1	5 (7.8%)
Myalgia	4 (6.3%)
Arthralgia G3	1 (1.6%)
Rheumatoid arthritis	1 (1.6%)
Pruritis	4 (6.3%)
Urticaria	1 (1.6%)
Rash	3 (4.7%)
G1	2 (3%)
G3	1 (1.6%)
Psoriasis	2 (3.1%)
Dermatosis G3	1 (1.6%)
Pneumonitis	6 (9.4%)
G2	5 (7.8%)
G3	1 (1.6%)
Hypothyroidism	4 (6.3%)
New condition	3 (4.7%)
Previous condition worsen	1 (1.6%)
Hyperthyroidism	1 (1.6%)
Diarrhea	2 (3.1%)
G1	1 (1.6%)
G3	1 (1.6%)
Thrombocytopenia G2	1 (1.6%)
Renal toxicity G1	1 (1.6%)
Deaths	None

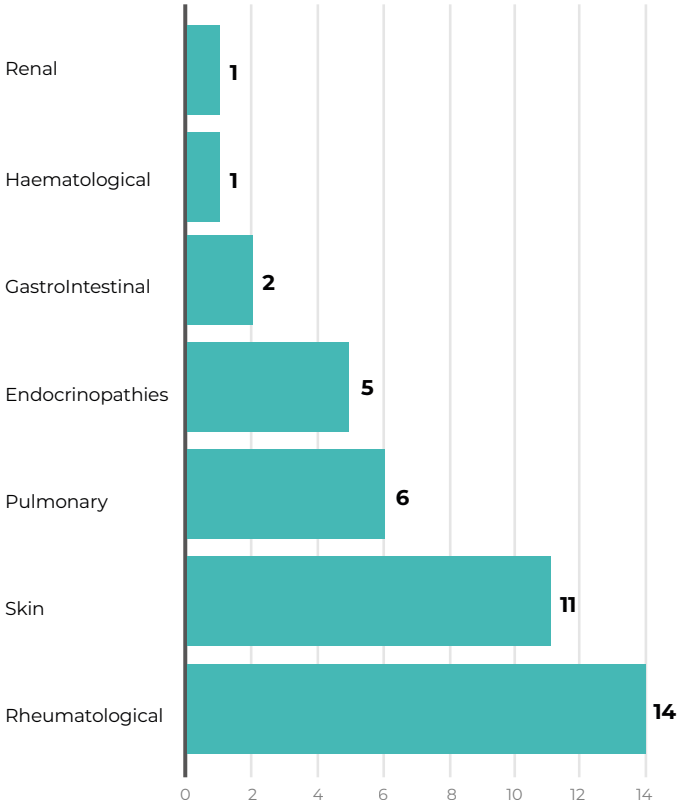

Figure 2 Organ Toxicity

29.7% (11) of the AE came up with pembrolizumab administration and 52.9% (9) with nivolumab. The average of the AE showing up, happens after C2 as shown in Fig. 3.

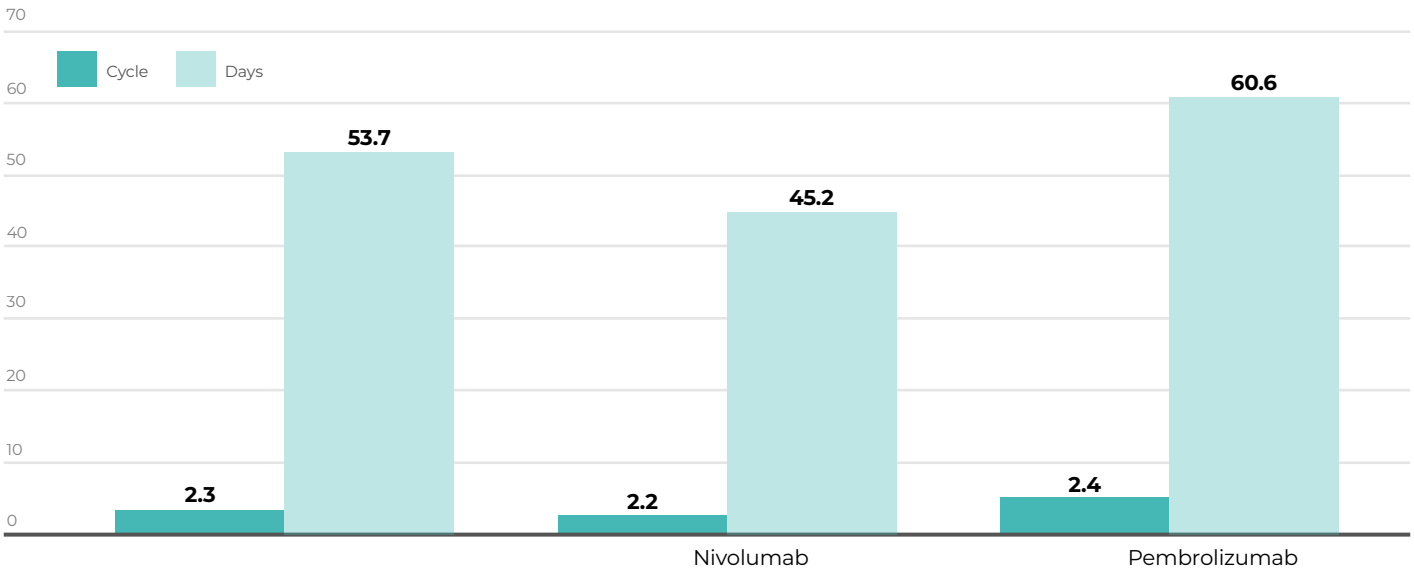

Figure 3 Patients´mean time of AE appearance

Relatively to the continuity of the Immunotherapy treatment:

- 4 temporarily suspended it, with 2 patients having a re-challenge;
- 7 definitely suspended it due to unacceptable toxicity;
- 22 was definitely suspended due to the progress of illness;
- 2 definitely suspended it due to the appearance of other pathologies (stroke).

Based on the analysis of symptomatology, the following steps were taken:

- 1 guided to the ER of his residence;
- 7 guided to the IPOLFG Unscheduled Service (SANP), of which 1 resulted in long-term patient admission (confirmed unacceptable lung toxicity) and 1 other suggested admission was refused by the patient (temporary lung toxicity and re-challenge 109 days later);
- 21 guided to the Pneumologist;
- 28 patients in need of counseling: analgesic adjustments, cough teaching, hemoptoic expectoration, nutrition, effort management, breathing optimization, energy conservation.

In all nursing consultations, strengthening alert signals in all contacts were reinforced and 10 new calls the next day were made in order to monitor the progression of the situation. With these contacts, 50 visits to the SANP were avoided.

DISCUSSION

The reported incidence of AEir has varied since initial observations depending on the immune modulating agent and the clinical setting.[16-18]

In our population, the most expressive toxicities are rheumatological and dermatological.

Dermatological toxicities are among the most common immune-related adverse events encountered in daily practice when treating lung cancer with an estimated incidence of 34% with PD-1/PD-L1 targeting treatment. Manifestation of dermatologic adverse events can vary widely in presentation from pruritus and a mild maculopapular rash to psoriasis flare.[17,18]

Of our patients, 17.3% had a skin manifestation such as pruritus, urticaria, rash, psoriasis, and dermatosis. None of them had a previous skin condition. Management was accomplished with anti-histamine drugs, topical ointments and corticosteroids. IO was definitely suspended in 1 patient.

With this data we should seek to continually anticipate potential intercurrences. Thus, health professionals should guide their practice with the help of the recent National Comprehensive Cancer Network (NCCN) recommendations, which include a careful dermatologic exam on all patients with planned immunomodulatory treatment to detect and manage any mild or early grade disease before provocation to flare, which was taken into consideration in the follow-up appointments.

Regarding rheumatological toxicities, our study population had a much higher percentage of EAir – 17.3% - when compared with the incidence ranging from 1% to 7% described in the studies.[17,18] In 5 cases, the symptoms were mild and treated with non-steroidal anti-inflammatory drugs as needed for pain relief and no need to interrupt the IO. One case (G3), symptomatic care was pursued initially with AINE and later with oral prednisone 20 mg daily and IO was hold and then definitely suspended. In 1 case due to RA suspicion, management was pursued in coordination with rheumatology referral with IO withdraw.

These numbers lead us to reflect on why our population has higher numbers. Can the age factor be preponderant for this EAir? It is a pertinent question for future studies.

Checkpoint inhibitor pneumonitis currently occurs in 3%–5% of all cases; however, that estimate rises to 7%–13% in the setting of NSCLC treatment.[16] We had 9.4% of pneumonitis treated with antibiotics and only 1 patient required hospitalization.

As for endocrine toxicity, the numbers are also similar.

In Keynote-001, 21% of patients receiving pembrolizumab for the management of NSCLC experienced thyroid dysfunction requiring eventual supplementation. Subsequent clinical experience with immunotherapy of NSCLC has confirmed an estimated incidence of endocrine irAEs of less than 23% with the overwhelming majority involving the thyroid and rarely exceeding grade.[17,18] Of our patients, 7.9% had developed hypothyroidism or hyperthyroidism.

Interestingly, patients with previous hypothyroidism were

associated with a risk of developing thyroid immune-related adverse events.[17,18] This was true for 1 of our patients who had is previous condition worsened.

All patients benefited from the creation of this consultation. Even patients who did not have AE felt and need for advice from the nursing team. They were contacted by telephone due to having uncontrollable pain/anxiety attacks/other symptoms and they were taught regarding the pharmacological and non-pharmacological measures (teaching of cough, reinforcement of teaching on nutrition, effort management, optimization of breathing, conservation of energy) and they were referred to the pneumologist and/or psychologist and social worker whenever justified.

In order to evaluate the project, patients were encouraged to carry out a questionnaire on satisfaction (LIKERT scale) with the nursing care, adherence to the recommendations provided and what they would do if the consultation did not exist.

A total of 93.7% (196) of the calls were successful and 6.2% (13) of the users did not answer. A follow-up adherence rate of 98.4% and recommendations of 87% were obtained. A percentage of 100% satisfaction was achieved with the nursing care provided, thus this study, since all patients expressed feeling they were accompanied, emphasizing that telephone contact should happen more often, as they have the opportunity to express their feelings/emotions/expectations about their illness situation, knowing that they will be heard and find answers to their problems. Patients reinforced the importance of the consultation as, if it did not exist, they would have to wait for the next medical appointment (28%) or go to ER (72%).

This nursing consultation has been struggling with some limitations, namely the opening hours (8-16h/working days) - 1 patient had to go twice to the SANP due to the presence of AE during the period the service was closed and 1 patient contacted SANP during the night. It should also be noted that at the first appointment the patients showed concern and wanted to know how to act in the event of the appearance of any AE at the weekend, being instructed to go to the hospital in the area of residence, having to emphasize their treatment.

CONCLUSION

The benefits and the advantages of the implementation of the nursing consultation follow-up are evident, since the nurse plays a key role as Educator, as well as Care Implementer, Counselor and Consultant, roles that have the main purpose of cutting back on hospital trips, early identification of immune- mediate toxicity, management and control of symptoms, one's empowerment so that you can have a healthy life, avoid complications, and continuing adherence to the therapeutic regime. Reducing patients' anxiety, clearing doubts at the right time and providing safety to the patient-family duo to enable them to manage the problems from home are some other objectives sought. All patients benefited from the creation of this consultation. Even patients who did not have AE felt and need for advice from the nursing team.

Ethical Disclosures:

Conflicts of Interest: The authors have no conflicts of interest to declare.
Financial Support: This work has not received any contribution, grant or scholarship.
Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of patient data.
Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2024).
Provenance and Peer Review: Not commissioned; externally peer-reviewed.

Responsabilidades Éticas:

Conflitos de Interesse: *Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.*
Fontes de Financiamento: *Não existiram fontes externas de financiamento para a realização deste artigo.*
Confidencialidade dos Dados: *Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.*
Proteção de Pessoas e Animais: *Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.*
Proveniência e Revisão por Pares: *Não comissionado; revisão externa por pares.*

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