Implementation of a Hybrid Care Model for Telemedicine-based Cancer Pain Management at the Cancer Center of Naples, Italy: A Cohort Study

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Abstract. Background/Aim: Telemedicine, the remote delivery of healthcare services, represents a great opportunity for cancer pain management. A care model of telemedicine that combines remote visits and hospital access could be an effective and safe strategy for pain management of cancer patients. Patients and Methods: A retrospective study was conducted using the dataset of the telemedicine program at the Istituto Nazionale Tumori of Naples, Italy for assessing the efficacy of a telehealth-based model of care. Demographic, clinical, and process variables were investigated. Results: A total of 226 cases and 489 visits were included in the analysis. The mean age of patients was 63.4 years (SD=12.4 years), and no sex differences were observed. Approximately 55% of patients were ECOG-PS ≤2 and 87% suffered from metastatic disease. More than half of the patients were treated with high doses of opioids. Each patient had a mean of 2 remote visits and half of the patients had more than I telehealth consultation. The dropout ratio was 5.3%. Most visits (n=472)were conducted on patients in the Campania Region, Italy. The maximum covered distance from the Cancer Center and the patients' location was 555.22 Km. A significant difference in the overall number of visits (p=0.006) and the number of procapita remote visits (p=0.010) was found, in favor of the group of patients treated before the end of the Covid-19 emergency in Italy, compared to those treated after the pandemic.

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Key Words: Cancer pain, telemedicine, telehealth, pain management, pain.



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Conclusion: Despite various positive outcomes, the analysis highlights several weaknesses, such as the need to assist patients with advanced and non-advanced disease located outside the regional territory. Overall, the telehealth processes should be adapted to post-pandemic scenarios towards their implementation in routine clinical practice.

Telemedicine is the remote delivery of healthcare services. It represents an important opportunity for chronic pain management (1), whilst promoting assistance for patients and enhancing their access to care (2). Nevertheless, mostly in the setting of cancer pain management, clinical experience is limited and not able to define an optimal treatment pathway (3). In these vulnerable patients, there exists a need to establish a process that guarantees rapid access to the hospital for diagnosis or to proceed to execution of nonpharmacological analgesic techniques. Moreover, this care model must also allow the management of emergencies occurring during the course of treatment that require rapid in-person assessment and care. For example, a sudden worsening of pain with the appearance of new-onset symptoms (e.g., due to bone lesion) or drug side-effects may require for in-person clinical evaluation.

During the Covid-19 pandemic, the National Cancer Center, Pascale Foundation, Campania Region, Italy launched a telemedicine program for assisting patients experiencing cancer pain. Based on previous clinical experience on the topic (4) and results from a Delphi study (5), a "hybrid" care model was developed. This approach, after a first in-person consultation, combines remote assessment and further in-person visits. It is a synchronous real-time communication telehealth process of video consultation combined with a store-and-forward system of clinical data enforced to grant protected electronic transmission of patient information.

In Italy, the state of emergency due to the Covid-19 pandemic started on January 31, 2020 and ended on March

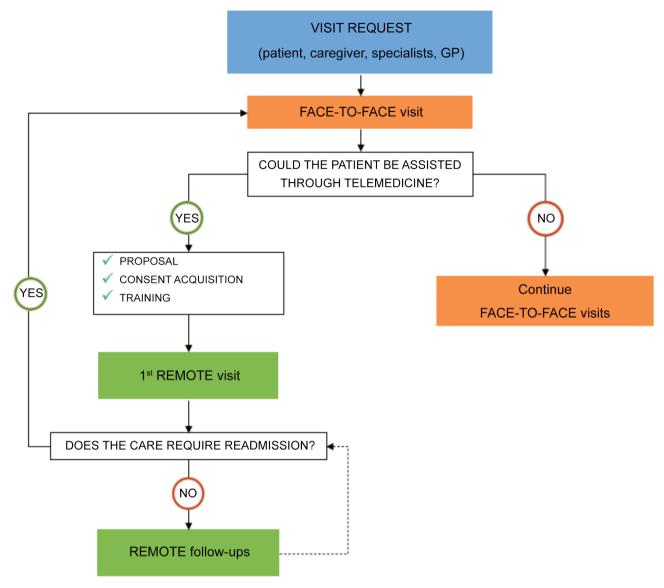


Figure 1. Care model. The Figure shows a care model based on telemedicine visits. GP, General practitioner.

31, 2022. It allowed the government to bypass bureaucracy and impose *ad hoc* rules. The health policy promoted a reduction of hospital access and implementation of telehealth services. Thus, evaluation of healthcare phenomena during and after the Covid-19 pandemic can offer important data for planning care strategies.

In previous studies, we assessed the degree of patient satisfaction (6) and developed predictive machine-learning models to identify patients who could have benefited from more remote visits (7). In this study, we sought to report and describe the collected data of a single-center experience on telemedicine employed for the treatment of cancer pain during and after the Covid-19 era. The aim was to provide

indications for optimizing the model of care and facilitate the implementation of telemedicine approaches in routine clinical practice.

Patients and Methods

Study population. Adult cancer patients suffering from pain were offered the possibility of assistance by telemedicine through a first in-person visit, remote consultations and eventually, in-person assessments. For individuals with poor health status or those not capable to use technology, the involvement of a caregiver was recommended. All patients provided the written informed consent (protocol code 41/20 Oss; date of approval: 26 November 2020). The analyzed dataset included 295 patients and 674 remote visits,

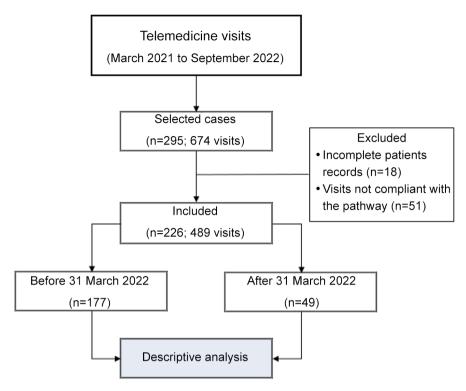


Figure 2. Study flowchart. Details regarding the study flowchart of telemedicine visits are shown.

in the realms of the telemedicine program at the Istituto Nazionale Tumori of Naples, Italy. The visits were conducted during the period from March 2021 to September 2022.

Information technology (IT) platform. The IT infrastructure (Platform "Sinfonia", Campania Region, Southern Italy) was developed during the Covid-19 pandemic and subsequently ameliorated. To date, the system allows management of the regulatory processes, such as reservation, generation of the link and sending it for the visit. Moreover, the platform is designated for data collection (e.g., imaging, laboratory tests, clinical findings, etc.), storage, and security. Thus, it is also a useful instrument for descriptive and predictive analyses (7). The booking system provides access to the hospital portal. An operator collects the reservation call and organizes the visits. A linked connection is established; the patient can forward the required clinical data, which is loaded into the platform. Patient data entry is limited to the operator, as a protected login to the platform is mandatory.

Telemedicine care model. The proposed care pathway usually provides a first in-person visit. It is used for legal and regulatory issues, such as acquisition of consent, clinical data collection, and patient/caregiver training. This preparatory step is fundamental for building fruitful and close cooperation with the patient, for diagnostic or therapeutic scopes as well as to acquire elements of patient competence about the implemented technology. In the course of remote consultation, pain physicians relate with the patient and caregiver, assess clinical conditions, and the laboratory and instrumental data. Other healthcare professionals can be engaged in a multidisciplinary consultation. Unexpected hospital readmissions

can be promptly guaranteed. Although remote follow-ups are scheduled, patients can require supplementary remote or face-to-face consultations (Figure 1).

Variables and end points. A descriptive and counting analysis was performed on 226 patients who proceeded to remote visits. From the dataset, several variables were analyzed. Demographic variables included age and sex. Clinical data included cancer type, Eastern Cooperative Oncology Group Performance status ECOG-PS, opioid prescription as Morphine Equivalent Dose, (MED), metastasis occurrence, remote consultations, and pro-capita teleconsultations. Finally, process variables included dropout rate from the remote process, multiprofessional consultations and distribution of visits on the national territory. Numerical variables are presented as mean (standard deviation, SD) and median (interquartile range, IQR); categorical variables by count (percentage).

Statistical analysis. A univariate analysis was performed to identify the differences between the group of patients enrolled before and after March 31, 2022 (the date of the end of the state of emergency in Italy). Patients who were enrolled before March 31, 2022 but continued to carry out teleconsultations even after this date, were still considered to belong to the first group. Differences were estimated by the Wilcoxon test (Wilcoxon signed-rank test) for the difference between medians or by the chi-square test (Pearson's chi-square test), both at a significance level of 95% (less than or reasonably close to the threshold value of 0.05).

Tests and graphs were carried out using the base and ggplot2 suits from the R software, version 4.1.3 (R Core Teams, R Foundation for Statistical Computing, Vienna, Austria).

Table I. Demographic and clinical data of patients who received telemedicine consultations during the study.

Patients	n=226	
Age		
Mean (SD)	63.4 (12.4)	
Median (IQR)	65 (55-73)	
Sex		
Female	117 (51.8%)	
Male	109 (48.2%)	
Cancer type		
Bladder	16 (7.1%)	
Breast	30 (13.3%)	
Gastrointestinal	62 (27.4%)	
Gynecological	9 (3.9%)	
Head and Neck	14 (6.2%)	
Kidney	7 (3.1%)	
Lung	32 (14.1%)	
Soft tissues and bones	22 (9.7%)	
Prostate	16 (7.1%)	
Other cancers	18 (8%)	
ECOG-PS†		
1	10 (4.4%)	
2	117 (51.8%)	
3	92 (40.7%)	
4	6 (2.7%)	
Metastases		
No	28 (12.4%)	
Yes	198 (87.6%)	
MED^{\dagger}		
≤60 mg	88 (39.9%)	
>60 mg	137 (60.1%)	
Remote consultations	n=489	
Pro-capita teleconsultations		
Mean and range	2.16 (1-17)	
1 visit	111 (49.1%)	
2 visits	55 (24.3%)	
3 visits	24 (10.6%)	
4 visits	18 (8%)	
>4 visits	18 (8%)	

†Missing data n=1. ECOG-PS, Eastern Cooperative Oncology Group Performance status; MED, morphine equivalent dose.

Results

A dataset including findings from 295 patients and 674 remote visits was analyzed. The visits were conducted from March 2021 to September 2022. After the exclusion of incomplete patient records (n=18) and records not compliant with the pathway (n=51), 226 cases and 489 visits were included in the descriptive analysis (8) (Figure 2).

The mean age of patients was 63.4 years (SD=12.4 years), and no sex differences were found. Each patient received a mean of 2 remote visits (range=1-17). Approximately 55% of patients were ECOG-PS \leq 2 and 87% suffered from metastatic disease. Half of the patients underwent more than 1 remote visit (Table I).



Figure 3. Distribution of visits on the national territory. A summary of the distribution of visits on the national territory is shown. Most remote consultations (n=472, 96.5%) concerned patients in the Campania region, Italy. The maximum covered distance (from the Cancer Center, Campania Region) was 555.22 Km.

Twelve patients (5.3%) discontinued the telehealth program. The causes of dropouts were the call for an invasive approach for pain (n=4), a comprehensive clinical and diagnostic evaluation for uncontrolled pain (n=4), or a hospital re-admission for disease complications (n=2). Two patients required in-person visits. Multiprofessional consultations were performed with a psychologist (n=14 visits), an oncologist (n=4), and a surgeon (n=2).

Concerning the distribution of visits on the national territory, most visits (n=472, 96.5%) were conducted from patients in the Campania region, Italy. The maximum covered distance (from the Cancer Center, Campania Region) was 555.22 Km (Figure 3). Univariate analysis between the group of patients enrolled before and after March 31, 2022, showed that, during the Covid-19 era, patients were 4 years younger than those who followed later, but the difference between the groups was not significant. There is a significant difference in the overall number of visits (p=0.006) and the number of p-capita remote visits (p=0.010). Both are in favor of the group before the end of the emergency (Table II).

Throughout the study period, most patients underwent one visit. During the COVID-19 emergency, 10 patients (4.4%) were submitted to more than 5 telehealth consultations. Differences in the number of *pro-capita* remote visits during

and after the Covid-19 emergency are shown in Figure 4. The trends and differences in ECOG-PS status and opioid prescription during and after the emergency status are shown in Figure 5 and Figure 6, respectively.

Discussion

To date, evidence on the potential applications of telemedicine towards assisting cancer patient pain is inadequate. Moreover, lacking indications on the most accurate model to be followed, the experience gained in different care settings are fundamental for designing studies with more defined aims. This paper presents the results of a telemedicine-based program conducted for addressing cancer pain management. The analysis highlights several strengths and weaknesses of the undertaken program.

The strengths of the provided service concern mostly the efficacy of the dedicated IT platform and the ability of the telehealth process to enable care of patients with different cancer types and disabling symptoms. The platform is a key element for telemedicine strategies (9). The system we adopted is an easy-to-use tool that allows for legal and organizational steps. It is also suitable for data collection. Besides, patients expressed a high degree of satisfaction with the platform used (7).

Concerning clinical advantages, the results showed that the majority of patients (87%) suffered from metastatic disease, and more than half (60%) were treated with high doses of opioids. Moreover, almost half of the patients had an ECOG-PS of 3 and 4. These data indicate that telemedicine is also indicated for complex patients who require greater care commitment (10).

The geographical distance covered by telemedicine is a quality element of the process. In cancer patients, pain poses an important functional limitation. Thus, a telemedicine approach can be fundamental for these types of patient needs. In a study conducted in an otolaryngology outpatient setting the average distance covered was 103 km (11). Our analysis confirms that the application of a telemedicine model is limited to a regional context. On the other hand, visits outside the region (n=17, 3.5%) indicate a wide use of the platform (which integrates with the health registers of other regions) and the possibility of assisting patients even at considerable distances. Nevertheless, a network with local hospitals for the management of emergencies or other problems that require hospital access should be built.

There are many weaknesses of the model, that need to be ameliorated. For example, since the average age of our sample group was 64 years, younger patients should also be included in the pathway. Although several investigations indicate that younger patients are more prone to use telehealth services (12), age and other demographic characteristics differ according to institution and population (13).

Table II. Telemedicine consultations during and after the Covid-19 era.

Variable	Period of treatment		
	During Covid-19, n=177 [†]	After Covid-19, n=49 [†]	<i>p</i> -Value [^]
Age (years)			0.054
N	173	48	
Mean (SD)	63 (12)	67 (13)	
Median (IQR)	64 (56, 72)	68 (58, 78)	
(Missing)	4	1	
Class of age			0.082
≤65	93 (54%)	19 (40%)	
>65	80 (46%)	29 (60%)	
(Missing)	4	1	
Sex			0.906
F	92 (52%)	25 (51%)	
M	85 (48%)	24 (49%)	
ECOG-PS			0.146
1-2	95 (54%)	32 (65%)	
3-4	82 (46%)	17 (35%)	
Cancer type			
Gastrointestinal	36 (20%)	9 (18%)	
Gynecological	9 (5.1%)	1 (2.0%)	
Breast	23 (13%)	7 (14%)	
Melanoma/skin	3 (1.7%)	2 (4.1%)	
Pancreas	8 (4.5%)	3 (6.1%)	
Soft tissue/bones	16 (9.0%)	6 (12%)	
Lung	25 (14%)	6 (12%)	
Prostate	11 (6.2%)	5 (10%)	
Kidney	5 (2.8%)	1 (2.0%)	
Head/neck	11 (6.2%)	3 (6.1%)	
Bladder	13 (7.3%)	3 (6.1%)	
Others	17 (9.6%)	3 (6.1%)	
MED (mg/day)			0.796
≤60	70 (40%)	18 (38%)	
>60	107 (60%)	30 (62%)	
(Missing)	0	1	
Visits§			0.006
Patients (n)	177	49	
Mean (SD)	2.32 (2.03)	1.61 (1.06)	
Median (IQR)	2.00 (1.00, 3.00)	1.00 (1.00, 2.00)	
Visits (categories)			0.010
1	78 (44%)	33 (67%)	
2-3	66 (37%)	13 (27%)	
>3	33 (19%)	3 (6.1%)	

†n (%); ^Wilcoxon rank sum test; Pearson's Chi-squared test; *During and after Covid-19 emergency (to March 31, 2022). Those who were enrolled during the pandemic but continued to carry out remote visits even after this date, were still considered to belong to the first group. ECOG-PS, Eastern Cooperative Oncology Group Performance status; MED, morphine equivalent dose.

During the Covid-19 pandemic, patients made multiple visits remotely. Undoubtedly, easier access to the hospital may reduce the number of requests for remote consultations, but also for repeated visits. Arguably, more effort is required for patient enrollment, fueling the process in its initial step.

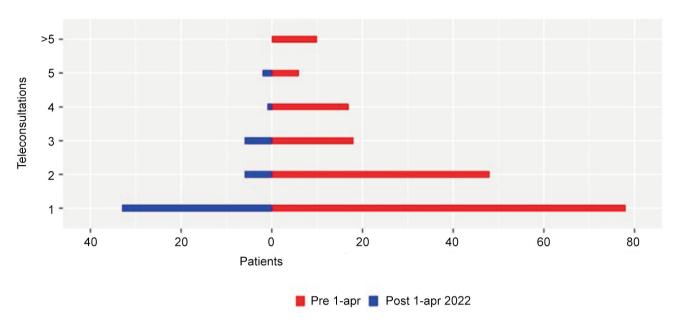


Figure 4. Patients and pro-capita teleconsultations before and after the Covid-19 emergency era. Differences in the number of pro-capita remote visits during and after the Covid-19 emergency (March 31, 2022) are shown.

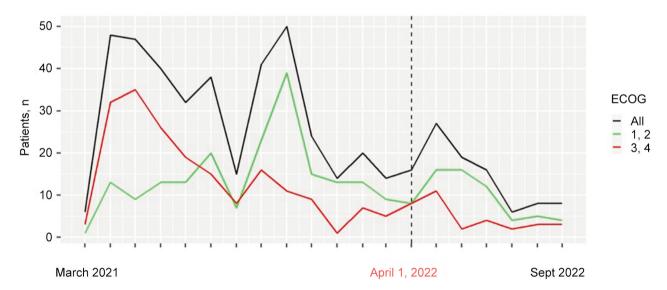


Figure 5. Diagram of trends and differences in ECOG-PS during and after the emergency status.

For this purpose, multi-professional involvement should be implemented. For example, the engagement of general practitioners and oncologists is advisable. Notably, only in 20 visits (4%), the multidisciplinary pathway was performed.

The proper timing for follow-up is also an important issue. It concerns the need to design differentiated pathways for distinct subgroups of patients. For example, in patients with gastrointestinal cancers and pain conditions, nutritional needs

are the main cause of an increased number of unscheduled hospital admissions (14). Addressing neuropathic pain is usually a great challenge (15). Probably, patients suffering from this subtype of cancer pain require greater attention because they are more candidates for visits in person to reevaluate drug therapy or for invasive pain management (16). Moreover, an augmented dropout rate from the telehealth pathway was observed in patients with neuropathic pain (6) probably, these patients.

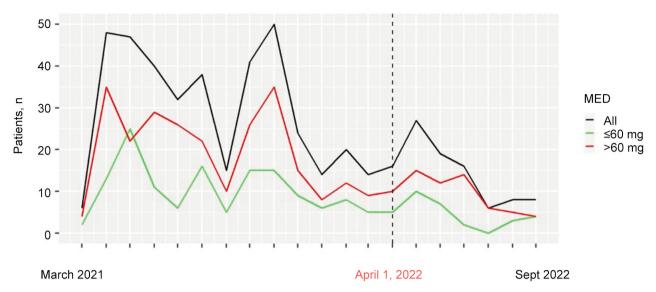


Figure 6. Diagram of trends and differences in opioid prescription, during and after the Covid-19 emergency status. Differences in opioid prescription as morphine equivalent dose (MED), in patients visited by telemedicine, are shown.

The modulation between remote visits and rapid hospital access is an important challenge for healthcare systems, demanding for significant resources. Our experience has shown us that it is often difficult to be able to continuously manage a large number of patients remotely unless pathways are structured that provide for the possibility for the patient to be able to interact in real-time with an operator to communicate related problems, the disease or treatment in progress. Cancer pain management is a dynamic process that requires careful re-evaluation of the therapy. The same patient who reports a positive analgesic effect may experience rapid worsening of pain or the appearance of side-effects from medications and procedures over the course of a few hours. Therefore, in addition to remote visits, the patient could have answers to clinical questions through the possibility of having a direct channel with an operator.

Conclusion

This single-center experience of a telemedicine program for addressing cancer pain can be useful to define effective and safe pathways for the management of a vulnerable population group. Further experience is needed to clarify doubts and establish the most suitable pathways for subcategories of patients for modulating care models according to available resources. Finally, telehealth processes must be adapted to post-emergency scenarios for their implementation in routine clinical practice. It becomes evident that telehealth processes should be implemented in routine clinical practice for cancer pain management.

Conflicts of Interest

The Authors have no conflicts of interest to disclose in relation to this study.

Authors' Contributions

M. Cascella: Conceptualization, writing—original draft preparation; S. Bimonte and M. Cascella: writing—review and editing; D. Schiavo: performing physiological teleconsulting; M. Grizzuti and M.C. Romano: organizing televisits; S. Coluccia: performing biostatistical analyses; A. Cuomo: language editing. All Authors have read and agreed to the published version of the manuscript.

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