



Medical treatment of patients with gynecologic cancer during the COVID-19 pandemic

Eleonora Palluzzi,¹ Giacomo Corrado,¹ Claudia Marchetti,¹ Giulia Bolomini,¹ Laura Vertechy,¹ Carolina Bottoni,¹ Mariagrazia Distefano,¹ Giovanni Scambia,^{1,2} Gabriella Ferrandina^{1,2}

¹Department of Woman, Child and Public Health, Fondazione Policlinico Universitario A Gemelli IRCCS, Rome, Italy
²Institute of Obstetrics and Gynecology, Catholic University of the Sacred Heart, Rome, Italy

Correspondence to

Dr Eleonora Palluzzi, Department of Woman, Child, and Public Health, Fondazione Policlinico Universitario A Gemelli IRCCS, Rome 00168, Italy; eleonorapalluzzi@gmail.com

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HIGHLIGHTS

- The spread of COVID-19 infection has required reorganization of the management of patients diagnosed with gynecologic cancers.
- The amount of admissions was similar in 2019 and 2020.
- Only one patient (0.1%) was diagnosed with COVID-19, and there were no cases among healthcare staff.

ABSTRACT

Background During the COVID-19 pandemic, cancer care had to be reorganized; national and international recommendations were published to manage anticancer treatments safely and to reduce the risk of SARS-CoV-2 infection for patients and health workers.

Objective To evaluate whether the adoption of recommendations for the management of patients with gynaecologic cancer receiving treatment during the pandemic resulted in containment of infections and continuing oncologic care.

Methods Based on the published recommendations, and according to the local Health Direction guidelines, we developed and drafted a security protocol to modify access of patients with gynaecologic cancer to the “Fondazione Policlinico Agostino Gemelli-IRCCS, Rome” between February 1 and April 30, 2020 and compared results with the corresponding 3 months of 2019.

Results Between February and April 2019, we registered 3254 admissions, including 2253 patients receiving intravenous chemotherapies, 298 receiving oral therapies, and 703 having hospital visits. Between February and April 2020, we registered 3213 admissions, including 2221 patients receiving intravenous chemotherapies, 401 receiving oral therapies, and 591 having hospital visits. Oral treatments and general visits were different in the two time periods ($p < 0.001$). Despite the elevated patient flow, only one patient (0.1%) tested positive for COVID-19 and there were no cases among healthcare staff.

Conclusions Based on the adopted security protocol we provided continuity of care for all patients and limited the spread of the COVID-19 infection.

INTRODUCTION

Coronavirus is a common pathogen that primarily affects the human respiratory system; in the past 20 years, epidemic diffusion of β -coronavirus pathogens occurred in 2002–2003 (SARS-CoV-1), and in 2013 (MERS-CoV).¹ On December 31, 2019, the Chinese authorities reported to the World Health Organization (WHO) some cases of atypical pneumonia

probably related to an unknown coronavirus in Wuhan (Hubei).^{1–3} WHO named this new coronavirus as COVID-19 on February 11, 2020,⁴ and, due to the health emergency that rapidly diffused worldwide, declared a pandemic status on March 11, 2020.⁵ Italy was the first country to establish a blockade in Europe from March 10 to the beginning of May 18; overall, on April 30, the number of COVID-19 positive cases was 101 551, and the number of documented deaths was 27 967 based on the data from the Istituto Superiore di Sanità.⁶

According to the published data,^{7–9} elderly people and patients with pre-existing co-morbidities develop the most severe and acute clinical consequences of COVID-19 disease,¹⁰ thus leading to a fatality rate ranging between 11.2% and 15.9%^{3 11 12} and up to 29% in a single Italian institution.¹³ However, patients with cancer showed a higher mortality (21%), severe/critical disease (45%), and intensive care unit admission rate (14.5%).¹⁴ The frailty and vulnerability of patients with cancer to infectious disease are probably associated with immunosuppression related to anticancer treatments.

In order to provide guidelines for management of patients with cancer during COVID-19 diffusion, Italian and European associations published recommendations.^{15–23} The Italian Association of Medical Oncology (AIOM) recommended, for all malignancies, evaluation of the case-by-case risk/benefit ratio of delaying adjuvant/neoadjuvant or first-line treatment; delaying all treatments with expected low efficacy, or maintenance therapies beyond the first line in patients with a low burden of disease; and switching scheduled visits to phone or email contact, unless emergency cases. Moreover, the management of risk reduction for medical and paramedical staff was also evaluated.¹⁶

The European Society of Medical Oncology (ESMO) also provided some recommendations for

gynecologic cancers, layering three different classes of priority for (i) visits, active treatment in (ii) early or (iii) advanced disease for ovarian, endometrial, and cervical cancer.^{17–19} In a recent editorial, a gynecologic oncology expert panel described potential options for prevention of COVID-19 infection, such as limiting visits to new patients or patients requiring urgent treatment and use of telemedicine for all other patients, one accompanying family member, and reduction of personnel staff.²⁰

Therefore, the aim of this study was to evaluate the total number of patients and admissions (intravenous chemotherapies, oral drug treatments, visits) in our day hospital between February 1 and April 30, 2020 compared with the same time interval of the year 2019.

METHODS

The protocol was developed and drafted on February 1, 2020 and then updated on the basis of the recommendations subsequently published.^{15–23} For patients actively receiving or needing to start intravenous treatments, we decided to keep the planned therapy, with the exception of those patients who specifically asked to postpone their chemotherapy treatment, due to fear of the risk of COVID-19 infection in the hospital setting. For patients receiving oral treatment (maintenance therapy, oral chemotherapy, or hormone therapy), the scheduled visits were converted to phone/telematic call, before which patients sent by email reports of the requested blood and instrumental test, and registration of current signs and/or symptoms, except for new symptoms or clinical or radiological signs of disease progression.

For outpatients, we allowed visits only for patients with a new diagnosis or clinical urgency signs and/or symptoms. The strong desire of patients to have a regular physical examination was managed by informing the patient of the risks related to hospital visits. Other scheduled visits were converted into phone/telematic contacts.

The day before a scheduled visit, a phone/telematic pre-triage was considered mandatory with the aim of investigating any respiratory disorders, fever, or other symptoms related to COVID-19 infection; when these symptoms were absent, the scheduled visit was confirmed. Otherwise, on the basis of the reported symptoms, the patient was sent to the emergency room where the fever path versus the COVID-19 path was performed. No caregiver was allowed into our unit, including the waiting room, for all patients scheduled for treatment or visit, except in cases of documented need of continuous assistance, such as physical and mental disability or under-age patients. After triage, only one family member was admitted in cases of clinical need.

On-site pre-triage was expected for all scheduled access and included measurement of body temperature with an infrared thermometer and administration of a survey for the self-certification of the absence of risk factors for COVID-19 infection. No access was allowed for patients with fever and/or respiratory symptoms. Surgical masks and hand washing with hydroalcoholic gel were provided for all patients at the entrance of the waiting room. Surgical masks and gloves were also obligatory for clinicians and paramedical staff, while FFP2/FFP3 masks were mandatory for nursing staff. Multidisciplinary tumor boards and organizational meetings were virtual.

All visits to our unit were for patients needing explanation and discussion of a histologic report, for triaging patients to follow-up versus medical treatment after surgery (any setting), or after radiotherapy in patients managed by a multimodal approach. There were no admissions for surgery or radiation treatment. After implementation of the recommendations according to the management of our unit in the Fondazione Policlinico Agostino Gemelli-IRCCS, Rome, we compared the level of activity between February 1 and April 30, 2020 with the corresponding 3 months of the year 2019. We analyzed the total number of patients/admissions to our unit (intravenous chemotherapies, visits for patients treated with oral drugs both performed in hospital and by phone/telematic contact) and visits (first visit, reevaluation visits during treatment, unscheduled visits, surveillance, end of treatment visits) both performed in hospital and by phone/telematic contact; antitumoral treatments were defined as follows: intravenous chemotherapy (adjuvant, first line, and treatments beyond the first line); oral treatments (maintenance therapy, oral chemotherapy, and oral hormone therapy) both performed in hospital and by phone/telematic contact. Visits were established as first visits (at primary diagnosis, or start of a new treatment or novel symptoms) or other types of visit (non-scheduled visits, reevaluation during treatment, surveillance and end of treatment visits). The collection of retrospective data was approved by the local ethics committee.

The χ^2 test was used to analyze the distribution of the number of patients with different gynecologic malignancies and the number of admissions to our unit in the 3 months activity in years 2019 and 2020. Statistical Package for Social Sciences software, version 25.0 (IBM Corporation, Armonk, New York, USA) was adopted for all statistical calculations. A *p* value <0.05 was considered significant for all analyses.

RESULTS

Between February and April 2019, we followed up 965 patients versus 930 patients admitted in the corresponding months of 2020: the vast majority of patients were diagnosed with ovarian cancer (67.7%), followed by endometrial cancer (15.2%), cervical cancer (10.3%), and other gynecological malignancies (10.4%). There was no statistically significant difference between the two groups in the number of patients according to types of malignancies (*p*=0.37; Table 1).

The distribution of types of treatment, clinical settings, and visits per patient in 2019 and 2020 according to gynecological malignancies, in the 3 month period of the year 2019, are summarized in Figure 1. A total of 444 patients with ovarian cancer were treated: 352 patients were treated with intravenous chemotherapy (28 in adjuvant setting, 179 in first line, and 145 in other lines), and 92 were treated with oral drugs with visits performed in hospital. Patients undergoing visits (gynecologic inspection, discussion of disease histology and treatment) were 209 (first visits: 40, other visits, such as reevaluation during treatment, unscheduled visits, surveillance, and end of treatment visits: 169). In the corresponding period of year 2020, 495 patients with ovarian cancer were administered antineoplastic chemotherapy including 361 patients treated with intravenous chemotherapy (31 in the adjuvant setting, 159 on the first line, 171 on the subsequent lines), and 134 patients

Table 1 Distribution of patients

	February–April 2019 No (%)	February–April 2020 No (%)	P value
All patients	965	930	
Types of malignancy			
Ovarian cancer	653 (67.7)	658 (70.8)	
Endometrial cancer	147 (15.2)	117 (12.6)	
Cervical cancer	100 (10.4)	96 (10.3)	
Other gynecologic malignancies	65 (6.7)	59 (6.3)	0.368

managed with oral regimens. Patients receiving oral treatment were managed on site (n=28) and by phone/telematic contacts (n=106). The total number of visits for patients with ovarian cancer was 163: 43 first visits for gynecologic inspection, explanation of disease histology, and description of the type of treatment that patients had to undergo, and 120 other visits (reevaluation during treatment, unscheduled visits, surveillance and end of treatment visits).

In 2019, 75 patients with endometrial cancer were given anti-cancer treatment (intravenous chemotherapy, but also hormone therapy), including 67 patients treated with intravenous chemotherapy (19 in the adjuvant setting, 30 on the first line, and 18 on subsequent lines), and eight patients managed with oral drugs on site (panel B). Outpatient visits numbered 72 (first visits: 22,

reevaluation during treatment, unscheduled, and end of treatment visits: 50). In 2020 of 117 patients with endometrial cancer, 67 were treated; 58 with intravenous chemotherapy (16 in the adjuvant setting, 14 on the first line, and 28 on subsequent lines), and nine patients managed with oral chemotherapy or hormone therapy in the hospital. The total number of visits by patients with endometrial cancer was 50 (first visits: 12, reevaluation during treatment, unscheduled visits, surveillance, and end of treatment visits: 38).

For cervical cancer, in 2019, of 100 patients with cervical cancer, 58 underwent chemotherapy, including 53 patients with intravenous chemotherapy (six in the adjuvant setting, 28 on the first line, and 19 on subsequent lines), and five patients were admitted to the hospital for oral drugs; patients undergoing visits numbered 42 (first visits: 9, other visits: 33). In 2020, of 96 patients with cervical cancer, 53 patients underwent chemotherapy (52 patients with intravenous chemotherapy, and only one patient was admitted to the hospital for oral medication). The total number of visits by patients with cervical cancer was 43, of which five were first visits and 38 other visits. In our hospital, patients with cervical cancer undergoing chemoradiotherapy are followed up by the radiotherapy unit, and therefore these patients were not included in the study.

As shown in Table 2, analysis of the distribution of all patients managed by intravenous chemotherapy, oral therapy, and visits demonstrated an increased adoption of oral treatments and a reduction of visits between February and April in 2020 in comparison with the same time period in 2019, resulting in a statistically significant difference (p<0.002). Between February and April 2019, we registered 3254 admissions, including 2253 intravenous chemotherapies, 298 hospital admissions for oral therapies, and 703 visits (Table 3). Between February and April 2020, we registered 3213 admissions, including 2221 intravenous chemotherapies, 401 oral

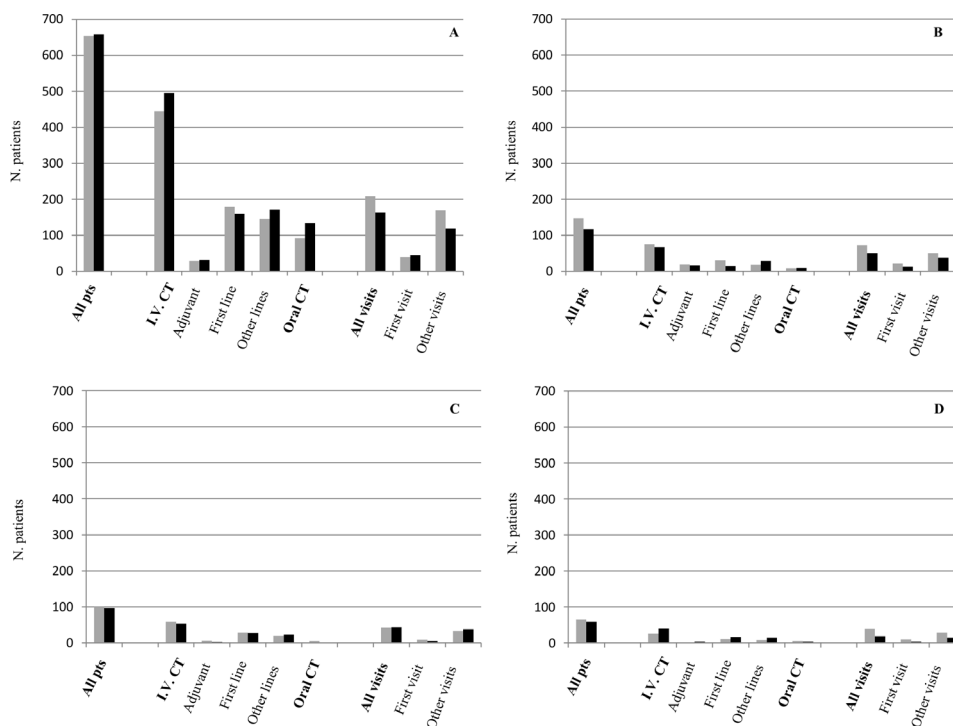


Figure 1 Distribution of types of treatment and visits of the year 2019 (gray columns) versus the year 2020 (black columns); (A) Patients with ovarian cancer, (B) patients with endometrial cancer, (C) patients with cervical cancer, (D) patients with other gynecological malignancies. IV CT, intravenous chemotherapy.

Table 2 Distribution of patients managed by intravenous chemotherapy, oral therapy, and visits

	Total No	February–April 2019 No (%)	February–April 2020 No (%)	P value
All patients	1895	965	930	
IV chemotherapy	1000	493 (49.3)	507 (50.7)	
Oral treatments	258	110 (42.6)	148 (57.4)	
Visits	637	362 (56.8)	275 (43.2)	<0.002

therapies, of which 294 were admitted to the hospital while 107 were performed by phone/telematic contact, and 591 visits (on site visits 470, phone/telematic visits 121). As shown in Table 3, admissions for oral therapies increased in 2020 in comparison with 2019 ($p < 0.001$), while the total number of visits decreased.

Overall, we documented COVID-19 positivity in only one patient (0.1%). No case of COVID-19 infection was reported among the healthcare staff.

DISCUSSION

Summary of Main Results

Results of this study offer two primary sources of information—first, the clinical impact of COVID-19 on the medical management of gynecological cancer and data on diffusion of infection between patients with gynecologic cancer, and second, the emerging role of telemedicine. During the pandemic, we provided continuity of care for all our patients. In 2020 we documented a statistically significant difference in the number of patients treated with oral drugs. Despite the high number of patients managed, adherence to the safety protocol limited the spread of infection, with only one patient (0.1%) affected by COVID-19. These results were possible thanks also to the use of telemedicine.

Results in the Context of Published Literature

In the early stage of the COVID-19 pandemic, some societies, associations and even expert panels developed recommendations to better manage the administration of treatments to patients with cancer while at the same time minimizing the risk of infection.^{15–24} Our study has shown that compliance with the rules recommended by national and international scientific societies, and by the decree of the presidency of the council of ministers March 8, 2020, has allowed us to maintain the same quality and quantity of oncological treatments as well as visits, compared with 2019, also safeguarding and preventing infection. We registered only one patient with COVID-19 (0.1%), who completed the planned regimen. This figure is lower than that published in the literature based on a recent

meta-analysis showing that the frequency of COVID-19 infection of patients with cancer was 2.1%.¹⁴

One could argue that although the overall number of patients was similar between 2019 and 2020, the patients might have differed according to the types of malignancy. We noted that there could be a distribution favoring patients with endometrial cancer admitted only for visits, since patients with early-stage and low-risk endometrial cancer do not require medical treatment or are managed by radiotherapy, and a reduction of patients with ovarian cancer. However, there was no significant difference in the distribution of patients by pathology. We documented in 2020 an increased number of patients who underwent oral treatments: our policy on heavily treated patients did not include the replacement of intravenous treatment with oral therapies. It is conceivable that the increase of oral therapies could be ascribed to the benefit of the expanded access program for poly-ADP-ribose polymerase inhibitors in first-line maintenance treatment in ovarian cancer.^{25–27}

We also noted in 2020, a relatively small decrease in the rate of patients (24%) evaluated by outpatient visits; indeed, patients with gynecologic cancer were found to be more fearful of cancer progression (70.9%) than developing SARS-CoV-2 infection, and only a minority of patients (18.3%) were concerned about visiting the oncologist or contracting COVID-19 from the hospital (17.5%).²⁸ Although there was a decrease in outpatient visits, the total number of patients admitted was higher in 2020. In the management of this high flow of patients the adoption of new technologies in the field of telemedicine have been of great value.^{22 29 30} Indeed, within the planned time frame, we were able to manage by telemedicine almost 27% of oral therapies, and 20% of outpatients visits (first visits, reevaluation during treatment, unscheduled visits, surveillance, and end of treatment visits). For medical and paramedical staff, the Fondazione Policlinico Agostino Gemelli-IRCCS numbers approximately 7000 employees, and only 38 healthworkers in other staff (0.5%) tested positive for COVID-19; however, we have to acknowledge that in our region, the number of COVID-19 positive cases was much lower than in the north of Italy.³⁰

Table 3 Number of admissions to our unit according to the 3-month activity of the year 2019 versus 2020

	February–April 2019 No (%)	February–April 2020 No (%)	P value
Total admissions	3254	3213	<0.001
IV chemotherapies	2253 (50.3)	2221 (49.6)	
Oral therapies	298 (42.6)	401 (57.4)	
Visits	703 (54.3)	591 (45.7)	

Strengths and Weaknesses

During this unprecedented health emergency we showed that by adopting the appropriate safety measures, supported by the guidelines of the main national and international scientific societies, we achieved the goal of containing the spread of COVID-19 infection in a frail population (1/930, 0.1%). This study has some limitations. The lack of data on surgery in patients for whom this treatment is crucial might be a limitation of the study. Moreover, the absence of data pertaining to neoadjuvant chemotherapy in patients with ovarian cancer could limit evaluation of the impact of COVID-19 on the therapeutic approach to these patients.

Implications for Practice and Future Research

This experience has favored the development of remote management of patients with gynecologic cancer. We learned that telemedicine could assist in diagnosis, treatment planning, administration of oral drugs, provision of palliative care and surveillance. Future implications in this area require careful consideration of the needs of patients, caregivers, clinicians, specialists and health system administrators.

CONCLUSIONS

In conclusion, our study demonstrates that it is possible to maintain the same quality/quantity of cancer treatments by respecting safety protocols and adherence to national and international scientific society recommendations.

We are still using and improving our rules due the second wave of the COVID-19 pandemic. This unprecedented health emergency has increased and accelerated the adoption of measures.

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