



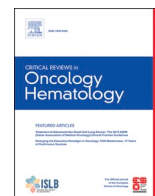
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Italian survey on the clinical management of non-small cell lung cancer patients during the COVID-19 pandemic: A lesson for the second wave

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ABSTRACT

This study investigated the clinical management of non small cell lung cancer (NSCLC) patients during the first wave of coronavirus disease 2019 (COVID-19) outbreak in Italy. A 29-questions survey was sent to 95 Italian thoracic oncologists, with 77 % of them declaring significant changes in the outpatients management and treatment. The results of this survey pointed out a significant delay of lung cancer diagnosis along with a relevant reduction of patients' accrual within clinical trials. Telemedicine emerged as a valid support for patient-healthcare interactions. Therapeutic indications followed the guidelines for adjuvant chemotherapy and concurrent chemo-radiation. Clinical indications to first-line therapies were largely confirmed, while major changes regarded the selection of second line treatment options as well as the management of elderly population.

This work may represent a valid source of information to improve the clinical management of NSCLC patients during second wave of COVID-19 pandemic.

1. Introduction

At the end of 2019, a novel viral pneumonia caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was reported at Wuhan, China (Guan et al., 2020). Since then, the related coronavirus disease 2019 (COVID-19) syndrome, has progressively involved countries outside China leading the World Health Organization (2020) to declare the state of pandemic on 11th March 2020. Since the initial detection of the virus, more than 48 million cases and more than 1.200.000 deaths from COVID-19 have been confirmed worldwide (WHO website, 2020). Italy has been one of the most affected countries with, as of 7th November 2020, 809.000 confirmed COVID-19 cases and 48.000 deaths, according to the National Institute of Health (ISS, Istituto Superiore di Sanità, 2020) data (ISS website, 2020).

In this challenging situation, the oncological community was called to protect cancer patients, considered one of the most vulnerable population, due to coexisting chronic diseases, overall poor health status, type of infection and systemic immunosuppressive condition caused by both cancer and anticancer therapies (Kuderer et al., 2020). In this

regard, the Italian Association of Medical Oncology (AIOM) has proposed specific recommendations to optimize the clinical management of patients and to regulate the access of both patients and caregivers to the hospitals, in order to encourage a careful evaluation of risk/benefit ratio case by case and, ultimately, minimize the risk of infection (AIOM website). Accumulating evidence suggest that lung cancer patients are more susceptible to infection since they are usually elderly and smokers, with poor nutritional status and compromised lung function. Several studies have already shown a higher risk of COVID-19 related complications in non-small cell lung cancer (NSCLC) patients, often related to their immunocompromised status (Rogado et al., 2020). Based on these evidences, the European Society for Medical Oncology (ESMO) has also provided management and treatment recommendations for NSCLC patients adapted to the COVID-19 era (Passaro et al., 2020). In this complex landscape, characterized by the recent occurrence of a second pandemic wave worldwide, where the emergency evolution continues to be uncertain and clinical decisions persistently difficult, sharing opinions and behaviors is of paramount importance to find new common "horizons" in the clinical management of NSCLC, and ultimately ensure,

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the best care to our patients. Based on these considerations, here we report the results of a national Italian survey carried out on April 2020, aiming to evaluate the clinical management of NSCLC patients and ultimately provide a reliable picture of real-world practice during the emergency of COVID-19.

2. Materials and methods

An online (Google form) survey (Supplementary Material) was developed by a group of thoracic oncologists working at the San Luigi Gonzaga Hospital, Orbassano (Turin), and distributed to different thoracic oncologists, across the different Italian regions. The online answers were systematically collected from the 12th of April 2020, until the 2nd of May 2020.

The current survey aimed to investigate the impact of COVID-19 outbreak on the attitudes and practice of thoracic oncologists in their clinical management of NSCLC patients.

The survey was confidential and anonymous and included four different sections, exploring the following topics: general questions about demographic and employment details of respondents (Q1-Q4); outpatient management of NSCLC patients (Q5-Q10); therapeutic decisions from the pandemic declaration to the following four weeks (March 11th -April 11th 2020) (Q11-Q21); clinical management of NSCLC patients with suspected or confirmed COVID-19 infection (Q22–23). Twenty-nine questions have been drawn up with multiple and single answers admitted for 17 and 12 questions, respectively. Descriptive statistics were used to summarize the data. Categorical variables were summarized as counts and percentages.

3. Results

The online survey was distributed to 95 thoracic oncologists from all over Italian Regions. A total of 79 responses were received, with an overall response rate of 83 %. The majority of responders (60) usually manage between 150–200 new cases of NSCLC patients per year. The general characteristics of responders are shown in Supplementary table.

3.1. Outpatient/Day hospital management of NSCLC patients

The majority of oncologists (77.3 %) declared a significant change in the outpatient/day hospital management of NSCLC patients during the COVID-19 emergency (Fig. 1A). In most cases (97.5 %), triage of patients, always including body temperature measurement, was regularly performed before entering the hospital and/or the Medical Oncology Unit (Fig. 1B). As compared to the pre-COVID-19 emergency period, the number of consultations in case of suspected NSCLC diagnosis decreased in about half of cases (46.8 %), with a major reduction when considering the number of patients coming from the emergency department, as reported in about 60 % of cases (Fig. 1C and D). As consequence, the total number of patients with any stage, newly diagnosed NSCLC, within the observational period, was reported to be lower than the pre-pandemic era by the 55.7 % of oncologists (Fig. 1E). Interestingly, multidisciplinary tumor boards were delayed or performed virtually in about half of cases (48.1 %) (Fig. 1F).

3.2. Treatment of NSCLC patients

3.2.1. Early and locally advanced disease

We asked physicians to consider their therapeutic indications for patients with stage I-III NSCLC, from the pandemic declaration to the following four weeks (March 11th -April 11th 2020) in comparison to the pre-COVID-19 period. As for chemotherapy administrated with adjuvant intent, clinical therapeutic indications did not change for the majority of responders (62 %) (Fig. 2A). Likewise, for the treatment of unresectable locally advanced disease, most of the Italian thoracic oncologists (72.2 %) confirmed, in accordance with available guidelines,

the unchanged indication to concomitant chemoradiation. However, a significant subgroup (25.3 %) of colleagues declared their preference for the sequential strategy, because they consider this approach safer in terms of pulmonary toxicity (Fig. 2B).

3.2.2. First-line therapy

Physicians reported their clinical indications to the different first line treatment options during the COVID-19 pandemic. As regards chemotherapy, the majority of them (81 %) declared that neither treatment recommendations were modified nor ongoing therapies were suspended (Fig. 2C). Similarly, clinical indications to first-line immunotherapy alone or in combination with chemotherapy remained unchanged for 78.5 % and 82.3 % of responders, respectively (Fig. 2D, E). However, the 17.7 % of them declared to have delayed the beginning of immune-based treatments as far as possible (Fig. 2D,E). As for frontline tyrosine kinase inhibitors (TKIs), almost all responders (96.2 %) confirmed that their clinical indication did not change, while only 7.6 % modified the therapeutic schedule of TKI administration (Fig. 2F). In elderly patients (over 75 years) with non-oncogene-addicted metastatic NSCLC and potentially candidate to first line therapy (chemotherapy or immunotherapy), therapeutic indications were subjected to relevant changes in the majority of cases, with about 33 % of colleagues declaring a significant decrease of treatment prescription and 27.8 % of them preferring alternative, less toxic schedules, or oral drugs, in order to reduce hospital accesses, and consequently risk of infection (Fig. 2G). Maintenance therapy with pemetrexed has been regularly administered from the majority of oncologists, but free-interval between administrations has been frequently prolonged by one week (44.3 % of cases) (Fig. 2H). Similarly, as regards first-line immunotherapy, a significant percentage of oncologists declared to have prolonged the free-interval between treatment administrations (42 %), to have suspended ongoing therapy in high-risk patients (19 %), and to have definitively discontinued treatment in case of partial or complete response confirmed at the last computed tomography (CT) as well as in cases of long-term disease control (> 18 months of treatment) (15.2 %) (Fig. 2I).

3.2.3. Second-line therapy

The management of second line treatment, including either chemotherapy or immunotherapy was subjected to relevant changes for most of responders (59 %), with about half of them declaring their preference for alternative schedules/drugs characterized by low toxicity profile and/or oral administration. In the remaining cases, treatment was discontinued in high-risk subgroups, like elderly or patients with multiple comorbidities. As for second line immunotherapy, schedule of treatment has been modified or suspended in high risk patients in 27 % of cases and 25 % of oncologists declared to have discontinued treatment in case of partial or complete response confirmed at the last CT scan or in case of achievement of more than 18 months of treatment (Fig. 2L,M). About 40 % of oncologists declared as the tendency to discontinue any active second-line treatment in favor of best supportive care (BSC) was slightly increased during the first wave of COVID-19 pandemic (Fig. 2N). For patients in follow up (out of any active treatment), a telemedicine approach through phone calls or emails was preferred by 78.5 % of responders. Finally, as regards clinical cancer research during the COVID-19 outbreak, the majority of oncologists (79.7 %) declared that the accrual of lung cancer patients within clinical trials decreased by more than 50 % (Fig. 2O,P).

3.3. Clinical management of NSCLC patients with suspected COVID-19

In case of suspected COVID-19 infection in NSCLC patients, in the majority of cases the nasopharyngeal swab was performed at the Emergency Department (60 %), followed by the Medical Oncology Unit (39 %) or general practitioners (37 %) (Fig. 3A). The majority of oncologists (73 %) declared to have had less than 5 NSCLC patients or none affected by COVID-19 infection at their Institution, within the

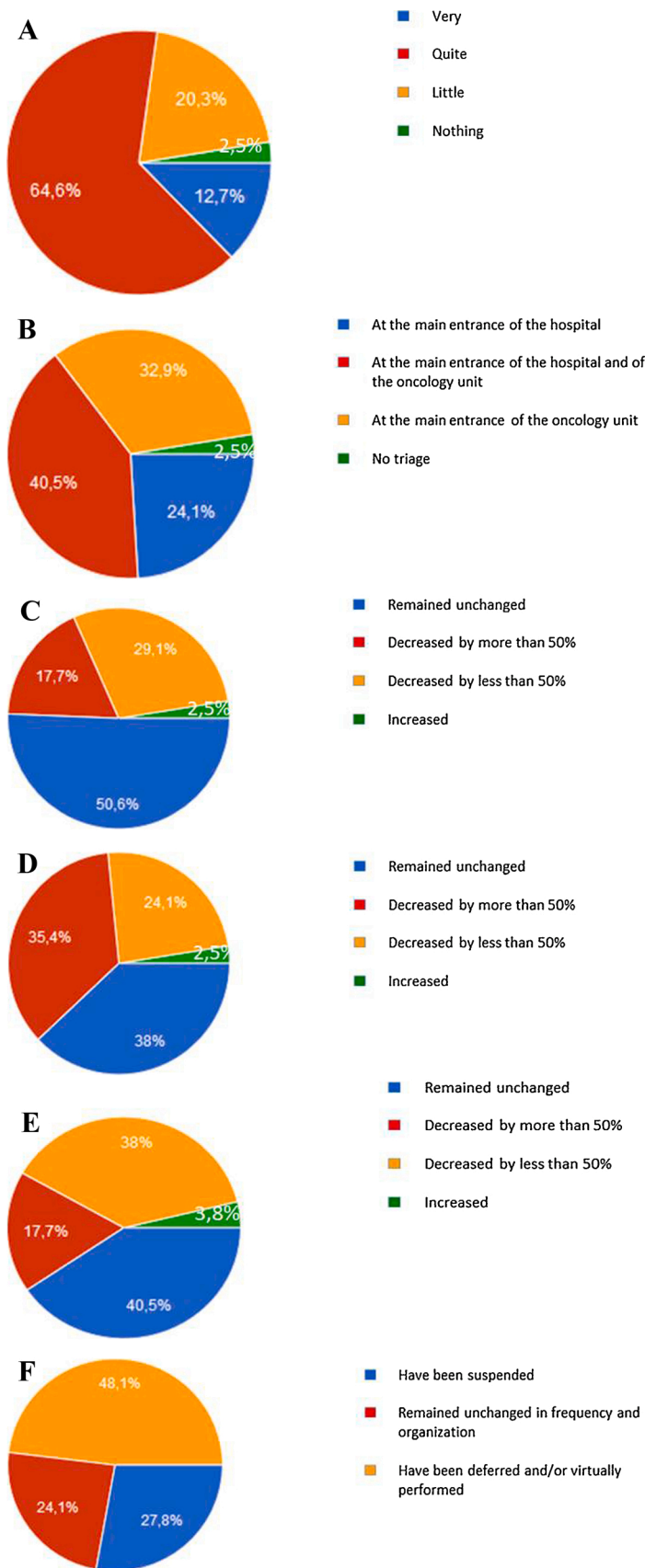


Fig. 1. Schematic representation of the responses to the following survey's questions: A Has the outpatient/Day Hospital organization for the management of NSCLC patients changed? B Where NSCLC patients underwent triage (body temperature measurement, questions about epidemiological status and clinical conditions)? C Did the number of consultations in patients with suspected NSCLC diagnosis vary?. D Did the number of consultations in patients with suspected NSCLC diagnosis coming from emergency department vary?. E Did the number of patients with newly diagnosed of NSCLC vary?. F Has multi-disciplinary tumor boards for the discussion of NSCLC patients management been maintained?.

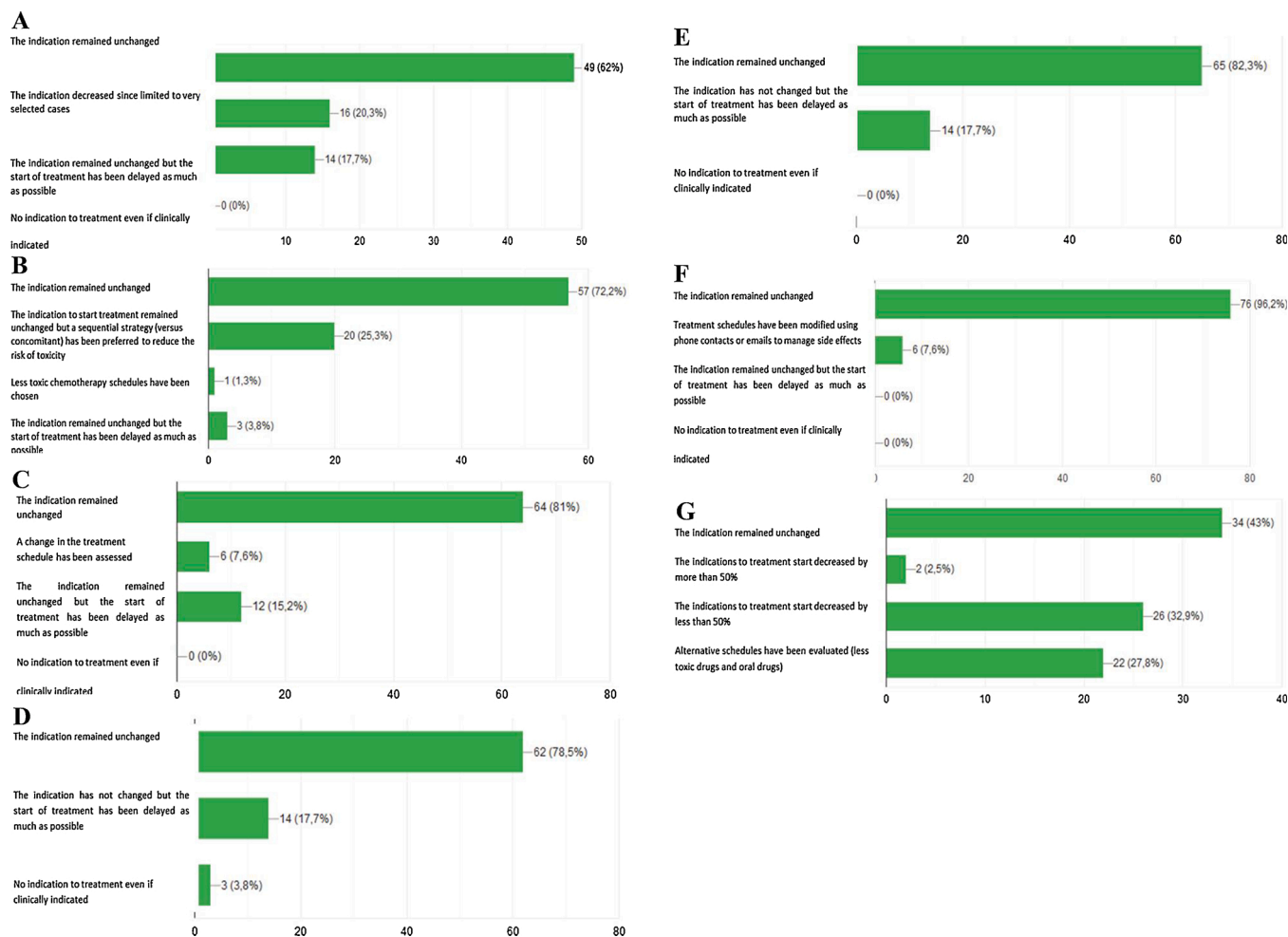


Fig. 2. Schematic representation of the responses to the following survey's questions: A Has the indication to adjuvant treatment been modified for surgically resected NSCLC patients? B Has the indication to concurrent chemo-radiotherapy been modified for NSCLC patients with unresectable locally advanced disease? C Has the indication to first-line chemotherapy been modified for patients with metastatic NSCLC? D Has the indication to first-line chemo-immunotherapy been modified for patients with metastatic NSCLC? E Has the indication to first-line single agent immunotherapy been modified for patients with metastatic NSCLC? F Has the indication to first-line targeted therapies been modified for patients with metastatic NSCLC? G Has treatment indication to first line chemotherapy or immunotherapy been modified in elderly patients (over 75 years) with non-oncogene addicted metastatic NSCLC? H Has treatment indication to maintenance therapy been modified for patients with metastatic NSCLC candidate to start/continue maintenance chemotherapy (pemetrexed). I Has treatment indication for metastatic NSCLC patients undergoing first line immunotherapy been modified? L Has treatment indication to second line chemotherapy been modified for metastatic NSCLC patients? M Has treatment indication to second line immunotherapy been modified for metastatic NSCLC patients? N Has the indication to interrupt active treatment and start best supportive care been modified in metastatic NSCLC patients? O Has follow-up management for NSCLC patients been modified? P Has NSCLC patients' accrual in ongoing clinical trials been modified?

observational period (Fig. 3B). The characteristics of COVID-19 infection management and outcomes in NSCLC patients were reported in Table 1.

4. Discussion

In general, the results of this survey highlighted as both management and treatment strategies of NSCLC patients have been profoundly modified after the COVID-19 outbreak. Particularly, the reduction of the total number of novel NSCLC diagnoses, partially ascribed to the significant decrease of patients with suspected lung cancer coming from the emergency department, certainly represents one of the most relevant aspects to be adequately addressed. A recent paper, published by Dinmohamed et al., showed also a significant decrease of cancer diagnoses in the Netherlands, when compared to the pre-COVID-19 emergency period (Dinmohamed et al., 2020). Specifically, between the 6th of January 2019 and the 12th of April 2020 the relative change in lung

cancer diagnoses was reported to be around 30–40%. This evidence has been partially explained by the lower access of individuals with non-specific cancer symptoms to their general practitioner, leading to a subsequent delay of clinical investigations. Furthermore, several hospitals primarily involved in the COVID-19 emergency, have had postponed diagnostic evaluation, while national screening programs for early diagnosis of breast, colorectal and cervical cancers have been temporarily halted. The ministerial decrees, which placed Italy under COVID-19 lockdown, forced all Regions to temporally suspend both first level examinations and screening programs, with potential relevant consequences in terms of health and social costs, which will likely emerge in the upcoming months. Despite the emergency status, the majority of Italian medical oncologists maintained their clinical indications to adjuvant treatments and to concurrent chemo-radiotherapy for NSCLC patients with resected and locally advanced disease, respectively. These data reflect the recommendations published by ESMO with three grades of priority (high, medium and low) based on the magnitude

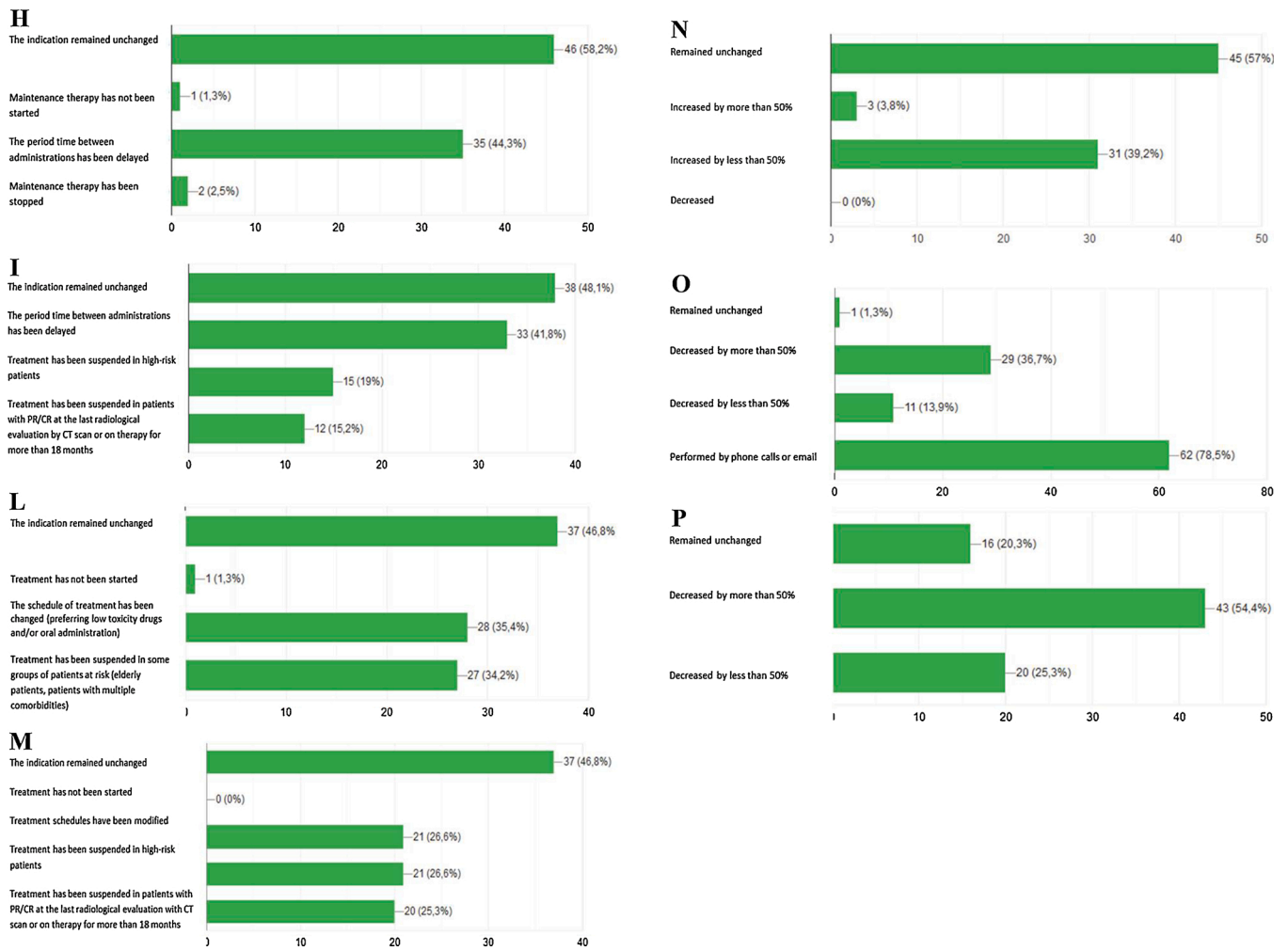


Fig. 2. (continued).

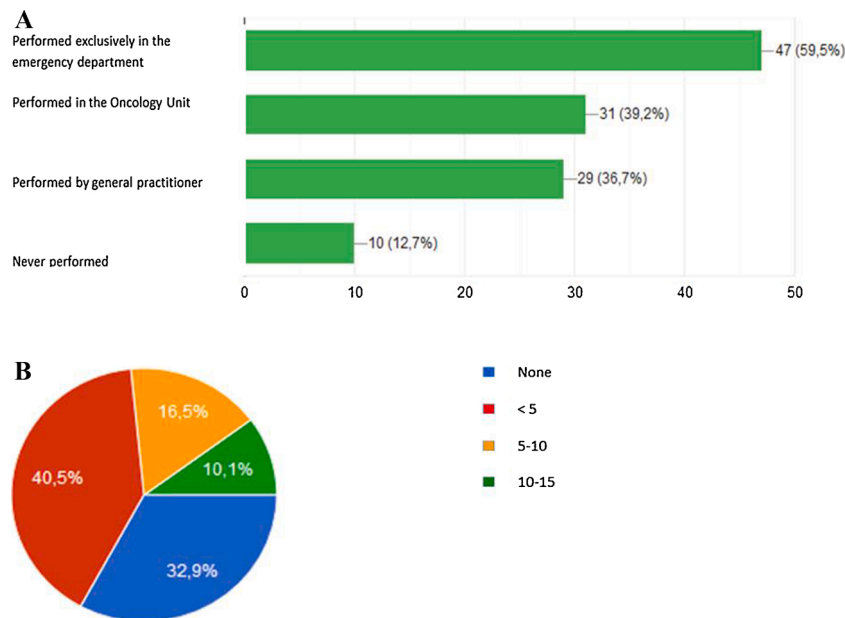


Fig. 3. Schematic representation of the responses to the following survey's questions: A In case of suspected COVID-19 infection in NSCLC patients, where the nasopharyngeal swab has been performed?. B How many NSCLC patients have been positive for COVID-19 infection in your Institution considering the period from the pandemic declaration to the following four weeks (March 11th-April 11th 2020)?.

Table 1
Characteristics of NSCLC patients with suspected/confirmed COVID-19 infection.

Characteristics	Number (%)
Mean age of patients:	
<50 years	1 (1.9 %)
50–60 years	8 (15.7 %)
60–70 years	29 (56.8 %)
>70 years	13 (25.5 %)
Patients treated with hydroxychloroquine +/-antiviral therapy:	
None	8 (15.7 %)
<20 %	12 (23.5 %)
20–50%	7 (13.7 %)
>50 %	17 (33.3 %)
All patients	7 (13.7 %)
Patients who have achieved recovery/stability:	
None	5 (10.2 %)
<20 %	7 (14.3 %)
20–50%	11 (22.4 %)
>50 %	17 (34.7 %)
All patients	9 (18.4 %)

of overall survival (OS) gain and improvement of quality of life (QoL) (Passaro et al., 2020). Particularly in the early stages, the high priority is related to the administration of adjuvant chemotherapy in T3/4 N2 for young (<65 years) and fit patients. Similarly, concomitant or sequential chemo-radiotherapy for unresectable NSCLC stage III has been prescribed without delay. For metastatic patients, there was a general consensus among the interviewed oncologists to not delay first-line therapies. ESMO guidelines also highlighted the high priority for therapeutic options in the metastatic setting to maintain survival benefit, along with cancer-related symptoms and QoL control. The final decision should be performed at single patient level, taking into account different factors, like patients' clinical conditions (age, comorbidities, symptoms), disease's pathological/molecular characteristics and treatments implications, including the number of hospital accesses required by treatment schedules, carefully balancing both predictable and unpredictable side effects. Despite the risks of toxicity associated with immune-checkpoint inhibitors were not well known during the first wave of COVID-19 emergency, a large fraction of oncologists declared to have spread the free-interval between treatment administrations both in first, and second line setting; to have suspended ongoing therapy in high-risk patients and to have definitively discontinued treatment in case of long-term clinical benefit. In this context, some preliminary evidence suggested that the frequency of severe illness and hospitalization was higher in cancer patients treated by immunotherapy, but the low number of patients included limited any definitive conclusions or changes in our current treatment practice (Robilotti et al., 2020). Moreover, a recent paper evaluated the impact of the programmed death-1 (PD-1) blockade on the severity of COVID-19 infection in NSCLC patients. The authors pointed out that PD-1 inhibition was not associated with an increased risk of severity of COVID-19 infection in patients with lung cancers (Luo et al., 2020). In the upcoming months, preclinical and clinical data will likely help oncologists to clarify the link between COVID-19 infection and possible worse outcome for NSCLC patients treated with immunotherapy. Another relevant aspect emerging from this survey regards the clinical management of elderly population, almost characterized by a significant reduction of first-line treatment prescriptions, including a therapeutic shift to alternative, less toxic schedules or oral drugs, in order to minimize their access to Oncology Departments. A multidisciplinary assessment by the Comprehensive Geriatric Assessment (CGA) emerged as an important tool during this emergency, to plan both medical and social health care for every patient (Passiglia et al., 2020). As for the follow-up visits, this survey pointed out that most of oncologists performed their clinical consultations by mails, phone call and/or web virtual meetings. This strategy has been supported by the AIOM statement, recommending a telemedicine follow-up approach in order to perform a quick triage of the clinical

condition, and allowing the examination of laboratory and/or imaging exams. Another major issue regards clinical research activities during the COVID-19 pandemic, characterized by a dramatic decrease of patients' accrual within clinical trials, with a relevant impact on the quality of care to be offered to our patients. Similarly, the management of patients already enrolled within a clinical trial may have undergone changes during this emergency time. Therefore, to face this risk, the Food and Drug Administration (FDA) (2020), the European Medicines Agency (EMA) (2020) and the Italian Medicines Agency have issued special guidance for the conduction of clinical trials during the COVID-19 emergency (Agenzia Italiana del Farmaco (AIFA), 2020).

Finally, this survey showed a small snapshot of NSCLC patients with COVID-19 infection. Most of oncologists had less than 5 patients infected by COVID-19, generally treated with hydroxychloroquine and antiviral therapy. Several evidences have showed a proportion of asymptomatic COVID-19 patients that play a critical role as source of transmission to cancer patient (Bai et al., 2020). Therefore, it is important to consider NSCLC patients as a specific population to be priority tested due to the increased risk of complications caused by older age, significant cardiovascular and respiratory comorbidities and smoking-related lung damage. In this pandemic scenario, the use of liquid biopsy might be implemented in order to reduce the risks of COVID-19 infection for NSCLC patients by limiting their access to the oncology departments (Rolfo et al., 2020) The proposed diagnostic approach might be practice changing even in the upcoming months when COVID-19 outbreak will be under control.

5. Conclusions

In conclusion, this survey provides a real-word "picture" of the clinical management of NSCLC patients in Italy during first wave of COVID-19 emergency. Although the majority of Italian thoracic oncologists have proven to follow both national and international treatment guidelines even during this difficult period, however major concerns regarded the selection of second or further lines of treatment as well as the clinical management of elderly population, characterized by a potentially unfavorable risk/benefit ratio. The most relevant issues emerging from this survey included the significant delay of lung cancer diagnosis and the dramatic decrease of patients' accrual within clinical trials, while telemedicine demonstrated to be a valid support to facilitate patient-healthcare interactions.

These data should be keep in mind in the upcoming months, characterized by the second wave of COVID-19 pandemic, in order to provide right solutions to the emerging criticisms and ultimately improve the worldwide clinical management of NSCLC patients.

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Passiglia F declared consultant's fee from MSD, Boehringer Ingelheim and AstraZeneca.

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Capelletto E declared consultant's fee from MSD, AstraZeneca, Boehringer Ingelheim.

Other co-authors have no COI to declare.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.critrevonc.2020.103189>.

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