Annals of Research in Oncology
Vol. 3(3), 119-127, 2023

RESEARCH ARTICLE

SURGICAL ONCOLOGY BEFORE AND DURING COVID-19 PANDEMIC: AN ASSESSMENT THROUGH THE DATA OF THE NATIONAL OUTCOMES EVALUATION PROGRAM - PNE

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ABSTRACT: In Italy, COVID-19 had a strong impact on health care, quite evident for urgent hospitalization but more marked for scheduled admissions. The aim of this study was to better understand the changes occurred in cancer care during the pandemic period (2020-2021) compared to the previous five years (2015-2019), in terms of differences in volumes, processes and outcomes, especially for breast cancer, for which screening is available, and lung cancer that instead does not benefit from any secondary prevention activity. The study was conducted using data from the National Outcomes Evaluation Program (PNE), which analyses the hospital discharge records provided annually by more than 1,300 public and private Italian hospitals. The findings show that in 2020 a marked reduction was observed in the number of all oncological interventions. In particular, for breast cancer surgery there was a decrease in 2020 of about 6,300 interventions (-10%) compared to 2019. With reference to the number of interventions per month of activity, the negative peak was observed in June 2020. Regarding surgical interventions for lung cancer, in 2020 there were about 1,000 interventions less than in 2019 (-8.6%). The negative peak observed in April 2020 was anticipated compared to breast cancer: in this case, there was no lagged effect on new diagnoses due to the suspension of screening programs. In 2021, there was a resumption of interventions that especially for the breast cancer led to a realignment to the pre-pandemic trend. Our analysis has allowed to appreciate the resilience of the Italian hospital system to the pandemic emergency. However, it will take years to fully assess the impact of delayed or non-performed interventions on the worsening of clinical conditions, especially for the oncological diseases, as well as on the mortality indirectly attributable to COVID-19.

Doi: 10.48286/aro.2023.75

Impact statement: This manuscript stems from the need to evaluate the impact of Covid-19 on the Italian Hospital System. In particular, we analyzed the dynamics that characterized cancer care during the pandemic and the subsequent resumption of activities.

Key words: *surgical oncology; COVID-19; outcome research; hospital data.*

Received: June 6, 2023/**Accepted**: Sept 11, 2023
Published: Sept 30, 2023

INTRODUCTION

The Italian National Agency for Regional Healthcare Services (AGENAS), on behalf of the Italian Ministry of Health and in collaboration with the Department of Epidemiology of the Lazio Region and the Italian National Institute of Health has been coordinating since 2012 a program called '*National Outcomes Evaluation Program*' (acronym in Italian: PNE) (1, 2). The PNE represents a permanent observatory on the performance and quality of healthcare services. This is carried out through comparative analysis of processes and outcomes of the Italian public and private hospitals, in the context of National Health Service (NHS), ensuring data with high territorial coverage, temporal continuity and systematicity. The PNE also produces epidemiological evidence, for example about the correlation between hospital volumes and health outcomes (3, 4) and detects critical aspects which may be managed through specific interventions (*e.g.*, clinical audit programs)

aimed at improving the overall quality of care.
In the last years, the PNE has been greatly strengthened in relation to its ability to read the dynamics of care, and this has allowed the impact of the pandemic on health service activity to be analyzed in more depth.
Currently, the PNE covers several nosological areas, including oncology. As regards the latter, the Program's evaluations have traditionally focused on some relevant aspects, such as the volume of activities, which is for high-complexity services a kind of prerequisite to good processes and outcomes; appropriateness and safety, with particular reference to endoscopic surgery in relation to open surgery, and the length of post-operative stay; and finally, results in terms of 30-day mortality, readmissions or reinterventions, after adjustment for clinical severity of the patient on admission (2). The aim of this study, using the PNE as a key tool of analyses, was to better understand the changes occurred in cancer care during the pandemic period in Italy, in terms of differences in volume, processes and outcomes compared to the pre-pandemic period and to describe the dynamics generated by COVID-19 in hospital care.

DATA AND METHODS

The PNE analyses data from 1,377 public and private Italian hospitals and currently calculates 194 indicators, of which 171 relating to hospital care (73 processes/outcomes, 83 volumes, 15 hospitalizations), and 23 relating to territorial care, indirectly measured by intercepting those hospital admissions that would be potentially "avoidable" if there were adequate primary care at the territorial healthcare level (this is the so-called avoidable hospitalization) (5).

Each indicator was calculated using the Hospital Discharge Records (acronym in Italian: SDO) and the National Tax Registry (NTR), according to a detailed operative protocol based on standard outline, available on the PNE institutional website (1, 5). SDOs are routinely collected by the Hospital Information System (HIS) and contain patient demographic information (gender, age), admission and discharge dates, up to 5 discharge diagnoses (International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM)), medical procedures or surgical interventions (up to 6), and status at discharge (alive, dead, transferred to another hospital). In addition, the NTR was used to collect information regarding vital status and out-of-hospital deaths. HIS records were linked with NTR records using deterministic record-linkage. To assess the impact of COVID-19 on health care, the decrease in hospitalizations in 2020-21 potentially attributable to the pandemic was also calculated as the difference between the observed and the expected volumes based on the linear trend of the previous 5 years (2015-2019).

RESULTS AND DISCUSSION

COVID-19 has had a strong impact on hospital care, quantifiable in 1.7 million fewer hospitalizations in 2020 than in the previous year (**Table 1**). This reduction was quite evident for urgent admissions (-13%), but more marked for scheduled admissions (decreased by about a quarter). In 2021, there was a resumption of hospital activity, with 500,000 more admissions than in 2020 (mostly scheduled hospitalizations). However, a reduction of 14% compared to 2019 persists (corresponding to about 1.2 million fewer hospitalizations). Considering the 2020-2021 biennium, the number of missing admissions compared to pre-pandemic levels (2019) amounts

Table 1. *Number of hospitalizations before and during the pandemic, by type of hospital admission. Italy, 2019-2021.*

HOSPITALISATIONS	2019	2020			2021		
	NO.	NO.	DIFF. 2020-2019	VAR % 2020-2019	NO.	DIFF. 2021-2019	VAR % 2021-2019
Urgent admissions	3,413,212	2,957,014	-456,198	-13.4	2,963,276	-449,936	-13.2
Scheduled admissions	2,957,347	2,218,385	-738,962	-25.0	2,483,653	-473,694	-16.0
Day-hospital	1,785,088	1,280,268	-504,820	-28.3	1,505,682	-279,406	-15.7
Overall *	8,537,077	6,817,109	-1,719,968	-20.1	7,318,867	-1,218,210	-14.3

** The overall number of hospitalisations includes missing values for the variable 'type of hospital admission'.*

Table 2. *Changes in surgical oncology before and during the pandemic. Italy, 2015-2021.*

CANCER	PRE-PANDEMIC PERIOD		PANDEMIC PERIOD			
	NO. 2019	VAR % PER YEAR (2015-2019)	NO. 2020	NO. 2021	VAR % 2020-2019	VAR % 2021-2019
Breast	62,343	+0.7	56,057	62,764	-10.1	+0.7
Colon	26,233	-0.5	23,078	24,796	-12.0	-5.5
Prostate	20,688	+2.4	17,115	18,645	-17.3	-9.9
Uterus	12,349	+0.9	11,643	12,103	-5.7	-2.0
Lung	12,116	+3.0	11,078	11,532	-8.6	-4.8
Kidney	11,907	+2.4	10,665	11,676	-10.4	-1.9
Thyroid	10,237	-0.9	9,014	10,346	-11.9	+1.1
Liver	6,610	+0.6	6,195	5,961	-6.3	-9.8
Rectum	6,051	-3.7	5,627	5,615	-7.0	-7.2
Stomach	5,824	-3.5	5,088	5,075	-12.6	-12.9
Bladder	5,211	-0.5	5,241	5,101	+0.6	-2.1
Pancreas	2,710	+1.2	2,778	2,766	+2.5	+2.1

to almost 3 million hospitalizations.

About all kinds of cancer, in 2020 there was a reduction in oncological surgery of 11% compared to 2019 (about 29 thousand fewer interventions). In 2021, a resumption was observed, with 29 thousand more interventions than in 2020, although a slight reduction of 4% persists compared to 2019 (about 14 thousand fewer surgical hospitalizations). Considering the two-year period 2020-2021, the missing interventions compared to pre-pandemic levels (2019) amounts to 58 thousand. **Table 2** shows for the main malignancies monitored by the PNE the trend observed in surgical interventions during the pre-pandemic period (2015-2019) and the subsequent reduction occurred after the pandemic emergency (2020 and 2021). In the pre-pandemic period (2015-2019), some malignancies showed an increasing annual trend in the number of interventions: in particular, lung (+3.0% per year), prostate (+2.4%) and kidney (+2.4%). On the other hand, in the same period a reduction in trend was observed in rectal (-3.7% per year) and stomach cancer (-3.5%). During the pandemic emergency, in 2020 a marked reduction was observed in the number of all oncological interventions, apart from bladder and pancreas cancers (**Table 2**). In 2021, there is a total recovery of breast and thyroid surgeries, whereas the negative trend continues for the stomach, prostate, rectum, and liver. In the following paragraphs, we analyze in detail some dynamics highlighted for two cancers among those with the greatest burden of care: breast cancer, for which screening is available, and lung cancer that instead does not benefit from any secondary prevention activity.

Breast cancer

Regarding breast cancer surgery, a slight increase in hospitalizations (+0.7 per years) was observed in the pre-COVID period (**Table 2**), with a fall in 2020 of around 6,300 interventions (-10.1%) compared to 2019. The largest decrease was in the Northern Italy (-14%), where the impact of the pandemic was greatest at least during the first lockdown (in March-May 2020), while it was less marked in the Centre (-4.8%) and in the South and Islands (-6.3%). Considering the pre-pandemic trend (**Figure 1**), in 2020 the observed number of interventions was 11% less than the expected. Although in 2021 there was a realignment with the pre-pandemic trend, the overall shortfall for 2020-2021 amounts to -7,845 interventions.

A particularly interesting aspect concerns the distribution of interventions by month of activity: there was a downturn following the first wave of COVID-19, with a negative peak in June 2020, while for the other cancers the peak occurred in April 2020 (**Figure 2**). This delay is largely attributable to the fact that interventions already scheduled were guaranteed, while new diagnoses were affected by the suspension of the screening programs. In fact, data on screening carried out in Italy during 2020 confirm a marked reduction in activities (on average -40% in the first half of 2020, compared

to the same period of 2019) (6), without however a direct correlation with the infection attack rate: a sign that this reduction was not only due to the overload directly attributable to COVID-19 (as the Local Health Units' prevention departments were engaged in contact tracing activities), but also to the generalized blocking of activities determined by the lockdown. In 2021, there was an important recovery of the gap created in 2020, with an increase of 6,700 interventions compared to the previous year, and a realignment to 2019 levels. However, a different distribution of interventions by month of activity was observed for other cancers for which screening is available in Italy, for example the colorectal cancer. In this case, the negative peak occurred in April, and not in June, probably due to lower colorectal cancer screening coverage, compared to breast cancer (7). Another important aspect of healthcare assessment concerns the concentration of interventions in high-volume hospitals. Since its enactment on 2 April 2015, the Decree of the Ministry of Health No.70 has provided a key framework for the reorganization of services to enhance the quality and safety of care (8). The Decree has introduced minimum volume thresholds for a series of nosological areas and diagnostic-therapeutic procedures.

Regarding breast cancer, it identifies a threshold of 150 interventions for breast cancer per ward every year, consistently with international literature on quality standards for Breast Units (9-12). In 2021, the number of hospital units with a volume equal to or higher than the threshold was 142 (**Figure 3**); it was 120 in 2020 and 136 in 2019. The corresponding proportion of cases treated in units above the threshold was 74% of the nationwide interventions, up from 67% in 2020 and 69% in 2019. There was, however, a considerable number of hospitals with volumes less than 50 interventions per year that merit further investigation as part of audit activities.

Lung cancer

In the pre-pandemic period, there was an increase (+3% per year) in the number of surgical interventions for lung cancer (**Table 2**). On the contrary, in 2020 there was a reduction of 8.6%, corresponding to about 1,000 interventions less than in 2019. Considering the growing pre-pandemic trend (**Figure 4**), the observed number of interventions was 11% less than the expected. In 2021 there was a slight resumption (+450 interventions compared to the previous year), with a deviation of -10% from the pre-pandemic trend (corresponding to 1,300 fewer hospitalizations). In the period 2020-2021, the overall reduction in interventions compared to the number predicted by the trend is estimated to be around 2,700 hospitalizations. Such reduction could be partly attributable to higher mortality due to COVID-19 among patients affected by pre-existing lung diseases, which may have decreased the number of persons with a lung cancer diagnosis

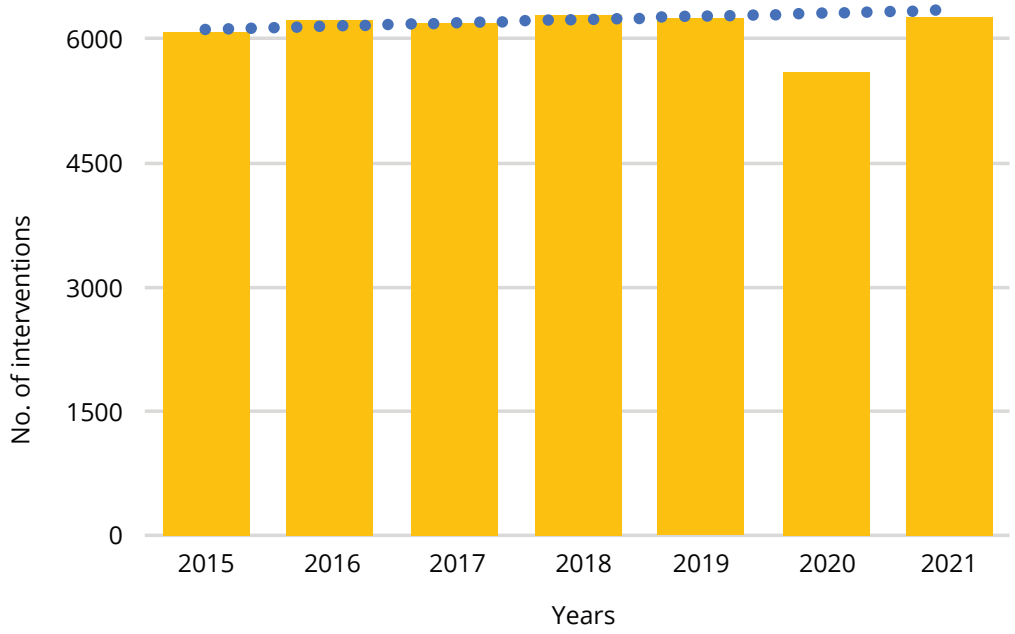

Figure 1. *Number of interventions for breast cancer. Italy, 2015-2021.*

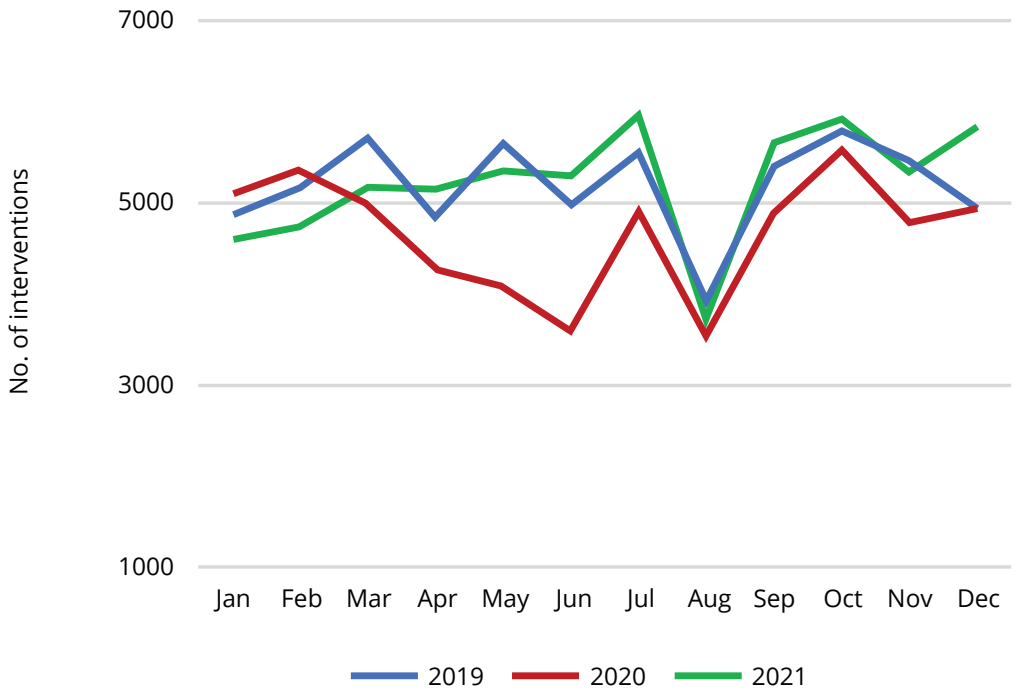

Figure 2. *Distribution of interventions for breast cancer per month. Italy, 2019-2021.*

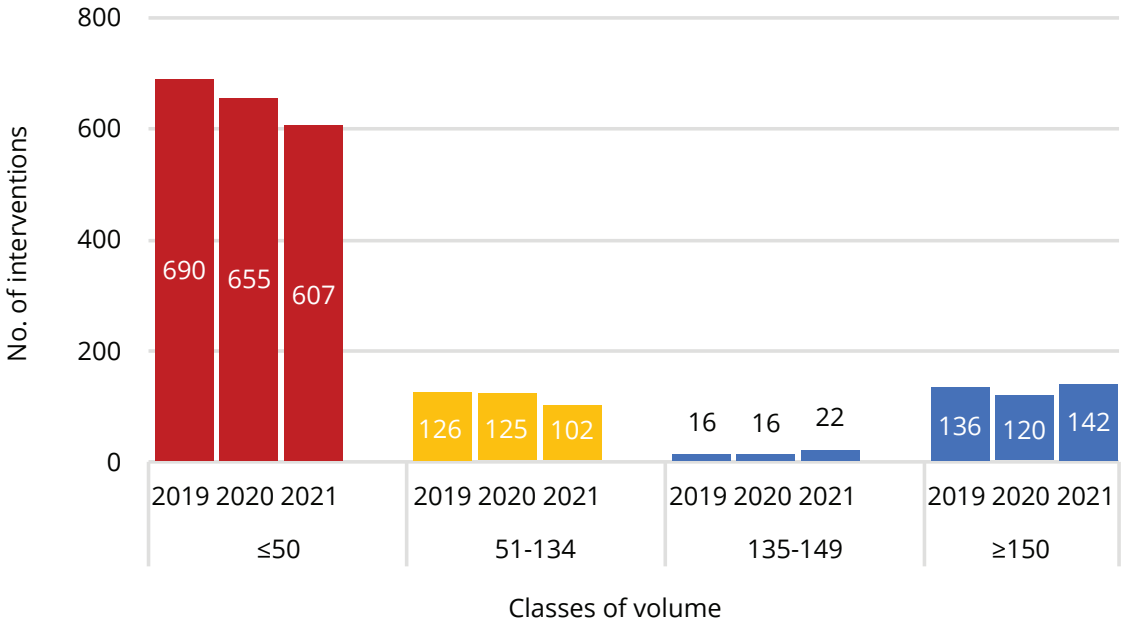

Figure 3. *Distribution of hospital units for treatment of breast cancer, by class of volume. Italy, 2019-2021.*

to undergo surgery. For other late-onset malignancies, such as pancreatic cancer, this effect may have been less evident, and this would explain the lack of reduction in the number of interventions (**Table 2**). With reference to the distribution of interventions for lung cancer per month (**Figure 5**), the negative peak observed in April 2020 was anticipated compared to breast carcer (in this case, there was no lagged effect on new diagnoses due to the suspension of screening programs). In 2021, the resumption in interventions was only partial compared to 2019. Concerning the concentration of interventions, the Decree of the Ministry of Health No.70/2015 does not indicate a minimum volume threshold for lung cancer, however several studies suggest a breakpoint in the correlation between volumes of activity and outcomes of hospital care within the range of 50-100 interventions per year

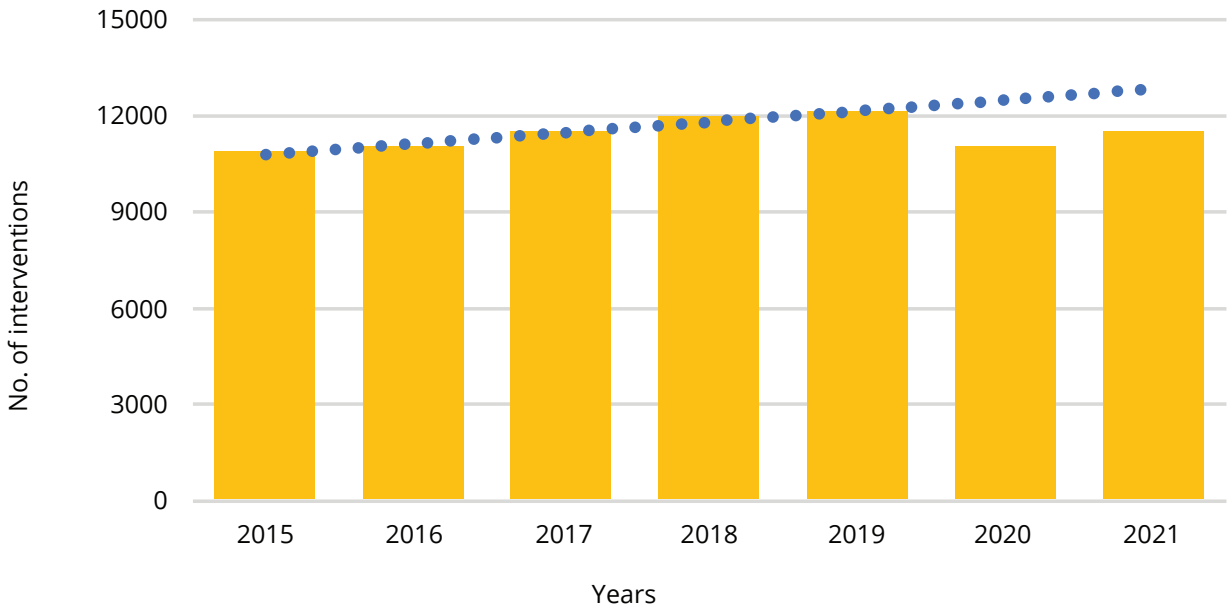

Figure 4. *Number of interventions for lung cancer. Italy, 2015-2021.*

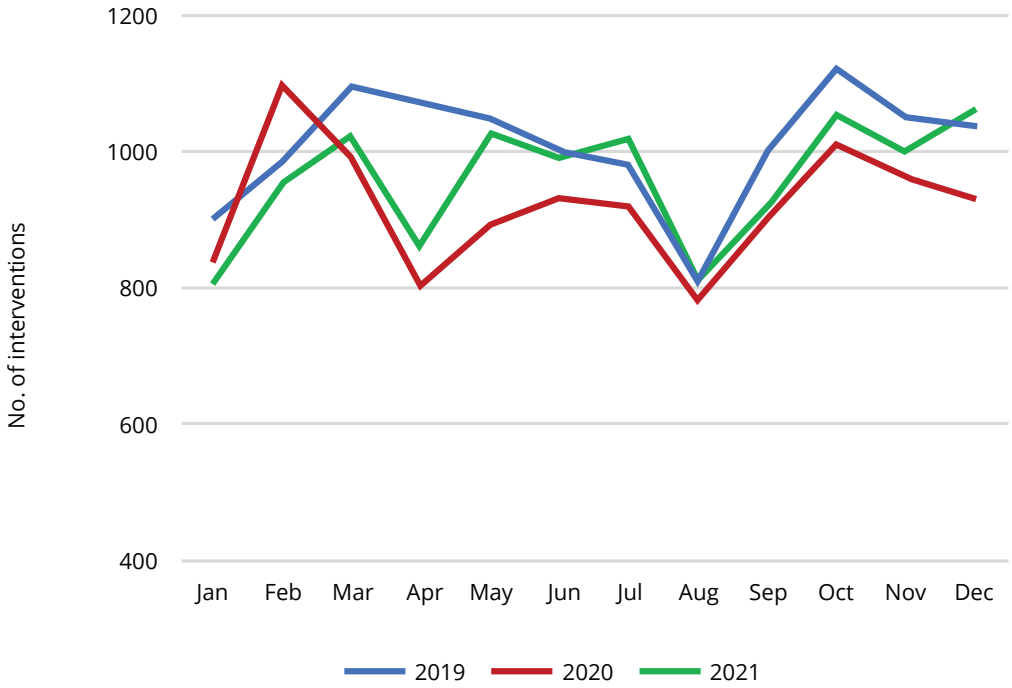

Figure 5. *Distribution of interventions for lung cancer per month. Italy, 2019-2021.*

(3, 4). Compared to these values, in 2021 only 35 hospitals out of 171 were above 100 intervention per year. The corresponding proportion of cases treated in these structures was 64% of the overall interventions in Italy; it reaches 90% when considering hospitals with 50 or more interventions per year (**Figure 6**).

CONCLUSIONS

Our findings suggest that the hospital system has shown a certain degree of resilience with regard to urgency, while on the side of scheduled admissions, the challenge will be to recover the planned and not carried out interventions. On the other hand, it will take years to fully assess the

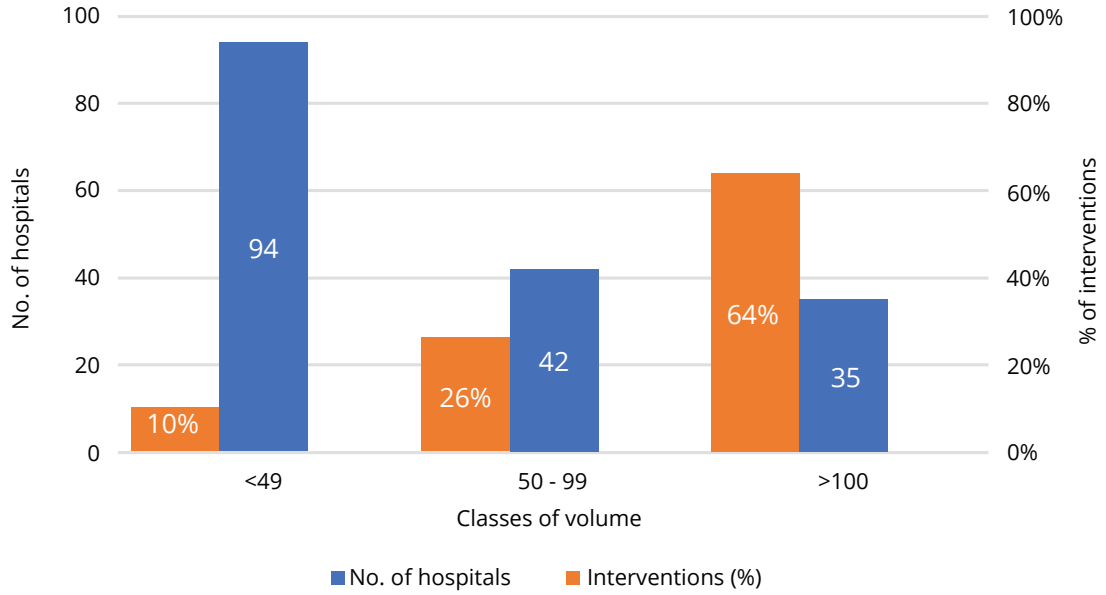

Figure 6. *Distribution of hospitals for treatment of lung cancer, by class of volume. Italy, 2021.*

impact of delayed or non-performed interventions on the worsening of clinical conditions, especially for the oncological diseases, as well as on the mortality indirectly attributable to COVID-19 (13, 14). Regarding the limitations of the study, our analysis was based on the SDOs, that were actually born for other purposes (administrative data). However, the results are quite in line with other studies carried out in Italy on breast cancer, which demonstrated (using data from Cancer Registries) a complete recovery of diagnoses and no shift towards more advanced tumors but also a drop in interventions in 2020 by 15% compared to 2019 (15). Even for other malignancies, including lung, a decline in surgical interventions has been demonstrated (16). About the development of PNE, especially in assessing oncological care, in the next future the analyses will be increasingly conducted at the level of single surgeon, using the new variables introduced in the SDO by the Decree of the Ministry of Health No. 261 of 7 December 2016. This will allow to estimate the impact of surgeon expertise, and not only of volumes per structure, on healthcare performance (17). Regarding outcome assessment, the availability of new information on cancer staging will allow more accurate analyses, thanks to a better control of confounding by clinical severity of patients at the moment of their admission to hospital. Finally, PNE is constantly engaged in research and develop of new indicators on outpatient and primary care services. The management of patients, especially those suffering from oncological diseases, entails a "global" care of the person, which involves not only the hospital but also secondary and primary care, through pathways that typically cross different settings of care and disciplinary areas. It is therefore necessary to integrate SDOs with other healthcare information, to measure important aspects such as the adherence to treatments and the overall quality of care. This becomes even more urgent in the perspective of the Recovery Plan (acronym in Italian: PNRR), which is introducing new organizational models whose impact deserves to be carefully evaluated and monitored over time.

ACKNOWLEDGEMENTS

The Authors thank Sara Incorvati (AGENAS) for the Italian-to-English translation.

COMPLIANCE WITH ETHICAL STANDARDS

Fundings

There were no institutional or private fundings for this article.

Conflict of interests

The Authors have declared no conflict of interests.

Authors' contributions

EE, BG and GB: writing; MC, GD, and EG: writing-review and references; GB: conceptualization. All Authors have read and agreed to the published version of the manuscript.

Availability of data and materials

The data presented in this study are available on request from AGENAS, by contacting direzione.ricerca@agenas.it.

Ethical approval

Human studies and subjects

N/A.

Animal studies

N/A.

Publication ethics

Plagiarism

The contents of the article are original and any overlaps with other articles are by the Authors themselves and appropriately cited.

Data falsification and fabrication

All the data correspond to the real.

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