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- 3 Nationwide Study

- 5 Italian title: Impatto della pandemia COVID-19 sulle Unità Operative di
- 6 Otorinolaringoiatria in Italia: uno studio nazionale.

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- 8 Running title: Geographic distribution and changes in the workload
- 9 management

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Abstract (English)

Objective. The aim of this study was to provide an accurate picture of the changes which have occurred during the COVID-19 pandemic, and the contributions given by Italian Otolaryngology Units.

Methods. A 29-item questionnaire was completed and returned by 154 Otorhinolaryngology Units across Italy. This investigated their geographic distribution involvement, the main changes which occurred in workload management and in clinical and surgical activities, and the screening procedures for COVID-19 in healthcare personnel and patients.

Results. Nearly half of the Otolaryngology Units that responded to the questionnaire were merged with other units, while 22% were converted into COVID-19 units or temporarily closed. A reduction of 8.55% in the number of team members was reported, and about 50% of the units applied uniform work shifts for all staff. Elective activities were uniformly stopped or delayed, passing from 30,295 (pre-COVID data) to 5,684 (COVID data) weekly procedures, with a mean decrease of 81.24% (p<0.001).

Conclusions. Most of the elective otolaryngology activities were suspended during the pandemic; the only procedures were for oncology and emergency patients. Italian Otolaryngologists have demonstrated a high availability to collaborate with non-surgery colleagues.

Keywords

COVID-19; Otolaryngology; SARS-CoV-2; Pandemic;

Riassunto in Italiano (for Italian authors only)

Obiettivo. Fornire un quadro accurato dei cambiamenti che si sono verificati e dei contributi forniti dalle Unità di Otorinolaringoiatria italiane durante la pandemia COVID-19.

Metodi. Un questionario di 29 domande è stato completato da 154 unità. Sono stati investigati la distribuzione geografica del loro coinvolgimento, i cambiamenti di gestione del carico di lavoro e delle attività clinico-chirurgiche e le procedure di screening applicate su personale sanitario e pazienti.

Risultati. Quasi la metà delle Unità che hanno risposto sono state fuse con altre unità operative, mentre il 22% è stato convertito in unità COVID-19 o

temporaneamente chiuso. È stata segnalata una riduzione dell'8.55% nel numero dei membri del gruppo di lavoro e circa il 50% dei dipartimenti ha applicato turni di lavoro per tutto il personale. Tutte le attività elettive sono state uniformemente interrotte o ritardate, passando da 30,295 (dati pre-COVID) a 5,684 (dati COVID) procedure settimanali, con una diminuzione media dell'81.24% (p <0.001).

Conclusioni. La maggior parte delle attività elettive in otorinolaringoiatria, a parte le procedure oncologiche e di emergenza, sono state sospese. Gli otorinolaringoiatri italiani hanno dimostrato un'alta disponibilità a collaborare con i reparti di medicina.

Parole chiave

COVID-19; Otolaringoiatria; SARS-CoV-2; Pandemia;

Introduction

The ongoing pandemic of Severe Acute Respiratory Syndrome CoronaVirus-2 (SARS-CoV-2) disease, also known as COVID-19, has spread rapidly worldwide since the first cases in Wuhan, China¹. The first cases in Italy were diagnosed in Rome on January 29, 2020, when two Chinese tourists tested positive for the virus and were hospitalized and isolated at the Spallanzani Hospital. On January 31st, the Italian government declared national emergency.

Since the first case of an Italian patient affected by COVID-19 in the town of Lodi, Lombardy, the number of patients and related deaths in Italy have progressively increased². In fact, despite attempts to limit the outbreak at the primary cluster of infections by quarantining citizens and isolating the area, similar cases were progressively diagnosed in other cities and neighboring regions, such as Veneto and Emilia-Romagna, without evidence of any epidemiologic correlation to the first case. Since then, the COVID-19 infection has spread across the country despite the containment measures applied by the Italian government, thus making Italy one of the worst hit countries with more than 214,457 confirmed cases and 29,684 deaths reported up to May 7, 2020³. On March 11, 2020, the Director-General of the World Health Organization (WHO) declared COVID-19 a pandemic⁴.

In the last 2 months, the Italian National Healthcare System has undergone multiple changes to face the pandemic, with closure or conversion of many units and hospitals into units solely dedicated to the treatment of COVID-19 positive patients⁵. Most elective outpatient clinical and surgical procedures have been delayed or suspended, allowing the confluence of most of the resources towards Emergency Departments, Infectious Diseases Units, Respiratory Disease Units, and Intensive Care Units (ICUs)^{6,7}.

In this setting, although Otolaryngology-Head and Neck surgeons were not in the frontline of action, they were asked to contribute to managing patients with upper airway impairment, provide basic assistance, perform screening procedures (i.e. upper airway swab) and perform temporary tracheotomies in ICUs. This new arrangement implied a significant change in otolaryngology activities across the country⁸.

The aim of this nationwide study, in accordance with the Italian Society of Otolaryngology Head and Neck Surgery (SIOeChCF), was to provide a picture of the changes and contributions of otolaryngologist specialists during the COVID-19 pandemic over the last 2 months through a questionnaire administered to Italian

171	Otolaryngology Units.
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173	Materials and methods
174	This study was performed by the COVID-19 Task Force of the Italian Young
175	Otorhinolaryngologists (GOS). On April 16, 2020, a 29-item questionnaire was sent
176	by e-mail to all Otolaryngology Units in Italy (n = 296); each unit was asked to
177	respond within 4 days and the final compilation deadline was set as April 22, 2020.
178	Data were subsequently collected and compiled anonymously in a unified dataset.
179	Duplicates, when present, were removed.
180	The questionnaire investigated three major aspects of Italian Otolaryngology
181	Units during the pandemic:
182	1. the geographic distribution of respondent units;
183	2. the main changes in workload management and distribution in terms of
184	outpatient and inpatient procedure volume;
185	3. COVID-19 screening procedures for patients and healthcare workers.
186	According to the Italian Instituto Superiore di Sanità (ISS) data ⁹ , Italian regions were
187	divided into five zones based on the total number of cases as follows: 1) >20,000
188	(Lombardia, Emilia-Romagna); 2) 10,000-20,000 (Piemonte, Veneto); 3) 3000-
189	10,000 (Toscana, Marche, Lazio, Provincia Autonoma di Trento, Campania, Puglia,
190	Liguria); 4) 1000-3000 (Abruzzo, Friuli Venezia Giulia, Umbria, Provincia
191	Autonoma di Bolzano, Sicilia, Valle D'Aosta, Sardegna); 5) <1000 (Molise, Calabria,
192	Basilicata).
193	
194	Statistical Analysis
195	Descriptive analysis was used to define the main clinical and demographic
196	characteristics based on the responses to the questionnaire. Unpaired T test was used
197	to evaluate differences for numeric values. A p-value less than 0.05 was considered
198	the cutoff for statistical significance. Prism Software version 8.3.1 (GraphPad
199	Software LLC) was used to perform statistical analysis.
200	

Results

One-hundred fifty-four Otolaryngology Units (52%) completed the questionnaire; 134 (87%) units were public and 20 (13%) were private and/or affiliated health facilities.

1. Geographic distribution of respondent Italian Otolaryngology Units

Lombardy represented the region with the highest number of Otolaryngology Units that replied to the questionnaire, while the lowest response rates were registered in Trentino Alto Adige, Valle d'Aosta, and Molise. Figure 1 reports the geographic distribution of respondent units. Figure 2 shows the division of zones and the number of responses received from each zone. Thirty-eight responses were received from units in zone 1, 27 from units in zone 2, 60 from zone 3, 21 from zone 4, and 8 from units in zone 5.

Based on the responses received, the majority of units (45.5%) were merged with other units, and 10.4% were temporarily closed. Interestingly, no changes were reported by 10.4% of the units while 11.6% were converted into COVID-19 wards. A significant reduction in hospital beds has been reported by the remaining percentage of units (22.1%). Table I summarizes the activity changes sorted by zone.

A reduction in the number of team members was reported, and its percentage change during the pandemic was compared to the pre-COVID-19 setting. A decrease of 6.07% was recorded in the total number of otolaryngology specialists belonging to the 154 units, which declared a pre-COVID staff number of 1,136 specialists which was reduced to 1,067 during the state of emergency. The difference was not statistically significant (p = 0.364). In addition, the number of residents on duty was reduced from 465 to 397 (percentage reduction: 14.6%; p = 0.054). The reduction in each unit was proportional to work shift changes applied by each zone (Table II).

Interestingly, nearly 70% (107/154) of the respondents declared a reallocation of staff members to Internal Medicine COVID-19 Units (52/107 - 48.6%), emergency departments (20/107 - 18.7%), ICUs (9/107 - 8.4%), respiratory disease units (7/107 - 6.5%), other services (7/107 - 6.5%), Internal Medicine non-COVID-19 Units (5/107 - 4.7%), infectious disease wards (5/107 - 4.7%), and basic assistance services (2/107 - 1.9%) (Figure 3).

The highest percentage of reallocated colleagues was present in zone 1 (46.7%), and these showed a progressive reduction passing from 20.5% in zone 2 and 23.4% in zone 3, to less than 10% in zones 4 and 5 (6.5% and 2.9%, respectively).

In this setting, 48% and 50% of reallocation changes to Internal Medicine COVID-19 Units and Emergency Departments, respectively, occurred in zone 1,

while units in zone 2 reported the majority of reallocations to Internal Medicine non-COVID-19 Units (Table III).

2. Main changes in workload management and distribution in terms of outpatient and inpatient procedure volumes

Questionnaire results showed a significant decrease in otolaryngology activities across the country during the pandemic with no substantial differences among the five identified zones. Outpatient visits showed a significant decrease in number of procedures per week (80.54%; p < 0.0001), passing from a pool of 26,035 evaluations usually performed during the pre-COVID-19 period to 5,067 registered outpatient procedures during the COVID-19 pandemic. A similar reduction (89.91%; p < 0.0001) was recorded for outpatient surgical procedures (i.e. surgical procedures under local anesthesia) and for inpatient surgical procedures that decreased from 2,823/week to 472/week, a reduction of 83.28% (p < 0.0001). A detailed summary of procedures performed per week in each zone and the corresponding percentage reduction is shown in Figure 4 and described by Table IV.

Among the different types of surgery, only a small percentage of respondent units declared a reduction in their head and neck and emergency surgical procedures (10.74% and 3.54%, respectively). On the other hand, the vast majority declared a drastic reduction in endoscopic sinonasal procedures (98.53%), pediatric otolaryngology surgery (97.59%), and ear surgery (94.90%). All elective surgical procedures (100%) were suspended uniformly across the country (Table V).

In this setting, upper airway management and tracheostomy procedures were performed by 42.86% of the units, while the remaining 57.14% declared that they were not involved in airway management procedures for COVID-19 patients. The vast majority of the units (70.94%) declared that the percutaneous tracheostomy technique was predominant over the surgical one in their hospitals. When asked about the timing of tracheostomy procedures, the majority of Otolaryngology Units performed this after more than 14 days of endotracheal intubation (38.5%), followed by 11–14 days (27.7%), 7–10 days (26.1%), and 3–6 days (7.7%) (Figure 5).

3. *COVID-19* screening procedures for patients and healthcare workers

In total, 35.71% of the respondent units declared that a HUB hospital was identified in their region to treat non-COVID-19 patients. In detail, 68.42% of HUBs

were located in zone 1, while zones 2, 3 and 4 declared significantly smaller percentages in their regions (22.22%, 33.33% and 4.76%, respectively). Interestingly, zone 5 recorded the highest percentage of HUBs (75%) although this data may be biased by the low number of respondents from this zone.

The majority of the units (72.73%) declared that COVID-19 screening procedures were performed for both patients and healthcare workers, and all of the departments performed screening procedures for inpatients scheduled for surgery.

About 20% of the otolaryngology specialists in the respondent units tested positive at COVID-19 screening tests; the highest percentages of cases were recorded in zones 1 and 2 (34.21% and 29.63%, respectively).

Discussion

Since the outbreak of the COVID-19 pandemic, the Italian National Healthcare System has abruptly reduced elective services to redirect resources to the units most affected by the pandemic. This has translated into a significant reorganization of the system which required immediate efforts by all workers throughout the country.

The results of this study confirm that clinical and surgical activities have radically changed in Otolaryngology Units across the country. According to the responses to our questionnaire, more than one-fifth (22%) of the units were converted or temporary closed, with a progressive and significant reduction according to the zone passing from 39.5% in zone 1, to 18.5% in zone 2, 15% in zone 3, 14% in zone 4 and 25% in zone 5.

The consequent marked reduction in outpatient and surgical services per week (81.24%) confirms that a significant response to the crisis was provided by Otolaryngology Units; however, this also meant a reduction of nearly 80,000 outpatient visits and almost 10,000 surgical procedures per month. This might have dangerous consequences for the health status of the population and a difficult-to-manage workload in the near future ^{10,11}.

The activities that were guaranteed during the pandemic were oncology and emergency procedures. In this scenario, it would be fair to assume an increase in overall numbers of these procedures. Nonetheless, results revealed that even these procedures decreased by nearly 10% across the country. The reduction of emergency

procedures may be explained by the total lockdown that kept the majority of people at home thus reducing risk factors for otolaryngology emergencies (abscess, bleeding, nasal bone fractures, laryngeal edema). On the other hand, head and neck cancer cannot be influenced by the lockdown, and some recent articles suggest continuing treating cancer as before but including some safety measures for healthcare workers and patients¹²⁻¹⁴. The reduction observed may be due to the reduced number of beds and personnel in Otolaryngology Units, and might result in more advanced-stage oncology cases in the near future.

Despite the five zones identified according to the total number of COVID-19 cases, a homogenous distribution of changes was recorded with a superimposable percentage reduction in staff members. On the other hand, specialist reallocations to other units were mainly recorded in zone 1, demonstrating the greater reorganization made in the Lombardy and Emilia-Romagna regions¹⁵.

COVID-19 cases are not distributed homogenously in Italy, therefore a different rate of activity change was expected in Otolaryngology Units across the country. Instead, we did not notice relevant differences in reductions of both outpatient evaluations and surgical cases among units in different regions. This shows a great sense of responsibility by the Italian National Healthcare System, which stopped elective activities even in less affected areas.

Tracheostomy is a common procedure for patients admitted to ICUs with acute respiratory distress and with difficult weaning. During the pandemic, many countries published their own guidelines, including the Italian Society of Otolaryngology and Head & Neck Surgery (SIOeChCF)¹⁶. Nonetheless, guidelines about timing and technical procedures for tracheostomy are still lacking. Indications and experiences have been published so far by Italian groups^{17,18}, but many questions remain about which technique should be preferred (surgical or percutaneous) and the correct timing to perform tracheostomies in COVID-19 patients. Experiences gained from previous severe acute respiratory syndrome coronaviruses (SARS-CoV and MERS-CoV) and from SARS-CoV-2 demonstrated that nurses and physicians who deal with infected patients are at high risk of infection; among physicians, otolaryngologists have been identified as having the highest risk of contracting COVID-19¹⁹. Tracheostomy has been demonstrated not to change the course of the disease and is among the most dangerous procedures for surgeons. For these reasons, many authors suggest performing tracheostomy after a longer intubation time. So far,

the surgical technique seems to be safer compared with the percutaneous approach since airway opening is short and controlled with the cuffed tube placed caudally to the trachea opening. Some modifications to the well-known percutaneous techniques have been proposed to minimize the risk related to COVID-19 infection²⁰. These uncertainties are reflected in Figure 5, where differences in terms of technique and post-intubation day are revealed. Another consideration is related to the high volume of patients admitted to ICUs in some hospitals during the first month of pandemic spread; in this setting, an elevated number of tracheostomies was motivated by the necessity for rapid weaning and transfer of patients to sub-intensive care units.

This Italian nationwide study showed that otolaryngologists have a high risk of contracting SARS-CoV-2. According to our data, more than 20% of Otolaryngology Units have had physicians with positive nasal swabs; this percentage was as high as 34% in the more severely affected regions and some Italian otolaryngologists have died.

Conclusions

Since the outbreak of COVID-19 in Lombardy and the following WHO declaration of a global pandemic, the Italian National Healthcare System has struggled to cope with the unpredictable load of affected patients. Otolaryngology Units have been involved in treating patients who need tracheostomy and guaranteeing diagnosis and treatment for oncology and emergency patients. This nationwide study showed how prominently phase 1 of the pandemic changed the organization and activity of Otolaryngology Units across the country. Italy is now starting phase 2 with many questions on the strategies to adopt in the near future to treat patients and protect healthcare personnel²¹.

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Conflict of Interest

All authors participated sufficiently in the intellectual content, analysis of data and writing of the article, as defined by the criteria for authorship by the International Committee of Medical Journal Editors (http://www.icmje.org/). The corresponding author certifies that the definitive version of the manuscript has been approved by all co-authors. All persons named in the acknowledgement section have provided written permission to be named. All authors have reviewed the final version of the article and approve it for publication. The article submitted has not been previously published and is not under consideration or accepted for publication (in whole or in part) elsewhere nor have the authors assigned any right or interest in the article to any third party. Written permission from the authors to reproduce any material with copyright elsewhere has been obtained prior to submission.

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472 TABLES

473 Table I. Activity changes in Otolaryngology Units sorted by zone

Zone		Total				
	No change	Reduction in beds	Merged with other units	Converted into COVID-wards	Temporarily closed	
1	1	5	17	10	5	38 (24.7%)
2	4	9	9	4	1	27 (17.5%)
3	6	16	29	3	6	60 (39%)
4	5	3	10	1	2	21 (13.6%)
5	0	1	5	0	2	8 (5.2%)
Total	16 (10.4%)	34 (22.1%)	70 (45.5%)	18 (11.6%)	16 (10.4%)	154 (100%)

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476 Table 2. Number of staff members sorted by zone and work shift changes

Zone	Number	of specialists ar	nd residents			Worl	shifts during (COVID-19	
	Pre- COVID	During COVID	Difference (%)	p	Not applied	Applied for all of the members	Applied for specialists only	Applied for residents only	Total
1	419	378	9.79%	0.645	16	21	0	1	38
2	330	309	6.36%	0.096	10	13	2	2	27
3	587	540	8.01%	0.217	20	28	9	3	60
4	227	203	10.57%	0.984	6	11	2	2	21
5	38	34	10.53%	0.677	4	3	1	0	8
Total	1601	1464	8.55%	0.069	56 (36.4%)	76 (49.4%)	14 (9%)	8 (5.2%)	100%

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479 Table 3. Reallocation of physicians sorted by zone

Zone		Reallocation to different departments											
	Internal	Internal	Emergency	Intensive	Infectious	Respiratory	Basic	Others					
	Medicine	Medicine	Department	Care Units	Disease	Disease	assistance						
	COVID	non-			Units	Units							
		COVID											
1	25	0	10	6	3	3	1	2	50 (46.7%)				
2	10	4	2	2	0	2	1	1	22 (20.5%)				
3	11	1	6	1	1	2	0	3	25 (23.4%)				
4	5	0	0	0	1	0	0	1	7 (6.5%)				

5	1	0	2	0	0	0	0	0	3 (2.9%)
Total	52 (48.6%)	5 (4.7%)	20 (18.7%)	9 (8.4%)	5 (4.7%)	7 (6.5%)	2 (1.8%)	7 (6.6%)	107 (100%)

481 Table 4. Otolaryngology procedures before and during COVID-19 pandemic

Zone			Otol	aryngology p	rocedures (d	ifference %	(6)			Total	l (difference ⁹	%)
	Outpatient	Outpatient	p	Outpatient	Outpatient	p	Inpatient	Inpatient	p	Procedures	Procedures	p
	visits	visits		surgery	surgery		surgery	surgery		before	during	
	before	during		before	during		before	during		COVID	COVID	
	COVID	COVID		COVID	COVID		COVID	COVID				
1	7702	1341	< 0.0001	375	34	< 0.0001	841	123	< 0.0001	8918	1498	< 0.0001
		(82.6%)			(90.9%)			(85.4%)			(83.2%)	
2	5912	1272	< 0.0001	303	31	< 0.0001	573	111	< 0.0001	6788	1414	< 0.0001
		(78.5%)			(89.8%)			(80.6%)			(79.2%)	
3	8470	1734	< 0.0001	506	42	< 0.0001	1011	164	< 0.0001	9987	1940	< 0.0001
		(79.5%)			(91.7%)			(83.8%)			(80.6%)	
4	3147	620	< 0.0001	192	33	0.0013	317	69	< 0.0001	3656	722	0.0002
		(80.3%)			(82.8%)			(78.2%)			(80.2%)	
5	805	100	0.0006	61	5 (91.8%)	0.081	81	5	0.003	947	110	0.0203
		(87.6%)						(93.8%)			(88.4%)	
Total	26036	5067	< 0.0001	1437	145	<0.0001	2823	472	<0.0001	30296	5684	<0.0001
		(80.5%)			(89.9%)			(83.3%)			(81.2%)	

Table 5. Percentage of variation in different type of surgical procedures during

485 the COVID-period in comparison to pre-COVID period.

Period	Head and	Emergency	Sinonasal	Pediatric	Ear surgery	Basic
	Neck	procedures	surgery	otolaryngology		otolaryngology
	oncology			surgery		surgery
	surgery					
Pre-COVID	121	113	136	83	98	141
During	108	109	2	2	5	0
COVID						
Percentage	10.74%	3.54%	98.53%	97.59%	94.90%	100%
reduction						
(%)						

- 492 FIGURES
- 493 **Figure 1.** Representation of the response rate to our questionnaire sorted by region.
- The total number of responses is reported on the abscissa axis, while the ordinate axis
- indicates the 20 Italian regions.
- 496 Figure 2. Graphical representation of A) the distribution of COVID-19 positive cases
- in Italian regions (ISS, April 16, 2020) and B) the response rate to our questionnaire
- sorted by the five zones identified according to the total number of cases.
- 499 Figure 3. Reallocation of otolaryngology team members to other departments during
- 500 the pandemic.
- Figure 4. Number of outpatient visits, outpatient surgical procedures, and inpatient
- surgical procedures comparing pre-COVID and during-COVID variation.
- 503 Figure 5. A) Surgical and percutaneous tracheostomies, and B) timing of surgical
- tracheostomies (days after intubation).