THE DRAMATIC COVID-19 OUTBREAK IN ITALY IS RESPONSIBLE OF A HUGE DROP IN UROLOGICAL SURGICAL ACTIVITY: A MULTICENTER OBSERVATIONAL STUDY

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Abstract

Objective

Italy is facing the COVID-19 outbreak with an abrupt reorganization of its national health-system, in order to augment care provision to symptomatic patients.

The sudden shift of personnel and resources towards COVID-19 care has led to the reduction of surgery, with possible severe drawbacks.

The aim of the study is to describe the trend in surgical volume in urology, in Italy.

Materials and Methods

Thirty-three urological units with physicians affiliated to the AGILE consortium were involved in a survey. Urologists were asked to report the amount of surgical elective procedures week-by-week, from the beginning of the emergency to the following month.

Results

The 33 hospitals involved in the study account, globally, for 22,945 beds and are distributed in 13/20 Italian regions. Before the outbreak, the involved urology units

performed an overall amount of 1,213 procedures per week, half of which were oncological.

One month later, the amount of surgery declined by 78%. Lombardy, the first region with positive-cases, experienced a 94% reduction. The decrease in oncological and non-oncological surgical activity was 35,9% and 89%, respectively. The trend of the decline showed a delay of roughly 2 weeks for the other regions.

Conclusion

Italy, the country with the highest fatality rate from COVID-19, is experiencing a sudden decline in surgical activity. It is inversely related to the increase in COVID-19 care, with potential harm particularly in the oncological field. The Italian experience can be helpful for future surgical pre-planning in other countries not so hardly hit by the disease yet.

Key words

COVID-19 outbreak; urologic surgery; trend of variation

Introduction

In late December 2019, a cluster of unexplained cases of viral pneumonia occurred in Wuhan, China; On the 11th of February 2020, the WHO officially named the disease caused by the 2019-nCoV as coronavirus disease (COVID-19), with its clinical presentation including a severe form of acute respiratory syndrome[1]. From the initial cluster, it rapidly spread into other countries; in Italy, the first patient - a healthy 38-year-old man - was diagnosed on the 18th of February [2,3]. 30 days later, the virus had caused 47,021 known infections and 4,032 deaths, the highest fatality rate in the world. Italy faced the emergency at different levels, moving from the initial

identification, tracking and isolation of cases, to public interventions for virus containment; however, the high hospitalization rate, due to the severity of the clinical syndromes, as well as the need for intensive care units (ICUs), rendered hospital preparedness impossible in a real-time fashion [2-4]. One month thereafter, the Italian health care system - ranked as one of the best in the world according to the WHO - had been abruptly redesigned to face the uncontrolled COVID-19 outbreak.

The redefinition of Italian care delivery was based on the creation of spaces entirely dedicated to COVID-19 patients, as novel triage areas; meanwhile, internal medicine wards, pre-existing ICUs and most of the anesthesiologists' staff moved to the assistance of symptomatic and critically ill patients [2-4]. In addition, in more involved areas, operating rooms were converted into ICUs, dedicated to COVID-19 patients.

As a drawback, nonurgent procedures were almost completely cancelled, at both outpatient and inpatient level; lots of diagnostic and surgical procedures are still pending, including those for oncological diseases of different risk classes [2-4]. Due to this sudden reduction, the less involved, contiguous regions experienced a prompt increase in demands from patients in critical areas. Such demands posed the issue of how to manage potential asymptomatic, infected subjects within hospitals free from COVID-19. Initally, specific protocols were used, but soon these requests were discouraged, as they were resource-demanding. In such a context further dilemmas arose on how to preserve the basic rights of all citizens.

Among surgical specialities, urology deals with the treatment of three highly frequent cancers, prostate, bladder and kidney cancer [5]. Furthermore, it includes endourological procedures for the minimally invasive treatment of urolithiasis, a disease affecting up to 20% of subjects in their lifetime [5].

As a consequence, urology is one of the surgical specialties mostly suffering the reduction of elective surgery, given the high burden of surgical activity and operating room (OR) occupation.

The aim of the current study is to describe how much, and how quickly the COVID-19 outbreak affected the regular activity in the urological setting in Italy, the country that is paying the highest tribute in terms of human lives to the sudden pandemic.

Materials and Methods

We considered 33 urological centres with physicians affiliated to a consortium known as the AGILE group (italian group for advanced laparo-endoscopic and robotic urologic surgery) (www.agilegroup.it)

A description of each Centre (name of the Author, city, region, name of the hospital, bed availability, academic vs non academic, public vs private) is provided in Table 1. All centres perform open and minimally invasive surgery (endourology, laparoscopic and or robotic surgery). By the 15th of March, an email questionnaire was sent to the aforementioned AGILE urologists, asking for a timely completion. The survey aimed to evaluate possible variations in the burden of surgical activity during the month following COVID-19 first case in Italy.

Time trend of OR activity was collected during 4 consecutive weeks (24/02/2020 to 01/03/2020; 02/03/2020 to 08/03/2020; 09/03/2020 to 15/03/2020; 16/03/2020 to 22/03/2020)

As a reference, we asked to provide data on the weekly regular OR occupation before the 22nd of February.

We report a list of items that were addressed in the survey:

- The overall number of procedures performed each week; we included all procedures under general and spinal anesthesia and emergency procedures
- The overall number of OR sessions each week (considering a single session from 8 am to 2 pm or 2 pm to 8 pm)
- The number of oncological and non-oncological procedures
- The amount of health professionals with a laboratory-confirmed COVID-19 and therefore, not allowed to work

The primary endpoint was to assess the overall trend of surgical activity, measured as the number of surgical procedures performed each week, compared to the baseline regular week.

As a secondary endpoint, we addressed the trend of OR occupation stratified by geographic areas (Figure 1), divided into:

- Centers from Lombardy (7 Centers)
- Centers from northern regions, bordering with Lombardy, with COVID-19 presence (Piedmont, Emilia-Romagna, Veneto; 10 Centers)
- Centers from other italian regions (16 Centers)

Data on the percentage reduction of procedures per week, calculated with reference to the pre-infection numbers, were summarized as median and interquartile range (IQR). Box plots depict the distributions of procedure reduction for the 33 centres, stratified by time interval and geographical area.

Data related to overall Incidence of COVID-19 and hospitalization were retrieved from the Protezione Civile database.

Results

The 33 urological centres, members of the AGILE group, are located in facilities with a global bed availability of roughly 23,000 units, distributed in 13 out of 20 italian regions, including the 10 most populated regions.

Before the COVID-19 outbreak, the urology departments of the AGILE's affiliated urologists performed an overall amount of 1,213 procedures in a standard working week in 2020, distributed over 375 OR sessions. Oncological procedures accounted for approximately 50% of overall activity.

One month later, the amount of urologic surgical procedures declined by 78% (IQR 60% - 91%). The trend appears inversely related to the increased COVID-19 related care, in terms of hospitalization and ICUs bed occupation (source: protezionecivile.gov.it; Figure 2).

The variation in terms of surgical activity, according to oncological and non-oncological indications, was 35,9% and 89%, respectively.

Lombardy, the first region with laboratory-confirmed presence of COVID-19, experienced a 94% (IQR 85% - 100%) decline in elective surgery (Figure 3a); a 73% (IQR 63% - 86%) and 78% (IQR 53% - 91%) decrease have been reported for regions neighbouring Lombardy and for other regions of Italy, respectively (Figures 3b and 3c).

The time trends showed some interesting differences between Lombardy and other regions. Lombardy had a marked reduction of elective activity from the beginning of the emergency, while the other regions experienced a similar reduction but delayed of two weeks, following the COVID-19 diffusion.

To note, the remodulation of the OR schedules was not homogeneous; Figure 3 shows (as box plots) the variability of surgical volumes between centers at different time frames, stratified by geographic area (Figures 3a, 3b, 3c).

A wide variability appeared at the beginning of the epidemic in Lombardy (Figure 3a) and was still sustained four weeks later for distant regions (Figure 3c), maybe reflecting regional variability of health care delivery and measures against COVID-19.

For regions neighbouring Lombardy (Figure 3b), there was a homogenous reduction of surgical volumes among centres, maybe reflecting common measures and prompt alignment of the surgical activity.

As far as urological workforce is concerned, one month after the COVID-19 outbreak, only 7/341 (2%) urologists at the involved centres had a laboratory-confirmed infection.

Discussion

One month after the first case in Italy, more than 4,000 people had passed away for COVID-19, 18,675 had been hospitalized and 2,655 had been admitted in ICUs (source: protezionecivile.gov.it). The health care system was getting more and more overwhelmed, thus, elective and semi-elective surgery was cancelled by 78% in the centres involved in our study.

The decline in the volume of surgery is mainly to be attributed to the sudden re-organization of facilities and human resources to accommodate symptomatic and critically ill patients: the hospitalization rate for COVID-19 is roughly 50% of the

infected, of whom 16% require ICUs [3], leading to the lack of workers, beds and operating rooms for elective, or semi-elective patients.

The workforce shortage may be related to their diversion on other activities, as happened for the anaesthesiologists, who were mostly diverted into the ICUs since the very beginning of the emergency.

Furthermore, health care workers are seriously prone to infections, deriving from either caregiving, or other daily activities, such as managing instruments, touching computers, seeing outpatients [4]. By the 19th of March, a total of 3,559 health care workers were infected, representing 8.3% of overall positive cases in Italy (source: gimbe.org).

As far as our study is concerned, only 2% of the urology staff from the involved centres had a laboratory-confirmed infection at the time of the survey, indicating a relatively partial involvement of urologists in dealing with highly suspected, or positive COVID-19 patients. It is important to note that according to the Italian laws, health care workers were not tested for COVID-19 if asymptomatic. Differently from other specialities, in our series the dramatic reduction in surgical procedures was not due to the consequences of surgeons' infections, but to the diversion of human resources.

One month after the COVID-19 outbreak, the scenario of Italian urological surgery had dramatically changed; an overall reduction of OR sessions of 40.2% was documented, with the amount of oncological procedures being reduced by almost 35,9%. Non-oncological surgery suffered from a decrease as high as 89%. Cancellations were performed homogeneously alongside centers, according to an

emergency/urgency principle: trauma, testicular torsion, urinary tract decompression were prioritized together with testicular and urothelial cancer.

Considering Italian areas as herein stratified, the geographic trend of the decline in surgical activity seems to be inversely related to the COVID-19 topographical spread. The first and most involved region, Lombardy, responded to the outbreak with massive prioritization of urgent care request. Four weeks later, this translated into an abrupt shortage of OR occupation with only 24 patients actively scheduled among the 7 AGILE Centres from Lombardy, previously accounting for 229 procedures per week, representing a reduction of nearly 90%. Analysing separately private and public clinical practice, we should remark that three out of six private clinics experienced a complete slowdown of elective surgery during the emergency.

The trend of COVID-19 outbreak of other European countries (source: gimbe.org) and ultimately of the USA (source: Worldometers.info, Figure 4) follows that of Lombardy, with similar curves, but with an evident - likely profitable – delay in time.

The knowledge of the disease trend and its drawbacks on health care may provide guidance for a timely and efficient re-planning of facilities, in order to avoid, or limit, the massive breakdown of surgical activity too [6,7]. Particularly, oncological patients may suffer from the consequences related to this delay that at the moment seem hardly predictable:

upgrading and upstaging of diseases may compromise the window of curability, or at least, determine the need for a higher number, or quantity of therapies, potentially increasing side effects and affecting the patients' functional outcomes.

Based on the Italian experience, in our opinion, some actions could be pre-planned to limit the burden of shortcomings:

- Adhere to the empirically suggested Surgical Priority Charts (as the ones from the Cleveland Clinic [8], from the Bristish Journal of Urology [9] and from the European Urology community [10,11], for the urology field);
- Create COVID-19-free Health care Facilities dedicated to patients undergoing major elective surgery (e.g. oncologic or cardiovascular surgery);

Possible advantages of creating COVID-19 free facilities:

- Preserving health care workers, allowing them to assist more patients;
- Avoiding the risk of nosocomial infections of those patients who, being affected by other diseases, would be more prone to an ominous response to the infection;

Preservation of a COVID-19 free Unit might be hard, as reported by Rosembaum et al [4]; the virus containment within a single institution is difficult or impossible, because “the infection is likely to be everywhere in the hospital”, despite the provision and use of protective gear; therefore, preserving COVID-19 free facilities rather than COVID-19 free areas inside a facility might be the key.

For this purpose, important steps might be:

- To improve the knowledge of the disease and train health care workers accurately;
- To improve health care workers’ safety, with timely and precise assignment of appropriate personal protective equipment and by regular testing of health care workers

- Patients' remote pre-triage on their health status (e.g. fever, symptoms etc) and possibly pre-quarantining and testing of the patients, before allowing them inside the facility
- To minimize, or forbid the access to visitors;

To our knowledge this is the first report that describes the modifications of regular clinical activities due to the COVID-19 pandemic, outside China. Italy, the hardest-hit country in the world by COVID-19, for cultural, social and political reasons, can be a more representative model than China, for western countries, on how the COVID-19 pandemic can impact the health care system.

Strong and quick social restrictions, together with a careful and appropriate health care planning might help to reduce the impact of the pandemic in other countries.

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- Worldometer - real time world statistics (worldometers.info)

Table 1 - Characteristics of the surveyed italian centres (name of the Author, region, city, name of the Institution, bed availability, academic vs non academic, public vs private)

Author	Region	City	Institution	Urology staff members	Beds	Academic vs non-Academic	Public vs private
Amenta	Veneto	Portogruaro	Azienda ULSS n.4 Veneto Orientale	9	240	non-academic	public
Annino	Tuscany	Arezzo	Ospedale San Donato , AUSL 8	9	510	non-academic	public
Antonelli	Veneto	Verona	Ospedale Maggiore Borgo Trento	15	682	academic	public
Borghesi	Liguria	Genova	Ospedale San Martino	15	1400	academic	public
Bove	Lazio	Rome	Ospedale San Carlo di Nancy di Roma	7	230	academic	public
Bozzini	Lombardy	Busto Arsizio	ASST Valle Olona	12	1564	non-academic	public
Caffarelli	Marche	Ancona	Villa Igea	6	224	non-academic	private
Celia	Veneto	Bassano	Ospedale San Bassiano	11	406	non-academic	public
Ceruti	Piedmont	Turin	AOU Città della Salute e della Scienza di Torino	22	1481	academic	public
Cindolo	Emilia Romagna	Modena	Hesperia Hospital	12	125	non-academic	privato
Cindolo	Lazio	Rome	Villa Stuart	2	50	non-academic	private
Falabella	Basilicata	Potenza	San Carlo di Potenza	7	500	non-academic	public
Falsaperla	Sicily	Catania	ARNAS Garibaldi Hospital, Catania,	9	1000	non-academic	public
Galfano	Lombardy	Milan	ASST Grande Ospedale Metropolitano Niguarda.	10	1213	non-academic	public
Gallo	Liguria	Savona	Ospedale San Paolo di Savona	10	472	non-academic	public
Greco	Lombardy	Bergamo	Humanitas Gavazzeni	8	311	non-academic	private
Leonardo	Lazio	Rome	Policlinico Umberto I	11	1200	academic	public
Minervini	Tuscany	Florence	AOU Careggi	26	1309	academic	public
Nucciotti	Tuscany	Grosseto	Azienda USLToscana Sud Est	6	445	non-academic	public
Pagliarulo	Apulia	Lecce	Ospedale Vito Fazzi	8	1249	non academic	public
Parma	Lombardy	Mantova	Ospedale Carlo Poma	10	628	non-academic	public
Pastore	Lazio	Latina	Sapienza University	4	341	academic	public
Pini	Lombardy	Milan	San Raffaele Turro	17	188	non-academic	private
Porreca	Veneto	Abano terme	Policlinico Abano Terme	7	205	non-academic	private
Pucci	Campania	Naples	Azienda Ospedaliera A. Cardarelli	16	850	non-academic	public
Rocco	Emilia Romagna	Modena	Azienda Ospedaliero Universitaria di Modena	12	1108	academic	public
Schiavina	Emilia	Bologna	AOU Policlinico Sant-	16	1487	academic	public

	Romagna		Orsola-Malpighi				
Sciorio	Lombardy	Lecco	ASST Ospedale Manzoni	7	750	non-academic	public
Varca	Lombardy	Garbagnate	ASAT Rhodense Ospedale Guido Salvini di Garbagnate	6	539	non-academic	public
Veneziano	Calabria	Reggio Calabria	AO Bianchi-Melacrino-Morelli	9	600	non-academic	public
Verze	Campania	Salerno	AOU San Giovanni di Rio e Ruggi d'Aragona	6	642	academic	public
Volpe	Piedmont	Novara	Ospedale Maggiore della Carità	9	711	academic	public
Zaramella	Piedmont	Biella	Ospedale degli Infermi	7	490	non-academic	public

Figure legend

Figure 1

Map of geographical stratification:

- Centers from Lombardy (7 Centers) (dark grey)
- Centers from northern regions bordering with Lombardy with COVID-19 presence as by (Piedmont, Emilia-Romagna, Veneto; 10 Centers) (grey)
- Centers from other italian regions (16 Centers) (white)

Figure 2

Overall Italian trend of elective surgery among urological involved centres (percent variation from the pre-infection baseline status). Trend of COVID-19 related care in Italy, defined as hospitalization and ICU's-bed occupation (whisker extending from minimum to maximum).

Red line: trend of variation of surgical procedures

Blue line: (continuous) number of new diagnosis

blue line: (dotted) number of hospitalized patients

% = percentage, Feb = February, Mar = March, k = thousand of cases

Figure 3

Trend of elective surgery among urological involved centres stratified by area (3a: Lombardy; 3b: regions neighbouring Lombardy; 3c: other regions).

Box plots indicate the variability of surgical volumes between centers at different time frames (whisker exteding from minimum to maximum).

% = percentage, Feb = February, Mar = March, k = thousand of cases

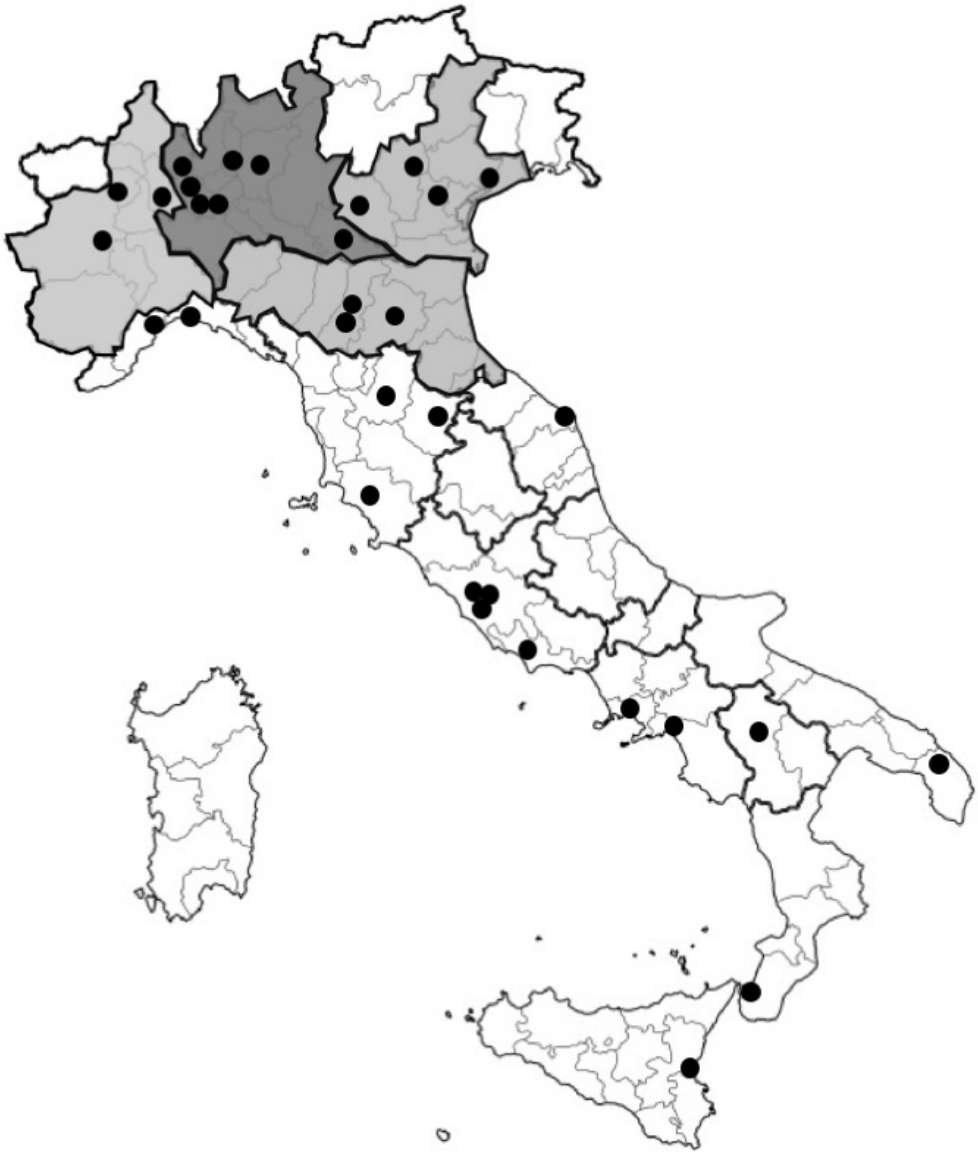
Figure 4

Curves and time-line trend of COVID-19 outbreak in Italy and in the USA (source of data: worldometers.info). The USA trend reflects the Italian one with a delay of roughly 9 days.

KEY OF DEFINITIONS FOR ABBREVIATIONS:

COVID-19: coronavirus disease 2019
OR: operating room
ICU(s): intensive care unit(s)
AGILE: Agile group consortium
Fig: figure
WHO: World Health Organization
2019-nCoV: 2019 novel coronavirus

IQR: interquartile range
USA: United States of America
DPIs: Individual Protection Devices
e.g: exempli gratia
etc: et cetera



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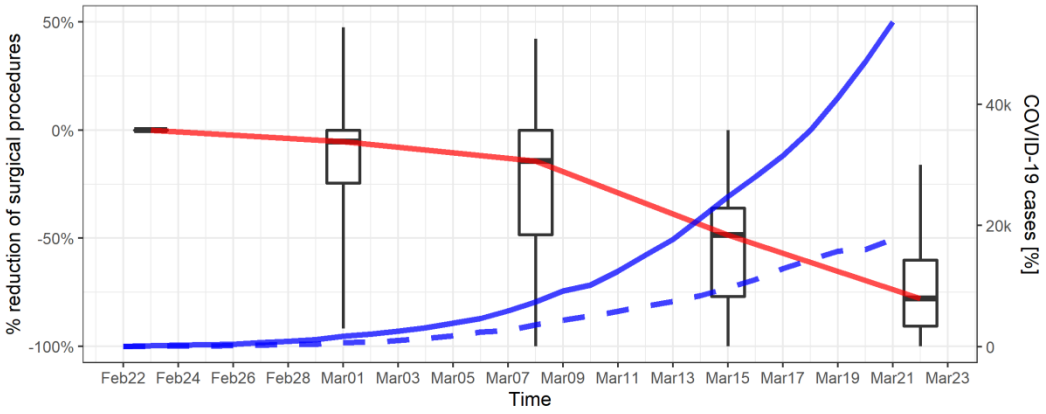

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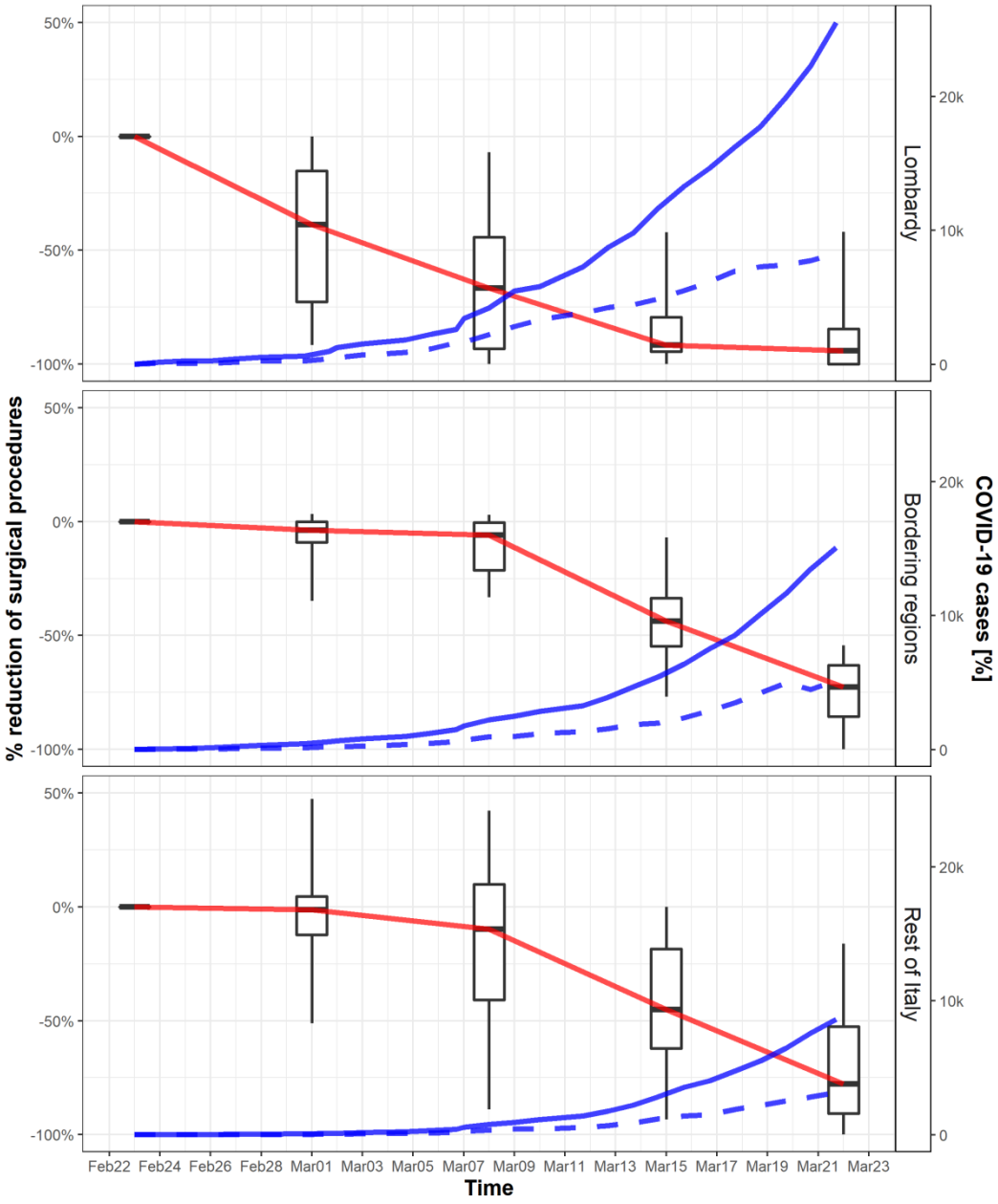

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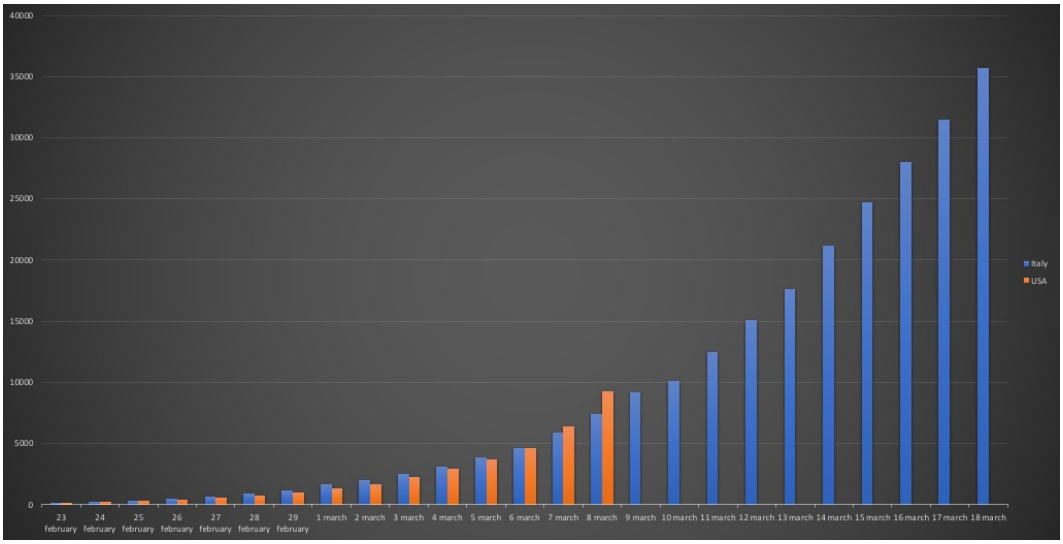

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