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Does the healthcare system know what to cut under the pandemic emergency pressure? Lessons by the Italian health system.

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Title page

Does the healthcare system know what to cut under the pandemic emergency pressure? Lessons by the Italian health system.

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Keywords: clincal practice variation, elective surgical procedure, hospitalization, population based planning.

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Abstract

Objectives: During 2020 many countries reduced the number of elective surgeries to free up beds and cope with the COVID-19 outbreak. This situation led health care systems to prioritize elective interventions and to reduce the overall volumes of treatments.

The aim of this paper is to analyze whether the pandemic and the prioritization policies on elective surgery were done considering the potential inappropriateness highlighted by the geographic variation measurement.

Setting: The setting of the study is acute care with a focus on elective surgical procedures. Data were analyzed at Italian regional level.

Participants: The study is observational and it relies on national hosptalization records of 2019 and 2020. The surgical procedures analyzed are those considered at high risk of unwarranted variation: coronary angioplasty, colecystectomy, colectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping.

Primary and secondary outcome measures: Primary measures were: the hospitalization rate and its reduction per procedure to understand the level of potential inappropriateness. Secondary measures were the standard deviation and the high low ratio to map the level of unwarranted variation.

Results: For some procedures there is a negative relationship between the hospitalization reductions and its starting point. In particular, data show that regions with higher 2019 hospitalization rates registered higher reduction.

Conclusions: The Italian data showed that the pandemic seems to have led hospital managers and health professionals to cut the surgical intervention more likely to be inappropriate. Hence, these findings can inform and guide healthcare system to manage unwarranted variation when coming back to the new normal. The aftermath should use this new starting point (lower volumes in some selected elective surgical procedures) to plan elective surgical treatments that can be canceled because of their high risk of inappropriateness.

Trial registration was not required.

Strenghts and limitations of this study

- This study provides evidence on the relationship between geographic unwarranted variation in elective surgery and Covid-19 reduction of the activities.
- This evidence may inform healthcare policy makers and managers in planning the future backlogs
- The analysis is limited to a selection of eight elective surgical procedures.
- The analysis is limited to the administrative data. Additional sources, such as patients' preferences could have provided further explanations related to the geographic variation occurred.

Introduction:

The COVID-19 outbreak has led many countries to reduce the number of elective surgeries to free up beds (both in ICU and acute care wards) and healthcare professionals (mainly anestesiologists) to cope with the acute care treatments for COVID-19 patients¹⁻⁴. This situation led countries, regions and counties (in the case of decentralized health care systems), as well as providers to prioritize treatments and to reduce the overall volumes. The polices adopted aimed to: i) ensure urgency treatments and time-dependent diseases such as stroke and AMI; ii) identify the elective treatments to be protected and ensured because not deferrable or life-saving like the surgical cancer interventions; iii) postpone the deferrable elective surgery.

In particular, elective surgery has been investigated for almost one century because of its treatments'variation. For instance, in the first decades of 1900, Sir James Allison Glover in his speech at the English Epidemiology and state of medicine on the 27th of May 1938 cited the studies of geographic variation about tonsillectomy; in the last decades of 1900, Wenneberg re-launched studies on the geographic variation use-rates promoting the Darthmouth Atlas of variation^{5,6} for several services; yet, in the first decade of 2000 scholars, reported wide variation in tonsillectomy hospitalization rates among different geographic areas in different countries^{7,8}. Nowadays, the pandemic can boost the importance of geographic variation studies in the rebound stage of elective surgery, supporting health system to plan a more appropriate new start.

Significant geographic variations have been revealed for several very common elective surgical interventions^{6,9-13}. In some cases, like tonsillectomy, there is consensus on the opportunity to reduce the rate especially in geographic areas presenting high hospitalization rates. Instead, in other cases the right rate and the determinants of variation are still discussed. Following the revised categories of Wenneberg by Nuti and Seghieri⁸, variation in elective surgery may occur in the following situations: i) when there is clinically proven effective services (e.g., volumes of specific surgical procedures such as the hip fracture operated within 2 days), in this case differences in quality should be avoided; ii) when services are delivered according to care settings determined by the organizational choices (e.g., in-patient admissions for interventions which could be instead performed on a day surgery basis), in this case differences may not have an impact on outcomes; iii) when variation reflects patients' different need or preferences or when it often reflects physicians' discretionary choices; iv) when variation depends upon supply (supply-sensitive services), it occurs when the number of services available increases (i.e., number of beds, number of specialists etc.).

On the basis of this stream of literature, when geographic variation does not depend upon patients' preferences or needs¹⁴, it can be classified as unwarranted ^{5,6,15}. Several studies ^{9,10} reported that patient characteristics and preferences do not completely account for geographic variation in the provision of elective surgery, rather, greater influence is exerted by clinicians' behavior and judgment. This classification and consideration have to be taken into account when planning the volumes of (appropriate) elective surgery to be ensured, especially in Beveridge-like systems where unwarranted variation can be seen as a signal of horizontal equity (because of the same level of patient need, variation may highlight disparities in the resource allocation, the quality of care or the access to the services across its territories)¹⁶ also known as "postcode lottery"¹⁷.

This seems particularly relevant in this stage of pandemic related to planning the rebound activities. Whilst some scholars reported how to deal with the growing backlog of healthcare procedures related to non communicable diseases during the pandemic crisis (such as the delay in cancer procedures and especially on time dependent

intervention²²); yet, poor debate has been stimulated on the relationship between the reduction of elective surgeries and the unwarrented geographic variation.

Indeed, this unprecedent situation can be considered as an opportunity to revise the intervention priority list with the aim to reduce (or at least frozen) the potential inappropriate interventions thus freeing up resources (operating room and professionals) that can be employed in bouncing back the (appropriate) interventions postponed.

The paper discusses the opportunity of managing unwarrented variation of elective surgeries in this emergency period using empirical evidence from Italy. Relying upon primary data of the Italian hospital discharge records of 2020 and 2019, this paper analyzes whether the pandemic and the prioritization policies of elective surgery have had an impact on the regional geographic variation. In particular, considering the Italian regional extant differences in providing elective surgery, the issue investigated is whether the healthcare system grabbed the opportunity in prioritizing beds to reduce the potential inappropriate elective surgery. Closing remarks have been formulated for the rebound stage.

Elective surgery in the Italian context

The Italian healthcare system is a Beveridge-like model that provides universal coverage through general taxation; it is characterized by high decentralization²³. The decentralisation process, following the market-oriented reforms of the early 1990s, culminated in the 2001 constitutional reform, with the introduction of an essential healthcare benefit pack- age (defined as Livelli Essenziali di Assistenza, LEA) guaranteed to all citizens. This reform granted more power to the Regions²⁴. The current institutional arrangement implies that the central government is responsible for channelling general tax revenues, defining benefit packages, exercising overall management and governments, and, more recently, monitoring regional budgets. Meanwhile, regional governments are responsible for the organisation and delivery of health services through the local health authorities and public and accredited private hospitals, and can also raise local taxes and fund additional health services.

Because of the joint responsibility on health care, both the national and the regional health systems monitor the performance using tools, mainly three have been identified by the 2016 European Report²⁵ with specific characteristics: LEA grid; National Outcome Program (known by the acronym of PNE) and Inter-regional Performance Evaluation Sytstem (IRPES).

All the three systems highlight that geographic variation occurs across and within regions on different dimensions: access, quality, appropriateness and efficiency. Whilst LEA grid does not have specific indicators to monitor elective surgery variation, PNE and IRPES monitor some common elective surgery procedures known to register high variability, often, because of the lack of standards. Figure 1 shows, as example, that the hospitalization rates for tonsillectomy can be even higher than four times between Regions.

In 2020, overall elective surgery at national level reduced up to 28% with the respect to 2019 volumes. Mild differences were registered across regions. Larger differences show up when comparing single surgical procedures such as the oncological interventions²⁶.

 The RECORD guidelines²⁷ have been applied to conduct the study. This study did not involve human participants and Ethics Committee approvali was not required. The RECORD checklist has been included in the supplementary materials.

Starting from the hospitalization records of the Italian National Health Service provided by Agenas, the paper analyzes geographic variation for the procedures selected by Nuti and Seghieri⁸ which usually present wide unwarranted geographic variation across and within countries: coronary angioplasty, colecystectomy, colectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping (details about ICD9CM and DRGs are in Appendix. Additional information can be requested to the authors).

These crude rates (number of procedures per 100,000 inhabitants) were indirectly standardized by age and sex through SAS software and then put into relationship with the reduction of surgical hospitalization rates of the two consecutive years 2020-2019.

Overall the analyses refer to 48,917 records for the 2019 and 33,821 for the 2020 that represents the entire database population for the selected eight elective surgery procedures. The variables used in the study were the ones considered mandatory at national level to can accept the record as a valid one. These data were put in relation with the population information gathered from the National Institute of Statistics (Istat). The match of data was carried out at regional level. No record linkage at person level was executed.

Following the Expert Panel on Effective Ways of Investing in Health definition of resilience²⁸, the percentage of reduction of non-COVID-19 services can be used to assess the capacity of healthcare systems to be resilient. In fact, one specific caracteristic of resilience is the capacity to adapt to shocks and structural changes sustaining requiring operations and resuming optimal performance as quickly as possible²⁸. In this perspective, the reduction of volumes of surgical procedures can be seen as the potential interventions to rebound after the emergency.

The matrix combining the 2019 hospitalization rates with the percentage of volumes reduction of 2020 on 2019 has been used to graphically understand whether the pandemic has had any effect on the unwarranted regional variation of the selected eletive surgery procedures.

The Pearson correlation has been also executed showing the p-value at 1%, 5% and 10%. A cutoff was introduced to the absolute volumes per procedures. The cut off was set at 10 volumes for the year 2019 to reduce the variability linked to a low number of cases occurred.

Patient and public involvement. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research. The analysis is based on aggregated administrative data, at this stage of the analysis the authors didn't involve patient and public layactors.

Results

Starting from the hospitalization records of the Italian National Health Service provided by Agenas we displayed in table 1 the descriptive statistics of the selected procedures in 2019.

Table 1 – Descriptive statistics for selected elective surgery hospitalization rates in 2019.

Hospitalization rate Mean Dev. Std Min Max High Low

					Ratio
Coronary Angioplasty	76.27	24.86	27.22	114.44	4.20
Cholecystectomy	158.47	18.85	120.37	209.29	1.74
Hysterectomy	3.11	2.77	1	11.42	11.42
Prostatectomy	145.22	31.94	90.24	238.07	2.64
Knee replacement	155.87	27.49	102.33	212.95	2.08
Hip replacement	342.90	106.27	176.63	598.78	3.39
Vein stripping	46.62	34.22	7.19	135.31	18.82
Tonsillectomy	197.63	74.72	81.63	350.37	4.29

Source: Elaboration of authors on 2019 data.

Table 1 shows wide variations across geographic areas (Italian regions). Moreover, regions with high (low) rates in one procedure have not been found to be associated with high (low) rates in another, most likely reflecting autonomous practices and failures in adhering to shared guidelines and protocols among professionals.

Considering the overall elective surgery reduction of 28%²⁶ table 2 reports that the mean reduction for the selected elective surgeries sometimes is lower but registering a wide variation across Italian regions.

Table 2 – Volumes reduction for selected elective surgery 2020 on 2019.

Procedures	Mean Reduction	Min Reduction	Max Reduction
Coronary Angioplasty	25%	-3%	57%
Cholecystectomy	34%	20%	50%
Hysterectomy	30%	-24%	100%
Prostatectomy	31%	20%	43%
Knee replacement	26%	8%	42%
Hip replacement	25%	20%	36%
Vein stripping	51%	38%	74%
Tonsillectomy	54%	27%	68%
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Source: Elaboration of authors on 2020 and 2019 data.

Concerning the selected elective procedures, figure 2 reports a chart of hospitalization rates and their difference between 2019-2020.

The charts exhibit that for some procedures there is a negative relationships between the hospitalization reductions and its starting point. In particular, the scatter plot of the hospitalization for vein stripping (b) and tonsillectomy (a) present a clear negative relation: regions with higher 2019 hospitalization rates registered higher reduction.

The Pearson correlation confirms that there is a statistically significant negative correlation between the hospitalization rates and the reduction of 2020 in all the charts analyzed. In particular, the table 3 reports the correlation coefficient and the p value. Tonsillectomy, hip replacement and prostatectomy are the procedures where the correlation is statistically significant at p<0.01, knee replacement is statistically significant at p<0.05 while a lower correlation and a lower significant p value was found for coronary angioplasty (p<0.10). No significant correlation was found for cholecistectomy and hysterectomy.

Table 3 – Correlation between 2019 hospitalization rates and hospitalization rate reduction.

Procedures		ρ	p-value
Tonsillectomy	-	0.92	0.00
Hip replacement	-	0.79	0.00
Prostatectomy	_	0.72	0.00
Coronary angioplasty	_	0.38	0.08
Cholecistectomy	-	0.22	0.31
Hysterectomy	U	0.22	0.33
Vein stripping	O -	0.93	0.00
Knee replacement -	0.51		0.01

Source: Elaboration of authors on 2020 and 2019 data.

Overall, the lower the 2019 hospitalization rate, the higher the reduction of hospitalization rates.

Discussions

Considering the selected elective surgery indicators, we found that regions with higher potential inappropriate elective surgery hospitalization rates are those that reduced more their volumes.

In particular, tonsillectomy and vein stripping which have been showed as among the procedures with wider variation across geographic areas are also those registering among the higher reduction (in both cases, the correlation coefficient is around -0.9 with a p-value<0.01). These straightforward results seem to support the idea that under the emergency pressure the health care system is more likely to provide stricter directions to allocate health care resources preserving them for elective surgical interventions which have stronger clinical evidence. Yet, there is no standard for a number of surgical treatments, in those cases the 2019 national median can be considered as a reference for all the regional health systems that overcame it in 2019 and the reduction occurred in 2020 could not be taken into account when planning the rebound and the new activities. This evidence supported, at least for the potentially inappropriate hospitalization rate, the rule of thumb known as the Romer's law.

Further reserach is needed to better understand the role played by the different stakeholders: regional managers or health authority managers, professionals and patients. At first evidence, although population fear have affected the surgical reduction, the impact seem to be rather limited, a 2021 survey on population highlighted that the 8% of Italians preferred to pospone or avoid surgical treatements because of the COVID-19 fear²⁹.

As a preliminary study on this topic, this research presents some limitations. First, the study context focused on the Italian healthcare system and its organisational structure. This study provides evidence to enlarge the debate on this relevant topic in Italy and also

in those countries aiming at analyzing what happened in 2020 to the unwarranted variation in elective surgery in their countries.

Second, there could be other indicators as valuable and informative as those measures included in the analysis. However, we considered the ones that are shared among a group of Italian regional healthcare managers and already included in two of the three performance evaluation systems actually used in Italy, the IRPES and PNE.

Moreover, although we used standardized hospitalization rates, further analyses can be done to better understand if patients'characteristics may have played any role in the volume reduction. Other investigations can be also useful in deepening if some factors (such as the presence of private providers or the patients'outflow) may explain variation in the volume reduction.

Conclusion

COVID-19 led healthcare systems to make hard choices in providing services. A large number of cuts, especially for acute care services, have been put in place. That led health care systems to reflect upon prioritizating access to services which is certainly an etical issue but also an opportunity to reduce the potential inappropriate interventions.

This study aimed at providing preliminary evidence on the impact of the pandemic on the geographic variation of selected elective surgery procedures. In particular, the group of oncological surgical interventions belongs to the preference-sentive categories of Wenneberg mostly influenced by the clinician decision. Wide variation in elective surgery rarely depends on patients' preferences or needs. In fact a recent study demonstrated that often the reservation of operating room does not depend upon the demand or the waiting times¹³. This variation category is also the one requiring a deeper involvement of the clinicians because it ask for aligning their behaviour to clinical guidelines or practices^{8,16}. The Italian data showed that the pandemic seems to have led hospital managers and health professionals to cut the surgical intervention more likley to be inappropriate. Hence, these findings can inform and guide healthcare system to manage unwarranted variation. In fact, when coming back to the new normal after this unpredictable situation given by the pandemic, it is important to use this new starting point (lower volumes in some selected elective surgical procedures) to plan elective surgical treatments that can be canceled because of their high inappropriateness.

Once the healthcare systems have achieved lower hospitalization rates for potentially inappropriate treatments, as it happened during the pandemic, it is important to reverse the burden of proof not asking "why we are so different?" trying to close the gap with the other practices but "why we should become different from the other practices?".

Statements

- a. **Contributorship statement:** All the authors conceived the paper; MV writes the original version and executed the calculations; SN & DM review the manuscript.
- b. Competing interests: None.
- c. **Funding Information:** The article is based on a collaboration between Agenas and Scuola Superiore Sant'Anna of Pisa settled in 2020.
- d. **Data sharing statement:** Aggregated data can be shared upon request to the corresponding author.

e. **Ethics statement:** This study does not involve human participants. Ethics Committee approval is not necessary.

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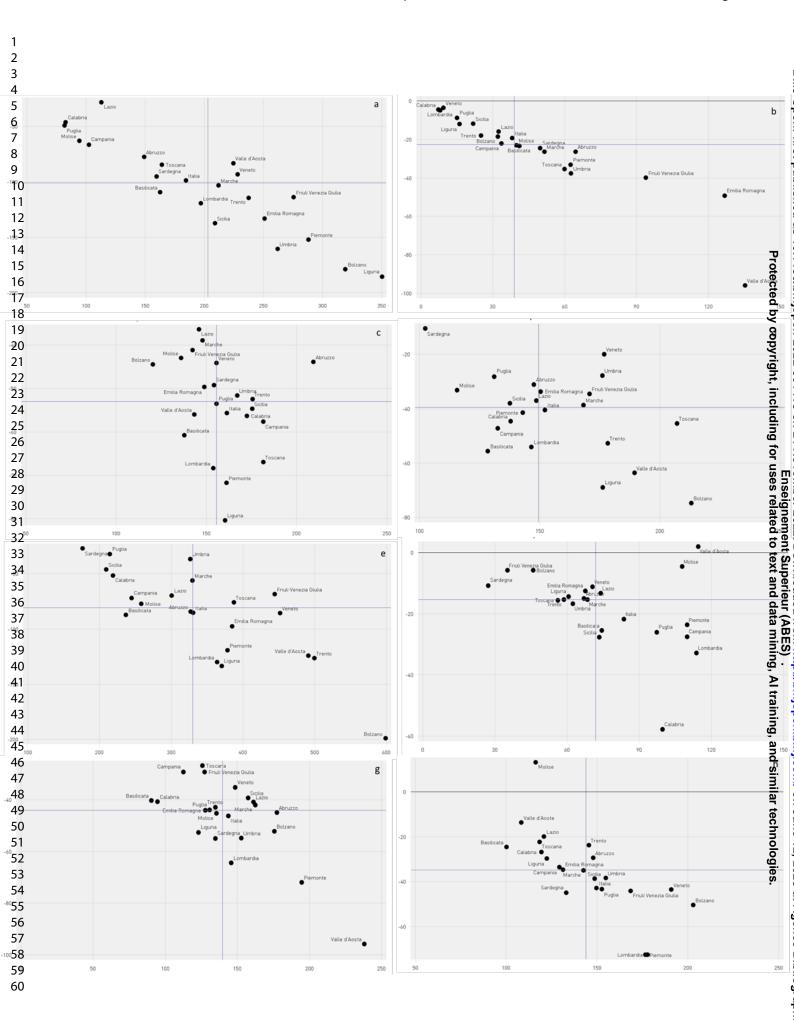
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Source: PNE, 2019

Figure 2 – The matrix of 2019 hospitalization rate and difference of hospitalization rate between 2020-2019 by selected elective surgery procedures.

Source: Elaboration of authors on 2020 and 2019 data.a)Tonsillectomy, b)Vein stripping, c)Cholecystectomy, d)Knee replacement, e) Hip replacement, f)Coronary angioplasty, g) Prostatectomy, h) Hysterectomy. Y-axis represents the 2020-2019 difference of hospitalization rate. X-axis represents the 2019 hospitalization rate. Reference lines represent the median values.



Appendix.

Codes of the ICD9CM and DRGs used for selecting cases, elective surgery.

ICD9CM codes/DRG	
Grouper XXIV	
codes	Notes
28.2x; 28.3x	Patients aged 0-18
DRG 119	
	All women aged 18
	yrs and over with
	benign uterine
68.3x-68.9x	conditions
	Total knee
81.54	replacement
	All patients aged
	65 and over,
	excludes diagnosis
	codes 820-821.39,
81.51	996.4x
	All patients with
	ICD-9-CM Diagnosis
45.71-45.76;	Code 153: malignant
45.79; 45.8x	neoplasm of colon
36.03; 36.04;	
36.06; 36.07;	
36.09; 00.66	
DRG: 493;494	
	Grouper XXIV codes 28.2x; 28.3x DRG 119 68.3x-68.9x 81.54 81.51 45.71-45.76; 45.79; 45.8x 36.03; 36.04; 36.06; 36.07; 36.09; 00.66

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items including for	061415 on 24 N	Location in manuscript where items are reported
Title and abstrac	t			Б п	ove	
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	In the abstract	RECORD 1.1: The type of a should be specified in the should be specified in the should be the databases used should be RECORD 1.2: If applicable geographic region and times within which the study to should be reported in the abstract. RECORD 1.3: If linkage better databases was conducted for this should be clearly stated.	aga used Evaluated of second of sec	Included in the abstract pg 2 The title reports the geographic frame. Data analyzed are reported in the abstract pg 1 The study did not require record linkage pg 5
Introduction				or abstract.	<u>J.</u>	
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	In the introduction section pg 3	similar tec	om/ on June 12	
Objectives	3	State specific objectives, including any prespecified hypotheses	In the abstract and in the introduction section pg 2,3		ne 12, 2025	
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Variables 7	controls per case Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	In the method section pg 5	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, and explanation should be provided.	In the method section pg 5
Data sources/ 8 measurement	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	In the appendix	2025 at Agence Bibliographique	
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Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study - If applicable, explain how loss to follow-up was addressed Case-control study - If applicable, explain how matching of cases and controls was addressed Cross-sectional study - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Method section inclu only a) at pg 5	on 24 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 1 Enseignement Superieur (ABES) . uding for uses related to text and data mining, Al training, and similar technology.	
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Outcome data	15	Cohort study - Report numbers of outcome events or summary measures over time Case-control study - Report numbers in each exposure category, or summary measures of exposure Cross-sectional study - Report numbers of outcome events or	In the results section pg 5,6	at Agence Bibliographique	

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Main results	16	(a) Give unadjusted estimates and, if applicable, confounderadjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	In the results section pg 5-7	n-2022-061415 on 24 November 2022. Downloaded Enseignement Superieur (copyright, including for uses related to text and dat	
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Does the healthcare system know what to cut under the pandemic emergency pressure? An observational study on geographic variation of surgical procedures in Italy

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ABSTRACT

Objectives During 2020 many countries reduced the number of elective surgeries to free up beds and cope with the COVID-19 outbreak. This situation led healthcare systems to prioritize elective interventions and to reduce the overall volumes of treatments.

The aim of this paper is to analyse whether the pandemic and the prioritization policies on elective surgery were done considering the potential inappropriateness highlighted by the measurement of geographic variation.

Setting The setting of the study is acute care with a focus on elective surgical procedures. Data were analysed at Italian regional level.

Participants The study is observational, and it relies on national hospitalization records from 2019 and 2020. The analyses refer to the 21 Italian regional health systems, using 48,917 records for 2019 and 33,821 for 2020. The surgical procedures analysed are those considered at high risk of unwarranted variation: coronary angioplasty, cholecystectomy,

colectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping.

Primary and secondary outcome measures Primary measures were the hospitalization rate and its reduction per procedure, to understand the level of potential inappropriateness. Secondary measures were the standard deviation and high/low ratio, to map the level of geographic variation.

Results For some procedures there is a linear negative relationship (e.g. tonsillectomy: rho = -0.92, p < 0.01; vein stripping: rho = -0.93, p < 0.01) between the reduction in hospitalization and its starting point. The only two procedures for which no significant differences were registered are cholecystectomy (rho = -0.22, p=0.31) and hysterectomy (rho = -0.22, p=0.33). In particular, in all cases, data show that regions with higher 2019 hospitalization rates registered a larger reduction.

Conclusions The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide the healthcare system to manage unwarranted variation when coming back to the new normal. This new starting point (lower volumes in some selected elective surgical procedures) should be used to plan elective surgical treatments that can be cancelled because of their high risk of inappropriateness.

Trial registration was not required.

Strengths and limitations of this study

- This study is based on observational routinely collected hospital discharge records of a national single-payer healthcare system.
- This study can be easily replicated in other healthcare systems.
- The analysis is limited to a selection of eight elective surgical procedures.
- The analysis is limited to administrative health data.

The COVID-19 outbreak has led many countries to reduce the number of elective surgeries, to free up beds (both in ICU and acute care wards) and healthcare professionals (mainly anaesthesiologists) to cope with the acute care treatments for COVID-19 patients[1-4]. This situation led countries, regions and counties (in the case of decentralized healthcare systems), as well as providers, to prioritize treatments and to reduce overall volumes. The polices adopted aimed to: i) ensure urgency treatments and time-dependent diseases such as stroke and AMI; ii) identify the elective treatments to be protected and ensured because they are not deferrable or are life-saving, like surgical

cancer interventions; iii) postpone deferrable elective surgery.

In particular, elective surgery has been investigated for almost a century because of its variation. For instance, in the first decades of the twentieth century, Sir James Allison Glover in his speech at the English epidemiology and state of medicine on the 27th of May 1938 cited studies of geographic variation in tonsillectomy; in the last decades of the twentieth century, Wenneberg re-launched studies on the geographic variation in userates, promoting the Dartmouth Atlas of Variation [5,6] for several services; yet, in the first decades of this century scholars have reported wide variation in tonsillectomy hospitalization rates among different geographic areas in different countries [7,8]. Nowadays, the pandemic has boosted the importance of geographic variation studies in the rebound stage of elective surgery, supporting health systems to plan a more appropriate new start.

Significant geographic variations have been revealed for several very common elective surgical interventions [6,9-13]. In some cases, like tonsillectomy, there is consensus on the opportunity to reduce the rate, especially in geographic areas presenting high hospitalization rates. Instead, in other cases the right rate and the determinants of variation are still discussed. Following revision of Wenneberg's categories by Nuti and Seghieri,[8] variation in elective surgery may occur in the following situations: i) when there are clinically proven effective services (e.g., volumes of specific surgical procedures such as hip fracture operated within 2 days) – in this case, differences in quality should be avoided; ii) when services are delivered according to care settings determined by organizational choices (e.g., in-patient admissions for interventions which could instead be performed on a day surgery basis) – in this case, differences may not have an impact on outcomes; iii) when variation reflects patients' different needs or preferences or when it often reflects physicians' discretionary choices; iv) when variation depends upon supply (supply-sensitive services), which occurs when the number of services available increases (i.e., number of beds, number of specialists etc.).

Based on this stream of literature, when geographic variation does not depend upon patients' preferences or needs [14], it can be classified as unwarranted [5, 6, 15]. Several studies [9,10] have reported that patient characteristics and preferences do not completely account for geographic variation in the provision of elective surgery; rather, greater influence is exerted by clinicians' behaviour and judgement. This classification and consideration have to be taken into account when planning the volumes of (appropriate) elective surgery to be ensured, especially in Beveridge-like systems where unwarranted variation can be seen as a signal of horizontal equity (because of the same level of patient need, variation may highlight disparities in resource allocation, the quality of care or access to the services across its territories)[16] also known as 'postcode lottery'[17].

This seems particularly relevant in this period related to the planning of rebound activities. Whilst some scholars have reported how to deal with the growing backlog of healthcare procedures related to non-communicable diseases during the pandemic crisis[18-21] (such as the delay in cancer procedures and especially in time-dependent intervention[22]),

there has still been poor debate stimulated on the relationship between the reduction of elective surgeries and unwarranted geographic variation.

Indeed, this unprecedented situation can be considered as an opportunity to revise the intervention priority list with the aim to reduce (or at least freeze) potential inappropriate interventions, thus freeing up resources (operating rooms and professionals) that can be employed in bouncing back the (appropriate) interventions that had been postponed.

The paper discusses the opportunity of managing unwarranted variation of elective surgeries in this emergency period using empirical evidence from Italy. Relying upon primary data from Italian hospital discharge records from 2019 and 2020, this paper analyses whether the pandemic and the prioritization policies for elective surgery have had an impact on regional geographic variation. In particular, considering the extant Italian regional differences in providing elective surgery, the issue investigated is whether the healthcare system grabbed the opportunity to prioritize beds to reduce potential inappropriate elective surgery. Closing remarks have been formulated for the rebound stage.

Elective surgery in the Italian context

The Italian healthcare system is a Beveridge-like model that provides universal coverage through general taxation; it is characterized by a high degree of decentralization[23]. The decentralization process, following the market-oriented reforms of the early 1990s, culminated in the 2001 constitutional reform, with the introduction of an essential healthcare benefit package (defined as Livelli Essenziali di Assistenza, LEA) guaranteed to all citizens. This reform granted more power to the regions[24]. The current institutional arrangement implies that the central government is responsible for channelling general tax revenues, defining benefit packages, exercising overall management and governments are responsible for the organization and delivery of health services through the local health authorities and public and accredited private hospitals, and can also raise local taxes and fund additional health services.

Because of the joint responsibility on healthcare, both the national and regional health systems monitor performance using tools; mainly three have been identified by the 2016 European Report[25] with specific characteristics: LEA grid; National Outcome Programme (known by the acronym PNE) and Inter-Regional Performance Evaluation System (IRPES).

All three systems highlight that geographic variation occurs across and within regions on different dimensions: access, quality, appropriateness and efficiency. Whilst LEA grid does not have specific indicators to monitor elective surgery variation, PNE and IRPES monitor some common elective surgery procedures known to have a high degree of variability, often because of the lack of standards. Figure 1 shows, as an example, that the hospitalization rates for tonsillectomy can as much as four times higher in one region compared to another.

In 2020, overall elective surgery at national level was reduced by up to 28% with respect to 2019 volumes. Mild differences were registered across regions. Larger differences show up when comparing single surgical procedures such as oncological interventions [26].

METHODS

The RECORD guidelines[27] were applied to conduct the study. This study did not involve human participants and ethics committee approval was not required. The RECORD checklist has been included in the supplementary materials.

Starting from the hospitalization records of the Italian National Health Service provided by Agenas, the paper analyses geographic variation for the procedures selected by Nuti and Seghieri[8] which usually present wide unwarranted geographic variation across and within countries: coronary angioplasty, cholecystectomy, prostatectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping (details about ICD9CM and DRGs are reported in the Appendix, in the supplementary materials. Additional information can be requested from the authors). These procedures have also been used by other authors, both separately and combined [28-30].

These crude rates (number of procedures per 100,000 inhabitants) were indirectly standardized by age and sex using SAS software and then put into a relationship with the reduction of surgical hospitalization rates of the two consecutive years 2019 and 2020.

Overall, the analyses refer to 48,917 records for 2019 and 33,821 for 2020 that represent the entire database population for the selected eight elective surgery procedures. The variables used in the study were those considered mandatory at national level so the record can be accepted as a valid one. These data were put in relation to the population information gathered from the National Institute of Statistics (Istat). Data matching was carried out at regional level. No record linkage at person level was executed.

Following the Expert Panel on Effective Ways of Investing in Health definition of resilience,[31] the percentage reduction of non-COVID-19 services can be used to assess the capacity of healthcare systems to be resilient. In fact, one specific characteristic of resilience is the capacity to adapt to shocks and structural changes, to sustain required operations and resume optimal performance as quickly as possible [31]. In this perspective, the reduction of volumes of surgical procedures can be seen as the potential of interventions to rebound after the emergency.

The matrix combining the 2019 hospitalization rates with the percentage reduction of volumes in 2020 compared to 2019 has been used to graphically understand whether the pandemic has had any effect on the unwarranted regional variation of the selected elective surgery procedures.

The Pearson correlation has been also executed, showing the p-value at 1%, 5% and 10%.

A cut-off was introduced to the absolute volumes per procedures. The cut-off was set at 10 volumes for the year 2019 to reduce the variability linked to occurrence of a low number of cases.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of our research. The analysis is based on aggregated administrative data; at this stage of the analysis, the authors did not involve patient and public lay actors.

RESULTS

Starting from the hospitalization records of the Italian National Health Service provided by Agenas, we display in Table 1 the descriptive statistics for the selected procedures in 2019.

Table 1 – Descriptive statistics for selected elective surgery hospitalization rates in 2019.

Hospitalization rate	Mean	Std Dev.	Min.	Max.	High/low ratio
Coronary angioplasty	76.27	24.86	27.22	114.44	4.20
Cholecystectomy	158.47	18.85	120.37	209.29	1.74
Hysterectomy	3.11	2.77	1.00	11.42	11.42
Prostatectomy	145.22	31.94	90.24	238.07	2.64
Knee replacement	155.87	27.49	102.33	212.95	2.08
Hip replacement	342.90	106.27	176.63	598.78	3.39
Vein stripping	46.62	34.22	7.19	135.31	18.82
Tonsillectomy	197.63	74.72	81.63	350.37	4.29

Source: Elaboration of authors on 2019 data.

Table 1 shows wide variations across geographic areas (Italian regions). Moreover, regions with high (low) rates in one procedure have not been found to be associated with high (low) rates in another, most likely reflecting autonomous practices and failures in adhering to shared guidelines and protocols among professionals.

Considering the overall reduction in elective surgery of 28%[26], Table 2 reports that the mean reduction for the selected elective surgeries sometimes is lower but registering a wide variation across Italian regions. In some cases, regions enhanced their volumes with respect to 2019. Specifically, in 2020, Valle d'Aosta increased the interventions in coronary angioplasty by 3% while Piemonte increased hysterectomy by 24%.

Table 2 – Volume reduction for selected elective surgery in 2020 compared to 2019.

Procedures	Mean reduction N	lin. reduction	Max. reduction
Coronary angioplasty	25%	-3%	57%
Cholecystectomy	34%	20%	50%
Hysterectomy	30%	-24%	100%
Prostatectomy	31%	20%	43%
Knee replacement	26%	8%	42%
Hip replacement	25%	20%	36%
Vein stripping	51%	38%	74%
Tonsillectomy	54%	27%	68%

Source: Elaboration of authors on 2020 and 2019 data.

Concerning the selected elective procedures, Figure 2 reports a chart of hospitalization rates and their difference between 2019 and 2020.

The charts exhibit that for some procedures there is a linear negative relationship between the reduction in hospitalization and its starting point. In particular, the scatter plots of hospitalization for vein stripping and tonsillectomy present a clear negative relation: regions with higher 2019 hospitalization rates registered a larger reduction.

The Pearson correlation confirms that there is a statistically significant negative correlation between the hospitalization rates and the reduction in 2020 in all the charts analysed.

In particular, Table 3 reports the correlation coefficient and the p-value. Tonsillectomy, hip replacement and prostatectomy are the procedures where the correlation is statistically significant at p < 0.01, knee replacement is statistically significant at p < 0.05 while a lower correlation and a lower significant p-value were found for coronary angioplasty (p < 0.10). No significant correlation was found for cholecystectomy and hysterectomy.

Table 3 – Correlation between 2019 hospitalization rates and hospitalization rate reduction.

Procedures	ρ	p-value
Tonsillectomy	-0.92	0.00
Hip replacement	-0.79	0.00
Prostatectomy	-0.72	0.00
Coronary angioplasty	-0.38	0.08
Cholecystectomy	-0.22	0.31
Hysterectomy	-0.22	0.33
Vein stripping	-0.93	0.00
Knee replacement	-0.51	0.01
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Source: Elaboration of authors on 2020 and 2019 data.

Overall, the lower the 2019 hospitalization rate, the larger the reduction of hospitalization rates.

DISCUSSION

Considering the selected elective surgery indicators, we found that regions with higher potential inappropriate elective surgery hospitalization rates are those that reduced their volumes more.

In particular, tonsillectomy and vein stripping, which have been shown to be among the procedures with wider variation across geographic areas, are also those with a larger reduction (in both cases, the correlation coefficient is around -0.9 with a p-value < 0.01). These straightforward results seem to support the idea that under emergency pressure, the healthcare system is more likely to provide stricter directions to allocate healthcare resources, preserving them for elective surgical interventions which have stronger clinical evidence. Yet, there is no standard for a number of surgical treatments; in those cases, the 2019 national median can be considered as a reference for all the regional health systems that overcame it in 2019 and the reduction that occurred in 2020 could not be taken into account when planning rebound and new activities. This evidence seems to confirm, at least for the potentially inappropriate hospitalization rate, the rule of thumb known as Romer's law.

The drop-offs occurred to different degrees. These differences are not strictly linked to the level of variation or the level of use-rates. For instance, in the case of hysterectomy, for which a very high level of geographic variation was registered (as shown by Table 1), no significant correlation was found between use-rates and their reduction (as shown by Table 3); similarly, relatively lower use-rates of vein stripping (as shown in Table 1) were linked to a higher correlation with their drop-offs (as shown in Table 3).

Tonsillectomy is the procedure that registered the second highest negative correlation coefficient between use-rates and their drop-offs (rho = -0.92, p < 0.01). After the introduction of Italian national guidelines there was a decrease in the total number of tonsillectomies and their geographical variation [32]. However, in 2019 a 4-fold geographic variation was registered (as shown in Table 1) and the uneven reduction that occurred across the Italian regions during 2020 seems to confirm that the doubts of the scientific community [33] related to the trade-offs of benefits against risks, discomfort and costs [7] are not solved yet.

Under the same national recommendation to protect those interventions with the highest degree of clinical relevance, the drop-offs among the procedures were different across regions, and they were not necessarily linked to the level of variation or the level of use-

rates. Different healthcare performance between northern and southern regions has already been reported by other authors [24,34]. Conversely, this study does not report a clear North-South pattern in the high(low) hospitalization rates analysed (detailed data of the regional use-rates with the North-South area labels are provided in the supplementary materials). This evidence is in line with that of a recent study on the impact of COVID-19 in Italy which found that the pandemic exacerbated some disparities related to socioeconomic or gender issues but there was no clear-cut evidence from the pandemic of a North-South divide for variations either in the quality of service provided during the first year of the pandemic or in the overall hospitalization rates[35]. Disparities instead were exacerbated, in both health and access to healthcare for some fragile population groups, such as the elderly and migrants [35]. It is possible that differences in performance between North and South mainly concern resource allocation and management while variation in medical practice such as that presented in this analysis occurred everywhere. In the former case, regions using a performance measurement system may help to change professional behaviours, while in the latter case the sharing process and a second opinion may provide that help [16, 36].

Further research is needed to better understand the role played by the different stakeholders: regional managers or health authority managers, professionals and patients. At first evidence, although fear of the population has affected the surgical reduction, the impact seems to be rather limited; a 2021 survey of the population highlighted that 8% of Italians preferred to postpone or avoid surgical treatments because of the fear of COVID-19 [37].

As a preliminary study on this topic, this research presents some limitations. First, the study context focused on the Italian healthcare system and its organizational structure so that it cannot be generalized. Nevertheless, geographic variation is a topic investigated in several countries, although with different intensity (e.g., the USA showed double the userate for hernia compared to the UK [29], while France showed a lower level of use-rates for some procedures with respect to the USA or UK[38]). Hence, evidence coming from this study may be analysed and replicated in both high-, and low- and middle-income countries [29, 38, 39].

However, this study provides evidence to enlarge the debate on this relevant topic in Italy and also in those countries aiming to analyse what happened in 2020 to the unwarranted variation in elective surgery in their countries.

Second, there could be other indicators as valuable and informative as those included in the analysis. However, we considered the ones selected by a group of Italian regional healthcare managers and already included in two of the three performance evaluation systems actually used in Italy, IRPES and PNE, as indicators monitoring variation in surgical procedures.

Third, although we used standardized hospitalization rates, further analyses can be done to better understand if patients' characteristics may have played any role in the reduction in volume. Other investigations could be also useful in understanding if some factors (such as the presence of private providers or patient outflow) may explain variation in the volume reduction.

Geographic variation may be a signal of inappropriateness related to overuse, for supplysensitive care such as that related to the absence of clinical theories; or to misuse, for preference-sensitive care such as treatment that should be linked to patients' preferences, weak for prostatectomy [40].

However, we cannot exclude the possibility that underuse may occur. Even if we selected procedures that are often considered as being overused, there is still the possibility that some of the patients who did not receive care ended up not getting the care they needed. Indeed, variation in use-rates is an indirect measure of inappropriateness [41,42] To

CONCLUSION

COVID-19 led healthcare systems to make hard choices in providing services. A large number of cuts, especially for acute care services, have been put in place. That has led healthcare systems to reflect upon prioritizing access to services, which is certainly an ethical issue but also an opportunity to reduce potential inappropriate interventions.

This study aimed at providing preliminary evidence on the impact of the pandemic on the geographic variation of selected elective surgery procedures. In particular, the group of oncological surgical interventions belongs to the preference-sensitive categories of Wenneberg mostly influenced by the clinician's decision. Wide variation in elective surgery rarely depends on patients' preferences or needs. In fact, a recent study demonstrated that often reservation of the operating room does not depend upon demand or waiting times.[13] This variation category is also the one requiring a deeper involvement of clinicians because it asks them to align their behaviour with clinical guidelines or practices.[8,16] The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut the surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide healthcare systems to manage unwarranted variation. In fact, when coming back to the new normal after this unpredictable situation given by the pandemic, it is important to use this new starting point (lower volumes in some selected elective surgical procedures) to plan elective surgical treatments that can be cancelled because of their high potential for inappropriateness.

Unfortunately, there are no gold standards for surgical use-rates. Under these circumstances, the public disclosure of information about use-rates among regions (and the risk of surgical intervention) can enable a discussion about appropriate care [16,29, 42,43].

In particular, once healthcare systems have achieved lower hospitalization rates for potentially inappropriate treatments, as happened during the pandemic, it is important to reverse the burden of proof in the cases of surgical intervention which are at high risk of inappropriateness. Hence, it could be useful to investigate if it is right that the region should come back to the past performance for interventions which have uncertain evidence instead of asking for a reduction of these cases.

Statements

- a. **Contributorship statement:** All the authors conceived the paper; MV wrote the original version and executed the calculations; SN and DM reviewed the manuscript.
- b. Competing interests: None.
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- d. **Data sharing statement:** Aggregated data can be shared upon request to the corresponding author.
- e. **Ethics statement:** This study did not involve human participants. Ethics committee approval was not necessary.

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Figure 1 – Hospitalization rates for tonsillectomy across and within Italian regions in 2019.

Source: PNE, 2019.

Figure 2 –Matrix of 2019 hospitalization rate and difference in hospitalization rate between 2019 and 2020 for selected elective surgery procedures.

Source: Elaboration of authors on 2020 and 2019 data. Y-axis represents the difference in hospitalization rate between 2019 and 2020. X-axis represents the 2019 hospitalization rate. Lines represent the linear fit of the values.

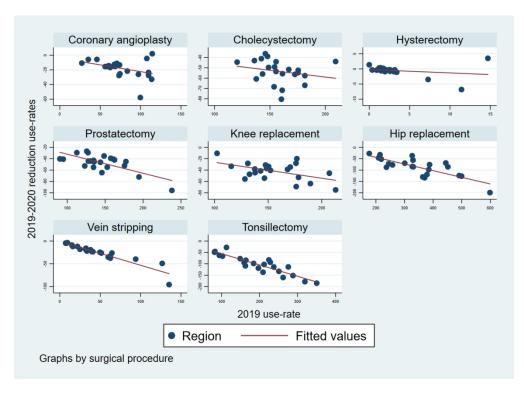


Figure 2 –Matrix of 2019 hospitalization rate and difference in hospitalization rate between 2019 and 2020 for selected elective surgery procedures.

Source: Elaboration of authors on 2020 and 2019 data. Y-axis represents the difference in hospitalization rate between 2019 and 2020. X-axis represents the 2019 hospitalization rate. Lines represent the linear fit of the values.

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Appendix.

Codes of the ICD9CM and DRGs used for selecting cases, elective surgery.

	ICD9CM codes/DRG	
	Grouper XXIV	
Procedure	codes	Notes
Tonsillectomy	28.2x; 28.3x	Patients aged 0-18
Vein stripping	DRG 119	
		All women aged 18
		yrs and over with
		benign uterine
Hysterectomy	68.3x-68.9x	conditions
		Total knee
Knee replacement	81.54	replacement
		All patients aged
		65 and over,
		excludes diagnosis
		codes 820-821.39,
Hip replacement	81.51	996.4x
		All patients with
		ICD-9-CM Diagnosis
	45.71-45.76;	Code 153: malignant
Colectomy	45.79; 45.8x	neoplasm of colon
	36.03; 36.04;	
Coronary	36.06; 36.07;	
Angioplasty	36.09; 00.66	
Cholecystectomy	DRG: 493;494	

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Title and abstra	act			or us	Teporteu
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Introduction				- 	
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Study Design	4	Present key elements of study design early in the paper	In the method section pg 5	Agence	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	In the method section 4,5	Agence Bibliograph	
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		eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> - Give the eligibility criteria, and the sources and methods of selection of participants (b) Cohort study - For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> - For matched studies, give matching criteria and the number of	In the method section pg 5	population selection (suck as codes or algorithms used to identify subjects) should be listed in detail. If the is is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided supported use of a flow diagram or other graphed linkage of databases, considered use of a flow diagram or other graphed linkage process, including the number of individuals with linked data as each stage.	Included in the method section pg 5 Included in the method section pg 5
Variables	7	controls per case Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	In the method section pg 5	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, and explanation should be provided.	In the method section pg 5
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	In the appendix	2025 at Agence Bibliographique gies.	
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Study size	10	Explain how the study size was arrived at	In the method section	(D	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	pg 5 In the method section	-061 <i>4</i>	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study - If applicable, explain how loss to follow-up was addressed Case-control study - If applicable, explain how matching of cases and controls was addressed Cross-sectional study - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Method section included only a) at pg 5	ovember 2022. Downloaded from http://bmjopen.bmj.com/ on June 1 Enseignement Superieur (ABES) . r uses related to text and data mining, Al training, and similar techno	
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Outcome data	15	Cohort study - Report numbers of outcome events or summary measures over time Case-control study - Report numbers in each exposure category, or summary measures of exposure Cross-sectional study - Report numbers of outcome events or	In the results section pg 5,6	5 at Agence Bibliographique	

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Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	In the discussions section	Agence Bibliographique de l	

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Generalisability	21	Discuss the generalisability (external validity) of the study results	In the discussions section, pg7,8		//bmjopen-2022-06	
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Procedure	Region	Area	2019 use-rate 2020 use-rat		2019-2020 reduction use rates
Tonsillectomy	Piemonte	North		136	-152
Tonsillectomy	Valle d'Aosta	North		141	-83
Tonsillectomy	Lombardia	North	197	78	-119
Tonsillectomy	Bolzano	North		141	-179
Tonsillectomy	Trento	North		123	-114
Tonsillectomy	Veneto	North		135	-93
Tonsillectomy	Friuli Venezia Giuli	a North		162	-114
Tonsillectomy	Liguria	North		165	-185
Tonsillectomy	Emilia Romagna	North	251	118	-133
Tonsillectomy	Toscana	Center	164	80	-84
Tonsillectomy	Umbria	Center		102	-160
Tonsillectomy	Marche	Center	212	109	-103
Tonsillectomy	Lazio	Center	113	85	-28
Tonsillectomy	Abruzzo	South	149	72	-77
Tonsillectomy	Molise	South	94	31	-63
Tonsillectomy	Campania	South	102	36	-66
Tonsillectomy	Puglia	South	82	32	-49
Tonsillectomy	Basilicata	South	163	54	-109
Tonsillectomy	Calabria	South	83	37	-46
Tonsillectomy	Sicilia	South	209	72	-137
Tonsillectomy	Sardegna	South	159	64	-95
Tonsillectomy	Italia	Italy	184	86	-99
Cholecystectomy	Piemonte	North	161	89	-72
Cholecystectomy	Valle d'Aosta	North	143	87	-56
Cholecystectomy	Lombardia	North	154	85	-68
Cholecystectomy	Bolzano	North	120	76	-44
Cholecystectomy	Trento	North		123	-52
Cholecystectomy	Veneto	North		111	-32 -44
Cholecystectomy	Friuli Venezia Giuli			101	-44 -41
			160	80	-80
Cholecystectomy	Liguria Emilia Romagna	North North	149	99	-50 -50
Cholecystectomy		Center			-50 -67
Cholecystectomy	Toscana			115	
Cholecystectomy	Umbria	Center		115	-52
Cholecystectomy	Marche	Center		109	-39
Cholecystectomy	Lazio	Center		110	-36
Cholecystectomy	Abruzzo	South		165	-44
Cholecystectomy	Molise	South	136	93	-43
Cholecystectomy	Campania	South		124	-58
Cholecystectomy	Puglia	South		102	-54
Cholecystectomy	Basilicata	South	138	77	-61
Cholecystectomy	Calabria	South		116	-56
Cholecystectomy	Sicilia	South		121	-55
Cholecystectomy	Sardegna	South		105	
Cholecystectomy	Italia	Italy		106	
Knee replacement	Piemonte	North		102	
Knee replacement	Valle d'Aosta	North	i i	126	-64
Knee replacement	Lombardia	North	147	92	
Knee replacement	Bolzano	North		138	
Knee replacement	Trento	North		126	-53
Knee replacement	Veneto	North		157	-20
Knee replacement	Friuli Venezia Giuli	a North	171	136	-35
Knee replacement	Liguria	North	176	107	-69
Knee replacement	Emilia Romagna	North		117	-34
Knee replacement	Toscana	Center	207	162	-45
Knee replacement	Umbria	Center	176	148	-28
Knee replacement	Marche	Center		129	-39
Knee replacement	Lazio	Center		111	-37
Knee replacement	Abruzzo	South		117	-31
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Knee replacement	Basilicata	South	128	73	-56
Knee replacement	Calabria	South	138	93	-45
Knee replacement	Sicilia	South	138	100	-38
Knee replacement	Sardegna	South	102	92	-10
Knee replacement	Italia	Italy	152	112	-40
Hip replacement	Piemonte	North	379	259	-119
Hip replacement	Valle d'Aosta	North	491	367	-124
Hip replacement	Lombardia	North	364	234	-130
Hip replacement	Bolzano	North	599	400	-199
Hip replacement	Trento	North	500	373	-126
Hip replacement	Veneto	North	452	366	-86
Hip replacement	Friuli Venezia Giuli		444	376	-68
Hip replacement	Liguria	North	370	237	-134
Hip replacement	Emilia Romagna	North	385	287	-97
Hip replacement	Toscana	Center	388	312	-76
Hip replacement	Umbria	Center	327	290	-37
Hip replacement	Marche	Center	330	274	-56
Hip replacement	Lazio	Center	301	231	-70
Hip replacement	Abruzzo	South	327	243	-84
Hip replacement	Molise	South	258	181	-77
Hip replacement	Campania	South	245	173	-72
Hip replacement	Puglia	South	214	182	-32
Hip replacement	Basilicata	South	237	149	-87
Hip replacement	Calabria	South	219	167	-52
Hip replacement	Sicilia	South	209	163	-46
Hip replacement	Sardegna	South	177	150	-27
Hip replacement	Italia	Italy	331	245	-85
Vein stripping	Piemonte	North	62	29	-33
Vein stripping	Valle d'Aosta	North	135	40	-96
Vein stripping	Lombardia	North	8	3	-5
Vein stripping	Bolzano	North	32	13	-19
Vein stripping	Trento	North	25	7	-18
Vein stripping	Veneto	North	9	6	-4
Vein stripping	Friuli Venezia Giuli	a North	94	54	-40
Vein stripping	Liguria	North	16	4	-12
Vein stripping	Emilia Romagna	North	127	78	-49
Vein stripping	Toscana	Center	60	25	-35
Vein stripping	Umbria	Center	63	25	-38
Vein stripping	Marche	Center	51	25	-26
Vein stripping	Lazio	Center	32	16	-16
Vein stripping	Abruzzo	South	65	38	-26
Vein stripping	Molise	South	40	17	-23
Vein stripping	Campania	South	34	11	-22
Vein stripping	Puglia	South	15	6	-9
Vein stripping	Basilicata	South	41	17	-24
Vein stripping	Calabria	South	7	3	-4
Vein stripping	Sicilia	South	22	10	-12
Vein stripping	Sardegna	South	50	25	-25
Vein stripping	Italia	Italy	38	19	-19
Coronary angioplasty		North	110	86	-24
Coronary angioplasty		North	114	116	2
Coronary angioplasty		North	114	81	-33
Coronary angioplasty		North	46	40	-6

Coronary angioplasty	Trento	North	59	43	-15
Coronary angioplasty		North		59	-13 -11
Coronary angioplasty			35	29	-11
Coronary angioplasty		North	61	46	
Coronary angioplasty		North	68	55	-13
Coronary angioplasty		Center	56	41	<u>-15</u> -16
Coronary angioplasty		Center	62	46	<u>-10</u> -17
Coronary angioplasty		Center	69	53	-15
Coronary angioplasty		Center	74	61	-13
Coronary angioplasty		South	67	52	<u>-15</u>
Coronary angioplasty		South	108	103	-15
Coronary angioplasty		South	110	82	-3
Coronary angioplasty		South	97	71	-26
Coronary angioplasty		South	74	49	-25
Coronary angioplasty		South	100	49	- <u>-23</u> -58
Coronary angioplasty		South	73	46	-28
Coronary angioplasty		South	27	16	-20 -11
		Italy	84	62	-22
Coronary angioplasty	Piemonte	North	195	123	- <u>-22</u> -72
Prostatectomy					
Prostatectomy	Valle d'Aosta	North	238	142	-96
Prostatectomy	Lombardia	North	146	81	<u>-64</u>
Prostatectomy	Bolzano	North	176	123	-52
Prostatectomy	Trento	North	135	92	-43
Prostatectomy	Veneto	North	149	113	-35
Prostatectomy	Friuli Venezia Giulia		127	98	-29
Prostatectomy	Liguria	North	123	70	-53
Prostatectomy	Emilia Romagna	North	128	84	-44
Prostatectomy	Toscana	Center	126	99	-27
Prostatectomy	Umbria	Center	153	98	-55
Prostatectomy	Marche	Center	162	120	-42
Prostatectomy	Lazio	Center	161	120	-41
Prostatectomy	Abruzzo	South	177	132	-45
Prostatectomy	Molise	South	135	90	-45
Prostatectomy	Campania	South	113	83	-29
Prostatectomy	Puglia	South	131	87	-44
Prostatectomy	Basilicata	South	90	50	-40
Prostatectomy	Calabria	South	95	54	-41
Prostatectomy	Sicilia	South	157	118	-39
Prostatectomy	Sardegna	South	135	80	-55
Prostatectomy	Italia	Italy	144	98	-46
Hysterectomy	Piemonte	North	1	2	0
Hysterectomy	Valle d'Aosta	North	15	18	3
Hysterectomy	Lombardia	North	1_	1	0
Hysterectomy	Bolzano	North	0	1	1
Hysterectomy	Trento	North	0	0	0
Hysterectomy	Veneto	North	2	1	-1
Hysterectomy	Friuli Venezia Giulia	North	2	1	-1
Hysterectomy	Liguria	North	2	2	0
Hysterectomy	Emilia Romagna	North	1	1	-1
Hysterectomy	Toscana	Center	1	1	0
Hysterectomy	Umbria	Center	1	2	0
Hysterectomy	Marche	Center	3	2	0
Hysterectomy	Lazio	Center	7	4	-3
Hysterectomy	Abruzzo	South	11	5	-7
Hysterectomy	Molise	South	3	2	-1
Hysterectomy	Campania	South	3	3	0
Hysterectomy	Puglia	South	3	2	-1
Hysterectomy	Basilicata	South	3	2	0
Hysterectomy	Calabria	South	2	2	0
Hysterectomy	Sicilia	South	2	2	0
Hysterectomy	Sardegna	South			0
Hysterectomy	Italia	Italy	3	2	-1
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Does the healthcare system know what to cut under the pandemic emergency pressure? An observational study on geographic variation of surgical procedures in Italy

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Does the healthcare system know what to cut under the pandemic emergency pressure? An observational study on geographic variation of surgical procedures in Italy

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ABSTRACT

Objectives During 2020 many countries reduced the number of elective surgeries to free up beds and cope with the COVID-19 outbreak. This situation led healthcare systems to prioritize elective interventions and reduce the overall volumes of treatments.

The aim of this paper is to analyse whether the pandemic and the prioritization policies on elective surgery were done considering the potential inappropriateness highlighted by the measurement of geographic variation.

Setting The setting of the study is acute care with a focus on elective surgical procedures. Data were analysed at the Italian regional level.

Participants The study is observational and relies on national hospitalization records from 2019 and 2020. The analyses refer to the 21 Italian regional health systems, using 48,917 records for 2019 and 33,821 for 2020. The surgical procedures analysed are those considered at high risk of unwarranted variation: coronary angioplasty, cholecystectomy,

colectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement, and vein stripping.

Primary and secondary outcome measures Primary measures were the hospitalization rate and its reduction per procedure, to understand the level of potential inappropriateness. Secondary measures were the standard deviation and high/low ratio, to map the level of geographic variation.

Results For some procedures there is a linear negative relationship (e.g. tonsillectomy: rho = -0.92, p < 0.01; vein stripping: rho = -0.93, p < 0.01) between the reduction in hospitalization and its starting point. The only two procedures for which no significant differences were registered are cholecystectomy (rho = -0.22, p=0.31) and hysterectomy (rho = -0.22, p=0.33). In particular, in all cases, data show that regions with higher 2019 hospitalization rates registered a larger reduction.

Conclusions The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide the healthcare system to manage unwarranted variation when coming back to the new normal. This new starting point (lower volumes in some selected elective surgical procedures) should be used to plan elective surgical treatments that can be cancelled because of their high risk of inappropriateness.

Trial registration was not required.

Strengths and limitations of this study

- This study is based on observational routinely collected hospital discharge records of a national single-payer healthcare system.
- This study can be easily replicated in other healthcare systems.
- The analysis is limited to a selection of eight elective surgical procedures.
- The analysis is limited to administrative health data.

INTRODUCTION

The COVID-19 outbreak has led many countries to reduce the number of elective surgeries, to free up beds (both in ICU and acute care wards) and healthcare professionals (mainly anaesthesiologists) to cope with the acute care treatments for COVID-19 patients[1-4]. This situation led countries, regions, and counties (in the case of decentralized healthcare systems), as well as providers, to prioritize treatments and reduce overall volumes. The policies adopted aimed to i) ensure urgent treatments and time-dependent diseases such as stroke and AMI; ii) identify the elective treatments to be protected and ensured because they are not deferrable or are life-saving, like surgical cancer interventions; iii) postpone deferrable elective surgery.

In particular, elective surgery has been investigated for almost a century because of its variation. For instance, in the first decades of the twentieth century, Sir James Allison Glover in his speech at the English epidemiology and state of medicine on the 27th of May 1938 cited studies of geographic variation in tonsillectomy; in the last decades of the twentieth century, Wenneberg re-launched studies on the geographic variation in userates, promoting the Dartmouth Atlas of Variation [5,6] for several services; yet, in the first decades of this century scholars have reported wide variation in tonsillectomy hospitalization rates among different geographic areas in different countries [7,8]. Nowadays, the pandemic has boosted the importance of geographic variation studies in the rebound stage of elective surgery, supporting health systems to plan a more appropriate new start.

Significant geographic variations have been revealed for several very common elective surgical interventions [6,9-13]. In some cases, like a tonsillectomy, there is consensus on the opportunity to reduce the rate, especially in geographic areas presenting high hospitalization rates. Instead, in other cases, the right rate and the determinants of variation are still discussed. Following revision of Wenneberg's categories by Nuti and Seghieri,[8] variation in elective surgery may occur in the following situations: i) when there are clinically proven effective services (e.g., volumes of specific surgical procedures such as hip fracture operated within 2 days) – in this case, differences in quality should be avoided; ii) when services are delivered according to care settings determined by organizational choices (e.g., in-patient admissions for interventions which could instead be performed on a day surgery basis) – in this case, differences may not have an impact on outcomes; iii) when variation reflects patients' different needs or preferences or when it often reflects physicians' discretionary choices; iv) when variation depends upon supply (supply-sensitive services), which occurs when the number of services available increases (i.e., number of beds, number of specialists, etc.).

Based on this stream of literature, when geographic variation does not depend upon patients' preferences or needs [14], it can be classified as unwarranted [5, 6, 15]. Several studies [9,10] have reported that patient characteristics and preferences do not completely account for geographic variation in the provision of elective surgery; rather, greater influence is exerted by clinicians' behaviour and judgement. This classification and consideration have to be taken into account when planning the volumes of (appropriate) elective surgery to be ensured, especially in Beveridge-like systems where unwarranted variation can be seen as a signal of horizontal equity (because of the same level of patient need, variation may highlight disparities in resource allocation, the quality of care or access to the services across its territories)[16] also known as 'postcode lottery'[17].

This seems particularly relevant in this period related to the planning of rebound activities. Whilst some scholars have reported how to deal with the growing backlog of healthcare procedures related to non-communicable diseases during the pandemic crisis [18-21] (such as the delay in cancer procedures and especially in the time-dependent

intervention[22]), there has still been poor debate stimulated on the relationship between the reduction of elective surgeries and unwarranted geographic variation.

Indeed, this unprecedented situation can be considered as an opportunity to revise the intervention priority list with the aim to reduce (or at least freeze) potential inappropriate interventions, thus freeing up resources (operating rooms and professionals) that can be employed in bouncing back the (appropriate) interventions that had been postponed.

The paper discusses the opportunity of managing unwarranted variation of elective surgeries in this emergency period using empirical evidence from Italy. Relying upon primary data from Italian hospital discharge records from 2019 and 2020, this paper analyses whether the pandemic and the prioritization policies for elective surgery have had an impact on regional geographic variation. In particular, considering the extant Italian regional differences in providing elective surgery, the issue investigated is whether the healthcare system grabbed the opportunity to prioritize beds to reduce potential inappropriate elective surgery. Closing remarks have been formulated for the rebound stage.

Elective surgery in the Italian context

The Italian healthcare system is a Beveridge-like model that provides universal coverage through general taxation; it is characterized by a high degree of decentralization[23]. The decentralization process, following the market-oriented reforms of the early 1990s, culminated in the 2001 constitutional reform, with the introduction of an essential healthcare benefits package (defined as Livelli Essenziali di Assistenza, LEA) guaranteed to all citizens. This reform granted more power to the regions[24]. The current institutional arrangement implies that the central government is responsible for channelling general tax revenues, defining benefit packages, exercising overall management and governments are responsible for the organization and delivery of health services through the local health authorities and public and accredited private hospitals, and can also raise local taxes and fund additional health services.

Because of the joint responsibility for healthcare, both the national and regional health systems monitor performance using tools; mainly three have been identified by the 2016 European Report[25] with specific characteristics: LEA grid; National Outcome Programme (known by the acronym PNE) and Inter-Regional Performance Evaluation System (IRPES).

All three systems highlight that geographic variation occurs across and within regions on different dimensions: access, quality, appropriateness, and efficiency. Whilst the LEA grid does not have specific indicators to monitor elective surgery variation, PNE and IRPES monitor some common elective surgery procedures known to have a high degree of variability, often because of the lack of standards. Figure 1 shows, as an example, that the hospitalization rates for tonsillectomy can be as much as four times higher in one region compared to another.

In 2020, overall elective surgery at the national level was reduced by up to 28% with respect to 2019 volumes. Mild differences were registered across regions. Larger differences show up when comparing single surgical procedures such as oncological interventions [26].

METHODS

The RECORD guidelines[27] were applied to conduct the study. This study did not involve human participants and ethics committee approval was not required. The RECORD

Starting from the hospitalization records of the Italian National Health Service provided by Agenas, the paper analyses geographic variation for the procedures selected by Nuti and Seghieri[8] which usually present wide unwarranted geographic variation across and within countries: coronary angioplasty, cholecystectomy, prostatectomy, knee replacement, hysterectomy, tonsillectomy, hip replacement and vein stripping (details about ICD9CM and DRGs are reported in the Appendix, in the supplementary materials number 2. Additional information can be requested from the authors). These procedures have also been used by other authors, both separately and combined [28-30].

These crude rates (number of procedures per 100,000 inhabitants) were indirectly standardized by age and sex using SAS software and then put into a relationship with the reduction of surgical hospitalization rates for the two consecutive years 2019 and 2020.

Overall, the analyses refer to 48,917 records for 2019 and 33,821 for 2020 that represent the entire database population for the selected eight elective surgery procedures. The variables used in the study were those considered mandatory at the national level so the record can be accepted as a valid one. These data were put in relation to the population information gathered from the National Institute of Statistics (Istat). Data matching was carried out at the regional level. No record linkage at the person level was executed.

Following the Expert Panel on Effective Ways of Investing in Health definition of resilience,[31] the percentage reduction of non-COVID-19 services can be used to assess the capacity of healthcare systems to be resilient. In fact, one specific characteristic of resilience is the capacity to adapt to shocks and structural changes, to sustain required operations, and resume optimal performance as quickly as possible [31]. In this perspective, the reduction of volumes of surgical procedures can be seen as the potential for interventions to rebound after the emergency.

The matrix combining the 2019 hospitalization rates with the percentage reduction of volumes in 2020 compared to 2019 has been used to graphically understand whether the pandemic has had any effect on the unwarranted regional variation of the selected elective surgery procedures.

The Pearson correlation has been also executed, showing the p-value at 1%, 5%, and 10%.

A cut-off was introduced to the absolute volumes per procedure. The cut-off was set at 10 volumes for the year 2019 to reduce the variability linked to the occurrence of a low number of cases.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting, or dissemination plans of our research. The analysis is based on aggregated administrative data; at this stage of the analysis, the authors did not involve patient and public lay actors.

RESULTS

Starting from the hospitalization records of the Italian National Health Service provided by Agenas, we display in Table 1 the descriptive statistics for the selected procedures in 2019.

Table 1 – Descriptive statistics for selected elective surgery hospitalization rates in 2019.

Hospitalization rate	Mean	Std Dev.	Min.	Max.	High/low ratio
Coronary angioplasty	76.27	24.86	27.22	114.44	4.20
Cholecystectomy	158.47	18.85	120.37	209.29	1.74
Hysterectomy	3.11	2.77	1.00	11.42	11.42
Prostatectomy	145.22	31.94	90.24	238.07	2.64
Knee replacement	155.87	27.49	102.33	212.95	2.08
Hip replacement	342.90	106.27	176.63	598.78	3.39
Vein stripping	46.62	34.22	7.19	135.31	18.82
Tonsillectomy	197.63	74.72	81.63	350.37	4.29

Source: Elaboration of authors on 2019 data.

Table 1 shows wide variations across geographic areas (Italian regions). Moreover, regions with high (low) rates in one procedure have not been found to be associated with high (low) rates in another, most likely reflecting autonomous practices and failures in adhering to shared guidelines and protocols among professionals.

Considering the overall reduction in elective surgery of 28%[26], Table 2 reports that the mean reduction for the selected elective surgeries sometimes is lower but registers a wide variation across Italian regions. In some cases, regions enhanced their volumes concerning 2019. Specifically, in 2020, Valle d'Aosta increased the interventions in coronary angioplasty by 3% while Piemonte increased hysterectomy by 24%.

Table 2 – Volume reduction for selected elective surgery in 2020 compared to 2019.

Procedures	Mean reduction M	in. reduction	Max. reduction
Coronary angioplasty	25%	-3%	57%
Cholecystectomy	34%	20%	50%
Hysterectomy	30%	-24%	100%
Prostatectomy	31%	20%	43%
Knee replacement	26%	8%	42%
Hip replacement	25%	20%	36%
Vein stripping	51%	38%	74%
Tonsillectomy	54%	27%	68%

Source: Elaboration of authors on 2020 and 2019 data.

Concerning the selected elective procedures, Figure 2 reports a chart of hospitalization rates and their difference between 2019 and 2020.

The charts exhibit that for some procedures there is a linear negative relationship between the reduction in hospitalization and its starting point. In particular, the scatter plots of hospitalization for vein stripping and tonsillectomy present a clear negative relation: regions with higher 2019 hospitalization rates registered a larger reduction.

The Pearson correlation confirms that there is a statistically significant negative correlation between the hospitalization rates and the reduction in 2020 in all the charts analysed.

In particular, Table 3 reports the correlation coefficient and the p-value. Tonsillectomy, hip replacement, and prostatectomy are the procedures where the correlation is statistically significant at p < 0.01, knee replacement is statistically significant at p < 0.05 while a lower correlation and a lower significant p-value were found for coronary angioplasty (p < 0.10). No significant correlation was found for cholecystectomy and hysterectomy.

Table 3 – Correlation between 2019 hospitalization rates and hospitalization rate reduction.

Procedures	ρ	p-value
Tonsillectomy	-0.92	0.00
Hip replacement	-0.79	0.00
Prostatectomy	-0.72	0.00
Coronary angioplasty	-0.38	0.08
Cholecystectomy	-0.22	0.31
Hysterectomy	-0.22	0.33
Vein stripping	-0.93	0.00
Knee replacement	-0.51	0.01
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Source: Elaboration of authors on 2020 and 2019 data.

Overall, the lower the 2019 hospitalization rate, the larger the reduction of hospitalization rates.

DISCUSSION

Considering the selected elective surgery indicators, we found that regions with higher potential inappropriate elective surgery hospitalization rates are those that reduced their volumes more.

In particular, tonsillectomy and vein stripping, which have been shown to be among the procedures with wider variation across geographic areas, are also those with a larger reduction (in both cases, the correlation coefficient is around -0.9 with a p-value < 0.01). These straightforward results seem to support the idea that under emergency pressure, the healthcare system is more likely to provide stricter directions to allocate healthcare resources, preserving them for elective surgical interventions which have stronger clinical evidence. Yet, there is no standard for a number of surgical treatments; in those cases, the 2019 national median can be considered as a reference for all the regional health systems that overcame it in 2019 and the reduction that occurred in 2020 could not be taken into account when planning rebound and new activities. This evidence seems to confirm, at least for the potentially inappropriate hospitalization rate, the rule of thumb known as Romer's law.

The drop-offs occurred to different degrees. These differences are not strictly linked to the level of variation or the level of use-rates. For instance, in the case of hysterectomy, for which a very high level of geographic variation was registered (as shown in Table 1), no significant correlation was found between use-rates and their reduction (as shown in Table 3); similarly, relatively lower use-rates of vein stripping (as shown in Table 1) were linked to a higher correlation with their drop-offs (as shown in Table 3).

Tonsillectomy is the procedure that registered the second highest negative correlation coefficient between use-rates and their drop-offs (rho = -0.92, p < 0.01). After the introduction of Italian national guidelines, there was a decrease in the total number of tonsillectomies and their geographical variation [32]. However, in 2019 a 4-fold geographic variation was registered (as shown in Table 1) and the uneven reduction that occurred across the Italian regions during 2020 seems to confirm that the doubts of the scientific community [33] related to the trade-offs of benefits against risks, discomfort, and costs [7] are not solved yet.

Under the same national recommendation to protect those interventions with the highest degree of clinical relevance, the drop-offs among the procedures were different across regions, and they were not necessarily linked to the level of variation or the level of use-

rates. Different healthcare performance between northern and southern regions has already been reported by other authors [24,34]. Conversely, this study does not report a clear North-South pattern in the high(low) hospitalization rates analysed (detailed data of the regional use-rates with the North-South area labels are provided in the supplementary materials number 3). This evidence is in line with that of a recent study on the impact of COVID-19 in Italy which found that the pandemic exacerbated some disparities related to socio-economic or gender issues but there was no clear-cut evidence from the pandemic of a North-South divide for variations either in the quality of service provided during the first year of the pandemic or in the overall hospitalization rates[35]. Disparities instead were exacerbated, in both health and access to healthcare for some fragile population groups, such as the elderly and migrants [35]. It is possible that differences in performance between North and South mainly concern resource allocation and management while variation in medical practice such as that presented in this analysis occurred everywhere. In the former case, regions using a performance measurement system may help to change professional behaviours, while in the latter case the sharing process and a second opinion may provide that help [16, 36].

Further research is needed to better understand the role played by the different stakeholders: regional managers or health authority managers, professionals, and patients. At first evidence, although fear of the population has affected the surgical reduction, the impact seems to be rather limited; a 2021 survey of the population highlighted that 8% of Italians preferred to postpone or avoid surgical treatments because of the fear of COVID-19 [37].

As a preliminary study on this topic, this research presents some limitations. First, the study context focused on the Italian healthcare system and its organizational structure so that it cannot be generalized. Nevertheless, geographic variation is a topic investigated in several countries, although with different intensity (e.g., the USA showed double the userate for hernia compared to the UK [29], while France showed a lower level of use-rates for some procedures with respect to the USA or UK[38]). Hence, evidence coming from this study may be analysed and replicated in both high-, and low- and middle-income countries [29, 38, 39].

However, this study provides evidence to enlarge the debate on this relevant topic in Italy and also in those countries aiming to analyse what happened in 2020 to the unwarranted variation in elective surgery in their countries.

Second, there could be other indicators as valuable and informative as those included in the analysis. However, we considered the ones selected by a group of Italian regional healthcare managers and already included in two of the three performance evaluation systems used in Italy, IRPES and PNE, as indicators monitoring variation in surgical procedures.

Third, although we used standardized hospitalization rates, further analyses can be done to better understand if patients' characteristics may have played any role in the reduction in volume. Other investigations could be also useful in understanding if some factors (such as the presence of private providers or patient outflow) may explain variation in the volume reduction.

Geographic variation may be a signal of inappropriateness related to overuse, for supplysensitive care such as that related to the absence of clinical theories; or to misuse, for preference-sensitive care such as treatment that should be linked to patients' preferences, weak for prostatectomy [40].

However, we cannot exclude the possibility that underuse may occur. Even if we selected procedures that are often considered as being overused, there is still the possibility that some of the patients who did not receive care ended up not getting the care they needed. Indeed, variation in use-rates is an indirect measure of inappropriateness [41,42] To

CONCLUSION

COVID-19 led healthcare systems to make hard choices in providing services. A large number of cuts, especially for acute care services, have been put in place. That has led healthcare systems to reflect upon prioritizing access to services, which is certainly an ethical issue but also an opportunity to reduce potentially inappropriate interventions.

This study aimed at providing preliminary evidence on the impact of the pandemic on the geographic variation of selected elective surgery procedures. In particular, the group of oncological surgical interventions belongs to the preference-sensitive categories of Wenneberg mostly influenced by the clinician's decision. Wide variation in elective surgery rarely depends on patients' preferences or needs. In fact, a recent study demonstrated that often reservation of the operating room does not depend upon demand or waiting times.[13] This variation category is also one requiring a deeper involvement of clinicians because it asks them to align their behaviour with clinical guidelines or practices.[8,16] The Italian data show that the pandemic seems to have led hospital managers and health professionals to cut the surgical interventions more likely to be inappropriate. Hence, these findings can inform and guide healthcare systems to manage unwarranted variation. In fact, when coming back to the new normal after this unpredictable situation given by the pandemic, it is important to use this new starting point (lower volumes in some selected elective surgical procedures) to plan elective surgical treatments that can be cancelled because of their high potential for inappropriateness.

Unfortunately, there are no gold standards for surgical use-rates. Under these circumstances, the public disclosure of information about use-rates among regions (and the risk of surgical intervention) can enable a discussion about appropriate care [16,29, 42,43].

In particular, once healthcare systems have achieved lower hospitalization rates for potentially inappropriate treatments, as happened during the pandemic, it is important to reverse the burden of proof in the cases of surgical intervention which are at high risk of inappropriateness. Hence, it could be useful to investigate if it is right that the region should come back to the past performance for interventions that have uncertain evidence instead of asking for a reduction of these cases.

Statements

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- d. **Data sharing statement:** Aggregated data can be shared upon request to the corresponding author.
- e. **Ethics statement:** This study did not involve human participants. Ethics committee approval was not necessary.

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Figure 1 – Hospitalization rates for tonsillectomy across and within Italian regions in 2019.

Source: PNE, 2019.

Pie (Piemonte); VdA(Valle d'Aosta); Lom (Lombardia); PAB (Provincia Autonoma di Bolzano); PAT(Provincia Autonoma di Trento); FVG(Friuli Venezia Giulia); Lig (Liguria); ER (Emilia Romagna); Tos (Toscana); Umb(Umbria); Mar(Marche); Laz(Lazio); Abr (Abruzzo); Mol(Molise); Cam (Campania); Pug (Puglia); Bas(Basilicata); Cal(Calabria); Sic (Sicilia)

Figure 2 –Matrix of 2019 hospitalization rate and difference in hospitalization rate between 2019 and 2020 for selected elective surgery procedures.

Source: Elaboration of authors on 2020 and 2019 data. Y-axis represents the difference in hospitalization rate between 2019 and 2020. X-axis represents the 2019 hospitalization rate. Lines represent the linear fit of the values.

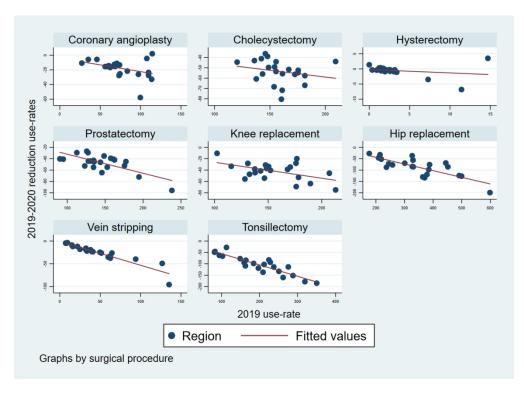


Figure 2 –Matrix of 2019 hospitalization rate and difference in hospitalization rate between 2019 and 2020 for selected elective surgery procedures.

Source: Elaboration of authors on 2020 and 2019 data. Y-axis represents the difference in hospitalization rate between 2019 and 2020. X-axis represents the 2019 hospitalization rate. Lines represent the linear fit of the values.

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The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items including for	61415 on 24 No	Location in manuscript where items are reported
Title and abstrac	ct			c us	шě	
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	In the abstract	RECORD 1.1: The type of should be specified in the abstract. When possible, the databases used should record the databases used should geographic region and time within which the study to should be reported in the abstract. RECORD 1.3: If linkage databases was conducted this should be clearly state or abstract.	ecor ecor econ	Included in the abstract pg 2 The title reports the geographic frame. Data analyzed are reported in the abstract pg 1 The study did not require record linkage pg 5
Introduction				<u>v</u>	<u>`</u>	
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	In the introduction section pg 3	milar tec	m/ on June 12,	
Objectives	3	State specific objectives, including any prespecified hypotheses	In the abstract and in the introduction section pg 2,3	imilar technologies.	ne 12, 2025	
Methods					at	_
Study Design	4	Present key elements of study design early in the paper	In the method section pg 5		Agence	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	In the method section 4,5		e Bibliograph	
Participants	6	(a) Cohort study - Give the	http://bmjopen.bmj.com/sit	RECORD 6.1: The method	ls of study	

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		eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> - Give the eligibility criteria, and the sources and methods of selection of participants	In the method section pg 5	population selection (sucle as codes or algorithms used to identify subjects) should be listed in detail. If the is is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation validation this study and not published elsewhere, detailed methods and results should be provided to select the population should be selected for this study and not published elsewhere, detailed methods and results should be provided to subject the population sho	Included in the method section pg 5 Included in the method section pg 5
		(b) Cohort study - For matched studies, give matching criteria and number of exposed and unexposed Case-control study - For matched studies, give matching criteria and the number of controls per case		linkage of databases, consider use of a flow diagram or other graphed display to demonstrate the data linkage process, including the number of individuals with linked data and each stage.	It is not the case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	In the method section pg 5	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, and explanation should be provided.	In the method section pg 5
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	In the appendix	2025 at Agence Bibliographique jies.	
Bias	9	Describe any efforts to address potential sources of bias		graphiq	

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Study size	10	Explain how the study size was arrived at	In the method section	n-2022 ≎opyrii	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	pg 5 In the method section	pen-2022-061415 on 24 N vy copyright, including fo	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study - If applicable, explain how loss to follow-up was addressed Case-control study - If applicable, explain how matching of cases and controls was addressed Cross-sectional study - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Method section incluonly a) at pg 5	on 24 November 2022. Downloaded from http://bmjopen.bmj.com/ on June ? Enseignement Superieur (ABES) . uding for uses related to text and data mining, Al training, and similar technology.	
Data access and cleaning methods				RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	In the method section pg 5
Linkage				RECORD 12.3: State whether the	

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				study included person-level, institutional-level, or other days linkage across two or more databæses. The methods of linkage and methods of linkage quality evaluations should be provided.	In the method section pg 5
Results				f Z	
Participants	13	(a) Report the numbers of individuals at each stage of the study (<i>e.g.</i> , numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram		RECORD 13.1: Describe in the selection of the persons in the study (i.e., study populations selection) including filtering based with the study data availability and linkage. The selection of included by sons can be described in the text and the study flow data and the	In the results section criteria in the method section pg 5 and pg 6
Descriptive data	14	(a) Give characteristics of study participants (<i>e.g.</i> , demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) <i>Cohort study</i> - summarise follow-up time (<i>e.g.</i> , average and total amount)	In the results section pg 5, 6	;p://bmjopen.bmj.com/ on June 12, g, Al training, and similar technolo	
Outcome data	15	Cohort study - Report numbers of outcome events or summary measures over time Case-control study - Report numbers in each exposure category, or summary measures of exposure Cross-sectional study - Report numbers of outcome events or	In the results section pg 5,6	5 at Agence Bibliographique	

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		summary measures		n-2	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounderadjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	In the results section pg 5-7	n-2022-061415 on 24 November 2022. Downloaded from h Enseignement Superieur (ABES) copyright, including for uses related to text and data mini	
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	None	ed from http:/ ur (ABES) . data mining, /	
Discussion				2 8 t	
Key results	18	Summarise key results with reference to study objectives	In the Discusions p	<u> </u>	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	In the discussions section pg 7,8	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research questions). Include discussion of misclassification bias, unmeasured confounding bias, unmeasured	In the discussions section pg 7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	In the discussions section	Agence Bibliographiqu	

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1 2 3	Generalisability	21	Discuss the generalisability (external validity) of the study results	In the discussions section, pg7,8		n-2022-0 copyrigh	
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5 6 7 8 9	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	in the authors'profile pg 1		61415 on 24 Novembe Ense t, including for uses r	
11 12 13 14 15 16	Accessibility of protocol, raw data, and programming code				RECORD 22.1: Authors provide information on any supplemental information the study protocol, raw of programming code.	s ន្ទាំទ ីប៉ៅ្កd h ស្ថិទីស្រី access h æ iទ្ធិរដ្ឋsuch as	
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Supplementary material n. 2

Appendix- Codes of the ICD9CM and DRGs used for selecting cases, elective surgery.

Supplementary material n. 3 2019 and 2020 use rates by procedure and Region

Procedure	Region	Area	2019 use-rate	2020 use-rate	2019-2020 reduction use rates
Tonsillectomy	Piemonte	North	288	136	-152
Tonsillectomy	Valle d'Aosta	North	224	141	-83
Tonsillectomy	Lombardia	North	197	78	-119
Tonsillectomy	Bolzano	North	319	141	-179
Tonsillectomy	Trento	North	238	123	-114
Tonsillectomy	Veneto	North	228	135	-93
Tonsillectomy	Friuli Venezia Giuli		276	162	-114
Tonsillectomy	Liguria	North	350	165	-185
Tonsillectomy	Emilia Romagna	North	251	118	-133
Tonsillectomy	Toscana	Center	164	80	-84
Tonsillectomy	Umbria	Center	262	102	-160
Tonsillectomy	Marche	Center	212	109	-103
Tonsillectomy	Lazio	Center	113	85	-28
Tonsillectomy	Abruzzo	South	149	72	<u>-77</u>
Tonsillectomy	Molise	South	94	31	-63
Tonsillectomy	Campania	South	102	36	-66
Tonsillectomy	Puglia	South	82	32	-49
Tonsillectomy	Basilicata	South	163	54	
Tonsillectomy	Calabria	South	83	37	-103 -46
Tonsillectomy	Sicilia	South	209	72	-137
Tonsillectomy	Sardegna	South	159	64	-137 -95
Tonsillectomy	Italia	Italy	184	86	-95 -99
	Piemonte				
Cholecystectomy	Valle d'Aosta	North	161 143	89 87	-72 -72
Cholecystectomy		North			-56
Cholecystectomy	Lombardia	North	154	85	-68
Cholecystectomy	Bolzano	North	120	76	-44
Cholecystectomy	Trento	North	175	123	-52
Cholecystectomy	Veneto	North	156	111	-44
Cholecystectomy	Friuli Venezia Giuli		142	101	-41
Cholecystectomy	Liguria	North	160	80	-80
Cholecystectomy	Emilia Romagna	North	149	99	-50
Cholecystectomy	Toscana	Center		115	-67
Cholecystectomy	Umbria	Center	167	115	-52
Cholecystectomy	Marche	Center	148	109	-39
Cholecystectomy	Lazio	Center	146	110	-36
Cholecystectomy	Abruzzo	South	209	165	-44
Cholecystectomy	Molise	South	136	93	-43
Cholecystectomy	Campania	South	182	124	-58
Cholecystectomy	Puglia	South	155	102	-54
Cholecystectomy	Basilicata	South	138	77	-61
Cholecystectomy	Calabria	South	172	116	-56
Cholecystectomy	Sicilia	South	175	121	-55
Cholecystectomy	Sardegna	South	154	105	-49
Cholecystectomy	Italia	Italy	161	106	-56
Knee replacement	Piemonte	North	143	102	-41
Knee replacement	Valle d'Aosta	North	189	126	-64
Knee replacement	Lombardia	North	147	92	
Knee replacement	Bolzano	North	213	138	
Knee replacement	Trento	North	178	126	
Knee replacement	Veneto	North	177	157	-20
Knee replacement	Friuli Venezia Giuli		171	136	-35
Knee replacement	Liguria	North	176	107	-69
Knee replacement	Emilia Romagna	North	150	117	-34
Knee replacement	Toscana	Center		162	-45
	Umbria			148	
Knee replacement		Center			
Knee replacement	Marche	Center		129	
Knee replacement	Lazio	Center	149	111	-37

Knee replacement	Abruzzo	South	148	117	-31
Knee replacement	Molise	South	116	82	-33
Knee replacement	Campania	South	133	85	-47
Knee replacement	Puglia	South	131	103	-28
Knee replacement	Basilicata	South	128	73	-56
Knee replacement	Calabria	South	138	93	-45
Knee replacement	Sicilia	South	138	100	-38
Knee replacement	Sardegna	South	102	92	-10
Knee replacement	 Italia	Italy	152	112	-40
Hip replacement	Piemonte	North	379	259	-119
Hip replacement	Valle d'Aosta	North	491	367	-124
Hip replacement	Lombardia	North	364	234	-130
Hip replacement	Bolzano	North	599	400	-199
Hip replacement	Trento	North	500	373	-126
Hip replacement	Veneto	North	452	366	-86
Hip replacement	Friuli Venezia Giulia		444	376	-68
Hip replacement	Liguria	North	370	237	-134
Hip replacement	Emilia Romagna	North	385	287	-97
Hip replacement	Toscana	Center	388	312	-76
Hip replacement	Umbria	Center	327	290	-76
Hip replacement	Marche	Center	330	274	-56
	Lazio		301	231	-
Hip replacement	Abruzzo	Center South	327	243	-70 -84
Hip replacement Hip replacement		South			-04 -77
	Molise		258	181	
Hip replacement	Campania	South	245	173	-72
Hip replacement	Puglia	South	214	182	-32
Hip replacement	Basilicata	South	237	149	-87
Hip replacement	Calabria	South	219	167	-52
Hip replacement	Sicilia	South	209	163	-46
Hip replacement	Sardegna	South	177	150	-27
Hip replacement	Italia	Italy	331	245	-85
Vein stripping	Piemonte	North	62	29	-33
Vein stripping	Valle d'Aosta	North	135	40	-96
Vein stripping	Lombardia	North	8	3	-5
Vein stripping	Bolzano	North	32	13	-19
Vein stripping	Trento	North	25	7	-18
Vein stripping	Veneto	North	9	6	-4
Vein stripping	Friuli Venezia Giulia	a North	94	54	-40
Vein stripping	Liguria	North	16	4	-12
Vein stripping	Emilia Romagna	North	127	78	-49
Vein stripping	Toscana	Center	60	25	-35
Vein stripping	Umbria	Center	63	25	-38
Vein stripping	Marche	Center	51	25	-26
Vein stripping	Lazio	Center	32	16	-16
Vein stripping	Abruzzo	South	65	38	-26
Vein stripping	Molise	South	40	17	-23
Vein stripping	Campania	South	34	11	-22
Vein stripping	Puglia	South	15	6	-9
Vein stripping	Basilicata	South	41	17	-24
Vein stripping	Calabria	South	7	3	-4
Vein stripping	Sicilia	South	22	10	-12
Vein stripping	Sardegna	South	50	25	-25
Vein stripping	Italia	Italy	38	19	-19
Coronary angioplasty		North	110	86	-24
Coronary angioplasty		North	114	116	2
Coronary angioplasty		North	114	81	-33
Coronary angioplasty		North	46	40	-6
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Coronary angioplasty		North	59	43	-15
Coronary angioplasty	Veneto	North	71	59	-11
Coronary angioplasty	Friuli Venezia Giulia	North	35	29	-6
Coronary angioplasty		North	61	46	-14
Coronary angioplasty		North	68	55	-13
Coronary angioplasty		Center	56	41	-16
Coronary angioplasty		Center	62	46	-17
Coronary angioplasty		Center	69	53	-15
Coronary angioplasty		Center	74	61	-13
Coronary angioplasty		South	67	52	-15
Coronary angioplasty		South	108	103	-5
Coronary angioplasty		South	110	82	-28
Coronary angioplasty	Puglia	South	97	71	-26
Coronary angioplasty		South	74	49	-25
Coronary angioplasty		South	100	42	-58
Coronary angioplasty		South	73	46	-28
Coronary angioplasty		South	27	16	<u>-11</u>
Coronary angioplasty		Italy	84	62	-22
Prostatectomy	Piemonte	North	195	123	-72
Prostatectomy	Valle d'Aosta	North	238	142	-96
Prostatectomy	Lombardia	North	146	81	-64
Prostatectomy	Bolzano	North	176	123	-52
Prostatectomy	Trento	North	135	92	-43
Prostatectomy	Veneto	North	149	113	-35
Prostatectomy	Friuli Venezia Giulia		127	98	-29
Prostatectomy	Liguria	North	123	70	-53
Prostatectomy	Emilia Romagna	North	128	84	-55 -44
Prostatectomy			126	99	-44 -27
	Toscana	Center			
Prostatectomy	Umbria	Center	153	98	-55
Prostatectomy	Marche	Center	162	120	-42
Prostatectomy	Lazio	Center	161	120	-41
Prostatectomy	Abruzzo	South	177	132	-45
Prostatectomy	Molise	South	135	90	-45
Prostatectomy	Campania	South	113	83	-29
Prostatectomy	Puglia	South	131	87	-44
Prostatectomy	Basilicata	South	90	50	-40
Prostatectomy	Calabria	South	95	54	-40
Prostatectomy	Sicilia	South	157	118	-39
Prostatectomy	Sardegna	South	135	80	-55
Prostatectomy	Italia	Italy	144	98	-46
Hysterectomy	Piemonte	North	1	2	0
Hysterectomy	Valle d'Aosta	North	15	18	3
Hysterectomy	Lombardia	North	1	1	0
Hysterectomy	Bolzano	North	0	1	1
Hysterectomy	Trento	North	0	0	0
Hysterectomy	Veneto	North	2	1	-1
Hysterectomy	Friuli Venezia Giulia		2	1	<u> </u>
			2	2	0
Hysterectomy	Liguria	North			
Hysterectomy	Emilia Romagna	North	1	1	-1
Hysterectomy	Toscana	Center	1	1	0
Hysterectomy	Umbria	Center	1	2	0
Hysterectomy	Marche	Center	3	2	0
Hysterectomy	Lazio	Center	7	4	-3
Hysterectomy	Abruzzo	South	11	5	-7
Hysterectomy	Molise	South	3	2	-1
Hysterectomy	Campania	South	3	3	0
Hysterectomy	Puglia	South	3	2	-1
					0
Hysterectomy	Basilicata	South	3	2	
Hysterectomy	Calabria	South	2	2	0
Hysterectomy	Sicilia	South	2	2	0
Hysterectomy	Sardegna	South	1	1	0
Hysterectomy	Italia	Italy	3	2	-1