

**DEADLOCK OF PROCTOLOGIC PRACTICE IN ITALY DURING COVID-19 PANDEMIC: A NATIONAL REPORT
FROM PROCTOLOCK 2020**

Gaetano Gallo, MD;¹ Alessandro Sturiale, MD;² Iacopo Giani, MD PhD;³ Stefano Mancini, MD;⁴ Gian Luca Di Tanna, PhD;⁵ Francesco Bianco, MD;⁶ Roberto Perinotti, MD;⁷ Veronica De Simone, MD;⁸ Ugo Grossi, MD PhD.⁹

1. Department of Medical and Surgical Sciences, University of Catanzaro, Catanzaro, Italy
2. Proctology and Pelvic Floor Clinical Centre, Cisanello University Hospital, Pisa, Italy
3. SOSD Proctologia USL Toscana Centro, Prato, Italy
4. Department of General Surgery, Università Politecnica delle Marche, Ancona, Italy
5. The George Institute for Global Health, Faculty of Medicine, University of New South Wales, Australia
6. General Surgery Unit, S. Leonardo Hospital, Castellammare Di Stabia, Napoli, Italy
7. Colorectal Surgical Unit, Department of Surgery, Infermi Hospital, Biella, Italy
8. Proctology Unit, Fondazione Policlinico Universitario 'A. Gemelli' IRCCS, Roma, Italy
9. IV Surgery Unit, Treviso Regional Hospital, University of Padua, Italy

Corresponding author

Dr Gaetano Gallo, Department of Medical and Surgical Sciences, University of Catanzaro, Catanzaro, Italy

E-mail: gaethedoctor@alice.it

ORCID: 0000-0003-1066-4671

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ABSTRACT

Purpose: Proctology is one of the surgical specialties that suffered the most during COVID-19 pandemic.

Using data from a cross-sectional worldwide web survey, we aimed to snapshot the current status of proctologic practice in Italy with differences between three macroareas (North, Center, South).

Methods: Affiliated to renowned scientific societies with an interest in coloproctology were invited to join a 27-item survey. Predictive power of respondents' and hospitals' demographics on the change of status of surgical activities was calculated. The study was registered at ClinicalTrials.gov (NCT 04392245).

Results: Of 299 respondents from Italy, 94 (40%) practiced in the North, 60 (25%) in the Center and 82 (35%) in the South and Islands. The majority were men (79%), at consultant level (70%), with a mean age of 46.5 years, practicing in academic hospitals (39%), where a dedicated proctologist was readily available (68%). Southern respondents were more at risk of infection compared to those from the Center (OR, 3.30; 95%CI 1.46;7.47, P=0.004), as were males (OR, 2.64; 95%CI 1.09;6.37, P=0.031) and those who routinely tested patients prior to surgery (OR, 3.02; 95%CI 1.39;6.53, P=0.005). The likelihood of ongoing surgical practice was higher in the South (OR 1.36, 95%CI 0.75;2.46, P=0.304).and in centers that were not fully dedicated to COVID-19 care (OR 4.00, 95%CI 1.88;8.50, P<0.001).

Conclusions: The results of this survey highlight important factors contributing to the deadlock of proctologic practice in Italy and may inform the development of future management strategies.

Keywords: proctology; survey; lockdown; COVID-19; SARS-COV-2; Italy.

INTRODUCTION

COVID-19 pandemic has critically impacted the surgical world.[1] More than 28 million procedures would be cancelled or postponed during the 12-week peak according to a recent global expert-response study.[2] The vast majority (90%) of operations would be treating benign diseases, with an estimated overall 12-week cancellation rate of 72%.

This scenario has strongly challenged proctologic practice, which include a large spectrum of conditions with a significant psycho-socio-economic burden.[3]

Detection of the novel coronavirus (SARS-COV-2) RNA in patients' stool samples and gastrointestinal epithelium has led to enhance infection control precautions.[4] Consequently, several guidelines have been developed to optimize treatment strategies while ensuring healthcare workers' safety by means of adequate personal protective equipment (PPE).[5-7] However, the ever-changing situation observed in most countries has often hampered the attempts to put these guidelines into practice.[8]

ProctoLock 2020 is a survey aimed to assess the current status of proctologic practice worldwide.

In our previous global report [9], the proportion of unaltered, reduced or fully stopped practice has been snapshotted in 69 countries.

The purpose of this study is to explore the impact of COVID-19 on proctologic practice in Italy, looking for differences between North, South and Central regions.

MATERIALS AND METHODS

Experts in the field who joined a previous qualitative study [10] (N=492) were invited to complete a web survey. The survey link was sent to national scientific societies of interest to coloproctologists and disseminated to their members. All collaborators committed to further recruitment of participants by direct invitation.

A 27-item survey (namely, 'ProctoLock 2020'; Appendix 1) was designed and developed by the authors using an online platform ('Online surveys' [formerly BOS – Bristol Online Survey], developed by the University of Bristol) in accordance with the Checklist for Reporting Results of Internet E-Surveys (the CHERRIES statement).[11] The finalized online survey was made available online from April 15th to 26th 2020.

The survey aimed to capture the current status of proctologic practice worldwide, first exploring the overall changes in terms of resource allocation, and secondly assessing in more details the various fields of application for both proctologic surgery (i.e. elective [oncological and non oncological] and urgent) and outpatient practice, with a focus on sexually transmitted disease and pelvic floor clinics. The availability of anorectal physiology testing was also assessed.

The study was registered at ClinicalTrials.gov (NCT 04392245).

Statistical analysis

Logistic models for binary or ordinal variables were performed to assess the association between respondents' preferences and their characteristics (adjusted odds ratio [OR]). Multivariable models were fitted using a pre-defined set of covariates which included respondents' and hospitals' demographics (i.e. geographical area, age, gender, type of hospital, hospital rearrangement, external facilities for proctologic surgery, use of PPE, pre-operative testing policies for COVID-19). Brant test to check the proportional odds assumption was performed for the ordinal logistic model. No formal correction for multiple testing has been made although we have critically assessed all p-values <0.05.

All analyses were performed using Stata 16 (StataCorp LLC, College Station, TX, USA).

RESULTS

From a total of 1,050 respondents worldwide, 570 (54%) were Europeans (Appendix 2), with 299 (52%) from Italy. Among these, 94 (40%) practiced in the North, 60 (25%) in the Centre and 82 (35%) in the South and Islands (Table 1). The majority were men (79%), at consultant level (70%), with a mean age of 46.5

years, working in academic hospitals (39%), where a dedicated proctologist was readily available (68%).

Overall, 34%, 54%, and 70% reported the presence of dedicated pathways for sexually transmitted disease, pelvic floor disorders, and anorectal physiology testing, respectively.

A multivariable logistic model showed that respondents from the South were more at risk of infection compared to those from the Center (OR, 3.30; 95%CI 1.46;7.47, P=0.004), as were males (OR, 2.64; 95%CI 1.09;6.37, P=0.031) and those who routinely tested patients prior to surgery (OR, 3.02; 95CI 1.39;6.53, P=0.005) compared to their counterparts.

The majority of Italian respondents worked in centers that were partially rearranged (N=216 [72%]) to guarantee the assistance to COVID-19 patients, with a similar distribution between regions (Table 2).

Conversely, hospitals fully converted to COVID-19 centers (N=30 [10%]) and those not directly involved in COVID-19 care (N=53 [18%]) were more prevalent in the North and South, respectively.

More than a half of respondents had modified the surgical informed consent for both COVID-19 positive (N=164 [55%]) and negative patients (N=177 [59%]), by mentioning the higher risk of infection and SARS-COV-2-related complications.

PPE readily availability and routine pre-operative testing for COVID-19 were more likely reported by respondents from the North (N=92 [45%] and N=93 [43%], respectively) compared to other regions (P=0.002 and P=0.033, respectively).

One third of respondents (N=97 [32%]) faced patients refusing surgery, with the fear of SARS-COV-2 infection as the main reason.

Forty percent (N=116) of respondents had yet to reschedule patients waiting for surgery or outpatient visit.

Compared to the rest of Europe, elective proctologic surgery in Italy was considerably reduced (with a test of heterogeneity at P=0.026) (Figure 1).

The likelihood of ongoing proctologic practice was higher in southern regions (OR vs central regions 1.36, 95%CI 0.75;2.46, P=0.304), and in centers that were not fully dedicated to COVID-19 care (OR 4.00, 95%CI 1.88;8.50, P<0.001) (Table 3).

Among the 116 (39%) respondents who found flaws or delay in the management of oncological patients, the majority was from the North (N=52 [56%]).

More than 82% (N=247) of participants declared that elective non oncological surgery was fully stopped, with the main reasons being hospital directions and/or reduced referrals.

Emergency surgery was fully stopped according to one fourth (N=61) of respondents, while half (N=150) experienced a reduced activity.

Among those still performing emergency surgery (N= 238 [80%]), the majority (N=212 [71%]) stated that patients were routinely tested for COVID-19 pre-operatively, with similar interregional distribution.

Following national or local hospital directions, outpatient activity was fully stopped or reduced in Italy according to 53% (N=158) or 45% (N=135) of respondents, respectively. The majority (127 [90%]) reported regular use of PPE during the visits.

Possible diagnostic delays resulting from a decreased outpatient activity concerned 265 [88.6%] respondents.

DISCUSSION

In Italy (and Europe), the hunt for patient zero has proven unsuccessful and only served to fuel the confusion on the origin of the outbreak.[12] SARS-COV-2 spread across Europe following multiple paths, and heterogeneously impacted on countries and between different geographical areas within the same nation.

The higher prevalence of male over female subjects was consistent with the results of our worldwide survey.[9]

Despite proctology has been recognized worldwide as subspecialty, only two thirds of Italian respondents reported the availability of dedicated proctologist in their center.

The alarmingly high prevalence of COVID-19 positivity among Italian respondents (twice that of all healthcare workers)[13] might suggest that proctologists carry a higher risk of contagion compared to other specialists. Several case studies have reported gastrointestinal symptoms and/or evidence that some patients with COVID-19 have viral RNA viable in stool or gastrointestinal epithelium, suggesting fecal-oral pathway as a further possible route of transmission.[4, 14] Compared to those from the Center, prevalence

of COVID-19 positivity among Southern respondents was 3 times higher. In this geographic area, PPE were less frequently deemed readily available and the likelihood of continuing the surgical activity was 36% higher. Such a worrying proportion of COVID-19 positive respondents in the South suggests that the different timing of the epidemic and the prompt lockdown measures put in place by the Italian government might have rescued this area from a potential catastrophe.

As proof of resilience during troubled times, a significant number of respondents were redeployed to other activities.[15]

More than 50% of respondents reported to have amended the surgical consent form, reflecting a great awareness of growing evidence from the literature about the increased operative risks in COVID-19 patients.[16, 17]

Compared to the rest of Europe, the reduction in elective surgical activity has been more pronounced in Italy. To further confirm the deadlock of proctologic practice in this country, almost 40% of respondents had yet to reschedule patients' outpatient visits or operations. While unable to access healthcare services, many patients refrained from attending the emergency department due to the fear of being infected.[18]

The suspension of oncological activity was reported by 39% of Italian respondents, with a peak of 56% in the North (the worst-hit area), where all activities were more likely to be put on hold and hospitals forced to shift resources to COVID-19 care.

Most respondents were concerned about the negative effects of delaying care, with potentially irreversible consequences especially for cancer patients.[19]

As recently suggested,[7] the outpatient/office surgical activity could have helped to diminish commitment to hospitals and optimize resource allocation in terms of operating spaces, staffing and beds. But this was not the case for at least two reasons, namely the full closure of all non-COVID-related activities (as per national directions) and the currently very limited experience with delivering this type of proctologic surgery. Undoubtedly, this should prompt health authorities and specialists to redesign and optimize the whole proctologic pathway across the national territory.[20]

This study has some limitations that are commonly observed in survey-based studies (e.g. recall and selection bias).[28-30] Nevertheless, the high percentage of consultants among respondents vouches for a satisfactory level of experience and supports the reliability of collected data.

The results of ProctoLock 2020 survey highlighted key critical issues that have emerged during COVID-19 pandemic worldwide and in particular in Italy, thus building foundations for future development of organizational solutions and nation-level initiatives.

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FIGURE LEGENDS

Figure 1. Current status of proctologic surgical practice in Italy and rest of Europe. Light to dark color scale represents a low to high prevalence of respondents across countries.

Table 1. Demographics and geographic distribution of respondents in Italy.

	N=299	North (%) N=118 (40)	Center (%) N=75 (25)	South (%) N=106 (35)
Gender				
Males	236 (79)	94 (40)	60 (25)	82 (35)
Females	63 (21)	24 (38)	15 (24)	24 (38)
Age, mean (standard deviation)	46.5 (12.0)	50.5 (11.7)	48.1 (13.0)	46.9 (12.7)
Training level				
Consultant	211 (70)	91 (43)	55 (26)	65 (31)
Resident	77 (26)	24 (31)	17 (22)	36 (47)
Fellow	11 (4)	3 (27)	3 (27)	5 (46)
Type of hospital				
Academic	116 (39)	34 (29)	36 (31)	46 (40)
Non-academic teaching	94 (31)	45 (48)	18 (19)	31 (33)
Non-teaching	89 (30)	39 (44)	21 (24)	29 (33)
Dedicated clinical pathways				
Sexually transmitted diseases	103 (34)	46 (45)	32 (43)	25 (24)
Pelvic floor disorders	160 (54)	72 (45)	53 (33)	35 (33)
Anorectal physiology testing	210 (70)	89 (42)	55 (26)	66 (31)
Type of surgeon performing urgent cases				
Dedicated proctologist	204 (68)	84 (41)	50 (25)	70 (24)
General surgeon	95 (32)	34 (36)	25 (26)	36 (38)
Tested COVID-19 positive	67 (22)	24 (36)	11 (16)	32 (48)

Table 2. Hospital preparedness to COVID-19 pandemic in Italy with differences among North, Center and South regions.

	N=299 (%)	North (%) N=118 (40)	Center (%) N=75 (25)	South (%) N=106 (35)
Hospital rearrangement				
Fully dedicated to COVID-19	30 (10)	21 (70)	3 (10)	6 (20)
Partially dedicated to COVID-19	216 (72)	85 (39)	58 (27)	73 (34)
Not involved in COVID-19 care	53 (18)	12 (23)	14 (26)	27 (51)
External facilities for proctologic surgery				
Available for benign and oncologic cases	9 (3)	2 (22)	5 (56)	2 (41)
Available for oncologic cases only	46 (15)	17 (37)	15 (33)	14 (22)
Unavailable	244 (82)	99 (41)	55 (30)	90 (37)
Surgical consent form redesigned for				
COVID-19+ patients	164 (55)	64 (39)	43 (26)	57 (35)
COVID-19- patients	177 (59)	72 (41)	44 (25)	61 (35)
Use of personal protective equipment in theatre with				
COVID-19+ patients				
Always	273 (91)	107 (39)	71 (26)	95 (35)
Case-by-case	21 (7)	9 (43)	4 (19)	8 (38)
Never	5 (2)	2 (40)	0	3 (60)
COVID-19- or untested patients				
Always	176 (59)	78 (44)	41 (23)	57 (32)
Case-by-case	99 (33)	34 (34)	24 (24)	41 (41)
Never	24 (8)	6 (25)	10 (42)	8 (33)
Personal protective equipment readily available	202 (68)	92 (45)	51 (25)	59 (29)
All patients are tested for COVID-19 prior to surgery	215 (72)	93 (43)	55 (26)	67 (31)
Experience with patients refusing surgery				
1-5 patients	97 (32)	36 (37)	22 (23)	39 (40)
6-10 patients	41 (42)	18 (44)	7 (17)	16 (39)
11-20 patients	18 (19)	4 (22)	7 (39)	7 (39)
11-20 patients	14	4 (29)	2 (14)	8 (57)
>20 patients	24	10 (42)	6 (25)	8 (33)
Current outcome of patients waiting for surgery or visits				
Rescheduled until the end of pandemic	54 (18)	25 (46)	8 (15)	21 (39)
Rescheduled upon balance of risks and benefits	88 (29)	35 (40)	24 (27)	29 (33)
Rescheduled in 1-3 months according to the waiting list	41 (14)	16 (39)	10 (14)	15 (37)

Yet to be established	116 (39)	42 (36)	33 (28)	41 (35)
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Table 3. Ordinal logistic regression model exploring the current status of proctologic surgery.

	Fully stopped vs. Emergency vs. Elective			<i>P</i>
	Adjusted Odds ratio	95%CI		
		Lower	Upper	
Regions				
Center (<i>reference</i>)				
North	.88	.49	1.57	.655
South	1.36	.75	2.46	.304
Age	.98	.96	1.00	.085
Gender				
Female (<i>reference</i>)				
Males	1.66	.90	3.04	.102
Type of hospital				
Non-teaching (<i>reference</i>)				
Academic or teaching	1.38	.85	2.24	.197
Hospital rearrangement				
Fully dedicated to COVID-19 (<i>reference</i>)				
Partially dedicated or not involved	4.00	1.88	8.50	<.001
External facilities for proctologic surgery				
Unavailable (<i>reference</i>)				
Available	1.16	.64	2.11	.620
Personal protective equipment				
Unavailable (<i>reference</i>)				
Readily available	1.36	.84	2.22	.213

CI: confidence interval.