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Impact of COVID-19 Related Lockdown Measures on Stroke Care Quality in Careggi University Hospital, Florence

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Abstract

Introduction: During the COVID-19 outbreak, a reduction of stroke patients' volume in hospitals worldwide has been reported, as well as a delay in all steps of hyperacute treatments.

Patients and methods: This was a single-centre, observational cohort study performed in Careggi Hospital, a Tertiary Stroke Center with endovascular facilities We retrospectively compared process timings, treatment and clinical variables between early pandemic phase (1stMarch to 30thApril 2020) and pre-pandemic (the same period of 2019) one, to evaluate the impact of COVID-19 related restrictions on overall stroke care efficiency.

Results: Across the study period, in 2020 the number of stroke patients admitted to our Hospital and those receiving intravenous thrombolysis showed a decline when compared to 2019 (114 vs 94 stroke patients and 22% vs 20% receiving rtPA), while the proportion receiving endovascular thrombectomy raised (from 23% to 31%, p=0.190). A delay in patients' shipment and treatment was detected in 2020 (an increase of 19min p=0.192 in door to needle and 18min p=0.220 in door to groin), but some intrahospital parameters improved during pandemic: door to neurological evaluation and to CT scan timings were lower in 2020.

Discussion: Our data indicate that, during lockdown, overall quality of care performance at our stroke center was preserved if compared to the prehospital pathway disruption.

Conclusion: These findings remark the need of population awareness of acute cerebrovascular disease, to encourage stroke patients to prompt seek emergency care even during pandemic period. Future studies with a larger cohort are needed to evaluate the long-term effect of COVID-19 on stroke pathway quality time metrics.

Keywords: COVID-19; Pandemic; Impact; Stroke; Timing

Abbreviations: EVT: Endo Vascluar Thrombectomy; RTPA: Recombinant Tissue Plasminogen Activator; SARS-CoV2: Severe Acute Respiratory Syndrome CoronaVirus 2; COVID-19: Coronavirus Disease 2019; IV: Intravenous; ST: Stroke Team

Introduction

After the end of January 2020, when the first COVID-19 cases were detected in Italy, the pandemic rapidly spread in the country, and coherently apprehension progressively raised in population and national authorities. On March 9th, 2020, the Italian government introduced restrictive measure (lockdown) with closure of all non-essential businesses and industries and limitation of people movement to control COVID-19 diffusion. This lasted until May 3rd and had a relevant impact on healthcare system [1], on time-dependent diseases such as stroke.

We aimed to assess the effect of restrictive measures applied to limit the spread of SARS-CoV2 on the quality of stroke care and identify which part of the care pathway was more affected, comparing the pandemic phase from March 1st to April 30th 2020 with the corresponding time period in 2019.

Patients and Methods

Study Design

observational cross-sectional study.

Patients

All consecutive adult patients ≥18 years of age admitted in Careggi University Hospital, Florence, for acute stroke between March 1st and April 30th, in 2020 and in 2019.

Study Setting

Careggi University Hospital, Florence. This Hospital serves as EVT reference center for Area Vasta Centro in Tuscany Region. The Spoke and Hub system in Area Vasta Centro implies that patients with acute ischemic stroke are carried to the nearest Hospital to avoid delay in i.v. thrombolysis, applying the drip and ship paradigm. If they also need EVT they are transferred from the Spoke to the Hub Hospital (Careggi University Hospital). Before stroke patient's arrival at Careggi, stroke neurologists are pre-alerted (Stroke Team activation) from the Spoke center or from emergency transport service (if the patients are shipped directly to Careggi).

Assessed variables

We assessed the process efficiency indicators related to stroke patient's pathway considering pre-, inter- and intra-hospital performance. Pre-hospital process efficiency indicator: time from the symptom onset (or from the last moment the patient was known well) to the arrival to the Hospital (Spoke or Hub center) [2].

Inter-hospital process efficiency indicator: transfer time from the Spoke to Hub Hospital (time elapsing from spoke arrival to hub arrival).

Intra-hospital process efficiency indicators: a- door-to-clinical evaluation, b- door-to-neuroradiological evaluation, c- door-to-needle for i.v. therapy, d- door-to-groin puncture for EVT therapy. For patients who underwent i.v. thrombolysis in a spoke center, door to needle time was correspondingly calculated [3].Data sources were the clinical reports of patients discharged from hospital with a confirmed diagnosis of stroke.

Statistical Analysis

All normally distributed continuous variables are presented as mean ± standard deviation while non-normally distributed as median and interquartile range. Categorical variables are presented as number and frequency (%). In bivariate analysis, the $\chi 2$ test, Fisher exact test, Student t test, and Mann-Whitney U test, were used as appropriate. A binomial logistic regression was performed to ascertain the effects of age, sex, type of stroke, date of stroke (2019 or 2020) and stroke treatment on the likelihood of intrahospital death. All statistical analyses were performed using IBM SPSS Statistics V.26, IBM. A p <0.05 indicated a statistically significant difference.

Result

A total of 114 acute stroke patients were admitted in Careggi University Hospital from 1st March to 30th April 2019 and 94 patients from 1st March to 30th April 2020, showing a reduction of 18%. No patients were admitted with a known SARS-CoV2 infection. In 3 patients COVID-19 was diagnosed during hospitalization, one of them died and two were regularly discharged.

Compared to patients admitted in 2019, those admitted 2020 were not significantly younger (70.6 vs 74.5 p=0.08), the proportion of female gender was not significantly lower (44% vs 56% p=0.72), the frequency of haemorrhagic stroke was not significantly higher (23.4% vs 15.8% p=0.16), and early neurological improvement measured by change in NIHSS at 24 hours was lower (NIHSS decreased in 64.3% vs 47.5%, p=0.054). No differences in stroke severity, main clinical characteristics and radiological features were found (Table 1, Table S1 & S2 in supplementary material).

Table 1: Demographic and clinical characteristics of stroke patients admitted to Careggi Hospital during lockdown period (from 1st March to 30th April 2020) and in the corresponding time period in 2019

Demographic and Clinical Characteristics	Total	2019	2020	*p*
Number pts	208	114	94	
Gender, female, No (%)	98 (47)	55 (56)	43 (44)	0,719
Mean age, year (SD)	72,7 (16,1)	74,5 (15,4)	70,6 (16,6)	0,085
Ischaemic stroke (%)	168 (80)	96 (84)	72 (77)	0,165
COVID19 + (%)	3 (1)	0 (0)	3 (3)	0,055
NIHSS presenting (Hub)	10,4 (8,6)	10,5 (8,6)	10,2 (8,5)	0,806
Mean (SD) (2019=92, 2020=77)				
NIHSS at 24h	7,3 (7,8)	7,3 (7,7)	7,2 (7,8)	0,929
Mean (SD) (2019=69 2020=61)				
Any NIHSS decrease at 24h (%) (2019 =70, 2020=61)	74 (56)	45 (64)	29 (47)	0,054
Coma at arrival_Spoke (%)	2 (3,3)	2 (6)	0 (0)	0,298

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Table S1: Main clinical characteristic of stroke patients at presentations.

Clinical factors at presentation	Total	2019	2020	*p*
Classification TOAST				0,216
Large artery atherosclerosis (%)	30 (19)	15 (17)	15 (21)	
Cardioembolism (%)	45 (28)	31 (36)	14 (20)	
Small vessel occlusion (%)	13 (8)	8 (7)	5 (7)	
Other determined etionlogy (%)	17 (11)	8 (9)	9 (13)	
Undetermined etiology (%)	53 (34)	25 (29)	28 (40)	
Concomitant myocardial infarct (%)	3 (2)	1 (1)	2 (2)	0,470
Previous myocardial infarct (%)	14 (7)	8 (8)	6 (7)	0,779
Hypertension (%)	136 (70)	73 (70)	63 (70)	0,884
Diabetes (%)	38 (20)	18 (18)	20 (22)	0,450
Dyslipidaemia (%)	61 (32)	33 (32)	28 (31)	0,813
Heart failure (%)	13 (7)	8 (8)	5 (6)	0,531
Atrial Fibrillation (%)	63 (32)	40 (36)	23 (26)	0,166
Pre-stroke antiplatelets (%)	60 (30)	34 (32)	26 (28)	0,528
Pre-stroke anticoagulants (%)	28 (14)	17 (16)	11 (12)	0,379
Any previous stroke (%)	35 (18)	20 (19)	15 (16)	0,591
Previous stroke ≤3 months (%)	7 (4)	2 (2)	5 (5)	0,191
Previous stroke >3 months (%)	32 (16)	19 (18)	13 (14)	0,415

Table S2: Main radiological parameters of stroke patients

Neuroimaging Parameters	Total	2019	2020	*p*
ASPECTS. Mean (SD) (2019=52 2020=37)	7,9 (2,1)	7,7 (2,1)	8,2 (2,0)	0,241
Anterior Circulation (%) (2019=97 2020=87)	140 (76)	70 (72)	70 (81)	0,192
Both anterior/posterior (%)	1 (1)	1 (1)	0 (0)	0,548
Right side hemisphere (%) (2019=102 2020=84)	95 (51)	59 (58)	36 (43)	0,225
Both hemispheres (%)	3 (1)	1 (1)	2 (2)	0,452
Multiple occlusion (%)	28 (21)	14 (20)	14 (23)	0,749
Site of occlusion (%) (2019=69 2020=62)				
ICA	35 (27)	21 (30)	14 (23)	0,310
MCA	74 (57)	37 (54)	37 (60)	0,485
BA	12 (9)	8 (12)	4 (7)	0,308
Complication at 24h (%)	27 (15)	15 (15)	12 (14)	0,793
Complication type (%)				0,733
Oedema	20 (11)	10 (10)	10 (12)	
Haemorrhagic transformation	7 (4)	4 (4)	3 (3)	
Both	1 (1)	0 (0)	1 (1)	

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Pre-Hospital pathway indicators were similar in 2019 and 2020, both in Spoke and Hub centers (Table 2).

Spoke to Hub transfer time (inter-Hospital indicator) and Stroke Team (ST) activation were longer? in 2020 (164 min vs 194 min, p=0.205 and 61% vs 69%, p=0.244 respectively).

Table 2: Stroke care pathways indicators of stroke patients admitted to Careggi Hospital during lockdown period (from 1st March to 30th April 2020) and in the corresponding time period in 2019

Stroke Care Pathways	Total	2019	2020	*p*
Pre-Hospital indicators				
Symptom onset to 1st Hospital door time (min).	168 (75-652)	165 (74-620)	210 (75-676)	0,484
Median (IQR) 2019=113 2020=93				
Symptom onset to Spoke Hospital door time (min).	75 (48-135)	65 (48-135)	97 (48-154)	0,659
Median (IQR) 2019=31 2020=26				
Symptom onset to Hub Hospital door time (min).	253 (139-675)	232 (136-657)	330 (150-676)	0,279
Median (IQR) 2019=113 2020=93				
Inter-Hospital indicators	177 (83)	164 (71)	194 (95)	0,205
Time from Spoke to Hub (min)				
Mean (SD) 2019=31 2020= 26				
Stroke Team Activation (%)	135 (65)	70 (61)	65 (69)	0,244
Intra-Hospital indicators				
Door _to_Clinical_Eval_time (min) Median (IQR) 2019=94 2020=78	0 (0-92)	12 (0-109)	0 (0-52)	0,005
Door_to_Clinical_Eval_time (min)	0 (0-11)	0 (0-34)	0 (0-0)	0,011
(with Stroke Team [ST] activation)				
Median (IQR) 2019=70 2020=65				
Door_to_Clinical_Eval_time (min)	345 (320)	425 (370)	208 (133)	0,007
(No ST activation)				
Mean (SD) 2019=24 2020=13				
Door_to_Scan_time	77 (73)	93 (90)	58 (56)	0,01
Mean (SD) (2019=107 2020=87)				
Door_to_Scan_time	40 (35)	42 (40)	37 (28)	0,454
(with ST activation) Mean (SD)				
Door_to_Scan_time	143 (113)	168 (127)	103 (72)	0,002
(No ST activation) Mean (SD)				
Door_to_Imaging_report_time Mean (SD) (2019=107 2020=87)	96 (89)	110 (106)	78 (56)	0,014
Door_to_Imaging_report_time	60 (38)	60 (41)	59 (34)	0,991
(with ST activation). Mean (SD)				
Door_to_Imaging_report_time	161 (113)	186 (128)	122 (70)	0,002
(No ST activation). Mean (SD)				
Admission in Stroke Unit (%)	133 (64)	70 (61)	63 (67)	0,401
Hospitalization (Stroke Unit) length (days) Mean (SD)	5,3 (3,9)	5,2 (3,8)	5,4 (4)	0,794
Hospitalization (Tot) length (days) Median (IQR)	7 (3-10)	6 (3-9)	7 (3-10)	0,483
Intrahospital Death (%)	27/208 (13)	13 (11)	14 (15)	0,456

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Intra-hospital indicators showed an opposite trend, with decrease of door to first clinical evaluation time in 2020 (12 vs 0 min, p=0.005), regardless of ST activation. Door-to CT scan and door-to-CT report time decreased in 2020 (93 vs 58 min, p=0.01 and 110 vs 78, p=0.014, respectively), but were unchanged in the subset of patients with ST activation. Stroke Unit admission, hospitalization length (in Stroke Unit and overall) and intrahospital death were comparable between 2019 and 2020. Even if reperfusion treatments administration was broadly comparable between 2019 and 2020 (22% vs 20%, p=0.763), the proportion of patients who received EVT raised in 2020 (23% vs 31%, p=0.190).

All time parameters were longer in 2020, both considering onset or door to treatment (Table 3). Onset to needle and onset to groin puncture time increased in 2020 of 27 and 91 minutes respectively. A smaller delay was detected in the intrahospital section of treatments administration: door to needle time raised both in Spoke and Hub from 66 minutes in 2019 to 85 minutes in 2020, while door to groin puncture time grew from 78 minutes (2019) to 96 minutes (2020).

Table 3: Time parameters in minutes.

Reperfusion Treatments	Total	2019	2020	*p*
Any reperfusion treatment (%)	79 (38)	43 (38)	36 (38)	0,932
Both i.v. and EVT treatment (%)	20 (10)	8 (7)	12 (13)	0,162
i.v. (%)	44 (21)	25 (22)	19 (20)	0,763
Onset to needle. Mean (SD) (2019=25, 2020=19)	158 (61)	147 (54)	173 (68)	0,178
Door to needle. Mean (SD) (2019=24, 2020=19)	74 (45)	66 (36)	85 (54)	0.192
EVT (%)	55 (26)	26(23)	29 (31)	0,190
Onset to groin puncture. Mean (SD) (2019=26, 2020=29)	328 (185)	280 (115)	371 (224)	0,066
Door to groin puncture. Mean (SD) (2019=26, 2020=28)	87 (55)	78 (55)	96 (54)	0,220

Categorized clinical and pathway parameters did not differ significantly between 2019 and 2020 as well as the reasons for exclusion from acute phase stroke treatment (Table S3 & S4 in supplementary material).

Table S3: Categorized clinical and stroke care pathway parameters.

Categorized Clinical and Pathway Parameters	Total	2019	2020	*p*
NIHSS presenting AOUC categorized (%) (2019=92, 2020=77)				0,960
≤4	60 (36)	33 (36)	27 (35)	
4<NIHSS≤14	53 (31)	28 (30)	25 (33)	
>14	56 (33)	31 (34)	25 (33)	
Hospitalization Stroke Unit categorized (%) (2019=70, 2020=63)				0,457
≤3	53 (40)	26 (37)	27 (43)	
3<days≤7	43 (32)	26 (37)	17 (27)	
>7	37 (28)	18 (26)	19 (30)	
Door to Scan categorized (%) (2019=107 2020=87)				0,209
≤30	76 (40)	36 (34)	40 (46)	
30<time≤60	36 (19)	21 (20)	15 (17)	
>60	82 (42)	50 (47)	32 (37)	
Door to needle categorized (%)(2019=24, 2020=19)				0,812
≤30	6 (14)	4 (17)	2 (11)	
30<time≤45	5 (12)	3 (13)	2 (11)	
>45	32 (74)	17 (71)	15 (79)	
Door to groin p. categorized (%)(2019=26, 2020=28)				0,462
≤90	35 (65)	19 (73)	16 (57)	
90<time≤120	6 (11)	2 (8)	4 (14)	
>120	13 (24)	5 (19)	8 (29)	

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Table S4: Reason excluding from acute phase treatment

Reason Excluding From Acute Phase Treatment	Total	2019	2020	*p*
Reason No tPA (%)(2019=72, 2020=53)				0,961
Anti-Coag Tp	17 (14)	10 (14)	7 (13)	
Clinical Evaluation	14 (11)	7 (10)	7 (13)	
Imaging	6 (5)	3 (4)	3 (6)	
Low NIHSS	9 (7)	5 (7)	4 (8)	
Timing	79 (63)	47 (65)	32 (60)	
Reason No EVT (%)(2019=26, 2020=28)				0,492
Aspect/Core/Haemorrhagic Tr.	24 (21)	16 (23)	8 (19)	
Clinical Evaluation	35 (31)	20 (28)	15 (35)	
No Major Occlusion	32 (28)	18 (25)	14 (33)	
Timing	23 (20)	17 (24)	6 (14)	

The binomial logistic regression showed that only the type of stroke had an effect on intrahospital death (haemorrhagic stroke OR 0.2, 95%CI 0.01 - 0.6, *p*=.004), while no statistically significant effect was induced by age, sex, year (2019 vs 2020) or reperfusion treatment administration.

Discussion

During COVID-19 pandemic, stroke care organization in Florence was generally affected, especially regarding the emergency territory and Spoke and Hub system, while the intrahospital pathways in Careggi underwent a minor disruption of efficiency.

Despite the assumption that SARS-CoV2 infection, through hypercoagulability, increase the risk of cerebrovascular events [4], a reduction in acute stroke volume in hospitals in Italy [5,6] and worldwide [7-9] has been extensively reported. With the limitations due to the small number of patients, our study allows some considerations though mostly not corroborated by a statistical significance. We reported a drop in number of stroke patients arrived at our hospital in March and April 2020 if compared to the same period of 2019. Even if possible explanations for the reduced admissions for stroke have been described by De Sousa et al., especially for older patients with milder symptoms, such as overcharge on emergency medical services, the fear of infection, the strict instructions to stay at home and social isolation, a degree of uncertainty remains behind the interpretation of these data [10].

It remains unclear if this reflect a decrease in stroke rate, or more likely, if it is linked to a reduction in seeking medical help. The slight modification of admitted patient's characteristics (younger age and more frequently male) suggests that older and female patients may have been less commonly conducted to the hospital if compared to pre-pandemic period. Female old patients more often live alone [11], and restrictive measures can have hampered the relatives' witnessing of stroke symptom onset.

Moreover, the fear of the consequences of virus contagious, [12], probably has driven to a delay and a reduction in reaching the hospital in elderly patients. This reluctance from seeking medical help can partially explain the slight delay in time from onset to hospital arrival showed in our analysis, along with the overload on emergency transport service due to COVID-19 patients and related hygienic procedures [13].

Reduced hospitalization of the less severe patients has been extensively reported [14], but it didn't occurred in our hospital, where no differences in mean NIHSS were observed before and during population confinement. The minor impact of COVID-19 outbreak in Florence can only partially explain the differences of our findings if compared with northern Italian regions, were the spread of the virus was more severe in the first months of 2020 [1].

In our analysis mean times of arrival to first hospital from stroke symptoms onset was delayed by almost 45 minutes (165 minutes pre-COVID-19 versus 210 minutes post-COVID-19) and is in line with the literature [15-17]. Similarly, time from spoke to hub transfer increased of around half hour in 2020 (164 minutes versus 194 minutes), and probably reflect the overload of peripheral center and the inefficiency of inter-hospital procedure during COVID-19.

Intrahospital performance instead resulted similar to pre-pandemic standard, and in some areas seemed even improved. Door to recanalization treatments timings only marginally increased in 2020 (19minutes for rTPa and 18 minutes for EVT), reflecting a preservation of efficiency in acute phase treatments administration in both spoke and hub center. Few authors have described [18,19] analogous results. More surprisingly, in our

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comprehensive stroke center, COVID-19 pandemic did not always worsened the quality of care, like few studies reported [15]. Other intrahospital metrics, such as door to clinical evaluation and to CT scan time, decreased during lockdown, demonstrating an improvement in those fundamental steps of stroke patients' pathways, unusual in literature of COVID-19 era. The reduction in the total number of patients admitted to hospitals may explain these data.

The decrease in tPA administration showed in our study was consistent with most of similar papers in literature [14,20]. Instead, the proportion of patients treated with EVT increased during lockdown in our hospital, which is in contrast with the majority of papers describing a significant reduction in EVT treatments during pandemic [21-23]. In Italy, also Sacco et al. reported an increase in the area of maximum expression of the outbreak in northern Italy [14], probably linked to the frequent ineligibility for rTPa in these regions, due to delayed hospital arrival of patients. An analogous evidence was reported only by Krogias et al in Germany [8]. Surprisingly regarding the recanalization strategies exclusion criteria, the proportion of patients not eligible for rTPa because exceeding time from onset limit (4,5hours) did not increase in 2020 in our spoke and hub system. Therefore, the increase in EVT we observed during the lockdown is not completely explained by the diminution of i.v. thrombolysis performed.

In our analysis, lockdown measures did not have a significant impact on stroke patients, regarding presenting and 24 hours mean NIHSS values, reason excluding from acute phase treatment, aetiology and neuroimaging parameters (Table S1&S2). Main comorbidities were equivalent in the two cohorts (Table S1).

Only NIHSS improvement from Hospital admission to 24 hours after stroke onset was considerably lower in 2020 (64,3% versus 47,5%, p=0.054, Table 1). Agarwal et al. also described a similar pattern in 2020 [19], and it may be hypothesized that the delayed arrival in Hospital could induce a slower and poorer recovery, even in treated stroke patients. Still, we couldn't evaluate the outcome (3 month modified Rankin Scale) as was unavailable for most of patients, so it is impossible to estimate the long-term effect of this finding.

Krogias et al. and Meza reported a significant increase in In-hospital mortality in stroke patients during the pandemic period [8,24], which is not reproduced in our cohort of patients, while Naccarato et al. described worse functional and independence outcomes, despite the similar proportion of reperfused patients [25].

In our analysis we described similar mortality and clinical variables, likewise some other authors [26,27], and in the binomial logistic regression the likelihood of intrahospital death was influenced by the type of stroke and not by the effects of age, sex, date of stroke (2019 or 2020) and stroke treatment.

Limitations and Strengths of the Study

This study has several limitations. The study period does not match exactly lockdown period, but we decided to include from 1st of March because even if maximal restrictive measures started in 11march, since the end of February all activities were markedly reduced. Sample size and the short observation period are the main limitations of this study. We excluded the modified Rankin Scale at 3 months as an outcome as in most of patients this variable was unavailable due to patient's management in spoke center and to disruption of in person follow-up evaluation during COVID-19 emergency.

The strengths of this study include the possibility to generalise our findings as the sample is representative of study population despite the sample size: we performed a comprehensive screening of all stroke patients admitted to our hospital, including those managed by different specialists other than neurologist. This analysis represents the accurate estimate of door to treatment and assessment the overall efficiency of as a single-center experience integrated in a spoke and hub system in Italy.

Conclusion

COVID-19 pandemics has been disruptive for the majority of existing protocols in healthcare, especially in time-dependent pathways, with massive effect on patient's outcome regardless of viral infection. In our centre, stroke care organization was mostly preserved and adapted during the lockdown period, resulting in a negligible impact on stroke patient's outcome. These findings remark the need of adequate population awareness of acute cerebrovascular disease, to encourage stroke patients to prompt seek emergency care even during pandemic period. Moreover, multi-disciplinary team efforts and specific integrated protocols for Spoke and Hub system are even more crucial in unusual activity period such us COVID-19, to optimise, preserve and ensure efficiency of hyperacute stroke care.

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Informed Consent

Informed consent was not sought for the present study because of the retrospective approach of the study.

Ethical Approval

Ethical approval was not sought for the present study because of the retrospective approach of the study. This study was completed in accordance with the Helsinki Declaration as revised in 2013.For this type of study formal consent is not required.

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Guarantor: AS

Contributorship

AS, CS, ML, MN, VP, FP, BP, AP and PN researched literature and conceived the study. AS, DA, SB, YF, VI, CMR and GDS were involved in protocol development, patient recruitment and data analysis. AS wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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