Identifying and Treating SARS-CoV-2 & CoronaVirus Disease – 2019 [COVID-19] Patients Using Quantitative FMTVDM Nuclear Imaging

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ABSTRACT

Background: SARS-CoV-2 and the associated InflammoThrombotic Response (ITR) COVID-19 is associated with significant morbidity and mortality. Quantitative Nuclear Imaging using FMTVDM has been shown to identify ITR and infectious disease and can be used to both identify and track treatment responses in such individuals. This study looked at a variety of treatments and measured treatment outcomes.

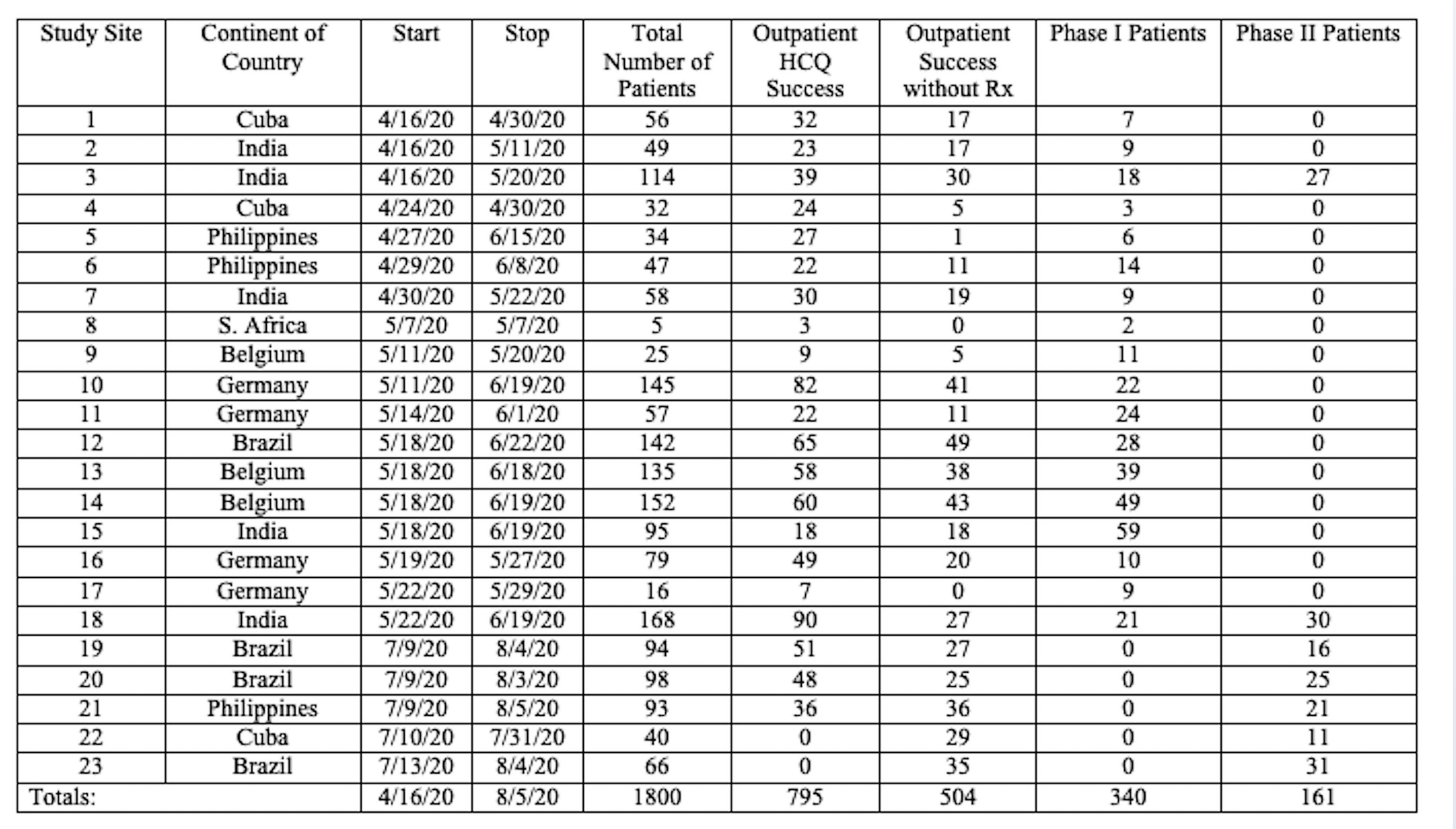
Methods: 1800 patients testing positive for SARS-CoV-2 were assigned to a treatment or observation group. Three days later they were re-evaluated. Those with disease progression and diagnosis of COVID-19 were admitted to hospital, underwent further testing including quantitative evaluation of the extent of disease using FMTVDM. Patients were randomly assigned one of ten treatments and re-evaluated 72-hours later. Patients were kept on the same treatment if they improved. Patients who did not improve were randomly assigned an additional treatment and re-evaluated 72-hours later. This sequence was continued until treatment was successful or patients expired.

Results: Of the 1800 outpatients, 501 required hospitalization. Among those not admitted 504 of the 847 not treated (59.5%) recovered without treatment. Among those treated in the outpatient setting 795 of the 953 (83.4%) responded to outpatient treatments. The remaining 501 patients from both the non-treatment and treatment groups were admitted. Initial labs and quantitative nuclear imaging testing were done upon admission and every 72-hours to guide treatment responses. Among those admitted 498 of 501 (99.83%) responded to a combination of treatments. Three died while on ventilator assistance. FMTVDM correlated with IL-6 and Ferritin levels at 0.718 and 0.673 respectively.

Conclusion: Quantitative FMTVDM imaging, IL-6 and Ferritin levels provided a useful method for diagnosing and treatment guidance of patients with COVID-19.

METHODS & RESULTS

- 1800 people testing positive for SARS-CoV-2 were enrolled from 7 countries at 23 sites. NCT04349410.



Study Site	Continent of Country	Start	Stop	Total Number of Patients	Outpatient HCQ Success	Outpatient Success without Rx	Phase I Patients	Phase II Patients
1	Cuba	4/16/20	4/30/20	56	32	17	7	0
2	India	4/16/20	5/11/20	49	23	17	9	0
3	India	4/16/20	5/20/20	114	39	30	18	27
4	Cuba	4/24/20	4/30/20	32	24	5	3	0
5	Philippines	4/27/20	6/15/20	34	27	1	6	0
6	Philippines	4/29/20	6/8/20	47	22	11	14	0
7	India	4/30/20	5/22/20	58	30	19	9	0
8	S. Africa	5/7/20	5/7/20	5	3	0	2	0
9	Belgium	5/11/20	5/20/20	25	9	5	11	0
10	Germany	5/11/20	6/19/20	145	82	41	22	0
11	Germany	5/14/20	6/1/20	57	22	11	24	0
12	Brazil	5/18/20	6/22/20	142	65	49	28	0
13	Belgium	5/18/20	6/18/20	135	58	38	39	0
14	Belgium	5/18/20	6/19/20	152	60	43	49	0
15	India	5/18/20	6/19/20	95	18	18	59	0
16	Germany	5/19/20	5/27/20	79	49	20	10	0
17	Germany	5/22/20	5/29/20	16	7	0	9	0
18	India	5/22/20	6/19/20	168	90	27	21	30
19	Brazil	7/9/20	8/4/20	94	51	27	0	16
20	Brazil	7/9/20	8/3/20	98	48	25	0	25
21	Philippines	7/9/20	8/5/20	93	36	36	0	21
22	Cuba	7/10/20	7/31/20	40	0	29	0	11
23	Brazil	7/13/20	8/4/20	66	0	35	0	31
Totals:		4/16/20	8/5/20	1800	795	504	340	161

Of the 1800 outpatients, 847 (47%) elected to receive no treatment. 504 (59.5%) improved without treatment, while 343 (40.5%) deteriorated and were admitted with COVID (left). 953 (53%) elected to receive 1 of 4 outpatient treatments, with 795 (83.4%) improving. 158 (16.6 %) failed to improve and were admitted to hospital with COVID (right).

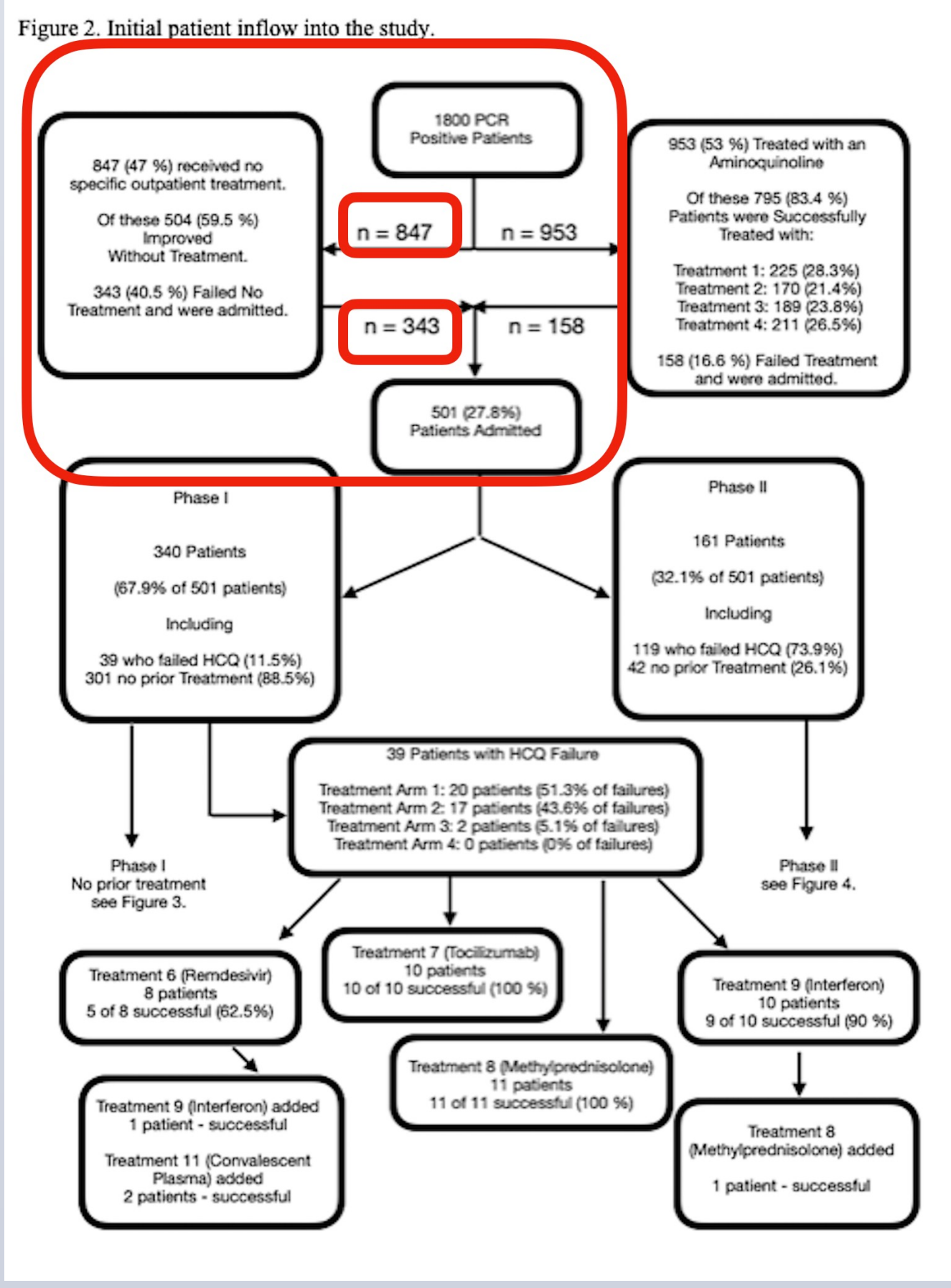


Figure 2. Initial patient inflow into the study.

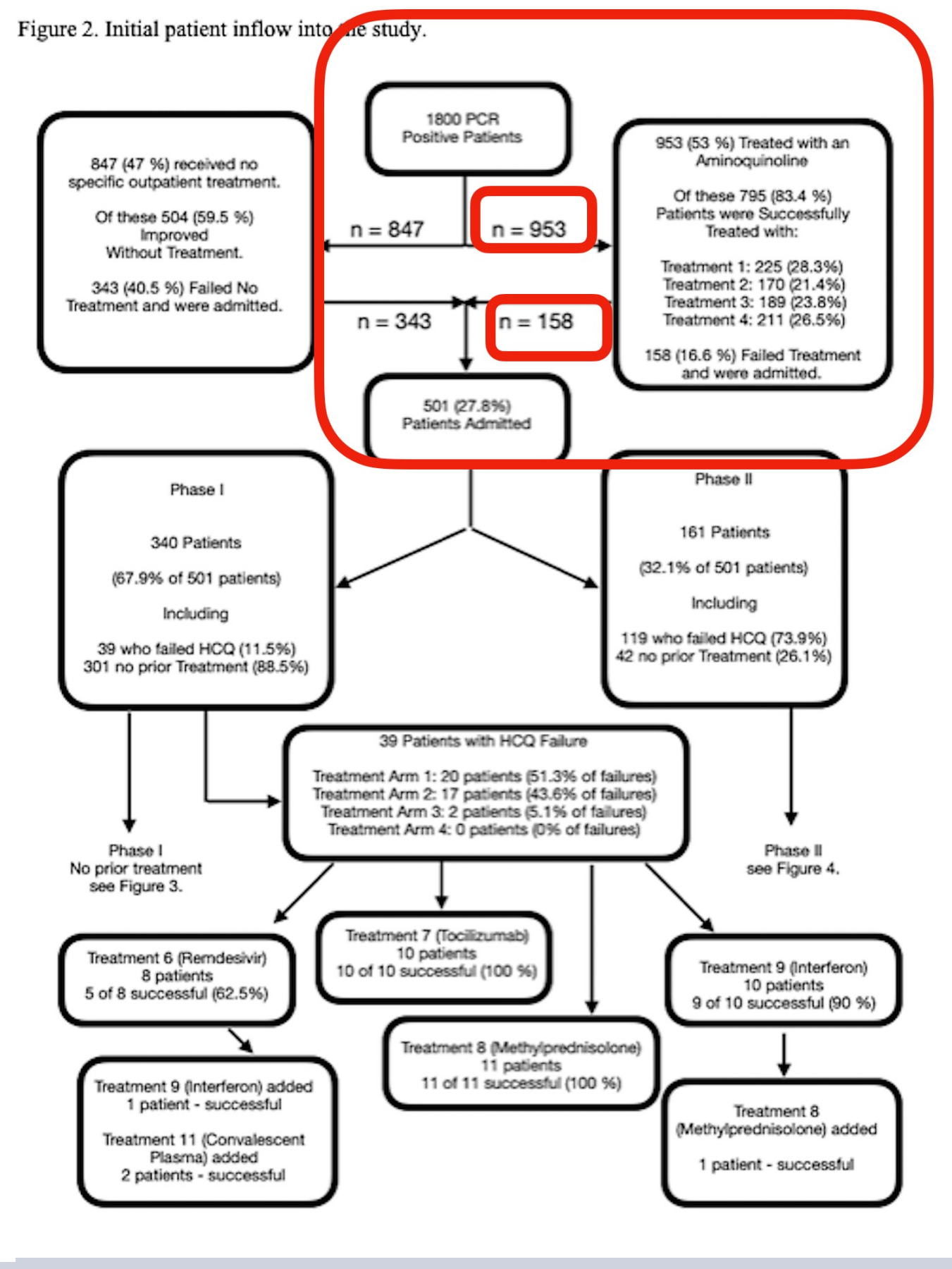
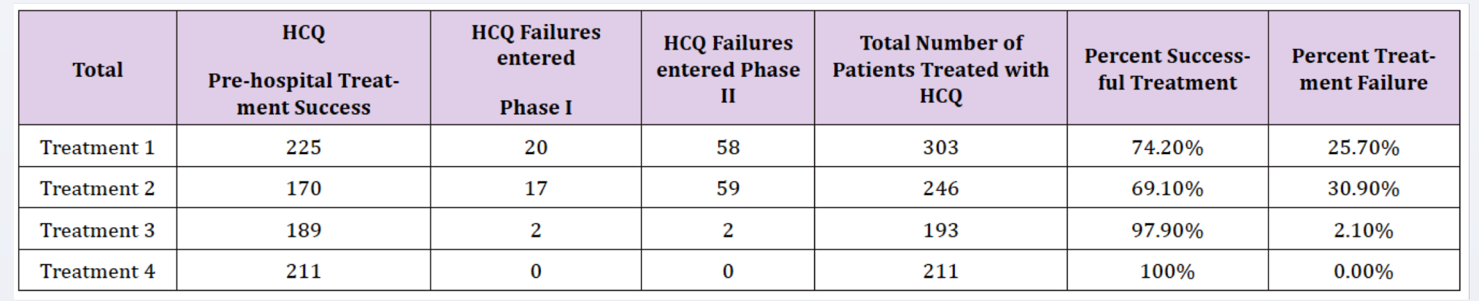


Figure 2. Initial patient inflow into the study.

METHODS & RESULTS (cont)

When Treatment was Started within 3-4 Days of Symptoms



Total	HCQ Pre-hospital Treatment Success	HCQ Failures entered Phase I	HCQ Failures entered Phase II	Total Number of Patients Treated with HCQ	Percent Successful Treatment	Percent Treatment Failure
Treatment 1	225	20	58	303	74.20%	25.70%
Treatment 2	170	17	59	246	69.10%	30.90%
Treatment 3	189	2	2	193	97.90%	2.10%
Treatment 4	211	0	0	211	100%	0.00%

(1) **100%** Effective [Treatment Regimen 4]
- Primaquine 200 mg by mouth on day 1.
- Clindamycin 150 mg by mouth every 6-hours for 7-days.
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.

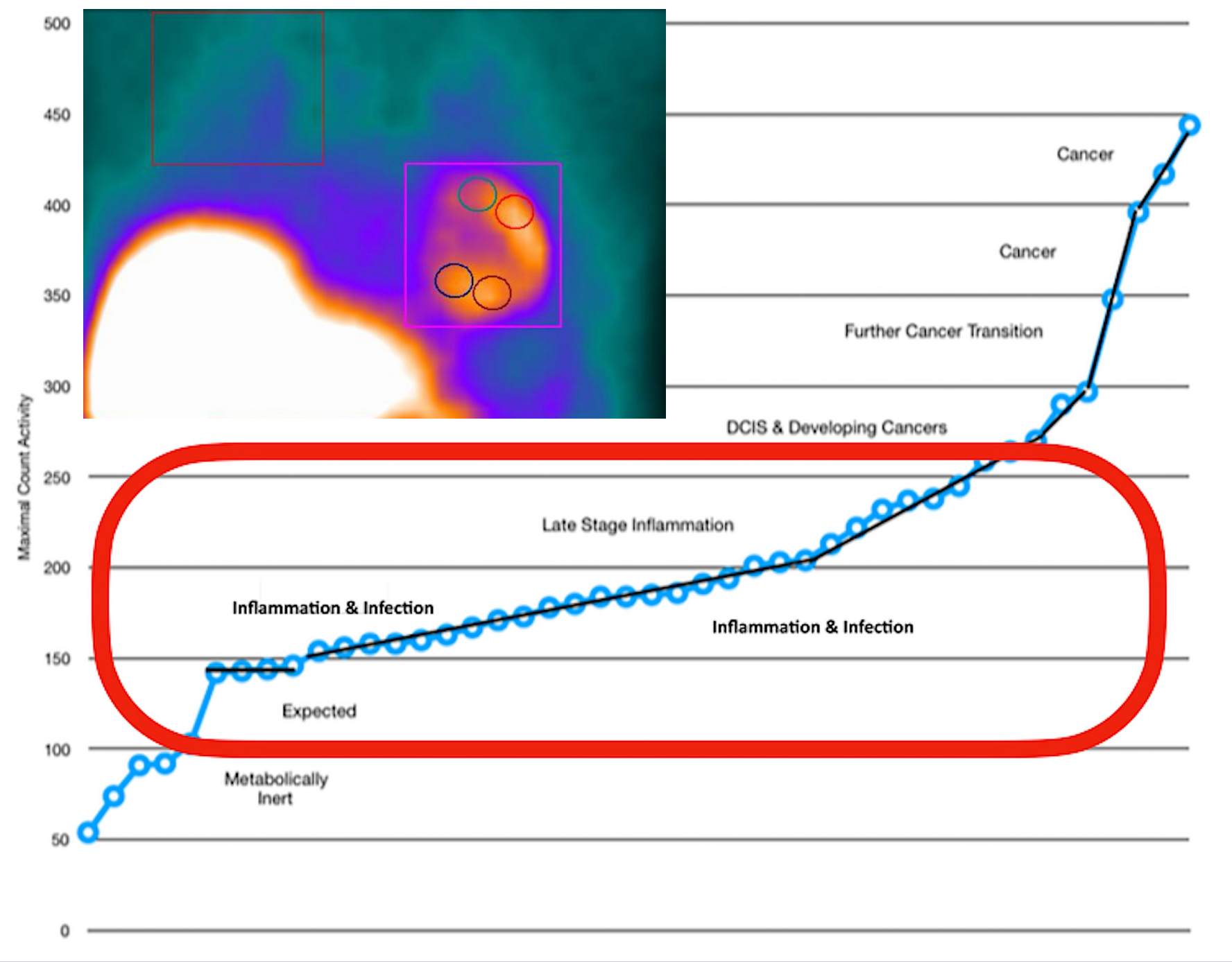
(2)**97.9%** Effective [Treatment Regimen 3]
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Clindamycin 150 mg by mouth every 6-hours for 7-days.

(3) **74.2%** Effective [Treatment Regimen 1]
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Azithromycin 500 mg by mouth on day 1, then 250 mg by mouth on days 2 through 5.

(4) **69.1%** Effective [Treatment Regimen 2]
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Doxycycline 100 mg by mouth every 12-hours for 10-days.

FMTVDM INPATIENT TREATMENT

A total of 501 patients were admitted including 343 (68.5%) who received no outpatient treatment and 158 (31.5%) who failed outpatient treatment. Prior to receiving randomized treatment, each patient underwent a series of tests including FMTVDM, IL-6 and Ferritin levels.



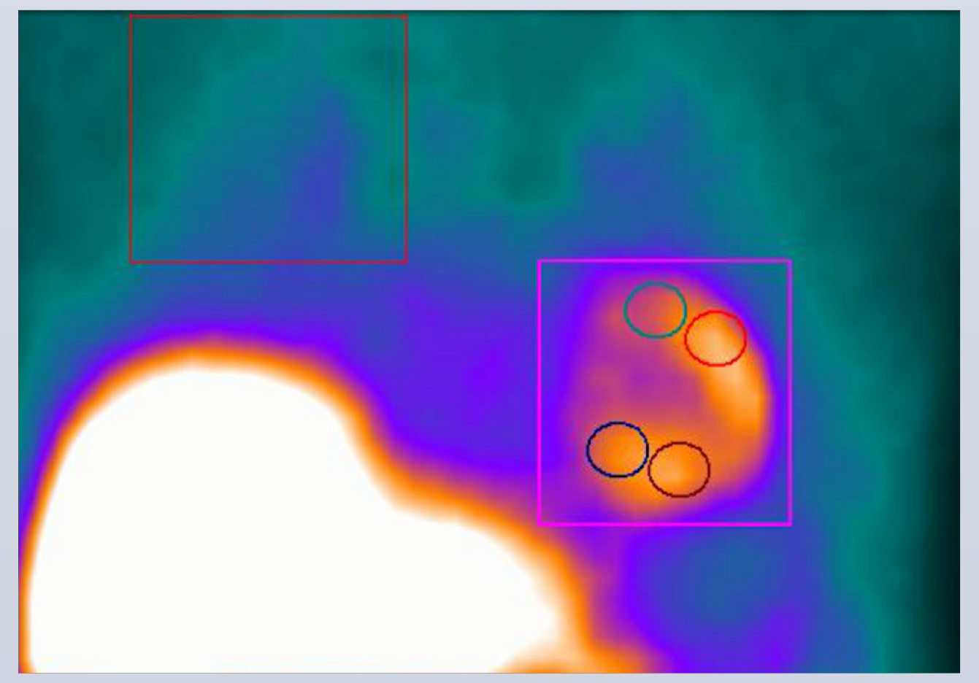
METHODS & RESULTS (cont)

Patients were then randomly assigned a treatment:

Treatment 1 (Hydroxychloroquine, Azithromycin)
Treatment 2 (Hydroxychloroquine, Doxcycline)
Treatment 3 (Hydroxychloroquine, Clindamycin)
Treatment 4 (Hydroxychloroquine, Clindamycin, & Primaquine)
Treatment 5 (Primaquine, Clindamycin)
Treatment 6 (Remdesivir)
Treatment 7 (Tocilizumab)
Treatment 8 (Methylprednisolone), or
Treatment 9 (Interferon-α2β)
Original Treatment 10 (Lorsartan an ARB) was deleted before study began, and
Treatment 11 (Convalescent Plasma) was not given as first Treatment but was randomly added as a second or third line Treatment.

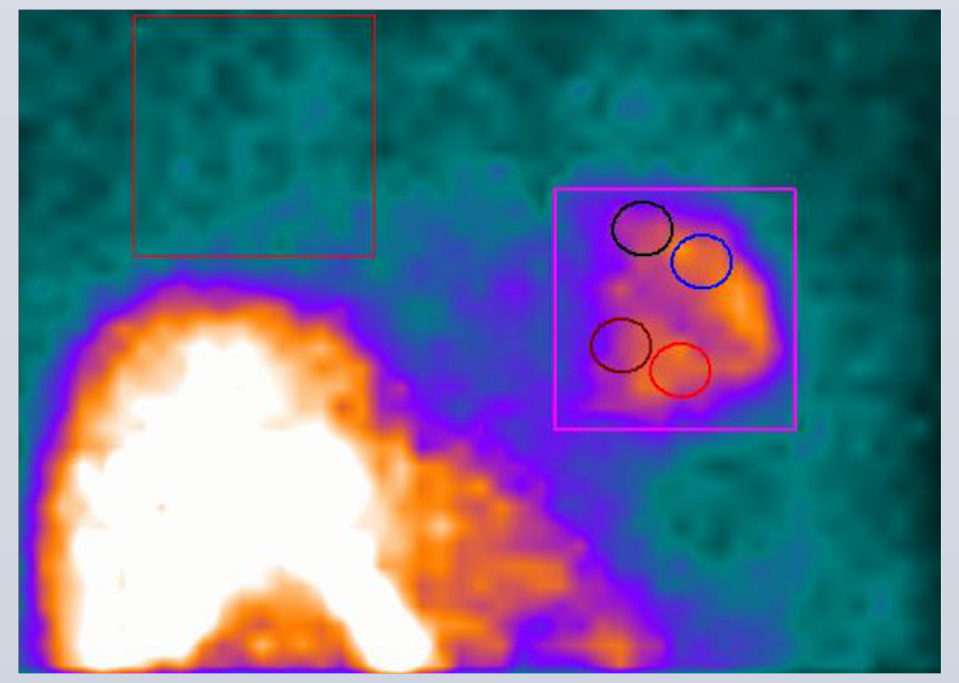
72 hours later FMTVDM, IL-6 and Ferritin were measured. If no improvement was noted a new treatment was randomly added and testing repeated every 72-hours until patients improved or expired. When patients improved, treatment was maintained.

Female Patient 3/1 Entered Phase I after Treatment 1 Failed.



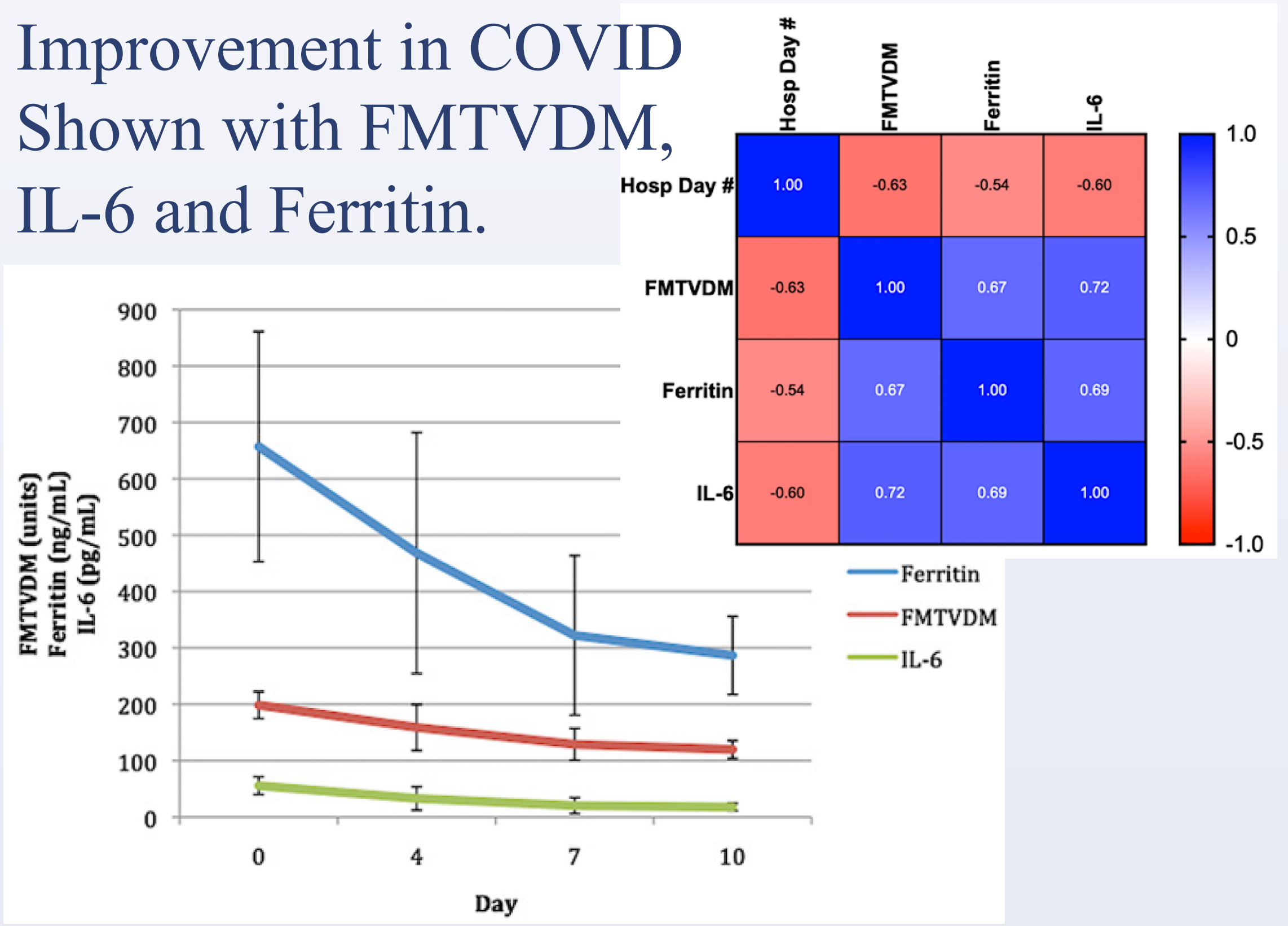
Day 1 FMTVDM 195 MCA; Ferritin 302 ng/ml; IL-6 45 pg/ml

Day 4 FMTVDM 170 MCA; Ferritin 195 ng/ml; IL-6 12 pg/ml



Treatment 8 (Methylprednisolone) Started

Improvement in COVID Shown with FMTVDM, IL-6 and Ferritin.



Successful outpatient treatment of SARS-CoV-2 as previously shown. Of patients requiring admission for COVID, all but 3 improved with treatment guided by FMTVDM, IL-6 and Ferritin.

Successful inpatient treatment of 498 of 501 (99.4) included with prior aminoquinoline:

(1)Methylprednisolone, or
(2)Tocilizumab and Interferon α-2β;

Or without outpatient aminoquinoline

(1) Primaquine, Clindamycin, Tocilizumab and Interferon α-2β.

CONCLUSIONS

- FMTVDM Quantitative Nuclear Imaging provides clinically valuable diagnostic data on COVID patient treatment response and defined successful SARS-CoV-2/COVID treatments in 99.83% of patients..

Fleming RM, Fleming MR. FMTVDM Quantitative Nuclear Imaging finds Three Treatments for SARS-CoV-2. BJSTR.2021.33.005443