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COVID and microsurgery: Did the microsurgical anastomosis failure rate in three hand surgery and orthoplastic units increase? A retrospective multicenter study

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ABSTRACT

Introduction: COVID-19 infection seems to have among its fundamental pathogenetic mechanisms the appearance of a pro-thrombotic state capable of causing severe damage to various organs (lungs, kidneys, eyes …). Furthermore, the vaccines marketed in Italy in December 2020, used to slow the spread and mortality of this virus, also seem responsible for a possible pro-thrombotic state in the subjects to which they are inoculated. The authors of this work then wondered if the COVID-19 pandemic may have somehow altered the results of microsurgical anastomoses performed at their centers.

Materials and methods: More than 270 patients who had at least one microsurgical vascular suture, in one of the three centers involved in this study, in the last four years were then retrospectively evaluated (two years pre-COVID vs. two years post-COVID). Planned surgeries of oncological, post-infection, or post-trauma) patients treated with microsurgical flap and patients who underwent digital or hand reimplantation were included. Failure rates were compared, taking into consideration whether patients had tested positive for COVID-19 or had a COVID-19 vaccine shot in the six months before the surgery.

Results: The anastomosis success rate of the entire "pre-COVID" group is 70.4 %, while that of the "COVID" group is 73.3 %. Different subgroups are analyzed, and the only statistically significant difference in results is obtained by comparing the success rate of the "pre-COVID" group to the subgroup, in the COVID era, of patients who have tested positive for COVID or had at least one dose of vaccine.

Conclusions: According to this study, failures of microsurgical anastomoses in patients previously affected by COVID or in previously vaccinated patients do not appear to have increased. On the contrary, COVID and/or vaccines might have a protective action.

1. Introduction

The new Coronavirus responsible for the 2020 pandemic hit Italy in early 2020, leading to a generalized lockdown from the 9 th of March to the 4 th of May, which was necessary to deal with this, up to then unknown pathogen.[1] Different theories quickly spread about how this virus

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could be so lethal, affecting many organs.[2] One of the most widespread theories is the one that claims that the various organs affected go into failure due to a pro-thrombotic picture generated by the virus,[3–5] in particular with the formation of large vessel strokes and deep vein thrombi.[6–8] Moreover, the risk of microvascular thrombi and vasculitis has been recently described in patients affected by SARS-COV-2 requiring microvascular anastomosis.[9,10] Similarly, vaccines marketed in Europe since the end of 2020 also appear to be able to cause arterial and venous thrombosis.[11–13] Following two failed upper limb reconstruction operations with free flaps in patients recently infected with COVID, the authors of this work asked themselves whether the virus – in addition to changing their activity from an organizational[14,15] and surgical[16] point of view - could have had an impact on the results of their surgery. In particular, the authors wanted to understand if the pro-thrombotic state generated by the virus and vaccines could influence the success of theirmicrosurgical anastomoses.

To answer this question, the authors retrospectively reviewed patients operated on with microsurgical anastomoses in the years that preceded and followed the onset of COVID-19 in their three centers. This study continues a preliminary survey carried out in one of the centers mentioned above, presented at the SIM (Società Italiana di Microchirurgia) Symposium in 2022.[17]

2. Methods

For this retrospective observational study, authors reevaluated all patients treated with microsurgical anastomosis in one of the three centers mentioned above between the 9 th of March 2018 and the 9 th of March 2022. The three hospitals involved are all university centers with specialized hand and microsurgery units: CTO Hospital in Turin, ASST Settelaghi in Varese, and Policlinico Gemelli in Rome. The three involved units are reference center, in the region to which they belong, for complex and amputative upper and lower limb trauma. All surgeries were performed by senior surgeons, certified by the Italian Society of Microsurgery (SIM), with at least ten years of experience in microsurgery.

Patients included in the study were divided into “pre-COVID” for those treated before the 9 th of March 2020 and “COVID” for those treated after this date.

Patients whose anastomosis occurred in the context of reimplantation/revascularization of a limb within 12 h of an amputation or subamputation and patients whose anastomosis occurred in the context of the transfer of a free flap to reconstruct a loss of substance (post-traumatic,oncological, or infectious) were included. Authors excluded patients whose free flap did not have a cutaneous island (e.g., vascularized fibula, femoral condyle, etc.) as evaluating the success or failure of the anastomosis was not possible in a brief time. Patients who underwent replantation surgery, although it was contraindicated (severe crush injury, multilevel amputations, concomitant life-threatening injuries, single finger amputation proximal to the flexor digitorum superficialis insertion, and prolonged non-thermic ischemia time),[18] were excluded, as well as patients with Diabetes. Patients whose follow-up was incomplete, patients who died at the time of the study, or who did not respond at the time of the call were also excluded.

Patients’ age, sex, smoking habits, and history of cardiovascular disease were collected to assess possible confounding factors. The definitive survival of the flap or the revascularized anatomical part was assessed clinically in the outpatient clinic two months after surgery. Any patient who did not need a revision surgery was assessed as a success. At the same time, any intervention that subsequently required re-operation on vessels (new anastomosis and/or amputation) was defined as a failure. These data were retrospectively collected by one independent author for each center –different from surgeons who performed surgery - using hospital outpatient software (TrakCare® in Rome and Turin, and Whospital® in Varese); in case of doubt, a fourth independent author revised the patient file and took a final decision. In the period between the 9 th of May 2022 and the 9 th of October 2022, all patients who met the inclusion criteria of this study were contacted by telephone (maximum of five calls in case of no response) to obtain a “COVID” asking the following questions: Have you already tested positive for COVID? If yes, when? How many doses of vaccine did you receive? When? Smoking and cardiovascular disease history were assessed.

Overall anastomotic failure and success rates between the “pre-COVID” group and the “COVID” group were compared, as well as failure and success rates between the “pre-COVID” group and the subgroups of patients in the “COVID” group: those who tested positive for COVID within six months before surgery, those who had – within six months before surgery - at least one dose of vaccine, those who have had one dose of vaccine, two doses of vaccine, three doses of vaccine, and finally those who have tested positive for COVID or received at least one dose of vaccine.

Moreover, patients in the “pre-COVID” group were also compared with those in the “COVID” group, differentiating urgent patients (revascularizations) from planned ones (free flaps).

All patients signed an informed consent to the surgery, and at the time of the phone call, they were told that the data collected would be used for this publication (maintaining their privacy). Furthermore, Institutional Review Board approval was not required for this retrospective observational study as all data was processed and presented as aggregated data, making it impossible to identify any individual patient, in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments.

Having no prior literature available, the sample size calculation was based on the preliminary study[17] overall success rate of anastomosis (67, 6 %). Considering a confidence level of 95 % and an acceptable difference of 6 %, the estimated sample size is at least 236 patients.

The statistical analysis aimed at comparing the significance of the different distributions of success rates was performed using the two-tailed CHI-SQUARE test with confidence interval alpha = 0.05, inserting data on Microsoft Excel (2019). Furthermore, involvement of confounding factors such as smoking habits and story of cardiovascular disease has been assessed calculating ODD RATIOS (OR) with 95 % confidence interval (CI) using MedCalc®.

3. Results

Of the 512 patients who underwent surgery implying microvascular anastomoses between the 9 th of March 2018 and the 9 th of March 2022, 277 were included in this study (Fig. 1).

Of these, 142 were in the “pre-COVID” group and 135 in the “COVID” group (Table 1).

Among those operated on before the 9 th of March 2020, 60 had a free flap, and 82 had a revascularization; while among those operated on after the 9 th of March 2020, 74 had a free flap, and 61 had a evascularization.

Specifically, regarding the patients in the “COVID” group, 67 (46 flaps and 21 revascularizations) tested positive for COVID or received at least one dose of the anti-COVID vaccine within six months before surgery.

The anastomosis success rate of the entire “pre-COVID” group is 70.4 %, while that of the “COVID” group is 73.3 %. Regarding the subgroups: the success rate of the flaps in the “pre-COVID” group is 78.3 %, while in the “COVID” group, it is 79.7 %; the success rate of the revascularizations in the “pre-COVID” group is 64.6 % and 65.6 % in the “COVID” group (Table 2).

Looking only at patients who have tested positive for COVID or had at least one dose of vaccine, the overall anastomosis success rate is 85.1 %, 91.3 % for flaps, and 71.4 % for revascularizations (Table 3).

The only statistically significant difference in results is obtained by comparing the success rate of the “pre-COVID” group to the subgroup, in the COVID era, of patients who have tested positive for COVID or had at least one dose of vaccine in the six months before surgery (“Immune for

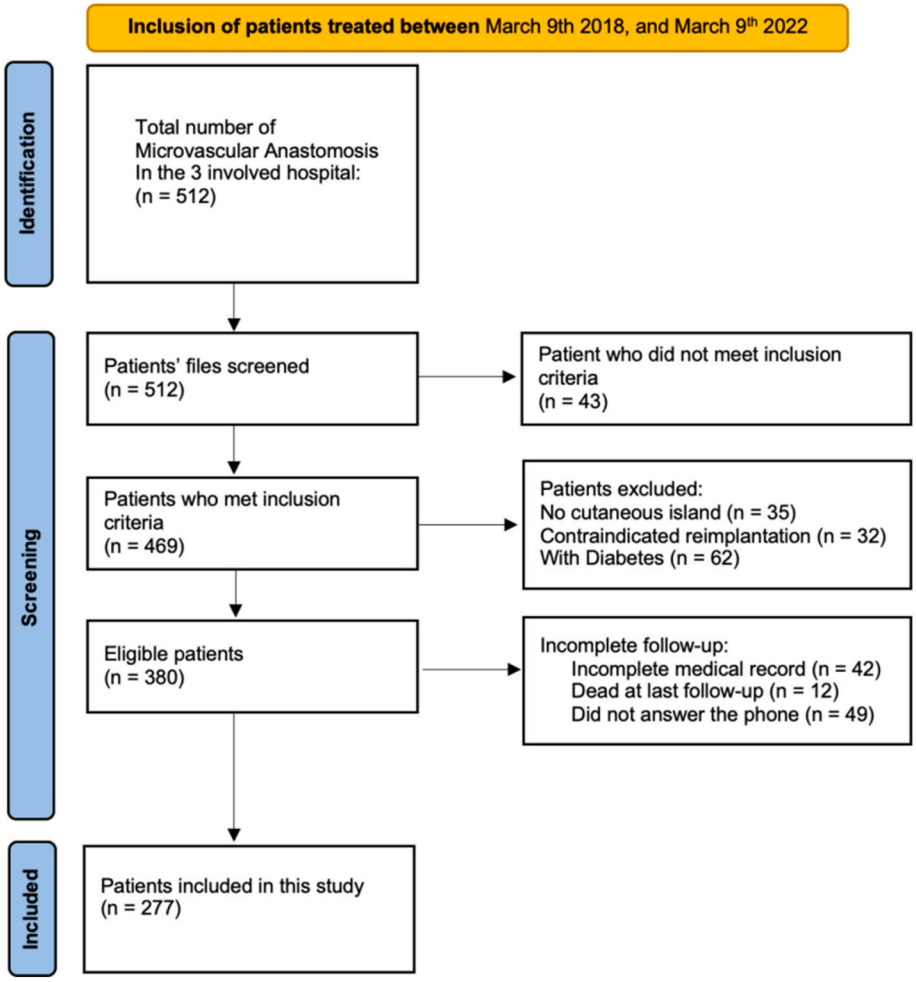

Fig. 1. Flowchart of patients selection.

Table 1
Patients' demographic data.

	N° of Patients	Sex	Mean Age in y. o. (Range)	% of smokers (Mean of cigarette/ day)	% with cardiovascular disease history
TOTAL	277	150 M 127 F	46,3 (18–70)	37,9 (10,1)	23,5
PRECOVID group	142	74 M 68 F	47,7 (19–69)	38,7 (11,2)	23,9
COVID group	135	76 M 59 F	45,2 (18–70)	37,0 (9,9)	23,0
COVID +	35	19 M 16 F	50,2 (23–65)	34,3 (12,0)	25,7
Immune for COVID*	67	36 M 31 F	46,9 (22–70)	38,8 (11,5)	23,9

COVID") (Fig. 2).

The percentage of patients with smoking or cardiovascular disease history was not significantly different in any of the groups mentioned above or sub-groups (Table 1). To evaluate any possible effect of possible confounding factors, OR have been evaluated, both for smoking and cardiovascular disease history, for total population, "pre-COVID" group and "Immune for COVID" group:

Table 2
Results for the pre-COVID group, the whole COVID group, and for patients who tested positive for COVID within six months before surgery.

		Total	Success	Failure	Success rate (in %)
PRECOVID group	total	142	100	42	70,42
	flap	60	47	13	78,33
	revascularization	82	53	29	64,63
COVID group	total	135	99	36	73,33
	flap	74	59	15	79,73
	revascularization	61	40	21	65,57
COVID +	total	35	27	8	77,14
	flap	20	17	3	85
	revascularization	15	10	5	66,67

- Regarding smoking habits
  - for total population OR = 0,5988, 95 % CI: 0,3174-1,1294
  - for "pre-COVID" group OR = 0,6809, 95 % CI: 0,3275-1,4159
  - for "Immune for COVID" group OR = 0,3604, 95 % CI: 0,0909-1,4283
- Regarding cardiovascular disease history
  - for total population OR = 1,0319, 95 % CI: 0,5121-2,0791
  - for "pre-COVID" group OR = 0,8418, 95 % CI: 0,3668-1,9319
  - for "Immune for COVID" group OR = 0,6894, 95 % CI: 0,1558-3,0507

Those results show that in the studied populations, smoking and

Table 3
Results for patients of the COVID group divided depending on the number of doses of vaccine and if they tested positive for COVID within six months before surgery.

		Total	Success	Failure	Success rate (in %)
At least one dose	total	47	38	9	80,85
	flap	28	24	4	85,71
	revascularization	19	14	5	73,68
One dose	total	6	4	2	66,67
	flap	3	2	1	66,67
	revascularization	3	2	1	66,67
Two doses	total	27	23	4	85,19
	flap	16	14	2	87,5
	revascularization	11	9	2	81,82
Three doses	total	14	11	3	78,57
	flap	9	8	1	88,89
	revascularization	5	3	2	60
Immune for COVID*	total	67	57	10	85,07
	flap	46	42	4	91,3
	revascularization	21	15	6	71,43

cardiovascular disease history seems to have no effects on microvascular anastomosis outcomes.

4. Discussion

The pandemic due to the new Coronavirus COVID-19 has undoubtedly changed everyone's life, especially surgeons', influencing their personal life,[19] their training,[20] their professional activity,[14,15] and even changing how they see and operate the patients.[16,21] The present study was created to evaluate whether a possible COVID infection of the patients or the vaccination could also impact the surgical outcome.

Confirming the results obtained in the preliminary study, it would seem - albeit not statistically significant - that the success rate is slightly higher in patients operated on after the onset of COVID than in those operated on before. This multicenter study makes this difference statistically significant when comparing patients who tested positive for COVID or obtained at least one vaccination before their microvascular anastomosis surgery to those operated on when COVID did not yet exist.

Those results are even more surprising considering all the logistical difficulties microsurgeons encountered after the outbreak of COVID.[22,23] On the other hand, the systematic use of thromboprophylaxis[24] in patients who underwent surgery with a microvascular anastomosis could justify a minimization of COVID and the vaccine's pro-thrombotic effects.

To the authors' knowledge, the only study published in the literature that evaluates the outcomes of microsurgery patients based on their "vaccination passport" against COVID is that of Taghioff et al.[25] At the same time, there are no studies that take into consideration a confirmed positivity to COVID. In the study by Taghioff et al. [25], 818 patients who had undergone microsurgery (both elective and "traumatic") were included, dividing them into a group of unvaccinated and a group that had received at least one dose of vaccine in the six months before surgery. Regarding the anastomosis failure rate, they obtained significantly better results at 30 and 60 days after surgery in the vaccinated group. They also demonstrated that this group of patients had a lower risk of infections, a lower need for outpatient visits, and a lower risk of surgical wound dehiscence. The reason for these differences remains unexplained.

Some might argue that survival rates in this study are lower than in the literature.[26,27] In this study, all patients needing further surgery on vessels were considered as failures as the authors focus on the pro-thrombotic effect. Whereas in most studies presenting over 90 % success rate in elective flap surgery, a flap taken back to the Operation Room overnight to make a new anastomosis and stays vital after all is considered a success. Furthermore, this study compares results on the pre-COVID era with the COVID era in the three same centers, so the results are not biased. Finally, results were comparable in the three centers making those results generalizable.

The results of this study should convince microsurgeons not to be discouraged when facing recently vaccinated patients or those recently affected by COVID. Further studies on molecular effects of virus and vaccine on peripheral blood flow explaining those results could help surgeons in this direction. Furthermore, understanding the power of thromboprophylaxis could reassure surgeons in carrying out their anastomoses not only when treating patients vaccinated for COVID or recently affected by this virus but also in all those other patients with

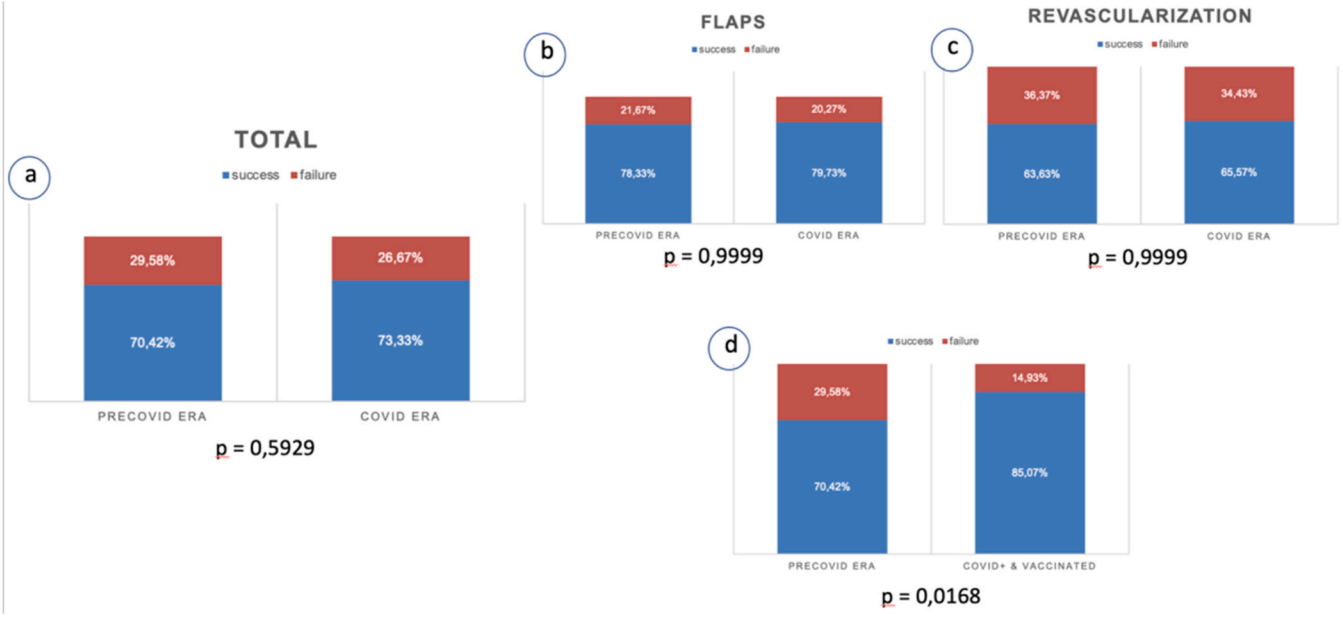

Fig. 2. Principal results presented as diagrams and p-values. (a) overall success and failure rate; (b) success and failure rate for flaps; (c) success and failure rate for revascularization; (d) success and failure rate of the total PRECOVID era compared to patients of the COVID era who have tested positive for COVID or had at least one dose of vaccine in the six months before surgery.

increased thrombotic risk due to other reasons.

Compared to the preliminary study, including patients from different centers allowed an increase in the number of patients in the investigation, leading to some statistically significant results. Nevertheless, limitations of this study remain numerous. Among those, due to the apparent ending of the pandemic due to COVID-19 virus, the retrospective aspect and the limited number of patients positive for COVID or vaccinated in the previous six months will difficultly be resolved in eventual further new studies. Linked to the retrospective aspect of this study, getting anamnestic COVID information by phone introduces the risk of a recall bias. Moreover, despite the authors' efforts, this study presents numerous unresolved possible biases. First of all, it should be taken into consideration that many people have been infected by COVID without having had a certain diagnosis of infection.[28] This can somehow underestimate effects of COVID infection on anastomoses success/failure rate; in the attempt to reduce the effect of this bias, authors have analyzed data regarding patients with a confirmed diagnosis of COVID infection, but also data relating to all patients operated on during the "COVID era". Furthermore, it is also difficult to compare operations performed urgently (revascularizations) to non-urgent procedures, which is why these patients have been divided into subgroups, in which it is still difficult to compare a patient who receives an elective free flap to a traumatized patient, or again to an oncological patient who underwent radiotherapy. Not all influencing comorbidities nor other factors possibly affecting anastomoses success rates, such as the nature of the injury and timing of surgery, have been taken into account due to partial unavailability in hospitals database. Not taking into account all possible confounding factors could somehow alter findings of this study, however authors believe that by analyzing smoking habits and history of cardiovascular disease they excluded effects of what they believe to be the most important possible confounding factors. Finally, in this study, the time relapsed between infection or vaccination and surgery was arbitrarily fixed at a maximum of six months - similarly to the only previous study found in the literature[25] -, as there is no certainty about the duration of the pro-thrombotic state generated by the virus and the vaccine. Possible future discoveries on COVID-19 virus effect on coagulation cascade could allow in future to determine a different timing for analysis of effects on microsurgical anastomosis. Although the end of the pandemic might make it difficult to accomplish, further prospective studies including only patients indeed infected by COVID or fully vaccinated, and taking into account more possible confounding factors, could lead to more precise results and could allow analyzing any different effects between one type of vaccine and the other.

5. Conclusion

According to this study, despite its numerous limitations and possible biases, the failure rate of microsurgical anastomoses in patients previously affected by COVID or previously vaccinated patients does not appear to have increased. Further studies could even confirm that COVID and/or vaccines might have a possible beneficial action regarding microsurgical anastomoses.

Authors contribution

Conceptualization, C.Fu. and D.C.; methodology, C.Fu.; software, C. Fa. and F.P.; validation, B.B., F.T., L.V. and M.C.; formal analysis, C.Fu.; investigation, D.C.; resources, B.B., D.C, G.R., F.T., L.V. and M.C.; data curation, C.Fu., C.Fa. and F.P.; writing—original draft preparation, C. Fu., S.*P. and* C.Fa.; writing—review and editing, S.P., C.Fu., D.C. and B. B.; supervision, D.C. All authors have read and agreed to the published version of the manuscript.

Ethics in publishing statement

This research presents an accurate account of the work performed, all data presented are accurate and methodologies detailed enough to permit others to replicate the work.

This manuscript represents entirely original works and or if work and/or words of others have been used, that this has been appropriately cited or quoted and permission has been obtained where necessary.

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All authors have been personally and actively involved in substantive work leading to the manuscript and will hold themselves jointly and individually responsible for its content.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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