

Impact of COVID-19 pandemic in the activity of a Therapeutic Apheresis unit in Italy

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ABSTRACT

Introduction: The recent Coronavirus Disease 2019 (COVID-19) outbreak has led to profound and rapid changes in the Italian and Veneto Region Healthcare System. This context also includes the quick reorganization which the Apheresis Unit (AU) of the Padova University Hospital, i.e. the Regional Reference Center for Therapeutic Apheresis (TA), had to face.

Material and Methods: The study retrospectively evaluated the TA activity (procedures performed, patients treated and consultations) during the COVID-19 pandemic, from March to April 2020, comparing the activity in the same time period in 2018 and 2019.

Results: In the period analyzed, a significant reduction in both the total number of procedures performed and of patients treated, respectively by 17 % and 16 % for the procedures and by 19 % and 20 % for patients treated compared to the same period of 2018 and 2019, respectively, was observed. A concomitant reduction in requests for TA consultation for new patients (both outpatients and inpatients) was observed, equal to 32 % and 21 % compared to 2018 and 2019, respectively.

Conclusion: Many reasons determined the observed reduction in the TA activity during the recent COVID-19 outbreak. The AU itself was quickly reorganized in terms of location and supplies to allow for the appropriate COVID-19 patients care. Many non urgent cases, after multidisciplinary discussion between Clinicians and Apheresis Specialists, were deferred, maintaining close phone and e-mail contact with patients.

1. Introduction

The ongoing outbreak of the Coronavirus Disease 2019 (COVID-19) pandemic has deeply impacted the health systems around the world [1]. The Veneto region is one of the first and the most Italian regions where the COVID-19 outbreak started spreading at the end of February 2020. In order to contain the epidemic diffusion, strict measures were progressively implemented by the Italian National Health Service and the Regional Authorities. In the Veneto Region a dedicated emergency multidisciplinary network was promptly formed leading to a reorganization of the Regional Healthcare System: some Hospitals became "COVID Hospital", exclusively reserved for COVID-19 patients, while in other Centers the activity of several Departments was reoriented, becoming sub-intensive or Intensive Care Units (ICU) [2].

For the same reason the Apheresis Unit (AU) of the University Hospital of Padova was relocated and a new ICU was opened in the spaces

previously occupied by the AU. The relocation of the equipment and furniture of the AU took place in just over 48 h on March 5th and the Therapeutic Apheresis (TA) activity was quickly rearranged. At the same time, the Regional Health Authorities decreed the suspension of the majority of non-urgent activities, including elective surgery and outpatient visits, with the exception of oncological and maternal and child health areas.

The Padova AU is the Regional Reference Center for TA. It has been active for over thirty years and covers the entire TA activity of the Province of Padova, including all the following procedures: Therapeutic Plasma Exchange (TPE), Red Blood Cell Exchange (RBCEX), Lipoprotein Apheresis (LA), Cascade Filtration (CF), Adsorptive Cytapheresis, Therapeutic Leukapheresis (TL), Extracorporeal Photochemotherapy/Photopheresis (ECP), Peripheral Blood Stem Cell Collection (PBSCC) for autologous and allogeneic use and Immunoabsorption (IA). In 2018 and 2019 2,134 and 2,006 procedures were performed, respectively,

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confirming the Padova AU among the mostly active in Italy [3]. The Apheresis team is composed by 3 physicians and 6 nurses highly specialized in apheretic technologies. The activity is usually carried out from Monday to Friday, from 8 a.m. to 7 p.m., both for outpatients and inpatients, and emergency treatments are also guaranteed, at nights and during the weekend through on call shifts.

2. Material and methods

We conducted a single center retrospective study aimed to evaluate the TA activity of the AU of Padova University Hospital throughout the COVID-19 outbreak, from March to April 2020. Data were collected from January to April in 2018, 2019 and 2020, recording the number of procedures and the number of patients treated per indication. Also the number of TA consultations for in and outpatients were collected. We used the GraphPad Prism version 6.04 for Windows, (GraphPad Software, San Diego, USA) for the basic statistics. The number of procedures and patients recorded at the AU are presented as absolute numbers and percentages. The odds ratios (OR) for retrospective analysis with 95 % confidence interval (95 % CI) were calculated to assess the differences between years and procedure groups, by Fisher’s exact test were calculate the P values. Values of $p < 0.05$ were considered statistically significant.

3. Results

In the period analyzed, we observed a significant reduction in both the total number of procedures performed and of patients treated, respectively by 17 % and 16 % (p -value $<0,001$; OR 0,503 95 % CI 0,399–0,635; OR 0,516 95 % CI 0,409–0,652) for the procedures and by 19 % and 20 % (p -value $<0,01$; OR 0,503 95 % CI 0,399–0,635; OR 0,516 95 % CI 0,409–0,652) for patients treated compared to the same period of 2018 and 2019, respectively (Fig. 1).

In Table 1 number of procedures performed and patients treated and their variation between years, expressed as percentage, are reported in detail. The percentage of procedures significantly decrease between 2018 and 2020 among ECP treatments (OR 0.361; 95 % CI 0.188–0.701), between 2019 and 2020 among RBCEx treatments (OR 0.325; 95 % CI 0.105–0.987), and between both periods among the treatments of TPE (OR 0.543; 95 % CI 0.399–0.744; OR 0.587; 95 % CI 0.434–0.793), IA (OR 0.067; 95 % CI 0.015–0.318; OR 0.000; 95 % CI 0.000–0.323) and adsorptive cytapheresis (OR 0.000; 95 % CI 0.000–0.719;OR 0.036; 95 % CI 0.008–0.170). The percentage of patients significantly decrease between 2018 and 2020 and between 2019 and 2020 only among the treatments of TPE (OR 0.543; 95 % CI 0.399–0.744; OR 0.587; 95 % CI 0.434–0.793).

Table 1

Detailed number of procedures performed and patients treated on March-April/ January-April 2018, 2019, 2020 and % variation calculated between years.

	2018 Mar–Apr/ Jan–Apr	2019 Mar–Apr/ Jan–Apr	2020 Mar–Apr/ Jan–Apr	Variation % 2020–2018	Variation % 2020–2019
Therapeutic Plasma Exchange					
Proc.	175/348	198/409	111/313	–15 % ***	–13 % ***
n.					
Pt. n.	41/53	46/59	25/51	–28 % **	–29 % **
Extracorporeal Photochemotherapy/Photopheresis					
Proc.	72/134	38/84	18/61	–24 % **	–16 %
n.					
Pt. n.	19/21	11/16	9/12	–15 %	+6 %
Immunoadsorption					
Proc.	15/27	19/25	0/5	–56 % *	–76 % **
n.					
Pt. n.	1/1	2/3	0/1	–100 %	–67 %
Cascade Filtration					
Proc.	3/8	1/8	0/2	–38 %	–13 %
n.					
Pt. n.	1/1	1/1	0/1	–100 %	–100 %
Red Blood Cell Exchange					
Proc.	14/27	20/33	9/27	–19 %	–27 % *
n.					
Pt. n.	8/10	14/16	7/11	–16 %	–24 %
Adsorptive Cytapheresis					
Proc.	20/36	30/43	2/26	–48 % ***	–62 % ***
n.					
Pt. n.	7/10	7/8	2/6	–37 %	–54 %
Cytoreductive Leukapheresis					
Proc.	5/8	1/3	0/1	–63 %	–33 %
n.					
Pt. n.	2/3	1/2	0/1	–67 %	–50 %
Lipoprotein Apheresis					
Proc.	28/49	35/73	26/55	–10 %	–1 %
n.					
Pt. n.	6/7	7/7	6/6	+14 %	0 %
Peripheral Blood Stem Cell Collection (autologous)					
Proc.	12/34	19/37	17/36	+12 %	–4 %
n.					
Pt. n.	11/27	14/29	15/30	+9 %	+2 %
Peripheral Blood Stem Cell Collection (allogeneic)					
Proc.	2/2	4/4	0/1	–100 %	–100 %
n.					
Pt. n.	2/2	3/3	0/1	–100 %	–100 %

Abbreviations: Proc. n.: procedures number; Pt. n.: patients number. Significance p value * $<0,5$, ** $<0,01$, *** $<0,001$.

In Table 2 we reported, for each treatment indication, the respective ASFA 2019 categories, and the number of patients recorded at the beginning of outbreak accordingly to the decision about to continue,

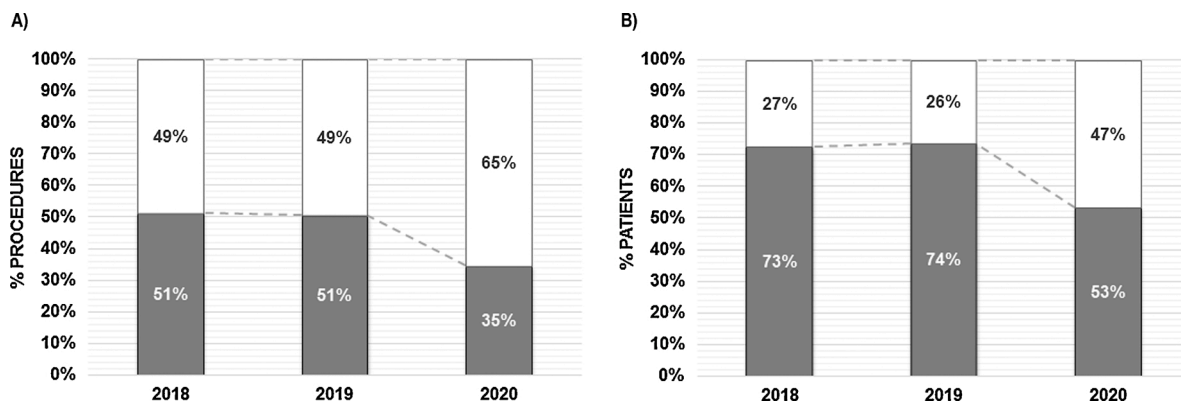


Fig. 1. Reduction of procedures performed and patients treated during the COVID-19 outbreak in the AU of the University Hospital of Padova, Italy. The histograms represents the percentages of procedures (A) and patients (B) recorded from January to February (white bars) and from March to April (grey bars) respectively in 2018, 2019 and 2020.

Table 2

Indications for treatment, ASFA 2019 categories, number of patients on treatment according to the decision about treatment, March –April 2020.

	ASFA 2019	Emergent treatment	Continued	Reduced frequency	Stopped
<i>Therapeutic Plasma Exchange</i>					
anti-P immunization in pregnancy	–		1		
Focal segmental glomerulosclerosis - Recurrent in kidney transplant	I		1		
Hyperviscosity in hypergammaglobulinemia – symptomatic	I	1			
Red cell alloimmunization in pregnancy	III		2*		
Myasthenia Gravis	II			9	
Thrombotic microangiopathy	I	1			
Neuromyelitis optica spectrum disorders	II		2		
Graves orbitopathy	–				1
Hypertriglyceridemic pancreatitis	III	1			
Pemphigus vulgaris	III			1	2
Chronic inflammatory demyelinating polyradiculoneuropathy	I		2	2	
Transplantation, renal – Antibody mediated rejection	I	1			
Scleroderma/Systemic Sclerosis	III			1	9
Antiphospholipid syndrome during pregnancy	–		1		
Transplantation, renal, ABO incompatible– Desensitization (living donor)	I				1
<i>Extracorporeal Photochemotherapy/Photopheresis</i>					
Graft Versus Host Disease – Acute	II				1 [§]
Graft Versus Host Disease – Chronic	II			6	
Cutaneous T cell lymphoma – Erythrodermic	I			3	
Atopic Dermatitis	III				1
<i>Red Blood Cell Exchange</i>					
Sickle cell disease – non acute (stroke prophylaxis/recurrent vaso-occlusive crisis)	I/II			7	
<i>Adsorptive Cytapheresis</i>					
Hidradenitis suppurativa	–				4
IBD	III			1	1
<i>Lipoprotein Apheresis</i>					
FH Oz	I		2		
FH Hz	II			2	
HyperLp(a)	II		1	1	

* One of the 2 patients continued the scheduled treatment in another Center.

§ Treatment cycle considered completed at the beginning of the COVID-19 outbreak.

reduce or stop the apheretic procedure.

TPE treatments for pregnant patients continued as scheduled, except for one case of anti-D immunization from outside the Region for which an indication was given to continue the treatment at the AU closest to home. Urgencies/emergencies, when requested, were guaranteed (a case of thrombotic microangiopathy, a case of symptomatic hyperviscosity in hypergammaglobulinemia, a case of hypertriglyceridemic acute pancreatitis and an antibody mediated rejection after kidney transplantation). Treatment was also guaranteed as scheduled in 2 cases of Neuromyelitis Optica Spectrum Disorders (NMOSD) not responding to high-dose steroids and in a pediatric patient affected by focal segmental glomerulosclerosis (FSGS), recurrent after kidney transplant. Some patients on "chronic" maintenance treatment [e.g., patients affected by myasthenia gravis (MG), systemic sclerosis/scleroderma (SS), pemphigus vulgaris, chronic inflammatory demyelinating polyneuropathy (CIPD)] have been suspended or the frequency of treatment has been reduced, but the AU physicians gave full availability for phone consultations and the resumption of treatment in case of disease flare-up. The staff remained in close telephone or e-mail contact with these patients. Most of the patients preferred to stay at home, fearing that they would get infected by attending the hospital. A desensitization treatment for ABO kidney transplantation incompatible from living donor has been suspended due to suspension of the transplantation program. ECP in a case of acute Graft Versus Host Disease (GVHD) was suspended because the patient was on complete remission at the beginning of the outbreak and the treatment program was considered completed. The frequency of ECP chronic treatments was reduced in case of chronic GVHD or Cutaneous T Cell Lymphoma (CTCL). The treatment was suspended in a patient affected by Atopic Dermatitis (AD). RBCEx chronic treatments in Sickle Cell Disease (SCD) patients continued but the frequency of treatments was reduced. Adsorptive cytappheresis treatment in Inflammatory Bowel Disease (IBD) and Hidradenitis Suppurativa were reduced in frequency or suspended. LA was continued as scheduled in 2 pediatric homozygous familial hypercholesterolemia (HoFH) patients

and in an adult patient affected by hyperlipoproteinemia(a) [HyperLp(a)], while the number of treatments were reduced in 2 cases of heterozygous FH (HeFH) and in a case of HyperLp(a). No IA, CF and TL procedures were performed in the period analyzed. All medical decisions were taken after multidisciplinary discussion with referring Clinicians. There were no differences in autologous peripheral blood stem cell collection (PBSCC), as the transplant programs in oncohematological patients continued. We did not receive any request of PBSCC for related or unrelated allogeneic donors. Furthermore, a concomitant reduction in requests for TA consultation for new patients (both outpatients and inpatients) was observed, equal to 32 % and 21 % compared to 2018 and 2019, respectively.

4. Discussion

The most relevant finding of the present study is the reduction of the number of TA procedures conducted, of patients treated and TA consultations performed during the COVID-19 outbreak (Fig. 1). Reasons for the reduction of activity in a reference TA unit are manifold. First, for some patients treated with maintenance TA the fear of contagion has discouraged the access to the Hospital and the AU. Moreover, the activity of the AU itself was quickly reorganized in terms of location and supplies because the healthcare of the Hospital and the entire Region were focused on COVID-19 patients. Many non urgent cases were deferred by Clinicians and less consultations for new cases were conducted, even if not significant. Nevertheless, close phone and email contact with chronic patients was maintained and reinforced and in case of exacerbation of symptoms, treatments were resumed. For some clinical indication treatments could not be postponed or interrupted and TA procedures continued (e.g., in severe HoFH in children). Physicians and nurses wore personal protection equipment for contact and droplets precautions for the whole duration of the working shift. No visitors or family members of patients treated were allowed in the AU during treatments, except for a single parent in case of pediatric patients. None

of the patients treated, as well as AU staff, become infected with COVID-19. At March, 1st 2020 4 pregnant patients were on TA treatment in our AU and after the outbreak treatments continued as scheduled, with the exception of one of the two cases with anti-D immunization that continued TA at a center closest to her residence. One pregnant patient had an anti-PP1Pk antibody causing recurrent spontaneous abortion in early pregnancy and one was affected by high-risk antiphospholipid syndrome, for whom after multidisciplinary discussion (Gynecologist, Immuno-hematology and Apheresis Specialists) the decision to continue was undertaken. These indications are not present in the current ASFA 2019 guidelines [4], but data in the medical literature, our previous experience and the discussion with Clinicians and Gynecologists justified the decision [5,6]. Also, treatment of pediatric patients with HoFH and an adult with hyperLp(a) with advanced cardiovascular disease continued as scheduled, while frequency of treatment in 2 adult patient affected by HeFH and one adult patients with hyperLp(a) was reduced from biweekly to monthly. Our decisions agree with later issued recommendations for FH patients, stating that patients in regular LA treatment, including very high-risk HoFH patients, should be enabled to access this procedure and, where this is not possible, treatment might be postponed safely by as much as 2 months, maintaining maximal lipid lowering therapy and strict monitoring of symptoms [7]. Treatment was also guaranteed in 2 cases of NMOSD not responding to high-dose steroids, in accordance with a recent consensus paper [8], and in a pediatric patient affected by FSGS recurrent after kidney transplant. For all the 9 patients affected by MG that were on maintenance treatment, TPE frequency was reduced and treatment was offered in case of flare-up of neurological symptoms. A recent Expert Panel paper suggested that MG patients in maintenance should continue treatment, but “extra precautions may need to be taken because of the need of travel to and from a healthcare facility” [9]. We believe that our clinical decisions have been in line with these recommendations. To note, we received request of consultation for 2 cases of respiratory failure secondary to COVID-19 in patients with MG. In accordance with Neurologists we decided not to proceed with TPE in order to avoid depletion of putative protective antibodies and patients received intravenous Immunoglobulins (IVIg). In the literature 5 more cases of COVID-19 in MG patients have been described until now, none treated with TPE [10]. At the beginning of the pandemic, 4 CIDP patients were on maintenance TPE treatment, with different schedules. Two cases of severely disabling CIDP continued treatments without changes; for the other 2 patients frequency was reduced and treatment schedule has been resumed at the end of the lockdown. This approach is consistent with recently issued treatment recommendations [11]. At March 1st, 10 patients affected by severe and rapidly progressive SS were on biweekly long-term maintenance therapy, according to our experience [12]. In SS lung involvement, such as interstitial lung disease and pulmonary hypertension, is a common manifestation, and along with immunosuppressive therapy, it places SS patients at high risk of severe course in case of COVID-19 infection. A recent paper by the World Scleroderma Foundation recommended that SS patients should continued immunosuppressive treatments but should limit their visit to the hospital [13]. Nine of 10 SS patients suspended apheresis treatment, while one patient with a severe form continued treatment with a reduced frequency. We remained in close phone/email contact with them and TPE treatment was soon resumed at the end of the lockdown. Decision about 3 patients with pemphigus vulgaris on maintenance TPE treatment was to suspend treatments. One of them had an exacerbation of symptoms and treatments were resumed. Expert recommendations about the management of autoimmune bullous disease during the COVID-19 pandemic suggest to weigh the risks about rituximab or apheresis treatments against conventional immunomodulatory regimens [14]. Maintenance TPE treatment in a case of Graves orbitopathy (not responding to antithyroid drugs) was suspended during the outbreak, in accordance with Endocrinologists.

Surprisingly, we did not receive any request of consultation for application of TPE as a rescue therapy in severe COVID-19 patients, as

recently published [15].

At the time of the SARS-CoV-2 outbreak 7 SCD patients were on chronic RBCEX program for stroke prophylaxis and recurrent vaso-occlusive crisis (VOC) or acute chest syndrome (ACS). In accordance with Hematologists, we decided to lengthen the interval between RBCEX procedures and we did not observe any change in the clinical course. Patients with SCD are at high risk of COVID-19 pulmonary severe course and hypoxia can cause VOC and/or ACS. Frequent hospital access, needed for cross-matching and RBCEX procedures, have been discouraged during the outbreak and regular treatments have been resumed at the end of the lockdown. This policy has been in line with the UK National Haemoglobinopathy Panel recent report [16].

ECP treatment in a patient with acute GVHD was stopped because the patient was in complete remission at the beginning of the outbreak and therapeutic cycle was considered completed. ECP procedures performed in patients affected by chronic GVHD were conducted with a reduced frequency. Despite the absence of specific recommendation about management of chronic GVHD in the COVID-19 era, chronic GVHD patients generally are severely immunosuppressed and are probably at higher risk of a severe COVID-19 course. The same decision was made in patients affected by CTCL. All patients were in partial remission or stable disease and they were treated with ECP as maintenance therapy. Our decisions were made in accordance with Dermatologists and we believe that they are in line with a EORTC CLTF guidelines [17]. Moreover, ECP maintenance treatment was suspended in a DA patients. Even if European Task Force on Atopic Dermatitis (ETFAD) recommended to continue all immune-modulating treatments [18], we preferred to avoid access in hospital during the pandemic and the disease was well controlled with the adjustment of steroid treatment. In accordance with Gastroenterologists, adsorptive cytapheeresis treatments were stopped or postponed in patients affected by mildly active IBD (ulcerative colitis) in maintenance treatment. The patients continued their oral and topic medications [19] and we have not observed an exacerbation of the disease. Even if there is no available evidence that supports discontinuation of immune-modulating treatments in cutaneous immune-mediated disease because of the risk of COVID-19 [20], we decided to stop adsorptive cytapheeresis treatments in all Hidradenitis Suppurativa patients.

We did not observe a reduction in the autologous PBSCC collection in the period analyzed. Oncohematologic adult and pediatric patients candidated to high dose therapy and autologous transplantation continued their treatment programs. In addition to the exams required by the National regulations and the FACT-JACIE Standards, all patients have been tested for SARS-CoV-2 before the mobilization regimen and the collection, as recently stated in the EBMT recommendations [21]. During the COVID-19 outbreak we did not perform any PBSCC in related and unrelated allogeneic donors, probably due to travel and logistic restrictions.

5. Conclusion

Many of the efforts and hospital resources during the COVID-19 pandemic have been oriented in the fight against COVID-19 spread and in the caring of COVID-19 patients. All the hospital activity, including TA and Transfusion Medicine in general have been quickly reorganized to face an unparalleled health emergency, with impact in blood donations and supply [22] and with great effort in the field of convalescent plasma [23–25]. Every clinical decision about modification of treatment plans have been shared with Clinicians and personalized based on the characteristics of patients and disease. Patients affected by chronic diseases themselves preferred to postpone visits and treatments during the pandemic and we do not know if this behavior could have worsened the outcome of diseases.

CRedit authorship contribution statement

A. Colpo: Conceptualization, Methodology, Data curation, Visualization, Investigation, Writing - original draft. **L. Astolfi:** Formal analysis. **T. Tison:** Writing - review & editing. **G. De Silvestro:** Writing - review & editing. **P. Marson:** Supervision, Writing - review & editing.

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