Research Article

Comparative analysis between Polymerized Type I Collagen (Fibroquel) and Baricitinib as a potential treatment for moderate-severe COVID-19 in outpatients and inpatients

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Baricitinib is a treatment authorized by the FDA for the treatment of moderate to severe COVID-19, despite this there are few approved drugs; polymerized type I collagen (PTIC) is a drug that has been used in Mexico with great potential for treating moderate to severe cases of COVID-19.

Methods

Comparative, descriptive, and retrospective analysis of two populations of adult patients affected by COVID-19 confirmed by antigen test or RT-PCR as well as CO-RADS 6 CT, who consented to be treated between 2020 and 2021, a population using oral baricitinib at a dose of 4mg/day/14 days and another using polymerized type I collagen intramuscularly at a dose of 1.5ml every 12 hours for 3 days, followed by 1.5ml every 24 hours for 4 days; The most affected age and gender, comorbidities and laboratory abnormalities are analyzed, as well as improvement in inflammatory and oxygenation indices measured by pulse oximetry and SAFI (SpO2/FiO2), finally the outcome of the patients and the presence of adverse events.

Results

80 patients for each group, the most affected gender was male; the average age in the PTIC group was 51 years and in the baricitinib group it was 56 years; the main comorbidities were obesity, diabetes, and hypertension in both groups; the decrease in acute phase reactants such as CRP, D-dimer and ferritin was greater in the PTIC group compared to the baricitinib group, the latter drug

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requiring a regimen of more days to achieve the objectives of the first drug (PTIC 7 days and baricitinib 14 days); Similarly, in oxygenation measured, the PTIC group reached goals in less time compared to the baricitinib group, which required twice as many days of treatment to achieve adequate oxygenation; Regarding the outcomes, there was higher mortality in the baricitinib group compared to the PTIC group (6.25% vs 3.75%). Regarding adverse events reported for the PTIC group, they were minor and related to the intramuscular administration of the drug in 7 patients, while in the baricitinib group, 5 patients were reported with added bacterial pneumonia.

Conclusion

Polymerized type I collagen has anti-inflammatory and immunomodulatory potential similar to baricitinib in cases of moderate to severe COVID-19, even reaching treatment goals in less time both in inflammatory indices and in oxygenation indices

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Introduction

Since the start of the pandemic, treatments for this entity have evolved. Antivirals such as nirmatrelvir and molnupiravir are currently available to be used in the initial stages with good efficacy. However, in cases that progress poorly and progress to severity, current drugs are Very few; Tocilizumab, Anakinra, and Baricitinib are treatments authorized by the FDA for the treatment of moderate to severe COVID-19 and be useful in reducing mortality, intensive care stays, and the use of mechanical ventilation. Despite this, there are few approved drugs; Polymerized Type I Collagen (PTIC) is a drug that has been used in Mexico with great potential for treating moderate to severe COVID-19 cases in both outpatients and hospitalized patients, due to its anti-inflammatory and immunomodulatory properties similar to those of baricitinib. Currently, there is a lot of experience with the use of this medicine and its main pharmacological properties are:

- Negatively modulate the expression of IL-1β, IL-8, TNF-a, TGF-β1, IL-17, Cox-1, and leukocyte adhesion molecules (ELAM-1, VCAM-1, and ICAM-1)
- It significantly increases the mediators and modulating mechanisms of inflammation (expression of IL-10 and the number of regulatory T cells) and decreases tissue fibrosis, without producing adverse effects.

- Negative regulation of the expression of the proinflammatory cytokine storm and the number of effector T cells Th1, Th17 and Th22

This ensures that it has potential in cases of moderate to severe COVID-19 with zero mortality rates. [1][2][3][4][5][6]

Material and methods

Comparative, descriptive, and retrospective analysis of two populations of adult patients affected by COVID-19 confirmed by antigen test or RT-PCR as well as CO-RADS 6 tomographic qualification, who consented to be treated between 2020 and 2021, a population using oral baricitinib at a dose of 4mg/day/14 days and another using Polymerized Type I Collagen intramuscularly at a dose of 1.5ml every 12 hours for 3 days, followed by 1.5ml every 24 hours for 4 days; The most affected age and gender, comorbidities and laboratory abnormalities are analyzed, as well as improvement in inflammatory and oxygenation indices measured by pulse oximetry and SAFI (SpO2/FiO2), finally the outcome of the patients and the presence of adverse events. Regarding the statistical analysis, the SPSS package was used and the statistical significance was estimated using the Chi-square test and the Student's t-test.

Results

80 patients were analyzed for each group, the most affected gender was male, the average age in the PTIC group was 51 years and in the baricitinib group it was 56 years; the main comorbidities were obesity, diabetes and hypertension in both groups; the decrease in acute phase reactants such as CRP, D-dimer and ferritin was greater in the PTIC group compared to the baricitinib group in the same period of time, the latter drug requiring a regimen of more days to achieve the objectives of the first drug (PTIC 7 days and baricitinib 14 days); Similarly, in terms of oxygenation measured by pulse oximetry, the PTIC group reached goals in less time compared to the baricitinib group, which required twice as many days of treatment to achieve adequate oxygenation; Regarding the outcomes, there was a higher mortality in the baricitinib group compared to the PTIC group (3.75% vs 6.25%), all these characteristics with statistical significance in the comparative analysis stratified by type of treatment. Regarding adverse events reported for the PTIC group, they were minor and related to the

intramuscular administration of the drug in 7 patients, while in the baricitinib group, 5 patients were reported with added bacterial pneumonic processes classified as severe events. See Table 1.

Variable	Polymerized Type I Collagen n = 80	Baricitinib n = 80	p
Demographic variables			
Gender			
Women	30	28	0.020
Men	50	52	0.021
Age, years	51	56	0.001
Previous comorbidities			
Hypertension	78%	67%	0.012
Diabetes	61%	77%	0.012
Obesity	60%	62%	0.010
Laboratory data			
Baseline D-dimer	1200ng/ml	1389ng/ml	
D-dimer 7 days	455ng/ml	776ng/ml	0.001
D-dimer 14 days	---	488ng/ml	
Basal ferritin	990ng/ml	1488ng/ml	
Ferritin 7 days	384ng/ml	922ng/ml	0.001
Ferritin 14 days	---	330ng/ml	
Baseline C-Reactive Protein	14mg/dl	12mg/dl	
CRP 7 days	3.6mg/dl	5.6mg/dl	0.001
CRP 14 days	---	3mg/dl	
Oxygen saturation			
Baseline (Day 0)	86%	84%	
7 days of treatment	94%	90%	0.001

Variable	Polymerized Type I Collagen n = 80	Baricitinib n = 80	p
14 days of treatment	---	96%	
Baseline SAPI (SpO2/FiO2)	132	135	
SAFI 7 days	320	220	0.001
SAFI 14 days	---	350	
Outcomes			
Improvement	77	75	
Death	3	5	
Mortality	3.75%	6.25%	0.001
Adverse events	Application site pain: 7	Bacterial pneumonia: 5	

Table 1. Comparative analysis of Polymerized Type I Collagen and baricitinib.

Conclusions

Type I polymerized collagen has anti-inflammatory and immunomodulatory potential similar to baricitinib in cases of moderate to severe COVID-19, even reaching treatment goals in less time both in inflammatory indices and in oxygenation indices, probably favored by the route of administration and a greater potential proinflammatory anti cytokines, as well as minor adverse events and lower mortality compared to baricitinib, a group that reported major adverse events, which places Polymerized Type I Collagen in a better position than baricitinib due to all its characteristics.

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Declarations

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