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SAFETY PROFILE OF EXPERIMENTAL THERAPIES USED IN THE COVID-19 PANDEMIC BASED ON DATA FROM THE NATIONAL MINIMUM DATA SET (NMDS)

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BACKGROUND AND IMPORTANCE

In response to the COVID-19 pandemic, scientific societies and regulatory agencies quickly reviewed any available evidence to fill the therapeutic gap. In this context, many drugs were used with an uncertain benefit/ risk profile that needs to be evaluated.

AIM AND OBJECTIVES

To analyze the safety profile of the experimental therapies that were used at the beginning of COVID-19 pandemic.

MATERIALS AND METHODS

- ❑ Retrospective observational study that analyzes the safety profile of anti-COVID therapy accessible according to the protocols that were approved.
- ❑ Patients admitted with COVID-19 diagnosis between March-May 2020 who had an adverse event (AE) coded in discharge/exitus medical report were obtained from the NMDS.
- ❑ The suspected drug was identified based on previous information. Those with AE attributed to anti-COVID therapy were selected.
- ❑ The causal relationship was evaluated using Naranjo algorithm (NA).

RESULTS

- ➢ 141 AE were coded in 105 patients admitted for COVID-19 diagnosis.
- ➢ 60.3% were attributed to anti-COVID therapy in 66 patients with a median age of 72 years [IC95% 68-76], 62.1% men [37.9% women].
- ➢ The AE intensity was: 63.5% mild, 29.4% moderate and 7.1% severe.
- ➢ The 23.5% AE did not require intervention, 37.6% required pharmacological treatment, 35.3% suspension the drug, 2.4% close monitoring and 1.2% dose reduction.

AE	n (frequency)	Suspected drug	n	NA Median (Min-Max)	Causal relationship
Gastrointestinal disorders	27(31.8%)	Lopinavir/Ritonavir	26	6(3-7)	Probable
		Codeine	1	6(6-6)	Probable
Blood glucose disorders	23(27.0%)	Glucocorticoid	20	5(3-7)	Probable
		Insulin	3	6(6-6)	Probable
Hypertransaminasemia	15(17.6%)	Azithromycin	6	5(3-5)	Probable
		Lopinavir/ritonavir	3	4(4-4)	Possible
		Hydroxychloroquine	3	3(3-5)	Possible
		Interferon beta-1a	3	3(3-3)	Possible
Anemia/thrombopenia	5(5.9%)	Heparin	3	9(8-9)	Definite
		Tocilizumab	2	6(6-6)	Probable
Skin disorders	4(4.7%)	Hydroxychloroquine	1	6(6-6)	Probable
		Interferon beta-1a	1	6(6-6)	Probable
		Penicillin	1	6(6-6)	Probable
		Contrast agent	1	6(6-6)	Probable
Cardiac disorders	4(4.7%)	Hydroxychloroquine	4	4(3-4)	Possible
Metabolism disorders	4(4.7%)	Lopinavir/Ritonavir	3	6(3-6)	Probable
Renal failure	2(2.4%)	Contrast agent	2	3(3-3)	Possible
Fever	1(1.2%)	Interferon beta-1a	1	6(6-6)	Probable

CONCLUSION AND RELEVANCE

NA establishes a probable drug-AE causal relationship for most events. Most AE were moderate to mild severity, however 75% required medical intervention. Consequently, it is important to know the AE-drug relationships to ensure a favorable benefit/ risk profile, especially in experimental therapies.