Ethical considerations in the treatment of pediatric patients with SARs-COV2 infection

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Abstract

One of the problems currently faced in the management of SARS-CoV2 infection is the absence of specific treatments that have proven their usefulness and their safety in studies with statistical validity, which allows to justify on reasoned evidence its use. In the case of paediatric patients although there are no serious cases in proportion to adults, there is the ethical limitation of not having reliable data to be able to justify therapeutic interventions on scientific evidence and to date there are few studies that analyze the safety of certain drugs and have not been included in paediatric groups in the evaluation of the use of COVID-19 vaccines.

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Since the beginning of 2020, following the outbreak in The City of Wuhan, China of Coronavirus infeccion (SARS-CoV2), one of the concerns that was raised is whether it affected all age groups alike or whether we had a clinical scenario that had varied clinical nuances based on them.

The paediatric patient appears to be participating with a very small percentage within symptomatic patients or in need of hospital management derived from the severity of the disease, as is the case with multi-inflammatory sistemic syndrome, in a smaller proportion in relation to the rest of the age groups. (1,2)

An analysis in Medline from December 2019 to April 2020 where 38 studies (1124 cases) were included, found that from all the cases, 1117 had their severity classified: 14.2% we were asymptomatic, 36.3% were mild, 46.0% we were moderate, 2.1% were severe, and 1.2% were critical (3). As of today, few cases of mortality

are reported and apparently appear to be a constant within what appears to be reported in different series since the beginning of the outbreak, although if it is clear that the paediatric patient has a high potential for contagion and spread of the disease, hence the importance of its detection and surveillance (4,5).

One of the questions that has been had since the beginning, is what is the best therapeutic option, being to date that the evidence has not allowed to support any management strategy as resolute and specific, and in many cases not even safe, being to date multiple recommendations on the usefulness of different strategies, without having on many occasions more value for its support than the anecdote.

On the other hand, we should consider that although there are protocols in the development of therapeutic strategies for serious expressions of the disease, as well as effectiveness and safety assessment in vaccine protocols, the paediatric patient is rarely considered as a target group.

From the outset, it has been proposed that decision-making in the context of therapeutic interventions should be evidence-based to safely support the use of these strategies without causing transient or permanent harm or involvement in the receiving population. The paediatric group is of particular interest derived not only from the ethical considerations involved in including it in drug study protocols, in which its dosage is estimated based on algorithms determined by behavior based on physiological responses obtained from adult patients, but must also be able to justify to all interested parties the benefit risk of its use, allowing to rule out the impact in acute form as well as the absence of consequences that impact the biological development and quality of life of the child (6,7).

Currently there are approximately 30 studies that are being carried out in paediatric patients in order to have conclusive data regarding the possibility of having epidemiological and clinical data that allow more objectively and not by transferring information of adult patients to be able to have data, these studies are endorsed by the National Institutes of Health (NHI) and World Health Organization (WHO), however the limitations given by the Best Pharmaceutical for Children Act and the Pediatric Research Equity Act do not allow pharmacological studies in the paediatric group to be prioritized, missing the opportunity to have rigorous data on potential treatments for COVID-19 (8-9).

It is relevant based on this scenario not to minimize the need for studies designed for the paediatric population, that does not allow robust information and that allows to safely support the therapeutic indications in the management of COVID-19 in the paediatric patient.

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Declaration of interest statement

The autor declare that there are no conflict of interests.