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ORIGINAL

A postmortem study of patients vaccinated for SARS-CoV-2 in Colombia

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Abstract

Introduction and objective: A new coronavirus produces a disease designated as coronavirus disease 2019 (COVID-19). Vaccination against COVID-19 has resulted in decreased mortality. Postmortems of vaccinated patients play an important part in the forensic analysis of adverse effects after vaccination, which is essential for determining its efficacy and security. The main objective of this study was to describe the results of autopsies of patients vaccinated for SARS-CoV-2 carried out in two major centers in Colombia.

Materials and methods: A descriptive cross-sectional study of 121 autopsies was performed following Colombian regulations in two main hospitals in Bogotá, Colombia, between March 1st and April 31st, 2021.

Results: 118 of the 121 patients (97.52%) had been vaccinated with CoronaVac (Sinovac); only 3 had received other vaccines. Sudden cardiac death was the leading cause of death, with pulmonary embolism another critical finding. No relation between the cause of death and vaccination against SARS-CoV-2 was found.

Conclusions: A clinical autopsy is a vital for an accurate post-mortem diagnosis. Any relation between the SARS-CoV-2 vaccine and the cause of death should be carefully studied in order to provide the general public with evidence-based information about the safety of the vaccination.

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PALABRAS CLAVE
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Autopsias clínicas en pacientes vacunados contra el SARS-CoV-2: estudio *post mortem* en una población colombiana

Resumen

Introducción y objetivo: Un nuevo virus del linaje de los coronavirus produce una enfermedad que se designó como enfermedad por coronavirus 2019 (COVID-19). Actualmente se están aplicando vacunas contra la COVID-19 y han mostrado disminución de la mortalidad en pacientes infectados. El análisis de los efectos adversos tras la vacunación ha sido fundamental para conocer la eficacia y la seguridad tras la administración. El examen forense y patológico de las muertes después de la vacunación representa un componente crítico. El objetivo principal del estudio fue describir una serie de casos de pacientes con inmunización previa contra el SARS-CoV-2 que fallecieron y a los que se les realizó una autopsia clínica en dos centros de referencia en Colombia para estudios *post mortem*.

Materiales y métodos: Se realizó un estudio descriptivo transversal basado en autopsias siguiendo la normatividad colombiana en dos hospitales de alta complejidad de la ciudad de Bogotá, Colombia, durante el período comprendido entre el 1 de marzo de 2021 y el 31 de abril de 2021. Se analizaron un total de 121 autopsias.

Resultados: Un total de 118 pacientes (97,52%) fueron vacunados con CoronaVac (Sinovac). La muerte cardíaca súbita fue la principal causa de fallecimiento en la población del estudio, y la embolia pulmonar fue otro hallazgo crítico encontrado en el estudio forense. No se pudo determinar la relación entre las causas de muerte y la vacunación contra el SARS-CoV-2.

Conclusiones: La autopsia clínica es una herramienta vital en las instituciones de salud para brindar un diagnóstico *post mortem*. Consideramos que el estudio de la causalidad de la vacunación contra el SARS-CoV-2 y las muertes es fundamental para futuros estudios, con la intención de proporcionar información basada en evidencia a la población para apoyar el concepto de vacunación segura contra la COVID-19.

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Introduction

A new coronavirus with human-to-human transmissibility was identified at the end of 2019 and due to it presenting a wide range of clinical symptoms and having a high contagion rate, it soon reached pandemic proportions.^{1,2} As a result, the World Health Organization (WHO) launched a health alarm on December 30, 2019 and a Public Health Emergency of International Importance was declared on January 30, 2020.³ The WHO designated the disease caused by the virus (Severe Acute Respiratory Syndrome (SARS)-CoV-2) as Coronavirus Disease 2019 (COVID-19).² Until September 2, 2022, according to Johns Hopkins Coronavirus Resource Center, 603,359,314 confirmed cases and 6,492,142 deaths secondary to COVID-19⁴ had been reported worldwide; the Colombian Ministry of Health reported 6,302,809 confirmed cases and 141,646 deaths.⁵

Vaccines against COVID-19 are currently being administered according to the regulations of the Ministry of Health or equivalent in each country. The vaccines currently validated for use by WHO and given emergency use are: BNT162b2 (Pfizer – BioNTech), mRNA-1273 (Moderna), ChAdOx1 nCov-19 (AstraZeneca), Ad26.COV2.S (Janssen COVID-19 vaccine), WIV04 and HB02 (Sinopharm), CoronaVac (Sinovac) and Covaxin (Bharat Biotech/Indian Council of Medical Research), NVX-CoV2373 (Covovax) and NVX-CoV2373 (Nuvaxovid).^{6,7}

The vaccination program in Colombia began on February 17, 2021. As of August 9, 2022, 87,566,541 doses had been administered nationwide and 36,479,814 people had received the complete vaccination schedule. The initial goal of the vaccination plan was to vaccinate 35 million people. The vaccines used until August 9, 2022 were: BNT162b2 (Pfizer – BioNTech), mRNA-1273 (Moderna), ChAdOx1 nCov-19 (AstraZeneca), CoronaVac (Sinovac) and Ad26.COV2.S (Janssen COVID-19 vaccine).⁸

Adverse effects after vaccination have been analyzed worldwide. After receiving a SARS-CoV-2 vaccination local affectations predominate, while systemic reactions are rare.⁹ In a study of 19,586 adults conducted by Beatty et al.¹⁰ the risk of allergic reactions or anaphylaxis was reported in 0.3% of cases after partial vaccination and 0.2% after complete vaccination. The most important factors associated with side effects were: full vaccination dose, vaccine brand, younger age, female gender and having had COVID-19 before immunization. However, rare cases of vascular problems in which clot formation is altered and the platelet count is low (vaccine-induced immune thrombotic thrombocytopenia (VITT)) have been identified between one to three weeks after vaccination, especially with ChAdOx1 nCov-19 (AstraZeneca) and Ad26.COV2.S (Janssen COVID-19 vaccine).¹¹⁻¹³

The forensic and pathological analysis of deaths after vaccination is an essential component in the

understanding of complex or new entities. Our study's main objective was to describe the findings of 121 autopsies of patients who had been vaccinated against SARS-CoV-2. The postmortems were carried out in two reference centers in Colombia. To our knowledge, this is the most extensive autopsy study of patients vaccinated against SARS-CoV-2.

Materials and methods

A serial case study based on autopsies was carried out following Colombian regulations, conducted in patients who had died from non-violent causes and who had received some degree of immunization against SARS-CoV-2 in Bogotá, Colombia, between March 1st and April 31st 2021, the period during which the first vaccines were administered in Colombia.

We collected and verified data obtained from clinical autopsy reports made by the pathology department. The information was classified and tabulated, with analysis of variables such as age, sex, comorbidities, name of the vaccine used, number of doses administered and final pathological diagnosis. As there were numerous comorbidities in the original reports, only those present in more than one patient were considered. The causes of death were grouped according to similar pathophysiological mechanisms to facilitate the analysis, as the list of diseases was long and detailed. We decided that the disease group outlined by Mendoza et al.¹⁴ would be referential as the study population was similar and thus a better comparative analysis could be made.

The diagnosis of sudden cardiac death (SCD) was defined as an abrupt loss of cardiac function in a person who may or may not have previous heart disease and when death occurred within one hour of the onset of symptoms. SCD patients with other pathological findings, for example coronary heart disease, were included in both diagnostic categories, in order to reach a consensus with previously reported data.¹⁵

Descriptive analysis was performed by calculating relative and absolute frequencies and measures of central tendency. The Excel and Stata13 programs were used to carry out the statistical study.

The study was approved by the Health Research and Ethics Committee of the Fundación Universitaria de Ciencias de la Salud in Bogotá, Colombia.

Results

A total of 121 autopsies were analyzed, 81 from the Hospital San Jose and 40 from the Hospital Infantil de San Jose in Bogotá, Colombia. 63 cases (52.06%) were female. The mean age of the patients was 84 years, with a range of 66 to 103 years. A total of 118 patients (97.52%) had been vaccinated with CoronaVac (Sinovac), of which 109 patients (92.37%) had received one dose, and nine patients (7.63%) two doses. Of the remaining cases, 2 patients (1.65%) received 1 dose of ChAdOx1 nCov-19 (AstraZeneca) and 1 patient (0.82%) received 1 dose of BNT162b2 (Pfizer – BioNTech).

Among the critical comorbidities reported in the medical history were: arterial hypertension in 93 patients (76.85%), chronic obstructive pulmonary disease (COPD) in 36 patients

(29.75%), diabetes mellitus in 24 patients (19.83%), congestive heart failure in 20 patients (16.52%), history of acute myocardial infarction in 18 patients (14.87%), history of neoplasia in 15 patients (12.39%), hypothyroidism in 15 patients (12.39%), dyslipidemia in 13 patients (10.74%), cardiac arrhythmia in 13 patients (10.74%), dementia in 11 patients (9.09%), chronic kidney disease in 8 patients (6.6%) and autoimmune disease in 4 patients (3.3%).

SCD was the leading cause of death with 69 cases (57.02%), followed by acute myocardial infarction in 53 patients (43.8%) and other cardiovascular diseases (aortic dissection, aortic aneurysms, arrhythmias) in 23 patients (19%). 45 of the SCD cases were secondary to acute myocardial infarction and a further 18 cases secondary to other cardiovascular diseases. In 6 cases of SCD no diagnostic findings were found. Pulmonary embolism (PE) was found in 25 cases (20.66%).

Other diagnoses included respiratory failure not secondary to bacterial pneumonia in 7 patients (5.78%), metabolic conditions in 3 patients (2.47%), bacterial pneumonia in 2 patients (1.65%), neoplasia in 2 patients (1.65%), 1 case of sepsis (0.82%) and one case of sudden unexpected death in epilepsy (0.82%). More detailed information on the final pathological diagnosis and comorbidities is shown in Table 1.

Discussion

The clinical autopsy continues to be a fundamental pillar of medicine. Despite significant clinical advances, discrepancies still occur between clinical and post-mortem diagnoses.¹⁶ We analyzed 121 autopsies of patients who had received some degree of immunization against SARS-CoV-2, which were carried out in two important Colombian forensic reference centers.

Presently there are concerns about a possible relationship between vaccination against SARS-CoV-2 and the cause of death, as it is still unclear whether the pathophysiological mechanism is related to vaccination against SARS-CoV-2 or to a different process.

Menni et al.¹⁷ studied 627,383 vaccinated people and demonstrated that the majority of the adverse effects of vaccination are mild and short. However, the report of a small number of severe adverse reactions related to the vaccine administration has generated mistrust among the general public which has slowed down the vaccination process both in Colombia and around the world.¹⁸

The leading cause of death in our study was cardiovascular pathology, the most frequent being SCD and coronary heart disease the main trigger. A previous study of more than 700 patients reported cardiovascular disease as the main cause of death.¹⁴ SCD is the leading cause of death in industrialized countries, accounting for 60–70% of deaths of cardiovascular origin.¹⁹ In the United States, there are 1–2 cases per 1000 people per year, while 0.36–1.28 cases per 1000 inhabitants per year are reported by the European Society of Cardiology.²⁰ The majority of SCD occurs in adults; all our patients were older than 65 years, agreeing with previous studies where incidence was found to increase with age, becoming more prevalent after 55 years.^{21,22}

Table 1 Main diagnosis by comorbidities.

			Comorbidities												
			Hyper- tension	Chronic obstructive pulmonary disease	Diabetes mellitus	Conges- tive heart failure	History of acute myocardial infarction	Neopla- sia	Hypothy- roidism	Dyslip- idemia	Arrhy- thmia	Demen- tia	Chronic kidney disease	Auto- immune disease	
Pathological diagnosis	Sudden cardiac death (SCD)	Acute myocardial infarction	36	14	8	5	10	3	3	6	7	2	2	1	
		Deaths related to other car- diovascular diseases (CVD) (aortic dissection, aortic aneurysms, arrhyth- mias)	14	5	6	4	1	0	4	1	6	3	3	2	
		No findings	3	4	0	0	0	2	1	0	0	0	0	0	
		Pulmonary embolism (PE)	16	10	7	6	1	6	4	1	0	5	1	1	
		Acute myocardial infarction without SCD	8	0	1	0	3	1	0	2	0	0	1	0	
		Deaths related to other CVD without SCD	5	1	0	1	1	0	0	1	0	0	0	0	
		Respiratory failure ruling out bacterial pneumonia	5	1	1	2	2	1	1	1	0	0	0	0	
		Deaths related to metabolic conditions	2	0	0	1	0	0	0	0	0	0	1	0	
		Bacterial pneumonia	2	1	0	1	0	0	0	1	0	0	0	0	
		Deaths related to neoplasias	1	0	1	0	0	1	1	0	0	0	0	0	
		Sepsis	0	0	0	0	0	1	1	0	0	0	0	0	
		Death related to epilepsy	1	0	0	0	0	0	0	0	0	1	0	0	
	<i>n</i>			93	36	24	20	18	15	15	13	13	11	8	4

Note: Numbers do not add up in the horizontal columns since patients might be included in more than one cell.

The prevalence of PE in our study is worthy of note; whereas it accounted only for 7.63% (57 cases) in the study by Mendoza et al.,¹⁴ we found an incidence of 20.66% (25 cases). Although cases have been reported of clots occurring after the administration of ChAdOx1 nCov-19 (AstraZeneca) and Ad26.COVS.2 (Janssen COVID-19 vaccine),^{11,12,23} all the patients with PE in our study had been vaccinated with CoronaVac (Sinovac) which, as an inactivated vaccine, has not been associated with clot formation.²⁴

We only found 9 cases (7.43%) of respiratory failure due to infectious diseases, which was much lower than the 20% found by Mendoza et al.¹⁴ However, as no autopsies of suspected COVID-19 patients are authorized in Colombia, this may explain the discrepancy.

To the best of our knowledge, our study is the most extensive autopsy study of a population immunized against SARS-CoV-2. Edler et al.²⁵ describe autopsies of 3 patients vaccinated with BNT162b2 (Pfizer – BioNTech) and discuss 22 deaths in vaccinated patients reported in Germany; 7 underwent autopsies and other postmortem studies which, as in our study, revealed no causal relationship between vaccination and death.

In 13 of 18 autopsies of patients who had been vaccinated against SARS-CoV-2, reported by Schneider et al.,²⁶ the cause of death was attributed to pre-existing diseases with no causal relationship with the vaccine. Myocarditis was found in one case, but without any specific causal association. VITT was evidenced in 3 patients after vaccination with ChAdOx1 nCov-19 (AstraZeneca) and in one case after administration of Ad26.COVS.2 (Janssen COVID-19 vaccine).

In a recent systematic review of 17 reports of autopsy findings in patients vaccinated against SARS-CoV-2, Sessa et al.²⁷ found 38 cases, 19 female and 19 male. 22 cases were of patients vaccinated with ChAdOx1 nCov-19 (AstraZeneca), 10 with BNT162b2 (Pfizer – BioNTech), 4 with mRNA-1273 (Moderna) and 2 with Ad26.COVS.2 (Janssen COVID-19 vaccine). It is important to note that the 22 patients vaccinated with ChAdOx1 nCov-19 (AstraZeneca) died immediately after the administration of the vaccine and thus any signs suggestive of VITT, such as intracranial hemorrhage and multiple foci of diffuse microthrombi, should be carefully considered during the autopsy, especially in cases of immunization with ChAdOx1 nCov-19 (AstraZeneca).

Our study had limitations, such as the lack of autopsies of patients positive for SARS-CoV-2, resulting in a difference in the distribution of pathological findings in comparison to previous studies. Furthermore, the causal relationship in these cases is difficult to determine, so diagrams such as those proposed by the WHO must be considered in the future to reach more reliable conclusions.²⁸

Conclusions

Our study highlights the importance of autopsies in patients with immunization against SARS-CoV-2. We found the leading cause of death to be sudden cardiac death, agreeing with previous studies the same center. However, the increase in the incidence of pulmonary thromboembolism is striking. However, our study could not provide causal relationships of deaths with immunization. In the future, we recommend

that clinicians and pathologists work together when the cause of death in immunized patients raises concern.

Author contributions

Juan José Chaves, Rafael Parra-Medina and Juan Carlos Bonilla assisted with study design and reviewed the manuscript. Juan José Chaves and Viviana Chaves-Cabezas reviewed the literature, drafted the manuscript, and performed data analysis. Andrés Castro, José Fernando Polo, Oscar Mendoza, Jennifer Correa-Rodríguez, Ana Carolina Piedrahita and Ivan Alberto Romero-Fandiño performed autopsies and performed data analysis. María Victoria Caro, Andrea Carolina González, Liseth Katherine Sánchez, Félix Murcia, Gloria Márquez, Alejandra Benavides, María del Pilar Quiroga and Jorge López reviewed the data and assisted performing autopsies.

Compliance with ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Conflict of interest

The authors declare no competing interests.

References

1. Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497–506.
2. Wang C, Wang Z, Wang G, Lau JY-N, Zhang K, Li W. COVID-19 in early 2021: current status and looking forward. *Sig Transduct Target Ther*. 2021;6:114.
3. World Health Organization. Coronavirus disease (COVID-2019) situation reports. World Health Organization; 2020.
4. Johns Hopkins Coronavirus Resource Center. COVID-19 data in motion: Friday, September 2; 2022. Available at: <https://coronavirus.jhu.edu/map.html>.
5. Ministerio de Salud y Protección Social-Instituto Nacional de Salud. COVID-19 in Colombia. Available at: <https://www.ins.gov.co/Noticias/paginas/coronavirus.aspx>.
6. World Health Organization (WHO). Coronavirus disease (COVID-19): vaccines; 2022.
7. Tregoning JS, Flight KE, Higham SL, Wang Z, Pierce BF. Progress of the COVID-19 vaccine effort: viruses, vaccines and variants versus efficacy, effectiveness and escape. *Nat Rev Immunol*. 2021;21:626–36.
8. Ministerio de Salud de Colombia. Vacunación contra COVID-19; 2022. Available at: <https://www.minsalud.gov.co/salud/publica/Vacunacion/Paginas/Vacunacion-covid-19.aspx>.
9. Yuan P, Ai P, Liu Y, Ai Z, Wang Y, Cao W, et al. Safety, tolerability, and immunogenicity of COVID-19 vaccines: a

- systematic review and meta-analysis. medRxiv [Preprint]. 2020, <http://dx.doi.org/10.1101/2020.11.03.20224998>.
10. Beatty AL, Peyser ND, Butcher XE, Cocohoba JM, Lin F, Olgin JE, et al. Analysis of COVID-19 vaccine type and adverse effects following vaccination. *JAMA Netw Open*. 2021;4:e2140364.
 11. Pomara C, Sessa F, Ciaccio M, Dieli F, Esposito M, Giammanco GM, et al. COVID-19 vaccine and death: causality algorithm according to the WHO eligibility diagnosis. *Diagnostics*. 2021;11:955. Available from: <https://www.mdpi.com/2075-4418/11/6/955>
 12. Wolf ME, Luz B, Niehaus L, Bhogal P, Bázner H, Henkes H. Thrombocytopenia and intracranial venous sinus thrombosis after "COVID-19 vaccine AstraZeneca" exposure. *J Clin Med*. 2021;10:1599. Available from: <https://www.mdpi.com/2077-0383/10/8/1599>
 13. Karpiński TM, Ożarowski M, Seremak-Mrozikiewicz A, Wolski H, Włodkowiec D. The 2020 race towards SARS-CoV-2 specific vaccines. *Theranostics*. 2021;11:1690–702. Available from: <https://www.thno.org/v11p1690.htm>
 14. Mendoza O, Bonilla JC, Moreno L, Piedrahita C, Mosquera A, Parra-Medina R. Review of clinical non-medico-legal autopsy: a descriptive study in 747 patients. *Egypt J Forensic Sci*. 2018;8:66.
 15. Bonilla JC, Parra-Medina R, Chaves JJ, Campuzano O, Sarquella-Brugada G, Brugada R, et al. La autopsia molecular en la muerte súbita cardiaca. *Arch Cardiol México*. 2018;88:306–12.
 16. Costache M, Lazaroiu AM, Contolenco A, Costache D, George S, Sajin M, et al. Clinical or postmortem? The importance of the autopsy; a retrospective study. *Maedica*. 2014;9:261–5. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25705288>
 17. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, et al. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study. *Lancet Infect Dis*. 2021. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S1473309921002243>
 18. Schultz NH, Sørvoll IH, Michelsen AE, Munthe LA, Lund-Johansen F, Ahlen MT, et al. Thrombosis and thrombocytopenia after ChAdOx1 nCoV-19 vaccination. *N Engl J Med*. 2021;384:2124–30. Available from: <http://www.nejm.org/doi/10.1056/NEJMoa2104882>
 19. Barletta V, Fabiani I, Lorenzo C, Nicastro I, Bello V. Sudden cardiac death: a review focused on cardiovascular imaging. *J Cardiovasc Echogr*. 2014;24:41–51. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28465902>
 20. Basso C, Aguilera B, Banner J, Cohle S, d'Amati G, de Gouveia RH. Guidelines for autopsy investigation of sudden cardiac death: 2017 update from the Association for European Cardiovascular Pathology. *Virchows Archiv*. 2017;471:691–705.
 21. Chugh SS, Jui J, Gunson K, Stecker EC, John BT, Thompson B, et al. Current burden of sudden cardiac death: multiple source surveillance versus retrospective death certificate-based review in a large U.S. community. *J Am Coll Cardiol*. 2004;44:1268–75.
 22. Rao BH, Sastry BKS, Chugh SS, Kalavakolanu S, Christopher J, Shangula D, et al. Contribution of sudden cardiac death to total mortality in India — a population based study. *Int J Cardiol*. 2012;154:163–7.
 23. Cines DB, Bussell JB. SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia. *N Engl J Med*. 2021;384:2254–6. Available from: <http://www.nejm.org/doi/10.1056/NEJMe2106315>
 24. Wu Z, Hu Y, Xu M, Chen Z, Yang W, Jiang Z, et al. Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy adults aged 60 years and older: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. *Lancet Infect Dis*. 2021;21:803–12. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/33548194>
 25. Edler C, Klein A, Schröder AS, Sperhake J-P, Ondruschka B. Deaths associated with newly launched SARS-CoV-2 vaccination (Comirnaty®). *Legal Med*. 2021;51:101895. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S1344622321000596>
 26. Schneider J, Sottmann L, Greinacher A, Hagen M, Kasper H-U, Kühnen C, et al. Postmortem investigation of fatalities following vaccination with COVID-19 vaccines. *Int J Legal Med*. 2021;135:2335–45.
 27. Sessa F, Salerno M, Esposito M, di Nunno N, Zamboni P, Pomara C. Autopsy findings and causality relationship between death and COVID-19 vaccination: a systematic review. *J Clin Med*. 2021;10:5876.
 28. WHO. Causality assessment of an adverse event following immunization. 2nd ed. Geneva, Switzerland: World Health Organization; 2019. ISBN 9789241513654.