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LETTERS TO THE EDITOR

A need for consensus on mortality reporting related to the coronavirus disease-2019 pandemic in ongoing and future vascular registries and trials.



As the severe acute respiratory syndrome coronvirus-2 continues to take more lives, quite a few of these will be from the vascular population,¹⁻³ typically older and with multiple comorbidities, recognised risk factors for coronavirus disease (COVID)-19–related mortality.⁴ Some such patients will be involved in ongoing vascular trials and registries.

Presenting an "overall mortality rate" is obligatory at registry/trial reporting, particularly specifying the cause of death (COD). There may be some "unknown COD," but these should be a minority, particularly in robust prospective studies. Some unknown COD may be attributable to COVID-19, with many dying without COD confirmation. This is related to lack of testing, or high false negative rates, with controversy surrounding the accuracy of oropharyngeal vs nasopharyngeal swabs⁵ particularly for late testing.⁶

The issues arising from COVID-19-related deaths are two-fold: first, to do with accurate capture of COD (reporting issues), and second, the influence of increased deaths on the completeness of data in ongoing studies (outcome issues). This is a research concern,^{7,8} with calls to extend trial durations,⁹ and may necessitate post hoc/ retrospective power calculations to reassess statistical validity of studies.

We therefore hypothesize four possible scenarios related to mortality reporting: (1) patients with accurate categorization of COVID-19-related COD; (2) patients with prior confirmed COVID-19 infection who recover but die later with unknown COD; (3) patients dying from an unknown cause during the pandemic, where COD is uncertain; and finally (4) accurate capture of non-COVID-19-related COD. Options 1 and 4 are qualitatively most desirable in terms of data capture.

Global clinical uncertainty¹⁰ has implications for registries that report on mortality. This concern pertains to both ongoing and to future study design, as we cannot predict patterns of disease chronicity or repetitiveness. This may lead to similar outcomes as indicated: (1) accurate COD capture, (2) inaccurate data capture leading to higher censoring at survival analysis, and (3) loss of patients in smaller studies due to high unexpected mortality, rendering them underpowered and redundant.

Some editorial consensus is needed to guide adequate mortality reporting, to avoid misguided assessments that may lead to misleading conclusions.

Andrés Reyes Valdivia, MD, PhD, FEBVS, FACS

Department of Vascular and Endovascular Surgery Ramón y CajaÍs University Hospital Madrid, Spain

Arindam Chaudhuri, MBBS, MS, FRCSEd, MSc, FRCS

Bedfordshire – Milton Keynes Vascular Centre Bedford, United Kingdom

REFERENCES

- Forbes TL. Vascular surgery activity condition is a common language for uncommon times. J Vasc Surg 2020 Apr 20. [Epub ahead of print].
- 2. Fankhauser GT. Delivering high-quality vascular care by telehealth during the COVID-19 pandemic. J Vasc Surg 2020;72:6-7.
- Melissano G, Mascia D, Baccellieri D, Kahlberg A, Bertoglio L, Rinaldi E, et al. Pattern of vascular disease in Lombardia (Italy) during the first month of the COVID-19 outbreak. J Vasc Surg 2020;72:4-5.
- 4. Inciardi RM, Adamo M, Lupi L, Cani DS, Di Pasquale M, Tomasoni D, et al. Characteristics and outcomes of patients hospitalized for COVID-19 and cardiac disease in Northern Italy. Eur Heart J 2020 May 14. [Epub ahead of print].
- Winichakoon P, Chaiwarith R, Liwsrisakun C, Salee P, Goonna A, Limsukon A, et al. Negative Nasopharyngeal and Oropharyngeal Swabs Do Not Rule Out COVID-19. J Clin Microbiol 2020;58:e00297-20.
- Carver K, Jones N. Comparative accuracy of oropharyngeal and nasopharyngeal swabs for diagnosis of COVID-19. Avaliable at: https://www.cebm.net/covid-19/comparativeaccuracy-of-oropharyngeal-and-nasopharyngeal-swabs-fordiagnosis-of-covid-19/. Accessed March 26, 2020.
- 7. Warnock DG. Clinical trials during the SARS-CoV-2 pandemic. Nephron 2020;144:248-50.
- A guide to clinical trials disrupted by the coronavirus pandemic. Avaliable at: https://www.biopharmadive.com/ news/coronavirus-clinical-trial-disruption-biotech-pharma/ 574609/. Accessed May 15, 2020.
- Clinical trials during the SARS-CoV-2 pandemic. Available at: https://www.clinicaltrialsarena.com/comment/covid-19pandemic-clinical-trials/. Accessed March 20, 2020.
- Koh D, Cunningham AC. Counting coronavirus disease 2019 (COVID-19) cases: case definitions, screened populations and testing techniques matter. Ann Acad Med Singapore 2020;49:161-5.

https://doi.org/10.1016/j.jvs.2020.06.013

A protocol for central venous access in patients with coronavirus disease 2019



From our single tertiary-center experience, many patients who develop coronavirus disease 2019 (COVID-19) infection require rapid escalation of care with mechanical ventilation, multiagent sedation and vasopressor support. Early on, more than 430 patients were hospitalized with approximately 25% requiring mechanical ventilation and intensive care unit care. These