

Commentary

We Need Proper Case Reports and Data to Interpret Reports of Peri-operative Deaths in Venezuelan Children

J Robert Sneyd*

Faculty of Medicine and Dentistry, University of Plymouth, John Bull Building, Plymouth Science Park, Plymouth PL6 8BU, UK

Abstract

A report describing several perioperative deaths amongst Venezuelan children raises substantial clinical concern and demands scientific scrutiny. Rozo L, Franco OH, Bonilla AJ. Mitochondrial genetic susceptibility to anesthetic neurotoxicity in Venezuelan pediatric patients: A Call for vigilance and further research. <https://doi.org/10.29328/journal.ascr.1001091>. Archives of Surgery and Clinical Research. 2025;9(2):042-4. According to the authors, the affected children experienced severe brain injuries or death following routine surgeries under general anaesthesia with sevoflurane, leading to the hypothesis that an inherited mitochondrial DNA variant may underlie a lethal drug-genome interaction. Whilst any paediatric peri-operative death warrants urgent investigation, the extraordinary nature of this claim requires equally compelling evidence. At present, the absence of detailed case descriptions, clinical data, and laboratory findings prevents meaningful evaluation by clinicians, scientists, or regulatory authorities. Premature recommendations for major changes in anaesthetic practice risk causing unintended harm without adequate justification. Immediate transparency is essential. Comprehensive case reports and supporting data should be shared with national regulatory bodies and the drug manufacturer, who are best positioned to assess the situation. Until such evidence is provided, no substantive clinical action can reasonably be taken.

Introduction

Recent reports about Venezuelan children dying during or after routine procedures that involved sevoflurane anesthesia have raised significant concern among scientists and the public. Rozo, et al. suggest that these deaths might stem from a change in mitochondrial DNA [1]. This implies a harmful interaction between the drug and the genome. However, this claim requires strong evidence. Currently, crucial information such as patient histories, monitoring during surgery, anesthesia doses, test results, and genetic data is not available. This lack of information makes it impossible to conduct a complete scientific and clinical evaluation. The absence of transparency leads to speculation and unnecessary changes to anesthetic practices. Since pediatric perioperative deaths are rare and large studies show that sevoflurane is safe [2-6], it is important to share detailed case data completely and

quickly before recommending any changes to clinical practice or drawing conclusions [7].

Discussion

I read the report of perioperative deaths in Venezuelan children [1] with scientific interest and great clinical concern. In their report, the authors tell us that: an unknown number ("several") of children are dead, the children were "Venezuelan", they suffered "severe brain injuries" or died, and this occurred after "routine surgeries with general anaesthesia". Those are the facts as stated. Presumably based on these facts, the authors tell us that they believe the deaths were due to an inherited change in mitochondrial DNA. The authors then go on to recommend an urgent and extensive programme of clinical and laboratory research and immediate alterations in practice. The latter includes major changes in drug choice, monitoring, history taking, as well as "enhanced perioperative vigilance".

More Information

***Corresponding author:** J Robert Sneyd, MB, BChir, FRCA, MD, PhD, Emeritus Professor, Faculty of Medicine and Dentistry, University of Plymouth, John Bull Building, Plymouth Science Park, Plymouth PL6 8BU, UK, Email: robert.sneyd@plymouth.ac.uk

 <https://orcid.org/0000-0003-3546-9856>

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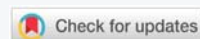
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Perioperative deaths are uncommon in children, occurring in 0.3 to 1.5% of surgeries [2]. Whereas deaths are binary, serious non-fatal complications (including neurological damage) are hard to capture, and data are generally unreliable [3]. Any perioperative death or serious complication is a tragedy, the more so if the patient is a child and the death or complication was avoidable. The episodes described in the report must therefore be taken seriously and their implications thoroughly evaluated. Unfortunately, at least at present, we can't do this. We need to see comprehensive case information, such as patient history, intraoperative monitoring data, anaesthetic dose details, metabolic and toxicological laboratory results, and genetic analyses. In the absence of detailed case reports and supporting data, readers (and regulators) are not in any position to make sense of the situation. Actually, it's worse than that. Carl Sagan reminds us that "*Extraordinary claims require extraordinary evidence*", and that principle will surely apply here. The report authors' proposition requires that a lethal interaction exists between the well-established anaesthetic sevoflurane and the mitochondrial genome and that this disaster has hitherto been missed by scientists, clinicians, and patients alike. That is certainly an extraordinary claim. However, that doesn't mean it is impossible. It took a hunch on the part of an Australian physician to link *H. pylori* to peptic ulceration [4], and it turned out that he was right. To keep us grounded, we should reflect that neither the GAS study [5] of general anaesthesia versus awake-regional anaesthesia nor the TREX trial [6] of low-dose sevoflurane/dexmedetomidine/remifentanyl anaesthesia versus standard-dose sevoflurane anaesthesia has shown any evidence of sevoflurane-induced harm.

So, what should we do? Graduating doctors, reciting the Hippocratic oath, are reminded that they should "do no harm," and that seems a good place to start. Massive changes in anaesthetic practice have significant potential for harm, and the evidence from the report is insufficient to justify such actions. Instead, we need the authors to immediately share all of the underpinning narratives and data. These episodes must be urgently reported to the appropriate national regulatory body and the drug's manufacturer, as those organisations are best placed to evaluate any information in the context of the data they have already reviewed. The authors owe it to their patients, their families, and the global clinical community to immediately engage with maximum transparency. Until then, we are in no position to do anything sensible.

Importantly, a recommendation against changing clinical practice does not imply indifference. Far from it. Urgent action is required by those with access to the clinical histories and supporting data. Whilst we await the details necessary to interpret these reports, it makes sense to follow the advice of the Society for Pediatric Anesthesia and the American Society of Anesthesiologists that "...there is insufficient data to make

any specific recommendations concerning the anesthetic care of Venezuelan children [7], and that the suspected cases be reported for further investigation.

Conclusion

The reports of peri-operative deaths in Venezuelan children require urgent attention. However, we cannot interpret them without detailed case information. The idea that a fatal interaction exists between sevoflurane and a mitochondrial DNA variant is a serious claim. It needs strong and clear evidence to support it. Until we have complete clinical and laboratory data, making changes to pediatric anesthetic practice risks unintended harm and is not justified.

The immediate priority is clear: those who have access to the original cases must provide full narratives and supporting data to national regulatory authorities and the drug manufacturer. They are best equipped to assess the situation in context. While we wait for these important details, the global clinical community should stick to established anesthetic standards and follow current professional guidance. Transparency, not guessing, is essential for protecting children and ensuring sound clinical decision-making.

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