Methylene Blue (MB) Safety

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MB is a generally safe and increasingly researched effective therapy for many conditions. Its effect on mitochondria likely lends it to a broad clinical use profile. [1,5,6]

Safety issues in the modern use of MB are rampant due to the use of non USP product available online, irregularities in pharmacies QC practices, and in some cases a low or non-awareness of the potential toxicant load in MB raw material. One author points this pout clearly stating "It is also important to note that adverse effects of MB are not explained solely on the basis of hormesis or oxidative damage, but also on that of its chemical purity. Even pharmaceutical (USP) grade MB contains impurities, such as arsenic, aluminum, cadmium, mercury and lead." [3] Additionally, MB toxicity is more related to overdose (i.e. extrapolating acute emergency medicine doses) to chronic use and disease care. [6]

Not all USP grade MB can pass QC. In pharmacies aware of the heavy metal contamination and who have appropriate QC limits and testing they may fail three to five raw material batches prior to obtaining one batch that passes QC. Heavy Metals are the usual contaminant causing QC failure. [4]

Toxicology studies, blue rodent organs, and oddly written papers. Starting with the "blue rat organ" issue, like many toxicology studies this one [2] looked at immediate distribution and not long-term tissue uptake. They gave IV and PO MB to the rats and sacrificed them one hour later. This is great to see kinetic shifts PO to IV and tissue changes but has not relationship to long term safety. (This is the error many make extrapolating heavy metal toxicology studies in animals to human effect.) It also is at odds with multiple papers citing safety detail such as "From a toxicological point of view, MB has an enviable safety record..." [1] Also, because it appears the writing of the "blue organ" paper can easily cause confused conclusions, the authors for reasons unclear to anyone mix human data and rat data in both the narrative and figures. The data are so non analogous (as to dose and targeted outcomes measures) they should have either been two papers or separated appropriately.

My opinion is that MB is an incredible drug when it passes QC and is dosed correctly. That said, the rampant use of poor quality USP grade and even worse reagent grade product is a considerable threat to human health.

References:

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