

ACCP Position Statement on Hydration and Vitamin Infusion Clinics

The Journal of Clinical Pharmacology 2024, 64(1) 10–12 © 2023, The American College of Clinical Pharmacology. DOI: 10.1002/jcph.2364

Peter L. Bonate, PhD, FAAPS, FISoP, FCP, Alexander J. Prokopienko, PharmD, PhD, Jean-Michel Gries, PharmD, PhD, FCP (1)
On behalf of the ACCP Public Policy Committee

Keywords

adverse drug reactions, clinical pharmacology (CPH), clinical research (CRE), complementary medicine, education (EDU)

Recently there has been a proliferation of wellness clinics offering on-site and mobile intravenous (IV) hydration and vitamin infusions, said to promote wellbeing and improved health. Some celebrities tout the benefits of these infusions and companies aggressively advertise their services on internet search engines.^{1,2} These companies advertise that hydration and vitamin infusions can be used to boost the immune system, increase energy levels, and treat everything from colds to hangovers, without any supportive data. Typical treatments can cost \$300-\$600,3 but are as low as \$100 for hydration. Although not a new phenomenon, the numbers can be quite staggering. For example, 172 attendees at the Complementary and Alternative Medicine Annual Meeting reported that in the 2-year period between 2006 and 2008, 11,233 and 8876 patients, respectively, were administered vitamin C infusions, with the mean number of infusions per patient being 19-24, and with a mean dose of 28 g; it was estimated that patients received approximately 318,539 and 354,647 dosing units of vitamin C per year!⁴ Since this report was published 13 years ago, those numbers have only increased. Additionally, the number of IV hydration clinics is not tracked at the federal or state level, and no statistics are available on their use.

The Issue

There is little evidence that these infusions provide benefit, as there is a lack of clinical trial data,^{5,6} except for some specific therapeutic situations. There is, however, evidence of the risks involved, albeit case reports. There are numerous accounts of adverse events, ranging from relatively minor infusion site reactions to thrombophlebitis, cellulitis, hematoma, and blood clots, and also to cases of fungal infection and septic

shock.^{7,8} In most cases, the side effects will develop in the few days following the infusion, at a time when there is no medical oversight. Additionally, underlying medical conditions, including chronic and acute kidney diseases, congestive heart failure, and liver diseases and cirrhosis, may be more sensitive to volemic changes. For example, both hypovolemia and increased fluid balance may cause acute kidney injury, through increased central venous pressure and kidney congestion.⁹

In the UK, since 2022, clinics must be registered with the Quality Care Commission (https://www.cgc. org.uk), a non-governmental independent regulator of health and social care, but in the USA, the field is unlicensed and instructions to open clinics are broadly available on YouTube. 10 Although some wellness centers have physician oversight, some do not. Whereas in most states, a medical doctor or nurse practitioner must supervise the administration of an infusion, there are reports of unqualified individuals without the proper credentials or training administering the infusions.¹¹ Furthermore, in the case of vitamin administration, there are no standards for the preparation of the administered product. Some companies have been cited for compounding under unsanitary conditions, leading the US Food and Drug Administration (FDA) to issue a nonbinding statement that compounding for these infusions should be performed in sterile conditions because of the risk of infection from contamination.¹²

Submitted for publication 5 September 2023; accepted 28 September 2023

Corresponding Author:

Peter L. Bonate, PhD, FAAPS, FISOP, FCP, ACCP Public Policy Committee, PO Box 1758, Ashburn, VA 20146.

E-mail: info@accpl.org

All authors contributed equally to this work.

Bonate et al

There is also the ethical issue of whether equal benefit could be derived from the oral administration of vitamins or just drinking a bottle of water in lieu of IV hydration therapy. Although there are some specific cases for using IV vitamins over oral administration, ¹³ from a purely pharmacological point of view, even in cases of vitamin deficiency, there is no evidence that IV infusion is superior to oral administration. Even in high-intensity sports, hydration strategies can be managed via oral administration. 14,15 Furthermore, there is no standardization of the mixtures administered. A frequently used mixture known as Myers' cocktail has been tried in fibromyalgia, unsuccessfully, ¹⁶ and was further implicated in a severe reaction that caused a media personality to be hospitalized in 2018.¹⁷ From a pharmacy point of view, it is not clear what is the source of the vitamins administered, their potency, their purity, or whether proper sterile conditions are maintained during their preparation and administration. The college therefore concludes that there is little to no evidence that the benefits outweigh the risks for hydration and vitamin infusions.

Recommendations

The following recommendations are made:

- Hydration and vitamin infusions should be given with physician approval for a valid medical reason, by an appropriately licensed and trained individual, such as a doctor or nurse, and compounded by a licensed pharmacist.
- 2. Appropriate medical care should be available immediately, should the need arise, such as having an automated external defibrillator (AED) on the premises and personnel trained in advanced cardiac life support (ACLS, or equivalent).
- 3. Only pharmaceutical-grade vitamins and fluids should be used, with compounding carried out under sterile, sanitary conditions at a state-licensed pharmacy (ideally registered under CFR 503A as a compounding pharmacy), using best practices with appropriate standard operating procedures (SOPs) for their formulation.
- All patients should receive and sign an informed consent listing the risks involved in the procedure.
- Coordination with the primary care provider of the subject before the procedure, and follow-up a few days after to collect any adverse reactions, should be mandated.
- Regulatory oversight in the USA is warranted to ensure patient safety, with at least a reporting of adverse reactions during or after the procedure to an appropriate institution, such as the FDA.

Conflicts of Interest

The authors declare that they have no conflicts of interest associated with this statement.

ACCP Public Policy Committee

Mark Rogge, Peter Bonate, Janelle Burnham, Mohit Gandhi, Sindura Gollamudi, Jean-Michel Gries, Amandeep Gupta, Priyanka Ingle, Mark Kirstein, Parag Kumar, Tao Long, Suresh, Mallikaarjun, Kenneth (Todd) Moore, Ken Ogasawara, Sudhakar Pai, Alex Prokopienko, Sreedharan Sabarinath, Aarti Sawant, Jinshan Shen, Suneet Shukla, and Karthik Venkatakrishnan.

References

- Romeyn K. Where to get Adele's favorite \$220 IV drip vitamin infusion in L.A. 2-17-2017. Accessed February 28, 2023. https://www.hollywoodreporter.com/lifestyle/style/get-celeb-loved-iv-vitamin-infusions-la-977990/
- Get the Gloss. IV drips. 6-20-2022. Accessed February 28, 2023. https://www.getthegloss.com/beauty/skincare/iv-driptherapy-vitamins
- Das LT. Trendy IV vitamin infusions don't work and might be unsafe. Experts explain why. Washington Post. 2022. https://www.washingtonpost.com/wellness/2022/02/24/ warnings-about-drip-bars/
- Padayatty SJ, Sun AY, Levine M. Vitamin C: intravenous use by complementary and alternative medicine practitioners and adverse effects. *PLoS One*. 2010;5:e11414.
- Gaby AR. Intravenous nutrient therapy: the "Myers' cocktail". *Altern Med Rev.* 2022;7:389-403.
- Ali A, Njike VY, Northrup V, et al. Intravenous micronutrient therapy (Myers' Cocktail) for fibromyalgia: a placebo-controlled pilot study. J Altern Complement Med. 2009;15:247-257.
- 7. D'Souza G, Pandian E, Hosea S. A nearly fatal case of *Pseudomonas fluorescens* bacteremia secondary to a naturopathic intravenous vitamin infusion. *J Investig Med High Impact Case Rep.* 2021;9:23247096211026481.
- 8. Livshits Z, Hoffman RS, Hymes KB, Nelson LS. If vitamins could kill: massive hemolysis following naturopathic vitamin infusion. *J Med Toxicol*. 2011;7:224.
- Chen KP, Cavender S, Lee J, et al. Peripheral edema, central venous pressure, and risk of AKI in critical illness. *Clin J Am Soc Nephrol*. 2016;11:602–608.
- Harris C. 4 Simple Steps For Nurses To Start an IV Hydration Business. 2023. Accessed February 28, 2023. https://www. youtube.com/watch?v=nUTgSMhw-I0
- Grotjahn J. Some Alabama IV therapy businesses letting 'unqualified' employees treat patients, health investigation shows. News19. 2022. https://whnt.com/community/somealabama-iv-therapy-businesses-letting-unqualified-employeestreat-patients-health-investigation-shows/
- 12. Food and Drug Administration. FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions. 2021. https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary
- Meehan R, Tavares M, Sweeney J. Clinical experience with oral versus intravenous vitamin K for warfarin reversal. *Transfusion*. 2013;53:491–498.

- 14. van Rosendal S-P, Osborne MA, Fassett RG, Lancashire B, Coombes JS. Intravenous versus oral rehydration in athletes. *Sports Med.* 2010;40:327–346.
- Kenefick RW, O'Moore KM, Mahood NV, Castrellani JW. Rapid IV versus oral rehydration: responses to subsequent exercise heat stress. *Med Sci Sports Exerc*. 2006;38:2125– 2131.
- Ali A, Njike VY, Northrup V, et al. Intravenous micronutrient therapy (Myers' Cocktail) for fibromyalgia: a placebo-controlled pilot study. J Altern Complement Med. 2009;15(3):247–257. https://doi.org/10.1089/acm.2008.0410;
- Stieg C. Refinery 29 March 9, 2018. https://www. businessinsider.com/vitamin-iv-drip-complications-kendalljenner-hospitalized-2018-3