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Abstract:

Context: Intravenous ascorbic acid (IVAA) has been used extensively as part of the management plan for cancer patients in various medical clinics throughout the United States. The current research team has evaluated its effectiveness in patients with cancer as part of an ongoing research program. However, no data are available that support the chemical stability of intravenously injectable ascorbic acid (AA) to ensure its safety and efficacy in that patient population. Its clinical use as well as its use in research conducted in US Food and Drug Administration-approved clinical trials require validation of its stability.

Objective: The study intended to evaluate the chemical stability of the compounded IVAA that it prepares.

Design: The research team conducted a stability analysis within a 6-h period, a period longer than the time required for most infusions, which typically take approximately 2 h. The study evaluated the stability of AA intravenous sets, which are compounded solutions for clinical or

hospital use. The IVAA was prepared in sterile water, together with magnesium chloride (MgCl) and calcium gluconate (CaGluc) as buffers.

Setting: The study took place at the Marcus Institute of Integrative Health at Thomas Jefferson University (Philadelphia, PA, USA).

Outcome Measures: The study was performed for 2 dosages of an infusion set: 75 g and 100 g of IVAA. Interval testing included pH, particulate matter by light obscuration, and high-performance liquid chromatography assay. Analyses were performed at baseline and at 2-, 4-, and 6-h test intervals.

Results: The results demonstrated that IVAA remained highly stable throughout the 6-h period. It also passed the US Pharmacopeia's criteria for pH and particulates when used with a 0.2 μ filter.

Conclusions: These data suggest that IVAA, when prepared with sterile water, in addition to MgCl and CaGluc, is highly stable and safe to use in patients for up to 6 h after preparation.

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Reference:

Monti, D.A., Bazzan, A.J., Zabrecky, G. and Newberg, A.B. (2017) Brief Report: Stability and Chemical Characteristics of Injectable Ascorbic Acid for Patients With Cancer. *Alternative Therapies in Health and Medicine*. October 2nd. .

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