Clinical Trial to Find An Oral Dosage of Vitamin C that May Prevent Recurrence of Superficial Bladder Cancer

Edward Folk, Kevin T. Palmer, Joseph L. Posthepp, Alison Deng, R. Madeleine R. Hallberg, Ayca Kaplan, Ozgun Kilic, Donna A. Roberts, Komari C. Walls, and Alfred B. "Roc" Ordman
Beloit College, Beloit, WI, 53511

Introduction
AA-ascorbic acid/vitamin C; BID-in divided doses, twice a day; BCG- Bacillus Calmette-Guerin; SBC-superficial bladder carcinoma; LUTS-lower urinary tract symptoms; DOPC-diphytanoylphosphatidylcholine; GRAS-generally recognized as safe

Method
The trial was approved by the IRB of Beloit College. Participants are 14 healthy members of the college, aged 17 to 20 years. Twice a day for 1 week, each Individual was given Green 500 mg AA. The next day, the trials were repeated for 7 days. The last day, the individuals were given Green 500 mg AA and 2 g BID to collect any urine. The urine samples were analyzed for AA and urine peroxide levels.

Results
The results of the trial were used to determine 2 g AA BID dosage (Table 2). The levels required for the highest AA in the bladder (the pilot trial showed that dosages above 500 mg BID were necessary to have continuous excretion from the bladder, and that dosages above 2 g BID could not be absorbed). The participants for this trial were from 18 to 22 y old and seemed to be of good health, with most being minimal smokers (Table 4). The results of the two trials reflect different results from volumes of urine production. Three of the 24 reported minor infections.

Comparison of the Maximum AA achieved vs. the level required to kill cancer cells:
The AA levels ranged from 2 to 27 mM AA which is much greater than the 1 mM level required to kill cancer cells (Chen 2005). The results of the in vitro studies were used to select patients who localized their bladder cancer with a cystoscope.

In vitro studies demonstrated to kill cancer cells.

Comparison of oral AA dosage and serum levels, confirming Ordman's conclusion that 500 mg AA BID produces the highest statistically significant response.

Exercise in cancer patients stimulates AA synthesis.

In order to reduce the chance of causing LUTS, and considering that cancer often develops tolerance for many forms of chemotherapy, the protocol to conduct a clinical trial on those with SBC will include 2g AA BID dosages, with the exception of patients who were determined in a recent study (Kong 2014) to have 2 g AA daily in their urine.

Discussion
AA is absorbed into the serum, and removed by the kidneys through the bladder in urine. Since it is unclear what effect high doses of vitamin C have on producing or preventing kidney stones, for this reason many physicians believe that consuming AA increases the risk of kidney stones. However, it is not possible to determine the effects of high doses of supplemental AA that is documented in peer-reviewed literature were reported in 2011 when it was shown that taking AA supplements regularly causes LUTS in 21% of older men (Manserijn 2011). LUTS is lower urinary tract symptoms, specifically more difficult with and frequency of urinating, similar to prostate hyperplasia. It remains unclear whether AA contributes to kidney stones. AA can be biochemically metabolized to oxalic acid, and oxalic acid forms kidney stones. However, a reduction in the risk of kidney stones was observed in those who take AA supplements (Koos 2012). We monitored 409 patients by Thomas et al (2013) reported a 0.15% increased risk of kidney stones. In Sweden, which takes single doses of 1 g or more through supplements. Other documented effects of AA are beneficial. These include a minor reduction in blood pressure (Newberry 2012), and a decrease in cortisol levels (Staffold 2001, 2012), and a reduction in the risk of stroke (Hollander 2013). In order to reduce the chance of causing LUTS, and considering that cancer often develops tolerance for many forms of chemotherapy, the protocol to conduct a clinical trial on those with SBC will include 2g AA BID dosages, with the exception of patients who were determined in a recent study (Kong 2014) to have 2 g AA daily in their urine.

Conclusion
Research in urinary excretion of AA indicates that the level in the bladder can be measured simply by oral consumption. The maximum AA achieved was 2g AA, by consuming 2g AA BID. For SBC, this method provides a level of AA in the bladder that can kill cancer cells, not harm normal tissue, and frequently reduces the rate of recurrence from 95% to at least 44%, and potentially even less.

References
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