Superoxide dismutase and its effect on interstitial cystitis pain

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Overview

Interstitial cystitis is a chronic condition causing bladder pressure, bladder pain and sometimes pelvic pain. The pain ranges from mild discomfort to severe pain (1). In our study, participants used superoxide dismutase applied topically over the bladder to see if pain symptoms would be improved.

Brief Summary

Superoxide Dismutase is an enzyme that is thought to inhibit neutrophils during oxidative stress. Neutrophils play essential roles in several inflammatory reactions. Oxidant/antioxidant imbalance is thought to be partially involved in the pathogenesis of the disorders. Under the conditions of oxidative stress, superoxide dismutase (SOD) acts as an endogenous cellular defense system to degrade superoxide (O2-) into oxygen and hydrogen peroxide. Therefore, SOD is potentially useful as a therapeutic agent for treatment of inflammatory disorders (2) There are three isoforms of SOD found in humans; copper/zinc (Cu/Zn)-SOD (SOD1), manganese (Mn)-SOD (SOD2) and extracellular Iron (Fe)-SOD (SOD3). (3) We conducted a randomized, double-blind, placebo controlled clinical trial of Human recombinant superoxide dismutase (SOD 1) in subjects with I.C./painful bladder syndrome.

We specifically used Human recombinant Superoxide Dismutase 1 (patented product) made from E. coli bacterial biosynthesis in our study of 27 patients. The purpose of the study was to determine if this product would help alleviate symptoms of interstitial cystitis (I.C.). Despite a number of potential treatments that have been tried on patients with I.C., many patients still suffer from its debilitating effects of pain, discomfort, urgency, and frequency of urination. This study shows a moderate decline of symptoms in patients with I.C.

Study Design

27 study participants received 1 bottle of S.O.D. combined with Lidocaine 0.5% and another bottle of plain Lidocaine 0.5%, which served as placebo. Participants were unaware of which bottle they were using on each of their weeks. On week 1, participants started with their first bottle at 2 squirts 3 times a day over the bladder region. Participants were instructed on how to apply the product with a video demonstration, and also with written instructions on email. Participants were called initially and 3 more times throughout the study to answer any questions and ensure successful application of product. A daily questionnaire was filled out and emailed. After 1 week, there was a 1-2 week washout period where no product was applied. Then on week 4, participants applied the second bottle in the same manner.

The initial study questions were as follows: (taken from the O'Leary/Sant voiding and pain indices(3))

1. In the past month, how often have you felt the strong need to urinate with little or no warning?
2. In the past month, have you had to urinate less than 2 hours after you finished urinating?
3. In the past month, how often did you most typically get up at night to urinate?
4. In the past month, have you experienced pain or burning in your bladder?

5. In the past month, how much has frequent urination during the day been a problem for you?
6. In the past month, how much has getting up at night to urinate been a problem for you?
7. In the past month, how much has needing to urinate with little warning been a problem for you?
8. In the past month, how much has burning, pain, discomfort or pressure in your bladder been a problem for you?

The daily survey questions were as follows:

1. In the past 24 hours, how often have you felt the strong need to urinate with little or no warning?
2. In the past 24 hours, have you had to urinate less than 2 hours after you finished urinating?
3. In the past 24 hours, how often did you most typically get up at night to urinate?
4. In the past 24 hours, have you experienced pain or burning in your bladder?
5. In the past 24 hours, how much has frequent urination during the day been a problem for you?
6. In the past 24 hours, how much has getting up at night to urinate been a problem for you?
7. In the past 24 hours, how much has needing to urinate with little warning been a problem for you?
8. In the past 24 hours, how much has burning, pain, discomfort or pressure in your bladder been a problem for you?

Responses were rated from the scale provided and emailed back to the investigator.

Results

27 participants started the study. One completely dropped out (she had a close relative pass away). Five patients were not full participants as they didn't completely answer the daily questionnaire. 21 completed the study with full participation in the questionnaire.

- 72% improvement in those needing to urinate with little to no warning using SERUM X
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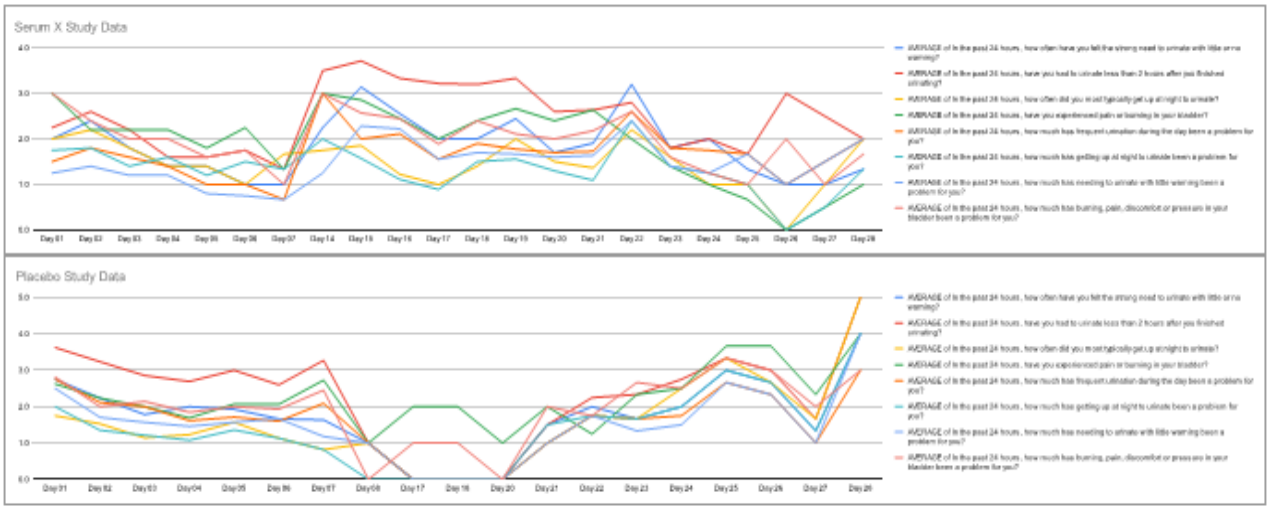
- 67% improvement in pain in those using SERUM X

- Average improvement of 22.07% between Serum X and the placebo amongst all categories studies (Questions 1-8)

- Average improvement of 29.53% between Serum X and the placebo amongst the two pain categories (Questions 4 and 8)
    - Found by averaging the improvement rates of Days 1-7 and Days 22-28 from the two categories

Interstitial Cystitis Symptom Study - November 2021 to February 2022

Conducted by Dr. Harline & Funded by AO Biologix



Serum X Pain Scores (Positive % Indicates Worse Pain, Vise Versa)	AVERAGE of In the past 24 hours, how often have you felt the strong need to urinate with little or no warning?	AVERAGE of In the past 24 hours, have you had to urinate less than 2 hours after you finished urinating?	AVERAGE of In the past 24 hours, how often did you most typically get up at night to urinate?	AVERAGE of In the past 24 hours, have you experienced pain or burning in your bladder?	AVERAGE of In the past 24 hours, how much has frequent urination during the day been a problem for you?	AVERAGE of In the past 24 hours, how much has getting up at night to urinate been a problem for you?	AVERAGE of In the past 24 hours, how much has needing to urinate with little warning been a problem for you?	AVERAGE of In the past 24 hours, how much has burning, pain, discomfort or pressure in your bladder been a problem for you?
Days 1-7	-22.14%	-18.04%	-13.67%	-18.93%	-16.79%	-7.32%	-12.32%	-27.30%
Days 14-21	-71.83%	-13.86%	-3.29%	-4.48%	-13.17%	-6.98%	-3.67%	-10.80%
Days 22-28	-25.29%	0.00%	-10.20%	-20.71%	-11.29%	-22.32%	-4.48%	-11.81%

Placebo Pain Scores (Positive % Indicates Worse Pain, Vise Versa)	AVERAGE of In the past 24 hours, how often have you felt the strong need to urinate with little or no warning?	AVERAGE of In the past 24 hours, have you had to urinate less than 2 hours after you finished urinating?	AVERAGE of In the past 24 hours, how often did you most typically get up at night to urinate?	AVERAGE of In the past 24 hours, have you experienced pain or burning in your bladder?	AVERAGE of In the past 24 hours, how much has frequent urination during the day been a problem for you?	AVERAGE of In the past 24 hours, how much has getting up at night to urinate been a problem for you?	AVERAGE of In the past 24 hours, how much has needing to urinate with little warning been a problem for you?	AVERAGE of In the past 24 hours, how much has burning, pain, discomfort or pressure in your bladder been a problem for you?
Days 1-7	-15.68%	-7.80%	-11.28%	0.19%	-11.78%	-13.72%	-14.40%	-4.81%
Days 14-21	65.00%	65.00%	30.00%	-10.00%	30.00%	65.00%	30.00%	20.00%
Days 22-28	21.43%	28.60%	28.57%	33.63%	16.71%	24.11%	24.70%	10.42%

Difference of Serum X Over Placebo (The More Negative %, the Better)	AVERAGE of In the past 24 hours, how often have you felt the strong need to urinate with little or no warning?	AVERAGE of In the past 24 hours, have you had to urinate less than 2 hours after you finished urinating?	AVERAGE of In the past 24 hours, how often did you most typically get up at night to urinate?	AVERAGE of In the past 24 hours, have you experienced pain or burning in your bladder?	AVERAGE of In the past 24 hours, how much has frequent urination during the day been a problem for you?	AVERAGE of In the past 24 hours, how much has getting up at night to urinate been a problem for you?	AVERAGE of In the past 24 hours, how much has needing to urinate with little warning been a problem for you?	AVERAGE of In the past 24 hours, how much has burning, pain, discomfort or pressure in your bladder been a problem for you?
Days 1-7	-6.68%	-10.23%	-2.39%	-19.07%	-5.01%	6.40%	2.08%	-22.68%
Days 14-21	-56.83%	-56.86%	-32.29%	5.52%	-43.17%	-91.98%	-32.67%	-30.80%
Days 22-28	-60.71%	-15.40%	-65.43%	-54.35%	-27.94%	-46.43%	-29.17%	-22.21%

Conclusion

Study participants who were experiencing pain symptoms of interstitial cystitis showed modest improvement with application of SOD 1 over the bladder region. This product could potentially be of benefit to thousands of patients suffering from this debilitating condition. It is the author's experience that this product seems to be more efficacious on painful conditions that are closer to the skin surface. Since this is a relatively small study, further studies are indicated.

References

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