

**The Therapeutic Effect of
Calcium Glycerophosphate (Preliel®)
in Interstitial Cystitis.**

**A Survey of
Interstitial Cystitis Support Group (UK)
Members**

January 2000

The Therapeutic Effect of Calcium Glycerophosphate (Prelief) in Interstitial Cvstitis. A Survey of I.C.S.G (Interstitial Cvstitis Support Group) Members.

Aim

To investigate the effects and improvement on symptoms of IC achieved through the oral administration of Prelief with food and beverages.

Background

Prelief is a dietary supplement that helps reduce acid in foods and beverages, thus rendering them more tolerable to IC sufferers. In the U.S.A., where Prelief is available "over the counter", prospective and retrospective studies have shown that Prelief is of positive value in allowing IC patients consumption of foods with an acid content.

Following the results of this U.K. survey, a controlled prospective study may be considered.

Method

- A maximum of 150 ICSG members were invited through their newsletter to take part in the study.
- The members that responded were sent information sheets giving "Procedure for entry onto the I.C.S.G. Prelief Survey", "Instruction form" and "Logging forms".
- Those members that met the criteria for being accepted into the survey were sent 3 months supply of Prelief in both powder and tablet form.
- At the end of 3 months recruits were sent a Prelief Questionnaire, which summarised the results kept on the logging forms, and other information regarding their perceived effects of Prelief. These were returned to the Prelief Survey coordinator by Dec 31st 1999.

Examples of these forms are given in the Appendix.

Timing

Participants started a 3-month trial of Prelief at varying times between May 1999 and September 1999.

Subject Population

Participants were all members of the ICSG and needed to fulfill the criteria that they had been diagnosed with IC or its symptoms. They also had to regularly suffer with some level of acid food intolerance on a regular basis.

Number of recruits onto the survey = 32

Profile of Prelief Survey Participants

26 Prelief Questionnaires were completed and returned by December 31st 1999.

In addition, 2 sets of Logging forms was returned without the Questionnaires, giving limited information, and one letter of withdrawal from the trial due to personal reasons.

Number of Female respondents =26 (93%) Number of Male Respondents = 2 (7%).

Age of respondents Average = 53 Youngest =21 Oldest =84.

Age at first I.C. Symptoms Average = 37 Youngest = 11 Oldest = 82.

Duration of symptoms.

Average = 15 years. Variation: 2-54 years.

Number of participants having undergone pelvic/abdominal surgery =15. (58%).

Medication taken during trial

All participants were taking medication(s) during the 3 month trial.

The most commonly used medications were as follows:

Amitriptyline taken by	12	46%
Elmiron taken by	5	19%
Ibuprofen taken by	5	19%
Ranitidine taken by	3	12%
Cimetidine taken by	3	12%
H.R.T. taken by	3	12%

Supplements taken during trial.

Most commonly:

Aleo Vera taken by	2	8%
Uva Ursi Complex taken by	2	8%
Multivitamin/mineral taken by	5	19%
Vitamin C taken by	5	19%
Evening primrose oil taken by	4	16%
Vitamin E taken by	3	12%
L-Arginine taken by	2	8%
Cod liver oil taken by	2	8%

Symptoms suffered by participants at the beginning of the trial. n=28

Urinary frequency	26	93%
Urinary urgency	25	89%
Bladder pain	24	86%
Back pain	18	64%
Excessive Fatigue	13	46%
Irritable Bowel Syndrome	10	36%
Arthritis	8	29%
Allergy	5	18%
Sinusitis	5	18%
Depression	3	11%
Thrush	3	11%
Bacterial Cystitis	2	7%
Fibromyalgia	2	7%
Flu like symptoms	2	7%
Perineal pain	2	7%
Migraine	1	4%

Results of Prelief Trial. n=26

Participants who found an improvement in symptom(s) whilst taking Prelief

Total: 18 69%

Symptoms which improved whilst taking Prelief estimated on a scale of slight (1) to completely disappeared (4).

Symptom	Number of participants noting improvement	average scale
Urinary frequency	13 48%	2
Urinary urgency	7 26%	2
Bladder pain	5 19%	2
Back pain	3 11%	3
General improvement	2 7%	3
Depression	1 4%	3
Flu like symptoms	1 4%	4
Irritable bowel	1 4%	2

Symptoms which worsened whilst taking Prelief

Depression	1 4%
Fibromyalgia	1 4%
Migraine	1 4%
Urinary frequency	1 4%

Prelief usage during trial

Average number of times a week 8. Maximum 21 Minimum 3
 Average dosage used: 2-3 tablets or sachets.

Participants were asked whether they would wish to continue taking Prelief after the trial. If so, how frequently.

Not at all	7 27%
Weekly	1 4%
3+ times a week	8 31%
Daily	10 38%

Number of participants who found an improvement in their ability to tolerate at least one food or beverage as a result of taking Prelief: 21 81%

Foods and beverages that participants were unable to usually tolerate before the trial but *could* tolerate when taking Prelief. (These were often small amounts).

Alcohol (general)	2	8%	Mayonnaise	4	15%
Apples	4	15%	Onions	3	11%
Baked beans	3	11%	Pears	1	4%
Banana	2	8%	Pineapple	1	4%
Beer	2	8%	Pizza	1	4%
Cheese	6	23%	Raspberries	2	8%
Chinese food	3	11%	Red wine	3	11%
Chocolate	4	15%	Spaghetti Bolognese	2	8%
Citrus fruit	3	11%	Strawberries	3	11%
Curry	4	15%	Tea/coffee	10	38%
Fruit juice	4	15%	Tomatoes	11	42%
Grapes	1	4%	Vinegar	1	4%
Ibuprofen *	1	4%	White wine	7	27%
Jam	1	4%	Wine sauce	1	4%
Lemonade	1	4%	Yogurt	1	4%

* Not a food or beverage, but of interest. See later comment.

Foods and beverages that participants were usually unable to tolerate before the trial that Prelief *did not* make more tolerable.

Apple	1	4%	Oranges	2	8%
Beetroot	1	4%	Pears	1	4%
Carbonated drinks	2	8%	Pineapple	2	8%
Cheese	1	4%	Pork	1	4%
Chinese food	1	4%	Red wine	1	4%
Chocolate (milk)	1	4%	Spices/curry	5	19%
Fruit juices	6	23%	Strawberries	2	8%
Grapefruit	2	8%	Tea/coffee	5	19%
Grapes	1	4%	Tomato sauce	2	8%
Kiwi fruit	1	4%	Vinegar	2	8%
Melon	1	4%	White wine	6	23%
Onion	3	11%	Yogurt	2	8%

Participants were asked if Prelief affected the taste of foods or beverages.

Number who felt that it did sometimes affect the taste	10	38%
Number who felt the powder left a slight bitter taste	4	15%

Selection of comments made by participants

The ICSG diet (low acid foods) did not help so I wasn't surprised Prelief didn't help my symptoms. (2).

Prelief helped greatly with acid foods, I will continue to use it. (8).

Prelief helped me tolerate a greater variety of foods. (7).

I will continue to log response for reference. (1).

Prelief has given me more confidence to eat out and try "risky" foods. (7).

Taking water with Prelief and acid foods helps to dilute the acidic effect. (2).

Powder sprinkled on foods was better than taking the tablets. (1).

I preferred the tablets to the powder. (1).

I would have liked to try larger doses of x6. but didn't know how safe this was. (1).

Prelief did not reduce symptoms, but prevented symptoms worsening with forbidden foods. (2).

There is a prolonged effect if taken regularly. (1).

Although Prelief did not help my symptoms. I will continue to take it for the extra calcium. (1).

Prelief helped. but how safe is it to take over the long-term? (2).

It was difficult at first being brave enough to tackle acid foods. (2).

* Prelief was particularly helpful following a fall as I was able to tolerate anti-inflammatory medication. (1).

Prelief gave me the confidence to attend wine-tasting classes. (1).

Symptoms worsened due to the acidic nature of the food. (2).

White wine and Prelief gave me diarrhea. (1).

Prelief aggravated my acid stomach and reflux. (2).

Summary of results

Participants in this trial were mainly female, which reflects the membership of the ICSG. There was a very wide distribution of age, duration of symptoms and type of symptom experienced.

This trial has indicated that the majority of participants found Prelief to be beneficial in reducing their I.C. symptoms (69 %) and enabling them to tolerate a wider variety of foods and beverages of an acidic nature (81%). Of those taking part, 73% stated that they would continue to take Prelief if given the opportunity at least once a week, and 37% would continue to use it daily.

Comments

There was an initial disappointing uptake of the trial, with substantially fewer volunteers than the 150 planned. This may have been due to a reluctance to try acid foods and risk side effects. It may be that the profile of those members who came forward was different than those who were more reticent. However, I consider this trial was a success in that it showed that a benign supplement, with none of the side effects of a pharmaceutical drug, was able to help the majority of participants. It confirms that Prelief can help certain sections of the I.C.S.G. membership. The range of improvement, and the type and quantity of food made more tolerable varied tremendously, but the results indicate that it is probably to the benefit of most I.C.S.G. members to at least try Prelief to see if it can help them.

Pamela Jones
Nutrition Consultant.
January 2000.

Appendix

1. Procedure for entry onto the I.C.S.G Prelief survey.
2. Instruction form for the Prelief survey.
3. Response/Logging forms for the Prelief survey.
4. Prelief Questionnaire. Summary of response.

Procedure For Entry Onto The I.C.S.G. Prelief Survey

- 1) You have been diagnosed with I.C.
- 2) You suffer with some level of acid food intolerance on a regular basis. (ie certain acid foods make your I.C. symptoms worse). Examples of these foods are citrus fruits, wine, tomato sauce, coffee, orange juice, pickles.
- 3) You are willing to test foods that may have given you symptoms in the past.
- 4) You are committed to following the survey guidelines for a period of 3 months.
- 5) This will involve keeping a Response log on the form provided of your Prelief usage, dosage, foods tested and scale of symptom if any (eg bladder pain).
- 6) You complete a more detailed questionnaire, which will be sent to you 2 weeks before the end of the survey. This will summarise your findings for analysis..
- 7) You must consult your G.P. before taking Prelief to confirm that there is no medical reason that you should not be included in the survey. This is very important in the case of renal impairment. Your G.P. should be aware that each serving of two tablets or sachets contain 130mg of calcium and 100mg of phosphorus, and you may be taking this dosage twice daily.
- 8) A.K. Pharma Inc. and the I.C.S.G. cannot be held responsible for any association between a medical condition and use of Prelief.
- 9) If you are happy to proceed, please register with the survey at I.C.S.G. The first 150 applicants will be accepted.
- 10) If accepted, you will receive a 3-month supply of Prelief in both tablet and powder form, together with instructions for use soon after registering. (anticipated May /June).

I.C.S.G. Prelief Survey Instruction Form

Prelief is a dietary supplement that helps reduce acid in foods, thus rendering acid foods and beverages more tolerable to I.C. sufferers. Prelief can be added to or taken with food. It works directly on the food, not on you, and claims not to affect the palatability of the food. Prelief comes in tablet or granule form, so you can use whichever is preferred.

1. Prelief should be tried with foods containing acid in varying doses to ascertain the scale of acid neutralisation, and reduction in symptoms.
2. **Foods** The foods to be tested are those that are acidic, but many foods contain a low level of acid. We suggest you try Prelief with the main foods listed below, and also with other foods that you know irritate you. The green form **IC and Diet** produced by the ICA, and available from the office, offers more detailed guidance on foods that can aggravate symptoms.
3. **Acid foods suggested** (If you avoid any of these on personal grounds, then leave them out). Tinned tomatoes, tomato sauce, pickled vegetables, red and green peppers, red and white wine, decaffeinated or regular coffee, tea, citrus fruits, tinned fruit, fruit juices (try a range), commercial sauces: pizza, barbecue, spicy etc, fizzy drinks, beer, low fat yogurt, soy sauce, vinegar, salad dressing.
4. **Dosage** You can use one, two or three doses (tablet or granules) of Prelief per food portion tested, one or two times a day. Start with the lower dosage, and if you experience any level of symptom, increase the dosage of Prelief when you next eat that food. Try and test foods in different forms (e.g. tomato sauce and uncooked tomato), and a range of fruits and juices.
5. **Symptoms.** Your symptoms should be logged on the Response form on a scale of 0 to 4 in severity.
Scale 0= no symptom,
Scale 1 =mild symptom
Scale 2= moderate symptom
Scale 3= severe symptom
Scale 4 = very severe symptom:
The type of symptom should be logged (e.g. bladder pain, urinary frequency, irritable bowel syndrome, heartburn).

Please remember that there can be a delay of hours before symptoms appear.

Obviously we do not want to make this painful for you, so if there is a very severe reaction to a food, retest with a smaller portion and larger Prelief dose (max 3 tablets or sachets), only if you feel happy doing so.

6. **Response Form.** This should be filled in whenever Prelief is used, we suggest on a daily basis.
7. Remember to carry Prelief with you on outings, as you may be exposed to foods outside your control.
8. You have probably been avoiding certain foods that have made your symptoms worse. Bring these foods back slowly, starting with smaller portions, logging the portion size on the response form.

Prelief Questionnaire

This questionnaire should be completed when you have used Prelief for a minimum of three months. Please fill it in the best you can, and return to the address below together with your Survey Response Forms. This information is entirely confidential, and the final report will be a summary of the results and comments from ICSG members enrolled in the trial.

Name _____ Age: _____ M/F: _____ Telephone number: _____

Date Started Trial: _____ Date Completed Questionnaire: _____

Clinical History

Age at first I.C. symptom: _____ Duration of symptoms: _____

Have you undergone any pelvic/abdominal surgery? _____

Please list any medication taken during the trial: _____

Please list any other supplements taken during trial: _____

At the beginning of the trial did you suffer from any of the following symptoms?

Urinary urgency	Bacterial cystitis
Urinary Frequency (over 8 voids a day.)	Thrush
Bladder pain	Excessive fatigue
Back pain	Depression
Arthritis	Sinusitis
Irritable Bowel syndrome	Other

Which symptom(s), if any, improved during the trial. Please estimate improvement on a scale of 1 (slight) to 4 (symptom completely disappeared).

Did any symptoms worsen as a result of taking Prelief? If so, please describe.

Summary of Prelief Effect

You will need your response forms for this.

Which foods or beverages were you unable to usually tolerate before the trial, but **could tolerate** when taking Prelief?

List any foods or beverages that you were unable to tolerate before the trial that Prelief **did not make more tolerable**.

How many times a week, on average did you use Prelief, and what dose?

Did Prelief affect the taste of foods? If yes, please describe.

Would you continue to use Prelief?

No / weekly / 3+ a week / daily. Please indicate.

Other Comments

This is your chance to let us know your comments and concerns about Prelief. It is confidential, and may help other I.C. sufferers.

Please return this questionnaire, together with your Survey Response Forms to:

Pamela Jones

Prelief Trial, Springwood, Chivery, Tring, Herts HP23 6LD.

Thankyou for your time.