

ANALYSIS OF BACTERIOLOGY AND SYMPTOMOLOGY IN THE 2011 ITALIAN ORAL GSH TRIAL

I. BACTERIOLOGY

Table 1: Number of Species

	GSH	Placebo
2 down to 1	8	3
1 down to 0	4	0
Same #	10	16
0 rising to 1 or 2	0	2
1 rising to 2	0	1

Table 2: Quality of Bacteria (that is Worse Bacteria versus Not as Worse Bacteria; for example, PA is worse than SA)

	GSH	Placebo
Worse Goes to Better	16	4
Same	6	14
Better Goes to Worse	0	4

Discussion: Regarding bacteriology, no patient in the GSH treatment group increased the number of bacterial species being cultured, nor did the identity of their bacterial species worsen, over the course of the trial. Indeed, four patients in the GSH treatment group reverted from culturing a bacterium to culturing only normal flora by the end of the trial. In contrast, while 3 patients in the placebo group did decrease their number of species from 2 to 1, 3 patients in the placebo group also increased the number of species cultured, and 4 patients in the placebo group went to culturing a worse bacterium by the end of the trial than cultured at baseline.

II. SYMPTOMOLOGY

Discussion: No patient in the GSH group worsened on any of the eleven measures of GI symptomology over the course of the trial, according to the qualitative symptomology assessment performed by each patient/parent.

TABLE A: Symptomology Results, p-value assessed on difference between GSH and Placebo patients on each symptom

Variable				
Abdominal pain	% improved	% steady	% worsened	p-value
GSH	55%	45%	0%	0.004
Placebo	18%	64%	18%	
Belching				
GSH	32 %	68%	0%	0.0006
Placebo	0%	77%	23%	
Flatulence				
GSH	59%	41%	0%	0.0003
Placebo	9%	77%	14%	
Lack of appetite				
GSH	91%	9%	0%	0.0001
Placebo	18%	59%	23%	
Bloating				
GSH	55%	45%	0%	0.0002
Placebo	5%	82%	14%	
Nausea				
GSH	23%	77%	0%	0.059
Placebo	9%	77%	14%	

Vomiting				
GSH	23%	77%	0%	0.013
Placebo	5%	77%	18%	
Heart Burn				
GSH	18%	82%	0%	0.12
Placebo	5%	91%	5%	
Diarrhea				
GSH	59%	41%	0%	0.004
Placebo	18%	64%	18%	
More than 2 BM daily				
GSH	73%	27%	0%	0.0004
Placebo	18%	64%	18%	
Less than 2 BM weekly				
GSH	18%	82%	0%	0.245
Placebo	9%	86%	5%	