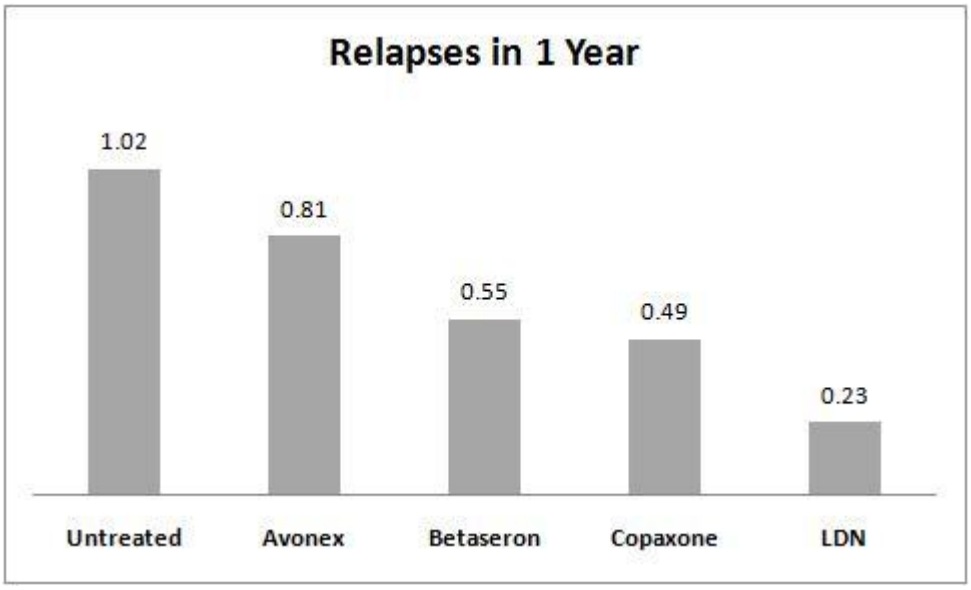
Survey of 267 Patients Using Low Dose Naltrexone for Multiple Sclerosis

Summary

In order to stimulate interest among other academic researchers in LDN trials for MS, an online patient tracking system has been devised. The subjects were self-selected, after seeing an invitation to participate in the survey posted at various online MS discussion forums. While not a scientific or controlled study, the survey form applies consistency across patient self-reports, allowing statistical analysis of medical facts such as relapses and symptoms. The most significant finding is an extremely low relapse rate of 0.226, or 1 in 5 years. For comparison, one study reports the following relapse rates for other MS therapies: Copaxone - 0.49; Betaseron - 0.55; Avonex - 0.81; Untreated - 1.02 [1]. The more subjective questions, such as symptom relief, are also surprisingly positive. The symptom relief rating ranges from 57-82% positive, by type of MS. These findings are put forth as a compelling indicator that Low Dose Naltrexone deserves clinical research attention, for the treatment of multiple sclerosis. The results showed:

- A very low relapse rate of 0.23, or 1 patient experiencing relapse in 5 years
- 70% of patients reported symptom improvement
- 45% of patients thought that their disease progression has stopped
- 76% of patients reported that LDN is working and they plan to continue using it

In order to understand how significant the low relapse rate reported by the LDN survey is, the following chart compares against relapse rates reported for the 3 primary FDA approved MS treatments[1]. The benchmark is the untreated patient, who typically experiences 1 relapse per year.



The data from this ABC (Avonex, Betaseron, Copaxone) drug study is shown as a benchmark for understanding that my survey participants reported a relapse rate lower than that reported for these MS drugs. I am not trying to draw a conclusive statement about the effectiveness of LDN against other therapies based on this comparison, because the studies were not

done in parallel. For instance, the ABC study was done only for RRMS, while my study includes patients with all types of MS. This could skew the average to a lower relapse rate, since relapses are not a prominent feature for patients in the progressive states of the disease. However, the RRMS subset of my survey was 116 subjects, or 68% of the total, and this group also reported a very low relapse rate of 0.26 per year (see detailed break out by MS type in survey detail).

The subjects in my survey were self-selected, meaning they volunteered to participate rather than being randomly selected, another reason I do not construe this as a scientific study. But it would seem that this sort of positive flag from a sizeable group makes a good epidemiologic argument that larger human trials are warranted to establish the effectiveness of LDN in treating MS. The length of time the subjects had remained with the treatment is another indication of its effectiveness; the average duration was 8 months, and 24% or 64 of them had been using it for 2 or more years.

Furthermore, as Dr. Agrawal points out, this patient survey is valuable because it indicates that LDN can make a positive difference in a disease like MS for which there are limited effective treatments, especially when the available drugs carry such a high price tag in terms of economic cost, and side effects. It also confirmed, to the 267 patients in the survey group, what we already knew; LDN was helping us.

Survey Population:

- 267 Subjects, avg. 10 yrs diagnosis, 65% female
- Avg. LDN treatment 8 months, 24% 2 years+ of LDN treatment
- 10%, 28 individuals out of 267, reported a total of 42 relapses, 0.2 /yr

Survey Results:

Type of MS

	PPMS	**PRMS**	**RRMS**	**SPMS**	**Total**
	13%	4%	43%	39%	267
Months on LDN (Avg)	10 mo.	13 mo.	7 mo.	9 mo.	8 mo.
Relapse Rate	0.07	0.23	0.26	0.25	0.2
Subjective Assessments:					
Symptom Improvement	53%	75%	82%	57%	70%
Progression Halt	50%	58%	34%	43%	45%
LDN Helpful, Will Continue	76%	83%	75%	70%	76%

Naltrexone is an FDA-approved drug. LDN is an off-label use of naltrexone in a low dosage. It does requires a prescription from a doctor.

[1] A prospective, open-label treatment trial to compare the effect of IFNbeta-1a (Avonex), IFNbeta-1b (Betaseron), and glatiramer acetate (Copaxone) on the relapse rate in relapsing--remitting multiple sclerosis: results after 18 months of therapy. PMID: 11795454

Overall Analysis of 267 Responses to the LDN Survey: Duration of Treatment and Relapse Rate as of 7/12/2004

Months of LDN	Subjects		Yrs Of LDN	Yrs Avg	Relapses On LDN	Relapse Rate / Yr	Years Diagnosed
0-3 Mo	133	50%	17.82	0.13	3	0.168	1150.35
4-6 Mo	45	17%	18.50	0.41	7	0.378	467.05
7-11 Mo	25	9%	17.25	0.69	3	0.174	227.50
> 12 Mo	64	24%	131.92	2.06	29	0.220	806.25
Total	267		185.49	0.69	42	0.226	2651.15

Breakdown by Type of MS: Duration of LDN Treatment and Relapse Rate

Months of LDN	Subjects		Yrs Of LDN	Relapses On LDN	Relapse Rate / Yr	Years Diagnosed
0-3 Mo	15	44%	2.61	1	0.383	139.50
4-6 Mo	4	12%	1.58	0	0.000	63.00
7-11 Mo	7	21%	4.92	0	0.000	112.50
> 12 Mo	8	24%	18.58	1	0.054	76.00
Total (PPMS)	34		27.69	2	0.072	391.00
0-3 Mo	5	42%	0.58	0	0.000	44.00
4-6 Mo	2	17%	0.75	0	0.000	13.00
7-11 Mo	1	8%	0.67	1	1.500	9.00
> 12 Mo	4	33%	11.00	2	0.182	64.00
Total (PRMS)	12		13.00	3	0.231	130.00
0-3 Mo	63	54%	7.60	1	0.132	391.85
4-6 Mo	17	15%	6.71	4	0.596	120.05
7-11 Mo	11	9%	7.58	1	0.132	65.50
> 12 Mo	25	22%	46.25	12	0.259	228.75
Total **(RRMS)**	116		68.15	18	0.264	806.15
0-3 Mo	50	48%	7.03	1	0.142	575.00
4-6 Mo	22	21%	9.46	3	0.317	271.00
7-11 Mo	6	6%	4.08	1	0.245	40.50
> 12 Mo	27	26%	56.08	14	0.250	437.50
Total (SPMS)	105		76.65	19	0.248	1324.00
Total	267		185.49	42	0.226	2651.15

Source: LDNers.org

Primary Progressive (PPMS)

Female	17
Male	17

Have Symptoms Improved After LDN?			What about disease progression?			Is LDN working for you?		
Symptoms have improved	18	53%	I think progression has stopped	17	50%	Yes, it is helping and will continue	26	76%
Symptoms have stayed the same	14	41%	I think progression has worsened	4	12%	Not sure at this time	5	15%
Symptoms are worse	2	6%	Too soon to tell	13	38%	No, I don't think it is helping	3	9%
Total (PPMS)	34		Total (PPMS)	34		Total (PPMS)	34	

	Months on LDN	Relapses since starting LDN	.072 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	332.30	2.00			391.00
Avg	9.77	0.06		3.88	11.50
Min	0.30	0.00		3.00	1.00
Max	43.00	1.00		6.00	27.00

Primary Progressive (PPMS) Total: 34 Percent of total responses 12.73%

Progressive Relapsing (PRMS)

Female	9
Male	3

Have Symptoms Improved After LDN?			What about disease progression?			Is LDN working for you?		
Symptoms have improved	9	75%	I think progression has stopped	7	58%	Yes, it is helping and will continue	10	83%
Symptoms have stayed the same	2	17%	I think progression has worsened	1	8%	Not sure at this time	1	8%
Symptoms are worse	1	8%	Too soon to tell	4	33%	No, I don't think it is helping	1	8%
Total (PRMS)	12		Total (PRMS)	12		Total (PRMS)	12	

	Months on LDN	Relapses since starting LDN	.231 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	156.00	3.00			130.00
Avg	13.00	0.25		4.33	10.83
Min	1.00	0.00		3.00	1.00
Max	48.00	1.00		4.50	21.00

Progressive Relapsing(PRMS) Total: 12 Percent of total responses 4.49%

Breakdown by Type of MS: LDN Patient's Subjective Symptom Observations as of 7/12/2004

Relapsing/Remitting (RRMS)

Female	75
Male	41

Have Symptoms Improved After LDN?			What about disease progression?			Is LDN working for you?		
Symptoms have improved	95	82%	I think progression has stopped	40	34%	Yes, it is helping and will continue	87	75%
Symptoms have stayed the same	17	15%	I think progression has worsened	4	3%	Not sure at this time	27	23%
Symptoms are worse	4	3%	Too soon to tell	72	62%	No, I don't think it is helping	2	2%
Total (RRMS)	116		Total (RRMS)	116		Total (RRMS)	116	

	Months on LDN	Relapses since starting LDN	.264 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	817.75	18.00			806.15
Avg	7.05	0.16		4.05	6.95
Min	0.00	0.00		2.00	0.25
Max	48.00	5.00		30.00	28.00

Relapsing/Remitting (RRMS) Total: 116 Percent of total responses 43.45%

Secondary Progressive (SPMS)

Female	73
Male	32

Have Symptoms Improved After LDN?			What about disease progression?			Is LDN working for you?		
Symptoms have improved	60	57%	I think progression has stopped	45	43%	Yes, it is helping and will continue	73	70%
Symptoms have stayed the same	34	32%	I think progression has worsened	11	10%	Not sure at this time	24	23%
Symptoms are worse	11	10%	Too soon to tell	49	47%	No, I don't think it is helping	8	8%
Total (SPMS)	105		Total (SPMS)	105		Total (SPMS)	105	

	Months on LDN	Relapses since starting LDN	.248 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	919.80	19.00			1324.00
Avg	8.76	0.18		3.73	12.61
Min	0.00	0.00		1.50	1.00
Max	54.00	4.00		6.00	35.00

Secondary Progressive (SPMS) Total: 105 Percent of total responses 39.33%

	Months on LDN	Relapses since starting	Mg Dosage LDN	# Years Diagnosed
Grand Total	**2225.85**	**42.00**		**2651.15**

Notes: 28 individual users out of 267 reported a total of 42 relapses.

Source: LDNers.org