To the Editor, In Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease) motor neurons die, leaving the patient progressively unable to move, speak, eat, or breathe. A small clinical trial indicated that lithium combined with riluzole slowed ALS progression[1]. A number of patients began taking lithium, and the patient community and PatientsLikeMe website organized to quantitatively track the progression of these patients using online tools. A focus of the effort was making data and graphs publically available in real time. We found that lithium does not slow ALS progression but does produce side effects in about 49% of patients, with severe side effects in 12%.

Patients took lithium under a doctor's supervision and were asked to report their ALS Functional Rating Score - Revised, or ALSFRS-R[2] monthly for six months. 60% of the patients opted to take lithium and riluzole, while 40% took only lithium. Of the 191 patients who started the study, 71 stopped taking lithium because of side effects or faster progression. Of the patients remaining on lithium 110 were still reporting data at 3 months and 50 at 6 months. 37 of the patients who stopped lithium reported scores at six months. 63 patients from the PatientsLikeMe data base who did not take lithium were used as controls. The study and control populations were very similar (mean ages differed by only 0.2 years, mean loss rate of ALSFRS-R by 7%). The study group had more men (82% vs 59%), but no difference in progression rates was seen as a function of gender in either group.

At least 7 patients passed away and at least 3 went on ventilators. Patients who remained on lithium progressed at the same rate as controls (Figure 1). Patients who stopped lithium reported a faster progression, indicating that lithium may have worsened their disease prompting the discontinuation. No difference in progression was seen as a function of lithium blood level, initial ALSFRS-R score, or riluzole usage. Common side effects included weakness, increased urination, increased fasciculations, headache, fatigue, and nausea. 16 patients reported positive effects of relief from severe cramping, fasciculations, spasticity, and depression.

A study of this nature would be expected to have positive bias as sicker patients are less likely to continue reporting and there is no placebo control. Thus the finding of a negative result is compelling.

More details and data are available at http://alslithium.atspace.com .

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References

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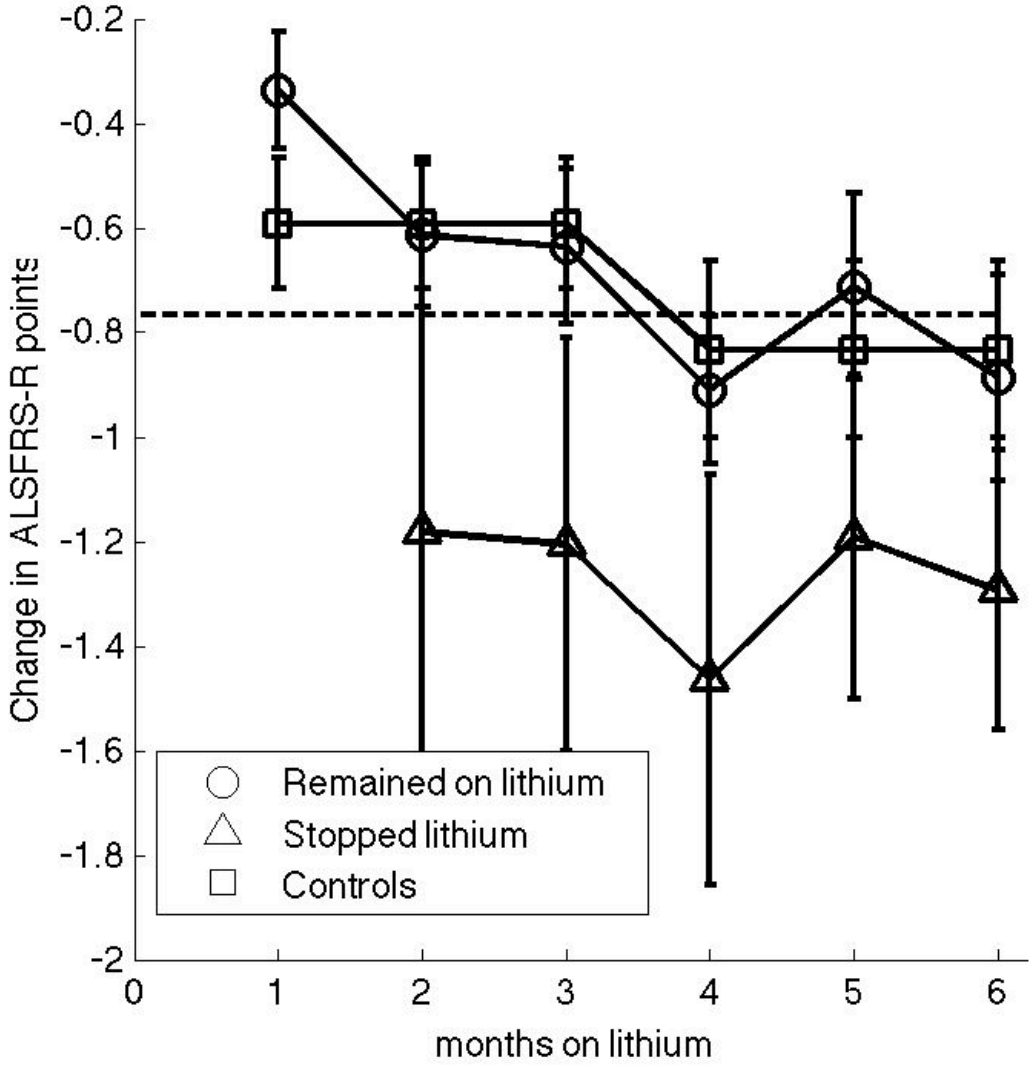

Figure 1: Average loss in ALSFRS-R points each month for patients remaining on lithium, patients who had stopped lithium, and controls. Error bars give one standard deviation. Linear interpolation was used for months in which a patient failed to report data. Patients on lithium were queried for data every month; control patients self reported data typically every 2 – 4 months. The dashed line gives the average monthly ALSFRS-R point loss from diagnosis to the beginning of the trial for the whole group.