INTRODUCTION

Amputees suffer commonly from chronic phantom limb pain, but conventional medical treatment has not been very effective in treating it. Thus, many amputees have turned to innovative, adjunctive therapy, such as Farabloc, to treat their phantom limb pain. Farabloc cloth is a noninvasive therapy, consisting of metallic fibers, that can be woven into a nylon fabric and be made into limb covers. There is preliminary data supporting the efficacy of Farabloc as an adjunctive therapy for chronic phantom limb pain. However, the prior study was limited by a small sample and short intervention time. We conducted a larger pilot study to assess the efficacy of Farabloc for treating chronic phantom limb pain in a veteran amputee population.

METHOD

We randomized 57 subjects into two groups: sham Farabloc (n=27) and true Farabloc (n=30). Our primary outcome measure was the numerical pain rating scale of phantom limb pain level (0-10). Our secondary outcome measures included overall pain level (0-10), frequency of phantom limb pain episodes/week, and the Veterans RAND 12-Item Health Survey (VR-12). The VR-12 is used to measure health-related quality of life for veteran amputees and has extensively evaluated in the veteran population. We collected data at baseline, 6-week, and 12-week follow-up. We used Student’s t-test to calculate statistical significance of improvement in pain between the true and sham Farabloc groups.

RESULTS

The demographic and clinical characteristics of the sham and true Farabloc were not significantly different. The mean age for the sham Farabloc group was 67 and the mean age for the true Farabloc was 62. Sixty-eight percent of subjects in the sham Farabloc group (versus 74% in the true Farabloc group) reported cause of amputation as diabetes and peripheral vascular disease, 28% (vs. 15%) reported trauma, and 4% (vs. 11%) reported other causes. Sixty percent of amputees in the sham Farabloc had below the knee amputation and 40% had above the knee amputation. Fifty-two percent of the true Farabloc had above the knee amputation and 48% had below the knee amputation. Both sham and true Farabloc groups had similar levels of phantom limb pain at baseline (6.5 and 5.9, respectively). The sham Farabloc group had average phantom limb pain levels of 6.5 at baseline, 4.3 at 6-week, and 4.2 at 12-week follow-up. The true Farabloc group had average phantom limb pain levels of 5.9 at baseline, 4.5 at 6-week, and 3.9 at 12-week follow-up. Phantom limb pain did not differ significantly between the two groups at 6 weeks (mean difference, +0.8, p=0.78) or at 12 weeks (mean difference between true and sham Farabloc, +0.3, p=0.38) using the Student’s t-test. In addition, overall pain level (mean difference, -1.4, p =0.22) and phantom limb pain episodes/week
(mean difference, +1.6, p =0.06) did not differ between the two groups at 12 weeks. We are unable to report the results of Farabloc’s impact on VR-12 because it is still under analysis.

**DISCUSSION**

Our study randomized 57 participants into sham and true Farabloc groups. There were no significant differences between the two groups in phantom limb pain, phantom limb pain episodes, and overall pain at follow-up. Our study was designed to have 80% power to detect a mean difference of -1.72 in phantom limb pain level (0.74 estimated effect size), which was based on a prior study. However, our observed effect size was much smaller than the estimated effect size, which might have decreased our power to find significant difference between the sham and true Farabloc groups.

**CONCLUSION**

True Farabloc did not significantly decrease phantom limb pain levels, overall pain levels, and frequency of phantom limb pain episodes/week compared with sham Farabloc in our veteran amputee sample. Farabloc does not appear to be an efficacious, adjunctive therapy for chronic phantom limb pain in veteran amputees.