

Restless Leg Survey Summary

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Introduction

Restless legs syndrome (RLS) is a neurological disorder characterized by unpleasant sensations in the legs and an uncontrollable urge to move when at rest in an effort to relieve these feelings. Symptoms usually occur in the legs between the knee and ankle; however, the thighs, arms and hands can also be affected. RLS occurs in both genders, although the incidence may be slightly higher in women. The syndrome may begin at any age, even as early as infancy, but most patients who are severely affected are middle-aged or older. In addition, the severity of the disorder appears to increase with age. Older patients experience symptoms more frequently and for longer periods of time. Most people find the symptoms to be less noticeable during the day and more pronounced in the evening or at night, especially during the onset of sleep. For many people, the symptoms disappear by early morning, allowing for more refreshing sleep at that time. Other triggering situations are periods of inactivity such as long car trips, sitting in a movie theatre, long-distance flights, immobilization in a cast, or relaxation exercises. The symptoms of RLS vary in severity and duration from person to person. Mild RLS occurs episodically, with only mild disruption of sleep onset, and causes little distress. In moderately severe cases, symptoms occur only once or twice a week but result in significant delay of sleep onset, with some disruption of daytime function. In severe cases of RLS, the symptoms occur more than twice a week and result in burdensome interruption of sleep and impairment of daytime function.

In most cases, the cause of RLS is unknown (referred to as idiopathic). A family history of the condition is seen in approximately 50 percent of such cases, suggesting a genetic form of the disorder. People with familial RLS tend to be younger when symptoms start and have a slower progression of the condition.

A diagnosis of RLS is normally given when the following 4 main symptoms are present:

- tingling, numbness,
- pain and/or a deep ache in the limbs,
- symptoms worsen with inactivity, symptoms worsen at night,
- sometimes causing sleep problems, and restlessness is eased when the limb is moved.

Despite efforts to establish standard criteria, the clinical diagnosis of RLS is difficult to make. Physicians must rely largely on patients' descriptions of symptoms and information from their medical history, including past medical problems, family history, and current medications.

Prevalence in the general UK population is between 3% and 9% (Trenkwalder C et al, 2005). This represents an estimated 2 to 5.5 million sufferers of restless leg syndrome in the UK. There are an estimated 12 million sufferers in the USA (National Institute of Neurological Disorders Website, www.ninds.nih.gov/disorders/restless_legs/detail_restless_legs.htm).

The syndrome is difficult to treat and the level of relief and consistency of effect with existing treatments is generally very variable. Furthermore, no one drug is effective for everyone with RLS. What may be helpful to one individual may actually worsen

symptoms for another. In addition, medications taken regularly may lose their effect, making it necessary to change medications periodically. The new drug, Mirapexin, has been approved for use by the European Medicines Agency to treat moderate or severe cases. There are currently no other medications licensed for the treatment of RLS in the UK. Experts believe that only around 500,000 of the estimated 4m sufferers in the UK were likely to benefit from the drug (Dr Chaudhuri, consultant neurologist and head of the National RLS Clinic at King's College Hospital, London <http://news.bbc.co.uk/1/hi/health/4969870.stm>).

RLS leads to significant negative effect on quality of life (Abetz L et al, 2004).

Methods

The *LegCare* wrap contains four powerful neodymium magnets (2000gauss). Each magnet has patented and unique directional plates that allow the negative (south-facing) enhanced magnetic field to be absorbed deeper into the tissues; it is thought that this gives more effective and longer lasting effect. The wraps are fitted below the knee and above the calf muscle (not under compression) and are held in place by “hook and loop” fastening tape. The leg wraps are double lined for comfort, and are adjustable and washable (available in 3 standard sizes). The product is registered as a Class 1 Medical Device. A similar device 4UlcerCare has been found to expedite healing (Eccles & Holinworth, 2005) of chronic leg ulcers and also to prevent their recurrence (Eccles, 2006).

459 subjects diagnosed with Restless Leg Syndrome responded to an advert placed in the *Daily Mail* newspaper offering a free trial of the static magnetic legwrap device called LegCare. No exclusions were made but they had to have had a diagnosis of RLS according to the criteria above. Subjects were asked to complete a questionnaire that requested them to report the duration of symptoms and to rate their symptoms (on a scale of 0-10 (where 1 represented mild symptoms and 9-10 more severe symptoms); prior to and after one month of using the device. Symptoms rated were: level of pain, tingling, sleep disturbance, quality of life as well as overall symptoms. They were also asked questions about their experience with other treatments, both conventional and non-conventional that they had tried previously. Patients were instructed to wear the device 24 hours a day (except during bathing) for the duration of the one month. Two devices were supplied for subjects to wear on both legs.

Results

The mean age of respondents was 64.8 ± 0.53 SE. 310 subjects (68%) were female and 148 (32%) were male.

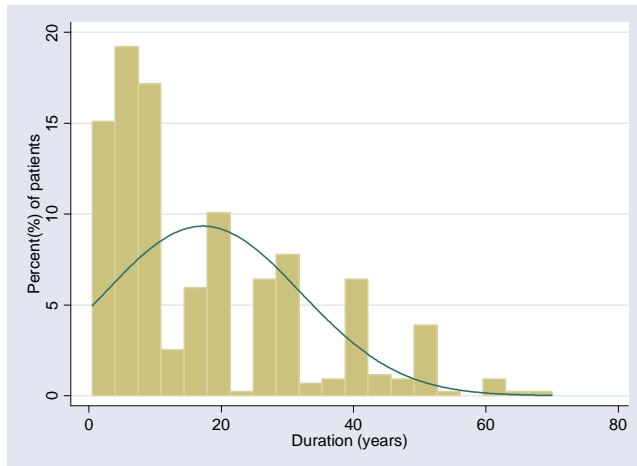


Fig 1. Duration of Symptoms

Median duration of symptoms was 10 years (5 -25 inter quartile ranges, IQR).

193 subjects (58%) had tried some form of drug treatment. Commonest treatments were quinine (25 subjects), amitriptyline (17 subjects), co-codamol/co-proxamol (8 subjects), ropinirole (5 subjects).

Fig 2 shows the distribution of the % relief obtained with drugs for this condition.

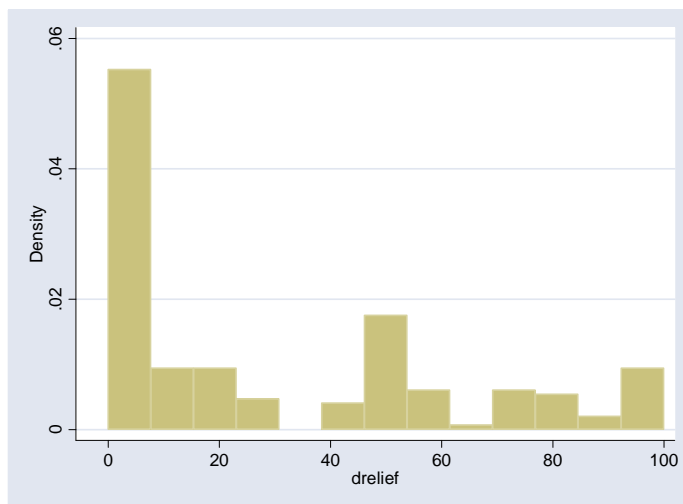


Fig 2. Relief obtained of symptoms with drug treatments.

Median level of relief of symptoms was 20% (0-50 IQR)

145 subjects (32%) had tried some form of non-drug treatment. These were most commonly magnesium (24 subjects), massage with creams or gels (22 subjects), acupuncture (10 subjects), herbal remedies (15 subjects). Median level of relief of symptoms was 10% (0- 35%, quartile ranges).

Results with LegCare

Fig 3- 7 shows the results graphically (as box plots) before and after one month exposure to LegCare.

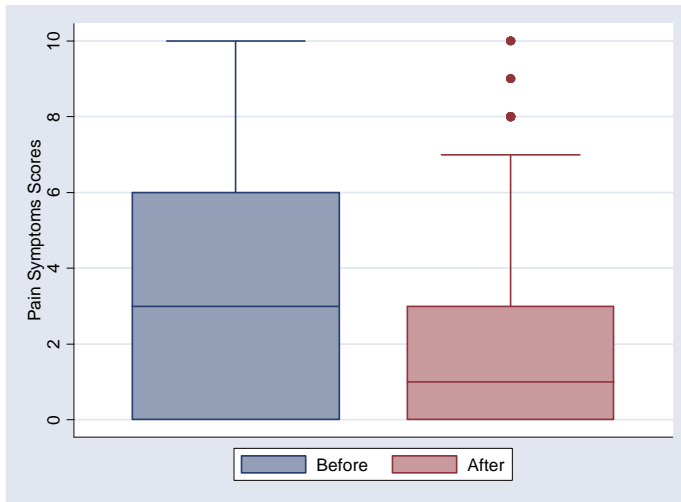


Fig 3. Pain symptoms before and after LegCare

Median pain scores before treatment were 3 (IQR 0-6) and 1 (IQR 0-3) after LegCare. The median score of pain after LegCare is statistically significantly lower ($p < 10^{-5}$, Wilcoxon signed-rank test).

This data suggests between 50 and 75% relief of pain symptoms.



Fig 4. Symptom of Tingling before and after LegCare

Shows the tingling symptom scores before (median 5, IQR 1-7) and after LegCare (median 2, IQR 0-4). The median score of tingling after LegCare is statistically significantly lower ($p < 10^{-5}$, Wilcoxon signed-rank test).

This data suggests 60% relief of symptoms.



Fig 5. Sleep disturbance before and after LegCare

Shows sleep disturbance scores before (median 8, IQR 6-10) and after LegCare (median 4, IQR 2-7).

The median score of sleep disturbance after LegCare is statistically significantly lower ($p < 10^{-5}$, Wilcoxon signed-rank test).

This data suggests 50% less sleep disturbance.



Fig 6. Quality of Life scores before and after LegCare (A higher score indicates a greater disturbance of quality of Life)

QOL scores before (median 6, IQR 5-9) and after LegCare (median 4, IQR 2-6).

The median score of QOL after LegCare is statistically significantly lower ($p < 10^{-5}$, Wilcoxon signed-rank test), indicating an improvement in QOL



Fig 7. Overall Symptom scores before and after LegCare

Overall RLS scores before (median 8, IQR 6-9) and after LegCare (median 4, IQR 2-6).

The median symptom score after LegCare is statistically significantly lower ($p < 10^{-5}$, Wilcoxon signed-rank test).

This data suggests an overall 50% reduction in symptoms.

At the outset, 85.4% of patients had overall symptom scores of greater than 5 (on a 10-point scale). The proportion of patients having symptoms at this level was reduced to 30.9% after 1 month of wearing LegCare. Thus almost two-thirds of subjects were removed from the greater symptom bracket after LegCare treatment.

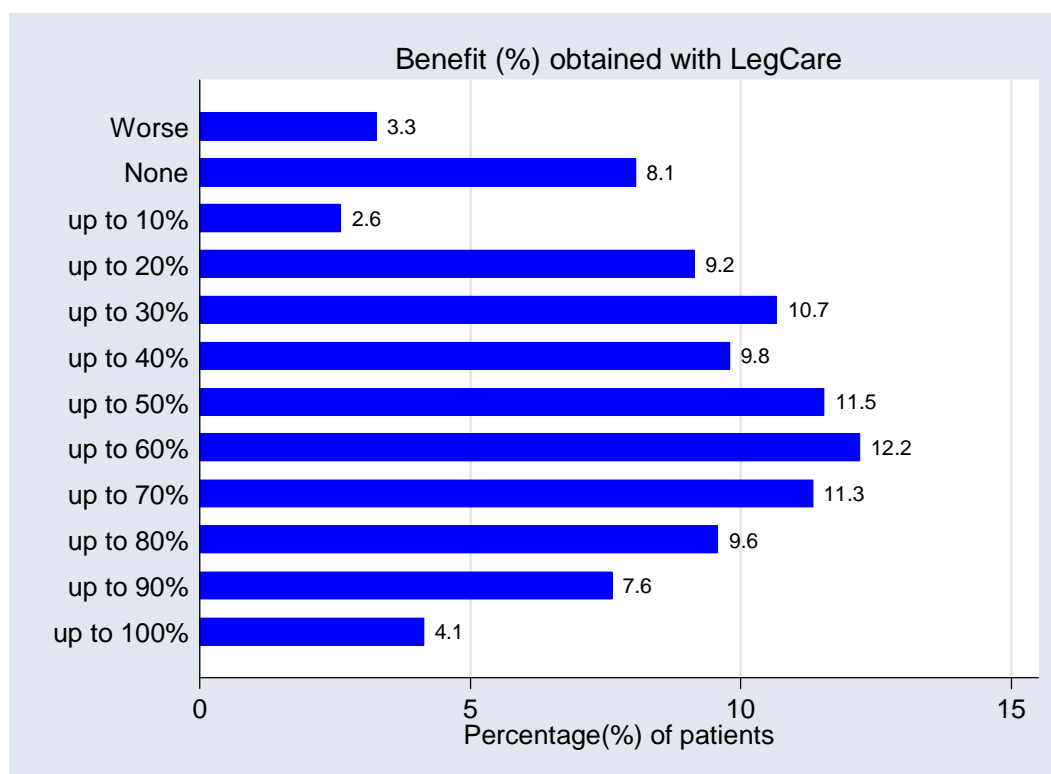
Comparison of LegCare effectiveness in relieving symptoms against drug and other non-drug treatments

The median relief obtained with drug treatments (about 20% reduction of symptoms), for those that tried drug treatments ($n=193$), was statistically significantly less compared with the median reduction in symptoms with the LegCare ($p < 10^{-4}$).

The median relief obtained with other non-drug treatments (about 10% reduction of symptoms), for those that tried non-drug treatments ($n=145$), was statistically significantly less when compared with the median reduction in symptoms with the LegCare ($p < 10^{-4}$).

Fig 8. Percentage relief of RLS symptoms obtained with LegCare

77.8 % had greater than 20% improvement, 66.1% had greater than 30% improvement and 45% had greater than 50% improvement in symptoms.



Conclusions

The median age of subjects surveyed was 64.8 ± 0.53 SE and median duration of symptoms was 10 years. It is likely that this cohort represented people with chronic and perhaps more severe symptoms, given the general age of the group. It is also more likely that this group would respond to a Press advert offering the possibility of “new help” with the syndrome.

There was a statistically significant reduction ($p < 10^{-5}$ for all symptoms) in all the symptoms associated with RLS (pain, tingling, loss of sleep) after wearing LegCare with overall symptoms being reduced by 50% ($p < 10^{-5}$). This was statistically significantly better than the amount of relief that these subjects had obtained with drugs (20%, $p < 10^{-4}$) and other non-drug treatments (10%, $p < 10^{-4}$). 66.1% of subjects had greater than 30% improvement and 45% had greater than 50% improvement in symptoms.

Moreover, a statistically significant improvement in quality of life was also reported.

The study was conducted for one month so it is not known how this effect may vary or whether it persists with long-term use of the device. This study was designed as a consumer survey and we accept that a controlled trial will be required to analyse the effects of the LegCare device in the treatment of RLS more rigorously. However, the size of the effects reported in this survey should generate interest in this novel non-invasive method for treating this difficult syndrome.

References

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