A clear definition of nocturnal leg cramps is essential for comparability of research

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Appraisal

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Prophylactic stretching is unlikely to prevent nocturnal leg cramps

In order to reduce the frequency of nocturnal leg cramps, leg stretching before sleep is commonly recommended. A little over a year ago in this journal, Hallegraeff et al[1] authored the first randomised controlled trial to support this practice – demonstrating 1.2 fewer cramps per night and less-severe cramp pain in the stretching group, compared to those receiving no treatment. Missing from the analysis of this trial, however, was an explanation of why (despite similar recruitment methods and similar inclusion/exclusion criteria) the cramp rate in the control group differed so dramatically from what had been observed in other randomised trials. Cochrane systematic reviews of both quinine (13 trials with 952 subjects) and magnesium (4 trials with 213 subjects) for the prophylaxis of rest cramps show mean cramp rates in placebo controls of 4.4 and 4.35 cramps/week.[2,3] In contrast, the control group cramp rate in the trial by Hallegraeff et al was 16.8 cramps/week (2.4 cramps/night) – a cramp rate that is nearly fourfold higher. Is the population from which these subjects were derived unique? Were there extreme outliers skewing the distribution? Can we be confident of the diagnosis?

An additional problem in interpreting the results of the trial by Hallegraeff et al[1] is the comparison of an intervention group to unblinded controls who were offered no treatment. This is problematic because there is potential subjectivity in the reporting of cramps. For example, is a brief cramp worth reporting? Was a long cramp episode really one single cramp, or multiple individual cramps occurring in close succession? Given that the subjects in this trial were unblinded and can be assumed to have had different expectations of potential benefit (an intervention versus no treatment), might those expectations have influenced the reporting of cramps?

The only other randomised controlled trial that has evaluated prophylactic stretch is by Coppin et al,[4] in which 191 quinine users used either bedtime stretch or control (ie, leg movements that did not stretch leg muscles). This trial didn't find a trend to benefit. This lack of benefit is consistent with a recent survey in which cramp sufferers were asked to rate the effectiveness of any therapies they had tried.[5] Of the 21 patients who tried prophylactic stretching, the vast majority (n = 18) found it to be 'useless' or 'a little help' and only three found it to be 'quite helpful' or 'very helpful'. This compares to the 18 users of quinine, the vast majority of whom (n = 16) found it to be 'quite helpful', 'very helpful' or '100% effective', with only two subjects reporting it to be 'useless' or 'a little help'. While it was reported that the stretching technique of some patients was clearly inappropriate (eg, plantarflexing the foot), there were still very few people who rated prophylactic stretching as an effective therapy.

The only randomised trial to compare prophylactic stretching with a sham intervention in a typical population of crampers remains with Coppin.[4] Given that Coppin found no trend to benefit, and given the vast majority of surveyed crampers who have tried prophylactic stretching report it to be ineffective, I believe that the current body of evidence does not support bedtime stretching for the prophylaxis of nocturnal leg cramps.

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In 2012, our randomised trial demonstrated that stretching before sleep reduces the frequency and severity of nocturnal leg cramps in older adults.[1] These episodic cramp attacks are characteristic: painful, sustained, involuntary muscle contractions of the calf muscles, hamstrings or feet. The sharp and intense pain may last from seconds to several minutes, accompanied by firm and tender muscles, and in some cases, with plantar flexion of feet and toes.[2–5] In his letter, Garrison argues that prophylactic stretching is unlikely to prevent nocturnal leg cramps.

Garrison's first point is that the frequency of nocturnal leg cramps in our trial was higher than would be anticipated from the data from the study populations in two recent Cochrane reviews of medications for cramps.[6,7] The participants in our study were a homogeneous group of adults aged over 55 years with regular episodes of nocturnal leg cramps occurring at least once per week. We excluded people who were using quinine or medication to assist sleep, or who had orthopaedic problems, severe medical conditions, or comorbidities known to cause muscular spasms or cramps. The homogeneity of our study cohort is important, because, for example, nocturnal leg cramps are more prevalent in older adults[6,8] and medications can affect the frequency of cramps.[6] The two Cochrane reviews,[6,7] however, include data from participants of any age with 'idiopathic', 'rest' or 'pregnancy-associated' cramps, with no clear eligibility criteria being applied that are diagnostic of nocturnal leg cramps. This permits a heterogeneous population with different types of muscular cramps, affecting any body part, from any cause, in any setting and at any time of day. Also, these cramps were measured at weekly intervals and cramp diaries were not commonly used, so recall bias may have caused underestimation of the true frequency. Finally, quinine users were excluded from our study and most participants in our study had tried quinine without success,

suggesting intractable cramps; so a high cramp frequency might be expected. In summary, although baseline cramp frequency differs between our trial and the two Cochrane reviews, this is reasonable due to the non-comparability of the participants and the ways in which cramp was measured.

Garrison's second point is that the lack of blinding may have led to biased reporting, especially because subjectivity may have allowed a run of cramps to have been reported as either multiple individual cramps or a single cramp episode. Unfortunately, neither blinding of the stretch intervention, nor objective measurement of cramps was feasible. However, all other criteria for methodological rigour were achieved (eg, concealed allocation, no loss to follow-up). To minimise the potential for knowledge of group assignment to influence the participants' expectations, participants were instructed individually to avoid contact with each other so as not to contaminate information.

Garrison also compares our results to those of the trial by Coppin et al,[9] which did not find even a trend to benefit from stretching for nocturnal leg cramps. We note, however, several important differences in the stretch intervention. In the Coppin trial, nurses provided the stretch technique, the time of day at which the stretch was performed is not described, and the actual stretch technique is not defined well enough to know whether only the calf was stretched or whether other muscle groups were also stretched. Furthermore, it remains unclear how the stretching technique was monitored during the study. In this context, Garrison discusses the qualitative data analysis of Blyton et al,[10] describing a heterogeneous group of cramp sufferers with no benefit from any current treatment option including stretching. In our opinion this arises by absence of a clear definition. We agree with the Blyton study that cramp sufferers attempt to relieve pain by doing the opposite of what is needed; they contract their muscles rather than stretch them. In addition, we want to reinforce that hamstrings, and often the whole leg, are involved in nocturnal leg cramps, so we still recommend stretching both calf and hamstring muscles.[1,10]

Finally, we emphasise the application of the Classification of Diseases (ICD-9), code 327.52 and the development of a diagnostic instrument for diagnosing nocturnal leg cramps for use by general practioners and physiotherapists.[5] Besides, treatment of nocturnal leg cramps should not be restricted to the calf muscles alone because the whole leg must be assessed, in particular the hamstrings.

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