review of nondrug therapies for lower limb muscle cramps,[3] in which 1 randomized controlled trial of calf stretching for nocturnal cramps in adults taking quinine was included. Since the publication of our systematic review, an additional randomized controlled trial has been published.[4] This well-designed and reported trial evaluated calf and hamstring stretching before sleep vs no intervention for nocturnal leg cramps in 80 people older than 55 years. After 6 weeks, the mean difference in change of cramp frequency between groups was −1.2 (95% CI, −0.6 to −1.8) cramps per night in favor of the stretching group. This difference represents a 35% reduction in cramp frequency from baseline with stretching. As calf and hamstring stretching were combined, it is not possible to extricate the effect of calf stretching alone for nocturnal cramps. Nevertheless, this study makes an important contribution to the evidence base for stretching prophylaxis for nocturnal cramps and will be included in an update of our Cochrane review.

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1. Daniell HW. Calf stretching prophylaxis for nocturnal cramps [letter]. *Arch Intern Med*. 2012;172(12):970.
2. Garrison SR. Calf stretching prophylaxis for nocturnal cramps [reply]. *Arch Intern Med*. 2012;172(12):971.
3. Blyton F, Chuter V, Walter KE, Burns J. Non-drug therapies for lower limb muscle cramps. *Cochrane Database Syst Rev*. 2012;1:CD008496.
4. Hallegraeff JM, van der Schans CP, de Ruiter R, de Greef MH. Stretching before sleep reduces the frequency and severity of nocturnal leg cramps in older adults: a randomised trial. *J Physiother*. 2012;58(1):17-22.

Should Health Care Systems and Health Care Providers Implement a New Pathway for Hospitalized Patients With Community-Acquired Pneumonia?

We read with interest the study recently published by Carratalà and coworkers.[1] The authors developed a 3-step critical pathway to reduce duration of intravenous antibiotic therapy and length of stay (LOS) of hospitalized patients with community-acquired pneumonia (CAP). The median duration of LOS was 3.9 days and 6.0 days in the interventional and usual care group, respectively. The authors found no significant differences between the 2 study groups in terms of 30-day mortality, and they concluded that this pathway is effective and safe to use. In his commentary, Sharpe[2] called for a rapid implementation of this strategy. However, some remarks should be pointed out in this regard.

Length of stay was used as the primary end point in the sample size calculation. The authors estimated a total sample size of 380 patients to achieve 82% power at a 5% significant level to detect a 1.5-day difference in LOS between the study groups. The 30-day death due to any cause was reported as a secondary end point. Secondary end points are not conclusive, and they should not be used to modify clinical practice. Further trials are needed to assess the safety of this pathway. Considering a mortality rate in the control group of 0.14, an α value of .05, and a β value of .20, the number of patients needed in each study arm to show significant differences of 25% and 50% is 1360 and 291, respectively.[3]

If health care costs for patients with CAP are relevant and interventions to increase the efficiency of patients' care are desirable, aggressive programs to shorten LOS may introduce unnecessary risks for the patient. Policies to save health care resources should take into consideration in-hospital costs as well as costs related to the occurrence of adverse outcomes after discharge.

Finally, the generalizability of the results of this study is affected by some important exclusion criteria, such as intensive care unit admission from the emergency department, imminent death, shock, complicated pleural effusion, pregnancy, aspiration pneumonia, and severe social problems. Because previous studies documented high rates of clinical failure and intensive care unit admissions during the first days of hospitalization, the results of the study of Carratalà et al[1] should not be generalized to patients with severe CAP.[4]

In conclusion, the study published by Carratalà and coworkers[1] should be an impetus to design clinical trials focused on evaluating the safety and the external validity of this new algorithm.

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1. Carratalà J, Garcia-Vidal C, Ortega L, et al. Effect of a 3-step critical pathway to reduce duration of intravenous antibiotic therapy and length of stay in community-acquired pneumonia: a randomized controlled trial. *Arch Intern Med*. 2012;172(12):922-928.
2. Sharpe BA. Putting a critical pathway into practice: the devil is in the implementation details. *Arch Intern Med*. 2012;172(12):928-929.
3. Garcia-Vidal C, Fernández-Sabé N, Carratalà J, et al. Early mortality in patients with community-acquired pneumonia: causes and risk factors. *Eur Respir J*. 2008;32(3):733-739.
4. Aliberti S, Amir A, Peyrani P, et al. Incidence, etiology, timing, and risk factors for clinical failure in hospitalized patients with community-acquired pneumonia. *Chest*. 2008;134(5):955-962.

In reply

We thank Carugati et al for their interest in our randomized trial.[1] As in other recent controlled trials evaluating strategies aimed to reduce the duration of hospitalization in patients with community-acquired pneumonia (CAP),[2] we selected length of stay as the primary end point. Accordingly, we used length of stay to determine sample size. Carugati et al were concerned that 30-day case-fatality rate was a secondary end point. They stated that secondary end points should not be used to modify clinical practice. However, although mortality is objective and important, most patients with CAP do not die. Because new interventions for CAP are likely to result in only small changes in mortality, large sample sizes are required to detect clinically important changes. Therefore, it has been suggested that mortality is an insensitive measure of quality of care or treatment failure in CAP.[3] In our article,[1] we clearly pointed out that our study was not powered to detect a survival difference. Nevertheless, we found that only 4 of 200 patients (2%) in the 3-step group and 2 of 201 patients (1%) in the usual care group died. Importantly, no patient died during the 30-day follow-up period after discharge. However, it should be noted that patients receiving usual care were more likely to experience adverse drug reactions, mainly phlebitis, probably related to the longer duration of intravenous antibiotic therapy in this group.

We believe that applying the 3-step critical pathway (early mobilization and use of objective criteria for switching to oral antibiotics and for deciding on hospital discharge) to the selected population analyzed is safe and effective and may allow cost savings. In this regard, the most recent Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the management of CAP[4] also recommend that patients should be switched from intravenous to oral therapy when they are hemodynamically stable and improving clinically, and they should be discharged as soon as they are clinically stable, have no other active medical problems, and have a safe environment for continued care. Moreover, inpatient observation while receiving oral therapy is not necessary.[4]

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1. Carratalà J, Garcia-Vidal C, Ortega L, et al. Effect of a 3-step critical pathway to reduce duration of intravenous antibiotic therapy and length of stay in community-acquired pneumonia: a randomized controlled trial. *Arch Intern Med*. 2012;172(12):922-928.
2. Meijvis SCA, Hardeman H, Remmelts HHF, et al. Dexamethasone and length of hospital stay in patients with community-acquired pneumonia: a randomised, double-blind, placebo-controlled trial. *Lancet*. 2011;377(9782):2023-2030.
3. Barlow GD, Lamping DL, Davey PG, Nathwani D. Evaluation of outcomes in community-acquired pneumonia: a guide for patients, physicians, and policy-makers. *Lancet Infect Dis*. 2003;3(8):476-488.
4. Mandell LA, Wunderink RG, Anzueto A, et al; Infectious Diseases Society of America; American Thoracic Society. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. *Clin Infect Dis*. 2007;44(suppl 2):S27-S72.

Acupuncture for Dyspnea on Exertion in Chronic Obstructive Pulmonary Disease: No Blindness

Suzuki et al[1] claim that their placebo-controlled trial of acupuncture clearly demonstrates that this is a useful adjunctive therapy in reducing dyspnea on exertion in patients with chronic obstructive pulmonary disease. They used a design in which a placebo acupuncture group (PAG) received treatment with a Park sham device "with a guide tube mounted on a base adherent to the skin."[1(p879-880)] The authors further describe that "[t]he tips of the placebo needles used for the placebo acupuncture group . . . were blunt and appeared to be penetrating the skin but actually telescoped back into place."[1(p880)] With no blinding of the practitioner, the authors assessed subjects' blindness after the study, letting subjects choose between "real acupuncture," "placebo acupuncture," and "don't know." Of the real acupuncture group (RAG), 25 of 30 subjects reported "don't know." Of the PAG, 26 of 32 subjects did so.

"Blindness" in this regard depends on what "don't know" means: does it mean "I have no clue" or "I am not 100% sure"? In the former case, blindness is very high, while in the latter case, very low. An additional forced choice and/or asking subjects to indicate their degree of doubt would have brought us closer to this vital information.

The authors say that "for the RAG patients, needles . . . were manually rotated clockwise and counterclockwise for 3 to 4 minutes at each point during a 50-minute treatment period" resulting in "[p]erception of *de qi* . . . during insertion and/or manipulation was confirmed at every point in the RAG," while "in PAG . . . no sensation like *de qi* was reported."[1(p880)] They do not say to what degree this was true for each subject or even for each procedure, repeated weekly for 12 weeks. With frequent "sensation of *de qi*," blindness was virtually nonexistent. In addition, up to 10 subjects in the RAG vs 0 in the PAG had subcutaneous hemorrhage or needle site pain, strongly diminishing blindness. A possible explanation for the high number of "don't know" responses may be because subjects said "don't know" because they did not want to be wrong. In addition, because placebo is a subconceptual phenomenon,[2] even subconscious "knowing" may have a substantial influence on outcomes.

Briefly, we see this study as hardly being a single-blind trial. As a result, this is probably another indication of the power of the placebo itself.[3] Because such studies get referred to in the lay press with the terms *blindness*, *placebo controlled*, *clearly demonstrates*, and *acupuncture*—and eventually influencing decision takers—we find the combination of these terms inopportune without there being more effort to ensure and assess blindness.

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