What is the best treatment for plantar fasciitis?

EVIDENCE-BASED ANSWER

Mechanical therapies—such as taping, tension night splinting, and rigid arch support—are the most effective treatment for plantar fasciitis (strength of recommendation: **A,** based on randomized controlled trials). If limited or no improvement is observed after 6 months of mechanical therapy, extracorporeal shock wave therapy (Orthotripsy) is the next treatment of choice (strength of recommendation [SOR]: **A,** based on meta-analysis of randomized controlled trials). When mechanical therapies and extracorporeal shock wave therapy have failed for more than 1 year, surgical treatment may be considered (SOR: **C,** based on a case-series study).

EVIDENCE SUMMARY

In a prospective, observer-blinded study, 103 subjects were randomized to 1 of 3 treatment categories: anti-inflammatory (etodolac plus corticosteroid injections); accommodative (viscoelastic heel cup); or mechanical (low-dye tapping for 1 month followed by rigid custom orthosis for 2 months).[1] After 3 months of treatment, 70% of patients in the mechanical treatment group rated their functional outcome as excellent, compared with only 33% of the anti-inflammatory group and 30% of the accommodative group (P=.005). Additionally, the mechanically treated group was less likely to terminate treatment early because of treatment failure (P<.001).

Several of the same researchers then went a step further to find out which specific mechanical treatment is best. They found no statistically significant difference among treatment with tension night splinting (**Figure 1**), custom rigid orthosis, and over-the-counter arch supports.[2] A retrospective study of 237 subjects also concluded that mechanical treatment is better than anti-inflammatory or accommodative treatments.[3]

Another prospective, observer-blinded study randomized 116 patients to 1 of 2 groups for 3 months.[4] The first group of patients were treated with a nonsteroidal anti-inflammatory drug (piroxicam) and Achilles tendon stretching 3 times a day. The second group received the same treatment but also wore plastic tension night splints in 5° of dorsiflexion. After 3 months, in an intention-to-treat analysis, no statistically significant difference was detected in subjective pain between the 2 groups. In this study, patient compliance with the tension night splinting was poor, and this likely affected the outcome.

From 1993–1995 an observer-blinded randomized controlled trial of 112 patients compared standard with sham extracorporeal shock wave therapy.[5] The main outcome measure was

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What is a Clinical Inquiry?

Clinical Inquiries answer real questions that family physicians submit to the Family Practice Inquiries Network (FPIN), a national, not-for-profit consortium of family practice departments, residency programs, academic health sciences libraries, primary care practice-based research networks, and individuals with particular expertise.

Questions chosen for Clinical Inquiries are those considered most important, according to results of web-based voting by family physicians across the U.S.

Answers are developed by a specific method:

- First, extensive literature searches are conducted by medical librarians.
- Clinicians then review the evidence and write the answers, which are then peer reviewed.
- Finally, a practicing family physician writes a commentary.

patient satisfaction on a 4-step score at 6 months and 5 years. At 6 months, the treatment group had a significantly better 4-step score than the placebo group ($P<.0001$). In fact, 51% of treatment-group patients were pain-free, while none of the 48 placebo-group patients were pain-free. After 5 years, the 4-step score only demonstrated a trend in favor of the treatment group ($P<.071$) because of a high rate of good results from subsequent surgery in the placebo group. Thirteen percent of the treatment-group patients had undergone a heel operation, compared with 58% of placebo-group patients.

A controlled and observer-blinded study of 302 patients with plantar fasciitis compared standard extracorporeal shock wave therapy with sham treatment.[6] The treated patients had significantly lower pain scores (as measured on a visual analog scale) than the placebo group (1.9 vs 4.7). Three months post-treatment, half as many treated patients were taking pain medication when compared with placebo patients. After 1 year of follow-up, 94% of the treatment group patients were still pain-free, with a pain score of <2.

One randomized controlled study of 166 patients found no evidence to support a beneficial effect on pain, function, and quality of life of extracorporeal shock wave therapy over a sham treatment.[7] Of note, this study enrolled patients who had a minimum of 6 weeks of symptoms. All recommendations in the US are to reserve extracorporeal shock wave therapy for patients with more than 6 months of symptoms.

A meta-analysis of 8 published studies involving 840 patients whose condition was not improved after conservative therapy for at least 6 months showed that up to 88% of patients experienced good to excellent outcomes with extracorporeal shock wave therapy and were satisfied with the result. [6]

As for surgical treatment, in a prospective study of 43 patients with 47 painful heels followed for an average of 31 months, only 49% of the patients were satisfied with their outcome.[8] Patient expectations should be considered in preoperative counseling. In contrast to surgery, either open or endoscopic, extracorporeal shock wave therapy does not require the patient avoid weight-bearing or a prolonged time for return to work.

FIGURE 1 **Tension night splinting**

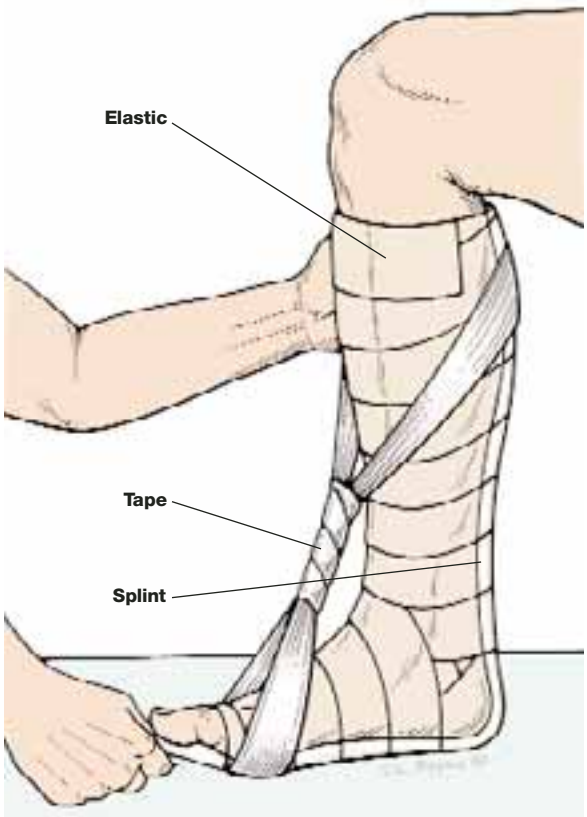

ILLUSTRATION BY CHARLES H. BOYTER

With the knee flexed 90°, secure the splint to the leg with elastic. Remove the splint and moisten, then reapply with the ankle at maximum dorsiflexion. Apply tape in a figure-8 until the fiberglass hardens.

RECOMMENDATIONS FROM OTHERS

Figure 2 has been modified from a clinical practice guideline on the treatment of plantar fasciitis published by the American College of Foot and Ankle Surgeons.[9]

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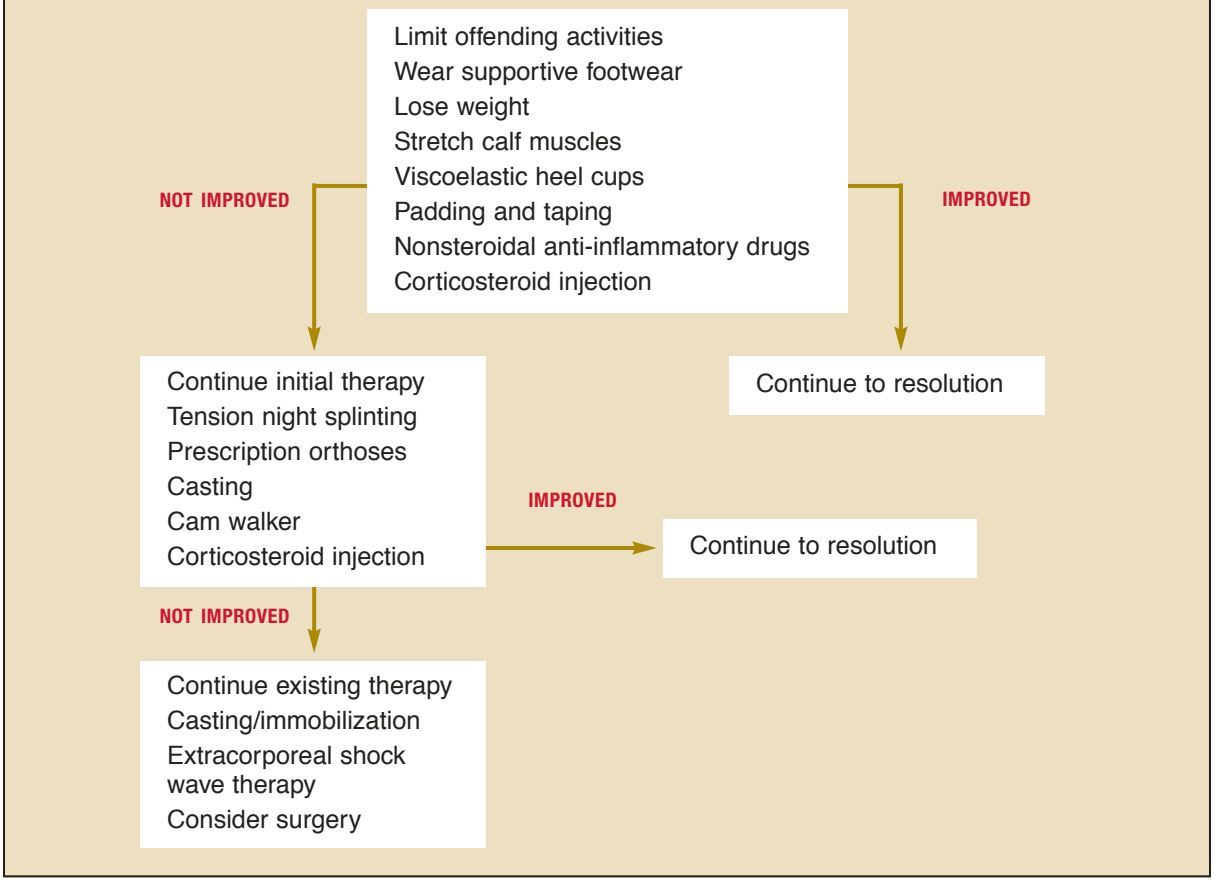
FIGURE 2

Treatment of plantar fasciitis



CLINICAL COMMENTARY

Keys to treatment: Avoid overuse, stabilize, be patient

Plantar fasciitis (heel pain syndrome) is one of the most common disorders of the foot and ankle and is notoriously difficult to treat. Patients are commonly symptomatic for months, leading to frustration, poor compliance, and general dissatisfaction.

From a pathophysiologic perspective, plantar fasciitis is a form of overuse syndrome. When approached in this manner, it makes intuitive (and now scientific) sense that stabilization of the proximal fascial enthesis at the point of its insertion to the calcaneus is the key to clinical resolution of symptoms. Activity modification, mechanical therapy, and patience are the essential elements for treating plantar fasciitis.

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Does physical therapy improve symptoms of fibromyalgia?

EVIDENCE-BASED ANSWER

Physical therapy is minimally effective in the treatment of fibromyalgia, with immediate post-treatment improvement in pain and tender points, and both short- and longer-term improved self-efficacy (confidence in performing tasks) (strength of recommendation [SOR]: **B,** 1 small, high-quality randomized controlled trial, 4 additional small randomized controlled trials).

Multidisciplinary rehabilitation is probably not effective for this disorder but warrants future research, as trial quality is poor (SOR: **B,** systematic review of 4 small or low-quality and 3 additional randomized controlled trials on widespread pain conditions).

EVIDENCE SUMMARY

The goal of physical therapy is to maximize function and reduce impairment to limit disability in patients with musculoskeletal conditions.[1] Based on a British study, physical therapists most commonly use exercise, education about correct posture and functional activity, relaxation, and energy conservation and fatigue management.[2] For this review, physical therapy is defined as a treatment program that includes patient education and supervised exercise.

In the highest-quality trial, Buckelew and colleagues[3] randomized 119 subjects to 1 of 4 groups: biofeedback and relaxation training, exercise training, combination treatment, and an education and attention control program. Individuals were evaluated on measures of pain, function, disease impact, and self-efficacy. Evaluators were blinded to treatment group. Patients were followed for 2 years, and follow-up information was available on 85% of patients.

At immediate postintervention follow-up, all treatment groups were significantly improved on tender-point index score compared with the control group, but this was due to a modest deterioration for the control group rather than improvements in the treatment groups. In addition, all groups showed improvements in self-efficacy for function compared with the control group but not for other self-efficacy measures. While within-group improvements in the treatment groups were seen, no significant differences were seen from the control group.

Another trial randomized 99 patients to 3 groups: education and cognitive behavioral therapy; education, cognitive behavioral therapy and exercise; or a wait-list control group.[4] At the 6-month follow-up, the education group scored significantly higher than the others—but only on self-reported measures of daily functioning and self-efficacy.

In another study, 45 patients with fibromyalgia were randomly assigned to a 6-week program combining exercise and multidisciplinary education or to a control group.[5] The treatment group had significant improvements in walking distance and for 2 measures on the Fibromyalgia Impact Questionnaire (feeling bad and morning fatigue). Keel and colleagues[6] found no immediate treatment benefit following 15 weeks of education, cognitive behavioral therapy, and exercise vs relaxation training in their small randomized controlled trial.[6]

In contrast, another study reported significant and immediate improvements in 2 groups—exercise and education; exercise, education, and

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cognitive behavioral therapy—when compared with control patients on self-reported symptoms and knowledge.[7] The exercise and education group was also better than the control patients in self-reported daily functioning.

We identified 2 additional trials examining different types of physical therapy for fibromyalgia that did not include control groups. In a trial of muscle strengthening vs flexibility training, investigators found no difference between groups on measures including tender points and disease and symptom severity.[8] They did find benefits in symptoms and self-efficacy over baseline, but it is not known whether these were sustained.

In a trial comparing 2 physical therapies—body awareness therapy and the Mensendieck system—Kendall and colleagues[9] found greater improvements at 18-month follow-up in the Mensendieck group.[9] Benefits were seen on the Fibromyalgia Impact Questionnaire, self-efficacy measures, and pain at worst site. The Mensendieck system uses individual interview, analysis of movement patterns, a discussion of possible corrections followed by practice, and relaxation exercises.

Multidisciplinary rehabilitation, often including physical therapy, has also been studied in a limited way. In a systematic review of 7 studies fulfilling inclusion criteria (a total of 1050 patients), Karjalainen and colleagues[10] concluded that although education combined with physical training seemed to have some positive results at long-term follow-up, the level of scientific evidence required for recommending these programs for fibromyalgia was lacking.[10]

Because exercise is believed to be an essential component of physical therapy, we examined the results of a systematic review of exercise for treating fibromyalgia. The authors found 7 high-quality studies, 4 of aerobic training, and concluded that supervised aerobic exercise training had beneficial effects on physical capacity, tender-point threshold, and pain.[11] Other investigators have questioned the usefulness of aerobic exercise because long-term benefit remains unclear and compliance is poor.

RECOMMENDATIONS FROM OTHERS

We were unable to find any guidelines for the treatment of fibromyalgia. Patient information sheets from both the American College of Rheumatology (www.rheumatology.org) and American Academy of Orthopaedic Surgeons (orthoinfo.aaos.org) recommend physical modalities such as heat application, massage, and exercise, including fitness training.

Authors of chapters on fibromyalgia in both *Kelly's Textbook of Rheumatology* and *Harrison's Principles of Internal Medicine* suggest that patients may benefit from regular low-impact aerobic exercise.[12,13]

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CLINICAL COMMENTARY

Exercise, physical therapy ease pain, "helplessness"

Fibromyalgia is a disease of chronic pain. It engenders feelings of helplessness, depression, and loss of control in many patients. In my experience, both physical therapy and exercise can help alleviate these feelings. Physical therapy helps motivated patients perform body movements that they believe may be painful. In this sense, it demonstrates to them the possibility of exercising without excruciating pain. As the evidence suggests, patients who exercise have less pain and feel better in general. Thus, physical therapy can teach patients to actively participate in the management of their disease.

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Do antiarrhythmics prevent sudden death in patients with heart failure?

EVIDENCE-BASED ANSWER

Beta-blockers (class II antiarrhythmics) reduce sudden death and total mortality in patients with heart failure (strength of recommendation [SOR]: **A,** based on systematic reviews of randomized controlled trials). Amiodarone (class III) may reduce sudden death in heart failure (SOR: **B,** extrapolation from randomized controlled trials), but evidence is weak that it reduces total mortality, and it has significant side effects. Class I and other class III antiarrhythmic agents appear cause an increase in mortality due to sudden death in heart failure (SOR: **B,** extrapolations from randomized controlled trials).

Beta-blockers were well-tolerated, and improved other endpoints besides heart failure

EVIDENCE SUMMARY

Antiarrhythmic agents have been studied in patients with heart failure because these persons have a high incidence of sudden death, presumably from ventricular arrhythmias. Although the implantable defibrillator is an alternative antiarrhythmic device that may be preferred for some patients, we restricted our review to pharmacologic antiarrhythmics.

The beta-blockers bisoprolol, carvedilol, and metoprolol[1–3] were studied in large randomized controlled trials. The relative risk reduction (RRR) for sudden death ranged from 10% to 52% in the larger trials and 30% to 39% in meta-analyses.[1–4] The absolute risk reduction (ARR) was about 2% to 3% per year for sudden death and 3% to 5% for total mortality (number needed to treat=20–33 per year).

These beta-blockers were well-tolerated, even in class IV New York Heart Association patients, and improved other endpoints. Although we cannot say whether the benefits are a class effect, they were seen with both beta-1 selective and nonselective agents.

Amiodarone was studied in 2 large randomized controlled trials enrolling patients with heart failure, in trials that included patients with or without heart failure at high risk for sudden death (usually post-myocardial infarction or with complex ventricular arrhythmias), and in meta-analyses.[5–8] The largest randomized controlled trial in heart failure showed a significant ARR of 2.9% for sudden death,[5] but was unblind-

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Beta-blocker therapy must be initiated using low doses and when patients are hemodynamically stable

ed. The largest placebo-controlled trial in heart failure failed to detect a significant decrease in sudden death.[6]

Meta-analyses, weakened by heterogeneity and the inclusion of patients without heart failure, detected a significant 21% to 25% RRR for sudden death,[7,8] and an ARR of 2% to 3% per year. The pooled data from the placebo-controlled heart failure trials showed nonsignificant trends: 1.6% per year ARR for sudden death, 0.6% per year for total mortality.

These possible benefits must be balanced against the risk of harm from amiodarone, including excess rates of pulmonary infiltrate (1.1% per year), thyroid dysfunction (6.8% per year), liver enzyme abnormalities (0.6% per year), neuropathy (0.3% per year), and bradycardia (1.6% per year), as well as a discontinuation rate of 41% compared with 27% for placebo.[7] No evidence suggested that use of amiodarone in patients with heart failure increased mortality.

Class I antiarrhythmics and other class III agents have not been studied in heart failure trials, but were associated with increased mortality in studies of patients at high risk for ventricular arrhythmia,[9,10] including patients with left ventricular dysfunction. Because this increase in mortality is thought to be due to pro-arrhythmic properties of the drugs, further trials in heart failure patients are unlikely to occur.

RECOMMENDATIONS FROM OTHERS

American College of Cardiology/American Heart Association (ACC/AHA),[11] European Society of Cardiology (ESC),[12] and Heart Failure Society of America (HFSA) guidelines[13] address heart failure. ACC/AHA and ESC reports specifically mention that beta-blockers reduce sudden death. Both strongly support the use of beta-blockers in patients with heart failure.

ACC/AHA finds "conflicting evidence and/or a divergence of opinion about the usefulness/efficacy" of amiodarone to prevent sudden death and advises: "routine use of amiodarone to prevent sudden death is not recommended." The ESC and HFSA also recommend against routine use of amiodarone.

All 3 guidelines, however, state that for the control of symptomatic arrhythmias in heart failure, amiodarone is the antiarrhythmic agent of choice. All 3 also recommend not using class I or other class III agents in heart failure.

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CLINICAL COMMENTARY

Beta-blockers reduce mortality in patients with heart failure

Numerous well-controlled clinical trials have conclusively demonstrated that beta-blockers reduce morbidity and mortality (including sudden death) in patients with systolic heart failure. They are considered disease-modifying agents and their use is strongly encouraged. Beta-blocker therapy must be initiated using low doses and only when patients are hemodynamically stable, with gradual dose titrations to prevent acute decompensation.

Evidence for amiodarone shows some reduction in sudden death, but these data are less compelling. Moreover, adverse effects and drug interactions complicate long-term amiodarone use. Use of class I (eg, flecainide, procainamide, propafenone) and other class III (sotalol) anti-arrhythmics to reduce sudden death is discouraged.

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Do nasal decongestants relieve symptoms?

EVIDENCE-BASED ANSWER

Oral and topical nasal decongestants result in a statistically significant improvement in subjective symptoms of nasal congestion and objective nasal airway resistance in adults' common colds (strength of recommendation [SOR]: **A,** based on randomized controlled trials). Evidence is lacking to support the use of decongestants in acute sinusitis.

EVIDENCE SUMMARY

Nasal congestion is the most common symptom of the common cold, and hundreds of millions of dollars are spent annually on decongestants. A Cochrane review of 4 randomized controlled trials compared single doses of oxymetazoline, pseudoephedrine, and phenylpropanolamine.[1] Included studies involved from 30 to 106 participants, were double-blinded and placebo-controlled, used either topical or oral decongestants for symptoms of less than 5 days' duration, and measured either subjective or objective relief or adverse events. All 4 studies used nasal airway resistance as an objective measure of nasal congestion, and a combined symptom score as a subjective measure of relief. One study also administered a side-effect questionnaire.

In all studies, topical and oral decongestants were equally efficacious, producing a 13% reduction in subjective symptoms and a significant decrease in nasal airway resistance after 1 dose of decongestant. Only 1 study investigated repeated doses of decongestants and found no significant additional improvement from repeated doses over a 5-day period.

More studies are needed to evaluate efficacy of multiple doses. Clinical interpretation of these results must take into consideration that quality-of-life measures were not evaluated and that none of the studies included children under 12.

Limited data are available on decongestants in sinusitis. Most studies focused on the use of nasal corticosteroids. One placebo-controlled, randomized controlled trial evaluated the effect on mucociliary clearance from adding nasal saline, nasal steroids, or oxymetazoline to antibiotics in acute bacterial sinusitis.[2] The group using oxymetazoline increased mucociliary clearance immediately (within 20 minutes). However, at 3 weeks, the improvement in mucociliary clearance in the oxymetazoline group was not significantly different than in the other groups.

An additional prospective, placebo-controlled study evaluated improvement in x-ray

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findings as well as subjective symptoms in acute sinusitis using phenoxymethyl-penicillin (penicillin V) in combination with oxymetazoline or placebo administered via a variety of nasal delivery systems.[3] Oxymetazoline was not significantly different from placebo. Controlled prospective studies are lacking to support the use of decongestants in acute sinusitis.

RECOMMENDATIONS FROM OTHERS

Expert opinion from Current Clinical Topics in Infectious Diseases does not recommend the use of decongestants in sinusitis or the common cold in the absence of concurrent allergic rhinosinusitis.[4] This recommendation is based on the lack of evidence regarding efficacy and the known rebound congestion associated with topical decongestants. If a decongestant is prescribed, the oral route is preferred, with the understanding of potential significant side effects of nervousness, insomnia, tachycardia, and hypertension.

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CLINICAL COMMENTARY

Decongestants can do more harm than good

Never one to have been impressed with most of the current symptomatic treatments available for the common cold, I have for years been amazed at how quick the public is to purchase and repeatedly use these products.

While a judicious course of decongestants can ease the congestion, when misused they often cause significant harm and discomfort that is difficult to resolve. Patients whom I have assisted through successful discontinuance of topical nasal decongestants are among the most appreciative in my practice.

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Is screening for lead poisoning justified?

EVIDENCE-BASED ANSWER

Evidence is insufficient to recommend for or against universal screening of young children for lead poisoning in high-prevalence communities (strength of recommendation [SOR]: **C**). In low-prevalence communities, evidence is insufficient to recommend for or against a targeted screening approach, employing locale-specific demographic risk factors and personal risk questionnaires to inform screening decisions (SOR: **C**).

Although evidence does not suggest that treatment of individuals with elevated blood lead levels improves individual outcomes, public health strategies aimed at decreasing lead in the environment appear to have resulted in a significant decline in the number of children with elevated blood lead levels in recent decades. One could thus argue that screening may identify communities with high rates of lead poisoning, where environmental strategies could be targeted.

Because the epidemiology of lead poisoning continues to change, local and state health authorities must continuously update information on which to base decisions about screening.

EVIDENCE SUMMARY

The prevalence of elevated blood lead levels varies widely among different demographic

groups and geographic regions, and it has decreased dramatically in the last several decades. Racial and ethnic minorities and children of families with low incomes, who live in the Northeast or Midwest, or who live in older houses continue to be at increased risk.[1] Children with blood lead levels ≥10 µg/dL have been shown to have poorer cognitive and behavioral functioning.[2]

No studies have demonstrated that screening for lead poisoning improves outcomes. To justify screening, one must therefore extrapolate from indirect evidence, demonstrating that screening tests are accurate and that treatment of children detected by screening is effective. Capillary blood samples are comparable with venous samples for detecting elevated blood lead levels. The sensitivity of capillary samples ranges from 86% to 96% compared with venous samples.[3]

In low-prevalence areas, questionnaires may inform screening decisions. A questionnaire inquiring about age of housing, presence of peeling paint, ongoing renovations, siblings or playmates with elevated blood lead levels, adults in the home with occupational exposures to lead, and proximity to industrial sources of lead has a sensitivity for detecting blood lead levels ≥10 µg/dL ranging from 32% to 87%. Sensitivity varies depending on the population and geographic location in which the questionnaire is tested. Accuracy is improved by tailoring the questionnaire based on locally important risk factors.[4]

Proposed treatments for elevated blood lead levels include chelation therapy, education about hygiene and nutrition, household dust control measures, and soil lead abatement. No good-quality trials have demonstrated that lowering slightly to moderately elevated blood lead levels (10–55 µg/dL) improves patient-oriented outcomes such as cognitive and behavioral functioning. Although 1 observational study of chelation therapy linked lowering blood lead levels with improved cognitive function,[3] a randomized controlled trial showed that chelation had no effect on cognitive or behavioral outcomes.[5]

All other trials evaluating treatment for lead poisoning looked at the intermediate outcome of blood lead levels. A systematic review of randomized controlled trials showed that home dust control interventions reduced the proportion of children with elevated blood lead levels (≥15 µg/dL) from 14% to 6%.[6] A randomized controlled trial of high-efficiency particulate air (HEPA) filtration vacuuming showed no effect.[7] More intensive interventions such as soil lead abatement and paint remediation have not proven effective in good-quality randomized controlled trials.

Because lead poisoning rates vary so widely, standard guidelines for screening are not possible

Increasing dietary calcium and iron and decreasing dietary fat are also commonly recommended for children with elevated blood lead levels, based on animal models and cross-sectional studies. The only randomized controlled trial that investigated calcium supplementation showed no effect on blood lead levels.[8] Our search revealed no good-quality studies on the effect of iron or fat intake on lead poisoning.

In summary, because the prevalence of lead poisoning varies between communities and continues to change, standard recommendations are not possible. Clinicians must rely on local epidemiologic data to make screening decisions. Although questionnaires are accurate in predicting elevated blood lead levels in some settings, no specific set of questions can be recommended for all populations.

No treatment options for those with mild to moderate elevations in blood lead levels have been shown to improve clinically important outcomes, although some interventions may decrease blood lead levels.

RECOMMENDATIONS FROM OTHERS

The Centers for Disease Control and Prevention (CDC) recommends

- that individual states develop screening plans based on local data

CONTINUED

- universal screening at 12 and 24 months of age:
  - in communities where the prevalence of blood lead levels ≥10 µg/dL exceeds 12% of children
  - in communities where ≥27% of housing was built before 1950
  - for all children enrolled in Medicaid.

Otherwise screening should be targeted based on a questionnaire on age of housing, recent or ongoing remodeling, and having a sibling or playmate diagnosed with lead poisoning, in addition to questions on locally important risk factors.[9]

The American Academy of Pediatrics endorses the CDC recommendations.[2] The US Preventive Services Task Force, the American Academy of Family Physicians, and the American College of Preventive Medicine all recommend screening for lead poisoning at 12 months of age in children with demographic or geographic risk factors.[3,10,11]

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CLINICAL COMMENTARY

Lead screening: Think locally

The local health department can provide information about lead screening in your community, whether based on blood levels or the housing conditions. If your patients need screening, you may want to add a reminder on a flow sheet in the chart to do a questionnaire or a blood draw. Finding and treating severely elevated lead levels can change outcomes, but for less elevated levels, the evidence shows no benefit. You should work with the health department when considering therapy for children with elevated blood lead levels.

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