A Cohort-Controlled Trial of Customized Foot Orthotics in Trochanteric Bursitis

Robert Ferrari, MD, MSc (Med) FRCPC, FACP

ABSTRACT

Customized foot orthotics are widely prescribed for patients with lower limb pain from a variety of disorders, but there are few trials demonstrating effectiveness and none for trochanteric bursitis. Sixty-eight consecutive patients presenting with symptoms and findings compatible with a case definition for acute or subacute trochanteric bursitis (pain <3 months, point tenderness along the femoral greater trochanter, and pain on resisted hip abduction) were included in the study. A total of 34 subjects were prescribed a local corticosteroid injection under fluoroscopic guidance (control group), and 34 subjects were prescribed a local corticosteroid injection with the addition of customized foot orthotics (orthotics group). All subjects completed the Oswestry Disability Index at baseline, and the number of subjects using prescribed analgesics for their hip pain was recorded at baseline and at follow-ups of 8 weeks and 4 months. Subjects were asked at each follow-up if they felt they had recovered from their "hip and thigh region pain," with recovery arbitrarily being defined as having pain or symptoms in this region for 1 day per week or less. All subjects who failed to report recovery at 8 weeks underwent a repeat corticosteroid injection. A total of 32 subjects in each group completed the study at 8 weeks, and 30 subjects in each group completed the 4-month follow-up. The 2 groups were well matched in terms of age, sex distribution, duration of pain, unilateral or bilateral nature of bursal involvement, and baseline Oswestry Disability Index score. At 8 weeks, 50% reported recovery in the control group and 75% reported recovery in the orthotics group. The number of subjects who reported recovery at 4 months, however, was markedly different between groups, with only 40% reporting recovery in the control group and 90% reporting recovery in the orthotics group. The control group thus reported a high rate of recurrence of trochanteric bursitis. In a cohort-controlled trial of primary care patients with acute or subacute trochanteric bursitis, the addition of custom-made foot orthotics to local corticosteroid injection appears to improve the short- and long-term outcome, with fewer recurrences. (*J Prosthet Orthot*. 2012;24:107–110.)

KEY INDEXING TERMS: foot orthotics, hip pain, trochanteric bursitis

Trochanteric bursitis is a common clinical problem,[1] also labeled as greater trochanteric pain syndrome or gluteus medius tendinitis, most commonly diagnosed by history and examination, being characterized by lateral hip region pain exacerbated by active abduction, and associated with pain on direct palpation of the region of the greater femoral trochanter.[1,2] The mechanism of onset of this disorder is unclear, but tears of the gluteus medius insertion and inflammation of this site have been described, especially in older subjects.[3] Although initial response rates to local corticosteroid injections are reasonably high,[4,5] recurrences are common,[5,6] physiotherapy has not been shown to be of proven benefit,[5] and otherwise, surgery is the only option for refractory cases.[5]

No trials of foot orthotics exist in clinical populations identified as having trochanteric bursitis. Cambron et al[7] measured the change in Oswestry Disability Index scores in subjects with chronic low back pain at the end of 6 weeks of orthotic treatment, compared with no orthotics. A number of these subjects had lower limb pain, but they were not specifically examined for findings typically associated with trochanteric bursitis. An uncontrolled trial[8] has shown reductions in lower limb pain with orthotics use but again was not a cohort of subjects with trochanteric bursitis. Given the common recurrence of trochanteric bursitis and the limited interventions available, long-term, effective strategies are needed. The purpose of this study was to determine the recovery rate from trochanteric bursitis in a group prescribed customized foot orthotics in addition to local corticosteroid injection versus corticosteroid injection alone.

METHODS

PARTICIPANTS

During the period of nearly 4 months in early 2009, the author was acting as a consultant in 2 nearby primary care clinics in Edmonton, Alberta, Canada. Both clinics served similar clinical populations near the inner city, mainly lower socioeconomic and worker populations. Primary care physicians referred patients with musculoskeletal disorders to the author. At one clinic, there was the space and administrative support to provide customized foot orthotics immediately at the time of the initial consultation visit. At the second clinic, this was not available for at least 3 months. The author had

ROBERT FERRARI, MD, MSc (Med) FRCPC, FACP, is affiliated with the Department of Medicine, University of Alberta, Edmonton, Alberta, Canada.

Disclosure: The author declares no conflict of interest.

Correspondence to: Robert Ferrari, MD, MSc (Med) FRCPC, FACP, Department of Medicine, University of Alberta, 13-103 Clinical Sciences Building, 11350-83 Avenue, Edmonton, Alberta, Canada, T6G 2P4; e-mail: rferrari@shaw.ca

been routinely collecting data using the Oswestry Disability Index in these types of patients as well as data concerning current medication use, typically reassessing patients at 8 weeks after consultation. Thus, the circumstances between these 2 clinics and the available data in all patients seen in follow-up provided an ideal opportunity for a cohort-controlled trial of customized foot orthotics, maintaining consistency of treatment approaches to the problem of trochanteric bursitis. That is, patient care was provided by the same consultant in both clinics. In addition, in come cases, the same primary care physician was also treating at both clinics. Data were collected by the author in both practices, and approval for this was obtained from the College of Physicians and Surgeons of Alberta.

Subjects were recruited from a sample of consecutive patients presenting to their family physician who had pain in the region of the thigh, hip, and low back and who were further suspected by the family physician to have trochanteric bursitis, based on location of pain, point tenderness, and pain with hip abduction. These subjects were routinely referred to the author for care. Prospective subjects were further assessed for inclusion and exclusion criteria at the time of initial interview. Subjects included for study met the following criteria. The inclusion criteria were being older than 17 years, able to read and write English at the grade 8 level or higher, and meeting the case definition for trochanteric bursitis (current pain in the region of the lateral thigh anywhere from the iliac crest to the knee, with pain reported on manual palpation of the greater trochanter, and pain reproduced with hip abduction). Exclusion criteria included current use of customized foot orthotics, neurological disorder (including sciatica with objective neurological signs), cancer, spinal stenosis, spinal or lower limb surgery, recent or complicated fracture, known inflammatory arthropathy, severe osteoarthritis of the lower limb joints, prosthetic joints, amputation, or congenital lower limb deformity. Mild to moderate lower limb joint osteoarthritis was not an exclusion criterion because this is a common condition in primary care, especially in older patients. Subjects in the control group were excluded if they obtained orthotics during the study period. Patients were also excluded if they had pain above the T12 level for any reason for more than 2 days per week (ie, if they had neck or upper back pain or upper limb pain, it was relatively minor compared with the hip region pain). Low back pain was not an exclusion criterion because it is a common condition associated with trochanteric bursitis. Thus, these cohorts represented trochanteric bursitis with or without other lower limb or low back pain. These cohorts reflect typical primary care patients in their presentation with trochanteric bursitis, who often have back pain and other lower limb pain. Referring physicians were aware of these criteria to refer patients who were likely to meet the criteria on evaluation by the author.

INTERVENTIONS AND GROUPS

ORTHOTICS GROUP

The author, after an appropriate history and physical examination and confirmation of a case definition of trochanteric bursitis, as defined earlier in *Methods*, prescribed a local corticosteroid injection to take place within 1 week at a local radiology clinic, with 40 mg Depo-Medrol injected into the region of the bursa unilaterally or bilaterally as the subject required. The injection protocol and procedure were determined by the radiology clinic. The author also provided advice to continue follow-up with the primary care physician for analgesics. As part of their usual practice, the author and the primary care physicians at the clinic routinely avoided prescribing other modalities for trochanteric bursitis, such as chiropractic therapy, acupuncture, or massage therapy, but allowed patients to seek these out if they so desired. The primary care physicians also had a typical medication regimen, which included either nonsteroidal anti-inflammatory drugs or acetaminophen products. They tended not to use narcotics or sedatives. These patients had already had appropriate investigations to rule out fractures, radiculopathies, osteoarthritis, and other nonbenign causes of hip region pain.

After assessment, each subject completed an Oswestry Disability Index. The author then obtained foam impressions of each patient in the seated position, with the patient asked to relax his/her lower limb and allow the examiner to place downward pressure on the knee along the axis of the tibia with the knee flexed to 90°. This created the foam impression. All subjects received a standardized orthotic composed of Footmaxx® Premium Allsport orthotic (Footmaxx, Toronto, Ontario, Canada) composed of a semirigid module, vinyl reinforcement, polyurethane foam cushioning, and large profile metatarsal pad aligned with the third metatarsal ray and placed distal to the semirigid module. Subjects were provided lifts for correction of leg length discrepancies if measured to be 1.5 cm or greater, and the lift was provided at a measure of half this discrepancy. None of the subjects received valgus or varus postings. Subjects received their orthotics within 1 week of the molding, and all received the same general instruction on usage and footwear. Thus, for the purposes of creating a cohort for analysis, patients who met the inclusion and exclusion criteria and who received the prescribed customized foot orthotics were deemed to be the orthotics group. When reassessed by the author at 8 weeks, subjects who reported ongoing or recurrent symptoms were referred for repeat corticosteroid injection.

CONTROL GROUP

Subjects for the control group were taken from patients consecutively referred to the author at a nearby second primary care clinic. Again, the primary care physicians (some of whom had worked in both clinics) were asked to refer patients with suspected trochanteric bursitis. The author undertook the same clinic activities as stated above for the orthotics group, including the completion of the Oswestry Disability Index and referral for a local corticosteroid injection. Because orthotics are not yet a standard or proven therapy in this clinical group and because these could be offered at a later date, no ethical concerns regarding standard of care were raised. When reassessed by the author at 8 weeks, subjects who reported

ongoing or recurrent symptoms were referred for repeat corticosteroid injection.

OUTCOMES

At baseline, subjects completed the Oswestry Disability Index, a 10-item questionnaire that indicates the extent to which a person's functional level is restricted by pain and which is responsive to improvements in pain with orthotic use.[8] Scores range from 0 to 5 for each item; higher scores indicate a greater degree of restriction by pain. The scores for each item are added and divided by the denominator of a possible total score of 50, then converted into a percentage. Thus, the scores range from 0% (no restriction due to pain) to 100% (severe restriction due to pain). In addition, at baseline, the medications that the claimant was using, including the type and number of different classes of medications, were recorded to determine if the subject was using some form of prescribed analgesic and if this was specifically for the hip pain. No data were gathered on compliance with orthotics use. No data were gathered on the dose of medications or use of over-the-counter medications. No data were gathered regarding other treatment modalities sought by the subject. Only analgesic use was ultimately recorded, without specifying the exact classes of drugs or number of drugs used (ie, use of ≥1 analgesic constituted "analgesic use").

At follow-up at 8 weeks, subjects were asked if they felt they had recovered from their "hip and thigh region pain," with recovery arbitrarily being defined as having pain or symptoms in this region for 1 day per week or less. All subjects who failed to report recovery at 8 weeks underwent a repeat corticosteroid injection. At this 8-week follow-up, the medications that the claimant was using, including the type and number of different classes of medications, were recorded to determine if the subject was using some form of prescribed analgesic and if this was specifically for the hip pain. The outcome of recovery and medication use was measured again at 4 months.

FUNDING

There was no source of funding for this project.

SAMPLE SIZE AND STATISTICAL METHODS

Sample size was based on the aforementioned study,[8] wherein a significant change in Oswestry Disability Index score was noted in a cohort of 30 subjects, suggesting the effectiveness of the orthotics. Thus, a sample size of at least 30 in each group was sought. There are no other studies in trochanteric bursitis from which to consider sample size. Data were analyzed using SPSS 11.0 (MacIntosh version). Descriptive statistics were calculated for the cohorts, as were baseline scores for Oswestry Disability Index. Differences between groups at baseline were analyzed using the Student t test. Proportions of subjects using prescription analgesics at baseline and follow-up points, as well as proportions of subjects reporting recovery at follow-up points, were compared using the χ^2 test with Yates correction.

RESULTS

In forming the orthotics group, 52 patients had been referred; 18 were excluded (10 with frequent [>1 day per week] neck and/or upper back pain, 2 had incomplete data, 2 did not read or write English at a grade 8 level, 3 had severe knee osteoarthritis, and 1 had obtained orthotics elsewhere). In forming the control group, 56 subjects were referred. Of these, 24 were excluded (12 with frequent [>1 day per week] neck and/or upper back pain, 1 had incomplete data, 4 did not read or write English at a grade 8 level, 2 had chest or abdominal surgery, 2 had severe hip or knee osteoarthritis, and 3 had obtained orthotics elsewhere). Thus, there were 34 subjects in the orthotics group and 34 subjects in the control group at baseline. Of these, two subjects were lost to follow-up in each group at 8 weeks. At follow-up at 4 months, the final group numbers were 30 in each group because of additional losses.

The baseline characteristics of the subjects in the orthotics group and control group are shown in Table 1. There were no significant differences between groups. Compliance with referrals for injections was equal between groups at baseline and 8 weeks. Considering all injection referrals (ie, both the initial and subsequent referrals at 8 weeks), the control group was 94% compliant with injection referrals and the orthotics group was 89% compliant with injection referrals.

At 8 weeks, the proportion of subjects reporting recovery (pain in the hip region ≤1 day per week) was 50% in the control group and 75% in the orthotics group. The number of subjects who reported recovery at 4 months was markedly different between groups, with only 40% reporting recovery in the control group and 90% reporting recovery in the orthotics group. The control group thus reported a high rate of recurrence despite referral for repeat corticosteroid injections at the 8-week

Table 1. Characteristics of subjects in the orthotics group and the control group at baseline

Group	Age, mean ± SD (range), y	Sex distribution, n (%) female	Hip pain duration, mean ± SD (range), wk	Prescribed analgesic use, % yes	Oswestry Disability Index, mean ± SD (range)	Bilateral/ unilateral cases
Control (n = 34)	37.1 ± 11.6 (19–66)	29 (85.3)	7.6 ± 3.2 (1–12)	64.7	22.4 ± 6.5 (12–36)	12/22
Orthotics (n = 34)	40.8 ± 11.4 (21–68)	31 (91.2)	7.4 ± 2.7 (2–12)	61.7	21.7 ± 5.2 (12–30)	14/20

Table 2. Follow-up recovery rates and prescription analgesic use in the orthotics group and the control group at 8 weeks and at 4 months

Group	Proportion with self-reported recovery at 8 wk (n = 32), % yes	Prescription analgesic use at 8 wk (n = 32), % yes	Proportion with self-reported recovery at 4 mo (n = 30), % yes	Prescription analgesic use at 4 mo (n = 30), % yes
Control	50	46.9	40	53.3
Orthotics	75	50.0	90*	13.3*

*Statistically significant difference between groups.

follow-up. At the 4-month follow-up, a smaller proportion of the orthotics group was using prescribed analgesics for pain ($p < 0.05$; Table 2). There was no statistically significant correlation between age, sex, or duration of pain and recovery.

DISCUSSION

This study shows that in a primary care setting, the addition of customized foot orthotics to the treatment of trochanteric bursitis improves clinical outcomes and reduces prescription analgesic use. It should be noted that there were no criteria set for determining whether a subject required customized foot orthotics. The orthotics were routinely offered and were essentially all of the same design. This raises the possibility that either arch disorder (collapse or pes cavus) is etiologic in trochanteric bursitis, and thus, this is a group of individuals who have a high prevalence of a clinically relevant disorder, or simply that, however, orthotics have their clinical effect, this effect can be achieved in clinical practice without knowledge of the arch and foot biomechanics. The key to this study is that simply adding customized foot orthotics as a routine measure generates a much higher recovery rate from trochanteric bursitis.

There are a number of limitations to this study. First, it was not a randomized controlled study. There could be a number of factors that affected the observed outcomes, including subject characteristics not measured, producing a selection bias. The author, although involved in the care of the subjects, did not have contact with any of them in the interval between baseline and follow-up, and the measures are unlikely to have been influenced by the author. It is possible that the primary care physicians learned of the subject's use of orthotics, and this may have influenced how they treated the subjects, thus affecting outcomes. It is also possible that there was a selection bias caused by practitioner style and treatments between the 2 groups because the subjects were from 2 clinics. At the same time, the author was involved in the clinical care in all subjects as was, in some cases, the same primary care physician. Thus, treatment approaches were highly standardized and very similar in both clinics. Given the innocuous nature of orthotics, however, compared with medications, and the ease with which they may be provided, their use in clinical practice should be further considered both for patient convenience and possibly for cost-effectiveness if they reduce the need for other therapies. Further studies will be required, with larger subject numbers, in a variety of clinical populations. As well, economic data should be gathered in future studies to quantify cost-effectiveness.

REFERENCES

1. Brinks A, van Rijn R, Bohnen A, et al. Effect of corticosteroid injection for trochanter pain syndrome: design of a randomised clinical trial in general practice. *BMC Musculoskelet Disord* 2007;8:95.
2. Karpinski M, Piggott H. Greater trochanteric pain syndrome. A report of 15 cases. *J Bone Joint Surg Br* 1985;67:762–763.
3. Bunker T, Esler C, Leach W. Rotator-cuff tear of the hip. *J Bone Joint Surg Br* 1997;79:618–620.
4. Brooker AJ. The surgical approach to refractory trochanteric bursitis. *Johns Hopkins Med J* 1979;145:98–100.
5. Lievense A, Bierma-Zeinstra S, Schouten B, et al. Prognosis of trochanteric pain in primary care. *Br J Gen Pract* 2005;55:199–204.
6. Lustenberger DP, Ng VY, Best TM, Ellis TJ. Efficacy of treatment of trochanteric bursitis: a systematic review. *Clin J Sport Med* 2011; 21:447–453.
7. Cambron JA, Duarte M, Dexheimer J, Solecki T. Shoe orthotics for the treatment of chronic low back pain: a randomized controlled pilot study. *J Manipulative Ther* 2011;34:254–260.
8. Ferrari R. Responsiveness of the Short-Form 36 and Oswestry Disability Index in chronic nonspecific low back and lower limb pain treated with customized foot orthotics. *J Manipulative Physiol Ther* 2007;30:456–458.