CHAPTER 44

THE EFFECTIVENESS OF LOCAL INJECTIONS OF TOREDAL VS DECADRON IN THE TREATMENT OF PLANTAR FASCIITIS

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ABSTRACT:

Twenty-seven patients who were diagnosed with heel pain associated with plantar fasciitis were enrolled in a randomized study to evaluate the effects of injection therapy using a local injection of dexamethasone phosphate (Decadron) vs. a local injection of ketorolac tromethamine (Toredal). A subjective pain score form was used to evaluate: AM pain, average daily pain and percentage of activities of daily living affected by pain levels prior to injection therapy and at two post-injection therapy visits. The mean levels of AM pain, average daily pain and percentage of activities of daily living affected by pain were significantly lower in patients receiving steroid injection therapy than in patients receiving ketorolac injections. The results imply that Toredal is not as effective in the treatment course of plantar fasciitis as injectable Decadron.

INTRODUCTION:

Heel pain is one of the most common symptoms reported to foot and ankle specialists by adult patients'.[28] Although not a serious medical condition, heel pain's often-intractable nature is a particular ailment that frustrates patients and practitioners alike.[39,40,20] The etiology of heel pain is often difficult to diagnose but is commonly related to biomechanical dysfunction, trauma, neuralgias, infections, arthritic factors and autoimmune disease. Most authors agree that the majority of heel pain stems from biomechanical factors that lead to chronic repetitive stress upon the soft tissue structures surrounding and including the plantar fascia, (Hence the term "Plantar Fasciitis").[37]

Steroid injection therapy and non-steroidal anti-inflammatory drugs (NSAIDs) are used alone, in combination with each other, and in combination with other modalities to treat the painful symptoms associated with plantar fasciitis. It can certainly be postulated that ketorolac tromethamine (Toredal), an injectable NSAID, will provide both the analgesic and anti-inflammatory action necessary to decrease the symptoms associated with plantar fasciitis.

The purpose of this study is to compare the short-term subjective results of a one-time injection of a ketorolac (Toredal) and lidocaine mixture with a one-time injection of dexamethasone phosphate (Decadron) mixed with lidocaine. It may be possible that the ketorolac injections are equivalent or superior to dexamethasone injections in terms of relieving painful symptoms. If this is shown to be true, then a local injection of ketorolac for plantar fascial may offer a useful alternative to steroids in the symptomatic treatment of plantar fasciitis. It may also reduce the risks associated with localized steroid injections at the plantar fascia insertion. (Ex. rupture fascia and weakening of other soft tissue structures in the foot.)

METHODS

Subject Selection

Subjects between the ages of 20 and 65 were selected from population of patients who presented to private podiatry practices and the Mercy podiatry clinic in San Diego, California as well as Lovelace Hospital podiatry clinics in Albuquerque, NM. All subjects were ambulatory and had a specific diagnosis of acute or chronic plantar fasciitis by a podiatrist. The patient population was limited to patients who had not received any previous form of injection therapy, surgical fasciotomy, or extensive therapy for plantar fasciitis.

Patient's with a history of gastric bleeding or active peptic ulcer disease, renal insufficiency, history of stroke, allergy to ketorolac, current pregnancy or current nursing mothers, and chronic NSAID use were excluded from the

study in order to reduce reported possible complications concomitant with ketorolac use. Pre-treatment x-rays to rule out stress fractures and neoplastic bony activity were performed for patients with atypical presentation. Patients with related or non-related podiatric pathologies were excluded from the study.

Study Design

Subjects were randomized into one of two groups. Each subject was assessed on three separate occasions by the treating podiatrist: the day of injection, post-injection visit #1, and post-injection visit #2. A Subjective evaluation form was placed in the medical record of each subject evaluating: level of AM pain (morning), average pain throughout the day, percentage of interference with activities of daily living, and whether of not activity levels increased or decreased throughout the treatment period. Doctors recorded the subjective data using a numerical pain scale (0-10). Other conservative treatment modalities prescribed or initiated by the subjects themselves were also recorded at each post-injection visit. A small percentage of the subject population also received a subjective questionnaire form recording symptoms for the first three days after injection therapy.

Injections

Both groups received a one time 2cc injection. Group 1 received a local injection of 4mg (1cc) dexamethasone phosphate (Decadron) mixed with 1% lidocaine (1cc). Group 2 received a local injection of 15mg (1cc) ketorolac (Toredal) mixed with 1% lidocaine (1cc). Both groups were blinded in terms of the type of injection they received. Injections were performed using a medial approach at the heel. (See Figure 1) Either a 25G or 27G needle penetrated the creases between the junction of the thick plantar skin and the more delicate medial heel skin. The needle was buried deep down to the plantar medial tubercle of the calcaneaus and the mixture was infiltrated about the insertion of the plantar fascia.

Statistical Analysis

Differences in the mean values of AM pain, average daily pain, and percentage of activities of daily living affected were compared before and after injection therapy.

Steroid and Ketorolac groups were analyzed separately. A Friedman's test was used to evaluate statistical significance regarding the pre-injection and post-injection mean values. In order to determine at which point statistical significance occurred between each of the three visits a Dunn test was used. GraphPad InStat was used to perform the statistical analysis. It was assumed that p-values <0.05 indicated a significant statistic.

RESULTS

Twenty-seven patients were included in the study and a total of 28 injections were performed. One patient received injections bilaterally. Of the 27 patients, 2 did not complete the 3rd post-operative visit and were, therefore, not included in the statistical analysis. Twenty-one females and 6 males received injections. The mean age and weight of all patients injected was 49.6 yrs (28 yrs – 77 yrs) and 171.4 lbs. (128 lbs – 209 lbs), respectively. Average duration of symptoms was 7.8 months (1-36 months).

The mean age of subjects receiving specific injections was similar for the two groups (49.6 yrs for the ketorolac

Figure 1. Injections were performed using a medial approach at the heel. A 25G or 27G needle was used to penetrated the creases between the junction of the thick plantar skin and the more delicate medial heel skin. The needle was buried deep down to the plantar medial tubercle of the calcaneaus and the mixture was infiltrated about the insertion of the plantar fascia.

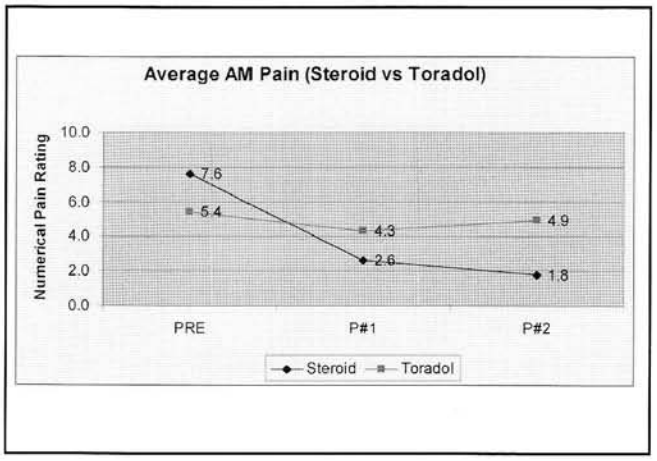

Figure 2. The chart represents the average AM pain scores for both ketorolac and steroid groups at presentation, post-injection visit #1 and post-injection visit #2.

group; 49.5 yrs for the steroid group). The ketorolac group had a slightly higher mean weight than the steroid group (175.6 lbs vs. 168.7 lbs.) Both groups had a similar mean duration of symptoms (8.6 mos for the Ketorolac group and 7.4 mos for the steroid group.) Figure 2 represents the average AM pain scores for both ketorolac and steroid groups at presentation, post-injection visit #1 and post-injection visit #2.

Ten patients received one-time injections of ketorolac. Patients receiving the ketorolac had a mean pre-injection morning (AM) pain score of 5.4 (0-10), a mean daily pain score of 6.1(0-10) and reported that activities of daily living (%ADL) were limited 39% (0-100%). At post injection visit #1 values for AM pain, daily pain and %ADL were 4.3, 5.5 and 27%. At post injection visit #2, mean values were 4.9 (AM pain), 4.5 (daily pain) and 9.4%. There was no significant difference noted between the measured variables at presentation, post-injection visit #1 and post-injection visit #2 . (Friedman was 3.556, P = 0.169 for AM Pain; Friedman = 4.563, P = 0.1002 for AverageDaily Pain; Friedman = 4.385, P = 0.1117 for %ADL).

Sixteen patients received Decadron injections. Patients receiving the steroid injections had mean pre-injection AM pain score 7.6, mean daily pain score 6.7, and %ADL limited values 40.3%. Post-injection visit #1 values were 2.6 (AM pain), 3.3 (daily pain) and 11.1 (%ADL). Post-injection visit #2 values were 1.8 (AM pain), 2.1 (daily pain) and 9.4 (%ADL). For the steroid treatments there was a statistically significant difference between AM pain before treatment, at post-injection visit #1 and at post-injection visit #2 (Friedman = 20.793, P < 0.001). The same was also true for average daily pain (Friedman = 20.633, P < 0.0001)and %ADL (Friedman = 12.766, P , 0.0017)}. Furthermore, statistical significance was present for mean AM pain, average daily pain and %ADL for patients receiving steroid injections between the pre-injection visit and both post-injection visits according to Dunn multi-comparison test results. However, there was no statistical significance for mean AM pain, average daily pain and %ADL when comparing post-injection visit #1 and post-injection visit #2. Figures 3 and 4 depict the mean values for average daily pain and % of daily activities affected.

Nine of the 27 subjects completed short forms recording symptoms for the 3 days after injection therapy. Seven subjects received ketorolac injections while 2 received steroid injections. Mean weight and duration of symptoms were 170.3 lbs. and 16.7 months for ketorolac subjects and 175.0 lbs. and 1.5 months for steroid patients. The mean daily pain scores for ketorolac subjects were 5.1(1-10) pre-injection and 3.1 post injection. The 2 steroid patients mean pre-injection pain was 3.5 while mean post-injection pain was 3.0.

There were no reported side-effects or adverse reactions associated with any of the steroid or ketorolac injections. There were no reports of plantar fascial rupture in any of the 27 subjects.

DISCUSSION

The heel pain associated with plantar fasciitis can range from mild episodic pain when first rising in the morning to more chronic bouts of severe pain that last throughout the day for months at a time. This pain associated with plantar fasciitis can significantly limit those individuals who are

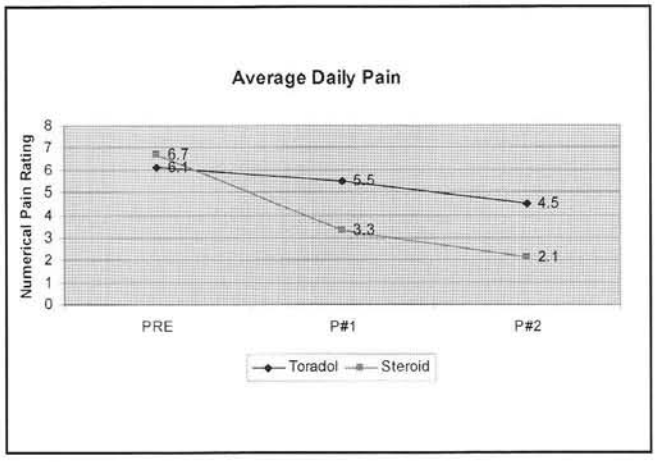

Figure 3. This chart depicts the mean values for average daily pain scores for Ketorolac and steroid groups at presentation, at post injection visit #1, and at post injection visit #2.

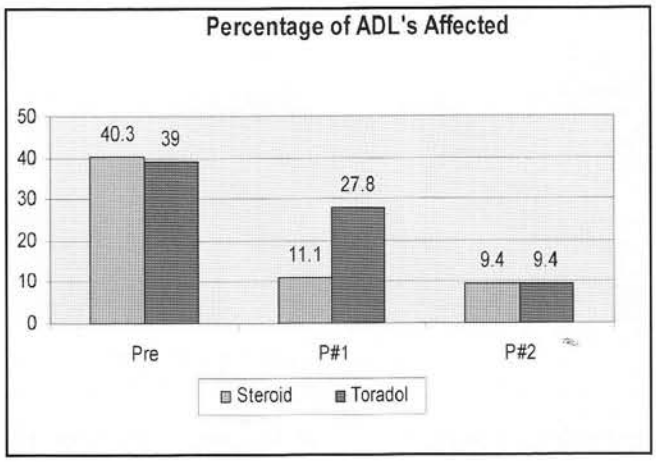

Figure 4. This chart depicts the mean values for % of activities of daily living scores for Ketorolac and steroid groups at presentation, at post injection visit #1, and at post injection visit #2.

affected in their daily and work related activities.[6, 28, 39,40]

The plantar fascia is a fibrous aponeruosis that arises from the plantar aspect of the calcaneal tubercle in the foot. Throughout its course it conforms to the arch of the foot as it runs distally to insert into the plantar plates that are associated with each of the five digits of the foot. The plantar fascia contributes to the formation of the "arch" of the foot and is related to its structure and function.[28]

There are many painful conditions that can mimic plantar fasciitis including entrapment of the 1st branch of the lateral plantar nerve, intrinsic heel pad pathology, stress fracture, heel spurs and seronegative arthropathies.[15] Although Hauser believed that an associated bony heel spur was the likely culprit of the heel pain subsequent studies have refuted this theory.[6] According to most recent reports in the literature true plantar fasciitis relates to pathology within and around the aponeurosis itself.[39,40]

In 1975, Furey[19] stated that the most common etiology is *inflammation* of the plantar fascia at its insertion on the calcaneous. Chronic repetitive stress can cause microtears within the tendinous substance and at its insertion. Overtime this constant "microtrauma" causes an inflammatory reparative response. This presentation has been documented with MRI studies revealing a chronically thickened plantar fascia.[5] Pathologic findings have revealed collagen necrosis, angiofibroblastic hyperplasia, condroid metaplasia and matrix calcification in biopsies obtained from individuals with plantar fasciitis.[28] In contrast to the beliefs that plantar fasciitis is related to an acute or chronic inflammatory condition, Khan, et al[25] has stated that plantar fasciitis is due to collagen degeneration similar to that of chronic necrosis or tendonosis.

Regardless of the micro-pathological etiology, most authors agree that the painful symptoms are related to the chronic micro-tears secondary to the repetitive stress translated throughout the aponeurosis and its surrounding soft tissue structures. The stress placed upon the fascia is often exacerbated by secondary conditions such as pes planus (flat feet) or pes cavus (high-arched feet), limb length discrepancies, a tight Achilles tendon and various other biomechanical abnormalities in the foot (i.e. abnormal pronation).[6,28,40]

The initial treatment for plantar fasciitis is conservative in nature. According to the literature upwards of ninety to ninty-five percent of plantar fasciitis is relieved with conservative therapies. Conservative therapy consists of the use of one or more of the following: ice therapy, stretching, night splints, physical therapy, NSAID's, over the counter orthoses, custom orthoses, heel cups, shoe modifications, casting and steroid injections.[6,15,20,24,28,40]

Studies have found that steroid injections can have a success rate of 70% or better when used alone or with other conservative modalities.[22,40] In 1956 Blockey[7] concluded that 10 of 13 heels injected with hydrocortisone were cured at 2 months. However, it could not be shown that steroid injections were any more beneficial that saline injections. In a study done by Miller et al[2] (1995), it was concluded that a single steroid injection is a reasonable adjunct in treating patients with plantar fasciitis with relief of symptoms lasting for 6-8 weeks. These steroid injections typically consist of a small amount of local anesthetic mixed with approximately 1ml of soluble or non-soluble steroid.

Despite the beneficial results associated with steroid injections and plantar fasciitis, there are some notable concerns that limit the amounts of and duration of treatment associated with injection therapy. In 1978 Leach et al,[26] described 5 cases of plantar fascia rupture, all associated with one or more steroid injections to the affected site. In 1988 Ahstrom 2 presented six plantar fascia ruptures, five of which had received at least one injection for plantar fasciitis. Similarly, Sellman[36] presented a series of 37 patients with a diagnosis of plantar fascia rupture. All 37 had been treated with previous steroid injections for plantar fasciitis. In 1998, Acevedo and Beskin 1 reported on 765 cases of plantar fasciitis. One hundred twenty two of the total cases were treated with steroid injections and 44 of these were associated with plantar fascia rupture.[1,2,26,36]

Early follow up of ruptures associated with steroid injections reported rapid resolution of the plantar fascial symptoms within 6-8wks.[2,26] However, more recent long term studies report the development of new problems including longitudinal arch strain, lateral and dorsal mid-foot strain, nerve dysfunction, stress fractures, hammertoe deformities, swelling and antalgia.[1,36]

Non steroidal anti-inflammatory drugs (NSAIDs) are a widely used medication for painful arthritic and inflammatory conditions. Ketorolac (Toradol) is an injectable NSAID that has comparable analgesic effects to Morphine in the peri-operative setting.[21,30] Ketorolac inhibits the synthesis of prostaglandins and is considered a peripheral acting analgesic. It possesses no sedative or anxiolytic property.[33] Ketorolac is FDA approved for intravenous, intramuscular and oral use. However, it has been shown to be efficacious and safe when injected locally. Recent studies have investigated the action of locally injected Ketorolac and its efficacy in the surgical setting. Ben-David et al found intra-wound injections of Ketorolac to have analgesic effects equal to intravenous and intramuscular administration at the same doses in

subjects undergoing outpatient hernia repair.[3] Again in post-hernia repair patients, Connelly et al, demonstrated that Ketorolac mixed with local anesthetic that was injected into the surgical site provided lower 24 hour pain scores and less consumption of oral analgesics when compared with an equal parenteral dose of Ketorolac.[12]

From unpublished data, Huang et al concluded in a randomized, double blinded study that ketorolac provides slightly stronger analgesia than dexamethasone phosphate in the initial 24-hour post operative period with immediate post-operative injection into the surgical site. Patients receiving ketorolac did, however, experience slightly more post-operative edema initially.[23] Neither of these findings was statistically significant. In 2000 Reinhart et al, used Ketorolac mixed with local anesthetic in podiatric surgery. Results revealed that the addition of ketorolac to lidocaine for pre-operative ankle blocks contributed to a longer duration and better quality of analgesia than either plain lidocaine or lidocaine with intravenous Ketorolac.[31]

One recent study has refuted the anti-inflammatory action of locally injected Ketorolac. Brooke, et al concluded that locally injected Ketorolac did not prevent the onset of an inflammatory process in eighty rabbit Achilles tendons at 3 days post trauma and injection.[9] However the beneficial anti-inflammatory action of ketorolac is well-documented in opthalmological surgery when compared to Dexamethasone.[17] Ketorolac was also shown to demonstrate no complications in terms of wound hemostasis, hematoma, delayed healing, or infections with local infiltration.[4]

STUDY FINDINGS

The current results appear to support the conclusion of Miller that a one-time steroid injection is a useful adjunct in the treatment of plantar fasciitis.[27] Steroids affect the inflammatory response by decreasing leukocyte function and inhibiting the function of phospholipase A2. Phospholipase A2 facilitates the breakdown of phospholipids from cell membranes into Arachidonic acid, which ultimately results in prostaglandin production (the primary mediator of the inflammatory response).

Although the hypothesis can be made that ketorolac should decrease inflammation and pain associated with plantar fasciitis, the subjective clinical findings in this study were not statistically significant. As previously mentioned, ketorolac is not FDA approved for local injection therapy but has been used with success for post-operative analgesia in orthopedic and general surgery.[3,12,31] The conclusion by Brook et al, that ketorolac does not prevent the inflammatory process, would appear to contradict the findings of several authors regarding post-surgical pain control. However, it cannot be assured that ketorolac is inhibiting the inflammatory process from occurring in these post-operative studies. The success of ketorolac may be more appropriately related to the peripheral analgesic properties, which can be comparable to morphine sulfate. Huang's unpublished work may also support this thought in that patients who underwent bunion surgery injected with ketorolac, displayed slightly less pain in the first 24 hour period yet had slightly more edema for 1-2 wks as compared with patients who received Decadron.[23] Although ketorolac has been shown to decrease inflammation in the eye, further studies should be undertaken to clearly identify and separate its analgesic and anti-inflammatory profiles.

A separate variable that could have interfered with the current study hypothesis is the unconfirmed etiology of plantar fasciitis. Although it is quite clear that bouts of plantar fasciitis are related to biomechanical dysfunction, the exact micropathological findings continue to be controversial. Most authors state that plantar fasciitis is an inflammatory process, whether acute or chronic in nature. Khan, however theorizes that "collagen degeneration" similar to that of chronic tendonosis rather that acute inflammation is the likely process. Further studies are needed to confirm or refute these theories or at least determine at which point in the process of long-standing plantar fasciitis signs of inflammation or collagen degeneration are present. The findings of this study would suggest that inflammation does play a role, secondary to the significance associated with subject pain scores in the steroid treated group.

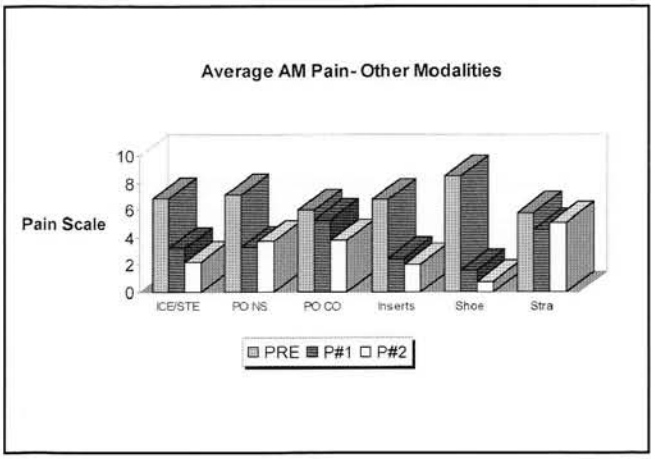

Figure 5. The conservative treatment modalities that patients used in addition to injection therapy could have affected the significance that was attributed to steroid or ketorolac therapy. Ice, Oral NSAIDS, Oral Cox II, Inserts, Shoe modifications or changes, and Strapings were also used in our study. Their effectiveness is charted above but with the small patient sample no statistical significance can be attributed to this part of the study.

The conservative treatment modalities that patients were used in addition to injection therapy could have affected the significance that was attributed to steroid therapy (Figure 5). Due to the nature of patient selection and factors related to health insurance, it was difficult to control these separate modalities provided by practitioner participants. The results attributed to these additional modalities are presented. However, statistical correlation was not performed. Therefore, caution must be used when interpreting the current results. If nothing else, the nature of the current study reinforces the current state of treatment regimens implemented by today practitioners which often takes the form of a "shotgun approach"

CONCLUSION

Despite the aforementioned study shortcomings (i.e.: lack of control group, the presence of multiple variables and small sample population) the findings support the efficacy of a one-time steroid injection with or without other conservative modalities in the treatment of plantar fasciitis. This is consistent with previously report in the literature. The current findings cannot support the use of ketorolac in the current therapeutic regimen for plantar fasciitis. Further studies are recommended to evaluate the local anti-inflammatory effects of ketorolac in acute and chronic inflammatory conditions.

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