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# Local Effects of Flowers of *Calotropis gigantea* in Patients of Painful Heel Syndrome

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## ABSTRACT

Different plant parts (roots, root-bark, leaves, flowers and latex) of *Calotropis gigantea* are widely used topically in different inflammatory and painful conditions by traditional heelers in rural and tribal areas in India. Topical traditional medicine therapy may prove more safe and effective remedy in treating painful heel syndrome. The present study was therefore designed to generate evidence-based support on the efficacy and safety of topical use of flowers of *Calotropis gigantea* in patients of painful heels. Settings and Design: An open trial was carried out in sixty patients of unilateral or bilateral painful heels. *Calotropis gigantea* flowers were applied locally twice a day for for ten days. Subjective clinical improvement was assessed on Visual Analog Scale (VAS) and Objective clinical improvement was assessed walking time on day1 and day10. Assessment of the safety was done by blood investigation like SGOT, SGPT and serum creatinine. Reassessment of VAS score and walking time was done on day 180 which was compared with day 10. Statistical analysis used: paired and unpaired t test. Subjective as well as objective clinical improvement was seen. Local application *Calotropis gigantea*n flowers were also safe to the patient. VAS score and walking time assessment at the end of 180 days also shows improvement. Local application *Calotropis gigantea*n flowers is effacious as well as safe in patients with painful heel syndrome. Increasing the duration of therapy may bring more improvement in painful heel.

**Keywords:** *Calotropis gigantea*, painful heel syndrome

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## INTRODUCTION

*Calotropis gigantea* belongs to family Asclepiadaceae commonly known as Swallow-wart or Milkweed. Different plant parts (roots, root-bark, leaves, flowers and latex) of *Calotropis gigantea* are widely used topically in different inflammatory and painful conditions by traditional heelers in rural and tribal areas in India. Many topical and oral multi-ingredient Ayurvedic preparations are marketed in India in which extracts of different plant parts of *Calotropis gigantea* are used as one of the ingredients. Painful heel syndrome is a condition in which an overnight rest will lead to early morning stiffness and pain in heels (the anteroinferior medial aspect of the calcaneus & inferomedial aspect of calcaneal tuberosity) while standing and walking which gradually disappears in 5 to 30 minutes with routine activities of the day. Various cushions, modern medicines (NSAIDs, Local infiltration of corticosteroids & local anesthetics) as well as various surgical techniques have moderate to good results in painful heels with high recurrence rate. Topical traditional medicine therapy may prove more safe and effective remedy in treating this ailment [1-4].

There are no published reports of the use of traditional medicine in painful heels. The present study was therefore designed to generate evidence-based support on the efficacy and safety of topical use of flowers of *Calotropis gigantea* in patients of painful heels.

## MATERIALS AND METHODS

### Trial design

An open trial was carried out in sixty patients of unilateral or bilateral painful heels. Initial two patients were treated on indoor basis while remaining fifty eight patients were treated on OPD and domiciliary basis for ten days. Flowers of *Calotropis gigantea* (known as Arka in Hindi-National Indian language & Rui in Marathi-Regional Indian language) warmed in little quantity of water for five minutes were applied over heel region with cover of polythene followed by fine woven cloth bandage. The bandage was released after eight hours and then after a gap of four hours fresh flowers were applied with same bandage cover. Patient himself locally applied this application twice a day for ten days as per the training given to him for the procedure of application of flowers. No analgesic, corticosteroids or local anaesthetic were given.

Diagnosis of painful heels was done independently by two orthopaedician. Plants of *Calotropis gigantea* were identified by qualified botanist. Permission from Institutional Ethics Committee was obtained. Written Informed Consent was obtained from patients. Inclusion and exclusion criteria were as follows.

### Inclusion criteria

- Age less than 60 years

- h/o three or more months showing no response or recurrence to standard modern medicine treatment.

**Exclusion criteria**

- Patients of anaemia (Hb% < 8 gm in females and < 9 gm in males)
- Uncontrolled Diabetic patients.
- Past history of fracture around ankle joint.
- Present/past history of any type of arthritis (rheumatic, rheumatoid, gout, ankylosing, psoriasis, lupus, tubercular, other infective and osteoarthritis), Tendinitis and bursitis (assessed by history & clinical examination).
- Osteoporosis (assessed by calcaneal X-rays).

**Withdrawal criteria**

Patient showing severe local reaction on topical application of flowers of *Calotropis gigantea* shall be withdrawn.

**Investigations carried out**

| Day of Investigation | Investigations carried out | Purpose for Investigations |
|---|---|---|
| Day 1 (base line)* | X-ray both heels- Lateral view | Presence/ absence of calcaneal spur |
| | Hb% | Inclusion / exclusion criteria |
| | Random blood glucose | |
| | ESR | Inflammatory parameter |
| | Serum for Creatinine, SGOT & SGPT | Safety parameters |
| Day 10 | ESR | Inflammatory parameter |
| | Serum for Creatinine, SGOT & SGPT | Safety parameters |
| * X-ray and investigations of inclusion/exclusion criteria were done 1 to 15 days before treatment. | | |

**Assessment of efficacy**

Patients were assessed daily by themselves or an orthopaedician for the followings:

a) Subjective clinical improvement was assessed on Visual Analog Scale [5] for the following clinical findings:

- Morning stiffness
- Pain on rest
- Pain on movement
- Swelling around the heel
- Local tenderness on calcaneal spur & anteroinferomedial heel surface
- Erythema on heel

Score was 10 on day 1 for each of the above 6 clinical findings irrespective of the severity of the disease. Score were reassessed on day 10 and results were assessed as excellent response (100% relief), good response (> 75% relief), fair response (>50% relief), poor response (>25% relief) and no response (<25% relief), drop out-discontinuation of the treatment during the trial. Score 0 shall be given for complete relief. On follow up scores were again assessed on day 180.

b) Objective clinical improvement was assessed on day 1 by functional test: walking time, [6] the patients were asked to walk a distance of 50 feet in morning immediately after awakening (after release of bandage) and time taken in seconds was recorded. Walking time was reassessed on day 10 and results were assessed as excellent response (100% relief), good response (> 75% relief), fair response (>50% relief), poor response (>25% relief) and no response (<25% relief), drop out-discontinuation of the treatment during the trial. On follow up walking time was again assessed on day 180.

c) Objective laboratory improvement was assessed by ESR on day 10 and was compared with day 1.

**Assessment of safety**

- Topical reactions were observed daily.
- Serum Creatinine, SGOT & SGPT were estimated on day 1 and day 10 to assess absorption through skin leading to systemic toxicity.
- Occurrence of any adverse event was also recorded.

**Treatment period**

Patients were treated as per trial design and were assessed after ten days of treatment. They were asked to report on recurrence of pain in future. They were advised not to take any other treatment for painful heels.

**Follow Up**

Patients were called for follow up after six months. Numbers of episodes of recurrences if any in six months were noted. On day 180 patients were assessed for severity of the disease by subjective clinical improvement (visual analog scale) and objective clinical improvement (walking time).

Paired students 't' test was utilized for inflammatory parameter, safety parameter and subjective and objective clinical assessment (day 10 compared with day1). Unpaired 't' test of unequal variance was used to compare subjective and objective clinical assessment on day 180 was with day 10 in terms of recurrence or non recurrence.

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**Quality control and quality assurance**

Diagnosis of painful heels was done independently by two orthopaedician.

Plants of *Calotropis gigantea* were identified by qualified botanist and fresh flowers were obtained on the day of its use.

Good Laboratory Practices were followed in carrying out X-rays, Hematological and Biochemical investigations of the patients.

## RESULTS

**Table-1: Age and sex distribution of patients**

| Age in years | Number of patients | | |
|---|---|---|---|
| | Male | Female | Total |
| 20-30 | 7 | 7 | 14 |
| 31-40 | 12 | 6 | 18 |
| 41-50 | 6 | 9 | 15 |
| 51-60 | 9 | 4 | 13 |
| Total | 34 | 26 | 60 |

**Table-2: Occupation of patients**

| Occupation | Number of patients | | |
|---|---|---|---|
| | Male | Female | Total |
| House hold | 1 | 21 | 26 |
| Deskwork (Sedentary) | 11 | 1 | 12 |
| Field work (walking and standing) | 22 | 4 | 26 |
| Total | 34 | 26 | 60 |

**Table 3: Details of foot ware used by patients.**

| Footware | | Male | Female | Total | Grand Total |
|---|---|---|---|---|---|
| **Sole** | Soft | 08 | 09 | 17 | 60 |
| | Medium | 10 | 09 | 19 | |
| | Hard | 16 | 08 | 24 | |
| **Size** | Proper | 30 | 23 | 53 | 60 |
| | Small | 4 | 3 | 07 | |
| | Large | 00 | 00 | 00 | |
| **Heel** | Normal | 22 | 17 | 39 | 60 |
| | High | 12 | 09 | 21 | |

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**Table-4: Details of treatment taken**

| Treatment | Male | Female | Total |
|---|---|---|---|
| **NSAIDs** | 11 | 09 | 20 |
| **Steroid** | 02 | 03 | 05 |
| **Dithermy** | 05 | 04 | 09 |
| **NSAIDs + Dithermy** | 07 | 03 | 10 |
| **Steroid + NSAIDs** | 05 | 02 | 07 |
| **Nil** | 04 | 05 | 09 |

**Table-5: Correlation between painful heel and calcaneal spur**

| Particulars | Number of patients | | |
|---|---|---|---|
| | Male | Female | Total |
| Bilateral painful heel with bilateral spur | 14 | 11 | 25 |
| Bilateral painful heel with left spur | - | - | - |
| Bilateral painful heel with right spur | - | - | - |
| Bilateral painful heel with no spur | 1 | - | 1 |
| Unilateral painful heel: Left with bilateral spur | 5 | 3 | 8 |
| Unilateral painful heel: Left with left spur | 2 | 2 | 4 |
| Unilateral painful heel: Left with no spur | 1 | 2 | 3 |
| Unilateral painful heel: Right with bilateral spur | 7 | 5 | 12 |
| Unilateral painful heel: Right with right spur | 2 | - | 2 |
| Unilateral painful heel: Right with no spur | 2 | 1 | 3 |
| Unilateral painful heel with contralateral spur | - | 2 | 2 |
| Total | 34 | 26 | 60 |

**Table-6: Results of Pretreatment and Post treatment investigations (Inflammatory and Safety parameters)**

| Variable | Mean | S.D. | t value | p value |
|---|---|---|---|---|
| ESR | | | | |
| Day 1 | 17.48 | 7.70 | 9.48 | 0.011* (Significant) |
| Day 10 | 11.9 [@] | 3.67 | | |
| Serum creatinine | | | | |
| Day 1 | 1.28 | 0.363 | 1.21 | 0.23 (Non Significant) |
| Day 10 | 1.183 | 0.362 | | |
| SGOT | | | | |
| Day 1 | 36.53 | 8.30 | 1.68 | 0.098 (Non Significant) |
| Day 10 | 33 | 7.58 | | |
| SGPT | | | | |
| Day 1 | 37.83 | 7.07 | 1.91 | 0.06 (Non Significant) |
| Day 10 | 34.63 | 6.05 | | |

[@] The decrease in ESR on 10th day as compared to day 1 was 31.93 %. * p Value < 0.05 is significant.

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**Table-7: Results of Pretreatment and Post treatment clinical assessment (Subjective and Objective)**

| Variable | Mean | S.D. | t value | p value |
|---|---|---|---|---|
| Score on VAS (Subjective clinical assessment) | | | | |
| Day 1 | 51.0 | 7.52 | 18.92 | 0.021* |
| Day 10 | 14.41[@] | 6.70 | | (Significant) |
| Walking Time (Objective clinical assessment) | | | | |
| Day 1 | 101.16 | 19.31 | 21.36 | 0.018* |
| Day 10 | 28.11[@] | 14.56 | | (Significant) |
| [@] Improvement on VAS on day 10 as compared to day 1 was 71.75% and in walking time on day 10 as compared to day 1 was 72.12%. * pValue < 0.05 is significant. | | | | |

**Table-8 Showing Mean, S.D. t value, p value of recurrence & non-recurrence on Day 180**

| Variable | Mean | S.D. | t value | p value |
|---|---|---|---|---|
| Score on VAS | | | | |
| Recurrence (n=18) | 43.88 | 7.77 | 12.83 | 0.004 |
| Non recurrence (n=42) | 9.85 | 6.06 | | Significant |
| Walking Time | | | | |
| Recurrence (n=18) | 64.44 | 20.61 | 15.66 | 0.0013 |
| Non recurrence (n=42) | 24.30 | 12.83 | | Significant |

Age wise and sex wise distribution of the patient is shown in table 1. Thirty four male patients (mean age± S.D., 39.25±12.15) and twenty six female (mean age± S.D., 37.25±11.41) were involved in the study. Body weight ranged from 44 to 68 kg. Mean body mass index was 24.23±12.12 kg. Details of the occupation and footware used is shown in the table 2 and 3. None of our patient was involved in dance, sports and athletic activities. Our patients were having complaints from last 3 to 12 months. A detail of the various modalities of treatment taken for the paiful heel syndrome is shown in table 4. Majority of them had used NSAIDS and diathermy. Age wise and sex wise Correlation between painful heel and calcaneal spur is shown in table 5. Inflammatory and safety parameters showed a significant reduction (table 6). Only 8 patients were having high ESR (> 25 mm), which came to normal after treatment. Remaining 52 patients were having ESR in the normal range. All patients were having normal serum creatinine, SGOT and SGPT before and after treatment showing no harmful effect on kidney and liver. Pretreatment and Post treatment clinical assessment is shown in table 7. Significant improvement in VAS score and walking time was seen. Reassessment of VAS score and walking time was done on day 180 which was compared with day 10 which also showed improvement (table 8). No local reaction and adverse events were seen during the treatment.

## DISCUSSION

Painful heel, a clinical syndrome usually occurs in middle aged persons (of either sex) but has been reported in patients ranging in age from 8 to 80 years [7]. The upper age limit

fixed for inclusion of patients in our study was 60 years to avoid excessive influence of senile osteoporosis and degenerative process while no lower age limit was fixed. Many different ideas exist regarding the etiology of the pain and different methods for treating painful heel. As stated in Campbell's Operative Orthopedics [4], "although it is familiar to all orthopedic surgeons, it is fully understood probably by none". According to Snook and Christman[8] "First, there appears to be no accepted explanations of the etiology of the conditions; secondly, there is no generally approved method of treatment". These authors suggested that the basic cause lies in the subcalcaneal pad, which in some unknown manner looses its compressibility, either by local fat loss with thinning of the pad or by rupture of the fibrous tissues septa.

Obesity is a predisposing factor, and the symptoms are even more difficult to control when a patient is overweight. None of our patient appears to be obese. Their body weight was in the range of 44 kg to 68 kg. Out patients were from variable socio-economic status and educational status. These factors perhaps do not influence the etiology as well as response to treatment. Occupation involving prolonged standing and walking seemed to influence as one of the etiological factor in our patients. The type of footwear used, its heel height and consistency of sole did not appear to influence symptoms of our patients although advise was given to patients to wear footwear of proper size, heel of about 3/8 inch height and sole of soft consistency [9, 10]. Our patients were having complaints from last 3 to 12 months.

Woolnough [9] had stated this clinical entity, as "tennis heel" to which is not farfetched to compare this to tennis elbow. Repeated jumping leading to pressure on heel pads in dance, sports and athletic activities lead to appearance of symptoms in early age. None of our patients was involved in these activities. Another possible cause of symptoms involves the windlass mechanism of the planter fascia as the toes are dorsiflexed [10] that elevates the longitudinal arch of the foot. Doubt whether pes planus, pes cavus or pronated foot can precipitate symptoms needs to be established. All our patients were free from having any defect in positioning and arches of the foot or rotation of the lower leg.

Lateral roentgenogram of heels of our patients showed calcaneal spurs. All 3 patients of bilateral painful heel were having bilateral spurs. Amongst 7 patients of unilateral painful heel 4 were having bilateral spurs, 2 were having unilateral spur while 1 was not having spur. In Lapidus and Guidotti's [10] series of 323 patients, 58 patients had unilateral symptoms with bilateral spurs and spurs were absent in another 75 painful heels. Exact significance of calcaneal spur is uncertain. The spur most probably is a normal manifestation of the process of aging with a general tendency towards ossification of the tendons and the ligaments at their insertion into the bone. The spur may sometimes be seen in younger patients also. Hauser [11] considered "the constant pull of fascial and muscular attachment to a bone" as producing planter spur, which may remain asymptomatic. If the projection points downward and presses into the muscle tissue, it will act as a foreign body and cause pain on pressure which had best to be removed rather than trying to relieve the pressure points by encircling with a rubber sponge or felt ring.

Inflammation of the origin of the planter fascia, muscle tendon or ostetitis of os calcis may sometimes be reflected in laboratory parameters i.e. Erythrocyte Sedimentation Rate and C- Reactive Protein. Our 2 patients showed high E.S.R. (40 mm and 25 mm respectively) that came to normal (12 mm and 10 mm respectively) after treatment. Remaining 8 patients were having normal E.S.R.

It is most unlikely to have nephrotoxicity and hepatotoxicity after topical treatment of moist and warm flowers of *Calotropis gigantea* to thick-skinned heel region. No alteration of Serum Creatinine, SGOT and SGPT was seen after 7 days of topical therapy. Also no topical or systemic reaction was seen.

Subjective clinical improvement on Visual Analog Scale as well as objective clinical improvement on functional test (walking time) was seen in almost all patients.

Improvement of painful heel by NSAIDs has been noted by several investigators, the duration of the treatment ranges from two weeks to nine month which has been reviewed by Murphy [4]. Response to NSAIDs and local corticosteroid injection therapy has been observed by Lapidus and Guidotti [10]. Graham [11] reported relief of pain within 6 months with the use of rigid or semirigid orthosis while Snook and Christman [13] reported with the use of heel cup. Rarely patient is subjected to surgery and surgical treatments have been reviewed by Anderson and Foster [14]. In thorough literature search we could not find any study on flowers of *Calotropis gigantea* or any other traditional medicine therapy in painful heel.

To summarize, increasing the duration of therapy may bring more improvement in painful heel. Study in large number of patients with prolonged follow up will establish the role of this traditional medicine therapy in treatment of painful heel. So we recommend more studies with more sample size and with the varying duration.

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