A study of effect of tarsal tunnel decompression on sensory improvement in diabetic foot: a prospective randomized control trial

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INTRODUCTION

India currently leads the world with an estimate of 41 million people with diabetes and this figure is predicted to increase to 66 million by 2025.1 Type 2 diabetes remains the most common metabolic disorder. Its incidence and prevalence are known to be growing rapidly in the developing world, the reasons being marked as demographic and socioeconomic changes in these regions. Certain factors like bare foot walking, illiteracy, low socioeconomic status, late presentation by patients and ignorance among diabetic foot care contribute to this high prevalence.

About 15% of diabetic population will have an ulcer foot once in their lifetime. 20% of hospitalizations of diabetics are due to ulcer foot and its complications.2 Although population-based data are not available, rough estimates...
indicate that in India approximately, 45000 legs are amputated every year and the numbers are increasing each year. Almost 75% of these amputations are carried out in neuropathic feet with secondary infection which are potentially preventable.³

Peripheral diabetic neuropathy is one of the major complications of diabetes. In India, the etiology of trophic ulcer is neuropathy alone in 80% and neuro ischemic in the remaining 20%.¹ Hence, neuropathic lesions are dominant cause of trophic ulcers. One of the components of metabolic toxicity of diabetes to neuronal cells is the conversion of glucose to sorbitol which on accumulating increases the intra neural water content, causing the nerve to swell. Glycosylated end products also accumulate in endoneural collagen making connective tissues stiffer around neurons that reduces perineural gliding, subjecting the neurons to stress. The metabolic insult to neuronal cells is irreversible and the management is aimed to prevent the complications of peripheral neuropathy like trophic ulcers.³

Diabetic peripheral nerves are at risk of entrapment neuropathies focally, the reason being that there are anatomical sites of narrowing especially in lower limbs termed as fibro-osseous tunnels where these nerves are contained in a closed space. These tunnels are unyielding to the neuronal changes in diabetes, thereby adding more stress. Diabetic trophic ulcers are more common in plantar aspect of foot, the reason primarily being loss of sensation. The sensation of plantar aspect of foot is supplied by posterior tibial nerve. Hence posterior tibial nerve supplying the weight bearing sole within tarsal tunnel is of special interest in diabetic ulcer foot.³

This study aims at finding out the effect of decompression of compressed posterior tibial nerve and its branches at tarsal tunnel by surgical release of tarsal tunnel in restoration of sensation in diabetic foot.

METHODS

After getting Institutional Ethical Committee approval, the study was conducted over a period of 18 months. Sample size was calculated after consulting with the statistician. About 70 patients who are attending diabetic foot care clinic at ESICH, KK nagar were selected by the computer, randomly selecting 5 patients for every consecutive 15 patients. They were counselled for surgery explaining the aim of the proposed study, its expected complications and consent in written format was obtained.

The study population included those diabetic patients who were having, solitary plantar ulcer in one foot (acting as test limb) of Wagner grade - 1 and 2, size <3 cm in diameter, and with contralateral non-ulcer foot, acting as control limb. Both limbs were evaluated for absence of vascular insufficiency by ankle-brachial index (<0.7). Also, the study population were confirmed to have sensory loss in the test limb as detected by monofilament testing (three site test) and posterior tibial nerve compression at the tarsal tunnel in the test limb by elicitation of Tinel's sign.

Patients excluded from the study were those with other known causes of ulcer foot, associated ischemic component (ankle-brachial index >0.7), actively infected ulcers, presence of neuropathic deformities, uncontrolled diabetic status (HbA1c>8), pregnant mothers, presence of other neurological illness and those with other co-morbid conditions (cardiac/renal/hepatic disease, immunosuppression).

All patients underwent thorough history, physical examination & local examination of both lower limbs. Site, size, depth, extent and position of ulcer was documented and graded according to Wagner's grading. Peripheral pulses and ankle-brachial index were tested to rule out vascular disease. Sensory examination of both test and control limb was done using

- Semmes-Weinstein 10 g force monofilament three site test involving testing the plantar aspects of the great toe, the third metatarsal, and the fifth metatarsals. The test was considered positive if the patient was not able to feel the filament and negative if the patient was able to feel the filament, on plantar aspect of foot at the above sites. A positive test refers to loss of 95% sensation (loss of protective sensation).⁶

- Elicitation of Tinel's sign over the course of posterior tibial nerve under tarsal tunnel was done by compression /percussion in disto-proximal direction. The sign was considered to be positive if there was distally radiating tingling sensation on plantar aspect. This indicated presence of focal compression of posterior tibial nerve in tarsal tunnel.⁷

The study population were also subjected to haematological, biochemical and radiological investigations including fasting and postprandial blood glucose levels, HbA1c levels, complete hemogram, renal function test, protein profile, X-ray chest and foot of affected limb, ECG and wound biopsy for culture and sensitivity.

The study limb with ulcer on plantar aspect was prepared for a week with daily hydrogel dressing and debridement. Appropriate antibiotics were given to control infection at the site of ulcer. Patients were taken up for surgery only after ensuring absence of active infection, as determined by type of discharge, absence of cellulitis, absence of systemic signs and symptoms and normal WBC. On the day of surgery, the study limb with ulcer was prepared with Povidone Iodine in ward. The ulcer was through washed, cleaned and walled of with dressing/Opsite as appropriate to exclude ulcer and allowing exposure to the site of incision before shifting to operating room.
Standard prophylactic antibiotics were given as per hospital protocol.

Figure 1: Line of incision, 6 cm in length perpendicular to the line joining medial malleolus and calcaneum at the midpoint.

In the operating room in supine position, with strict aseptic precautions, under local anesthetic infiltration containing 1:100000 adrenaline, skin was incised for about 6 cm in length over the midpoint of line joining medial malleolus and calcaneum in smooth curve along the tarsal tunnel (Figure 1). Subcutaneous tissue was divided. Flexor retinaculum was identified, delineated and incised. Edges of retinaculum were excised 0.25 cm from each leaf de-roofing the tunnel. The edges were cauterized to prevent reformation of roof and post-operative adhesions.

Figure 2: Intra-operative picture, showing posterior tibial nerve branching into medial plantar, lateral plantar and calcaneal nerves. Posterior tibial vessels are identified anterior and superficial to the nerve.

Under 4.5x loupe magnification Structures within the tunnel were dissected out and properly identified. Posterior tibial nerve was identified deep to posterior tibial vessels. The nerve was carefully separated from posterior tibial vessels. The nerve was inspected for compression and proximal neuroma formation. Careful neurolysis was done releasing the epineurium. The branches of posterior tibial nerve medial plantar, lateral plantar and calcaneal nerves were identified (Fig.2). These divisions were traced distally up to their entrance into plantar aspect of foot in their respective tunnels. Fibro-osseous tunnels overlying these corresponding nerves were also released. Epineurium of these nerve divisions were also opened up. Wound was washed and hemostasis was obtained with bipolar cautery. Finally, the skin was closed with non-absorbable interrupted sutures and dressed. External compression dressing was applied, and patient was advised leg elevation post operatively.

In the peri-operative period patients were managed with leg elevation and analgesics. Dressings were changed on 2nd postoperative day and patients were discharged. They were reviewed on 7th post-operative day for suture removal. Care for the ulcers was continued as per standard with off-loading, appropriate dressings, with address to nutrition, glycemic control and rehabilitation.

The follow up was scheduled at 6 weeks, 3 months, 6 months and 9 months from the time of surgery. During follow up, both the lower limbs were examined for sensory improvement by Semmes-Weinstein 10 g force monofilament sensory test and the study limb for adequate decompression of posterior tibial nerve at the tarsal tunnel by elicitation of Tinel’s sign.

The results were documented systematically and statistically analysed using SPSS EXCEL software. Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the Z test for proportions, Chi-Square Test and Fisher Exact Test. Statistical significance was taken as P < 0.05. The data was analysed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

RESULTS

Among 70 patients, 80% were of the age between 41-70 years and 14.28% were between 31-40 years, with the mean of 53.03 years and standard deviation of 12.05, with no statistical significance (p = 0.500) (Table 1).

Table 1: Age distribution of the study population.

<table>
<thead>
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<th>Age (in years)</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
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<td>2.86</td>
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<tr>
<td>31-40</td>
<td>10</td>
<td>14.28</td>
</tr>
<tr>
<td>41-50</td>
<td>19</td>
<td>27.14</td>
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<td>71-80</td>
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<td>1.43</td>
</tr>
<tr>
<td>81-90</td>
<td>1</td>
<td>1.43</td>
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<tr>
<td>Total</td>
<td>70</td>
<td>100</td>
</tr>
</tbody>
</table>
Among 70 patients, males contribute to 62.86% of study population when compared to females (37.14%), with no statistical significance ($p = 0.9768$) (Table 2).

**Table 2: Sex distribution of the study population.**

<table>
<thead>
<tr>
<th>Gender</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
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<td>62.86</td>
</tr>
<tr>
<td>Female</td>
<td>26</td>
<td>37.14</td>
</tr>
<tr>
<td>Total</td>
<td>70</td>
<td>100</td>
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</table>

Tinel's sign was positive in all the test limbs of the study population, indicating compression of nerves in tarsal tunnel. Among the contralateral non-ulcer control foot of the same patients, only 59 (84%) were Tinel's sign positive and 11 (16%) were Tinel's sign negative, suggesting that 16% of patients were having asymmetrical compressive neuropathy and was found to be statistically significant ($p = 0.0000$) (Figure 3).

![Figure 3: Tarsal tunnel compression among study limbs as detected by Tinel's sign.](image)

After de-compressive surgery on the test limb, 69 patients (98.6%) were documented to have resolving of Tinel sign in the test limb, suggesting adequate decompression and 1 patient (1.4%) was documented to have persistent Tinel sign suggesting inadequate decompression.

![Figure 4: Tarsal tunnel compression among control limbs as detected by Tinel's sign.](image)

All the patients included in the present study had sensory loss in ulcer bearing study foot. Among the non-ulcer bearing contralateral control feet, only 65 (93%) had sensory loss and 5 feet (7%) had their sensation preserved on clinical sensory examination. So, among the present study population 7% of patients had distal asymmetric sensory neuropathy and 93% of patients had distal symmetric sensory neuropathy. Following tarsal tunnel decompression surgery on test limb, 65 patients (93%) had sensory gain and 5 patients (7%) had documented no sensory gain on test limb, with statistical significance ($p = 0.0000$) (Figure 4, 5 and 6).

We also noted that the sensory gain in all 65 cases was observed at the 1st follow up visit at 6 weeks. No further improvement was noted in remaining 5 cases.

**DISCUSSION**

Peripheral diabetic neuropathy is one of the most important complications in patients with long standing Diabetes, having poor glycemic control. One of the most dreaded outcome of diabetic neuropathy is trophic ulcer foot, accounting for 75% of leg amputations in diabetic
patients. Also, nearly 80% of trophic ulcers in diabetic patients are due to sensory loss. This study was designed primarily to assess the effect of tarsal tunnel decompression in diabetic ulcer foot patients on the recovery of lost sensation on the plantar aspect of foot.

In the current study, 70 diabetic patients with ulcer foot in one limb (test limb) and contralateral foot having no ulcer (control limb) were included (Table 1 and 2). Among the study population 80% were of the age between 41-70 years, with males contributing to 62.86% of study population without any statistical significance. Since there is no statistical significance among age and gender of the study population, it indicates that the study population contains subjects with the same basic demographic characteristics.

In the current study, the difference between monofilament test positive and monofilament test negative when mapped among study and control limbs, pre and post operatively was 57.14% with a confidence interval of 11.06% to 95.92% (Figure 4-6). It was statistically significant with a p-value of 0.000 according to McNemar Chi-squared test. All study limbs which tested monofilament test positive preoperatively and after undergoing decompression surgery has 27 times more chance to get converted into monofilament test negative compared to control limb. The occurrence of monofilament test positive was meaningfully more (100%) in the study limb compared to 84% in control limb pre-operatively. But post operatively 1 patient (1.4%) was monofilament test positive which in turn converts the monofilament test positive limbs into monofilament test negative limbs significantly.

Present study confirms adequate tarsal tunnel decompression, removes stress over compressed posterior tibial nerve and its branches, leading to restoration of sensory sensation which in turn will prevent ulcerations and infective complications, thereby avoiding leg amputations. Study conducted by Gondring WH et al, also concluded that a successful quantitative measure of sensory recovery was obtained after nerve decompressions for tarsal tunnel syndrome in diabetic patients, as tested by Semmes-Weinstein monofilament testing.4

Valdivia JM et al, showed that diabetic neuropathy patients who had numbness preoperatively had successful improvement in sensation and improvement in balance, following decompression of chronic nerve compressions in lower limbs and suggested it as an effective method in improving the symptoms of peripheral neuropathy.7

In the present current study the difference between Tinel’s sign positive and Tinel’s sign negative when mapped among study and control limbs pre and post operatively was 5.72% with a confidence interval of 1.80% to 9.22% (Figure 3). It is statistically significant with a p-value of 0.000 according to McNemar Chi-squared Test. All test limbs which tested Tinel’s sign positive preoperatively and underwent decompression surgery had 27 times more chance to get converted into Tinel’s sign negative postoperatively, when compared to the control limb. The occurrence of Tinel’s sign was meaningfully more (100%) in the study limb compared to 84% in control limb pre-operatively. But post operatively Tinel’s sign positivity was meaningfully less (1.4%) in the study limb when compared to 84% in control limb.

Present study confirms that there is real advantage of performing tarsal tunnel decompression surgery in diabetic foot ulcer limbs, which in turn helps in restoration of sensory signals. This restoration of protective sensation in foot would be helpful in prevention of new ulcer formation. In our study , after decompressive surgery, 69 patients (98.6%) were documented to have resolving of Tinel’s sign ,suggesting adequate decompression and 1 patient (1.4%) was documented to have persistent Tinel’s sign suggesting inadequate decompression. The same patient was also reported to be the one among the 5 who had no sensory gain following decompression surgery (Chart2), explaining the importance of adequate, meticulous and proper decompression of tarsal tunnel in order to recover the sensory loss.

Study conducted by Dellon AL et al, concluded that positive Tinel’s sign at tarsal tunnel in compressive diabetic neuropathic patients was an excellent predictor of symptomatic improvement after de-compressive surgery in a multi-centre prospective study of 628 patients.8 Study conducted by Lee CH et al, had demonstrated high probability of good successful outcome of decompressive surgery in terms of restoration of sensation and pain relief with positive Tinel’s sign preoperatively.9

Valdivia JMV et al have reported that the decompression of lower extremity compressed nerves resulted in gain of sensation and have recommended the same for all neuropathic patients who have failed improvement of symptoms with medical treatment.10

CONCLUSION

This study was one of the attempts to establish the role of de-compressive surgery of tarsal tunnel in diabetic patients.
compressive neuropathies with the possible adequate controlling with the contralateral limb in respect to sensation recovery in Indian subpopulation. The aim of our treatment approach is to help restore sensation to plantar aspect of foot involved with compression neuropathy at tarsal tunnel by reversing the underlying pathophysiological mechanisms.

Our study proves that decompression of tarsal tunnel in diabetic ulcer foot patients leads to improvement in sensation of foot. Resolving Tinel's sign and monofilament test post decompression significantly proved the restoration of neuronal continuity beyond the site of compression. This restoration of protective sensation in diabetic foot will prevent ulceration and infective complications and thereby help avoiding amputations and related morbidity. In view of around 45000 diabetic legs that are amputated every year in India, adoption of this procedure as a prophylactic measure as part of standard of care will definitely result in reduction of foot related complications and amputations in diabetic populations.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES
