Assessment of Preprocedure Difference in the Supine and Dependent Transcutaneous Tissue Oxygenation to Prognosticate Pain Relief, Following Chemical Lumbar Sympathectomy for Critical Limb Ischemia in Thromboangiitis Obliterans

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Abstract

Context: Chemical lumbar sympathectomy (CLS) is performed in thromboangiitis obliterans (TAO) for relief of rest pain. Interruption of sympathetic innervation causes improvement in tissue oxygenation and is reflected in transcutaneous partial pressure of oxygen (TcPo2). There is very little data available to guide patient selection for CLS. Aims: The primary objective was to assess if preprocedure difference in TcPo2 measured in supine and dependent positions on the foot correlated with relief of rest pain. The secondary objectives were to measure postprocedure TcPo2 on the foot and assess preprocedure predictors of rest pain relief following sympathectomy. Settings and Design: Prospective observational study in patients undergoing CLS for TAO carried out from October 2009 to August 2014 in the Vascular Surgery Unit at Christian Medical College, Vellore. Subjects and Methods: Patients diagnosed to have TAO based on Shionoya’s criteria, who were planned for a sympathectomy for rest pain, were included in the study. Statistical Analysis Used: Outcomes were compared using Mann–Whitney U-test and Wilcoxon signed-rank test. Data were entered and analyzed using SPSS 16.0 software. Results: There was a significant reduction of pain after sympathectomy (P < 0.001). There was a significant increase in TcPo2, supine to dependent position, independently before and after sympathectomy (P < 0.001). However, preprocedure difference in supine and dependent TcPo2 did not correlate with the change in pain scores following sympathectomy. Conclusions: CLS provides relief of rest pain in TAO by improving tissue oxygenation. Preprocedure difference in the supine and dependent TcPo2 did not correlate with pain relief.

Keywords: Buerger’s disease, lumbar sympathectomy, rest pain, thromboangiitis obliterans, transcutaneous oxygen saturation

INTRODUCTION

Thromboangiitis obliterans (TAO) is an inflammatory, obliterative medium, and small-vessel arthritis which often involves the surrounding nerves by ischemic neuritis. Of who patients present with critical ischemia and tissue loss, although bypass is possible in a few, majority lack revascularization options.[1] The mainstay of treatment is smoking cessation. Chemical lumbar sympathectomy (CLS) is used for relief of rest pain and may promote ulcer healing in nonreconstructable arterial disease, Raynaud’s and complex regional pain syndromes.[2,3] Although exact mechanism is not well understood, CLS alleviates neuropathic, nociceptive, and ischemic pain by different modes.[4,5] Microcirculatory changes and vasodilation due to interruption of sympathetic denervation are known to occur. The degree and duration of relief obtained may vary. While this aspect has been studied using TcPo2 and laser Doppler flowmetry for atherosclerotic disease; data

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on critical limb ischemia in Buerger’s disease is limited.\textsuperscript{[46]} In TAO, surgical (open and laparoscopic) sympathectomy or CLS promote ulcer healing and provide short-term pain relief.\textsuperscript{[7]} However, there are no guidelines to guide patient selection for CLS or prognosticate outcome.\textsuperscript{[8,9]}

Transcutaneous partial pressure of oxygen (\(\text{TcPo}_2\)) is a noninvasive test that measures skin oxygenation, the microcirculatory component of circulation. Values <40 mmHg can be used to diagnose ischemia and prognosticate poor wound healing. Change in limb position, exercise, and oxygen inhalation are adjunctive measures to help prognosticate wound healing in patients with low values.\textsuperscript{[10-12]}

Johnson \textit{et al.} showed that in patients with nonreconstructable peripheral arterial disease, a preoperative increase in \(\text{TcPO}_2\) by at least 20 mmHg in response to dependency predicted a favorable response to sympathectomy measured by ulcer healing.\textsuperscript{[13]} Tissue oxygen levels do not change significantly in response to foot dependency in the absence of arterial insufficiency, indicating the role of collaterals. Oh \textit{et al.}\textsuperscript{[14]} reported that the increase in tissue oxygen levels with dependency can occur only if there is an increase in hydrostatic pressure, which results in increased capillary perfusion pressure. Hydrostatic pressure can only increase if collateral vessels are present in sufficient numbers and caliber, to increase tissue perfusion in response to changes in leg position. Increase in tissue oxygen levels associated with dependency is believed to favor clinical improvements, ulcer healing, relieve pain, and avoid amputations. Oh \textit{et al.} showed a correlation between poor increase in \(\text{TcPO}_2\) in response to dependency with poor response to vascular reconstructive procedures indicating poorer collaterals, suggesting that there may be a similar relationship between \(\text{TcPO}_2\) and sympathectomy response.\textsuperscript{[14]}

The primary objective of our study was to assess if the preprocedure difference in the \(\text{TcPO}_2\) measured in the supine and dependent position on the foot correlated with and could predict the outcome, relief of rest pain, following sympathectomy. The secondary objectives were to measure the postprocedure \(\text{TcPO}_2\) on the foot in supine and dependent positions, to look for other preprocedure predictors of rest pain relief following sympathectomy and follow-up outcomes following sympathectomy.

**SUBJECTS AND METHODS**

This was a prospective observational study in patients undergoing CLS for TAO carried out from October 2009 to August 2014 in the Vascular Surgery unit at a tertiary care center in South India. Using baseline data from the study quoted by Johnson \textit{et al.},\textsuperscript{[13]} with an \(r = 0.8, \alpha = 5\%\), and a power of 90\% for a one-sided test, the calculated sample size was 36. The sample size was calculated using nMaster 2.0. Sample size calculation software (Department of Biostatistics, CMC, Vellore).

Patients diagnosed to have TAO based on Shionoya criteria were included in the study.\textsuperscript{[15]} They were asked to grade their pain on the symptomatic leg by a standardized visual analog. Patients with rest pain were admitted for pain relief and started on the WHO step ladder pattern of pain control. Color Doppler was performed on the affected limb as primary imaging and if required computed tomography (CT) angiogram to confirm the nonreconstructable nature of the disease. Patients with wet gangrene in whom amputation was necessary at presentation were excluded from the study.

Patients were asked to grade their pain on the symptomatic leg by a standardized visual analog scale: “0” for no pain and “10” for the worst imaginable pain that was recorded by the primary investigator. Presympathectomy pain assessment was done the day before the procedure in the ward and postsympathectomy assessment was done twice, initially 8–12 h after the procedure in the ward and later at the first outpatient department (OPD) visit between 7 and 10 days. Transcutaneous oxygen saturation measurement was performed using a radiometer Copenhagen TCM 4 series (Radiometer Medical Aps DK-2700 Bronshoj) that uses a Clark’s type electrode. Preprocedure \(\text{TcPO}_2\) was measured over the skin of the forefoot of the affected limb first in the supine position and 15 min later in the dependent position. All patients included in the study underwent a CT-guided CLS with 10 ml of 10\% phenol injected to obliterate the lumbar sympathetic chain on the side of the affected limb using the retroperitoneal approach. Following the procedure, they were monitored in the ward for pain relief and possible complications. \(\text{TcPo}_2\) measurements were repeated 24-h postsympathectomy. Patients who complained of persistent pain, severe pain, worsening of the pain or no relief of rest pain were started on oral analgesics. Patients were discharged only when they were comfortably ambulant.

The preprocedure difference in the \(\text{TcPO}_2\) in the supine and dependent positions was correlated to pain relief postsympathectomy. Association between continuous variables was tested using Pearson correlation coefficient and Spearman correlation coefficient for nonnormal data. The mean differences of continuous variables according to categorical variables were done using \(t\)-test or ANOVA. The data that did not follow normal distribution were analyzed by the Kruskal–Wallis test and Mann–Whitney test. Paired observations were compared using the Wilcoxon signed-rank test. Data were entered and analyzed using Data was entered and analyzed using IBM SPSS statistics Version 21.

The study protocol was approved by the Institutional Review Board, ethics committee, and all the patients were enrolled following informed consent. Multivariate regression analysis was performed to identify prognostic factors for pain relief following sympathectomy using fall in pain relief as graded from the OPD visit.

**RESULTS**

All the 36 patients with TAO in this study were male. The mean (standard deviation [SD]) of age at presentation was 39.4 (8.0) years; the mean (SD) duration of tobacco use was 17.7 (8.0) years. The most common form of tobacco used was smoking.
bidi (58%) (thin Indian cigarette filled with tobacco flake and wrapped in tendu leaf). The mean (SD) duration of claudication and rest pain was 541 (752) and 58 (53) days, respectively. About 25% of patients continued to smoke. The distribution of the demographic profile, behaviors, symptoms, and outcomes are illustrated in Table 1. Table 2 presents the mean (SD) of pre- and post-sympathectomy TcPo2, pre- and post-sympathectomy pain scores, and the differences between them.

The mean (SD) of presympathectomy supine TcPo2 was 24.5 (14.2) mmHg and dependent TcPo2 was 47.2 (17.1) mmHg.

### Table 1: Distribution baseline, behaviors, symptoms, and outcomes

| Variables                        | Mean (SD)       |
|----------------------------------|-----------------|
| Age (years), mean (SD)           | 39.4 (8.3)      |
| Number of years smoked, mean (SD)| 17.7 (8.0)      |
| Duration of claudication (days), mean (SD) | 541.2 (752)  |
| Duration of rest pain (days), mean (SD) | 58.4 (53.1)   |
| Duration before next intervention (days), mean (SD) | 289.6 (383.2)  |
| If patients were still using tobacco, n (%) |                    |
| Still smoking/chewing tobacco    | 9 (25)          |
| Quit smoking/chewing tobacco     | 27 (75)         |
| Type of tobacco used, n (%)      |                  |
| Cigarette                        | 9 (25)          |
| Beedi                            | 21 (58)         |
| Both                             | 4 (11)          |
| Chews tobacco                    | 2 (6)           |
| Presentation of symptoms, n (%)  |                  |
| Hyperpigmentation with trophic changes | 5 (14)          |
| Dry gangrene                     | 17 (47)         |
| Nonhealing ulcers                | 14 (39)         |
| Outcome on follow-up (31/36), n (%) |              |
| Alprostadil                      | 8 (24)          |
| Debridement                      | 3 (9)           |
| TMT                              | 4 (13)          |
| BKA                              | 3 (9)           |
| Followed up but no intervention required (two patients had two interventions) | 15 (45)        |

SD: Standard deviation, TMT: Trans-metatarsal amputation, BKA: Below knee amputation

### Table 2: Mean (standard deviation) of presympathectomy and pain scores

| Variables                                      | Mean (SD)       |
|-----------------------------------------------|-----------------|
| Presympathectomy supine TcPo2                 | 24.5 (14.2)     |
| Presympathectomy-dependent TcPo2              | 47.2 (17.1)     |
| Presympathectomy difference in TcPo2          | 22.8 (10.8)     |
| Postsympathectomy supine TcPo2               | 31.1 (17.7)     |
| Postsympathectomy-dependent TcPo2             | 53.4 (15.7)     |
| Postsympathectomy difference                  | 22.8 (12.0)     |
| Pain-graded presympathectomy                  | 8.8 (1.0)       |
| Pain-graded postsympathectomy in the ward     | 4.2 (1.3)       |
| Pain-graded postsympathectomy at the first OPD visit | 3.9 (1.3) |

SD: Standard deviation, OPD: Outpatient department, TcPo2: Transcutaneous partial pressure of oxygen

The mean (SD) presympathectomy difference between supine and dependent TcPo2 was 22.8 (10.8) mmHg. The mean (SD) of postsympathectomy supine TcPo2 was 31.1 (17.7) mmHg and dependent TcPo2 was 53.4 (15.7) mmHg with a mean (SD) postsympathectomy difference of 22.8 (12.0). There was an increase in mean differences (supine-dependent TcPo2) after a sympathectomy; however, it did not reach statistical significance ($P = 0.40$).

The mean (SD) pain score before a sympathectomy was 8.8 (1.0). The mean (SD) pain scores immediately following a sympathectomy and at the first OPD visits were 4.2 (1.3) and 3.9 (1.3), respectively. The fall in pain immediately post-sympathectomy ($P < 0.001$) and at the first OPD visit ($P < 0.001$) was statistically significant. The increase in presympathectomy TcPo2 did not correlate with pain relief following a sympathectomy ($r = 0.05$, $P = 0.78$) and ($r = 0.05$, $P = 0.77$), respectively, as measured in the ward [Figure 1] and OPD [Figure 2]. Pain scores recorded immediately postsympathectomy correlated with pain scores recorded in the OPD at the patients first visit ($P < 0.001$), which is presented in Figure 3.

Patients who quit smoking had a higher increase in presympathectomy TcPo2 (16.4 vs. 25, $P = 0.03$). Patients who smoked for longer duration had a smaller increase in supine to dependent TcPo2 presympathectomy ($P = 0.02$) and postsympathectomy ($P = 0.02$) that were statistically significant. Five patients were lost to follow-up. Of the 31 that followed, 3 (9%) required below-knee amputations, 15 (46%) required other minor interventions including alprostadil infusions, transmetatarsal amputations, and debridement. Two patients required more than one intervention. No patient was offered a repeat sympathectomy. Mean duration till the next intervention for rest pain or a nonhealing ulcer was 287 days. Fifteen (49%) of patients following a sympathectomy on follow-up did not require a further intervention and a sympathectomy was adequate for wound healing and relief of rest pain. All patients who were still smoking required some form of

![Figure 1: Presympathectomy difference in TcPo2 with pain difference at the ward](image-url)
intervention for recurrent symptoms at follow-up ($P = 0.12$). Of the patients who followed up and required reintervention, all patients who were still smoking ($n = 8$) required surgical intervention (amputation or debridement), against 38% of patients requiring amputations in the group that had quit smoking ($n = 27$) ($P = 0.08$) indicating disease progression in smokers, the former group.

On simple linear regression analysis to assess predictors of pain relief following a sympathectomy, patients presenting with rest pain without tissue loss (Rutherford Grade IV) had better pain relief ($P = 0.028$) than those with tissue loss. Patients who had quit smoking had better pain relief ($P = 0.05$), postsympathectomy. On multivariate regression analysis for predictors of pain relief, only rest pain without tissue loss emerged as a significant predictor of pain relief ($P = 0.033$) following a CLS. Many other variables were tested, but none emerged as independent predictors of pain relief following a CLS. These included age, pre- and post-sympathectomy TcPO$_2$ values, if patients were still smoking or had quit smoking, type of tobacco smoked, number of years smoked, duration of claudication pain, rest pain and pain grading at various stages in the study.

**Discussion**

Patients with Buerger’s disease are known to have occlusion of the medium and small vessels and opening up of the vasa vasorum – tree root, spider leg, and corkscrew collaterals. Obliterative endarteritis of the small vessels produces a state of tissue ischemia which is difficult to treat. Although CLS has been used clinically with relief of rest pain in this patient group, there are no studies to demonstrate an objective basis of this effect. The physiological explanation for the benefit of lumbar sympathectomy is thought to be by increasing blood flow through collaterals with vascular pliability. This increase in blood flow occurs as a result of a marked decrease in peripheral resistance due to the opening of arteriovenous anastomosis. The alternate basis for rest pain relief after lumbar sympathectomy has been explained by the division of afferent pain fibers traveling in the lumbar sympathetic chain. Data on the use of CLS in Buerger’s disease as against atherosclerosis is sparse. The role of CLS is often questioned. Numerous clinical studies have advocated its use with local tissue management in selected patients with localized pregangrenous lesions, superficial ischemic ulcers where arterial reconstruction is not feasible or for those who refuse major surgery. It provides short-term pain relief and ulcer healing in a majority. Complications rates are low. This is a “last ditch” effort in considered before major amputation.

We assessed the predictive value of the difference in presympathectomy TcPO$_2$ toward pain relief following a sympathectomy and followed them up for outcomes. Sasaki et al. studied a total of 825 patients with Buerger’s disease. The mean age in their series was 50.8 ± 0.4 years. The mean age of our patient group was 39.4 years with bidi being the most common type of tobacco smoked (58%). This high incidence of TAO in India and the developing world strongly suggests the relationship between unprocessed tobacco with high nicotine and tar content and TAO. TAO continues to be a prevalent disease in India and the developing Asian countries, especially among the lower socioeconomic groups where bidi smoking is popular.

Pain is the most common presenting symptom in patients with Buerger’s disease which is usually out of proportion to the physical findings. All patients included in our study had rest pain. The second common presentation was dry gangrene (47%). The studies have demonstrated 46% of patients have lower extremity ischemic ulceration at the time of diagnosis with amputation rates ranging from 20% to 30%. Habitual use of tobacco has been clearly implicated in disease progression in patients with Buerger’s disease. We noted that with increase in the number of years of tobacco use in any form, there was a smaller increase in TcPO$_2$ level with dependency, both before ($P = 0.026$) and after a sympathectomy ($P = 0.026$).
Rates of pain relief in Buerger’s disease after sympathectomy vary from 26% to 87%, but some still consider it unpredictable and speculative. In our study, all patients following a sympathectomy had pain relief, rate of pain relief being 52.7% immediately following a sympathectomy and 56% at the first visit which was within 10 days following a sympathectomy, reiterating that, sympathectomy provides good short-term pain relief.

Johnson et al. showed that an increase in TcPo2 by 20 mmHg before sympathectomy with dependency predicted a favourable response to sympathectomy measured in their study by wound healing and the avoidance of amputation. In our patient group, presympathectomy TcPo2 could not predict pain relief following a sympathectomy. The mean increase in presympathectomy TcPo2 was 22.8. The mean increase in TcPo2 in the above mean group was 32.5 and in the below mean group was 14.63. Patients in the above mean group had lower pain scores and greater pain relief following a sympathectomy, but it was not statistically significant.

Presympathectomy supine and dependent TcPo2 values correlated with postsympathectomy supine and dependent TcPo2 values respectively ($P < 0.001$ - 0.004). Patients with higher presympathectomy TcPo2 (supine and dependent TcPo2) values had proportionately higher post sympathectomy TcPo2 (supine and dependent) values, respectively. Patients with greater increases in TcPo2 have a greater number of collaterals, and hence a greater response to tendency, which explains the proportionate increase in pre- and postsympathectomy TcPo2. On simple linear regression analysis, rest pain with no tissue loss ($P = 0.028$) and cessation of smoking emerged as independent predictors of pain relief ($P = 0.028$) for a sympathectomy; whereas, only the former emerged an independent predictor on multivariate regression analysis ($P = 0.0033$).

Bidis are the more commonly smoked cheaper tobacco. They are made of unprocessed and unrefined tobacco, and it is presumed that they have larger amounts of various substances that initiate pathological changes that lead to TAO. Bidi needs to be puffed more frequently to keep them burning compared to cigarettes, the rates of puffs being 4.75 per minute to 2 per minute, respectively. This would directly increase the amount of tar and nicotine intake in bidi smokers that are probable inciting factors for TAO. Multivariate analysis of the types of tobacco smoked showed that patients who smoked both bidi and cigarette had a slightly earlier onset of the disease (mean age = 36.00 years) though this did not reach statistical significance ($P = 0.426$). Subset analysis revealed no further statistical differences.

Cessation of tobacco use in any form is the only means of halting disease progression and is necessary for success of any intervention. Limb salvage rates are also better in patients who stop smoking following vascular bypass procedures with amputations rates being significantly higher in patients who continue to smoke (pp). In our study, one-fourth of the patients continued to smoke. 38% of patients on follow-up required surgical intervention and all patients who continued to smoke required surgical interventions (amputation or debridement).

CLS has a role in patients with vascular disease. Short- and long-term efficacy is acceptable. Although pain relief did not correlate with presympathectomy difference in TcPo2, there was a postsympathectomy increase in TcPo2 in all patients which is an objective evidence for the efficacy of CLS in this patient group. Rest pain without ulceration emerged an independent predictor of pain relief following a sympathectomy. This helps to elucidate the role of CLS and its physiological effect in relation to the state of the peripheral circulation and predict the outcome.

In our study, patients with rest pain without tissue loss (Rutherford IV or Fontaine III) had better pain relief than those with tissue loss ($P = 0.033$) and on multivariate regression analysis looking for independent predictors of pain relief following a sympathectomy, this emerged as an independent predictor.

**Limitations**
We aimed to assess only short pain relief following a sympathectomy and follow-up of outcomes of treatment as a secondary objective was included during the study. Longer follow-up periods for pain might have increased its relevance as would have assessment of wound healing in the study.

**Conclusions**
CLS provides good short-term relief of rest pain in TAO by increasing tissue oxygenation. The preprocedure difference in the supine and dependent TcPo2 did not correlate with pain relief; patients with rest pain without tissue loss (Rutherford IV or Fontaine III) are better candidates for a sympathectomy.

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**Conflicts of interest**
There are no conflicts of interest.

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