

STUDY OF PROSTAGLANDINS E1 THERAPY IN LIMB ISCHEMIA IN TELANGANA POPULATION

Siva Mandadapu¹, Thakur Vimal Singh¹, Sanjay Namadar²¹Associate Professor, Department of Surgery, Dr. Patnam Mahender Reddy Institute of Medical Sciences & Hospital, Chevella, Telangana, India²Professor, Department of Surgery, Dr. Patnam Mahender Reddy Institute of Medical Sciences & Hospital, Chevella, Telangana, India

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Corresponding Author:

Dr. Sanjay Namadar,

Email: drsanjaynamdar23@gmail.com

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**Abstract**

Background: Peripheral arterial disease has a significant impact on quality of life, pain, fear of limb loss, increased inactivity, and poor lifestyle. PGE are potent vasodilators with anti-platelet action, which promotes healthy survival without amputation. **Materials and Methods:** 50 (fifty) patients aged between 30 to 65 were studied. 25 patients are classified as group A (20 having Buerger's disease and 5 having Raynaud's disease), and 25 as group B (having extensive peripheral atherosclerosis due to long-standing diabetes). Every patient underwent hematological investigations, i.e., Hb%, CBC, BT, CT, RBS, lipid profile LFT, and renal function test cardiac profile such as ECG, 2D-Echo for arterial status Doppler study, CT angiography PGE, and infused by adding in normal saline, repeated after 3 weeks for three times. The pain scores used in the study were Rutherford and Fontaine stages. **Result:** The pain scores before and after the infusion of PGE and therapy were compared in both groups, and both groups had significant relief. Both groups had the same number of cycles and were relieved of pain. **Conclusion:** PGE infusion in critical limb ischemia has significant relief due to profuse vascularity in healing ulcers and prevention of amputation of gangrenous limbs or toes.

INTRODUCTION

Prostaglandins (PGS) were discovered in 1935 as a blood pressure lowering substance from prostate gland secretion. Von Euler found that several fluid and seminal vesicles from the most animate animals, including men, contain a substance that causes contraction of the smooth muscle of the uterus. He named this new substance "Prostaglandin." Since they were originally thought to be secreted by the prostate gland, After 20 years, i.e., in 1957, Bergström and Sjövall discovered the basic chemical structure to be unsaturated fatty acids with 20 carbon atoms, prostacyclin was discovered as a potent inhibitor of platelet function and as a strong vasodilator. The PGE1 and PGE2 have been widely used since 1973 for the treatment of cardio-vascular disease and peripheral vascular disease.^[1] Diffuse peripheral arterial disease, or peripheral occlusive vascular disease (POVD), involving the lower limb, is a debilitating illness with a high incidence of morbidity and mortality.^[2] The very purpose of treating critical limb ischaemia is to relieve claudicating pain and rest pain, heal ulcers, prevent amputation of limbs, improve quality of life, and prolong healthy survival.^[3] Peripheral arterial disease has a significant impact on quality of life, pain, fear of limb loss, increased

inactivity, and poor lifestyle choices such as continued smoking.^[4] Smoking also further debilitates these patients. Hence, an attempt is made to study the usage of PGE1 in patients with peripheral arterial disease, and the outcomes are evaluated.

MATERIALS AND METHODS

50 (fifty) patients aged between 30 to 65 visited the department of surgery at Dr. Patnam Mahender Reddy Institute of Medical Sciences, Chevella, Telangana were studied.

Inclusive Criteria

Patients with peripheral occlusive vascular disease (POVD) not suitable for angioplasty, stenting, or bypass procedures who have not received prostaglandin E1 treatment and patients who gave written consent for treatment were included in the study.

Exclusion Criteria

patients not willing for PGE1 treatment and hypersensitive to PGE1 were excluded from the study.

Method: Out of 50 patients, 20 patients had Buerger's disease, and 5 patients had Raynaud's disease with upper extremities. Involvement is classified as group A. The remaining 25 patients had extensive peripheral atherosclerosis changes due to long-standing diabetes (Group B).

Every patient underwent hematological investigations that included Hb%, CBC, bleeding time, clotting time, blood sugar levels, lipid profile, liver function test and renal function test, cardiac profile such as ECG, and 2D echo for arterial status, arterial Doppler study, and CT angiography.

All patients showed a very poor run-off with a total occlusion of all three vessels: dorsalis pedis artery, posterior tibial, and anterior tibial, slightly distally to trifurcation. Five patients with Berger's disease had additional involvement of the popliteal artery. Three patients had Rayneurds disease with dry gangrene of the tips of the fingers of the upper extremities. No patient was suitable for by-pass surgery because, on selective CT arteriography, no adequate distal vessels were identified. All the patients suffered from significant rest pain, and one type of amputation could be speculated for them as the only potential treatment of choice.

The pain scores used in the study

Rutherford stage	Fontain stage	Description
0	I	Asymptomatic
1	II a	Mild claudication
2	II b	Moderate claudication
3	II b	Severe claudication
4	III a	Rest pain
5	III b	Ischemic ulcer digits of foot
6	IV	Severe ischemic ulcer or gangrene (major tissue loss)

Duration of study was June 2023 to January 2024

All the patients admitted to intravenous prostaglandin E1 (PGE1) therapy were given one ampoule of 500 micrograms in 1 ml for one cycle. On average, 50 kg of adult patients received 1 ml of solution in a syringe and diluted it to 5 ml with distilled water, so each ml contained 100 micrograms of PGE1 and was added to 500 ml of normal saline. and infused slowly for 8 (eight) hours in a day for five days. The same cycle was repeated after 2 weeks. Three such cycles were administered to the patients.

Vital signs for fever and bradycardia, BP for hypotension and ECG

Respiratory rate and respiratory depression or apnea
Hypersensitivity of PGET

Statistical analysis: comparison of pain scores before and after PGE1 infusion therapy, relieved pain, and cycles of PGE1 therapy were studied. The statistical analysis was carried out in SPSS software. The ratio of males and females was 2:1.

RESULTS

[Table 1] Comparison of pain scores of patients before and after PGE1 infusion therapy Fontain score III-IV-25, II-25 After in group A. In group B, III-IV 25 before - II 25 after infusion

Rutherford's score in group A-5, after infusions 1-2 (13), 3 (12),

In group B, 4 before infusion score 1-2 (25), after infusion group A

Wong Baker Faces pain: group A Before infusion 8-10, after infusion pain 2-4 (13), 4-6 (12). In group B, the score was 8-10 (25), before the infusion, and 2-4 (25) after the infusion

[Table 2] Study of the number of patients relieved of pain with cycles: 13 group A, 13 group B, cycle one 7 group A, 7 group B in cycle two, 5 group A, 5 group B in cycle three.

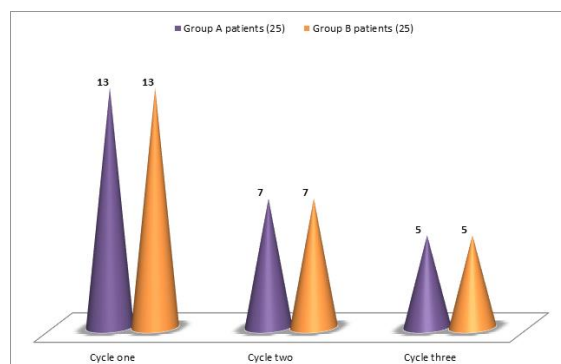


Figure 1: Study of Number patients relieved of pain with cycles

Table 1: Comparison of pain scores of patients before and after PGE1 infusion therapy

Pain score system	Group (A) Before infusion (25)	Group (A) After infusion (25)	Group (B) Before infusion (25)	Group (B) After infusion (25)
Fontain score	III-IV (25)	II b (25)	III-IV (25)	II b (25)
Rutherford Buckler score	5	1.2 (13) 3 (12)	4	1.2 (25)
Wong Baker Faces pain	8-10	2-4 (13) 4-6 (12)	8-10	2-4 (25)

Table 2: Study of Number patients relieved of pain with cycles

Number of cycle	Group A patients (25)	Group B patients (25)
Cycle one	13	13
Cycle two	7	7
Cycle three	5	5

DISCUSSION

Present study of prostaglandin E1 therapy in limb ischemia in the Telangana population. Various pain scores were compared before and after the infusion of prostaglandin R1 therapy. Fontain score III-IV (25), before infusion II-b (25) after infusion in group A patients, III-IV (25) before infusion II-b after infusion in group. Rushur-Ford Bucker score: 5 before infusion: 1-2 (13), 3 (12), after infusion in group A, and 4 before infusion: 1-2 (25) after infusion in group B patients. Wong Baker faces pain scores of 8–10 before infusion, 2-4 (13), and 4-6 (12) patients after infusion in group A; 8–10 score before infusion, 2-4 score (25), after infusion [Table 1]. In the study of pain relief with patients: 13 group A, 13 group B in cycle 2, 5 group A, 5 group B in cycle 3 [Table 2]. These findings are more or less in agreement with previous studies.^[5-7]

PGs are potent vasoactive agents with a wide variety of other actions that depend on the species and organ tested, and PG used. They are synthesized from 20 carbon-polyunsaturated fatty acids that contain three, four, or five double bonds. These fatty acids are present in the phosphor lipids of the cell membranes of all mammalian tissues.^[8] PGE1 has been shown to affect protein kinase C, calcium movement, and adenylate cyclase, yielding a multitude of physiological effects. PGE has been reported to benefit patients with significant peripheral vascular disease and limb-threatening ischemia.^[9]

Critical limb ischemia is a manifestation of peripheral artery disease, which describes patients with typical chronic ischemic rest pain, ischemic skin ulcers, or gangrene. There will be a presence of recurring rest pain that persists for more than two weeks, requiring regular analgesics, and ulceration or gangrene of the foot or toes. This criteria corresponds to stages 3 to 4 of the Fontaine classification of POCD.^[10] There are many different regimens with different durations of the injections, including PGE, infusion therapy, as reported in the literature,^[11] but ideal medication for 6 months and follow-up at regular intervals for 6 months to relieve pain, heal ulcers, and prevent amputation.

CONCLUSION

The present study of prostaglandin E1 therapy in limb ischemia in Telangana population proved that prostaglandins are potent vasoactive agents with a wide variety of actions, including vasodilation, fibrinolysis, and inhibition of platelet aggregation. It is beneficial for limb-threatening ischemia and non-healing ulcers. The present study demands that such clinical trials be conducted on a large number of patients in a hi-tech hospital where the latest techniques are available to confirm the present findings and results because the mechanism of action and pharmacokinetics of PGE1 are partially understood.

Limitation of study: Owing to the territory location of the research center, the small number of patients, and the lack of latest techniques, we have limited findings and results.

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