Section: General Surgery

Original Research Article

COMPARATIVE STUDY ON THE ROLE OF RETROGRADE VENOUS PERFUSION THERAPY AND SYSTEMIC ANTIBIOTIC THERAPY IN THE TREATMENT OF DIABETIC ULCER FOOT

E. Elamaran[1], M .Arulrajkumar[1], D. Gowthin[2], V.T. Sathish[1]

[1]Assistant Professor, Department of General Surgery, Madurai Medical College, Tamilnadu, India
[2]Senior Resident, Department of Plastic and Reconstructive Surgery, Tirunelveli Medical College, Tamilnadu, India

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Corresponding Author:
Dr. V.T.Sathish,
Email: vtsathish2003@gmail.com

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Abstract

Background: Diabetic foot is one of the most prominent and serious consequences of diabetes and is characterised by ulceration in the lower limbs of diabetic patients with neuropathy. This study aimed to compare the effectiveness of retrograde venous perfusion therapy with that of systemic antibiotic therapy in the treatment of diabetic foot ulcers. **Materials and Methods:** This prospective analytical study was conducted at Govt Rajaji Hospital, Madurai, between January 2018 and January 2019, in 100 patients (study group-50, control group-50) diagnosed with diabetic foot ulcers. Patient history included age and symptoms, and assessments were performed based on Wagner's classification of ulcers of grades 0, 1, and 2 of both sexes presenting with diabetic foot. **Result:** Of the 100 patients, the majority were between 40-69 years old. The mean age at systemic antibiotic therapy was 55.8%, whereas that at RVP therapy was 54.54%. Systemic antibiotic therapy had a higher rate of grade 1 patients, while RVP therapy had a higher rate of grade 2 patients. There were no significant differences in the mean ulcer surface area between the groups (p=0.302). There was a significant difference in granulation tissue formation, SSG% uptake (mean graft uptake), and length of hospital stay between the groups (p<0.001). Wound improvement in systemic antibiotic therapy was only 90%, whereas in RVP therapy, it was approximately 96%. **Conclusion:** Compared with systemic antibiotics, retrograde venous therapy worked more effectively, showing significant advantages such as reduced ulcers, improved granulation, increased absorption of SSG, shorter hospital stay, and fewer amputations.

INTRODUCTION

The world is currently facing a pandemic of Diabetes Mellitus, especially type 2 or adult-onset diabetes mellitus. The prevalence of diabetes is high; by 2030, there will be 366 million diabetics worldwide due to longer life expectancy and changes in dietary habits.[1-3] In the future, India will have the largest number of diabetics. Most patients with diabetes are approximately 35-45 years of age. Approximately 15% of these patients presented with foot problems. Moreover, 1% of these patients may lose a limb due to foot pathology.[4-6] However, in Indian patients, a neuropathic-infective foot is more common than an ischaemic-infective foot.[7] The ischaemic infective foot is more difficult to treat than neuropathic ulcers. Sadly, as of today, regular foot examinations and monitoring are not routinely done. The routine practice is "No complaints- No examination". However, when a patient complains of some symptoms, the pathology is usually advanced, and the foot is mostly beyond salvage. Early detection and intervention of warning signals in the foot can salvage the limb to a greater extent.[8] Diabetic foot is a group of syndromes characterised by neuropathy, ischaemia, and infection, leading to tissue breakdown, which results in increased morbidity and possible amputation. The foot of a diabetic patient has the potential risk of pathologic consequences, including infection, ulceration or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease and or metabolic complications of diabetes in the lower limb.[9,10]

This study aimed to investigate the effects and advantages of retrograde venous perfusion therapy over systemic antibiotic therapy in treating diabetic foot ulcers in Madurai.

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MATERIALS AND METHODS

This prospective analytical study was conducted on 100 patients with foot ulcers at Govt Rajaji Hospital, Madurai, between January 2018 and January 2019.

Inclusion Criteria

Patients more than 25 years of age in both sexes presenting with diabetic ulcers consented, and Wagner's classification ulcers of grades 0, 1, and 2 were included.

Exclusion Criteria

Patients <25 years of age, osteomyelitis, patients who did not consent to inclusion, and arterial and venous Doppler studies with abnormal findings were excluded.

One hundred patients were divided into equal and comparable groups. Patients who underwent retrograde venous perfusion therapy were classified under study, and those who underwent systemic antibiotic therapy with dressing were classified as controls.

The affected area was assessed, and photographs were taken. Pus culture and sensitivity were determined based on the antibiotics used. RVP with IV antibiotics (for example, cefotaxime (1 g), gentamycin (80 mg), heparin (2500 units), and 2% lignocaine with adrenaline 0.4 ml in 100 ml normal saline) should be administered intravenously to the affected limb daily for up to 6 days.

Photographs were taken, six doses were given after one week, and a photograph of the affected limb was taken. If required, another course of the same therapy was administered after six weeks, and sensitivity to lignocaine was assessed. The patient was placed in the supine position. The affected limb was elevated for 5 min to empty the veins, and then a sphygmomanometer cuff was applied to the thigh. The pressure applied was approximately 20 mmHg below the systolic pressure, which affects the venous flow but maintains the arterial flow to the distal part. The combination of drugs was infused retrogradely at an appropriate pressure. After 20 minutes, the cuff was released. The ulcer surface area was measured twice using butter paper. Graft uptake was assessed at the end of POD 5 as a percentage of ulcer surface area. The patient's quality of life in both groups was assessed by the assessment of total hospital stay as the number of days of hospital admission. The main postoperative parameters noted in both groups were wound size, contracture, pain, and infection. The outcome was based on a reduction in wound size, amount of exudate, and healing time, and those derived from conventional systemic antibiotic and dressing methods.

RESULTS

Among the 100 patients, the majority of the 100 patients were within the age group of 40-69 years in both groups. In the systemic antibiotic therapy group, 33 patients were grade 1, and 17 were grade 2. In the RVP therapy group, 18 patients had grade 1 and 42 had grade 2 [Table 1].

The mean age of the systemic antibiotic therapy group was 55.8, and that of the RVP therapy group was 54.54. There was no significant difference in age between the groups (p=0.565). The mean ulcer surface area was 38.5489±5.4668 cm2 with RVP Therapy and 40.5102±3.1418 cm2 with RVP therapy. The groups showed no significant differences in the ulcer surface area (p=0.302).

The mean granulation tissue formation in the systemic antibiotic therapy group was 35.162 cm2 ± 7.348 (SD) of the total ulcer surface area, whereas that in the RVP therapy group was 39.7878 ± 2.894 (SD). There was a significant difference in granulation tissue formation between groups (p<0.001).

The mean graft uptake in the study and control groups was 86.43% ± 8.29 (SD) and 57.4% ± 21.63 (SD). There was a significant difference in SSG% uptake between the groups (p<0.001). The mean hospital stay in the control group was 31.8 ± 4.63 (SD) days, and that in the study group was 27.56 ± 2.68 (SD) days. There was a significant difference in the length of hospital stay between groups (p<0.001) [Table 2]. Wound improvement in systemic antibiotic therapy was only 90%, whereas in RVP therapy, it was approximately 96%. The percentage of amputation in RVP therapy was zero compared with that in systemic antibiotic therapy (6%) [Table 3]. The postoperative wound size, contracture, pain, and infection were lower in the study group than in the control group.

Table 1: Demographic data of the study

		Systemic antibiotic therapy	RVP therapy
Age	25-39	4	4
	40-54	26	20
	55-69	23	21
	70-84	7	5
Wagner's grading distribution	Grade 1	33	17
	Grade 2	18	42

Table 2: Comparison of parameters between groups

	Systemic antibiotic therapy	RVP therapy	P value
Age	55.8±10.836	54.54±0.576	0.565
Ulcer surface Area	38.54±5.466	40.51±3.141	0.302
Amount of granulation	35.16±7.348	39.79±4.150	<0.001
SSG% uptake	57.4±21.637	86.43±8.292	<0.001
Hospitalisation	31.8±4.633	27.56±2.682	<0.001

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Table 3: Distribution of wound improvement and amputation %

		Systemic antibiotic therapy	RVP therapy
Wound improvement	Optimal	45	5
	Suboptimal	48	2
Amputation %	SSG	45	48
	Suboptimal wound	5	2
	Amputation	3	Nil

DISCUSSION

Diabetic foot ulcers (DFUs) are a serious and challenging complication of diabetes mellitus, often leading to significant morbidity and potential amputations if not managed effectively.[11] Typically situated on the underside of the foot, a foot ulcer can lead to hospitalisation in six per cent of cases, primarily due to infection or complications related to the ulcer.[12] RVPT is a novel therapeutic approach focused on improving blood perfusion in the affected limb by targeting the venous system. Concurrently, systemic antibiotic therapy has been a cornerstone in managing DFUs, addressing the infectious component that often accompanies these wounds.[13]

In our study, the age groups of both the study and control groups were between 40 and 69 years, and the mean ages of both groups (systemic antibiotic therapy and RVP) were 55.8 and 54.54, respectively. Similarly, various studies reported no significant difference in age and gender between the groups.[14-16]

In our study, the mean ulcer surface area was higher in the RVP group than in the systemic antibiotic therapy group. Still, the surface area had no statistically significant differences (p=0.302). Wang et al. found no significant differences in the size or location of the ulcers between the groups.[14] Larijani et al. also reported an insignificant difference in the surface area of ulcers between the treatment and control groups.[17]

In our study, the mean granulation tissue formation in the systemic antibiotic therapy group was 35.162 cm2 ± 7.348 (SD) of the total ulcer surface area, whereas that in the RVP therapy group was 39.7878 ± 2.894 (SD), showing a significant difference between the groups (p<0.001). The mean graft uptake was higher in the study group, which was 86.43% ± 8.29 (SD), and in the control group was 57.4% ± 21.63 (SD). A study by Jayalal et al. reported a significant difference in the mean granulation tissue formation between the study and the control group.[16] Similarly, Tauro et al. found that the average rate of granulation tissue formation in the study group was 87.94% ± 7.33 (SD) of the total ulcer surface area. In contrast, in the control group, it was 74.64% ± 8.04 (SD) of the total ulcer surface area, which is a significant difference (p<0.001). The average graft takeup in the study group was 92.31% ± 3.94 (SD), while in the control group, it was 86.15% ± 6.93 (SD). This difference is statistically significant, with a p-value of <0.001.[17]

In our study, the mean hospital stay was higher in the control group, which was 31.8 ± 4.63 days. The results showed significant differences between the study and control groups (p<0.001). 96% of wound improvement was found in RVP therapy compared to systemic antibiotic therapy. This result was similar to that of the study by Seidel et al., who reported that RVP therapy had seven days of hospitalisation, whereas it was higher in systemic therapy. In contrast to systemic antibiotic therapy, no non-responders were found with RVP therapy.[19] Jayalal et al. reported that patients' hospital stays in the control group were significantly longer than in the study group. While the mean duration of stay for the study group was 19 days, the control group's mean duration of stay was 25 days.[16]

In our study, the percentage of amputation in RVP therapy was zero compared with that in systemic antibiotic therapy (6%). The postoperative wound size, contracture, pain, and infection were lower in the study group than in the control group. A similar study by Seidel et al. reported that no patient had undergone toe amputation with RVP therapy, which was 25% with systemic antibiotic therapy.[20] This study was similar to the study by Jina et al., who reported that gangrene or pre-gangrene was prevented in most patients.[21]

CONCLUSION

In conclusion, retrograde venous therapy has more significant advantages than systemic antibiotic therapy. RVP therapy has demonstrated a significant reduction in ulcer size, improved granulation tissue formation, enhanced SSG uptake, decreased hospital stay duration, and a decreased incidence of amputation.

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