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The Efficacy of Intermittent Controlled Phlebotomy in Reverse Sural Artery Flap Surgery in Terms of Flap Congestion and Flap Survival

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ABSTRACT

Objectives: To determine the efficacy of intermittent controlled phlebotomy in reverse sural artery flap surgery in terms of flap congestion and flap survival.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Plastic Surgery, Combined Military Hospital, Rawalpindi Pakistan, from Mar 2021 to Feb 2022.

Methodology: A total of 76 patients with lower limb skin defects requiring reconstruction were included in our study. Patients who suffered from neoplastic disease, those who had active infections or had received previous surgery for the defect were excluded. All patients underwent reverse sural artery flap repair. Patients in Group A received intermittent controlled phlebotomy by inserting 18 Gauge IV cannula in short saphenous vein during initial phase of flap harvest, while those in Group B did not. All patients were followed up for six-weeks post-surgery for the development of complications such as venous congestion.

Results: Our patients had a mean age of 46.32±19.06 years, of whom 43(56.6%) were women. Venous congestion occurred in 2(5.3%) cases with intermittent phlebotomy versus 10(26.3%) without it, (p=0.012). Flap necrosis also occurred at a lower rate: 2(5.2%) versus 8(21.1%) in those without it, (p=0.042). Remaining complications such as surgical site infections, paraesthesias, limitation of mobility and donor site complications had similar incidences across the two groups, (p>0.05).

Conclusion: Cases undergoing intermittent controlled phlebotomy have better outcomes in terms of the occurrence of complications versus those patients who do not receive the intervention.

Keywords: Intermittent Controlled Phlebotomy, Reverse Sural Artery Flap.

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INTRODUCTION

Reconstruction of distal lower limbs skin defects is a real challenge for the plastic surgeon, mainly due to lack of local sources of tissue for reconstruction, and the variability in vascular anatomy and blood flow, thus limiting the value of locally sourced flaps.[1] Surgery is aimed at covering the defect, preserving mobility and sensations, providing a good cosmetic outcome with minimal donor-site morbidity.[2] Consequently, management is carried out with free tissue transfer methods which mitigate some of the aforementioned disadvantages.[3] However, free tissue transfer is not always practical and, as an alternative, the reverse superficial sural artery flap has been advocated in selected patients.[4,5]

This flap is associated with the advantage of having a reliable blood supply without requiring the need for modifying the anatomy of the arterial system of the lower limb but, while it has a low complication rate for the most part, the reverse sural artery flap is associated with significant flap venous congestion.[6,7] This occurs because microsurgical connections are made between the lesser saphenous vein and the venae comitantes of the sural nerve, this system results in the bypassing of the deep venous system, more importantly its valves, resulting in flap congestion.8 Flap congestion leads to an impairment in blood which can culminate in flap necrosis.[8]

Consequent to the aforementioned complications, the need arose to modify the surgical technique to improve outcomes. Specific measures included using a wider pedicle to enhance venous drainage and the use intermittent short saphenous vein phlebotomy to reduce the degree of venous congestion of the flap, which showed encouraging results.[9,10] This study was performed to assess the utility of cannulation with 18G IV cannula soft part and then intermittent phlebotomy with reverse superficial sural artery flap reconstruction of the distal lower limb in an effort to

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determine whether this translated into improved outcomes in terms of flap survival and the decreased occurrence of complications, as well as an improvement in cosmetic outcomes. If these benefits could be substantially demonstrated, then the utility of the reverse sural artery flap would be further strengthened and the procedure would come to represent a substantive tool in the repertoire of the plastic surgeon in the repair of distal lower limb defects.

METHODOLOGY

This was a quasi-experimental study which was conducted from Mar 2021 to Feb 2022 in the Department of Plastic Surgery, Combined Military Hospital, Rawalpindi Pakistan, on 76 consenting patients with skin defects involving the distal leg specially heel area and exposed Achilles tendon requiring repair, selected via non-probability consecutive sampling. Informed consent was obtained from all patients. The WHO sample size calculator was used to calculate the sample size keeping a level of significance (α) of 5%, power of the test (1-β) at 95%, anticipated population proportion 1 (P1) at 70% and anticipated population proportion 2 (P2) at 20%.[11]

Inclusion Criteria: The patients who were aged between 10 to 80 years suffering from a solitary distal leg skin defect due to any cause which required coverage were included in the study.

Exclusion Criteria: The patients who have received previous surgery to repair the aforementioned defect, with an ASA scale of IV or higher, those who have defects over load-bearing areas such as sole of the foot, active defect site infection, had autoimmune or neo-plastic disease or had taken immunomodulatory drugs within the past month were excluded from the study.

All patients were thoroughly evaluated by history and clinical examination on enrollment in the study and were assigned to the treatment group, with both the treatment and the control groups having an equal number of patients. Patients in Group A received intermittent controlled phlebotomy, which was then compared to a historical control of patients who did not receive the procedure and were placed in Group B. General anaesthesia was used for all surgeries and the patient was positioned in the prone or later decubitus position.

Doppler ultrasound was used to determine the location of the perforators of the peroneal artery, and a tourniquet was placed at the start of the procedure, which was followed by debridement of the defect. The axis of the flap was then marked from a point starting between the lateral malleolus and the Achilles tendon and the mid-point between the two heads of the gastrocnemius muscle. The defect template was then marked with an outline at the donor site, which was followed by a proximal to distal incision and dissection. The lesser saphenous vein and the sural nerve were identified in the mid-calf region and any perforators originating from the gastrocnemius muscles were cauterized along the way. At this point an 18-gauge cannula was inserted in the open lumen of short saphenous vein and secured with Prolene 3/0 suture. The extent of dissection ranged from the medial edge of the fibula up to the lateral margin of the Achilles tendon, and was ceased at the pivot point of the flap, which is approximately 4 cm proximal to the lateral malleolus. The flap was then rotated along the pedicle, ensuring that there was no tension, and set into the defect, secured and the tourniquet was removed, and blood loss controlled. Both pedicle and the donor site were covered using a split thickness skin graft and dressed with a gap, for observation.

During the procedure, in Group A, the lesser saphenous vein was divided, leaving a long proximal vein stump with the flap which was cannulated with 18-gauge cannula and secured. This setup was used to perform intermittent drainage of blood which was conducted every hour for the first six hours post-procedure, followed by two-hourly drainage for the next eighteen hours, and then every four hours for the next seventy-two hours. Group B did not receive intermittent drainage. In patients of both groups, the affected leg was elevated at a 45^{o} to promote venous drainage. All patients were monitored for six weeks post-operatively for the development of complications. All patients were allowed to place weight on the limb after six weeks post-surgery.

Data was analyzed using Statistical Package for the Social Sciences version 26.0. Mean and SD was calculated for quantitative variables specifically age, body mass index and total operation time. Qualitative variables like gender, site of defect, comorbidities (ischaemic heart disease, hypertension, diabetes mellitus), etiology of skin defect, development of complications at recipient site (venous congestion, surgical site infection, flap necrosis), complications at donor site (haematoma, infection, epidermolysis) and the occurrence of general complications (decrease mobility, altered sensations) were recorded in terms of

frequency and percentage. Chi square test was applied to all qualitative variables, while the independent samples t test was applied to quantitative variables for comparison between the groups. The *p*-value of ≤0.05 was considered significant.

RESULTS

We studied a total of 76 patients, divided into two equal groups of 38 patients each. The mean age of the sample was 46.32±19.06 years, with a higher proportion of patients being women: 43(56.6%). Our study sample had a mean body mass index of 26.12±2.26 kg/m^2. The majority of patients: 27(35.5%) had a defect of the right distal leg, which was followed lesions of the left and right ankle with 21(27.6%) and 16(21.1%) patients, respectively. The left distal leg was involved in 12(15.8%) patients. We studied the presence of comorbidities in our patients and found that 16(21.1%) suffered from diabetes mellitus, 13(17.1%) from hypertension, 5(6.6%) from ischaemic heart disease, 17(22.4%) from both diabetes mellitus and hypertension, while 2(2.6%) patients suffered from all three of the aforementioned conditions simultaneously. 23(30.3%) patients did not have any of these comorbidities. A total of 25(32.9%) patients had a defect resulting from trauma, 41(53.9%) had a neuropathic ulcer, while 10(13.2%) had an ischaemic ulcer. The pre-procedure characteristics of the patients are displayed in Table-I.

Table-I: Pre-Surgery Patient Characteristics (n=76)

Variable	Group A (n=38)	Group B (n=38)	*p*-value
Age	42.53±20.82	50.11±16.53	0.083
Gender			
Male	18(47.4%)	15(39.5%)	0.488
Female	20(52.6%)	23(60.5%)	
Body Mass Index (kg/m2)	25.66±2.26	26.58±2.19	0.073
Comorbidities			
None	13(34.2%)	10(26.3%)	0.577
Diabetes Mellitus	8(21.1%)	8(21.1%)	
Hypertension	5(13.2%)	8(21.1%)	
Ischaemic Heart Disease	3(7.9%)	2(5.2%)	
Diabetes Mellitus/ Hypertension	7(18.4%)	10(26.3%)	
Diabetes Mellitus/ Hypertension/ Ischaemic Heart Disease	2(5.2%)	-	
Etiology of Defect			
Traumatic Defect	16(42.1%)	9(23.7%)	0.151
Neuropathic Ulcer	19(50.0%)	22(57.9%)	
Ischaemic Ulcer	3(7.9%)	7(18.4%)	

The mean operation time for both groups was 130.12±11.02 mins. A total of 12(15.8%) patients developed venous congestion of the flap, 14(18.4%) developed surgical site infections at the recipient site, while 10(13.2%) developed flap necrosis. A total of 4(5.3%) patients develop a haematoma at the donor site, other complications included surgical site infections at the donor site and the occurrence of epidermolysis at the donor site, with incidences of 1(1.3%) and 3(3.9%), respectively. Lastly, 6(7.9%) patients noticed decreased mobility at the ankle joint post-surgery, while 22(28.9%) complained of altered sensations. The surgery and post-surgery results are shown in Table-II.

Table-II: Surgery and Post-Surgical Results (n=76)

Variable	Group A (n=38)	Group B (n=38)	*p*-value
Total Operation Time (mins)	128.53±11.50	131.71±10.44	0.210
Recipient Site Complications			
Venous Congestion	2(5.3%)	10(26.3%)	0.012
Surgical Site Infection	6(15.8%)	8(21.1%)	0.554
Flap Necrosis	2(5.2%)	8(21.1%)	0.042
Donor Site Complications			
Haematoma Formation	3(7.9%)	1(2.6%)	0.304
Surgical Site Infection	1(2.6%)	-	0.314
Epidermolysis	3(7.9%)	-	0.077
Other Complications			
Decreased Mobility	4(10.5%)	2(5.3%)	0.395
Altered Sensations	9(23.7%)	13(34.2%)	0.312

DISCUSSION

The reverse sural artery flap is an important weapon in the armoury of the plastic surgeon in the repair of soft tissue defects of the distal leg, however, careful selection of patients is required if the procedure is to be a success and, despite appropriate care, complications still occur, which can threaten the survival of the flap.[12] Our study had a mean sample age of 46.32±19.06 years, and 43(56.6%) were female. Sugg *et al.*, studied a population with a mean age of 44(12-91), with 70.4% males,[13] while Olawoye *et al.*, studied a population composed of 13(65%) with a mean age of 30(7-58) years. We attribute these differences to the selection of patients of different etiologies for which the surgery was performed. Our study had a higher preponderance of women as compared to other studies, which we attribute to the higher prevalence of obesity in women in Pakistan which leads to an increased frequency of secondary problems such as diabetes mellitus and hypertension with a consequent increase in neuropathic and ischaemic ulcers.[14,15]

The reverse sural artery flap is associated with a number of complications, Baumeister *et al.*, reported

that the overall incidence of complications for reverse sural artery flap in their study was 59%, in the early days of the introduction of surgery into mainstream use, and noted that risk factors such as advancing age, diabetes mellitus, arterial atheromatous disease and venous insufficiency were associated with a marked increase in incidence.[16] Our study showed that 35(46.1%) of all patients reporting with lower limb skin defects suffered from diabetes mellitus, either alone or in combination with other comorbidities such as hypertension or ischaemic heart disease. Parett *et al.,* also looked at risk factors for the formation of these defects and found advancing age, smoking, obesity, diabetes mellitus and atherosclerotic disease were all important risk factors.[17]

Flap necrosis is an important complication of reverse sural flap surgery; in our study 2(5.2%) developed flap necrosis with intermittent controlled phlebotomy while 8(21.1%) developed this complication in the control group, (p=0.042). Rihan *et al.,* reported that 40% patients in their study developed complete flap necrosis with supercharging to effect decongestion of the flap, while this number was 70% in the control group.[11] Jafar *et al.,* reported that there were no cases of flap necrosis in their study with only 1(12.5%) case developing partial necrosis, similar to Wong *et al.,*who saw partial necrosis in only 1(8.3%) out of the twelve for whom phlebotomy was performed.[18]

Venous congestion is an important complication of the reverse sural flap surgery, and commonly leads to poor cosmetic outcomes and flap necrosis.[19] In our study, venous congestion occurred in 2(5.3%) cases with intermittent controlled phlebotomy and 10(26.3%) in the control group, (p=0.012). Rihan *et al.,* also reported a decreased incidence of venous congestion using flap decongestion techniques, which occurred in 20% of cases versus 70% in controls.[11] Our studies showed that this measure results in a reduction in the incidence of venous congestion when compared to controls, a conclusion that was shared by Dragu *et al*.[20]

Our study also noted that there was no difference between intermittent controlled phlebotomy and controls in terms of other recipient and donor site complications such as surgical site infection, haematoma formation, epidermolysis, decreased mobility and altered sensations. Thus, the practice may be employed as a standard during the performance. It is pertinent to note here that minimal comparative studies have been conducted on the subject, therefore, it is hard to establish a basis for comparison.

LIMITATION OF STUDY

Distal limb defect coverage is a difficult task, and is not a comparatively common malady, therefore there is a general dearth of research. Our study attempted to expand the knowledge base on the subject, however, there were some limitations. Firstly, the presence of multiple comorbidities in patients may have resulted in confounding within the results. Moreover, patients had a varying degree of compliance with their medical treatment (for example, with medications for the management of diabetes mellitus) which we did not account for. Second, despite the large number of patients included in this study as opposed to previous ones, the sample size was comparatively small, and the study itself was conducted in a single center. Lastly, there was limited comparative data available on the subject in international literature, which made a basis for comparison difficult.

CONCLUSION

Intermittent controlled phlebotomy represents a viable, cheap and technically simple method of effecting flap decongestion in reverse sural artery flap surgeries. This is associated with a lower frequency of developing complications such as flap venous congestion and flap necrosis. Further research is required with larger sample sizes, in a larger variety of populations before the results of this study can be generalized to other populations.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MAN & SH: Data acquisition, data analysis, critical review, approval of the final version to be published.

SJ & MWUB: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

FM & KA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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