

## Effect of *Taleeq* (Leech Therapy) in *Dawali* (Varicose Veins)

\*Zar Nigar, Md. Anwar Alam

National Institute of Unani Medicine, Kottige Palya, Magadi Main Road, Bangalore.

### ABSTRACT

*Dawali* (varicose vein) is first described in Ebers Papyrus over 3500 years ago. *Dawali* is a disease in which veins of legs and feet become dilated, tortuous, and greenish in colour due to excess accumulation of blood which is derived from *saudavi madda* (atrabilious matter) & *balgham ghaleez* (thick phlegm). The etiology of varicose veins is still incompletely understood, despite the fact that it is a very common disease affecting all ages from teenagers to elderly people. The complication of varicose veins like venous eczema, venous pigmentation, lipodermatosclerosis, superficial thrombophlebitis, venous ulceration, etc impair health related quality of life significantly. The objective of the study is to evaluate the efficacy of *Taleeq* in *Dawali* and to provide safe & cost effective alternative treatment. Randomized controlled clinical open trial was conducted in regimen unit of NIUM Hospital. 50 patients were divided into 2 groups, 30 in test & 20 in control group. Test group was treated with *Taleeq* on alternate day & control group was treated with grade 2 compression stockings & limb elevation for 2 months. Response was measured by assessment of pain / leg discomfort, limb girth at calf, ankle, and feet, pigmentation area & colour on every 15<sup>th</sup> day. Hb% was assessed on every 15<sup>th</sup> day to check anemia. Effect on anatomy of vein was assessed by Colour flow Doppler USG. Test group showed significant reduction in pain, limb girth, pigmentation, number of perforators. Control group showed significant reduction in pain & limb girth, but there was no improvement on pigmentation. Both groups do not show significant improvement on SFJ & SPJ incompetency. Test group has major effects in improvement of all parameters. Study stresses that leech therapy should be administered in combination with compression stockings & other effective treatment modalities like weight normalization for obese patients, physical therapy, dietary modification etc for optimal results.

**Key words:** Compression Stockings and leg elevation, *Hirudin*, hypovolumic hemodilution.

### Introduction:

The word varicose is an old one. The origin of the word comes from the Greek "grape like". It was probably first used as a medical description by Hippocrates in 460 BC. Varicose veins were first described in Ebers papyrus over 3500 years ago. This ancient Egyptian work described it as "Serpentine windings".<sup>1</sup>

*Dawali* (varicose veins) is a disease in which veins of lower limbs become dilated, tortuous, prominent and greenish in colour.<sup>2,3</sup> The etiology of varicose vein is still incompletely understood despite the fact that it is a very common disease

affecting all ages from teenagers to elderly people. Greco Arab physicians postulated that it is caused by accumulation of non-purulent *balghami* (Phlegmatic), *saudavi* (Atrabilious) or *damvi matter* (Sanguinous matter) in leg veins or due to weakness.<sup>4,5,3</sup> Today it is assumed that the etiology of varicose veins is multi-factorial. Patients may report aching especially on standing, itching, restlessness in legs, & ankle swelling. Complications of varicose veins may develop like venous eczema, venous pigmentation, lipodermatosclerosis, superficial thrombophlebitis, and venous ulceration which are most troublesome, distressing and painful condition for patient<sup>6,7</sup> and financial burden for health care providers. Health related quality of life is significantly impaired in individuals with vascular diseases.

Approximately 15% adults have varicosity of veins.<sup>8</sup> The prevalence of varicose veins varies substantially in different parts of the world, being highest in the western world; mostly from 10-30% in men and 25-55% in women in population based studies.<sup>9</sup> A study conducted among railway men of identical socio-economical status and doing identical work of sweepers in North & South of India showed over all prevalence was significantly higher among south Indian workers than North Indian (6.8%).<sup>10</sup>

Surgical treatment of varicose veins is widely used. The main principles of surgical treatment are to ligate the source of the venous reflux and to remove the incompetent saphenous trunks and the associated varices. Sapheno-femoral ligation is associated with a high rate of recurrence of varices. Removal of the saphenous veins has the disadvantage that vein is accompanied by a nerve that may be damaged in the vein stripping operation, further the chances of recurrence of such cases are also very high.<sup>6</sup> Due to high rate of recurrence and disadvantages of surgical treatment the need of hour is to find efficient & low cost alternative management. All the sign & symptoms or complications of varicose veins develop due to plethora (venous congestion). In order to save the limb & relieve the sign & symptoms, the venous blood must be removed and pressure must be reduced. Greco-Arab physicians have mentioned bloodletting in cases of plethora. Zakaria Razi, Ibn Sina, Ismaiel Jurjani etc have mentioned *fasd* in *Dawali*,<sup>2,11,4</sup> but M. Azam Khan<sup>12</sup> and A. Arzani<sup>3</sup> mentioned *Taleeq* (Leech Therapy) in *Dawali* (varicose veins) for bloodletting. *Taleeq* seems to be effective for the management of varicose veins & their complications. Therapeutic effect of *Taleeq* to control the complications of varicose veins may be attributed to the salivary secretions of leech which contains certain bio-chemicals with vasodilating, anticoagulant, anesthetic, thrombolytic, analgesic, antibiotic & anti-inflammatory properties.<sup>13,14</sup> In Indian leeches *H. granulosa* has medicinal properties.<sup>15</sup>

\* Corresponding author

Venous disease is typically progressive; no treatment can prevent the appearance of new varicose veins in future. Apart from numerous complications, recurrence may also occur in future after surgical treatment. Modes of treatment that offers efficacy (long term control of symptoms or complications) without medication or surgery are given most priority.

The study aimed at evaluating the effect of leeching in the rehabilitation of varicose vein patients as it is acclaimed for the beneficial effects in the management of this disease by Unani physicians. It further evaluated the treatment procedure with the conventional measures of tight stocking and foot elevation. The study tried to validate the unani claims. If these claims are found true, it will help in the better management of varicose vein patients to decrease the DALY (disability-adjusted life year) and increase the productive hours of these patients.

### Methodology

The present study is a randomized controlled open study conducted to know the effect of *Taleeq* in *Dawali*. This study was carried out over a period of 12 months from April 2009 to March 2010 in National Institute of Unani Medicine. 50 patients were assigned randomly to 2 groups, 30 in test group & 20 in control group by using random allocation software. Test group was treated with *Alaq* (leeches) alternate day for two months and control group was given compression stockings grade 2 for wearing and also advised limb elevation.

Diagnosis was made on the basis of history, physical examination and Colour Flow Doppler Ultra Sound. While taking history emphasis was given on the past history of hypertension, hyperlipidemia, Diabetes mellitus, and Myocardial infarction, Claudication, Varicose vein, and DVT. After history, general examination was done with special emphasis on pulse, (rate, rhythm, character and volume), B.P respiratory rate, respiratory distress, anemia, edema, and lymphadenopathy, BMI etc. CT, BT, blood sugar fasting, and P.P, HBsAg, Elisa test for HIV and AIDS were carried out to confirm application of leech. Hb% assessment was done on every 15<sup>th</sup> day to check anemia. Color flow Doppler was done before and after treatment to observe the effect of treatment on vein anatomy. Leeches were sent for identification to Zoology department of Bangalore University. Dr. P. Mahboob Basha has identified leeches as *Hirudinaria granulosa*. Fresh unused, well cleaned leeches gathered 24 hours before starting a leeching session. Small sealable containers partly filled with water for used leeches. These containers were labelled with patient's name, Water proof padding and towels, Bandages or highly absorbent material, Adhesive tape, Water, Scissor, disposable razor, surgical gloves, were required and gathered before starting a leeching session. Patients were advised not to use perfumes, chemicals to the skin at the intended application site for at least 2 days before treatment. Skin of the target area was thoroughly cleaned with soap and water or remove all substances with strong odour or taste, because leeches are very sensitive to strong odour. Application site was shaved and rubbed dry until the skin become rosy or red, it helps to get the leeches to bite quickly. A dampen square gauze with 1 cm square hole in the middle was placed in close contact

with the area to be treated to protect the leech from wandering. After wearing surgical gloves, active and healthy leeches were selected and the head of the leech was put in the hole of the gauze, attachment generally occurs quickly. If the leech was reluctant to bite, a small needle prick was made on the skin to produce a tiny droplet of blood, which results in enthusiastic attachment. The gauze square can be removed without disturbing the animal. The target area was kept warm and dark by covering it with a towel or other material. Leeches usually stay attached for 30-60 minutes and fell down itself. When the leeches drop off they were placed in a jar labelled with patients name to avoid confusion between used and unused animals and to prevent use on another patient. The tripartite jaw of the leech makes a three pronged Y shaped bite wound. After the leech has dropped off it usually takes 3-48 hours for the wound to stop bleeding. The slow drainage of blood is an important part of treatment. The drainage of blood reduces venous congestion. When there was a good outflow of blood after leech feeding, the wound was loosely covered and checked the extent of bleeding 15-30 minutes later, if satisfactory, a loose dressing was applied. Patient was advised to avoid strenuous physical activity until the bleeding stop naturally. Primary dressing was consisting of a wide and thick sterile pad to absorb all the blood oozing from the wound. The layers of padding were loosely secured with a gauze bandage that is not so tight that it obstructs the blood flow. Area around leech bite was routinely observed for local infection. Patients in control group were advised to put the stockings on as soon as get out of bed, before gravity gets a chance to cause pooling of blood in varicose veins. Keep the stockings on all day. Take them off when lying down, with legs kept raised above the level of the heart. For efficacy assessment the Baseline observations were recorded on zero day thereafter at an interval of 15 days till 2 months. At every visit the patients were asked about the improvement and worsening in their symptoms and subjected to examination to assess clinical findings. Concomitant treatment was not allowed during the protocol period. The patients who were taking any medicine for the treatment were advised to observe abstinence from that drug, then after one week, treatment with leech was started. An arbitrary grading of various parameters was improvised for appropriate assessment of the efficacy of leech therapy. Intensity of leg pain / leg discomfort during walking was assessed on 4 point scale ranging from 0-3 (0 for no pain, 1 for mild pain ie, Irritating & uncomfortable, 2 for moderate ie. Dreadful & Horrible and 3 for severe pain ie. unbearable or Agonizing). Pigmentation was assessed by colour of pigmentation & area of pigmentation. Colour of pigmentation was scored as 0 for none, 1 for Reddish to light brown, 2 for Light brown to dark brown, 3 for dark brown to blackish. Area of pigmentation was obtained by multiplying the greatest length (head to toe) and greatest width (side to side) of pigmented area i.e. length × width. Both dimensions were measured by centimeter ruler. Edema was measured by taking difference between the values of limb girth, before and after the treatment. Limb girth was measured at 3 points i.e. calf, ankle and foot. Colour flow Doppler ultra sound was carried out to exclude arterial disease and to determine the patency of veins; a bidirectional flow probe was used to detect venous reflux. This investigation was carried out with the patient standing.

The data was analyzed by computerized statistical package Graph pad (Instat version 3)

**Result**

**Table.1 Distribution of patients according to Sex**

Sex	No. of patients	%
Male	34	68
Female	16	32
<b>Total</b>	<b>50</b>	<b>100</b>

In the study population 68% (34) subjects were Male and 32% (16) were Female.

**Table.2 Distribution of patients according to Occupation**

Occupation	No. of Patients	%
House wife	15	30
Labourer	8	16
Businessmen	5	10
Clerk	4	8
Shopkeeper	4	8
Nurse	2	4
Retired	2	4
Farmer	2	4
Driver	2	4
Printer	2	4
Tailor	1	2
Engineer	1	2
Editor	1	2
Doctor	1	2
<b>Total</b>	<b>50</b>	<b>100</b>

In the study population 30% (15) subjects were House wife, 16% (8) were Labourer, 10% (5) were Businessmen, 8% (4) were Clerk, 8% (4) were Shopkeeper, 4% (2) were Nurses, 4% (2) were Retired, 4% (2) were Farmer, 4% (2) were Driver, 4% (2) were Printer, 2% (1) were Tailor, 2% (1) were Engineer, 2% (1) were Editor and 2% (1) were Doctor

**Table.3 Effect of leech application on pain in varicose vein patients (Median rating with range)**

Groups	0 day	15 <sup>th</sup> day	30 <sup>th</sup> day	45 <sup>th</sup> day	60 <sup>th</sup> day
Test	2 (1, 3)	2 (1, 2)	1 (0, 1) <sup>+</sup>	1 (0, 1) <sup>+</sup>	0 (0, 1) <sup>+,*</sup>
Control	2 (2, 3)	2 (1, 2) <sup>++</sup>	2 (1, 2) <sup>++</sup>	1 (1, 2) <sup>+,*,++</sup>	1 (1, 2) <sup>+,*,++</sup>

N=30 in test and 20 in control group, test used: Friedman test for intra group and Kruskall Wallis test for inter group comparison with Dunn's pair comparison test.

\*-p<0.01 w. r. t. control 0 day, +- p<0.01 w. r. t. test 0day, ++- p<0.01 w. r. t. test 60 day.

**Table.4 Effect of leech application on Limb girth (cm) in varicose vein patients (Mean + SEM)**

Assessment day	Test Group			Control Group		
	Calf	Ankle	Foot	Calf	Ankle	Foot
0 Day	37.17 ± 0.83	26.93 ± 0.54	25 (20, 27)	37.45 ± 1.08	26 ± 0.70	23 (21, 29)
15 <sup>th</sup> Day	36.03 ± 0.83 <sup>+</sup>	26.06 ± 0.53 <sup>+</sup>	24 (20, 27)	36.75 ± 1.07 <sup>++</sup>	25.4 ± 0.75 <sup>++</sup>	23 (21, 28)
30 <sup>th</sup> Day	33.93 ± 0.78 <sup>+</sup>	22.30 ± 0.50 <sup>+</sup>	23 (19, 26)	36.20 ± 1.04 <sup>++</sup>	25.0 ± 0.70 <sup>++</sup>	23 (21, 28)
45 <sup>th</sup> Day	32.53 ± 0.83 <sup>*,+</sup>	22.90 ± 0.48 <sup>*,+</sup>	23(19, 26)	33.90 ± 1.08 <sup>++</sup>	22.55 ± 0.71 <sup>++</sup>	22.5(21, 28)
60 <sup>th</sup> Day	32.67 ± 0.78 <sup>*,+</sup>	21.55 ± 0.55 <sup>*,+</sup>	22(19, 26)	33.7 ± 1.01 <sup>*,++</sup>	22.5 ± 0.68 <sup>*,++</sup>	22 (20,27)

N=30 in test and 20 in control group, test used: One way ANOVA with Tukey Kramer pair comparison test Calf and Ankle girth comparison; Friedman test for intra group and Kruskall Wallis test for inter group comparison with Dunn's pair comparison test for foot girth

\*-p<0.01 w. r. t. control 0 day, +- p<0.01 w. r. t. test 0day, ++- p<0.01 w. r. t. test 60 day.

**Table.5 Effect of leech application on pigmentation colour in varicose vein patients (Median with range)**

Groups	0 Day	15 <sup>th</sup> day	30 <sup>th</sup> Day	45 <sup>th</sup> Day	60 <sup>th</sup> Day
Test	3 (0, 3)	2 (0, 3) <sup>++</sup>	2 (0, 3) <sup>++</sup>	(0, 2) <sup>+</sup>	1 (0, 2) <sup>+,*</sup>
Control	2 (0, 3) <sup>++</sup>	2 (0, 3)	2 (0, 3)	2 (0, 3)	2 (0, 3)

N=30 in test and 20 in control group, test used: Friedman test for intra group and Kruskall Wallis test, for inter group comparison with Dunn's pair comparison test.

\*-p<0.01 w. r. t. control 0 day, +- p<0.01 w. r. t. test 0day, ++- p<0.01 w. r. t. test 60 day.

**Table.6 Effect of leech application on pigmentation area in varicose vein patients (Median with range)**

Groups	0 Day	15 <sup>th</sup> Day	30 <sup>th</sup> Day	45 <sup>th</sup> Day	60 <sup>th</sup> Day
Control	210(72, 754)	225(70, 350)	220(70, 350)	230(62, 350)	230(62,350) <sup>*,++</sup>
Test	210 (56,1110)	140(45,870)	120(24,650) <sup>+,++</sup>	115(12,500) <sup>+</sup>	90(4,380) <sup>+,*</sup>

N=23 in test and 13 in control group, test used: Friedman test for intra group and Kruskal Wallis test, for inter group comparison with Dunn's pair comparison test.

\*-p<0.01 w. r. t. control 0 day, +- p<0.01 w. r. t. test 0day, ++- p<0.01 w. r. t. test 60 day.

**Table.7 Number of incompetent valves before and after treatment**

	Test group		Control group	
	BT	AT	BT	AT
SFJ	20	19	14	12
SPJ	12	10	7	6

(p>0.05)

In test group before treatment total number of SFJ (Saphenofemoral Junction) incompetence was 20 and after treatment total number of SFJ incompetence was 19. In control group before treatment total number of SFJ incompetence was 14 and after treatment total number of SFJ incompetence was 12. In test group before treatment total number of SPJ (Saphenopopliteal Junction) incompetence was 12 and after treatment total number of SPJ incompetence was 10. In control group before treatment total number of SPJ incompetence was 7 and after treatment total number of SPJ incompetence was 6. Inter & intra group comparison showed the difference is not significant (p>0.05)

**Table.8 Effect of leech application on Incompetent perforators, colour flow Doppler USG results (Median with range)**

Groups	BT	AT
Test	11 (10, 13)	4 (3, 6)*,+
Control	11 (9, 13)	7 (4, 8)*,+ ,++

N=30 in test and 20 in control group, test used: Friedman test for intra group and Kruskal Wallis test, for inter group comparison with Dunn's pair comparison test.

\*-p<0.001 w. r. t. control BT, +- p<0.001 w. r. t. test BT, ++- p<0.05 w. r. t. test AT,

Before treatment in test group the median numbers of perforators were 11 and after treatment number of perforators were 4. Test group showed reduction in number of perforators. Intra test group comparison was assessed by applying Friedman test. It showed significant reduction in number of perforators after completion of treatment with respect to 0 day p<0.001. Before treatment the median numbers of perforators in control group were 11 and after treatment the median numbers of perforators were 7. Intra group comparison was assessed by applying Friedman test, it showed significant reduction in number of perforators with respect to 0 day P<0.05. When these two groups were compared with each other using Kruskal Wallis test for inter group comparison with Dunn's pair comparison test, it showed significant reduction (p<0.01) in comparison to median number of perforators before

## Discussion

Our study population predominantly comprised of males 68% (34) while remaining 32% (16) were females (Table 1). Most studies showed higher incidence of varicose veins in females than in males.<sup>16,17</sup> The male to female prevalence ratio is about 1.5: 3.5. There are some studies which suggest that prevalence of varicose veins is higher in males than in females. The result of study published by Evans [1999] in which on the contrary, a higher occurrence was found in men.<sup>18</sup> A Polish study showed that advanced form of venous pathology was more prevalent in male as compared to female.<sup>19</sup> This finding is comparable to our study that patients with sign, symptoms & complication come to hospital for treatment and asymptomatic patients did not need treatment.

In present study population 30% (15) were House wives, Businessman 10% (5), Clerk 8% (4), Driver 4% (2), Tailor

2% (1), Editor 2% (1) (Table 2) all these constitute 56% (28) of study population, all are involved in prolong sitting at work place or low level of physical activities. Our results are in accordance of Framingham study that showed subjects with varicose veins had lower level of physical activities.<sup>20</sup> Another study conducted in former Czechoslovakia reported prevalence of varicose veins was lower in those who were physically active compare to those with no physical activity.<sup>21</sup> In our study labourers were 16% (8), Shopkeeper were 8% (4), Nurse 4% (2), Farmer 4% (2), Printer 4% (2) (Table 2) all were involved in prolong standing at work place and others 8% (4) including Doctors 2% (1), Retired 4% (2), Engineers 2% (1). In our study 36% (18) were involved in prolong standing at work place. Prolong standing is associated with development of varicose veins. Our results are in accordance with a Danish study reported that working in standing position was even associated with subsequent hospitalization due to varicose veins for both men & women.<sup>22</sup>

In present study test group showed significant reduction in median pain score after treatment as compared to before treatment. Median pain score before treatment was 2(1, 3) and after treatment was 0 (0, 1) ( $p < 0.01$ ). Whereas in control group median pain score was 2 (2, 3) on 0 day and 1 (1, 2) was on 60<sup>th</sup> day. When these two groups were compared with each other using Kruskal Wallis test with Dunn's pair comparison test, it was found that median pain score at 60<sup>th</sup> day test was significantly reduced ( $p < 0.01$ ) in comparison to median score at 0 day test and 60<sup>th</sup> day control. (Table 3) The result indicated that both regimens (*Taleeq* and compression stockings with leg elevation) were effective in reducing pain but *Taleeq* was found more efficacious in comparison to compression stockings & leg elevation. In case of venous stasis the pathogenesis of the pain not only involves the concept of pain receptors but also the appearance of algogenic metabolites at the site of the microcirculatory units to which endothelial cells are particularly sensitive.<sup>23</sup> When leech bite the skin it sucks the stagnated blood thereby reduces the mechanical pressure. It also injects secretions containing anticoagulant, antithrombotic, vasodilating & anesthetic agents from the salivary ductules by pumping action.<sup>24,25</sup> Hirudin, Calin & Factor Xa inhibitor present in leech saliva are anticoagulant. Hirudin is a most potent natural inhibitor of thrombin. It binds to and inhibits only the activity of thrombin with a specific activity on fibrinogen.<sup>26</sup> Therefore Hirudin prevents & dissolves the formation of clots, thrombi and has therapeutic value in superficial varicose veins. Calin is another anticoagulant compound present in leech saliva, it works by prohibiting the Von Willebrand factor to bind itself to collagen, and it is also an effective inhibitor of platelet aggregation caused by collagen. Factor Xa inhibitor present in leech saliva block the action of the coagulation factor Xa. Enzyme Destabilase has thrombolytic effect; it breaks up any fibrin that has formed. Leech saliva has 3 compounds that act as a vasodilator agent; they are the histamine like substance, the acetylcholine and the carboxypeptidase, an inhibitor, widen the vessels and increases the flow of blood to the bite site.<sup>27</sup> Anticoagulant, thrombolytic and vasodilating substances present in leech saliva prolong bleeding and causes hypovolumic haemodilution which reduces pressure of blood and also remove the metabolites at the site of the microcirculatory units, in combination of these, anesthetic substances present in leech saliva deaden pain on the site.<sup>27,28</sup>

Limb girth was measured at 3 points i.e. at calf, at ankle & at foot. It is the measure of edema. Reduction in limb girth showed reduction in oedema. Test group showed significant reduction in mean limb girth at calf after *Taleeq* as compared to before *Taleeq*. Mean calf girth before *Taleeq* was  $37.17 \pm 0.83$  cm & after *Taleeq* was  $32.67 \pm 0.78$  cm. When two groups were compared with each other by using one way ANOVA with Tukey Kramer pair comparison test, it was found that test group showed significant reduction at 45<sup>th</sup> day in comparison to 0 day control (Table 4).

In test group mean limb girth at ankle showed significant reduction after *Taleeq* as compared to before *Taleeq*. Mean ankle girth before *Taleeq* was  $26.93 \pm 0.54$  and after *Taleeq* was  $21.55 \pm 0.55$ . Control group also showed significant reduction in mean limb girth at ankle after treatment as compared to before treatment. Mean limb girth at ankle before treatment was  $26 \pm 0.70$  & after treatment was  $22.5 \pm$

0.68. When these two were compared by applying Tukey Kramer pair comparison test, it showed significant reduction in mean limb girth at ankle in comparison to 0 day test & 60<sup>th</sup> day control. (Table & Figure: 11). Median foot girth also showed significant reduction after *Taleeq* as compared to before *Taleeq*. Median limb girth at foot before *Taleeq* was 25 (20, 27) and after *Taleeq* median limb girth at foot was 22 (19, 26). In control group, median limb girth at foot before treatment was 23 (21, 29) and after treatment was 22 (20, 27). The median foot girth when compared in test and control group at various assessment days and between each other showed reduction in foot girth but it was not statistically significant ( $p > 0.05$ ) (Table 4). The result indicates that both regimens are effective in reducing limb girth (edema) but *Taleeq* is more efficacious in reducing oedema than compression & leg elevation. In case of varicose veins the movement of blood toward heart is decreased due to incompetent valves and patient may develop stasis (pooling) of blood which contributes to edema.<sup>29</sup> Biochemicals present in leech saliva due to their anticoagulant, thrombolytic & vasodilating effects cause hypovolumic haemodilution, thus reducing stasis or blood pooling.<sup>27,28</sup>

In this study the effect of leech therapy on pigmentation was assessed by change in colour & area of pigmentation. In test group median score of colour of pigmentation was significantly reduced after *Taleeq* as compared to before *Taleeq*. Median score of pigmentation colour before *Taleeq* was 3 (0, 3) & after *Taleeq* was 1 (0, 2) in control group the colour of pigmentation before treatment was 2 (0, 3) and after treatment was 2 (0, 3). Control group showed no significant reduction ( $p > 0.05$ ) in pigmentation colour when compared with 0 day control. When both groups were compared, it was found that median rating for pigmentation colour at 60<sup>th</sup> day test was significantly reduced ( $p < 0.01$ ) (Table 5). When compared with 0 day control. These results indicates *Taleeq* reduces pigmentation colour but control group has no effect on pigmentation colour.

Test group showed significant reduction in median area of pigmentation. In test group the median area of pigmentation before *Taleeq* was 210 (56, 1110)  $\text{cm}^2$  & after *Taleeq* was 90 (4, 380)  $\text{cm}^2$ . Control group showed no significant reduction in median area of pigmentation. In control group median area of pigmentation before treatment was 210 (72, 754)  $\text{sq cm}$  and after treatment median areas of pigmentation was 230 (62, 350)  $\text{sq cm}$ . when these two were compared with each other by using Kruskal Wallis test with Dunn's pair comparison test, test group showed significant reduction in area of pigmentation with respect to 0 day control & control 60<sup>th</sup> day ( $p < 0.01$ ) (Table 6). Pigmented lesions in stasis dermatitis are caused by deposition of haemosiderin in the dermis. Haemosiderin is formed from the decomposition of haemoglobin within the cytoplasm of phagocytic cells in association with post inflammatory pigmentation that induces pigment incontinence. Dermal haemosiderin deposition has a stimulatory effect on melanogenesis.<sup>30</sup> Macrophages of reticulo-endothelial system play the major role in relieving iron, from catabolism of erythrocyte haemoglobin to plasma for reuse in haem synthesis, part of this iron is rapidly returned to plasma and part is exchanged with shortage iron in macrophages and is reutilize slowly.

Hypovolumic haemodilution caused by Biochemicals present in leech saliva improves circulation of skin on the affected site, thus the haemosiderin deposited in skin is reutilized as a source of Iron.

Colour flow Doppler USG was done in all patients of both groups before & after treatment. In test group SFJ incompetency was detected in 20 patients before treatment as compared to 19 after treatment. In control group SFJ incompetency was detected in 14 patients before treatment as compared to 12 after treatment. When both groups were compared with each other by using Chi square test, there was no significant difference ( $p > 0.05$ ). In test group SPJ incompetency was detected in 12 patients before treatment as compared to 10 patients after treatment. In control group 7 patients detected with SPJ incompetency before treatment as compared to 6 after treatment. Inter group comparison showed there was no significant difference ( $p > 0.05$ ) (Table 7). This result may be attributed to the degeneration of valve cusps.<sup>6</sup> Test group showed significant reduction in number of perforators before *Taleeq* as compared to after *Taleeq*. In test group median number of incompetent perforators before treatment was 11 (10, 13) & after treatment was 4 (3, 6). Control group also showed significant reduction in number of perforators as compared to before treatment. In control group number of incompetent perforators before treatment was 11 (9, 13) & after treatment was 7 (4, 8). When both groups were compared with each other by using Kruskal Wallis test with Dunn's pair comparison test. Test group showed significant reduction in number of perforators (Table & Figure: 8).

### Control group

In present study the control group showed significant reduction in median pain score after treatment as compared to before treatment. Control group showed effect on pain reduction from 45<sup>th</sup> day where as test group showed reduction in pain score from 30th day. In control group mean limb girth (at calf, ankle & foot) showed significant reduction after treatment as compared to before treatment. Both groups showed significant reduction in limb girth at calf & ankle from 15<sup>th</sup> day; in limb girth at foot from 45<sup>th</sup> day. Control group showed no reduction in colour of pigmentation and area of pigmentation. Graduated compression stocking are a mechanical method of prophylaxis against varicose vein & DVT used in various settings. Their mechanism of action is multifactorial. Graduated compression stocking exerts graduated circumferential pressure from distal to proximal segments of lower limbs increasing venous out flow and reducing stasis within the leg veins.<sup>32</sup> The graduated compression stockings work by increasing the ejection fraction, decreasing reflex & reducing the residual volume fraction & heightening the linear velocity of venous outflow, which prevent stasis & venous distension and enhance emptying of the valvular cusps.<sup>33</sup> Improve the muscle function & venous pressure in limbs with chronic venous insufficiency.<sup>34</sup> The beneficial hemodynamic effects of elastic compression stoking have been demonstrated in chronic venous insufficiency with various kinds of compression & different levels of pressure using ambulatory venous pressure measurements & various methods of plethysmography.<sup>35,36</sup>

### Conclusion

*Taleeq* has significantly positive effect on the course of superficial phlebitis; patients perceive a noticeable improvement of symptoms right after treatment due to potent anti-inflammatory, blood thinning and lymph flow accelerating effect of leech secretion. Compression stockings and leg elevation also showed significant improvement but less than *Taleeq*. Thus from the above result we conclude that *Taleeq* was safe & well tolerated and has encouraging potential in prevention of complications of varicose veins. We must stress that leech therapy should be administered in combination with compression stockings and other effective treatment modalities like weight normalization for obese patients, physical therapy, dietary modification, etc for optimal result.

### References

1. Leeches. Dent Register, 1881, 35: 246-48. Available at www.fauchard.org.
2. Jurjani I. *Zakhira Khawarzam Shahi*. Vol. VI. (Urdu Trans. by Khan HH) 17.
3. Arzani MA. *Tibbe Akbar*. (Urdu Trans. by Hussain M) Deoband: Faisal Publications; YNM: 628-29.
4. Ibn Sina. *Alqanoon Fil Tib*. Vol. III. (Urdu Trans. by Kantoori GH) New Delhi: Idara Kitabul Shifa; 2007: 371-73.
5. Quamri MH. *Ghina Muna maa Tarjuma Minhajul Ilaj*. PNM; YNM: 286.
6. Russell RCG, William NS, Christopher JK, Bulstrode. *Bailey & Love's Short Practice of Surgery*. 24<sup>th</sup> ed. London: Arnold a member of the Hodder Head line Group; 2004: 956-66.
7. Berkow Robert, Beers MH, Fletcher AJ, Altman LK, Gabbard GO, Blumenthal SJ, et al. *The Merck Manual of Medical Information*. Home Edition. New Jersey: Merck Research Laboratories; 1997: 144-46.
8. Shah SN, Anand MP, Acharya VN, Karnad DR, Bichile SK, Kamath SA, et al. *API Text book of medicine*. 7<sup>th</sup> ed. Mumbai: The Association of Physicians of India; 2003: 519-20.
9. Robertson L, Evans C and Fowkes FG (2008): *Epidemiology of chronic venous disease*. Phlebology 23:103-111.
10. Malhotra SL. *An epidemiological study of varicose veins in Indian railroad workers from the south and north of India, with special reference to the causation and prevention of varicose veins*. Int. J. Epid 1972; 1: 17783.
11. Razi AZ. *Kitab Al-Hawi Fil Tib*. Vol. XI. (Trans. By CCRUM) New Delhi: CCRUM Ministry of Health & Family Welfare; 2004: 189-98.
12. Khan MA. *Alakseer*. Vol. II. (Urdu Trans. by Kabiruddin M) New Delhi: Ejaz Publishing House; 2003: 1428-29.
13. Kaestner A. *Invertebrate Zoology*. Vol. I. New York: Interscience Publishers; 1967: 541-63.
14. Anonymous. *The McMillan Family Encyclopaedia*. London: McMillan Press Ltd; 1995: 271.
15. Verma PS. *A manual of practical zoology invertebrates*. New Delhi: S Chand & Company Ltd; 2006: 288-91.
16. Laurikka J, Sisto T, Auvinen O, Tarkka M, Hakama M. *Varicose veins in a Finnish population aged 40-60*. J Epidemiol Community Health 1993; 47: 355357.
17. Canonico S, Gallo C, Paolisso G, Pacifico F, Signoriello G, Sciaudone G, Ferrara N, Piegari V, Varricchio, Rengo F. *Prevalence of varicose veins in an Italian elderly population*. Angiology 1998; 49: 129135.12.

18. Evans CJ, Fowkes FGR, Ruckley CV, Lee AJ. *Prevalence of aN, Hannerz H, Burr H, Kristensen TS. Standing at work and varicose veins.* Scand J Work Environ Health 2000; 26: 414420.
19. Jawien A, Grzela T, Ochwat A. *Prevalence of chronic venous insufficiency (CVI) in men and women in Poland: Multicentre cross-sectional study in 40,095 patients.* Phlebology 2003; 18: 110-122.
20. Brand FN, Dannenberg AL, Abbott RD, et al. *The epidemiology of varicose veins. The Framingham Study.* Am J Prev Med 1988 Mar-Apr; 4 (2): 96-101.
21. Stvrtinova V, Kolesar J and Wimmer G (1991): *Prevalence of varicose veins of the lower limbs in the women working at a department store.* Int Angiol 10:25.
22. Tuchsén F, Krause N, Hannerz H, Burr H, Kristensen TS. *Standing at work and varicose veins.* Scand J Work Environ Health 2000; 26: 414420.
23. Cofet JM, Millien JP. *Clinical characteristics of pain in chronic venous insufficiency.* 1992 Jan-March; 45 (1) 9-16.
24. Whitaker IA, Cheung CK, Chahal CA, et al. *By what mechanism do leeches help to sawage ischaemic tissues? Review.* Br. J. Plast Surg 2005; 43 (2): 155-160.
25. Elder A, Orevi M, Rigibi M. *The role of the leech in medical therapeutics.* Blood Rev. 1996; 10 (4): 201-209.
26. Rydell TJ, Tulienky A. *Refined structure of Hirudin thrombin complex.* J. mol. Bio 1991; 221 (2) 583-601. doi: 10' 1016/0022-2836 (91) 80074-5. PMID 1920434
27. <http://www.triedtastedserved.com/health-trends/benefits-leechtherapy.php>. cited on 15.04.2010.
28. *Leech therapy for heart diseases, hyperpigmentation & osteoarthritis* 2009-10-31 14:52 <http://sindivestms.com.Br/index/modules/news/article.php?>
29. Ogilvie C, Evans CC. *Chamberlain's Symptoms and Signs in Clinical Medicine an Introduction to Medical Diagnosis.* 12<sup>th</sup> ed. Oxford: Butterworth Heinemann; 1997: 43-44, 134,185.
30. Rosarco M, Rivera P, Ishihara M. *A case of non selective phagocytosis of haemosiderine & melanin of dermal histiocytes in stasis dermatitis.* Arch dermato. Res 2003; 295: 19-23 DOI 10.1007/00 403-003-0382-y
31. *Ultrastructural pathology-an introduction to interpretation* by Normen F. Cheville. P 318
32. Lambarera I, Bassoon JL, Savestre MA, Delmas AS, Dupas S, Thenault MH, Legaguex A et al. *Graduation compression stocking thromboprophylaxis for elderly inpatients. A propensity analysis.* J Gen intern med 2006 Dec; 21(12): 1282-1287.
33. Agur O, Hamiltén G, Backer D. *Graduated compression stockings in prevention of venous thromboembolism.* Br J surg 1999; 86: 992-1004.
34. Miranda AR, Hassouna HI. *Mechanism of thrombosis in spinal cord injury.* Hemetol oncol chin North Am 2000.
35. Hirai M, Iwata H, Hayakawa N. *Effect of elastic compression stockings in patients with varicose veins and healthy controls measured by strain gauge plethysmography.* Skin Res Technol 2002; 8: 236239.
36. Khan SB, Shbaklo H, Wells SSPS, Kovacs MJ, Rodgu MA et al. *Effectiveness of compression stockings to prevent the post thrombotic syndrome: a randomized controlled trial.* BMC cardiovascular disorder 2007; 7: 21.