Healing Rates of Venous Leg Ulcer Using Four Layer Bandage and Short Stretch Bandage- A Comparative Study in Aspect of Bangladesh

RAKIBUL HASAN, MD. SAIF ULLAH KHAN, MAINUL MAHMUD, SAMARESH CHANDRA SAHA, SOURAV BHOWMICK
Department of Vascular Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

Address of Correspondence: Dr. Rakibul Hasan, Assistant professor, Department of Vascular Surgery, Room no – 1431, D-block, BSMMU, Shahbag, Dhaka, E-mail: optio_28@yahoo.com.

Abstract:
Background: Chronic venous leg ulcer is one of the common medical conditions encounter by the vascular surgeons in Bangladesh. Many of these patients develop venous leg ulcer as a sequel of the disease. In advance chronic venous disease such as development of ulcer, single or multilayer dressings are usually used. Objective: To find out a compression therapy (single layer crepe/short stretch bandage and multilayer/four layer bandage) in patients with venous leg ulcer. Materiel & Methods: This study was conducted on 200 patients with in last two years, march 2017 to february 2019 at Bangabandhu Sheikh Mujib Medical University (BSMMU), Department of vascular surgery. In which 100 patients with venous leg ulcer where treated with four layer bandage and another 100 patients with same condition were treated with single layer crepe bandage. Before application of bandage, proper history of patient was taken and duplex scan was done. The primary outcome was measured by time duration of ulcer healing. Secondary outcome included incidence and number of adverse events in every patient. Results: Healing time of venous ulcers was accessed with periodic interval. The four layer bandage was associated with significantly shorter time of healing. P value reached from unpaired t-test. Primary outcome shows 68% of patients who received four layer bandages achieved healing within one month. On the other hand, 12% of patients who received single layer/crepe bandage did so. Conclusion: Four layer bandages heals venous leg ulcer more rapidly than the single layer crepe bandage. These data suggest that the benefits observed the consistent despite prognosis is different. Patients with large ulcers have poor healing prognosis regardless of its treatment modalities.

Keywords: Chronic venous disease, Multi layer bandage, Single layer/crepe bandage

Introduction:
The successful management of venous leg ulcers represents a significant clinical problem and a major drain on limited financial resources. Research has shown that the majority of ulcers can be induced to heal by the application of adequate levels of sustained graduated compression although this technique is contra-indicated for the treatment of ischaemic ulcers. Bandages vary greatly in their ability to provide sustained compression due to differences in their structure and the content of elastomeric yarns. Other factors, such as limb circumference and shape, will also have an important influence on the pressure produced beneath a compression bandage. Bandages are grouped according to their function and performance, in order to facilitate the choice of an appropriate product. Leg ulcers are a chronic condition, it can be caused by a number of physiological or biochemical disorders, either individually or in combination, but the majority, approximately 70%, are associated with venous disease. The prevalence of venous ulceration increases with age and the condition is also more common in women than men. A significant number of ulcers (about 20%), are caused by some form of arterial disease. Depending upon the location and severity of the problem, this may affect large parts of the leg or smaller localized areas of tissue. A rapid onset of ischaemia may be due to an embolism but a more gradual reduction in blood flow can be caused by progressive occlusion of the vessels by the deposition of fatty substances on the internal walls leading to the formation of atheromatous plaques. As this is a time related process, the prevalence of ischaemic or arterial ulcers rises with increasing age. Other important causes of ulceration

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include diabetes and rheumatoid disease, although numerous other medical conditions can also lead to ulcer formation. Ulcers which are caused by arterial disease should be referred to a specialist vascular surgeon for assessment and possible surgery. Venous ulcers, however, can be managed by more conservative means, although surgery may subsequently be considered to correct the underlying physiological disorder. Venous leg ulcers are a common and recurring chronic wound caused by damage to the vein sand consequent high venous pressure. The estimated lifetime prevalence for leg ulceration in developed countries is 1% and the point prevalence is 0.1-0.2%. Prevalence increases with age and is higher among women. A substantial proportion of the costs is attributable to nursing time. These ulcers are also associated with increased costs and reduced health related quality of life for patients. Compression bandaging is thought to assist ulcer healing by reducing distension in the leg veins and accelerating venous blood flow. A previous systematic review of published trial level data concluded that compression was more effective in healing venous leg ulcers than no compression, multi-layered systems were more effective than single layer systems, and high compression was more effective than low compression, but no clear differences in effectiveness were detected between different types of high compression.

The four layer bandage and the short stretch bandage are examples of high compression (defined as ankle sub-bandage pressure 35-40 mm Hg). Such systems are deemed to deliver the optimum therapeutic effect in eligible patients but are contraindicated in people with clinically significant arterial disease. The four layer bandage (an elastic system), the standard method in the United Kingdom, comprises orthopaedic wool, crepe bandage, elastic bandage, and a final cohesive retaining layer. All layers are applied from toes to knee and normally require weekly renewal but can be changed more often if necessary. The short stretch system, used as standard treatment in mainland Europe and Australia, is an inelastic bandage, meaning that it has minimal extensibility (or “give”) when handled. An orthopaedic wool layer is covered by the bandage at full stretch to create a rigid casing around the limb that generates resistance against calf muscles and other tissues with reapplication every few days. The short stretch bandage has the advantage of being washable and reusable. The four layer bandage commonly available as a proprietary kit, designed to be discarded after a single use. Leg ulcers are defined to be loss of epidermal and dermal tissues of leg or foot. Leg ulcers are most commonly caused due to venous Insufficiency, arterial insufficiency, neuropathy often due to diabetes and ulcer from prolonged pressure and ischemia. Less common causes include; trauma, inflammation, malignancy, metabolic Conditions and due to Infections. Approximately 1% of the population suffers from a leg ulcer at some stage during their lives.

Venous leg ulcers are consequence of chronic venous insufficiency. The goals of non-operative treatment: for venous ulceration are to promote healing of the existing ulcer and prevent recurrences while allowing the patient to maintain a normal ambulatory status. Compression therapy remains the primary non-operative treatment for chronic venous insufficiency despite progress in both ablative and reconstructive venous surgery.

Compression = N (No. of Bandage Layer) x t (Bandage Tension)/ R (Radius of Leg)

Compression pressure of a least 30mm Hg to 40mm of Hg at the ankle should be utilized in the management of venous leg ulcers. All compression bandage systems must create a pressure gradient from ankle to knee. According to the law of laplace, which mathematically relates bandage tension compression pressure, the shape of leg will create this gradient. Hence compression will be found maximum at the gaiter area just proximal to ankle joint of 30-42mm Hg and as we go up the leg it decreases and at the knee it in 17-20mm Hg. Recommended pressures for the treatment of venous disorder include; ankle pressure of 14-17mm/ Hg in superficial or early varices, 18-24mm/Hg in varices of medium severity or with ulcer treatment and prevention of mild edema and 25-35mm/Hg in gross varices, post-thrombotic syndrome, gross edema, ulcer treatment and prevention.

- First layer dressing:
  Gamgee applied from foot to above knee to absorb the discharge from ulcers and protect bony prominences.

- Second layer dressing:
  Banding with cotton bandage to keep the 1st layer in place

- Third layer dressing:
  Crepe bandage which applies the compression pressure

- Four layer dressing:
Micropore to keep compression bandage in place / adhesive bandage to keep compression bandage in place

Type of bandages

Type 1 - Light weight conforming - stretch bandages. Which have simple dressing retention function, it has light weight elastomeric threads, which impart a high degree of elasticity but little power to the bandage.

Type 2 - Light support bandages called short or minimal stretch bandages. The crepe-type products of British pharmacopoeia. These have been used for the treatment of venous ulcer. They form an inelastic covering to the leg which tends to resist any change in the geometry of the calf muscle during exercise.

Type 3 - Compression bandages, deliberate application of pressure to control edema and reduce swelling.

Type 3a - Light compression bandages maintain low level of pressure up to 20mm Hg indicated in superficial or early varices and varicosity during pregnancy.

Type 3b - Moderate compression bandages, pressure of 30 mmHg the ankle, used in the treatment of varicosis during pregnancy, varices of medium severity.

Type 3c - Have pressure of 40mm of Hg - Gross varices, gross edema, post thrombotic venous insufficiency and leg ulcers.

Type 3d - extra high performance compression bandages have pressure of >50 mmHg used for most edematous limbs.

In order to achieve the pressures described in the classification system described above, it is assumed that the bandages in question will be applied in the form of a spiral with a 50% overlap between turns, effectively producing a double layer at any point on the limb. Different application techniques such as a figure of eight bandage will produce larger numbers of layers at any one point and therefore higher sub-bandage pressures. It is also important to recognize that the pressures quoted for the various types of bandages are intended only as a general guide. If a bandage was to be applied with constant tension to legs of different dimensions, the pressures achieved would also be very different. This variation is clearly demonstrated. The aim of the study is to compare the healing rate and area of healing in chronic venous ulcer with the topical use of H-EGF along with regular four layer compression bandaging as versus four layer compression bandaging alone. The importance of leg geometry and application tension cannot be over emphasized when selecting or applying a bandage to produce a specific level of pressure, in order to treat a particular clinical disorder. Applied too loosely, the bandage will be ineffective, too tight and it may cause tissue damage and necrosis. In extreme cases, this may lead to amputation, particularly if arterial disease is present. Research has shown that the tension with which bandages are applied varies between practitioners. Although one individual may produce reasonably consistent results from patient to patient, major variations have been recorded in the pressures achieved by different bandagers. In an attempt to overcome this problem, bandages have been produced which have a geometrical design printed at intervals along their length which changes shape when the bandage is stretched to a predetermined level of tension.

Fig.-1: Venous ulcer showing staining of surrounding skin
Fig.-2: Single layer/Crepe bandage

Fig.-3: Multi/Four layer bandage

Fig.-4: An oven cotton bandage

Fig.-5: An oven bandage containing viscose and nylon
Material & Methods:
This study was conducted on 200 hundred patients with in last two years in which 100 patients with venous leg ulcer where treated with four layer bandage and another 100 patients with same condition were treated with single layer crepe bandage. Before application of bandage, proper history of patient was taken and duplex scan was done. The primary outcome was measured by time duration of ulcer healing. Secondary outcome included incidence and number of adverse events in every patient.

Results:

| Gender | Four layer bandage (n=100) | Crepe bandage (n=100) | P value |
|--------|---------------------------|------------------------|---------|
|        | n  | %  | N  | %  | 0.138 ns |
| Male   | 70 | 70.0 | 60 | 60.0 |         |
| Female | 30 | 30.0 | 40 | 40.0 |         |

In table I shown that, according to gender wise total patients’ distribution, male patients were 70% & 60% and female patients were 30% & 40% respectively of four layer and crepe layer bandages. P value was 0.138

ns= not significant
Table II

| Age group (years) | Four layer | Crepe bandage | P value |
|------------------|------------|---------------|--------|
| 21-30            | 9          | 11            |        |
| 31-40            | 21         | 19            |        |
| 41-50            | 41         | 38            |        |
| 51-60            | 22         | 24            |        |
| >60              | 7          | 8             |        |
| Mean±SD          | 42.5±13.2  | 44.3±11.7     | 0.308ns|

In table II shown that, 41-50 age groups were highest 41% & 38% of four layers and crepe bandage patients followed by immediate group 51-60 age group 22% & 24% respectively. The mean score was 42.5±13.2 & 44.3±11.7. P=0.308ns

Table III

|                  | Duplex | Four layer (n=100) | Crepe bandage (n=100) | P value |
|------------------|--------|---------------------|------------------------|--------|
|                  | n      | %                   | N                      | %      |
| CVI              | 73     | 73.0                | 66                     | 66.0   | 0.282ns  |
| Chronic DVT      | 27     | 27.0                | 34                     | 34.0   |          |

In table III shown that, CVI were heighest of 73% & 66% in both four layer and crepe layer bandage patients. P value - 0.282ns

Table IV

|                  | Duplex | Four layer (n=100) | Crepe bandage | P value |
|------------------|--------|---------------------|---------------|--------|
|                  | n      | %                   | N             | %      |
| First            | 16     | 16.0                | 18            | 18.0   | 0.706ns  |
| Recurrent        | 84     | 84.0                | 82            | 82.0   |          |

In table IV shown that, recurrent were height of 84% & 82% in both four layer and crepe layer bandage patients. P value - 0.706ns

Table V

| Ulcer duration (months) | Duplex | Four layer (n=100) | Crepe bandage | P value |
|-------------------------|--------|---------------------|---------------|--------|
|                         | n      | %                   | N             | %      |
| <1                      | 32     | 32.0                | 41            | 41.0   |        |
| 1-6                     | 34     | 34.0                | 44            | 44.0   |        |
| 7-12                    | 22     | 22.0                | 5             | 5.0    |        |
| >12                     | 12     | 12.0                | 10            | 10.0   |        |
| Mean±SD                 | 5.7±2.6| 4.3±2.1             |              | 0.001s |

S= significant

In table V shown that, regarding ulcer duration of patients, 1-6 month were highest 34%, 44% both of four layer & crepe layer bandage patients. Mean score were 5.7±2 and 4.3±2.1. P value 0.001s
### Table VI

**Distribution of the patients by presence of slough (N=200)**

| Presence of slough | Four layer bandage (n=100) | Crepe bandage (n=100) | P value |
|--------------------|-----------------------------|-----------------------|---------|
| Sloughy            | 63                          | 59                    | 63.0    | 59.0   | 0.562<sup>ns</sup> |
| Non sloughy        | 37                          | 41                    | 37.0    | 41.0   |                |

In table VI shown that, presence of slough were heighest 63% & 59% in both four layer and crepe layer bandage patients. P value 0.562<sup>ns</sup>

### Table VII

**Distribution of the patients by presence of granulation tissue (N=200)**

| Presence of granulation tissue | Four layer bandage (n=100) | Crepe bandage (n=100) | P value |
|-------------------------------|-----------------------------|-----------------------|---------|
| Granulating                   | 79                          | 58                    | 79.0    | 58.0   | 0.001*        |
| Non granulating               | 21                          | 42                    | 21.0    | 42.0   |                |

In table VII shown that, presence of granulation tissue were heighest 79% & 58% in both four layer and crepe layer bandage patients. And p value 0.001*

### Table VIII

**Distribution of the patients by healing time (N=200)**

| Healing time (months) | Four layer bandage (n=100) | Crepe bandage (n=100) | P value |
|-----------------------|-----------------------------|-----------------------|---------|
| <1                    | 68                          | 12                    | 68.0    | 12.0   |                |
| 1-3                   | 29                          | 16                    | 29.0    | 16.0   |                |
| 3-6                   | 2                           | 28                    | 2.0     | 28.0   |                |
| >6                    | 1                           | 44                    | 1.0     | 44.0   |                |
| Mean±SD               | 1.1±0.8                     | 5.7±2.2               | 0.001*  |

In table VII shown that, healing time of the patient was higher 68% of <1 month with four layer bandage whereas with single layer/crepe layer was 12%. Mean score were 1.1±0.8 & 5.7±2.2, P value 0.001*

#### Discussion:

The exact cause of venous ulcers is not certain, but a common denominator is generally venous stasis, which may be caused by chronic venous insufficiency, and/or congestive heart failure.<sup>20,21</sup> Venous stasis causes the pressure in veins to increase. The body needs the pressure gradient between arteries and veins in order for the heart to pump blood forward through arteries and into veins. When venous hypertension exists, arteries no longer have significantly higher pressure than veins, and blood is not pumped as effectively into or out of the area.<sup>22-25</sup> Venous hypertension may also stretch veins and allow blood proteins to leak into the extravascular space, isolating extracellular matrix (ECM) molecules and growth factors, preventing them from helping to heal the wound.<sup>22,25</sup> Leakage of fibrinogen from veins as well as deficiencies in fibrinolysis may also cause fibrin to build up around the vessels, preventing oxygen and nutrients from reaching cells.<sup>22</sup> Venous insufficiency may also cause white blood cells (leukocytes) to accumulate in small blood vessels, releasing inflammatory factors and reactive oxygen species (ROS, free radicals) and further contributing to chronic wound formation.<sup>22,25</sup> Buildup of white blood cells in small blood vessels may also plug the vessels, further contributing to ischemia.<sup>23</sup> This blockage of blood vessels by leukocytes may be responsible for the “no reflow phenomenon,” in which ischemic tissue is never fully reperfused.<sup>23</sup> Allowing blood to flow back into the limb, for example by elevating it, is necessary but also contributes to reperfusion injury.<sup>20</sup> Other comorbidities may also be the root cause of venous ulcers.<sup>21</sup> It is in the crus that the classic venous stasis ulcer occurs. Venous stasis results from damage to the vein valvular system in the lower extremity and in extreme cases allows the pressure in the veins to be higher than the pressure in the arteries. This pressure results in transudation of inflammatory mediators into the subcutaneous tissues of the lower extremity and subsequent breakdown of the tissue including the skin.

#### Conclusion:

Venous ulcers are costly to treat, and there is a significant chance that they will recur after healing, one study found that up to 48% of venous ulcers had recurred by the fifth year after healing.<sup>22</sup> However treatment with local anaesthetic endovenous techniques suggests a reduction of this high recurrence rate is possible.<sup>23</sup> Graduated external compression plays a major role in the successful treatment of venous ulcers. Several different types of bandaging systems are available, each of which may have
advantages over the others for particular applications. The enhanced performance of some of the new bandages means that if they were to be applied with excessive tension, unlike the older cotton based products, they will maintain these levels for extended periods with potentially disastrous consequences for the patient. A sound grasp of the theory of bandaging and a good application technique are therefore essential if these new bandages are to be used safely and cost effectively. To this end, bandaging and advice on product selection should once again form a part of a nurse’s training. The importance of good bandaging technique was described in 600 BC by Sushruta who suggested that practitioners should practice on life sized manikins made of stuffed linen. If such manikins could be produced with multiple pressure sensors in the legs to monitor bandage performance, they could provide a useful method for assessing the performance of both bandage and bandager. Without proper care, the ulcer may get infected leading to cellulitis or gangrene and eventually may need amputation of the part of limb in future.

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