A newly designed SIPC device for management of lymphoedema

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Abstract

Purpose Using (Sequential) intermittent pneumatic compression (SIPC) is one of the most appropriate non-surgical treatments for lymphoedema. In this study, we introduce a new mode for SIPC and evaluate its clinical results with higher pressures.

Methods Participants included 43 lower limb lymphoedema patients who underwent high pressure SIPC. Limb circumference pre- and post-SIPC were evaluated.

Results The mean reduction of the affected limb oedema was approximately 75%, which is regarded as a good response to the short-term treatment. Patients with disease duration more than 20 years didn't show a good or excellent response. Also the foot area had the least degree of reduction of oedema.

Conclusion We concluded that, the suggested mode may provide more acceptable results compared with the other

This mode allows unidirectional forward lymph flow and associated high pressure usage well tolerated in chronic cases of the disease.

Keywords Lymphoedema · Sequential intermittent · Pneumatic · Compression lymphatic drainage

Introduction

Lymphoedema has been defined as swelling of the soft tissue caused by abnormal quantity of lymph [1]. Nearly 200 million (20% of the world population) live in the endemic zone, while more than 19 million actually suffer from the disease [1].

In industrial countries, highest incidence of lymphoedema has been observed among patients undergone lymph node resection and irradiation but in developing countries the most common cause is postinfectious lymphoedema [2].

This is a challenge either for the attending physicians or the patients, because despite various suggested treatments, no definite medical or surgical treatments have yet been identified for the disease (Fig. 1) [3–7].

Though various physical therapies offered for the disease, using (Sequential) intermittent pneumatic compression (SIPC) is among most useful approaches [8–11].

Justification of new mode

Functionally, there are many suggested modes of cuffs inflation in multiple encasing machines (Using SIOC) that

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Fig. 1 Algorithm of suggested treatments for lymphoedema

generally include two types. In first type, cuffs are inflated from distal to proximal, and after a specific time, the entire encasing would be emptied at once. The deficiency of this type of machine is that the pressure is exerted on distal of the limb for a longer period; as a result, there is a disproportion in applied pressure which results in a feeling of discomfort in distal segments.

In second type of multiple encasing devices, the cycle begins with inflation of the distal cuff and continues with inflation of the proximal (second cuff) after a specific time and deflation of the distal cuff. The cycle continues to the last cuff (usually the 4th cuff) which is the most proximal one on the limb. In this approach, in fact at each period of time only a segment of the limb is subjected to the pressure which interferes with adequate milking mechanism. In other words, some of the lymph is driven to the distal part, since the distal positive pressure has been removed at the second stage of the cycle.

We designed and evaluated a new device with a different mode of SIPC for management of lymphoedema.

Patients and methods

We designed a device with multiple encasing mechanism which allows lymph to flow only forward. It was named as Pneumolymph® and passed the safety and quality control

in Iranian Department of Industrial Proprietary (IDIP). Then evaluation of the Pneumolymph® on lymphoedema treatment was planned and the study was conducted after ethics committee approval (Mashhad University of Medical Sciences, Iran) from January 2002 to September 2003.

The Pneumolymph® is a multiple encasing machines with a new mode. It has 4 valves each connected to one chamber which located sequentially, the cuffs covered the limb so as to overlap one another (C1-4). At the beginning of the cycle the cuff covering foot and ankle (C1) is inflated and after a specific time ($T = 15$ seconds) the cuff covering the distal segment of calf (C2) begins to inflate. After passing the “T” time, foot and ankle cuff (C1) is emptied and simultaneously proximal cuff to the calf (C3) is inflated. That’s while the distal cuff to calf is still full of air (Table 1). Therefore, in the approach on one hand, all segments of the limb are subjected to the equal force and time of pressure. On the other hand, positive pressure due to inflating a cuff with the residual positive pressure arising from the former cuff permits milking mechanism to be done completely (contrary to the second type of multiple encasing machines).

In this study 43 patients with lower extremity lymphoedema hospitalised for 48 hours. Patients with congestive heart failure, as well as patients known to suffer from renal dysfunction, hepatic failure and lower limbs venous or arterial insufficiency were excluded from the

Table 1 Pattern of cuffs inflation of the Pneumolymph®

Encasing time	Foot and ankle	Distal of calf	Proximal of calf	Thigh
T ₁	■			
T ₂	■	■		
T ₃		■	■	
T ₄			■	■
T ₅	■	■		
T ₆	■	■		

T* = 15 seconds

*T: Period of time for each cycle

study. There was no evidence of cellulites and ulceration in involved limbs.

None of the patients had an experience of using the SIPC devices formerly.

During hospitalisation, the Pneumolymph® was applied for a period of 8 hour/day (total time: 16 hours) and the patient limb was subjected to the pressure of 80–120 mmHg. Before application of the device we took following actions:

- A history of the disease was taken and the patient was evaluated for other causes of oedema
- Written informed consent was obtained from all participating patients
- Limb circumference was evaluated by serial measurements at fixed points. These points are placed midfoot, ankle, calf and mid-thigh. Circumference of the uninvolved limb is also measured to index severity of disease as well as to assess the goal for therapy
- Patient's weight was measured
- Skin changes (dryness, tightness, abnormal folding, infection, hair changes and epidermal atrophy) were recorded
- Some photos were taken of the limb.

After 48 hours and disconnecting the device from the patients, we performed below actions:

- Reassessment of limb circumference in previous specific points
- Assessment of patient's weight
- Taking photos of the involved limb
- Asking for problems associated with application of the device
- Asking for satisfaction and convenience of the patient.

As a criterion for efficacy of treatment the limb normalisation was considered in unilateral cases. For this reason to define degree of limb normalisation, the difference between circumference of the affected and that of the healthy limb was noted (Table 2).

In cases of bilateral involvement, since there was no possibility of comparing the limb to the normal limb

Table 2 Difference in circumference between the affected and healthy (normal) limbs in unilateral involvements

Assumed status of the limb	ACDL*
Normal	<2 cm
Approximately normal	2–5 cm
Fair	5.1–10 cm
Unacceptable	>10 cm

then reduction percentage of the limb circumference was calculated by comparing pre- and post-SIPC circumference (Table 3). After data collection, statistically analysis was performed using SPSS (version 16), by means of pare t-test $\pm 2SE$ for determination of confidence interval of 95%.

Results

Totally, 54 limbs in 43 patients underwent the treatment (9 men and 34 women). The mean age of patients was 37.8 years (ranging from 14 to 80 years). Among these, 24 cases had primary and 19 cases had secondary lymphoedema.

Eleven patients (55%) of the studied patients of primary group had an onset age of 10–35 years which correspond to the Praecox group in lymphoedema classifying, while onset age of 5 patients (25%) was above 35-year-old that belongs to Tarda group. Also, 4 patients (20%) were congenitally involved with the lymphoedema and 4 patients didn't remember the exact onset age of the disease.

Most of the patients have duration of the disease between 1 and 4 years (Table 4).

Table 3 Response assessment in bilateral involvements

Response	R _c
Excellent	>15%
Good	10–15%
Fair	5–9.9%
Poor	<5%

$$\frac{C_1 - C_2}{C_1} \times 100 = R_c$$

Pre-SIPC limb circumference = C₁Post-SIPC limb circumference = C₂Percentage of limb circumference reduction = R_c**Table 4** Frequency distribution of disease duration

Duration	<1 year	1–4 year	5–10 year	10 <year	Unknown	Total
Patients	5	18	3	11	6	43

Among secondary cases, postsurgical lymphoedema was the most common cause of the involvement (Table 5).

Thirty-two of all patients (67%) had a unilateral involvement while, bilateral involvement included 11 (33%) patients.

The most prevalent complaint of the patients was cosmetic concerns (86.3%), while feeling of limb heaviness, dull pain and feeling of tension comprised 54.5%, 36.3% and 13%, respectively.

Dermal abnormalities were, dryness (59%), dermal thickness (36.3%), hair loss (14%), infection (9%) and epidermal thinning and shining (4.5%).

In patients with unilateral involvement the maximum reduction of 94.5% was observed in foot area, while it was 66% at ankle (Table 6).

In cases of bilateral involvement, the highest reduction was in thigh (4.22 cm averagely) and the least in foot (2.25 cm averagely) (Table 7). 33.33% of cases with disease duration <4 years revealed a good or excellent response to the therapy. In contrary, there were no excellent or good

responses for patients suffered from the disease for more than 20 years (Table 8).

With respect to onset age of the disease, all congenital cases showed unacceptable response compared to the other groups (Table 9).

No complications occurred during therapy.

Table 8 Frequency distribution of highest degree of limb circumference reduction according to the disease duration

Response	<1 year	1–4	5–10	11–20	>20	Total
Excellent	0	2	0	2	0	4
Good	1	6	1	2	0	10
Fair	4	8	3	7	3	25
Poor	2	4	0	1	0	7

Table 9 Frequency distribution of highest degree of limb circumference reduction according to the onset age of the disease

	Excellent	Good	Fair	Poor
Congenital	0	0	5	0
10–35	3	6	13	4
>35	1	3	7	3

Table 5 Frequency distribution of the studied patients according to the cause of disease

Percentage	No. of patients	Cause of disease
52.9	27	Unknown
5.8	3	Congenital
13.7	7	Trauma
1.9	1	Infection
1.9	1	Bite
7.8	4	NVD
15.6	8	Surgical Dissection

Table 6 Limb normalisation in unilateral involvements

Rate of normalisation	Limb area			
	Foot	Ankle	Calf	Thigh
Normal	25	16	14	15
Approximately normal	7	8	10	6
Fair	0	8	7	5
Unacceptable	0	0	1	2

Table 7 Circumference reduction in cases of bilateral involvement

	Min	Max	Mean
Foot	0	10	2.25
Ankle	1.5	7.5	3.84
Calf	1	21	3.56
Thigh	1	17	4.22

Discussion

Owing to the insufficient sample size, statistics of the study with respect to prevalence of sex and side of involvement can not be extended.

Response of patients with more than 20 years disease duration was not excellent or good. This well suggests direct relation between disease duration and fibrosis formation, and consequently its inverse relation to the efficacy of treatment [1, 10].

Regardless of patient's age group, there was a high rate of good and fair response, while rate of excellent or poor responses was low which indicates favourable response to the modality.

Having the above mentioned definition of normalisation we come to two interesting results, evaluating two groups of patients; one with unilateral and the other with bilateral lower limbs oedema. The ratio of oedema reduction in the former group over the normal limb size varies in different parts of that where foot has the greatest amount. But in the later group, as only the absolute oedema reduction size can be measured, foot has the least amount of that.

Should know that the least oedema collection would be around the foot, one can explain those facts.

Other reports suggest that foot and calf stands in the first order of weak response to the therapy which is the same as ours results in bilateral lower limbs oedema [12]. This problem may arise from poor fitting of cuff to the site specially in ankle.

The 66–94% mean reduction of oedema in the study indicates a comparable result with the other multiple encasing devices for lower extremity lymphoedema management [1, 23]. Using high pressure helped us to obtain acceptable responses, which is due to some degrees of fibrosis in most of our patients.

Our designed device and its especial mode permits to apply it safely for 8 hour/day continually with high pressures of 80–120 mmHg without any complications. The mode makes a feeling of less discomfort, and permits its application in higher pressure. It minimises risk of arterial obstruction, since each cuff applies pressure just for a 30 seconds period of time. On the other hand, this high pressure does not affect the arterial circulation because it is absorbed by the fibrous subcutaneous tissue.

However, in the case of congestive heart failure or renal problems applying the approach may lead to pulmonary oedema. Therefore, likelihood of occurrence, it is better to use ever lower pressure and time setting, and give diuretics in addition if needed [1]. Also we recommend using high pressure SIPC in patients with some degree of fibrosis formation because in new onset lymphoedema low pressure SIPC is affective and more comfortable.

Our findings suggest that the Pneumolymph® with its especial mode is useful in lymphoedema management. It is also safe and well tolerated in higher pressure setting when patients are properly selected.

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