Non-Pharmacological Methods and Night Leg Cramps among Patients Having Varicose Veins

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Abstract: Aim: This study aims to investigate the effect of non-pharmacological methods on night leg cramps among patients having varicose veins. **Methods:** A quasi-experimental design was used in the conduction of this study that was conducted in the Out-patients clinics at El-Demerdash Surgical Hospital, which is affiliated to Ain Shams University. **Sample:** A purposive sample included 80 adult and old age patients from both genders with varicose veins and have developed night leg cramps. **Tools:** 1) Patients' interviewing questionnaires to assess the knowledge about night leg cramps and non-pharmacological methods. 2) Calf - stretching exercises record. 3) Diet regimen record. 4) Patients' condition assessment sheet: A)Outcome measures to identify number, duration and severity of leg cramps and sleep disturbances and B) Symptoms development. **Results:** More than half of the studied patients had unsatisfactory knowledge in pre-test, added to poor levels of exercises and diet regimen. Moreover mixed group (calf - stretching exercises and diet regimen, added to traditional treatment) had the highest improvement in post-tests regarding cramps frequency and persisting symptoms, as well as outcome measures and symptoms development. **Conclusion:** Non-pharmacological methods (calf - stretching exercises and diet regimen) in combination with traditional treatment could be used to reduce night leg cramps among patients having varicose veins. **Recommendation:** Further studies are needed to elucidate the effect of other therapeutic measures on preventing night leg cramps.

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Key words: Non-pharmacological methods (calf – stretching exercises and diet regimen) - night leg cramps with varicose veins.

1. Introduction:

Varicose veins are the most clinical manifestations of chronic venous disease and occurring in one-quarter to one-third of adult people. In epidemiological studies, they can be defined as any dilated, tortuous and elongated subcutaneous veins of the leg. Moreover, can be small e.g flare veins, reticular veins), as well as large e.g truncal saphenous and tributaries. The etiology and risk factors for varicose veins are still subject to debate, but several studies have shown that higher risks for varicose veins have been associated with age, female gender, family history, pregnancy, obesity and prolonged standing or sitting (Potter & Perry, 2011 and Bahk, *et al.*, 2012).

Night leg cramps and varicose veins are common lower extremity symptoms. It has been suggested that limb circulation may be disturbed in patients with muscle cramps due to leg venous insufficiency. Muscle cramps (or charley horse) occur as a result of the stimulation of reflex and through hyper excitation of the motor neurons in any leg nerve or in spinal cord, added to, is a strong, painful contraction or tightening of a muscle that comes on suddenly and lasts from a few seconds to several minutes and often occurs in the legs. Night leg cramps can be defined as involuntary, painful, sudden contractions of muscles, usually in the calf but also in other areas of the leg and commonly disrupt sleep. It is caused by sudden contraction of gastrocnemius or sole- us muscle, with the foot in a passively planter flexed position, from which involved muscles shorten beyond the physiologic limit into a painful cramps. Moreover, when muscle cramping is corrected, it often lets up within days/weeks (Katzberg, *et al., 2010* and Blyton, *et al., 2012*).

In one research study, it was found that 59% of outpatient veterans reported nocturnal leg cramps. In addition, it is a common health problem in the ambulatory setting. Pharmacological treatment for leg cramps has potentially serious unwanted effects. Moreover, quinine sulfate has been prescribed for decades for the treatment of nocturnal leg cramps, but clinical trials have only recently been performed. Given the risks of serious side effects, this treatment has to be carefully evaluated to weigh the benefits against potential risks (Young, 2009 and El - Tawil, *et al.*,2010).

An alternative management strategy should be used to deal with leg cramps which appears as a theoretically attractive technique counteracting undesirable physiological changes. Currently, many interventions are available for preventing night-time calf-muscle cramps (e.g. magnesium and muscle stretching, strengthening and splinting), but no drug or physical therapy has demonstrated adequate efficacy and safety. In addition, preventive measures involve ensuring adequate fluid intake before undertaking physical exercises or activities. For those who experience muscle cramps due to illness and may be affected by the treatment. Cramp may be avoided by changing or adjusting medications. dosage or medication combinations when possible (Coppin, et al., 2005 and Garrison et al., 2011).

An uncontrolled study suggested that calfstretching exercises could prevent night leg cramps. The two muscles of calf are the gastrocnemius and soleus. It's especially important to stretch them, they're the most common muscles to suffer from cramp. Doing stretches for the calf is a great exercise for leg cramps at night. Muscles for walking and exercise act as a pump by contracting and relaxing and helping to force blood towards the heart. There are various calf muscle stretching exercises e.g. gastrocnemius stretch, soleus static stretch and achilles tendon stretch, that can not only lengthen the muscles in calves but also reduce the risk of foot problems such as shin splints, ankle pain and plant fasciitis (Miller and Layzer, 2005). There is a significant relation between diet and leg cramps e.g. fluid imbalances and mild dehydration can trigger muscle cramping, low sodium intake is the cause of cramps in most athletes. muscle cramps are commonly listed as symptoms of calcium deficiency. calcium is one of the nutritional factors people most associate with relieving cramps, second only to the potassium-rich banana.. Muscle weakness, muscle twitching, and muscle cramps are common symptoms of magnesium deficiency. Inadequate carbohydrate stores have also been implicated as a potential cause of muscle cramps (Larson-Meyer, 2013). Moreover, following a healthy lifestyle and having healthy foods rich in potassium. Bananas, grapes, beans, apricots, dates, raisins, cabbage, broccoli, tomatoes, oranges, grapefruits, potatoes, corn, saltwater fish like tuna, all are good sources of potassium and other required minerals (Hart,2012).

Justification of the problem:

Many studies suggested that non pharmacological measures (diet and exercises therapy) are considered as a significant contribution in addition to the pharmacological treatment to prevent or at least limit the magnitude of nocturnal leg cramps. It is considered as a cheap, easy and readily available technique. Moreover, it decreases patient exposure to more medications and their side effects(Garrison, *et al.*, 2011 and Ignatavisicus & Wokman,2011). Quinine is not a routine treatment for nocturnal leg cramps and should only be considered: when cramps are very painful or frequent; when other treatable causes of cramp have been ruled out and when non-pharmacological measures have not worked (eg, passive stretching exercises). After an initial trial of 4 weeks, treatment should be stopped if there is no benefit (Le Mone and Burke,2009).

Aim:

The aim of this study was to investigate the effect of non-pharmacological methods (calf-stretching exercises and diet regimen) on night leg cramps among patients having varicose veins.

Hypothesis:

Non-pharmacological methods (calf-stretching exercises and diet regimen), in addition to traditional treatment have a positive effect on reducing night leg cramps among patients having varicose veins.

2. Subjects and Methods:

Operational definitions:

- Body Mass Index (BM1): Is the degree of obesity which was classified by **Smeltzer and Bare, (2006)** as follows: [less than 20= under weight, from 20-30 = normal weight and more than 30= over weight].
- Non-pharmacological methods: Mean calf stretching exercises and diet regimen.

Design: A quasi-experimental design was used in the conduction of this study.

Setting: the current study was conducted in the outpatients clinics at El-Demerdash Hospital which is affiliated to Ain Shams University.

Subjects: a purposive sample including 80 adult and old age patients with varicose veins, from both genders and having developed nocturnal leg cramps constituted this study sample. The sample was allocated randomly to the following:

Group 1 (traditional treatment): This group acted as a control group.

Group 2 (calf - stretching exercises and diet regimen).

Group 3 (mixed group)

Inclusion criteria:

Patients who were still suffering significantly and were given repeated prescriptions of medications for night leg cramps in the previous 3 months. In addition,

patients having normal neurological examination results of both legs.

Exclusion criteria:

Severe osteoarthritis, pregnancy, terminal disease and dementia.

Tools of data collection:

1-Patients' interviewing questionnaire (pre / post and follow-up tests) that was designed and filled by the researchers. It was designed in the light of relevant references to assess patients' knowledge regarding night leg cramps and non-pharmacological methods. It was written in simple Arabic language. Data obtained were related to:

- Demographic characteristics of patients which included (age, gender, occupation, BMI, smoking, frequency of cramps during the last 2 3 weeks, duration and symptoms persistence the following day).
- Patients' knowledge regarding nocturnal leg cramps (definition, causes, signs and symptoms, suitable position and traditional treatment), added to diet regimen and exercises technique as non-pharmacological methods. It was scored into either unsatisfactory knowledge (less than 60%) or satisfactory (60% and more).

2- Calf - stretching exercises record (pre/ post and follow-up tests), which was guided by Coppin, et al., 2005, Smeltzer &Bare, 2006 and Potter &Perry, 2011, included type, time, duration of exercises and frequency. It was completed by the researchers. Exercises included gastrocnemius stretch, soleus static stretch, achilles tendon stretch and walking. Total duration of cxercises/3 months = 12 weeks x 4 times/week = 48 time. Level of exercises was determined as follows: Good = 30-48 times/3 months. Average = 20-30 times/3 months. Poor = <20 times/3 months.

A correct practice of exercises was scored as (1), while the incorrect (zero). It was scored into either inadequately done (less than 80%) or adequately done (80% and more).

3-Diet regimen record (pre/ post and follow-up tests), which was guided by (**Timby & Smith, 2008 and Garrison,** *et al.,* **2011)**, included contents of daily patients' meals. It was completed by the researchers and determined through the two levels: Satisfactory = Daily balanced diet was taken by the percentage of 60% and mor*e*, or unsatisfactory if the percentage less than 60.

4- Patients' condition assessment sheet:

A) Outcome measures (post / follow - up tests), which was completed by the researchers and included (number, duration and severity of leg cramps and any sleep disturbances). It was guided by (Coppin, *et al.*, 2005, Wilson, 2007, Wood, 2008 and Young, 2009). It included the following items:

- Number of cramps which was measured by a modified numerical scale (0 4), whereas no = zero, mild = 1, moderate = 2 and sever = 3 4.
- Duration of cramps which was measured in intervals as follows: 0 <5 minutes, 5 <10 minutes, 10 < 30 minutes and more than 30 minutes. Whereas, short = < 10 minutes, moderate = 10 < 15 and long = 15-20 minute.
- Severity of cramps which was measured by the modified numerical pain scale (0-10), whereas, no = zero, mild = 1-< 4, moderate = 4 <7 and severe = 7-10.
- Number of sleep disturbances which were measured by the modified numerical scale (0-4). whereas, no = zero, mild = 1-2, moderate = 3 and severe = 4.

B) Symptoms development (follow-up test) which included the following: entirely free of symptoms, considerably improved, unchanged and worsened.

Content validity:

Content validity was ascertained by a group of experts from Vascular Surgery, Medical– Surgical Nursing and Community Health Nursing. Their opinions were elicited regarding to the tools format layout, consistency and scoring system. Contents of the tools were tested regarding to the knowledge accuracy, relevance and competence.

Ethical considerations:

In the planning stage approval was obtained from the directors of the above mentioned setting. All patients were informed about the study and their rights according to medical research ethics that they were free to decide whether or not they would participate in the study. Then a written informed consent was obtained from each patient who agreed to participate in the study.

Pilot study:

A pilot trial was carried out on 10% of the total study sample to test the clarity and practicability of the tools, in addition to subjects and settings. Pilot subjects were later included in the study as there were no radical modifications in the study tools.

Procedure:

- Sampling was started and completed within 6 months.
- Purpose of the study was explained to the patients who agreed to participate in the study prior to data collection.
- The data were collected by the researchers weekly at the morning shifts in the Outpatients Clinics.
- Filling in the tools was done by the researchers according to the patients' understanding and health condition.

• The information leaflet was designed in simple Arabic language according to the predetermined patient's educational needs about night leg cramps, therapeutic diet (which included calcium, potassium, vit. E, magnesium and increase fluid intake) and calf stretching exercises (Gastrocnemius Stretch, Soleus Static Stretch, Achilles Tendon Stretch and Walking exercises). Its contents were consistent with the related literatures and the actual medical treatment. It was distributed to patients at first with orientation to its contents and purpose. Practice of calf stretching exercises was done through demonstration, redemonstration and pictures.

Gastrocnemius Stretch exercises:

*Standing straight and place one foot in front of the other.

*Non stretching leg is the one in front and bears weight of body as extending the other leg behind.

*Keeping stretched leg straight with heel flat on the floor.

Moving body forwards and feel stretch on the calves.

*Holding for 30 seconds, release and repeat with the other leg.

Soleus Static Stretch: The soleus muscle is located in the lower part of calf muscle.

*Standing straight and bend one knee forward with the heel of this leg flat on the ground.

*Lowering hips till feeling a stretch on the lower calf muscle.

*Holding for 30 seconds and repeat with the other leg.

Achilles Tendon Stretch exercises:

*Standing near a wall at arms length distance away.

*Placing both hands on the wall in front of the body and lean in front, keeping hands shoulder distance apart at all times.

*Placing foot that needs to be stretched behind the body and the other foot closer to the wall.

*Bending knee of the leg to be stretched with the heel flat on the floor.

*Leaning into the wall until feeling the stretch in calf muscles.

*Lowering hips to intensify the stretch.

*Changing sides after 30 seconds and repeat.

Walking exercises:

Should be done daily for 20 - 30 minutes.

The sample was allocated randomly as follows:

Group1: Patients were guided only regarding their pharmacological treatment. This group acted as a control group.

Group2: Patients were informed about diet regimen,

added to exercises technique to be done 3-4 times / per week for 12 weeks. Hold each stretch for at least 30 seconds as this gives the muscles enough time to relax into the posture. Try and repeat each stretch two to three times. Moreover, walking exercises daily.

Group3: Patients were instructed regarding exercises technique, diet regimen in addition to pharmacological treatment.

- All patients were contacted by telephone for any explanation.
- Post-test was done after one month from pre test and follow- up test after 2 months later.
- All patients were assessed individually using the previously mentioned study tools according to their physical and mental readiness.

Statistical analysis:

Data were presented using numbers, percentages, mean, standard deviation and t-test. Level of significance was threshold at 0.05.

3. Results:

Table (1): Presents characteristics of the studied groups. More than half of the patients were in the age group of 45 < 60 years (56.2%) and 82% out of 50 females were multipara. About two third of them were non smokers (65%). In addition nearly two fifths (41.3%) had BMI 25-30 and more than one third (36.2%) of them had more than 30.

Figure (1): Shows patients' knowledge about night leg cramps and non-pharmacological methods in pre/post tests. Results revealed that about three fourths (75.0%) of them had unsatisfactory knowledge in pre test. Meanwhile, significant improvement was noticed in post – test whereas, 85.0% of them had satisfactory knowledge.

Figure (2): Present distribution of studied patients according to diet regimen in pre/post tests. Nearly two thirds (65.0%) of them had poor diet regimen in pre – test. Meanwhile, significant improvement was indicated in post and follow – up tests.

Figure (3): Shows levels of exercises and diet regimen among the studied patients in pre/post tests. More than half (60.0%) of them had poor exercises in pre- test. Meanwhile, significant improvement was indicated in post and follow – up tests.

Table (2): Reveals leg cramp frequency and symptoms persistence on the day after nightly cramps. As noticed G3 (mixed group) had the highest improvement followed by G2 (diet and exercises group) and the later G1 (treatment group).

Table (3): Shows the outcome measures among studied groups in pre and follow up tests. A statistically significant difference was found between pre and follow-up tests and between G1 (treatment

group) and G2 (mixed group) whereas G3 was the best. In addition, the mean difference was higher in G3 (mixed group) than other groups.

Table (4): Displays patients' distribution in relation to symptoms development. As shown G3 (mixed group) had the highest improvement as regards symptoms development, followed by G2 (diet & exercises group), then later G1 (treatment group), with mean \pm SD=49.0 \pm 29.7, 31.7 \pm 24.7 & 30.0 \pm 21.8 respectively.

Table (1): Characteristics of the studied patients(n=80)

Items	Total patients			
Items	No	%		
Age/Year	10	12.5		
30-<45	45	56.2		
45-<60	25	31.3		
60&more	25	51.5		
$X \pm SD$	$= 27.5 \pm 24.7$			
Occupation				
Hard work	21	26.2		
Sedentary	19	23.8		
Retired	16	20.0		
Housewife	24	30.0		
Gender		37.5		
Male	30	62.5		
Female	50	02.5		
BMI:				
20<25	18	22.5		
25-30	33	41.3		
>30	29	36.2		
Parity: (N=50)				
Nullipara	9	18.0		
Multipara	41	82.0		
Oral contraceptive:	20	40.0		
(N=50)	20	40.0		
Smoking habits:				
Current	16	20.0		
Excessive	12	15.0		
None	52	65.0		

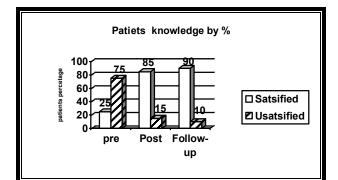


Fig. (1): Distribution of studied patients' knowledge in pre/post tests about night leg cramps and non-pharmacological methods

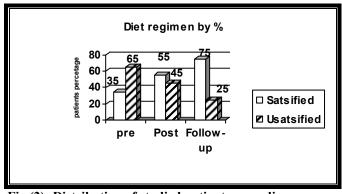


Fig (2): Distribution of studied patients according to diet regimen in pre/post tests

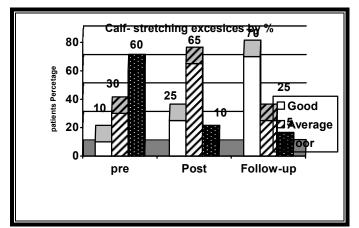


Fig (3): Distribution of studied patients according to levels of calf - stretching exercises in pre/post tests

Table (2): Percentage distribution of studied	
patients as regards leg cramps frequency and	
symptoms persistence in pre and follow-up tests	

Group1			Group2		Group 3	
(n=20)			(n=30)		(n=30)	
Items	Pre	F.U	Pre	F.U	Pre	F.U
	%	%	%	%	%	%
Cramps frequency:						
 Daily Every other day Twice weekly None 	60	15	55	10	60	5
	25	20	35	15	30	10
	15	30	10	20	10	15
	0	35	0	55	0	70
Persisting symptoms in days after cramps:						
- Always - Sometime s - Never	55 20 25	20 25 55	50 25 25	10 20 70	55 20 25	0 20 80

G1= Treatment G2=Diet and exercises regimen G3= Mixed

 Table (3): Presentation of outcome measures among studied patients in pre and follow-up tests

Outcome	Pre- test	Follow-up test	Mean difference	T1 value	T2 value
Measures	$\mathbf{X} \pm \mathbf{S}\mathbf{D}$	$X \pm SD$			
Number					
Group1	3.8 ± 1.0	2.8 ± 1.4	1.0	2.5	-
Group 2	3.7±1.0	1.8 ± 1.3	1.9	4.8	2.5
Group 3	3.9 ± 1.2	1.2 ± 0.8	2.7	9.7	4.0
Duration					
Group1	18.6 ± 10.9	11.8 ± 9.9	6.8	2.1	-
Group2	18.3 ± 11.0	8.3 ± 9.5	10.0	3.03	1.1*
Group 3	18.7 ± 10.9	5.0 ± 5.4	13.7	5.1	4.9
Severity					
Group1	8.91 ± 0.5	5.94 ± 1.1	2.97	9.9	-
Group2	8.88 ± 0.5	3.96 ± 1.0	4.92	16.4	6.6
Group 3	8.75 ± 0.5	1.65 ± 0.9	7.1	35.5	14.3
Sleep					
disorder					
Group1	3.45 ± 0.5	2.4 ± 1.08	1.1	3.7	-
Group2	3.35 ± 0.5	1.7 ± 1.1	1.7	5.7	1.8*
Group 3	3.40 ± 0.6	0.8 ± 1.0	2.6	8.7	4.0

*insignificant

Table (4): Percentage distribution of studied
patients as regards symptoms development in
follow-up test

Symptoms development	(G1) n=20	(G2) n=30	(G3) n=30	
1	%	%	%	
Entirely free of symptoms	15	20	28	
Considerably improved	55	60	70	
Unchanged	20	15	2	
Worsened	10	5	0	
Mean ± SD	30.0±21.8	31.7 ±24.7	49.0± 29.7	

4. Discussion:

Muscle cramps in patients with varicose veins occur more frequently and more often at night in the calf. They occur with a higher incidence of more than 12 episodes per year in patients with varicose veins than general population (**Young, 2009**). The present study aimed to investigate the effect of nonpharmacological methods on reducing nocturnal leg cramps among patients having varicose veins.

Regarding to gender, about two thirds of the sample were females with varicose veins. This finding is confirmed by **Garrison**, *et al.*(2011) who concluded that a prevalence rate for women was 25%-46% as compared to 7%-19% among men. Women generally predominate at all ages and nulliparous women are less likely to develop varicose veins. Moreover, oral contraceptives have increased venous dispensability and decreased tone. Muscle cramps were occurring on higher parity.

Body mass index above 30 was found in slightly more than one third of patients. In accordance with these study findings **Potter and Perry (2011)** reported that obesity has a variable risk factor for varicose veins more often in women than men. A body mass index of greater than 30 has been associated with a five fold increased prevalence of varicose veins in postmenopausal women. According to **Timby and Smith (2008)** obesity places an added burden on blood vessels. Excess fat compromises blood vessels and contributes to increased venous congestion.

Considering occupation, almost one quarter of the studied sample had sedentary work. The previous result was consistent with **El- Tawil**, *et al.* (2010), who clarified that leg cramps may be more common in affluent sedentary societies where muscle use and stretching is less. In the same context as regards smoking habits, one fifth of the sample was heavy smoker. In this respect, **Blyton**, *et al.* (2012) stressed that smoking is a major contributory factor in the development of varicose veins.

As evident from this study findings patients satisfactory knowledge about diet therapy and exercise control were higher in post-test. These findings might be due to lack of health education about diet therapy and exercises control and that patient obtain unsatisfactory required knowledge from other sources rather than health team. In this regard, Hegazy, et al. (2003) and Friedman, et al. (2011) claimed that, teaching patients involves dispelling misconceptions and providing them with factual information. Coppin, et al. (2005) emphasized on teach patient to eat enough dairy products and other foods that contain calcium to keep the bones strong and healthy. Similarly, Katzberg, et al. (2010) recognized that potassium, magnesium and vitamin E had a positive effect in relieving muscle cramps.

In the same line Smeltzer and Bare (2006) highlighted that, for mild cramps a trial of stretching exercises for the affected muscles before sleep is useful in reducing cramps. In a similar study, Bahk, et al. (2012) emphasized that, during cramps the patient should straighten the leg, heel first, wiggle toes and relax the affected muscle through gentle massage. Garrison, et al. (2011) suggested that placing a pillow to prop up the feet at end of bed or lying in prone position with feet hanging over end of bed help to reduce the occurrence of cramps.

Exercises can decrease venous blood pressure 20-30 mmHg which activates muscle pumping action that rejuvenates the venous blood circulation system. Continuous exercises for 8 weeks can enhance functionality of the calf muscle and enhance the venous blood circulation. So, to maintain a normal condition of the venous blood circulation functionality, patients are recommended to walk at least 20-30 minutes a day, 3-4 days a week. After finishing the activity of daily living in the evening patients are recommended to lie down and raise their leg above heart level or 15-20 cm above the mattress to enhance blood flow back to heart (Yang, et al., 2007).

As detected from this study results, there were significant improvements regarding leg cramps frequency and symptoms persistence the following day. The previous results were supported by Young (2009), who concluded that 25% of their patients with nightly leg cramps sometimes or always had more persisting symptoms the following day in the study group than 50% in the control group.

In relation to the outcome measures (severity, number, duration of leg cramps and sleep disturbances, a significant improvement was noticed among the studied groups in the follow-up tests.

Miller & Layzer (2005), Nicholas (2007) and Wood (2008) reported that careful attention should be paid to onset time and duration of cramps. They added that, duration is helpful to differentiate short muscle spasms from longer and more painful cramps which require a more thorough work-up.

This study postulated that the mixed group was the best, which could be related to the combination of correct information about diet regimen and exercises control adding to the pharmacological treatment. In this regards El- Tawil, et al. (2010) and Blyton, et al. (2012) stated that, stretching exercises or diet regimen are helpful in reducing frequency or intensity of sever cramps, added to traditional medications of cramps.

Conclusion and Recommendations:

On the light of the study results, it is concluded that non-pharmacological methods (calf - stretching exercises and diet regimen), adding to traditional treatment could be used in reducing night leg cramps among patients having varicose veins, therefore, it is recommended that diet and exercises therapy should be used as a therapeutic measures because they are cheap, easy and readily available to reduce night leg cramps in combination with pharmacological treatment. Further studies are needed to elucidate the effect of other therapeutic measures on preventing night leg cramps for patients with varicose veins.

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