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Effect of 'bedside ankle active exercise monitoring device' as an aid in the prevention of deep vein thrombosis among post- surgical geriatric population

Arun Thachil, Mahesh Subhash Nair

Professor, College of Physiotherapy, Medical Trust Institute of Medical Sciences, Irimpanam, Kochi-682309, Kerala, India

Supervising Physical Therapist, American Senior Communities, Cypress Grove Rehabilitation, 4255 Medwell Drive, Newsburgh, IN, USA, 47630

***Corresponding Author: Arun Thachil**

Email id: thachilarun@yahoo.com

ABSTRACT

Background

Deep Vein Thrombosis (DVT) with venous stasis is a serious complication in patients with a history of major lower extremity surgery. The elderly are in greatest jeopardy. DVT in rehabilitation setting can delay functional recovery. Encouraging the active movements of the leg pre and post operatively is an important role for physiotherapist. The most common prophylaxis method used to prevent DVT and to reduce the risk of pulmonary embolism is ankle exercise. Researchers have found that augmented information or feedback is effective in motivation and learning. There is a lack of devices which could be used in the field of DVT prophylaxis involving active exercises for bedridden patients providing augmented information and feedback both to the patients as well as to the rehabilitation team. This lead to the conceiving of a new simple "Bed Side Ankle active exercise monitoring device" (Ankle Plantar Flexion Dorsi flexion movement monitoring device), Which would be of help in monitoring the ankle exercise protocols.

Nair Mahesh Sukumaran Sudish, co-author was Granted Patent for Ankle Dorsiflexion-Plantar Flexion Active Movement Monitoring device published by Indian Patent Office on 07/08/2015 U/S 43(2) of The Indian Patent Act, Indian Patent News, # India Patent. According to the controller of Patents, Designs & Trade Marks Ankle Dorsiflexion-Plantar Flexion Active Movement Monitoring device is helpful for the patient as well as the medical and paramedical staff.

Aim

The study is to investigate the effect of ankle active exercise monitoring device as an aid in the prevention of DVT when used as an adjunct to conventional ankle exercise among Post-surgical geriatric population.

Methodology

The Population includes post –surgical, hospital stay geriatric patients who underwent open reduction internal fixation of Garden’s classification, Type 2 Neck of femur fracture (non- displaced). A total of 30 patients satisfying the criteria, sampled into two groups of 15 each using convenient sampling. Group A is control group and Group B is experimental group. Prophylactic treatment period begins wright after the surgical procedure for both control and experimental group, as soon as the spinal anesthetic wears off. Duration of prophylactic treatment was for the period during hospital stay of each patient (07 days).The patients were assessed every day during the period of study for any signs and symptoms of DVT using Wells probability scale. The outcome measurement was taken using Doppler Ultrasonography (Color flow duplex scanning) for the identification of DVT if any. The Group A receives Conventional physiotherapy. The Group B receives Ankle Active Movement Monitoring device and Conventional physiotherapy. Statistical analysis used was Chi-square test.

Result

26.67% of the patients in control group are diagnosed to have DVT in Ultrasound scan results. Whereas none of the patients in Experimental group showed any symptoms of DVT in Ultrasound scan results. Statistical analysis of the post Ultrasound scan result showed $\chi^2=4.6154$ ($p<0.05$). Which shows bedside ankle active movement monitoring device has significantly reduces symptoms of DVT.

Conclusion

‘Bedside ankle active exercise monitoring device’ is effective as an aid in the prevention of DVT among post-surgical geriatric population. The device is significantly effective as an aid for performing active ankle exercise for the prevention of DVT in abdominal, Pelvic, Extremity, Cardiac and Pulmonary surgeries. This device could be of assistance for the bedridden risk group also.

Keywords: Bedside Ankle Active Exercise Monitoring Device, DVT, Wells probability scale, Geriatric Population.

INTRODUCTION

Deep Vein Thrombosis (DVT) is a condition where there is a blood clot in a deep vein commonly located in calf or thigh. D V T (blood clot) is an intravascular deposit that is composed of fibrin and RBC’s with a variable platelet and leukocyte component. Clinical risk factors related to venous thromboembolism include increasing age, abdominal, pelvic, leg, cardiac or pulmonary surgery and prolonged immobility. The Virchow triad (ie, stasis, hypercoagulability, intimal injury) is often used to explain the development of perioperative DVT. The first component of the triad is stasis, which is a result of the venous pooling that accompanies both the spine positioning and the effects of anesthesia. The second component, hypercoagulability occurs as a consequence of decreased clearance of the procoagulant factors, with or without underlying coagulopathies .The third component, intimal injury, results from excessive vasodilatation caused by vasoactive amines and anesthesia. The combined influence of these factors promotes the development of venous thrombi in low flow areas. The propagation of thrombus leads to the

development of overt DVT. Deep veins are surrounded by powerful muscles that contract to help bring blood back to heart. The quick and efficient return of blood to the heart using these muscles is an essential part of the circulatory process. When the rhythm of circulation of blood slows down due to illness, injury or immobility, there is tendency of blood to pool. A static pool of blood offers an ideal environment for clot formation and possess a potential risk for DVT. DVT is one of the major risk factors for pulmonary embolism. The muscle pump plays a major role in the increasing cardiac output by increasing venous return during muscle contraction, which compresses the veins and squeezes blood back towards the heart. About 40-60 % of patients undergoing hip fracture repair sustain deep vein thrombosis and 20% at least on pulmonary embolus. The incidence of venous thromboembolism in the geriatric population increases with age from 1.8 to 3.1 per thousand for DVT in those aged between65-89. DVT usually form in the calf as a result of circulatory stasis imposed by activity restrictions. The most common mechanical method to prevent DVT and to reduce

the risk of pulmonary embolism is ankle exercise. The thrombus formation becomes obvious only by the end of a week or ten days following surgery. Researchers have found that augmented information or feedback is effective in motivation and learning. There is a lack of devices which could be used in the field of DVT prophylaxis involving active exercises for bedridden patients providing augmented information and feedback both to the patients as well as to the rehabilitation team. This led to the conceiving of a new simple "Bed Side Ankle active exercise monitoring device" (Ankle Plantar Flexion- Dorsiflexion movement monitoring device), which would be of help in monitoring the ankle exercise protocols.

METHODOLOGY

Study Approach: Experimental

Sampling method: Non probability Convenient Sampling.

Study settings: Dept. of Orthopedics, Government Medical College, Kozhikode.

Sample size: 30

Duration of the Study: 6 months.

Inclusion Criteria:

1. Type 2 fracture neck of femur as referred by the Orthopedic surgeon after open reduction internal fixation.
2. Unilateral case of internal fixation.
3. Age Group 65 to 75 years.
4. Gender both males and females
5. Patients who are able to actively contract their muscles.
6. Unimpaired Vision

Exclusion criteria

1. Recent or acute DVT
2. History of Peripheral vascular diseases like Buerger's disease.
3. History of smoking
4. Acute fractures around foot, ankle and knees
5. Tropical ulcers around feet
6. Compartment syndromes around the lower limbs.
7. Sensory impairments.
8. Coagulation disorders.
9. Malignancy
10. Acute pulmonary odema.
11. Any systemic diseases
12. Patients who are confused or under psychiatric treatment.

13. Patients who are administered with anticoagulants.

PROCEDURE

Thirty patients who underwent open reduction internal fixation for type 2 fracture neck of femur (Gardens) and fulfill inclusion criteria were included. Ethical approval from ethical committee and written consent from patients was taken. Referring orthopedic surgeon was informed purpose of the study. Patients were divided into two groups using convenient sampling. Duration of Prophylactic treatment was for the period of 07 days. Patients were assessed every day during the period of study for any signs and symptoms of DVT using Wells DVT probability Scale. The outcome measurement was taken using Doppler Ultrasonography for the identification of DVT if any.

Group A-CONTROL GROUP

Only prophylactic treatment procedure (Conventional Physiotherapy).

Prophylactic treatment period begins right after the surgical procedure for both control and experimental group, as soon as spinal anesthetic wears off. The following were given during their hospital stay (07 days).

Isometric gluteal and quadriceps exercise

Patients were instructed to hold the particular muscle group tight for 10 sec and relax for next 10 sec. 10 times at a time (1set), 10 sets a day.

Relaxed deep breathing and coughing

Slow relaxed deep breaths with emphasis on the expiratory movement and coughing were advised to be performed every 2 hours during the day.

Ankle active exercise protocol

- Patients were instructed to do ankle exercise as the spinal anesthetic wears off.
- Patients were asked to point both toes gently away from them, hold for 2 counts.
- Flex back, feet toes pointed up 2 seconds, performed with 30 degree leg elevated position.
- This protocol was performed 10 times at a time (1set) and was advised to perform 6 sets a day.

Group B-EXPERIMENTAL GROUP

All treatments were same except the ankle active protocol was performed using ankle active movement monitoring device. Patients performed the prescribed sets of exercise protocol (6 sets a day) .The device was preset to a count of 10, ie: 1 set. The patient were instructed to make sure that they see the green light glow as soon as they complete each set. The researcher made that patients performed the prescribed sets of exercise by periodically checking the counter number on the device and the number of times the green light was on ,ie;6 times a day.

Assessment procedure

Doppler Ultrasonography (Color flow duplex scanning).

Patients were assessed every day during the period of study for any signs and symptoms of DVT using Wells probability scale. Doppler scanning was performed to identify the presence or absence of DVT. Patients were informed about the procedure .The test was performed by experienced radiologist .The same radiologist had done the test for the whole population and was not informed about the sample group. Those patients who showed early signs and symptoms of DVT were send for the test immediately. The radiologist detects thrombi in the veins by directly visualizing and then compressing the vein with a transducer. Veins filled with clot do not collapse like a normal vein. In addition the radiologist can distinguish fresh clot from an old clot based on echogenicity, homogeneity and collateral flow.

Recording materials

- Recording sheets
- Wells DVT probability scale
- Consent forms
- Data collection sheets.

Bedside ankle active exercise monitoring device

A bedside Ankle Dorsiflexion / Plantar flexion active movements monitoring device. This device monitors the number of times the patients had performed active isotonic contractions of his/her dorsiflexion and plantar flexion. As the patient performs this movements over the foot pads, the parallel rod moves simultaneously with the pads and sets the limit switches on and off. This is sent in through the relay wires to the timer which is in turn connected to the counter and to the light system.

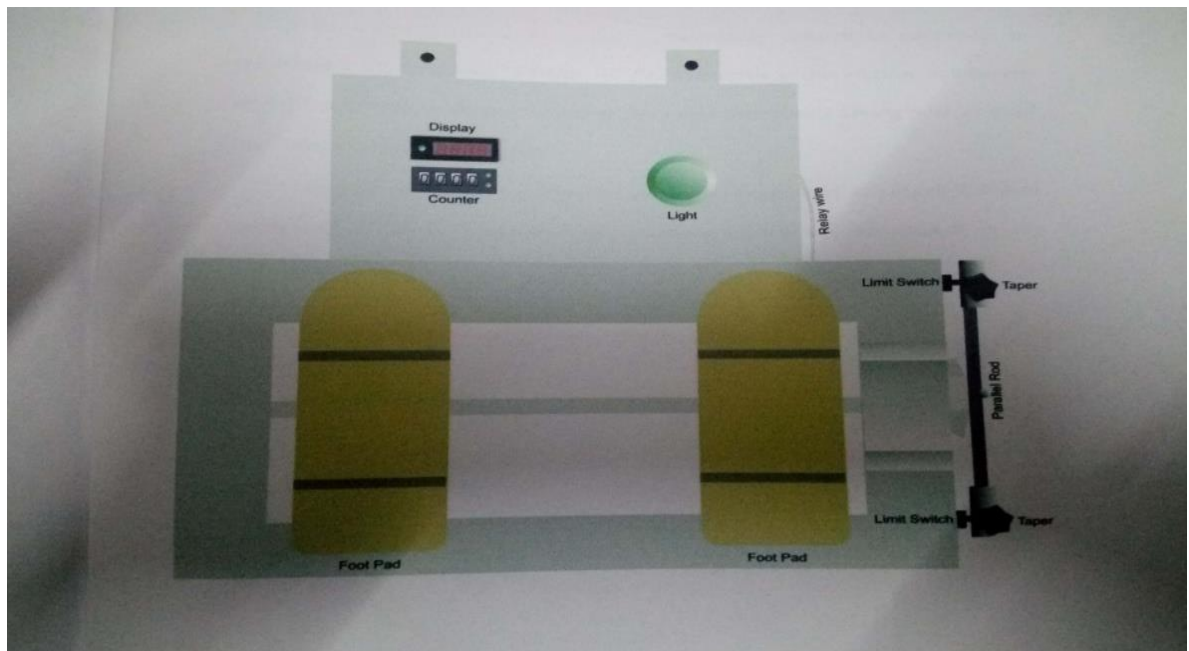
Following are the important parts of the device.

1. Footpads
2. Parallel rod with two tapers
3. Two limit switches
4. Relay wires
5. Timer
6. Counter system
7. Light bulb
8. Power supply.

The counter could be present by the therapist with a desired number of movements. As the patient performs the movements the counter displays the numbers and as soon as the preset count is achieved by the patient a green light glows providing an augmented feedback in the form of visual stimulus.



Picture 1



Picture 2

STATISTICAL ANALYSIS

Chi-Square Test is used

- As a non-parametric test is based on frequencies and not on parameters like mean and standard deviation.

- Testing hypothesis and not useful for estimation
- As no rigid assumptions are necessary in regard to type of population, no need of parameter values and relatively less mathematical details are involved.

Demographic presentation of data

Variables		Control Group	Experimental Group
Age	65-70	8	8
	71-75	7	7
Gender	Male	8	9
	Female	7	6

The control group consists of 15 patients in which 8 were in 65-70 age group and 7 were in 71-75 age group. The experimental group consist of 15 patients in which 8 were in 65-70 age group and 7 were in 71-75 age group.

Among 15 patients in control group 8 were males and 7 were females. In experimental group 9 were males and 6 were females.

Statistical Analysis using Chi- Square test for Doppler Ultrasound scan results

Thrombus	Control Group		Experimental Group		χ^2	df	p-Value
	Frequency	%	Frequency	%			
Present	4	26.67%	0	0%	4.6154	1	<0.05
Absent	11	73.33%	15	100%			

26.67% of the patient in control group are diagnosed to have DVT in scan results. Whereas none of the patients in experimental group showed any symptoms of DVT in scan results.

Statistical analysis of the post scan results, showed $\chi^2= 4.6154$ ($p<0.05$). Which shows the Bedside ankle active movement monitoring device has significantly the symptoms of DVT.

The null hypothesis is rejected there by proving that Bedside ankle active movement monitoring device has significant effect as an aid in the prevention of DVT among post-surgical bed ridden geriatric population.

DISCUSSION

The study is an experimental design to find out the effect of bed side ankle active movement monitoring device as an aid in the prevention of DVT among post- surgical geriatric patients.

The duration of the hospital stay was identical for the whole population (07days).Regular clinical examination was performed every day for any symptoms of DVT. Those who had shown clinically evident symptoms based on Wells DVT Probability scale were sent in for an early investigation .In order to identify any silent cases of DVT, the rest of the population was also screened using Doppler ultrasound scanning.

Ankle exercise protocol was immediately stopped for 4 patients who showed moderate to high probability on the Wells DVT probability scale and subsequently diagnosed as having DVT in the control group.

The tool therefore taken for measuring the outcome was Doppler ultrasound scanning for the presence or absence of thrombus. The control group was given conventional physiotherapy which includes Gluteal and Quadriceps isometric

exercises, slow relaxed deep breathing coughing and an ankle exercise protocol to be performed during the whole hospital stay period. The experimental group was given the same ankle active exercise protocol using the ankle movement monitoring device in addition to the rest of the conventional treatment .The researcher was able to make sure that the experimental group performed the prescribed set of exercises regularly by checking the number of times the green light was made to glow during the day i.e (6 times a day) over the device.

On statistical analysis of the Doppler ultrasound scan result using Chi- square test, null hypothesis was rejected.

Muscle pump plays a major role in increasing cardiac output by increasing venous return during muscle contraction which compresses the vein and squeezes blood back towards the heart. Venous drainage of the lower limb is described in relationship to the muscle fascia. The pump action of the thigh and calf muscles powers this flow. Deep vein thrombosis usually forms in the calf as a result of circulatory stasis imposed by activity restrictions. Studies have demonstrated that ankle and leg exercises have beneficial effects in increasing venous return in the lower extremities. The most common prophylaxis method used to prevent DVT and to reduce the risk of pulmonary embolism is ankle exercise. Ankle active exercise protocol for the patients who undergo joint replacement surgeries advices active ankle pumping exercises 10 times a set, 6 sets every day during the period of hospital stay. Encouraging active movement’s pre and post operatively is an important role of physiotherapist.

Geriatric population has been regarded as one of the major risk groups for venous thromboembolism.

Researchers have found that augmented information or feedback is effective in motivation and learning. Patients with high motivation emphasized the importance of learning to perform rehabilitation exercises in a manner spoken by therapist. Rehabilitation professionals have long held that patient motivation is important and affects outcome. Motivated patients in the rehabilitation setting think that they have an active role in rehabilitation and have to apply effort to make gains.

From the above mentioned statements and statistical analysis, the study suggests that 'Bedside ankle active exercise monitoring device' could be used as an aid for performing ankle exercise protocols for the prevention of DVT by providing feedback and eventual motivation to the patients together with providing the physical therapist the vital information of whether or not the patient was performing the prescribed exercise protocols.

Hence the discussion could be concluded as 'Bedside ankle active exercise monitoring device' is an effective aid in the prevention of DVT among post-surgical geriatric patients.

Limitations

1. The study was conducted for a short period of time.
2. Since the study was short, only limited sample size could be considered for the study.

REFERENCE

Patent for the device published by Indian patent office on 07/08/2015 U/S 43(2) of The Indian patent Act, Indian patent News.

Indian Patent Claims

1. The bedside ankle dorsiflexion- plantar flexion movement monitoring device as in Fig. 1 to 3 which is effective as an aid in the prevention of Deep Vein Thrombosis (DVT) among movement restricted geriatric population and as an aid for performing active ankle exercise for such prevention of DVT for bedridden risk groups by monitoring the number of ankle dorsiflexion plantar flexion isotonic contractions performed and by providing augmented feedback to the bedridden patients under prescribed exercise protocol, wherein the said device as in fig. 1, fig. 2, fig. 3 comprises foot pads or a ankle joint movement facilitators (1), parallel rods with two tapers (2), two limit switches (3), relay wires (4), display or timer (5), counter system (6), light emission system (7), wherein bedridden patients performs the foot movement over the foot pads (1) setting the limit switches (3) on and off, sending the message through the relay wires (4) to the timer (5) which in turn is connected to the counter system (6), and the light emission system (7), wherein the counter system is preset by the therapist with the desired number of foot movements and light emission system activates to indicate completion of the set number of exercises which is reset in the counter system.
2. A bedside monitoring device as claimed in claim 1, wherein the device is made up of a metal or fiberglass or reinforced plastic.

3. No follows- ups could be done.
4. Ultrasound may involve slight human errors, which could threaten the study's reliability.
5. The device being a prototype is quiet bulky and heavy.
6. The device being expensive individual patients won't be able to bear the cost.

CONCLUSION

The study provides 'Bedside ankle active exercise monitoring device' as an effective aid in the prevention of DVT among Post-surgical geriatric population. This device could be also used as an aid to prevent DVT for risk groups (abdominal, pelvic, leg, cardiac, pulmonary surgery and prolonged immobility).

Conflict of interest

None

Source of funding

Self.

Ethical clearance

The procedure followed was in accordance with the ethical standards and after the attainment of informed consent from patients and Orthopedic surgeon.

3. A bedside monitoring device as claimed in claim 1, wherein the said ankle joint movement facilitators, for both ankles, detects the number of movements performed and sends a corresponding signal as an output to the processor, displayed through the counter and light emission system.
4. A monitoring device claimed in claim 1, wherein the said display or timer (5) displays the number of movements performed by both the joints, date, time.
5. A monitoring device claimed in claim 1, wherein the light emission system comprises of a green light or a smiling face with a motivational or congratulating message which is displayed on completion of the prescribed number of foot exercise.

<https://www.google.com/amp/s/www.techlaw.attorney/nairmahesh-sukumaran-granted-patent-for-ankle-dorsiflexion-plantar-flexion-active-movement-monitoring-device-indian-patent-office/amp/>

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