INFORMATION BRIEF (RAPID REVIEW)

GEKO DEVICE TO PREVENT VENOUS THROMBOEMBOLISM

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
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PURPOSE

To provide brief information on the safety, effectiveness and cost-effectiveness of Geko Device in preventing venous thromboembolism based on request from the Procurement and Privatisation Division, Ministry of Health Malaysia following proposal by a company to introduce the technology to Ministry of Health Malaysia.

BACKGROUND

Venous Thromboembolism (VTE) is a leading cause of death and disability worldwide with approximately 10 million cases of VTE, and 100,000 (US) to 544,000 (Europe) VTE-related deaths were reported annually.[1,2,3] The annual incidence rates ranged from 0.75 to 2.69 per 1000 individuals in the population, and increased to between two and seven per 1000 among those aged more than 70 years. VTE associated with hospitalization was the leading cause of disability adjusted life-years (DALYs) lost in low and middle-income countries, and the second most common cause in high-income countries.[4] Hospital-acquired VTE, also known as hospital-acquired or hospital-associated thrombosis, covers all VTE that occurs in hospital and within 90 days after a hospital admission is potentially preventable problem.[5] Up to 60 percent of VTE cases occur during or after hospitalization, making it a leading preventable cause of hospital death.1Treatment of non-fatal symptomatic VTE and related long-term morbidities is associated with a considerable cost to the health service.[5] VTE can occur without any warning signs or symptoms and can go unrecognized and undiagnosed by a healthcare professional.[6] In the UK, VTE costs the National Health Service €640 million per year.[5]

The spectrum of VTE risk is broad, and understanding the scale of the problem has led to a paradigm shift in preventing and managing VTE in the NHS,UK with VTE risk assessment conducted as a routine event in all care pathways.[5] Prevention is the key to reducing death and disability resulting from VTE, including thromboprophylaxis in patients at risk (primary prevention), such as those undergoing surgery or those hospitalized with medical illnesses, and prevention of recurrent thromboembolic events in patients with established DVT or Pulmonary Embolism (secondary prevention).[5,8] Deep Vein Thrombosis and PE are life-threatening conditions that require immediate medical attention needing these treatments; anticoagulants (injectables such as heparin, enoxaparin, or low molecular weight heparin, or tablets such as apixaban, dabigatran and rivaroxaban, edaxaban and warfarin), mechanical devices (e.g. compression stockings, intermittent pneumatic compression (IPC) devices or rapid inflation venous foot pumps) or thrombolytic therapy (eg., tissue plasminogen activator (tPA)).[6]

Mechanical prophylaxis of DVT including graduated compression stocking (GCS), intermittent pneumatic compression device (IPC) and neuromuscular electrical stimulation system (NEMS) gains more popularity as its use is not associated with adverse events seen in pharmacologic prophylaxis.[10] Graduated compression stocking and IPC have been shown to

effective in VTE prophylaxis.[11]However, despite their effectiveness and common use, these methods may be associated with poor compliance due to discofort, excessive heat, itchiness, sweating and potential for peroneal nerve palsy.[12,13] Most compression devices enclose the whole leg, hence were uncomfortable in addition to its size, weight and external power source requirements that contributed to poor compliance.[14] Older NEMS delivery system produced painful stimuli that could be used during general anaesthesia.[15]

The geko device system operates by use of OnPulse Technology, activating the calf and foot pumps of the leg by low-intensity neuromuscular electrical nerve stimulation of the common peroneal nerve.[14] The device which resembles a wristwatch is battery operated, compact, portable, disposable neuromuscular electrostimulation device designed to increase venous blood flow, with the aim of reducing the risk of VTE. The device uses a patented electrical impulses delivery system, which stimulate the common peroneal nerve and cause muscular contraction in the lower leg and foot hence facilitating the emptying of vein to increase venous, arterial and microcirculatory blood flow. The mechanism of action emulates the blood flow rate normally achieved by walking (up to 60%) without the patient having to move or exert energy. The device is non-invasive, small in size (149mm x 42mm x 11mm), lightweight (16gram), self-adhesive, encased in a flexible moulded strap, fits comfortably to the leg, with small contact area (35cm^2) to minimise skin irritation and sweating. (Figure 1 and 2) It is applied to the skin over the fibular head (or other application site) and held in position wrapped around the leg (one or both legs as needed).[6] As claimed, the device could reduce cost of treatment by reducing hospital stay, reducing time in patient management (two to five minutes as compared to 12 to 30 minutes using IPC), reduce risk to healthcare staff, and can shift the balance of coagulation towards a lower risk of thrombosis.

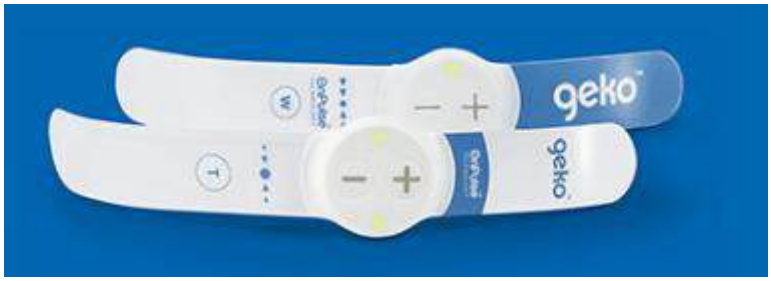

Figure 1: Geko device

Figure 2: Geko device applied over the fibular head and wrapped around the leg

EVIDENCE SUMMARY

A total of 75 titles were retrieved from the scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and from the general search engines [Google Scholar and US Food and Drug Administration (USFDA)]. Studies with less than ten subjects and case series were excluded. Last search was conducted on 15 July 2020. Nine articles were found to be relevant and included in this review which comprised of systematic review of RCT (one), randomised controlled trials (five), non-randomised trial (one), pre-post intervention (two), with NICE medical technology guidance and clinical guidelines from NICE and Malaysia. Two of the included studies were assessing neuromuscular electrical stimulation (NMES) in general. A total of 266 participants were enrolled in the included studies for geko device, and 926 participants were enrolled in the studies assessing NMES.

EFFICACY/ EFFECTIVENESS

Geko device

Jingwei et al. (2017) in a randomised trial observed the clinical efficacy of GEKO neuromuscular electrical stimulation (NEMS) in the prevention of DVT after total hip arthroplasty (THA). The study used THA in operative treatment of 72 cases (45 male, 27 female) of femoral head necrosis (Ficat stage III-IV) from January to August 2016, which were randomly assigned to observation group, n=36, (mean age 53.7±11.7 years, basic prevention method plus NMES) and the control group n=36, (mean age 53.1±8 years basic prevention method). Basic preventive methods consisted of VTE preventive education, instruction in rehabilitation exercise including early stage muscle relaxation and contraction, active joint movement and massage, and five sets of exercises per day with 100 repetitions of muscle relaxation and contraction and active joint movement, and 20 repetitions of massage in each set. The NEMS was employed immediately for 24hours after the operation, with three

days being one treatment course, and gradually enhanced intensity stimulation. They found one case of DVT in the observation group (2.7%), compared to six in the control group (16.7%). They found no statistically significant difference ($p>0.05$) between the two groups in post-operative negative pressure drainage. The observation(intervention) group was superior than the control group in terms of post-operative Visual Analogue Score, DVT incidence rate and three days post surgery plasma D-dimer content ($p<0.05$). They concluded application of NMES in early recovery of patients after THA could increase the lower limb venous blood flow, alleviate pain and serve as effective physical therapy in the prevention of DVT. Due to relatively small sample in this study, further high quality study is required.[16]

Yilmaz et al. (2016) in a RCT investigated potential role of electrostimulation in augmentation of femoral vein venous blood flow after total knee replacement (TKR). A total of 30 patients undergoing TKR following severe knee osteoarthritis in a university hospital in Turkey were involved, which were randomized to receive either peroneal nerve electrostimulation plus low molecular weight heparin (LMWH) and below knee compression stockings (CS) (group1, electrostimulation group, n=15, mean age:63.40±5.91years, male; female ratio 9:6) or LMWH and below knee CS alone (group 2, control group, n=15, mean age:63.86±7.47 years, male: female ratio 8:7). Electrostimulation was performed for one hour in every four hour after the operation. Peak blood velocity in the femoral vein was evaluated with Duplex ultrasonography in supine position. Presence of leg oedema and calf diameter was also taken into consideration as outcome measures, which were recorded both before surgery and at the time of discharge from hospital. They found postoperative peak blood flow velocity in the femoral vein was significantly higher in the electrostimulation group compared to control group (17.46±2.86 cm/s vs 13.84±3.58 cm/s,$p<0.02$). Electrostimulation group achieved a significant increase in peak blood flow velocity in the femoral vein after the operation (mean increase 67.48±17.38%, $p<0.001$). None of the patients had clinical symptoms or ultrasound findings of VTE postoperatively. They concluded electrostimulation of the common peroneal nerve enhanced venous flow in the lower limb and may potentially be of use as a supplementary technique in DVT prophylaxis following lower limb orthopaedic operation. [17]

Jawad H et al. (2014) in a non-randomised trial evaluated effectiveness of a novel neuromuscular stimulation method versus intermittent pneumatic compression (IPC) (Huntleigh Flowtron Universal, Huntleigh Healthcare Ltd, Cardiff, UK and the Kendall SCD Express, Dublin) in enhancing lower limb blood flow. The subjects' tolerance of the devices was also compared. The study involved ten healthy subjects aged between 18 and 65 years (eight men and two women) with median age of 40.5 years. The devices were fitted bilaterally, in a sequential manner, for 30 minutes. The geko T1 device has seven stimulation settings relating to pulse width ranging70 to 560μs. It operates at a fixed frequency (1Hz) with a constant pulse current of 27mA. Each device was active for 30minutes followed by ten minutes recovery phase to allow vascular re-equilibration before application of next device. The two IPC devices differ in their pumping cycle, with similar compression pressure of 40mmHg. Baseline measurement of blood flow, volume and microcirculatory capacity was performed using ultrasound (femoral artery and superficial femoral vein) and laser Doppler fluxmetry assessments (dorsum of foot). After each program, subjects evaluated acceptance and tolerance of each device by discomfort questionnaire using a discrete rating scale. The subjects' deep veins were re-examined with duplex ultrasound to exclude the development of DVT. They found the geko T1 device was superior to both IPC devices in increasing both venous and arterial blood volume flow by 30% (95%CI 23.7% to 82.4%,$p<0.001$). The geko T1 increased arterial blood velocity by 24% (95%CI 9.7% to 24.5%, $p<0.001$), compared to

both IPC devices (IPC-HF; -4% 95%CI -8.6% to 6.2% and IPC-Kendall, -1% 95%CI -8.9% to 5.9%). A substantial increase in the total microcirculatory blood velocity by 370% (95%CI 13.5% to 39.7%) was reported after the use of geko T1 ($p<0.001$), compared to IPC-HF (44%, 95%CI -8.3% to 17.9%) and IPC-Kendall (59%, 95%CI -8.2% to 18.0%). With the use of visual analog scale, no significant differences in discomfort were found between geko T1 device and IPC. They concluded the geko T1 device is more effective than the IPC devices in increasing venous, arterial and microcirculatory blood velocity. The devices studied were safe and well tolerated by healthy subjects.[18]

Tucker et al. (2010) investigated the safety and efficacy of a novel neuromuscular device that augments peripheral blood flow in the leg by isometric neuromuscular stimulation via the peroneal nerve. The effects of electrical stimulation on lower limb blood flow were evaluated in 30 healthy volunteers during a four hour sitting in an economy airline seat. Randomly selected leg was stimulated (connected to the stimulator), while the contralateral leg remained immobile as a control. The modified electrical stimulator pulse amplitudes ranged from 1mA to 40mA, with frequencies ranging from 1 to 5Hz. In all cases, the pulse consisted of a charge-balanced pulse of 200µs in width. Fifteen sequential electrical stimulations were applied for 5 minutes each followed by a 10-minute recovery phase. The following non-invasive measurement were performed before, during voluntary muscle action (dorsiflexion), during five minutes stimulation period and after the stimulation programs: photoplethysmography (PPG), strain gauge plethysmography (SPG), laser Doppler fluxmetry, transcutaneous oxygen tension, pulse oxymetry, superficial femoral vein blood flow and vessel diameter (ultrasound). Acceptance and tolerability questionnaires were also administered. During the second visit (within two weeks), the stimulation sequence was reversed for each subject. They found significant increase in blood volume flow and velocity, and skin capillary blood flow during neuromuscular stimulation in the stimulated leg compared with baseline. All stimulations showed significant increase in venous volume flow compared with baseline ($p<0.01$). Significant increase in blood flow velocity at all stimulations compared with baseline was demonstrated ($p<0.01$).The venous blood flow increases 100% in the superficial femoral vein. PPG measured in dorsal foot vein showed significant venous emptying at all stimulation programs. Laser Doppler fluxmetry measurement was increased up to 25fold in the stimulated leg compared with baseline. Transdermal skin oxygen level was maintained. No changes observed in heart rate, blood pressure, oxygen saturation or femoral vein vessel diameter between baseline values and values at each stimulation program. The author concluded the device has the potential for DVT prophylaxis in outpatient setting, as well as prevention of DVT in hospitals, community care setting and in preventing travel-related thrombosis. [14]

Zhang Q et al. (2014) evaluated the effect of electrical nerve stimulation on force generation, oxygenation and blood volume in muscles of the immobilized human leg. In this study, a novel electrical stimulator (geko device 27mA) was applied to 28 legs of 14 healthy subjects (age ranged between 22 and 59 years, BMI ranged between 20 and 31 kg/m2). Investigations included measuring the force during voluntary isometric ankle joint dorsiflexion and the stimulation-induced myoelectric responses produced by the leg muscle contraction. Muscle oxygen saturation, blood volume and deoxygenated hemoglobin in the tibialis anterior and medial gastrocnemius muscle were measured by near-infrared spectroscopy during venous stasis (40mmHg thigh tourniquet), with or without electrical stimulation. Myoelectric signals (EMG) were recorded using bipolar surface electrodes by placing the electrodes over the central muscle bellies of the tibialis anterior, extensor hallucis brevis, peroneus longus,

and medial gastrocnemius of the lower leg. Force generation during isometric ankle joint dorsiflexion was measured while the foot was rigidly maintained in a neutral position, 15degrees plantar flexion, during the stimulation test period. Experimental protocol consisted of two interventions; a dynamic concentric test model and isometric test model. One of the subject's leg tested in the morning, and the other leg tested in the afternoon. They found the force produced during ankle joint dorsiflexion at the maximal stimulation intensity (level 7) was 2.25N (0.02-14.14) in the resting leg. Significant correlation was found between force generation and stimulation intensity in the leg ($r2=0.93$, $p<0.001$).Changes in muscle oxygen saturation during venous stasis, with or without electrical stimulation, were similar. Electrical stimulation during venous stasis caused 4.0 to 9.0% and 0.2 to 6.0% less increase in total muscle blood volume and deoxygenated haemoglobin compared to venous stasis alone. They concluded nerve stimulation with a newly developed device partly counteracts, increases in muscle blood volume and deoxygenated haemoglobin of the resting leg during venous stasis. The device stimulates active and passive mechanism enhancing venous return in patients at risk for venous stasis during immobilization.[19]

Bahadori S te al. (2017) in another RCT evaluated the effect of calf Neuromuscular Electrical Stimulation and intermittent pneumatic compression on thigh microcirculation. The effectiveness of a NMES device and an IPC device on enhancing microcirculatory blood flow in the thigh of healthy individuals were evaluated when stimulation is carried out peripherally at the calf. In this study conducted in Bournemouth, UK, blood microcirculation of ten healthy individuals (male, aged between 25 and 46 years) was recorded using Laser Speckle Contrast Imaging (moorFLPI full-field, Devon, UK). The NMES device is geko (Firstkind Ltd, UK) and the IPC was VenaPro (DJO Global, US). The geko has seven stimulation modes and a frequency rate of 1Hz, with maximum charge of 20µC per pulse, while the VenaPro consists of a calf cuff that holds an electronically controlled pump delivering air to the calf cuff, applying 50mmHg once per minute. Participants were sitting throughout the assessments with their feet flat on the ground. A region of interest (ROI) was marked on each participant thigh. Participants were randomized to sequence of assessment using sealed envelope with five minutes washout in between each test. The mean flux within the ROI was calculated as the mean blood flow amplitude in skin area perfusion for the participants; calculated at four states; rest, NMES device with visible muscle actuation (VMA), NMES device with no visible muscle actuation and IPC device. They found both NMES and IPC devices increased blood flow in the thigh when stimulation was carried out peripherally at the calf. The NMES device increased mean blood perfusion from baseline by 399.8% at the VMA state and 150.6% at the NVMA state. The IPC device increased the mean blood perfusion by 117.3% from baseline. They concluded the NMES device at VMA state increased microcirculation by more than a factor of three in contrast to the IPC device, hence NMES is superior to the IPC in increasing thigh microcirculation.[20]

Barnes et al. (2014) in another study evaluated the efficacy of geko neuromuscular electrical stimulation device to produce muscle contraction (stimulate visible muscle twitch) in vascular patients. The study involved 100 patients with many types of vascular disease (abdominal aortic anurysm,13%; claudication,57%; critical limb ischaemia 4%; post-op femoro-popliteal bypass graft, 7%; post-angioplasty, 1%; diabetic ulcers, 8%; varicose veins, 5% and healthy volunteers, 5%. The mean age study population was 69 years, comprised of 66 males and 34 females. Background information, clinical examination and neuropathy scores were evaluated. Following device application, the presence of a response was recorded. They found calf circumference >35cm, (OR 5.77, 95%CI: 1.12, 29.65, p=0.036); and neuropathy

score >5 (OR 17.83, 95%CI: 2.71, 117.19, p=0.03) were associated with non-response in the multivariable analysis. They concluded failure to respond to transcutaneous neuromuscular stimulation device may be predicted by greater calf circumference and neuropathy score >5. Identifying such patients may save time and possibly cost saving.[21]

A retrospective clinical audit in Royal Stoke University hospital was conducted which included the geko device on VTE incidence across all interventions. This new strategy, the enhanced VTE pathway, included mandatory four hourly reviews to maximise patient comfort and compliance of both mechanical prophylaxis interventions. They reviewed 1000 patients admitted to the Stroke Unit at Royal Stoke University Hospital between 1 November 2016 and 3 March 2018. In line with the UK guidelines, patients unable to mobilize independently were prescribed IPC in addition to standard measures, such as hydration, mobilization, and aspirin where indicated, unless patients were palliative, fully anticoagulated, or refused the intervention. Patients who could not use IPC (intolerance, falls risk, out of stock) were switched to the geko device. They found 688 patients required a mechanical intervention. Besides, the enhanced VTE pathway, which included the geko device and four-hour mandatory patient checks to maximise mechanical prophylaxis compliance, has dramatically reduced the incidence of VTE in acute stroke patients (1.5% versus 2.8%). The geko device was well tolerated by patients with no adverse events reported. [22]

NICE medical technologies guidance (2014) on geko device reported post-market surveillance data presented by the sponsor, based on self-completed questionnaires from 216 people who had used the device in the UK after either vascular, orthopaedic surgery or non-surgical treatment. The data showed the device adhered well to the leg, easy to apply and use, and was comfortable to wear. The NICE medical technologies guidance supported the use of geko device in people who have a high risk of VTE and for whom other mechanical and pharmacological method of prophylaxis are impractical or contraindicated. Though clinical evidence is limited, the adoption is supported because of the plausibility that the geko device may reduce the high risk of venous thromboembolism in patients who cannot use other form of prophylaxis, and the low risk of the device in causing harm.[5]

The Malaysian CPG of Prevention and Treatment of VTE (2013) highlighted category of patients with risk factors for VTE and hospitalised patients at increased risk for VTE. The guideline recommended that the choice of mechanical VTE prophylaxis should be based on individual patient factors including clinical condition, surgical procedure, patient preference and if bleeding risk outweighs the risk of VTE. [23]

NICE guideline (2019) recommended assessing all patients to identify the risk of VTE and bleeding for medical patients, surgical patients, pregnant women and all women who gave birth or had a miscarriage or termination of pregnancy in the past six weeks, people admitted to critical care unit and all acute psychiatric patients. The guideline recommended balancing the person's individual risk of VTE against their risk of bleeding when deciding whether to offer pharmacological or mechanical prophylaxis to these patients. People discharged with prophylaxis and their carers should have verbal and written information on the importance of using the prophylaxis correctly, continuing treatment for the recommended duration, sign and symptom of adverse events and notify the person's family doctor if the person has been discharged with prophylaxis at home. [24]

Neuromuscular Electrical Stimulation (NMES)

Hajibandeh S et al. (2017) in a Cochrane systematic review assessed the effectiveness of neuromuscular electrical stimulation (any form of NMES) in the prevention of VTE. The review included five RCT and three quasi-randomised trials, enrolling a total of 904 participants. Among these, four studies included patients undergoing major surgery; surgery for hip fracture (one), trauma patients contraindicated for prophylactic heparin (one), operated patients with neurosurgical problem (one), non-functional spinal cord injuries (one).Eight studies investigated 22 treatment arms; four studies compared NMES arm with no prophylaxis and five studies compared with alternative prophylaxis arms (low dose heparin, GCS, IPC and Dextran 40). No difference found in total risk of DVT (OR 1.01, 95%CI: 0.60,1.70, six studies, low quality evidence), asymptomatic DVT (OR 1.61, 95%CI: 0.40, 6.43, one study, low quality evidence), symptomatic DVT (OR 0.40, 95%CI: 0.02, 10.07, one study, low quality evidence), PE (OR 1.31, 95%CI: 0.38, 4.48, two studies, low quality evidence) and total VTE (OR 0.92, 95%CI: 0.34, 2.52, one study, low quality evidence) between NMES and using alternative method of prophylaxis.

Compared with no prophylaxis, NMES showed lower risk of total DVT (OR 0.40, 95%CI: 0.23, 0.70, four studies, moderate quality evidence) and total VTE (OR 0.23, 95%CI: 0.09, 0.59, one study, low quality evidence). No difference in risk of asymptomatic DVT (OR 0.32, 95%CI: 0.06, 1.62, one study, low quality evidence), symptomatic DVT (OR 0.06, 95%CI: 0.00, 1.36, one study, low quality evidence) or PE (OR 0.36, 95%CI: 0.12, 1.07, one study low quality evidence). In comparison with low-dose heparin, NMES was associated with higher risk of total DVT (OR 2.78, 95%CI:1.19, 6.48, two studies).

Overall, the quality of evidence was low following high or unclear risk of bias and small number of studies. Low quality evidence showed no difference in the risk of DVT between NMES and alternative method of prophylaxis, but suggesting NMES was associated with lower risk of DVT compared with no prophylaxis (moderate quality evidence), and higher risk of DVT compared with low-dose heparin (low quality evidence).The best available evidence about the effectiveness of NMES in the prevention of VTE is not adequately robust for allowing definitive conclusion. Hence, adequately powered RCT are required to provide more robust evidence.[25]

Ravikumar R et al. (2015) in a pilot RCT investigated the effect of a NMES device in treating venous disease. The effect of NEMS that causes sequential contraction of the foot and calf muscles in patients with chronic venous disease was investigated. This study involved 22 patients (mean age of 62 years, BMI 28.6) with CEAP C2-C4 venous disease were randomised to a sham or test device. Patients were asked to use the device for 30 minutes per day for six weeks. Hemodynamic measurements (duplex ultrasound and laser Doppler fluximetry), limb volume (perometer), venous refill time (digital photoplethysmography) and quality of life outcome measures were measured at baseline and after six weeks. They found at week 0, there was a significant improvement in femoral vein hemodynamics (from baseline) whilst using the device in the test compared to sham group (time averaged mean velocity 102.4% versus -9.1%, $p<0.0001$; volume flow 107.9% versus -3.7%, $p<0.0001$; peak velocity 377.7% versus -6.7%, $p<0.0001$). The sham group demonstrated increase in limb volume, which was prevented with the use of device in the test group, (sham +2.0%, $p<0.0001$; test +0.8%, $p=0.0623$). There was no improvement in limb volume in either the sham or test group over the six weeks (sham +0.7%,$p=0.16$; test +2.3%, $p=0.74$). A non-statistically significant improvement in disease specific quality of life outcome measures was

observed in the test group over the six weeks. Significant improvement in venous haemodynamics and reduction in limb swelling with the test device compared to the sham group has been demonstrated following immediate usage. Further trials are required to determine optimal frequency of device usage and the effect on different subgroups of patients with venous disease.[26]

SAFETY

The geko™ T-2 and geko™ Plus R2 Neuromuscular Stimulators were approved by USFDA as class II medical device (Classification Name: Stimulator, Muscle, Powered Product Code, CFR: IPF, 21 CFR 890.5850). The indications were to increase local blood circulation, for iImmediate post-surgical stimulation of the calf muscles to prevent venous thrombosis and to reduce oedema. [27]

The geko device received a CE mark as a class IIa medical device in October 2010, to increase blood circulation and for the prevention of venous thrombosis.[5] In Canada, it was registered as class II medical device, and as class IIa device in Australia.[28,6] The device had received ISO 13485:2016 certification in Australia, Brazil, Canada and United States for the design, manufacture and distribution of electrostimulation devices for the area of neuro-muscular and neuromodulation applications.[6]

Jingwei et al. (2017) in the RCT conducted among patients underwent total hip arthroplasty found no apparent adverse reaction in the intervention group using geko device. [16] Yilmaz et al. (2016) in the RCT investigated potential role of electrostimulation in augmentation of femoral vein venous blood flow after TKR and found no procedure related complications including bleeding, infection, inability to mobilize occur in any patients. None of the patients in electrostimulation group discontinued using the device throughout their stay. Device related complaints or discomfort, when occurred could be eliminated in all patients by making further adjustments in energy delivery. [17]

COST-EFFECTIVENESS

NICE medical technologies guidance (2014) on geko device reported a cost analysis in UK estimating cost associated with geko device compared with no mechanical prophylaxis. The assumption used were underlying risk of DVT was 29.1% with no prophylaxis, proportion of DVT progressing to pulmonary embolism was 10.5% and relative risk of DVT after treatment with geko device was 0.39. The cost of the device was £22 per pair, and cost of purchasing the device per course of six days to treat both legs was £132. The cost analysis estimated using the geko device is cost saving in patients at high risk of VTE who would otherwise receive no prophylaxis. The amount saved depends on the level of reduction in relative risk of deep vein thrombosis associated with geko treatment compared to no treatment. There is no direct evidence on the size of this reduction, but when values obtained with other mechanical methods of prophylaxis were used in cost modelling, the estimated cost saving for the geko device was £197 per patient in patients at high risk of VTE compared with no prophylaxis.

The list price per pair of geko devices is £22 (excluding VAT) as stated in the sponsor's submission in the NICE medical technologies guidance.[5]

CONCLUSION

There was limited evidence retrieved on geko device for the prophylaxis of VTE. Based on the above review, the geko device appeared to be effective in increasing the lower limb venous, arterial and microcirculatory blood flow and velocity, alleviate pain, reducing post-operative plasma D-dimer in patients following lower limb surgery namely THA or TKR, compared to control or baseline in the prevention of DVT. None of the patients had clinical symptoms or ultrasound findings of VTE postoperatively. The geko device is effective in increasing venous, arterial and microcirculatory blood volume flow and velocity compared to IPC in healthy subjects. However, the long term effect could not be determined. The device appeared save with no apparent adverse reaction reported, well tolerated and has been approved by USFDA as class II medical device. Cost analysis in the UK estimated a cost saving of £197 per patient in patients at high risk of VTE following its use compared with no prophylaxis.

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