The use of the geko™ device and the resulting activation of the foot and calf muscle pumps for the prevention of venous thromboembolism in patients with acute stroke

Indira Natarajan[ii,iv], Jodie Williams[ii,iv], Christine Roffe[ii,iii,iv], Lucy Richards[i], Claire Moss[ii], Caroline Lambert[ii],
[i]Undergraduate Medical School, Keele University, [ii]University Hospital of North Midlands NHS Trust, [iii]Institute for Applied Clinical Sciences, Keele University, [iv]Stroke Research in Stoke.

Introduction

Venous thromboembolism (VTE) is a common and potentially fatal complication of acute stroke. The UK National Clinical Guidelines for Stroke[1] recommend intermittent pneumatic compression (IPC) as the primary method of VTE prevention after acute stroke, as the risk of symptomatic intracerebral haemorrhage outweighs the benefit from VTE prevention with routine anticoagulation with low dose heparin (including low molecular weight heparin) after stroke[2].

UK Stroke Guidelines also state that pharmacological VTE prevention should not be used routinely or in any potentially higher risk subgroup, as work by Whiteley et al[3] has shown that it is not possible to predict which patients with acute stroke may be at sufficiently high risk of VTE to outweigh the risk of haemorrhagic complications. However, IPC is contraindicated in patients with peripheral vascular disease, leg ulcers, high risk of falls, restlessness or agitation[4] (NICE CG92, 2015), and others do not tolerate IPC[5] (CLOTS-3, 2013). The risk of VTE in the CLOTS-3 control group not receiving IPC was 6.3%. Current UK Stroke Guidelines make no recommendation for alternative methods for VTE prophylaxis for this high risk group.

Neuromuscular electrostimulation devices (NMES) prevent venous stasis by stimulation of muscle contractions in the lower leg and might be an alternative method of VTE prevention. A meta-analysis of studies using neuromuscular stimulation for VTE including 904 surgical and spinal injury patients suggested that NMES is better than no VTE prophylaxis treatment (4 studies). There is no clear difference in the effectiveness between NMES stimulation and standard methods of VTE prevention (5 studies), however the evidence was not sufficient to support recommendations[6].

The geko™ device (Firstkind Ltd) is an NMES device which prevents stasis in the deep veins of the calf[7] by activation of foot and calf muscle pumps via stimulation of the peroneal nerve. As the mechanism is plausible and the device is considered safe, it is approved by NICE for VTE prophylaxis in medical and surgical patients where standard prophylaxis treatments are impractical or contraindicated[8] (NICE MTG19, 2014). There is currently no evidence to support this form of VTE prophylaxis in stroke patients.

As VTE prophylaxis using IPC is not possible in all stroke patients, we amended our VTE prevention pathway to include the geko™ device as an alternative for patients with acute stroke who had contraindications to IPC or did not tolerate IPC. The aim of this audit was to assess the acceptability of this new procedure for patients and staff and its impact on VTE.

Methodology

Population

The audit included every patient admitted to the Acute Stroke Unit at Royal Stoke University Hospital (RSUH) in Stoke-on-Trent, Staffordshire, UK. RSUH is a 32 bed combined hyperacute and acute stroke unit admitting about 1200 patients with suspected acute stroke per annum. As a primary stroke centre it provides thrombolysis and mechanical thrombectomy, and receives secondary referrals from other stroke centres not providing these services.

The VTE prevention pathway

All stroke patients who are immobile (defined as not able to walk independently) are given VTE prophylaxis, unless they are dying, refusing the intervention, or fully anticoagulated. Every patient is reviewed daily on a nurse-led VTE ward round to monitor compliance with VTE prophylaxis and complications. Patients are also assessed at regular intervals throughout the day by a member of the stroke unit nursing team to check for compliance and complications.

In addition to generic measures (adequate hydration, early mobilization, aspirin 300 mg/day for the first 3 weeks for patients with ischemic strokes) the primary method of VTE prophylaxis in immobile stroke patients is IPC **(IPC alone)**, unless contraindicated.

Prophylactic low-dose anticoagulation is not given routinely. If patients are fully anticoagulated for other reasons no VTE prophylaxis other than the generic measures above is provided. Surface neuromuscular stimulation of the peroneal nerve using the geko™ is used as primary VTE prophylaxis **(geko™ alone)** for patients with contraindications to IPC (*Table 1*). The geko™ is also used when IPC pumps or sleeves are not available. Patients are switched from IPC to geko™ if they do not tolerate IPC **(IPC Primary + geko™ secondary)**. If patients are non-compliant this is documented and an alternative form of VTE prophylaxis is considered.

Contraindications to IPC

High risk of falls	Restlessness or agitation	Peripheral vascular disease	Leg ulcers

Table 1

Data collection

Data on VTE prevention method, compliance, duration of use, tolerance, and complications were collected daily by the VTE nurse for every patient on the unit. Patients not resident in the catchment area for RSUH and transferred to other hospitals for ongoing care were excluded from the audit, as the pathway was restricted to RSUH. Data on VTE incidence while the patient was in hospital was collected centrally from the VTE registry. This registry has details of every inpatient where a diagnosis of DVT or pulmonary embolism was made using Doppler, angiograms, computed tomography or ventilation perfusion scanning. Information on VTE following discharge was ascertained via telephone follow-up by the VTE nurse at 90 days.

Results

581 patients (mean age 75 years, 286 (49.2%) males) had 90 day outcomes and were included in the audit *(Table 2)*.

Demographic details

Patient demographics	Total no of patients in the audit n=581	
Males	286	49.2%
Females	295	50.8%
Haemorrhagic strokes	75	12.9%
Ischaemic strokes	506	87.1%

Table 2

VTE prophylaxis

126/561 (22%) did not require VTE prophylaxis, as they were independently mobile. The remaining 455 (78%) of patients were prescribed VTE prophylaxis. Of these 331 (72.7%) were initially given IPC devices **(IPC alone)**, 59 (13.0%) were initially given geko™ **(geko™ alone)**, and 65 (14.3%) were initially given anticoagulants **(primary anticoagulant)**. 80 (24.1%) patients who were initially prescribed IPC became intolerant to this intervention and were then changed to the geko™ device as a secondary intervention **(IPC primary + geko™ secondary)**. The final distribution of VTE prophylaxis methods after changing to a second method, if needed, is shown in table 3 and figure 1.

Primary and secondary methods of VTE prevention

Intervention	n (%)	
IPC alone	251	55.2%
IPC Primary + geko™ secondary	80	17.6%
The geko™ device alone	59	13.0%
Primary anticoagulant	65	14.2%
Total Patients	**455**	**100%**

Table 3

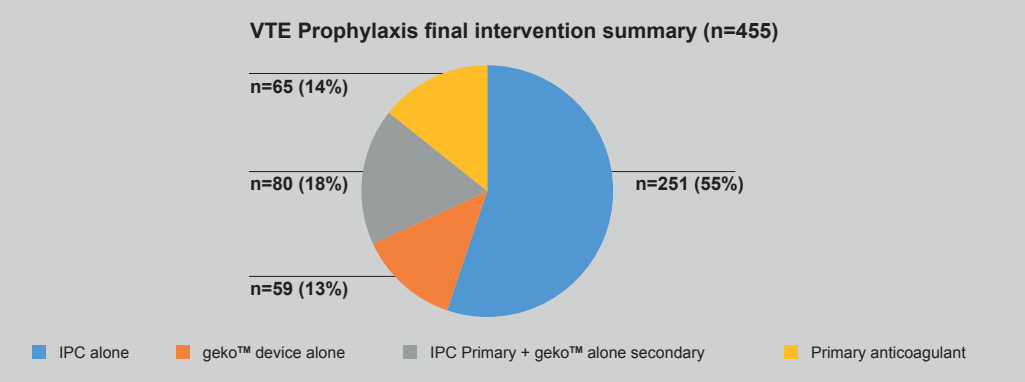

Figure 1. Final VTE prophylaxis intervention

Of the 390 patients prescribed mechanical VTE prophylaxis, 59 were treated by primary geko™ and 80 received IPC as a Primary and the geko™ as a secondary intervention, with 139/390 (35.6%) being treated with the geko™ device either as primary or secondary mechanical prophylaxis. The median length of patient use for the geko™ device was 5 days.

Patient tolerance

71 patients (22.1%) prescribed IPC did not tolerate IPC and 10 patients prescribed the geko™ (7.4%) did not tolerate the device (*Figure 2*).

VTE incidence

In total 6/455 (1.3%) patients developed symptomatic VTE (3 DVTs and 3 PEs) within 90 days. Of these, 4 patients (1.6%) were prescribed IPC, 1 patient (1.3%) was prescribed the geko™ device as a secondary intervention and 1 patient (1.5%) patient was prescribed anticoagulation. There was no DVT or PE in patients treated with the geko™ device as the primary VTE prophylaxis. (*Figure 3*)

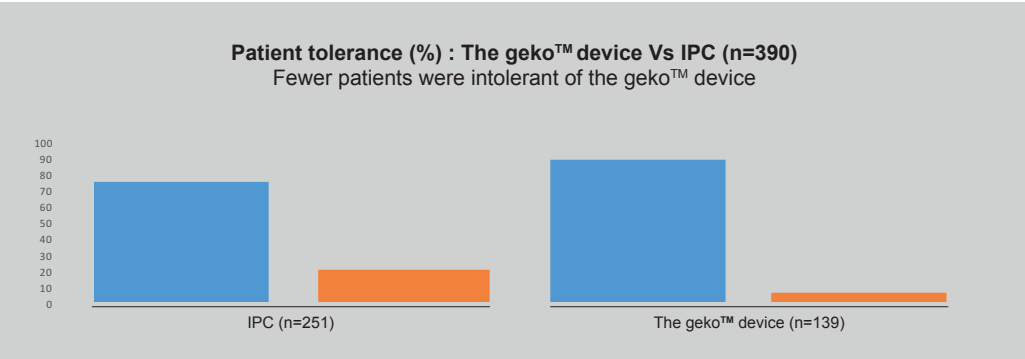

Figure 2. Patient Tolerance of each mechanical intervention prescribed.

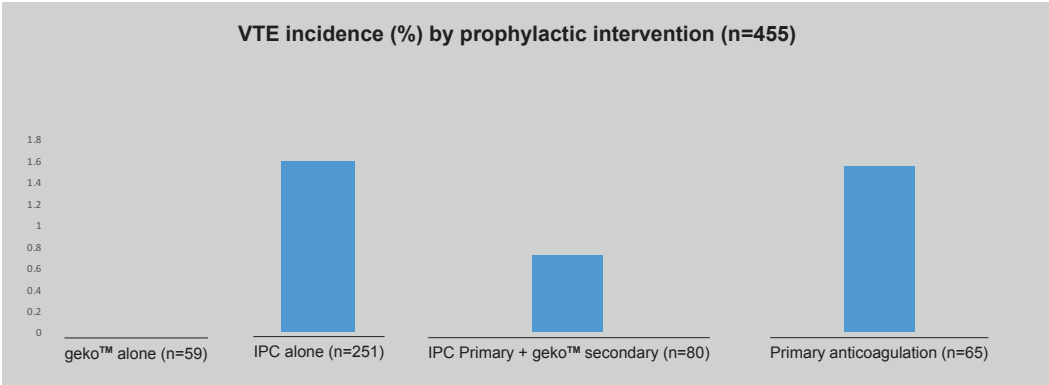

Figure 3. Incidence of DVT and PE by intervention.

Conclusion

This audit shows a low incidence (1.3%) of symptomatic VTE in a high risk population of immobile stroke patients.

We introduced NMES via the geko™ device as an alternative to IPC, where IPC was contraindicated or not tolerated. The audit also shows that the use of the device was feasible within an acute stroke unit environment, and well tolerated by patients. A significant proportion of acute stroke patients (36%) had contraindications to or did not tolerate IPC, a similar proportion as described in the original CLOTS-3 paper which provided the evidence underlying the guideline recommendation for IPC as first line VTE prophylaxis.

The number of patients treated with geko™ in this project is low (n=139), but, while limited, our data suggests that the device may be as effective as IPC in our patient cohort. Fewer patients were intolerant of the geko™ device than of IPC, but, as the majority of patients treated with geko™ were changed to the device because IPC was not tolerated, a direct comparison is not possible.

The geko™ device provided an alternative VTE prophylaxis strategy in immobile stroke patients. These patients were at high risk of VTE due to foot and calf pump paralysis and would otherwise have had no form of VTE prophylaxis other than general measures.

The findings of this audit suggest that geko™ is safe and well tolerated in patients with acute stroke.A randomized controlled study is needed to provide evidence for effectiveness in comparison with established methods of VTE prophylaxis. In the absence of such data the results of this audit support the use of geko™ as a meaningful addition to our prophylactic options for stroke patients at high risk of VTE who have contraindications to IPC.

References

1. Intercollegiate Stroke Working Party. National clinical guideline for stroke. 5th edition. Royal College of Physicians, London 2016.
2. Geeganage CM, Sprigg N, Bath MW & Bath PM. Balance of symptomatic pulmonary embolism and symptomatic intracerebral hemorrhage with low-dose anticoagulation in recent ischemic stroke: a systematic review and meta-analysis of randomized controlled trials. Journal of Stroke & Cerebrovascular Diseases 2013; 22, 1018-27.
3. Whiteley WN, Adams HP, Bath PMW, Berge E, et al. Targeted use of heparin, heparinoids, or lowmolecular-weight heparin to improve outcome after acute ischaemic stroke: An individual patient data meta-analysis of randomised controlled trials. The Lancet Neurology 2013;12, 539-545.
4. NICE Guideline CG92: Venous thromboembolism: reducing the risk for patients in hospital. National Institute of Health and Clinical Excellence. Available from: https://www.nice.org.uk/guidance/cg92/chapter/1-recommendations [Accessed on 05 November 2017]
5. CLOTS 3: M. Dennis; P. Sandercock; J. Reid; C. Graham; J. Forbes; G. Murray. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. Lancet. 2013; 382(9891):516-24
6. Hajibandeh S, Hajibandeh S, Antoniou GA, Scurr JRH, Torella F. Neuromuscular electrical stimulation for the prevention of venous thromboembolism. Cochrane Database of Systematic Reviews 2017, Issue 11. Art. No.: CD011764. DOI: 10.1002/14651858.CD011764.pub2. [Accessed on 11th December 2017]
7. Griffin M, Bond D, Nicolaides A. Measurement of blood flow in the deep veins of the lower limb using the geko™ neuromuscular electro-stimulation device. Int Angiol. 2016;35:406-10.
8. NICE medical technologies guidance [MTG19] Published date June 2014. Available from: https://www.nice.org.uk/guidance/mtg19/chapter/6-Conclusions

ACKNOWLEDGEMENT

Firstkind Ltd has provided funding to conduct the audit.

MPSTKGN0360

Stroke in Stoke

University Hospitals of North Midlands NHS Trust

Keele University