

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

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Introduction

Venous thromboembolism (VTE) is a common and potentially fatal complication of acute stroke. NICE and the UK National Clinical Guidelines for Stroke recommend intermittent pneumatic compression (IPC) as the primary method of VTE prevention after acute stroke (NICE NG89 2018, ICSWP 2016), 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 (Geeganage et al, 2013).

UK Stroke Guidelines also state that pharmacological VTE prevention should not be used routinely or in any potentially higher risk subgroup, as work by Whitely et al (2013) has shown that it is not possible to predict which patients with acute stroke may be at sufficiently high risk of VTE compared 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 (NICE CG92, 2015), and others do not tolerate IPC (CLOTS-3, 2013). The risk of symptomatic VTE (DVT or PE) in the CLOTS-3 control group not receiving IPC was 8.7%. 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 effectiveness between NMES stimulation and standard methods of VTE prevention (5 studies), however the evidence was not sufficient to support recommendations (Hajibandeh et al, 2017).

The geko™ device (Firstkind Ltd) is an NMES device which prevents stasis in the deep veins of the calf (Griffin et al, 2016) 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 (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 contradictions 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 or if they satisfy the criteria in Table 1 (IPC Primary + geko™ secondary). If patients are non-compliant this is documented and an alternative form of VTE prophylaxis is considered.

Table 1. Contraindications to IPC

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

1000 patients (mean age 75 years, 495 (49.5%) males and 505 females (50.5%)) had 90 day outcomes and were included in the audit (Table 2).

Table 2. Demographic details

Patient demographics	Total no of patients in the audit n=1000	
Males	495	49.5%
Females	505	50.5%
Haemorrhagic strokes	126	12.6%
Ischaemic strokes	874	87.4%

VTE prophylaxis

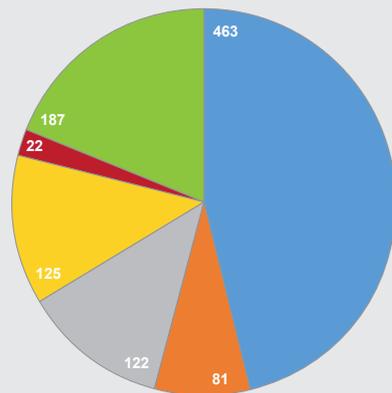
187/1000 (18.7%) did not require VTE prophylaxis, as they were independently mobile. The remaining 813 (81.3%) of patients were prescribed VTE prophylaxis. Of these 544 (54.4%) were initially given IPC devices (IPC alone), 122 (12.2%) were initially given geko™ (geko™ alone), and 125 (12.5%) were initially given anticoagulants (drug prophylaxis). 81 (8.1%) 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) and 22 patients refused IPC or the geko device. The final distribution of VTE prophylaxis methods after changing to a second method, if needed, is shown in Table 3 and Figure 1.

Table 3. Primary and secondary methods of VTE prevention

Intervention	n (%)	
IPC alone	463	46.3%
IPC Primary + geko™ secondary	81	8.1%
The geko™ device alone	122	12.2%
Drug Prophylaxis	125	12.5%
No prophylaxis required	187	18.7%
Refused mechanical prophylaxis	22	2.2%
Total Patients	1000	100%

Figure 1. VTE prophylaxis by intervention (n=1000)

- IPC alone
- IPC Primary + geko™ secondary
- The geko™ device alone
- Drug prophylaxis
- Refused prophylaxis
- Prophylaxis deemed unnecessary



Of the 688 patients prescribed mechanical VTE prophylaxis, 203/688 (29.5%) were treated with the geko™ device either as primary or secondary mechanical prophylaxis. The median length of patient use for the geko™ device was 9 days.

Patient tolerance

In total 116 patients (21.7%) prescribed IPC did not tolerate IPC and 21 patients prescribed the geko™ (9.17%) did not tolerate the device (Figure 2).

VTE incidence

In total 15/1000 (1.5%) patients developed symptomatic VTE (9 DVTs and 6 PE's) within 90 days. Of these, 11 patients (2.4%) developed VTE were prescribed IPC alone, 1 patient (1.2%) was prescribed IPC and the geko™ device as a secondary intervention and 1 patient (0.8%) was prescribed anticoagulation. There was 1 VTE event in a patient who reused prophylaxis (4.8%) and 1 event in a patient who was deemed mobile and was not prescribed prophylaxis (0.5%). There was no DVT or PE in patients treated with the geko™ device as the primary VTE prophylaxis (Figure 3).

Figure 2. Patient tolerance (%) IPC vs geko™

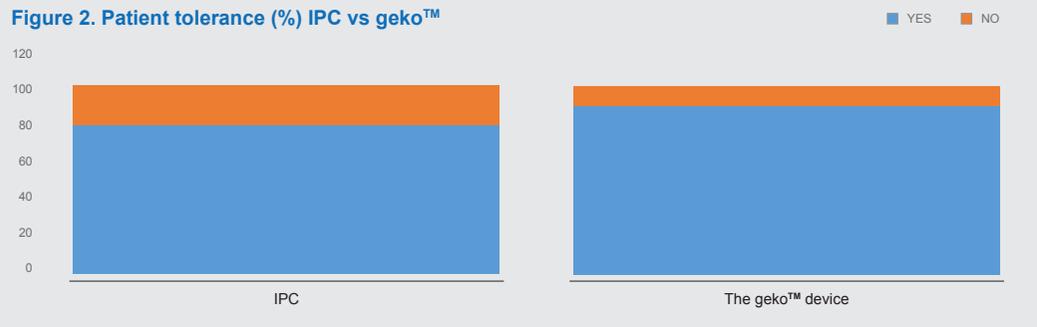
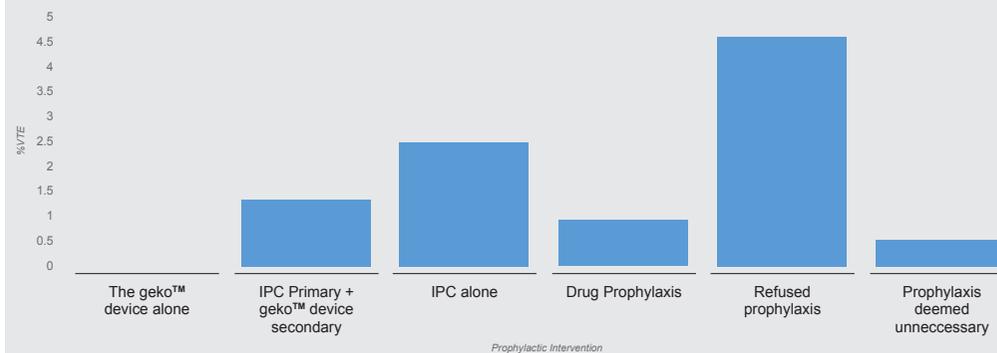


Figure 3. VTE incidence (%) by intervention (n=1000)



Conclusion

This audit shows a low incidence (1.5%) 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 (29.5%) 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 clinical audit was (n=203). Our data suggests that the device is safe and 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.

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