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, 2016). 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. We also introduced daily nurse led VTE prevention rounds. The aim of this audit was to assess the acceptability of this new pathway 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 and resident within Staffordshire or Newcastle. 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. Patients admitted from other centers for tertiary care were not included, as they were repatriated to their local hospitals.

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, refuse the intervention, have contraindications, or are 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 ischaemic 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

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

1383 patients (mean age 75 years, 689 (49.8%) males and 694 females (50.2%)) 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=1383	
Males	689	49.8%
Females	694	50.2%
Haemorrhagic strokes	165	11.9%
Ischaemic strokes	1218	88.1%

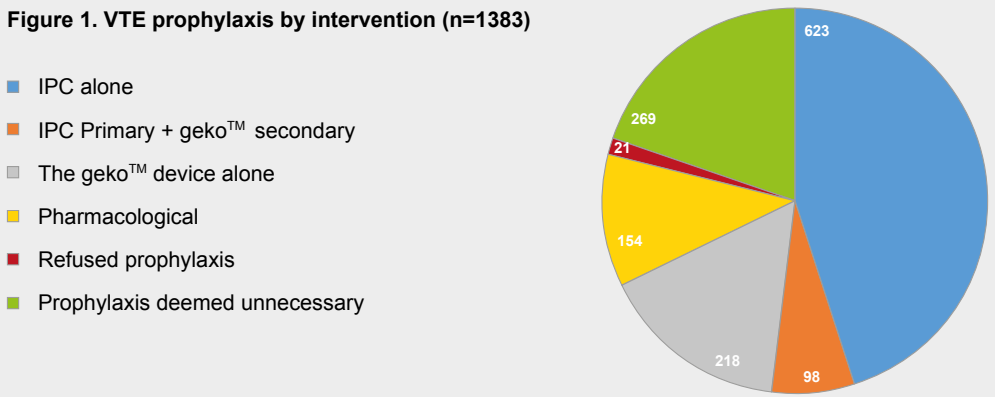
VTE prophylaxis

269/1383 (19.5%) did not require VTE prophylaxis, as they were independently mobile. The remaining 1114 (80.5%) of patients were prescribed VTE prophylaxis. 623 (45%) were initially given IPC devices (IPC alone), 218 (15.8%) were initially given geko™ (geko™ alone), and 154 (11.1%) were initially given anticoagulants (Pharmacological prophylaxis). 98 (7.1%) 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 21 patients (1.5%) 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	623	45%
IPC Primary + geko™ secondary	98	7.1%
The geko™ device alone	218	15.8%
Prophylactic (low dose) anticoagulation	0	0%
Full anticoagulation for non VTE prevention indications	154	11.1%
No prophylaxis required	269	19.5%
Refused mechanical prophylaxis	21	1.5%
Total Patients	1383	100%

Figure 1. VTE prophylaxis by intervention (n=1383)



Of the 939 patients prescribed mechanical VTE prophylaxis, 316/939 (33.7%) were treated with the gekoTM device either as primary or secondary mechanical prophylaxis.

Patient tolerance

In total 142 patients (19.9%) prescribed IPC did not tolerate IPC and 26 patients prescribed the gekoTM (7.5%) did not tolerate the device (Figure 2).

VTE incidence

In total 20/1383 (1.4%) patients developed symptomatic VTE (10 DVTs and 10 PE's) within 90 days. VTE was diagnosed in 15/623 patients (2.4%) prescribed IPC alone, in 1/98 patients (1%) prescribed IPC initially and the gekoTM device as a secondary intervention, and in 2/154 patients (1.3%) who were prescribed pharmacological prophylaxis. There was 1/21 VTE event in a patient who refused prophylaxis (4.8%) and 1/269 (0.4%) VTE event in a patient who was mobile and did not require prophylaxis (0.4%). There was no DVT or PE in patients treated with the gekoTM device as the primary VTE prophylaxis (Figure 3).

Figure 2. Patient tolerance (%) IPC vs gekoTM (n=1383)

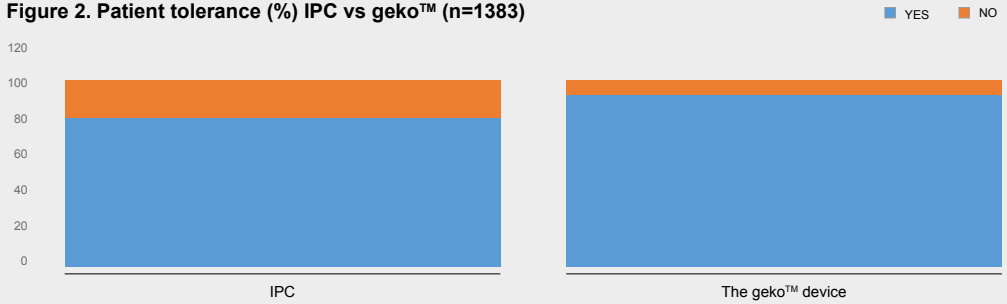
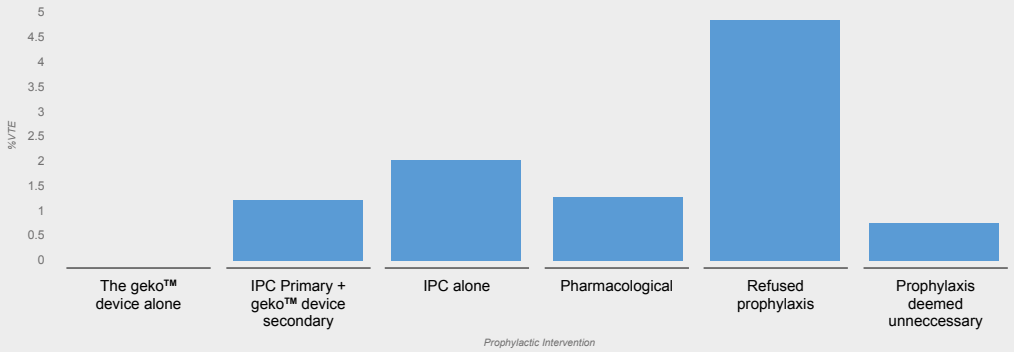


Figure 3. 90 day VTE outcome (%) by intervention (n=1383)



Conclusion

This audit shows a low incidence (1.4%) of symptomatic VTE in a high risk population of immobile stroke patients.

We introduced NMES via the gekoTM device as an alternative to IPC, where IPC was contraindicated or not tolerated as part of our new VTE pathway, which also included daily nurse led VTE prevention rounds.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 (33.7%) 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 gekoTM in this clinical audit was (n=316). Our data suggests that the device is safe and as effective as IPC in our patient cohort. Fewer patients were intolerant of the gekoTM device than of IPC, but, as the majority of patients treated with gekoTM had contraindications to IPC or were changed to the device because IPC was not tolerated, a direct comparison is not possible. The gekoTM device provided an alternative VTE prophylaxis strategy in immobile stroke patients. These patients were at high risk of VTE due to leg paralysis and would otherwise have had no form of VTE prophylaxis other than general measures.

The findings of this audit suggest that gekoTM 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 gekoTM as a meaningful addition to our prophylactic options for stroke patients at high risk of VTE who have contraindications to or who do not tolerate IPC.

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