J.12 Acute stroke patients

Study	[CLOTS Trials Collaboration[184], Dennis 2015[248], Denis 2015[247]]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost-effectiveness**
Economic analysis: CUA (health outcome: quality-adjusted life-days) **Study design:** Randomised Controlled Trial **Approach to analysis:** Within-trial analysis of individual patient level data of costs and outcomes using generalised linear modelling of cost data and **Perspective:** UK NHS **Follow-up:** 6 months	**Population:** Immobile stroke patients admitted to 92 UK centres from days 0 to 3 of admission. **Cohort settings: (n=2876)** Start age: 74.6 years Male: 48% **Intervention 1: (n=1438)** Usual care only. Routine care defined as early mobilisation hydration and anti-platelet or anti-coagulant medication.	**Total costs of IPC plus hospital days (mean per patient):** Intervention 1: £12,116 Intervention 2: £12,567 Incremental (2−1): £451 (95% CI: NR; p=NR) **Currency & cost year:** UK pounds [2013] **Cost components incorporated:** Hospital stay IPC cost (capital and equipment)	**Quality-adjusted life-days (mean per patient):** Intervention 1: 26.7 days Intervention 2: 27.6 days Incremental (2−1): 0.9 days (95% CI: -2.1 to +3.9; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £610.88 per quality adjusted life day (da) 95% CI: NR Probability Intervention 2 cost-effective (£20K/30K threshold): NR **Analysis of uncertainty:** Sensitivity analyses based on multiple imputations of the EQ5D-3L to account for missing data did not alter the conclusions. No other one way sensitivity analysis was conducted. Subgroup analysis based on predicted prognosis at randomisation showed that IPCD appeared to reduce the risk of DVT and probably improve survival in all immobile

Treatment effect duration:[(a)] 6 months **Discounting:** Costs: n/a ; Outcomes: n/a	**Intervention 2: (n=1438)** Thigh length IPC in addition to usual care. IPC the IPC system used as the Kendall SCD™ express sequential compression (Covedien Ltd, Mansfield, MA, USA) with thigh length sleeves worn continuously on both legs for 30 days or next CDU (if >30 days) or until the patient was independently mobile, discharged from randomising hospital or refused to wear the sleeves or the staff became concerned about his/her skin condition.			stroke patients except those in the fifth quintile (those with best prognosis). The authors concluded that IPC is likely to be most effective in the subgroups of immobile stroke patients In the three intermediate quintiles.
Data sources				
Health outcomes: 6 month quality of life data gathered during associated trial. Base-line utility modelled using a Bayesian Network incorporating data from the other CLOTS studies because of the questionable validity of asking patients or carers to rate their quality of life shortly after admission to hospital with a severe stroke. **Quality-of-life weights:** EQ-5D-3L UK tariff. **Cost sources:** NHS reference costs for English centres, Scottish Health Service Costs for Scottish centres.				
Comments				
Source of funding: University of Edinburgh, NHS Lothian and NIHR HTA Program. Covidien LtD provided IPCs **Limitations:**Most of the cost difference was derived from a per diem amount applied to a non- significant difference in length of stay rather than the actual cost of the hospital stay. Important costs were excluded from the analysis such as readmissions, post-hospital care, deep vein thrombosis, and pulmonary embolism. The timeframe was only 6 months which is unlikely to be sufficient to capture important cost and health consequences. The statistical methods used to estimate quality of life at baseline was experimental and had not been independently verified. The EQ-5D-3L generic quality of life measurement tool was known to have limitations in detecting small functional improvements in severely disabled people. There is a high degree of uncertainty around the estimates provided.				
Overall applicability:[(b)] Directly applicable **Overall quality**[(c)] Potentially serious limitations				

Abbreviations: 95% CI: 95% confidence interval; CUA: cost-utility analysis; da: deterministic analysis; EQ-5D-3L: Euroqol 5 dimensions 3 levels (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; IPC: intermittent pneumatic compression; NR: not reported; pa: probabilistic analysis; QALYs: quality-adjusted life years.

(a) For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.
(b) Directly applicable / Partially applicable / Not applicable
(c) Minor limitations / Potentially serious limitations / Very serious limitations