

ABSTRACT

- Are graduated compression stockings as effective as intermittent pneumatic compression in the prevention of DVT?
- CLOTS (Clots in Legs Or sTockings after Stoke) trials that researched the effectiveness of thigh-high graduated compression stockings (GCS) compared to no stockings, thigh-high versus knee-high stockings and IPC in prevention of DVT
- Participants: all studies included immobilized stroke patients, CLOT 1 trial: 2,518 patients from 55 hospitals in UK, Italy and Australia, CLOT 2 trial: 3,114 patients from 112 hospitals in 9 countries, CLOT 3 trial: 2,876 at 105 hospitals in UK
- Methods: CLOTS 1, 2 and 3 were all randomized, outcome-based, multicenter controlled trials with CLOTS 1 and 2 also being international
- Results: CLOTS 1 trial found that thigh-high stockings were ineffective at preventing DVT, CLOTS 2 trial found thigh-high stockings were more effective than knee-high and CLOTS 3 trial found that IPC is effective in reducing DVT in immobilized stroke patients
- Data analysis: CLOTS 1 trial had 90% power to detect 4% reduction in DVT, CLOTS 2 trial results skewed d/t interruption in recruitment, estimated that 2,500 patients would be needed to provide 90% power ($\alpha=0.05$) to identify 4-percentage point absolute reduction in primary outcome
- Conclusions: use of GCS is not clinically significant with many risks involved with treatment. The use of IPC is an effective method of reducing DVT in immobile stroke patients.

BACKGROUND

- Preventative care is major focus in healthcare
- Venous thromboembolism is most common preventable cause of death in hospitalized patients
- DVT and pulmonary embolism (PE) are 2 common avoidable complications after stroke
- 42% of stroke patients develop DVT
- VTE prophylaxis has been prioritized by The Agency for Healthcare Research as the number one patient safety practice in nearly 70 practices
- The Center for Medicare and Medicaid will not pay for any expenses related to DVT or PE that occurs while a patient is hospitalized

OBJECTIVES

All of the trials examined results in prevention of DVT in the popliteal and femoral veins with routine care plus:

- CLOT 1 trial: the use of thigh-high GCS compared to the use of no stockings
- CLOT 2 trial: the use of thigh-high GCS compared to knee-high stockings
- CLOT 3 trial: the use of intermittent pneumatic compression (IPC)

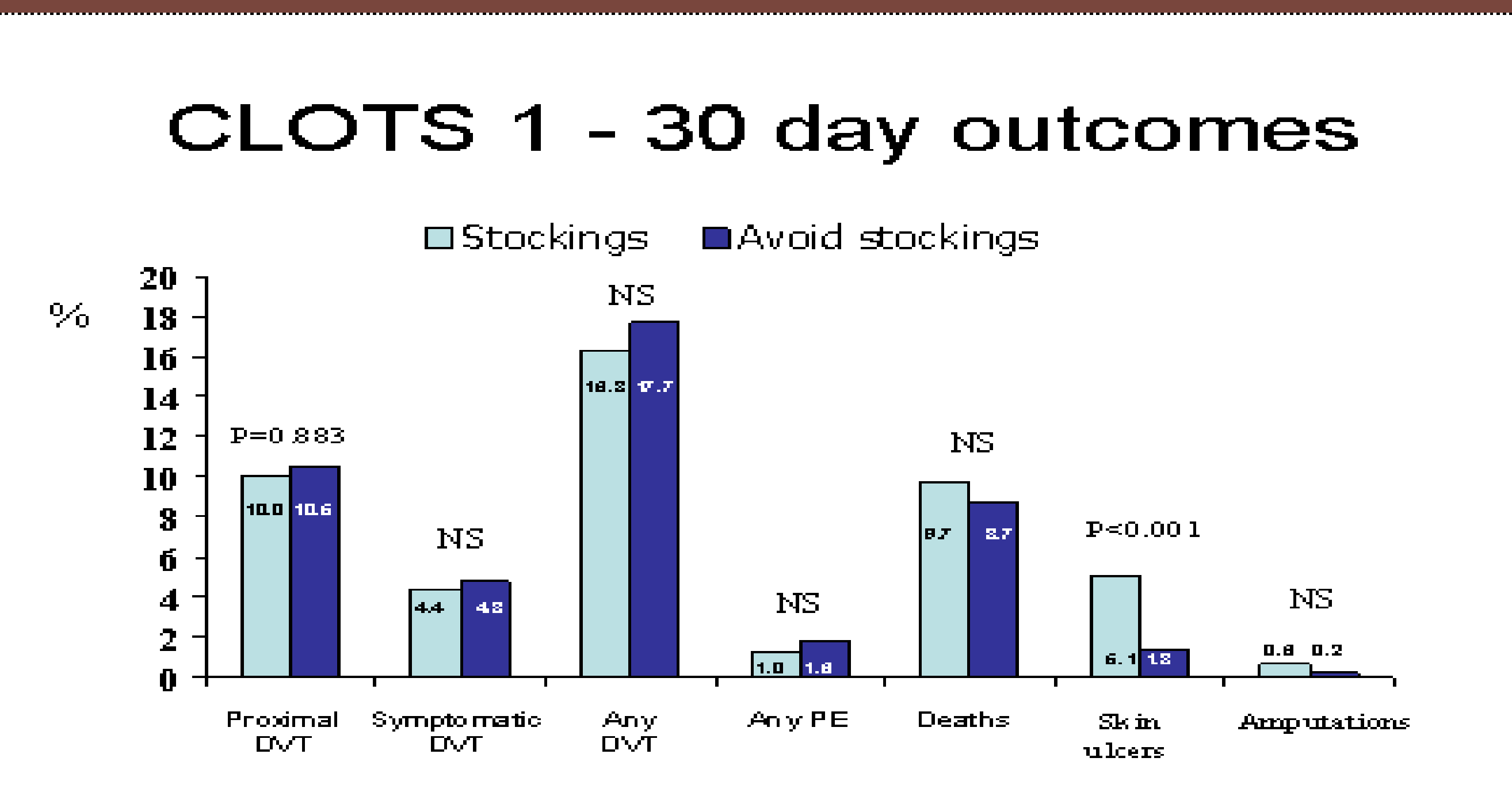
METHODS

For both CLOTS 1 and CLOTS 2 trial, patients received routine care. Eligible patients data was entered into computer program to generate groups. Stockings were applied as soon as possible and maintained 24 hours as day until patient was independently mobile, refused, concern of skin integrity or discharge. Both studies, ultrasound of lower extremities was performed at 7-10 days and 25-30 days.

- CLOTS 1 trial: 1,256 patients allocated thigh-high stockings while 1,262 received routine care
- CLOTS 2 trial: 1,552 patients allocated thigh-high stockings, 1,562 allocated knee-high stockings
- CLOTS 3 trial: 1,438 patients allocated IPC, 1,438 allocated no IPC

Primary outcome for all studies was presence of DVT in femoral or popliteal veins

RESULTS



CLOTS 2 outcomes

Table 2. Primary and Secondary Outcomes

Outcome	Thigh-Length Stockings Group (n = 1552), n (%)	Below-Knee Stockings Group (n = 1562), n (%)	Difference in Proportion (95% CI), percentage points	Adjusted Odds Ratio (95% CI)*	P Value From Logistic Regression
Primary outcome					
Proximal DVT	98 (6.3)	138 (8.8)	-2.5 (-0.7 to -4.4)	0.69 (0.53 to 0.91)	0.008
Alive and free of primary outcome	1246 (80.3)	1213 (77.7)			
Died before any primary outcome	170 (10.9)	161 (10.3)			
Missing†	38 (2.4)	50 (3.2)			

Clots 3 outcomes

	IPC (n=1438)	No IPC (n=1438)	Absolute risk difference (95% CI)	Risk ratio (95% CI)‡	Odds ratio (95% CI)	p value
Dead by 6 months	320 (22.3%)	361 (25.1%)	-2.9 (-6.0 to 0.3)	0.87 (0.75 to 1.00)	0.85 (0.70 to 1.01)	0.059
Any DVT	240 (16.7%)	312 (21.7%)	-5.0 (-7.9 to -2.1)	0.76 (0.64 to 0.89)	0.72 (0.60 to 0.87)	0.001
Any symptomatic DVT 77 (5.4%)	101 (7.0%)		-1.7 (-3.4 to 0.1)	0.76 (0.56 to 1.01)	0.75 (0.55 to 1.02)	0.061
Any confirmed PE	42 (2.9%)	49 (3.4%)	-0.5 (-1.8 to 0.8)	0.86 (0.57 to 1.29)	0.86 (0.56 to 1.30)	0.463
Any death, DVT, or PE 526 (36.6%)	626 (43.5%)		-7.0 (-10.5 to -3.4)	0.83 (0.75 to 0.92)	0.74 (0.63 to 0.86)	

RESULTS

- CLOTS 1 trial: showed 0.5% (95% CI -1.9 to 2.9) absolute reduction in primary outcome
 - Thigh-high stockings: (n=1,256)
 - 126 (10.0%) developed proximal DVT
 - 974 (77.5%) remained living and free of DVT
 - 115 (9.2%) expired before any development of DVT
 - 41 (3.3%) missing
 - No GCS : (n= 1,262)
 - 133 (10.5%) developed proximal DVT
 - 1,000 (79.2%) remained living and free of DVT
 - 101 (8.0%) expired before developing DVT
 - 28 (2.2%) missing
- CLOTS 2 trial showed 2.5% (CI, 0.7 to 4.4 percentage points; $p=0.007$) and a difference in odds of 31% (CI, 9% to 47%)
 - See table 2
- CLOTS 3 trial showed an absolute reduction in risk of 3.6% (95% CI 1.4-5.8) of the primary outcome
 - See table 3

CONCLUSIONS

Findings of CLOTS 1 trial found that thigh-high GCS were clinically ineffective and did pose risks. Skin breakdown occurred in 64 (5.1%) in group wearing GCS as opposed to 16 (1.3%) in those that did not wear them. Amputation occurred in 7 (0.6%) for GCS group and 2 (0.2%) for those without GCS.

Findings in CLOTS 2 trial also posed same risks with little benefit. Skin breakdown occurred in 61 (3.9%) for those that receive thigh-high GCS and 45 (2.9%) in those with knee-high GCS.

Findings in CLOTS 3 found that IPC is an effective method of reducing the risk of DVT and possibly improving survival in stroke patients. Skin breakdown was reported in 44 (3%) of patients allocated IPC and 20 (1%) patients allocated no IPC. Falls with injury were reported in 33 (2%) of patients in IPC group and 24 (2%) of patients in no IPC group.

REFERENCES

References

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