T.E.D.™ Anti-Embolism Stockings

Clinical guide

Your partner in VTE prevention

CardinalHealth
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Contents

Facts

Think VTE think prevention

Venous thromboembolism (VTE) is the leading preventablecause of death in hospitalised patients.[1]

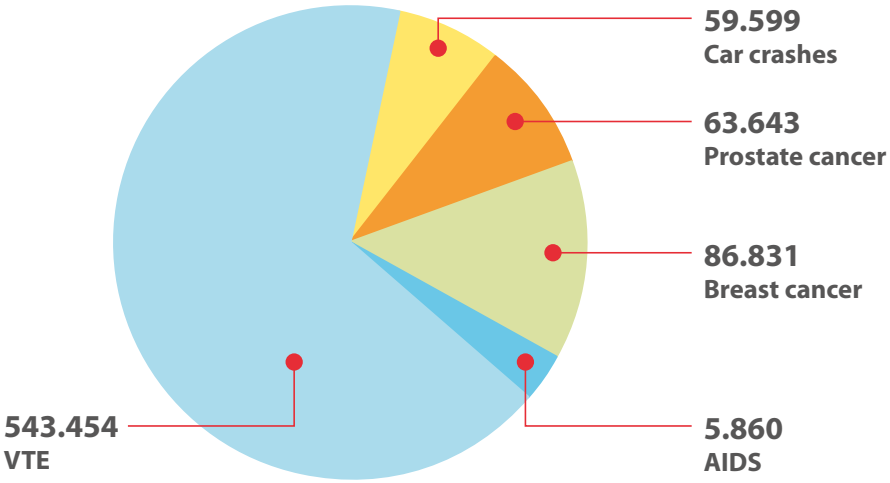
Common

- Over **1 million** of VTE events are estimated annually in Europe, **60%** of which are hospitalised patients[1,2]
- Only **58%** of surgical and **39%** of medical patients receive the appropriate prophylaxis despite the availability of effective preventive measures[3]

Costly

- The annual estimated cost of VTE in Europe is **€3 billion**[2,4]
- The health care costs in patients with VTE can reach **€60.000** per year[5]
- Daily cost of DVT[6] **€1.255**
- Daily cost of PE[6] **€1.366**
- Additional length of stay from **4.7** (DVT) to **5.4** (PE) days[6]

VTE kills more Europeans each year than breast cancer, prostate cancer, motor vehicle crashes, and AIDS combined[2]



T.E.D.™ Anti-Embolism Stockings

- Have been shown to reduce the incidence of DVT and PE in over 20,000 patients for over 50 years and have been clinically proven to reduce DVT by over **60%**[1]
- Provide baseline DVT protection when pneumatic/impulse compression is interrupted. Protect after discharge reducing the chance of unwanted DVT complications
- Are available in 3 styles and 40 sizes to fit all the patients even including obese ones

Clinical Studies

Author:	Sigel, et al.
Title:	Type of compression for reducing venous stasis – a study of lower extremities during inactive recumbency
Journal:	Archives of Surgery
Year:	1975

Study purpose

To determine how much compression should be exerted by graduated compression stockings (GCS) and whether compression should be applied as a gradient or uniformly to the lower extremities.

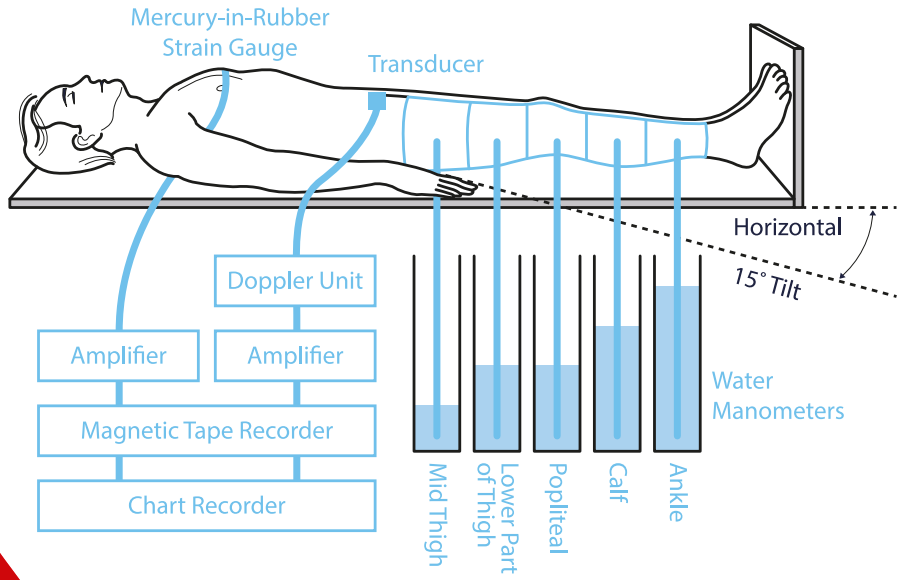
Patients & methods:

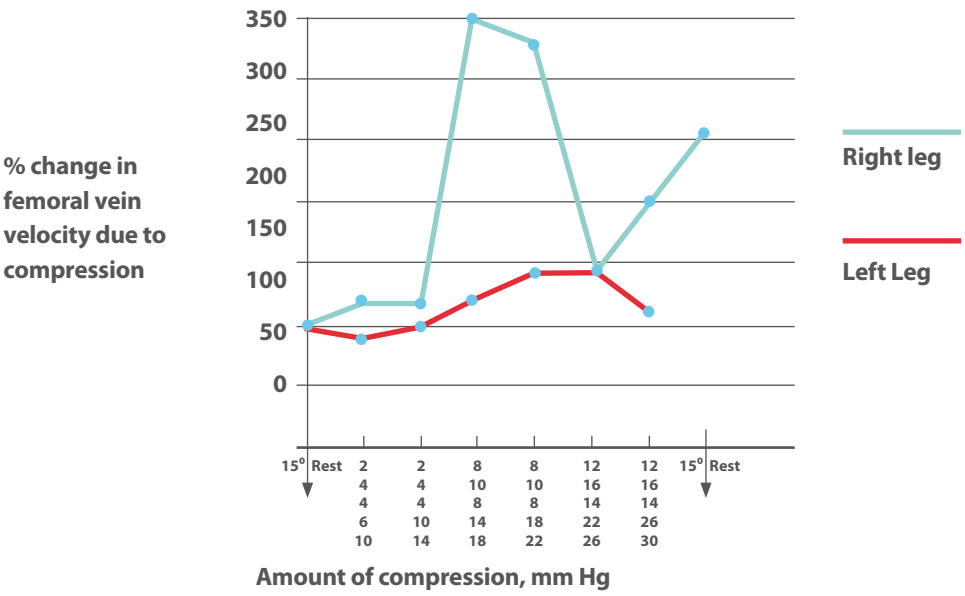
In order to determine the optimal compression* a series of experiments were conducted simulating the body position of an inactive bedridden patient in hospital.

7 volunteers, 5 women and 2 men were enrolled in the trial. All the subjects were considered to have normal venous system except one with an history of thrombophlebitis.

To compress the legs a pneumatic device with 5 chambers vinyl sleeve was used. The pressure within each chamber could be regulated individually. The five chambers were placed at ankle, calf, popliteal region, lower part of the thigh and mid thigh respectively. The common femoral vein blood flow was measured transcutaneously by doppler ultrasound.

12 tests were performed applying the compression profile employed by commercial producers of GCS. The level of femoral vein flow velocity during the last 5 minutes of each test was detected and averaged.





Study conclusion

"At the body position considered most characteristic of the hospitalized subjects, a 15° foot down tilt, the recommended ankle to mid thigh pressure gradient for anti embolic stockings is 18 to 8 mm Hg. This compression increases the femoral vein blood flow up to 138,4% of the baseline. This compression profile is the appropriate gradient for hospitalized patients who are confined to bed.

Furthermore the application of a gradient compression (18 to 8 mm Hg) increases the venous velocity to a higher level than the application of a uniform pressure."

Value proposition

The Kendall T.E.D.™ Graduated compression stockings deliver Sigel's recommended gradient pressure pattern (18, 14, 8, 10, and 8 mm Hg from the ankle to the upper thigh) providing optimal results for blood flow velocity in the femoral vein without compromising patient safety. Thanks to their gradient pressure pattern, The Kendall T.E.D.™ stockings reduce the threat of blood clots forming in lower limbs.

* The optimal compression was defined by the study as the amount of externally applied pressure that produces the greatest increase in femoral vein flow velocity consistent with safety and practicality of hospital use of elastic stockings.

Author:	Lewis et al.
Title:	Elastic compression in the prevention of venous stasis: a critical re-evaluation
Journal:	The American Journal of Surgery
Year:	1976

Study purpose

To perform a clinical evaluation of an anti-embolic stocking providing a gradient pressure by using a venographic technique.

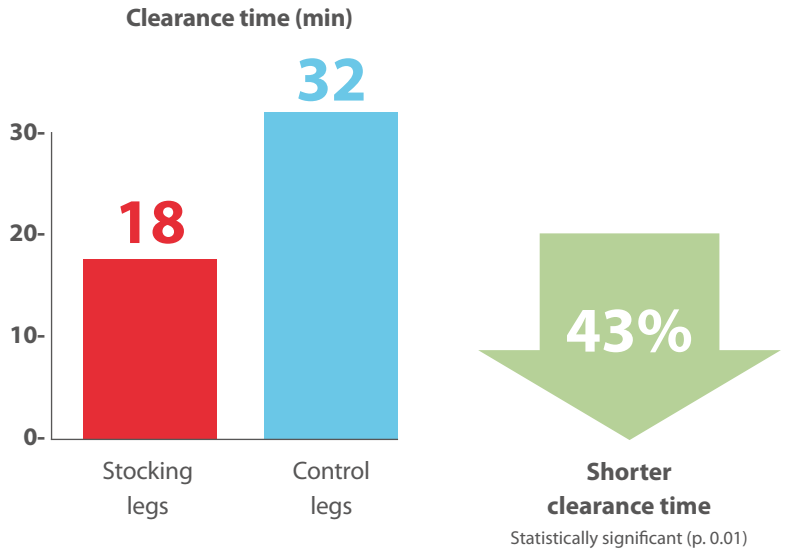
Patients & methods:

15 patients (8 males, 7 females) undergoing abdominal surgery with general anaesthesia were included in the trial. A stocking was placed on one leg chosen randomly with the alternate leg serving as a control. The stockings chosen for the experiment provided a gradient pressure, were equipped with a pressure relief panel to avoid tourniquet effect and/or inverse gradient and were available in a sufficient number of sizes to allow an acceptable fit for each patients. The leg clearance time was detected at thigh, knee and calf level using a venographic technique.

Picture of TED stockings which are designed with a pressure relief panel similar to that in the study

Main outcomes

The average whole-leg clearance time observed in legs with stockings was 18,3 min. compared to 32 min. observed in the corresponding control legs. The difference of 13,7 min. was found statistically significant .



Study conclusion

"The data presented show that stockings not only result in an increased velocity of venous flow in the legs, but also result in a more rapid clearance of stagnant blood from behind venous valves. Furthermore these data suggest that the routine use of carefully fitted GCS will result in a decreased incidence of VTE and provide a safe, convenient and non-invasive method of prophylaxis."

Value proposition

The Kendall TED™ Graduated compression stockings are manufactured using the clinically tested and recommended pressure gradient of 18, 14, 8, 10, and 8 mmHg from the ankle to the upper thigh, are available in 40 sizes to fit all the patients and have an uninterrupted band and 2-ply gusset to promote the return of blood through the femoral vein, avoiding the tourniquet effect thereby increasing patient safety .

Author:	Scurr . et al.
Title:	Regimen for improvement effectiveness of intermittent pneumatic compression in deep venous thrombosis prophylaxis
Journal:	Surgery
Year:	1987

Study purpose

To asses the effectiveness of intermittent pneumatic compression (IPC) alone with the simultaneous use of graduated compression stockings and IPC for DVT reduction.

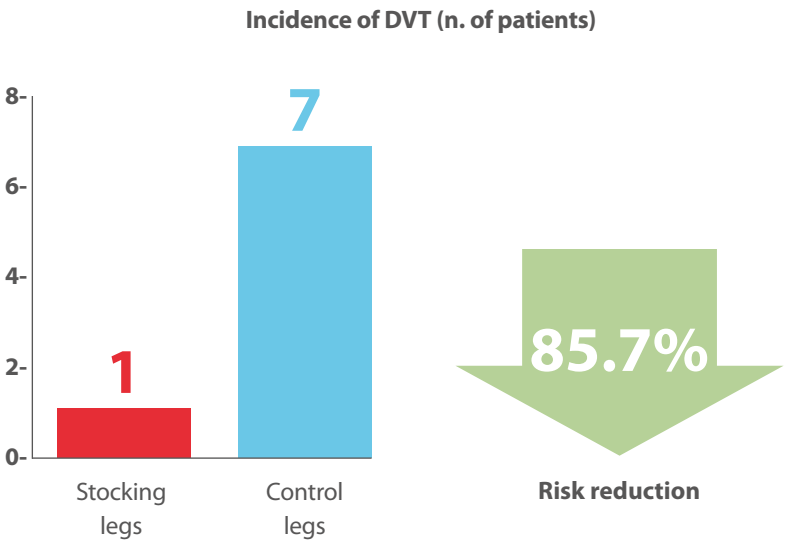
Patients & methods:

78 consecutive patients (43 males, 35 females) undergoing general surgical procedures were included in the study and properly sized and fitted with T.E.D.™ stockings at hospital admission. At the time of surgery one stocking was removed from either the right or left leg, randomly allocated, and IPC with full length sleeve was applied to both legs. All patients were preoperatively screened and any positive sign of DVT caused exclusion from the study.

Postoperative diagnosis of DVT was conducted with I-125 Fibrinogen Uptake Test followed by Doppler Ultrasound and Contrast Venography to confirm any positive DVT diagnosis.

Main outcomes

The overall incidence of DVT was 9%. No pulmonary embolism (PE) was diagnosed. The incidence of DVT in non stocking group was 9% (7/78) compared with 1% (1/78) of stocking group.



Study conclusion

"These results are surprising because it was previously believed that both mechanical modalities produced prophylactic effect by increasing linear blood flow velocity and by decreasing venous blood clearance time. This study has demonstrated that it's possible graduated compression stockings, while providing continuous stimulation of blood flow velocity, also prevent venous distension due to general anaesthesia. These outcomes indicate that the combined regimen of GCS with IPC is a more effective prophylactic regimen than IPC only."

Value proposition

The Kendall T.E.D.™ Graduated compression stockings improve blood circulation while preventing venous distension due to general anaesthesia. The use of combined mechanical prophylaxis (Kendall T.E.D.™ stockings + Kendall SCD) is significantly more effective than the use of IPC alone in preventing DVT in general surgery patients.

Results show up to 86% DVT risk reduction with addition of T.E.D.™ stockings.

Author:	Coleridge Smith et al.
Title:	Deep vein thrombosis: Effect of graduaed compression stockings on distension of the deep veins of the calf
Journal:	British Journal of Surgery
Year:	1991

Study purpose

Deep veins of the lower limbs have been proven distending in patients undergoing surgical procedures. This study has been designed to assess whether GCS are effective in preventing the venous distension observed in deep veins of the lower limbs.

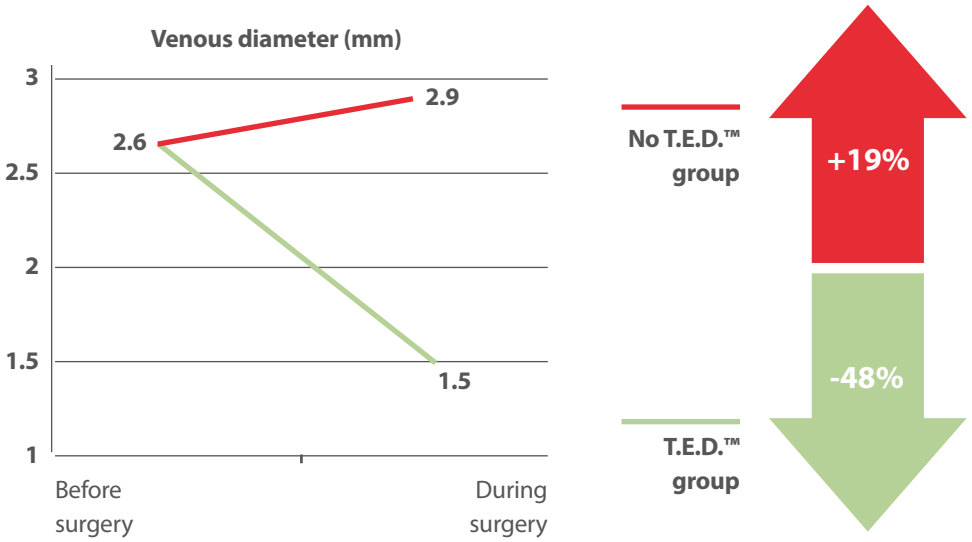
Patients & methods:

41 patients (14 males, 27 females) undergoing a variety of surgical procedures were included in the study. After anaesthesia was inducted images of the veins were taken by using an ultrasound scanner. All patients received appropriate pharmacological prophylaxis usually in the form of low dose subcutaneous heparin (LDSH). They were furthermore randomly allocated to receive T.E.D.™ stockings or no additional mechanical prophylaxis. Subsequently the vein under study was maintained in constant view and its diameter observed until the operative procedure was completed.

Main outcomes

After induction of anaesthesia but before the start of surgical procedure the diameter of gastrocnemius veins was the same in both the groups. During surgery in the stocking group there was an immediate reduction in the vein diameter which fell to 1,6 mm in response to application of T.E.D.™ During surgery there was a further decrease in the vein diameter to 1,5 mm. The total reduction in vein diameter seen in the T.E.D.™ group was 48% between induction of anaesthesia and the end of surgery.

The patients in the control group showed the same capability to undergo distension of gastrocnemius veins during surgery. The median distension observed between induction of anaesthesia and the end of surgery was 19% to 2,9 mm.



Study conclusion

"There can be no doubt that T.E.D.™ stockings resulted in an impressive reduction in diameter of gastrocnemius veins in the patient studied, amounting in total to a median reduction of 48% of the original size. This clearly will have a substantial effect on emptying and flow these vessels.

In addition, no venous distension occurred during surgery in the T.E.D.™ group. In fact the gastrocnemius veins showed a small decrease in diameter."

Value proposition

Blood vessels distend during surgery and the significant increases observed in the diameter of the deep veins may potentially lead to damage of the endothelial wall which can stimulate the coagulation cascade and can contribute to the formation of DVT.

The Kendall T.E.D.™ Graduated compression stockings have been shown to reduce venous distention by 48% providing protection from the negative effects of venodilation thus reducing the risk of DVT.

Author:	Ishak et al.
Title:	Deep venous thrombosis after total hip arthroplaty: a prospective controlled study to determine the prophylactic effect of graded pressure stockings
Journal:	British Journal of Surgery
Year:	1981

Study purpose

To assess whether GCS are effective in reducing venous thromboembolism (VTE) in orthopaedic patients undergoing total hip arthroplasty.

Patients & methods:

76 consecutive patients undergoing total hip arthroplasty were randomly divided into two groups. 35 patients enrolled in the stocking group were fitted with T.E.D.™ stockings the day before surgery.

During surgery, both the stockings were drawn back to knee level but replaced before the patient returned to the ward. Stockings were changed every 5 days but worn until discharge from hospital.

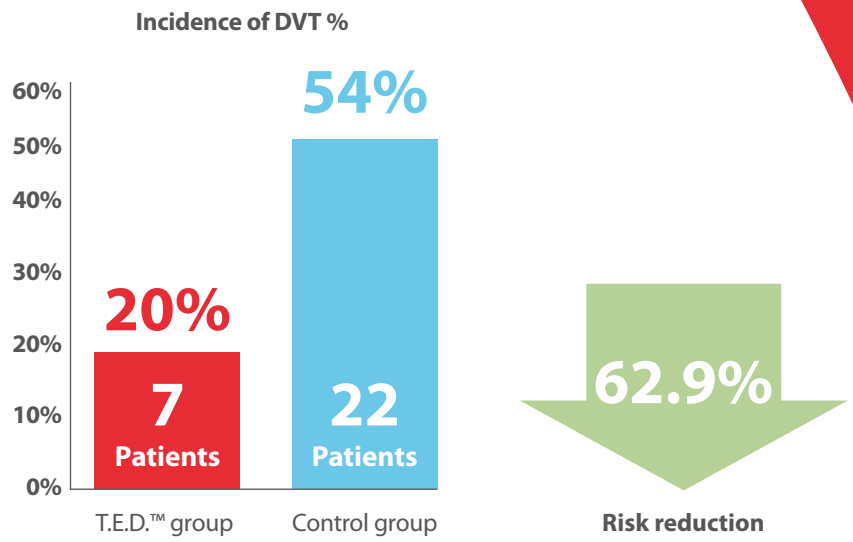
41 patients were included in the control group.

26 patients in the stocking group and 33 of the control patients received Dextran.

All patients had bilateral ascending venography performed between the 10th and 14th postoperative day.

Main outcomes

The group wearing T.E.D.™ stockings had a significantly lower incidence of DVT (20%) than in the controls (54%). The difference was significant in both males and females. Furthermore a significantly increased incidence ($P < 0.01$) of DVT was detected in over transfused patients. However It was of interest that 8 patients in the stocking group were over transfused without developing DVT but only one over transfused control patient had a negative venogram as if the GCS reduced the risk of thrombosis in over transfused patients.



Study conclusion

"This study shows that GCS significantly reduce the incidence of DVT after total hip arthroplasty and they can be recommended as a simple, inexpensive, prophylactic measure in patients undergoing orthopaedic surgery."

Value proposition

The Kendall T.E.D.™ Graduated compression stockings have been shown to reduce the incidence of DVT in patients undergoing total hip arthroplasty.

They can be offered to high risk patients in combination with anticoagulants and/or IPC, and used pre, peri and post-operatively until the full mobilization.

Author:	Amaragiri et al.
Title:	Elastic compression stocking for prevention of deep vein thrombosis (review)
Journal:	The Cochrane collaboration
Year:	2008

Study purpose

To determine the magnitude of effectiveness of CGS in preventing DVT in various groups of hospitalized patients. 4 hypotheses were tested:

1. **Compression stockings are effective in preventing DVT in all hospitalised patients**
2. **In all moderate risk patients, compression stockings alone are adequate for DVT prophylaxis, except in patients where stockings are specifically contraindicated**
3. **Stockings are unnecessary in low risk patients**
4. **Complications are associated with the use of compression stockings**

Patients & methods:

16 randomized controlled trials (RCTs) which involved the use of GCS for DVT prophylaxis were included in the review. In all the trials GCS were worn either on the day of admission or on the day of operation until the day of discharge or the full mobility, except in two trials where patients wore GCS for 14 days or until discharge. Data were collected in two groups comprising of:

- **Group 1** – GCS only in the treatment group and nothing in the control group
- **Group 2** – GCS in the treatment group and another method of DVT prophylaxis in both the treatment and control group

All RCTs used radioactive I 125 fibrinogen uptake (FUT) to screen for DVT post operatively and phlebography to confirm the diagnosis.

Main Outcomes Group 1:
GCS only in the treatment group and nothing in the control group

1.027 Patients screened

536 GCS Group

DVTs 81 (15%)

491 Control Group

DVTs 144 (29%)

Main Outcomes Group 2:
GCS in the treatment group and another method of DVT prophylaxis in both the treatment and control group

1.184 Patients screened

589 GCS Group

DVTs 18 (3%)

595 Control Group

DVTs 84 (14%)

Risk reduction

Risk reduction

Study conclusion

"The 16 RCTs analysed show that, in post surgical patients, use of GCS lowers the risk of DVT and therefore GCS should be considered in all patients at risk of DVT unless they have specific contraindications. GCS on their own are effective in decreasing the risk of DVT, but the data obtained suggest that combining another method of prophylaxis with GCS is more effective than a single prophylaxis."

Value proposition

The Kendall T.E.D.™ stockings have been used in the majority of the trials included in this review providing a baseline protection against DVT. Used alone or in combination to anticoagulants Kendall T.E.D.™ stockings yield a lower DVT rate in all surgical patients at risk for VTE.

Author:	Sachdeva A, Dalton M, Amaragiri SV, Lees T
Title:	Graduated compression stockings for prevention of deep vein thrombosis (review)
Journal:	The Cochrane collaboration
Year:	2014

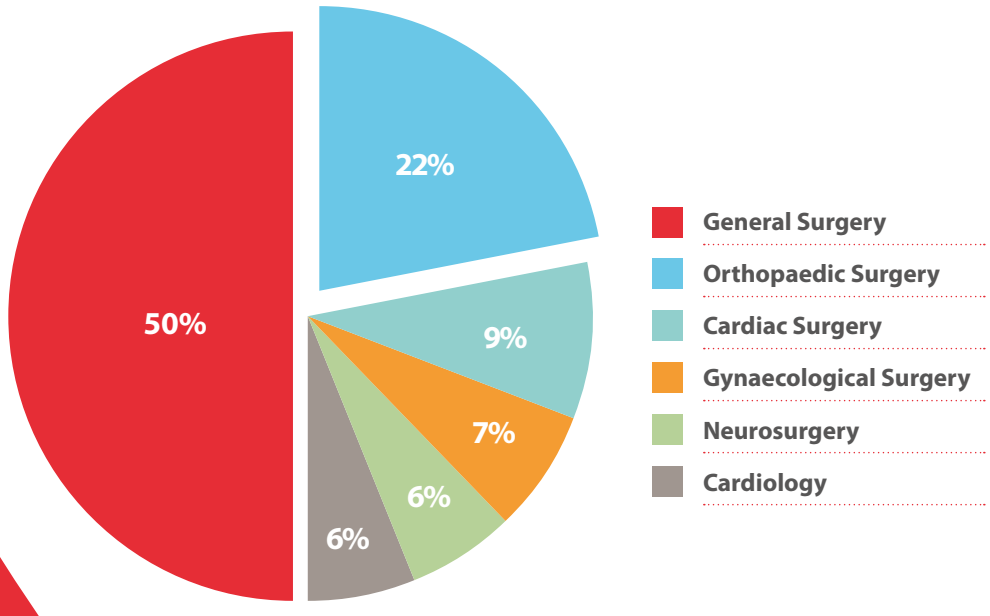
Study purpose

Update of a Cochrane review most recently published in 2010 undertaken to assess the effectiveness and safety of GCS in preventing DVT in various groups of surgical and medical patients. 4 hypotheses were tested:

1. **Compression stockings are effective in preventing DVT in hospitalised patients (excluding stroke)**
2. **In all moderate risk patients, compression stockings alone are adequate for DVT prophylaxis, except in patients where stockings are specifically contraindicated**
3. **Stockings are unnecessary in low risk patients**
4. **Complications are associated with the use of compression stockings**

Randomised controlled trials (RCTs) involving GCS alone or GCS used on a background of any other DVT prophylactic method were included in the research. Results from both these groups of trials were combined in the update.

Number of patients by specialty included in the meta-analysis



Patients & methods:

19 randomized controlled trials (RCTs) involving GCS alone or GCS used on a background of any other DVT prophylactic method were included in the research. Results from both these groups of trials were combined in the review. The GCS were applied on the day before surgery or on the day of surgery and were worn up until discharge or until the patients were fully mobile.

8 trials (Group 1) compared GCS only in the treatment group and no prophylaxis in the control group and 10 (Group 2) compared GCS in the treatment group and another method of DVT prophylaxis, including Dextran 70, aspirin, heparin and IPC, in both the treatment and control groups.

Since both these groups of trials test the same treatment effect (with GCS versus without GCS), all trials were merged to increase the power of the review.

DVT was diagnosed using an method of assessment such as ultrasound, venogram or isotope studies.

Main Outcomes:

Incidence of DVT

2.745 Analytic units*

1.319 GCS Group

DVTs 126 (9%)

1.354 Control Group

DVTs 282 (21%)

Risk reduction

* According to the review methodology analytic units include both individual patients and individual legs

Secondary Outcome:
Incidence of proximal DVT (8 studies)

1.355 Analytic units*

517 GCS Group

DVTs 7 (1%)

518 Control Group

DVTs 28 (5%)

80%

Risk reduction

Secondary Outcome:
Incidence of PE (5 studies)

569 Patients

283 GCS Group

DVTs 5 (2%)

286 Control Group

DVTs 14 (5%)

60%

Risk reduction

Study conclusion

"GCS are effective in diminishing the risk of DVT in hospitalised patients, with strong evidence favouring their use in general and orthopaedic surgery. It's also demonstrated that GCS may reduce the risk of developing DVT in the thighs (proximal DVT) and PE in such patients, though these results were based on a much smaller number of participants."

Value proposition

The Kendall T.E.D.™ stockings have been used in the majority of the trials included in this review providing a baseline protection against DVT. They have been shown to reduce the incidence of DVT and PE in over 20,000 surgical and medical patients and have been clinically proven to reduce DVT by over 60%[11].

Used alone or as supplement to anticoagulants T.E.D.™ stockings yield a lower DVT rate in all patients at risk for VTE. %

* According to the review methodology analytic units include both individual patients and individual legs

Abbreviations

DVT: Deep Vein Thrombosis

GCS: Graduated Compression Stockings

IPC: Intermittent Pneumatic Compression

LDSH: Low Dose Subcutaneous Heparin

PE: Pulmonary Embolism

RCTs: Randomized Control Trials

VTE: Venous Thromboembolism

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T.E.D.™Anti-Embolism Stockings

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