Thrombo-embolie veineuse (TEV)
Prophylaxie hospitalière pour l'AVC

- Vision d'ensemble
- ACCP 9ème édition "CHEST"
- Pneumo-compression intermittente: CLOTS 3

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Thrombosis Canada
Thrombose Canada

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Conflits d'intérêts potentiels 2012 à 2014

Comités aviseurs ou aviseur expert:

Bayer HealthCare, Boehringer Ingelheim, Bristol-Myers Squibb, Janssen, Novartis, Pendopharm, Pfizer et Roche

Fonds de recherche:

Bayer HealthCare, Bristol-Myers Squibb et Sanofi

Conférencier:

Bayer HealthCare, Boehringer Ingelheim, Bristol-Myers Squibb, Covidien, Merck, Pfizer et Sanofi

Risque thrombo-embolique
Principaux facteurs de risque

- **CHIRURGIE**
  - ➔ Surtout orthopédique et pour un cancer
- **HOSPITALISATION POUR UNE CONDITION MÉDICALE**
  - ➔ Cancer, TEV ancienne, mobilité réduite et thrombophilie
  - ➔ Trauma ou chirurgie récente (< 1 mois)
  - ➔ Âge avancé, IResp, ICard, IM, AVC, sepsis, obésité.
- **CANCER**
- **HORMONOTHÉRAPIE** (CO ou HTR)
- **IMMOBILISATION PROLONGÉE**
  - ➔ Voyages de plus de 4 (ou 6 sinon 8-10) heures

Stratification du risque de TEV à l'hôpital

Score prédictif de PADUA pour patients "médicaux"

Facteur de risque	Points
Cancer actif (meta. locales ou à distance et/ou chimio-radio < 6 mois)	3
TEV auparavant (excluant TVS)	3
Mobilité réduite (lit + toilette ≥ 3 jours)	3
Thrombophilie	3
Trauma et/ou chirurgie récents (≤ 1 mois)	2
Âge avancé (≥ 70 ans)	1
Insuffisance cardiaque ou respiratoire	1
IM aigu ou AVC ischémique	1
Infection aigue et/ou condition rhumatologique	1
Obésité (IMC ≥ 30)	1
Hormonothérapie	1

Barbar S et al. J Thromb Haemost 2010; 8(11): 2450-57

Stratification du risque de TEV à l'hôpital

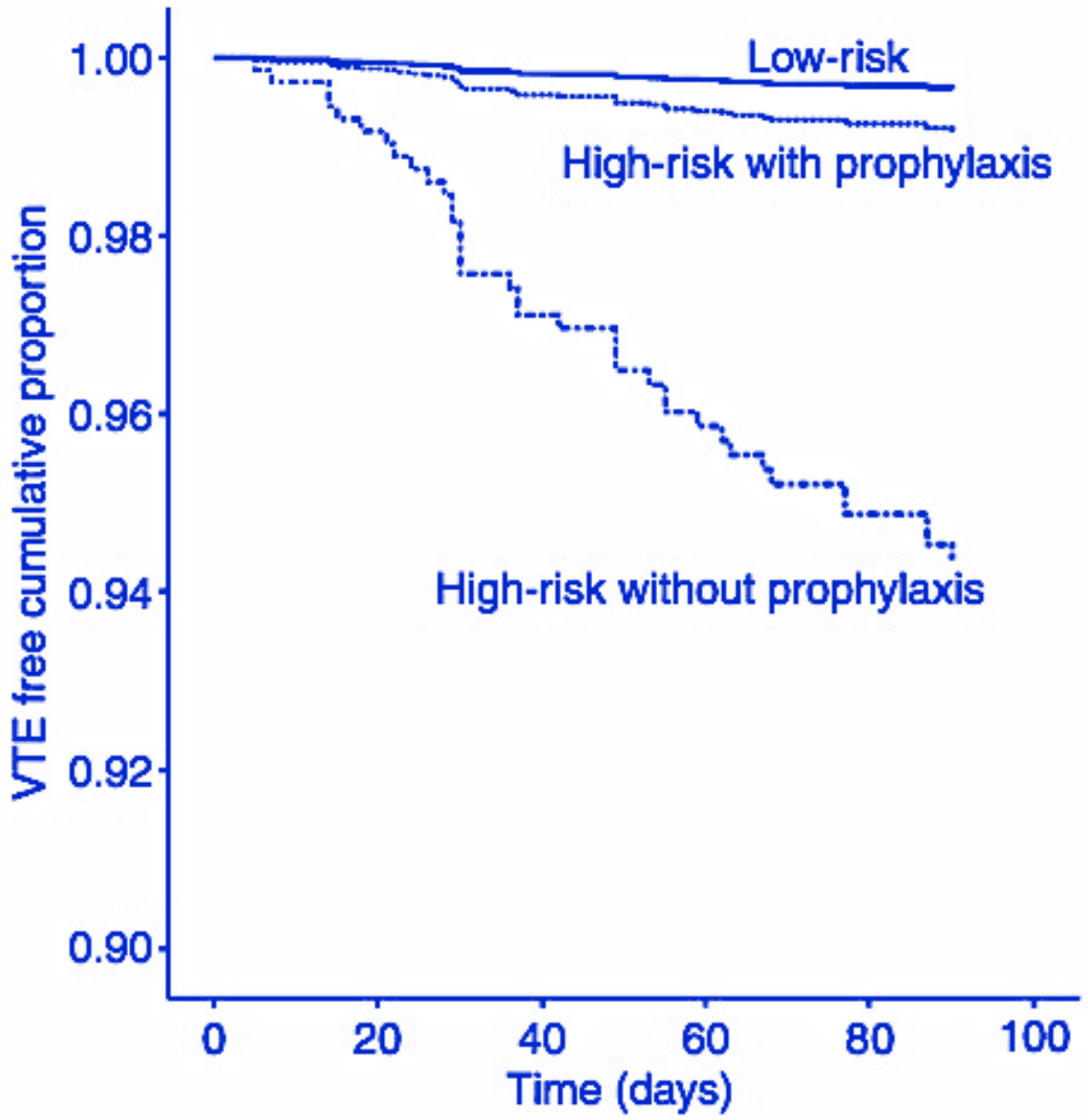
Incidence d'événements selon le score de PADUA

SCORE	Prévalence 1,180 pts	TEV	TVP	EP	EP fatale
Risque élevé ≥ 4 points	39.7%	11.0%	6.7%	3.9%	0.4%
Risque faible ≤ 3 points	60.3%	0.3%	0	2 cas	0

Barbar S et al. J Thromb Haemost 2010; 8(11): 2450-57

Incidence d'événements selon le score de PADUA

Effet de la thromboprophylaxie



Barbar S et al.
J Thromb Haemost 2010;
8(11): 2450-57

Risque de saignement pour 10,866 patients "médicaux"

Étude IMPROVE et OR des facteurs de risque

Facteur de risque	% des patients	OR
Ulcère gastro-duodénal actif	2.2	4.15
Saignement ≤ 3 mois	2.2	3.64
Plaquettes < 50	1.7	3.37
Âge ≥ 85 ans (vs < 40 ans)	10.8	2.96
Insuffisance hépatique (INR > 1.5)	2	2.18
IRC (Clear. Créat. < 30 ml/min)	11	2.14
USI ou Unité coro. À l'admission	8.5	2.10
Catheter central	7.5	1.85
Maladie rhumatologique	6.8	1.78
Cancer actif	10.7	1.78
Sexe masculin	49.4	1.48

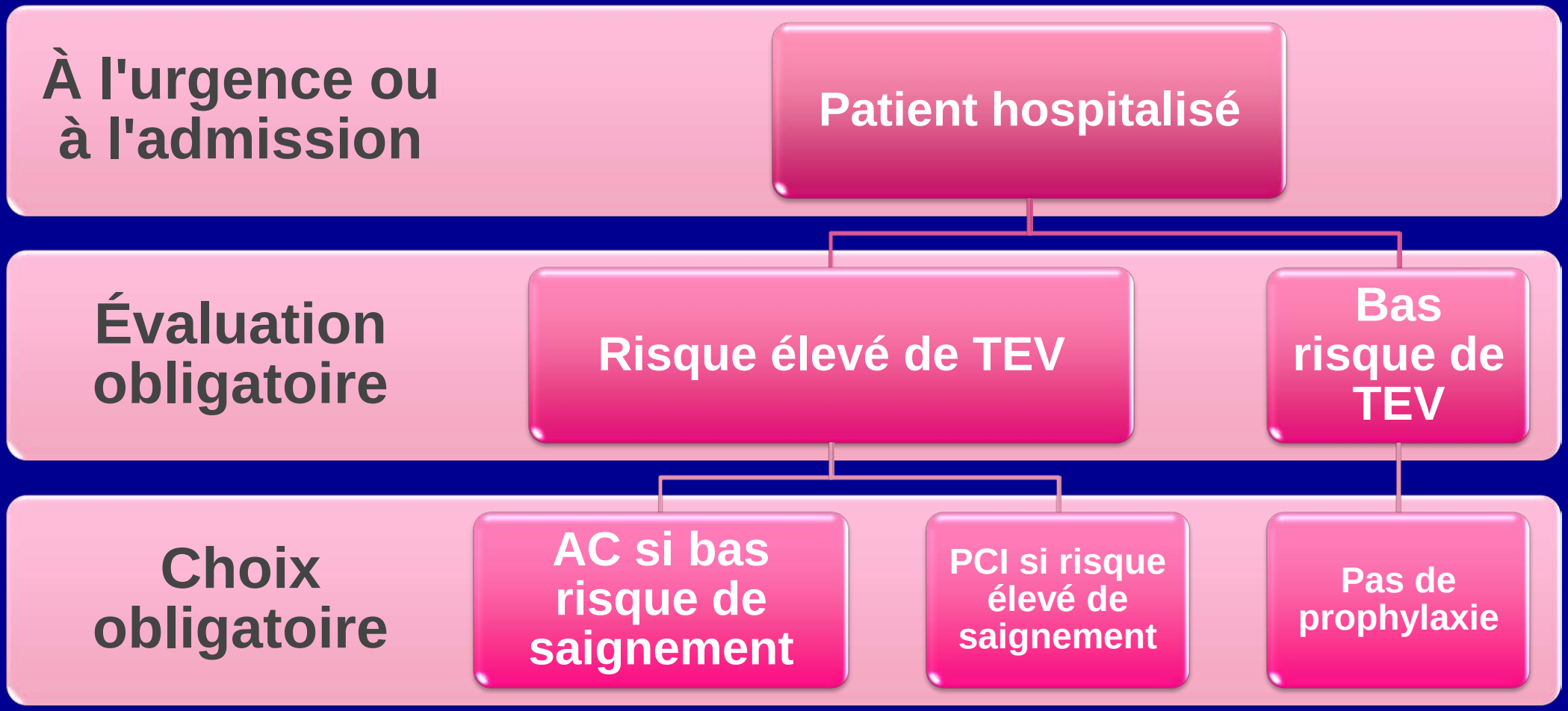
Risque *élevé* si un des trois facteurs avec OR > 3 est présent ou si combinaison des autres facteurs (selon AT9)

Decousus H et al. CHEST 2011; 139(1): 69-79

Risque de TEV et prophylaxie: ACCP 2012
Patients hospitalisés pour une condition médicale

Situation	Recommandation	Grade
Risque élevé de TEV	•HBPM ou •HNF SC BID ou TID ou •Fondaparinux (sans extension)	1B 2B
Risque élevé de TEV et de saignement	PCI ou BEG	2C
Risque faible de TEV	Aucune prophylaxie	1B

Politique hospitalière de thromboprophylaxie
Principes de base



TVP et AVC: prévalence
CLOTS 1 et 2

- 5632 patients AVC immobiles, 135 hôpitaux, 9 pays
- 11.4% TVP à 8 jours + 3.1% additionnelles à 28 jours
- 35% symptomatiques et 5% embolies pulmonaires
  - ➔Majorité traitées
- 83% unilatérales
- 39% mollet, 21% poplitée, 40% fémorale
- Si jambe faible: 73% côté faible, 11% fort, 16% bilatéral

Dennis M et al. JTH 2011, 9: 2113-2200

Prévention TEV et AVC avec HBPM vs HNF
Étude PREVAIL

The efficacy and safety of enoxaparin versus unfractionated heparin for the prevention of venous thromboembolism after acute ischaemic stroke (PREVAIL Study): an open-label randomised comparison

*David G Sherman, Gregory W Albers, Christopher Bladin, Cesare Fieschi, Alberto A Gabbai, Carlos S Kase, William O'Riordan, Graham F Pineo, on behalf of the PREVAIL Investigators**

Interpretation Our results suggest that for patients with acute ischaemic stroke, enoxaparin is preferable to unfractionated heparin for venous thromboembolism prophylaxis in view of its better clinical benefits to risk ratio and convenience of once daily administration.

Sherman DG et al. Lancet 2007; 369: 1347-55

TVP et AVC: Bas élastiques gradués

CLOTS 1

Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke (CLOTS trial 1): a multicentre, randomised controlled trial

*The CLOTS Trials Collaboration**

Findings All patients were included in the analyses. The primary outcome occurred in 126 (10·0%) patients allocated to thigh-length GCS and in 133 (10·5%) allocated to avoid GCS, resulting in a non-significant absolute reduction in risk of 0·5% (95% CI –1·9% to 2·9%). Skin breaks, ulcers, blisters, and skin necrosis were significantly more common in patients allocated to GCS than in those allocated to avoid their use (64 [5%] *vs* 16 [1%]; odds ratio 4·18, 95% CI 2·40–7·27).

Lancet 2009

TVP et AVC: Bas élastiques gradués
CLOTS 2

Annals of Internal Medicine | ORIGINAL RESEARCH

Thigh-Length Versus Below-Knee Stockings for Deep Venous Thrombosis Prophylaxis After Stroke

A Randomized Trial

The CLOTS (Clots in Legs Or sTockings after Stroke) Trial Collaboration*

Limitation: Blinding was incomplete, 2 scans were not obtained for all enrolled patients, and the trial was stopped before the target accrual was reached.

CLOTS 1…

Conclusion: Proximal DVT occurs more often in patients with stroke who wear below-knee stockings than in those who wear thigh-length stockings.

Ann Intern Med 2010; 153: 553-562

TVP et AVC: Pneumo compression intermittente
CLOTS 3

Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial

*CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration**

NHS – National Institute for Health Research: Health Technology Assessment

NHS Scotland – Chief Scientist Office

Covidien – Covidien donated Kendall SCD™ sleeves and controllers during the course of the study; no additional funding provided

Lancet on line 31 mai 2013

TVP et AVC: CLOTS 3
Devis de l'étude: PROBE

PROBE: Prospective, randomisée, ouverte, issues évaluées à l'aveugle. Étude multicentrique.

Patients enrôlés jours 0 à 3 puis randomisés pour PCI ou sans PCI

Echo-Duplex 2 jambes à l'aveugle jours 7-10 puis, si possible, jours 25-30

Patients suivis pour 6 mois pour déterminer la survie et la TEV symptomatique

TVP et AVC: CLOTS 3
Devis de l'étude: inclusion et exclusions

Critère d'inclusion:

- Patients immobiles* admis à l'hopital pour AVC < 3 jours

Critères d'exclusion:

- Âge < 16 ans
- Hémorragie sous-arachnoidienne
- Contre-indications à PCI
- Dermatite
- Ulcères jambiers
- Oedème sévère
- MAP sévère
- Insuffisance cardiaque congestive

* Un patient est considéré immobile s'il a besoin d'aide pour aller à la toilette

TVP et AVC: CLOTS 3

Pneumo-compression intermittente (PCI)

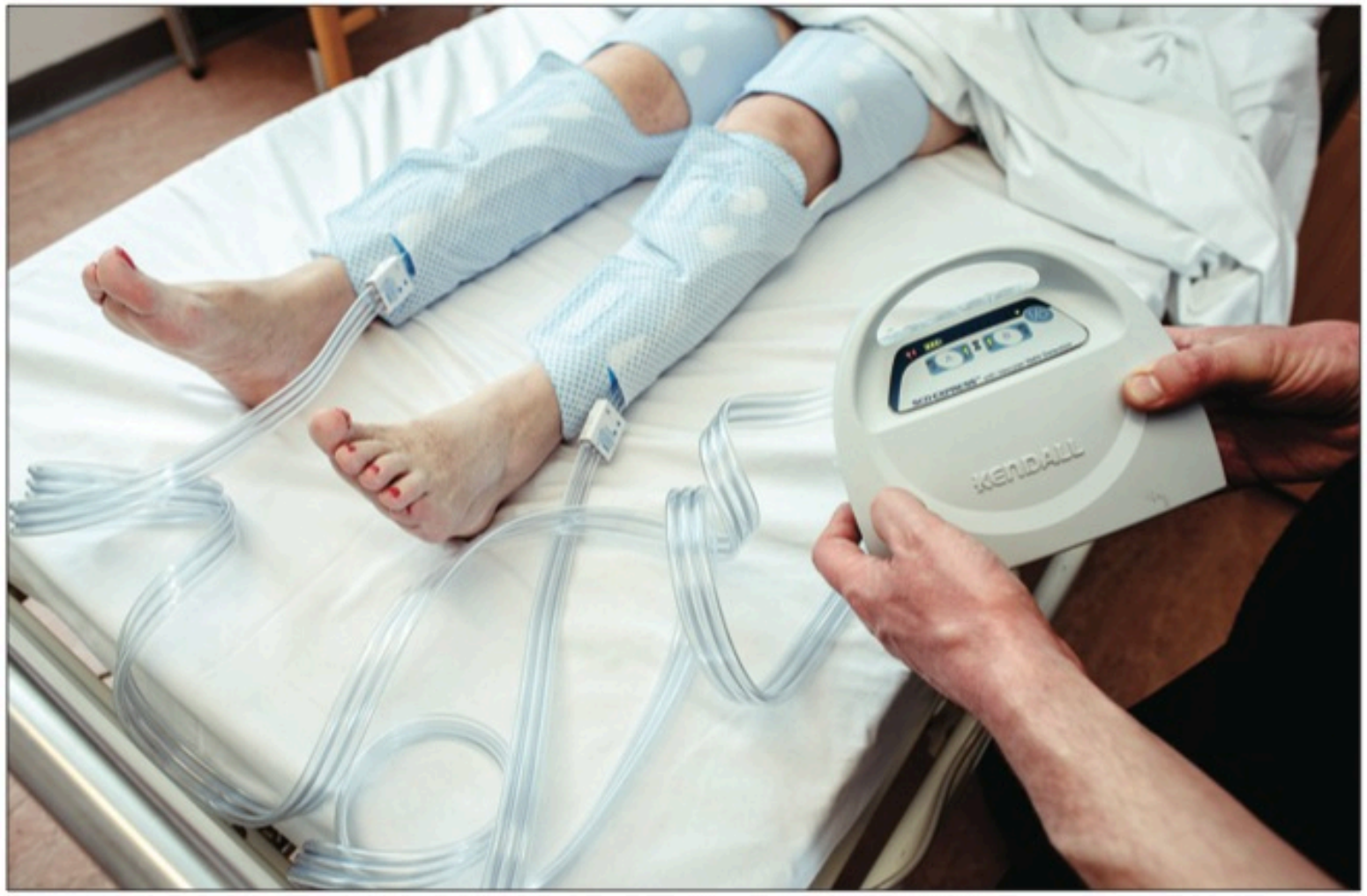


Figure 1: The Kendall SCD™ express sequential compression system (Covidien, MA, USA) with Comfort sleeves applied to a patient's legs

TVP et AVC: CLOTS 3
Issues primaire et secondaire

ISSUE PRIMAIRE:

✓TVP proximale (symptomatique ou non) confirmée par Duplex dans les 30 jours de la randomisation

ISSUES SECONDAIRES:

➢*Dans les 30 jours:*

- ✓ Décès
- ✓ Toute TVP (mollet, poplitée ou fémorale)
- ✓ TVP symptomatique
- ✓ EP confirmée à l'imagerie ou autopsie
- ✓ Complications de la PCI (ie: bris cutanés, chutes avec blessures, fractures)
- ✓ Compliance du patient pour la PCI

➢*À 6 mois:*

- ✓ Mortalité totale; toute TVP ou EP confirmée

TVP et AVC: CLOTS 3

Caractéristiques des 2876 patients

	PCI (n=1438)	Pas de PCI (n=1438)
Age (years)		
Median (range)*	76 (67-83)	77 (68-84)
Mean age (SD)	74·2 (12·3)	74·9 (11·9)
Sex		
Male	695 (48%)	688 (48%)
Final diagnosis at hospital discharge		
Stroke or TIA (definite or probably ischaemic)	1211 (84%)	1217 (85%)
Confirmed haemorrhagic stroke	187 (13%)	189 (13%)
Unknown type	19 (1%)	14 (1%)
Non strokes (included in primary analysis)	19 (1%)	18 (1%)
Missing (no discharge form)	2 (<1%)	0
Past history and risk factors		
Previous deep vein thrombosis or pulmonary embolism	66 (5%)	74 (5%)
Diabetes mellitus	256 (18%)	247 (17%)
Peripheral vascular disease	24 (2%)	31 (2%)
Overweight	417 (29%)	457 (32%)
Current cigarette smoker	250 (17%)	228 (16%)
Independent in daily activities before stroke*	1301 (90%)	1295 (90%)
Lives alone before stroke*	500 (35%)	503 (35%)

*Factors included in model to predict probability of being alive and independent at 6 months.[16] †Variables included in minimisation.

TVP et AVC: CLOTS 3

Caractéristiques des 2876 patients

Indicators of stroke severity		
Able to lift both arms off bed*	499 (35%)	502 (35%)
Able to talk and oriented in time, place and person*	886 (62%)	845 (59%)
Able to lift both legs off bed†	494 (34%)	493 (35%)
Able to walk without help*	0	0
Stroke severity—probability of being alive and independent in daily activities=0-0·15)†	898 (62%)	892 (62%)
Stroke severity—median (IQR) probability of being alive and independent in daily activities	0·09 (0·02-0·31)	0·09 (0·01-0·31)
On warfarin at recruitment	25 (2%)	29 (2%)
On heparin at recruitment	86 (6%)	78 (5%)
Taken aspirin, dipyridamole, or clopidogrel in the past 24 h at recruitment	970 (67%)	971 (68%)
Received thrombolysis since admission	249 (17%)	255 (18%)
On heparin or warfarin at recruitment or received thrombolysis since admission†	347 (24%)	352 (24%)
Delay		
Delay since stroke onset to randomisation= 0-1 days†	624 (43%)	620 (43%)
Delay since stroke onset to randomisation= 2 days†	478 (33%)	457 (32%)
Delay since stroke onset to ranomisation≥3 days†	336 (23%)	361 (25%)
Compression duplex ultrasound at 25-30 days deemed unlikely to be practical at time of randomisation	225 (16%)	215 (15%)

Data are number of patients (%) unless otherwise stated. IPC=intermittent pneumatic compression. TIA=transient ischaemic attack. *Factors included in model to predict probability of being alive and independent at 6 months.[16] †Variables included in minimisation

TVP et AVC: CLOTS 3

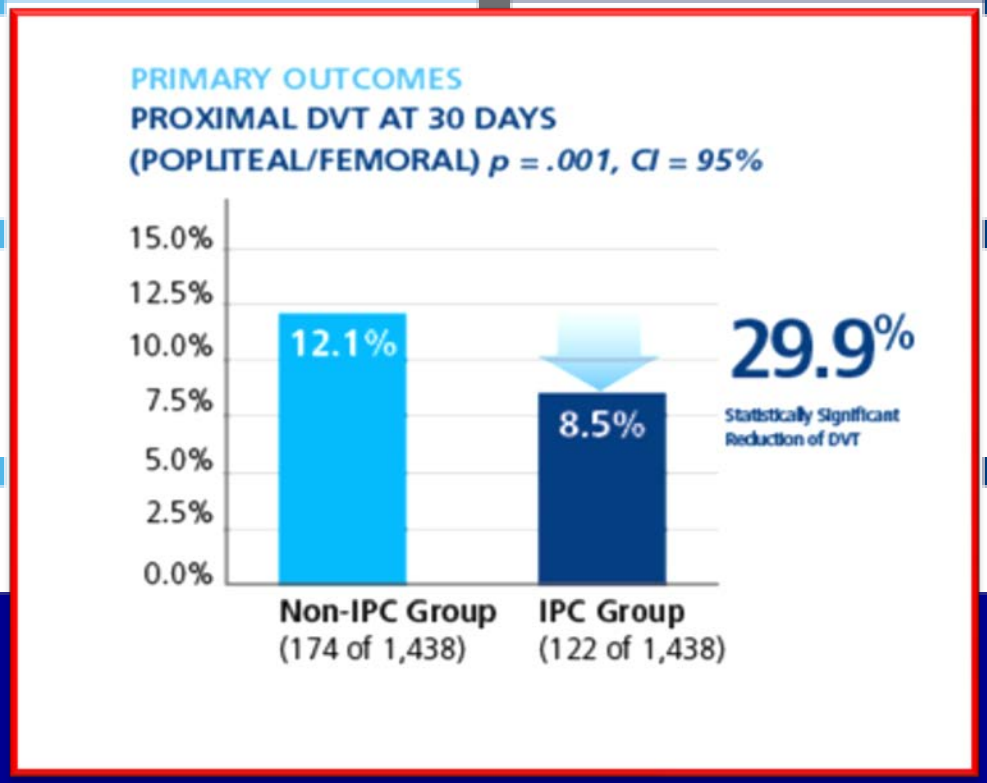
Issue primaire: TVP proximale à 30 jours

2,876
Acute Stroke Patients, Hospitalized & Immobile

1,438
No IPC + Routine Care

1,434 (99.72%)
Adhered to Treatment Allocation

(174) **12.1%**
Proximal DVT



1,438
IPC + Routine Care

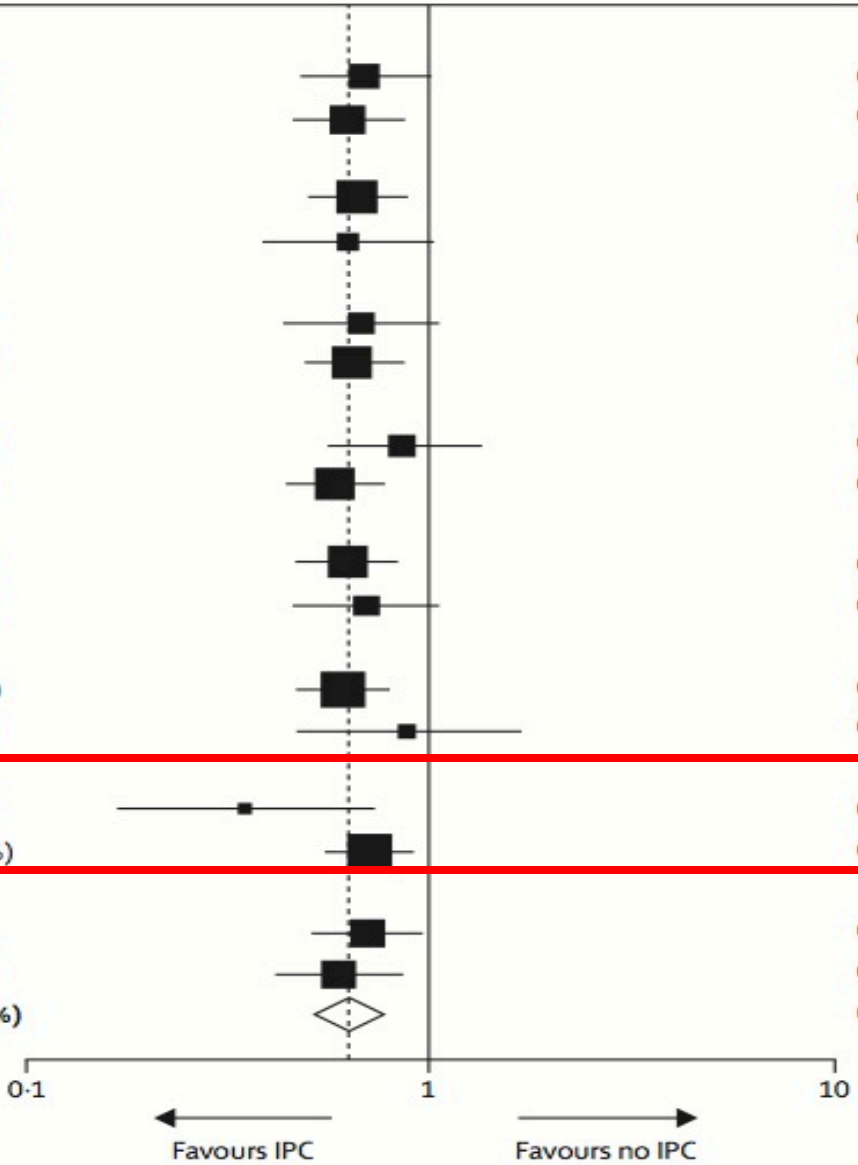
1424 (99.02%)
Adhered to Treatment Allocation

8.5% (122)
Proximal DVT

TVP et AVC: CLOTS 3

Issue primaire: selon les sous-groupes

	IPC n/N (%)	No IPC n/N (%)	OR (95% CI)	p value
Delay: onset to randomisation				
0–1 day	52/550 (9·5%)	70/536 (13·1%)	0·71 (0·48–1·04)	0·572
≥2 days	70/717 (9·8%)	104/709 (14·7%)	0·61 (0·44–0·85)	
Delay: onset to randomisation				
0–2 days	94/967 (9·7%)	129/926 (13·9%)	0·67 (0·51–0·89)	0·758
≥3 days	28/300 (9·3%)	45/319 (14·1%)	0·61 (0·37–1·01)	
Heparin, warfarin, or alteplase used				
Yes	38/306 (12·4%)	54/313 (17·3%)	0·68 (0·43–1·06)	0·897
No	84/958 (8·8%)	120/932 (12·9%)	0·65 (0·48–0·87)	
Can lift both legs off bed				
Yes	84/807 (10·4%)	131/792 (16·5%)	0·84 (0·53–1·34)	0·164
No	38/460 (8·3%)	43/453 (9·5%)	0·58 (0·43–0·78)	
Probability of favourable outcome				
0–0·15	82/765 (10·7%)	117/730 (16·0%)	0·64 (0·47–0·86)	0·793
0·16–1·0	40/502 (8·0%)	57/515 (11·1%)	0·69 (0·45–1·05)	
High risk of DVT				
Yes	104/981 (10·6%)	153/946 (16·2%)	0·61 (0·47–0·80)	0·294
No	18/286 (6·3%)	21/299 (7·0%)	0·87 (0·45–1·67)	
Stroke due to haemorrhage				
Yes	11/163 (6·7%)	27/159 (17·0%)	0·36 (0·17–0·75)	0·057
No	111/1104 (10·1%)	147/1086 (13·5%)	0·72 (0·55–0·93)	
Type of sleeves				
Original	70/735 (9·5%)	95/727 (13·1%)	0·70 (0·51–0·98)	0·510
Comfort	52/532 (9·8%)	79/518 (15·3%)	0·60 (0·41–0·87)	
All	**122/1267 (9·6%)**	**174/1245 (14·0%)**	**0·65 (0·51–0·84)**	**0·001**



TVP et AVC: CLOTS 3

Issues secondaires à 30 jours

	IPC (n=1438)	No IPC (n=1438)	Absolute risk difference (95% CI)	Risk ratio (95% CI)*	Odds ratio (95% CI)	p value
Secondary outcomes by 30 days or later second compression duplex ultrasound						
Dead by 30 days	156 (10·8%)	189 (13·1%)	−2·3 (−4·7 to 0·1)	0·82 (0·66 to 1·01)	0·80 (0·63 to 1·01)	0·057
Symptomatic proximal DVT	39 (2·7%)	49 (3·4%)	−0·7 (−2·0 to 0·6)	0·79 (0·52 to 1·20)	0·79 (0·51 to 1·21)	0·269
Asymptomatic proximal DVT	83 (5·8%)	125 (8·7%)	−2·9 (−4·8 to −1·0)	0·66 (0·50 to 0·87)	0·65 (0·48 to 0·86)	0·003
Symptomatic DVT (proximal or calf)						0·045
Any DVT (symptomatic or asymptomatic, proximal or calf)						0·001
All confirmed pulmonary embolism (imaging or autopsy)						0·453
Any DVT or confirmed pulmonary embolism						0·00035
Any DVT or death						<0·0001
Any DVT, pulmonary embolism, or death	391 (27·2%)	491 (34·1%)	−7·0 (−10·3 to −3·6)	0·78 (0·68 to 0·88)	0·72 (0·61 to 0·84)	<0·0001

Mortalité à 30 jours

11% avec PCI, 13% sans PCI

OR 0.80, p= 0.057

TVP et AVC: CLOTS 3

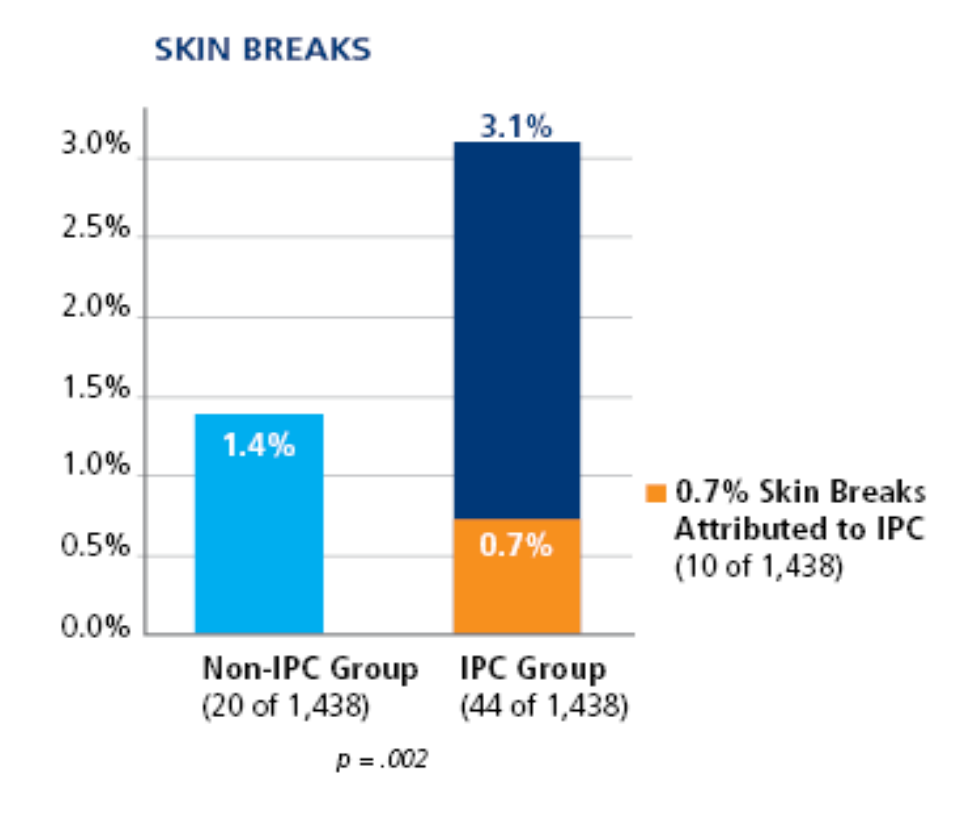
Issues secondaires adverses: PCI à 30 jours

	IPC (n=1438)	No IPC (n=1438)	Absolute risk difference (95% CI)	Risk ratio (95% CI)*	Odds ratio (95% CI)	p value
Potential adverse effects of IPC						
Skin breaks	44 (3·1%)	20 (1·4%)	1·7 (0·6 to 2·7)	2·15 (1·30 to 3·50)	2·23 (1·31 to 3·81)	0·002
Skin breaks attributed to IPC	10 (0·7%)	0 (0·0%)	0·7 (0·3 to 1·1)			
Lower limb ischaemia or amputation	0 (0·0)	2 (0·1%)	-0·1 (-0·3 to 0·1)			
Falls with injury in 30 days	33 (2·3%)	24 (1·7%)	0·6 (-0·4 to 1·6)	1·38 (0·82 to 2·29)	1·39 (0·82 to 2·37)	0·221
Falls with injury in 30 days attributed to IPC	1 (0·1%)	0 (0·0)	0·1 (-0·1 to 0·2)			
Fractures within 30 days	4 (0·3%)	4 (0·3%)	0·0 (-0·4 to 0·4)			

TVP et AVC: CLOTS 3

Issues secondaires adverses à 30 jours: PCI

Patients allocated to IPC had significantly more skin breaks than did patients allocated to no IPC (3.1% vs. 1.4%)
IPC-attributed skin breaks were .7%

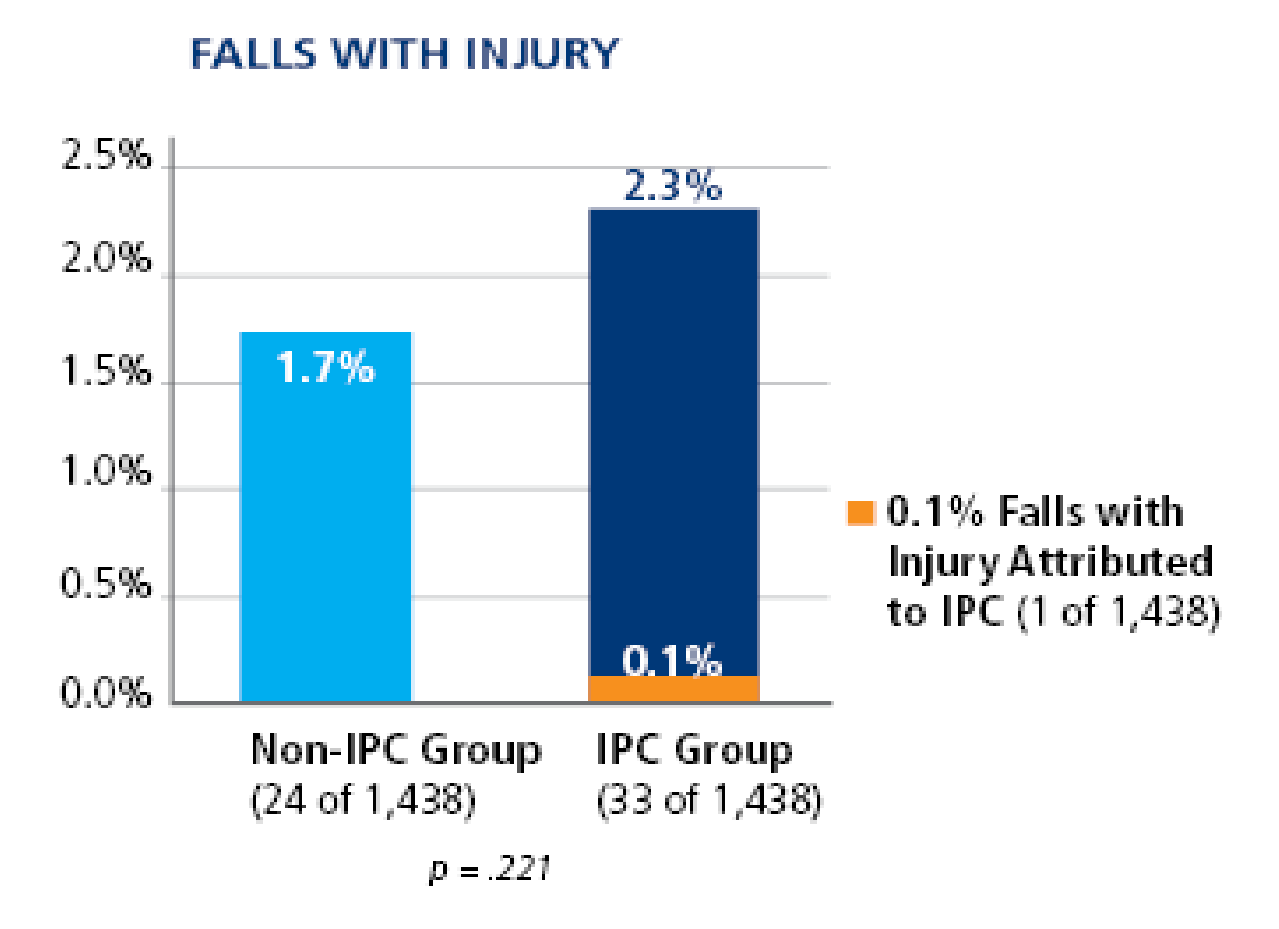


Few of the skin breaks or falls with injury were attributed to IPC. Most adverse events either occurred when IPC had been removed, or skin breaks affected the heels (which are not covered by the IPC sleeves)

TVP et AVC: CLOTS 3

Issues secondaires adverses à 30 jours: PCI

No statistically significant difference in risk of falls with injury or fractures within 30 days between the IPC and no IPC groups



TVP et AVC: CLOTS 3

Issues secondaires à 30 jours: héparine

	IPC group	No IPC group
30-day clinical outcomes and background treatment		
Discharge form received (after hospital discharge or death)	1436 (99·9%)	1438 (100%)
Vital status at 30 days known	1432	1431
Post-randomisation prophylactic dose heparin/LMWH prescribed	248 (17%)	240 (17%)
Post-randomisation treatment dose heparin/LMWH prescribed	182 (13%)	219 (15%)
Graduated compression stockings worn	118 (8%)	42 (3%)
Thigh-length stockings only	90 (6%)	22 (2%)
Below-knee graduated compression stockings worn only	17 (1%)	19 (1%)
Both long and short worn	10 (<1%)	1 (<1%)
Unknown length	1 (<1%)	0

TVP et AVC: CLOTS 3

Issues secondaires à 6 mois

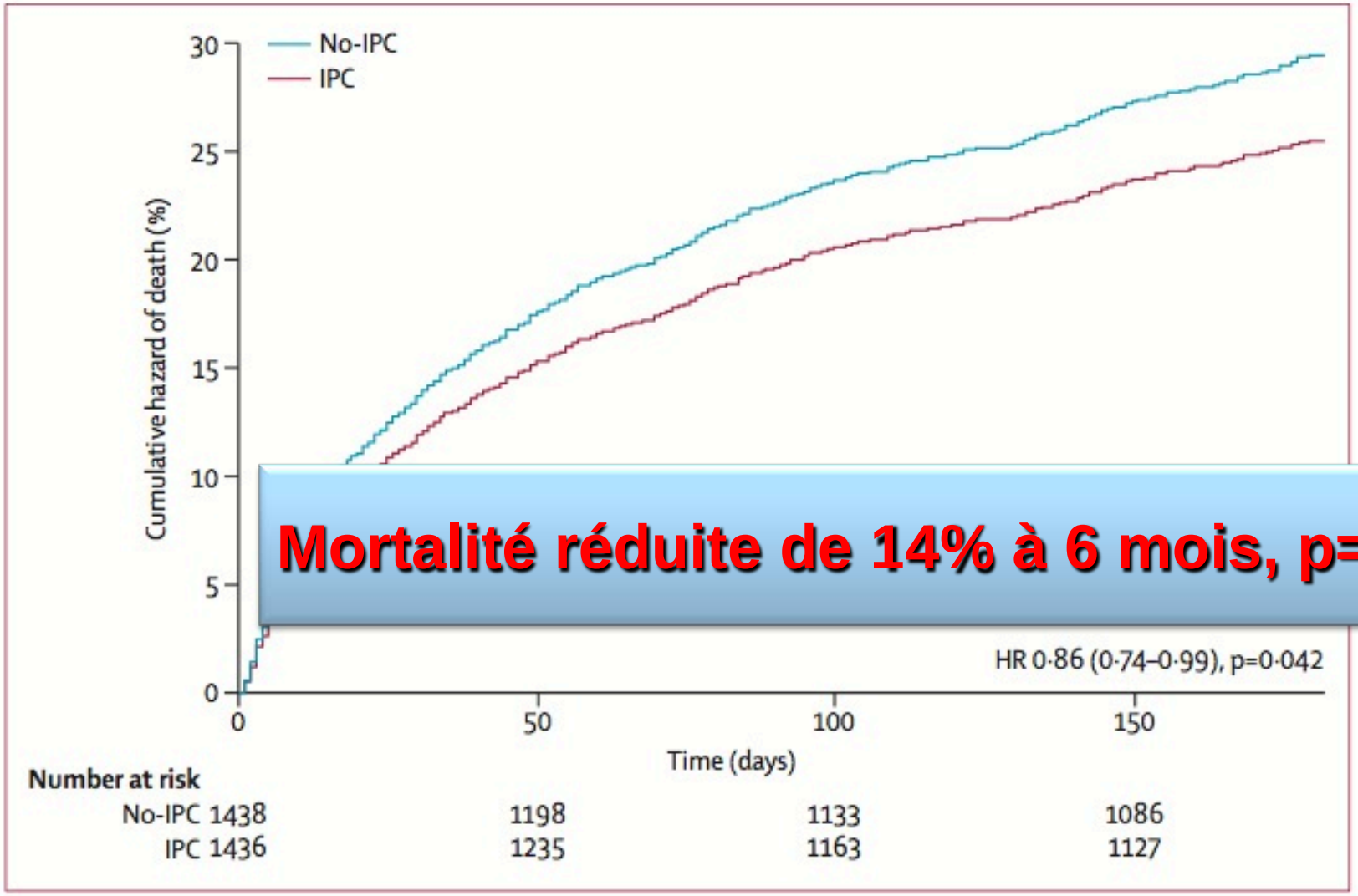
	IPC (n=1438)	No IPC (n=1438)	Absolute risk difference (95% CI)	Risk ratio (95% CI)*	Odds ratio (95% CI)	p value
Dead by 6 months	320 (22·3%)	361 (25·1%)	-2·9 (-6·0 to 0·3)	0·87 (0·75 to 1·00)	0·85 (0·70 to 1·01)	0·059
Any DVT	240 (16·7%)	312 (21·7%)	-5·0 (-7·9 to -2·1)	0·76 (0·64 to 0·89)	0·72 (0·60 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	512 (35·6%)	608 (42·3%)	-6·7 (-10·2 to -3·1)	0·82 (0·73 to 0·91)	0·74 (0·64 to 0·87)	0·002

Odds ratios and risk ratios are adjusted for factors included in our minimisation algorithm, as specified in the statistical analysis plan. IPC=intermittent pneumatic compression. DVT=deep vein thrombosis. PE=pulmonary embolism. *Risk ratios were not prespecified in our statistical analysis plan but are presented to enhance interpretation of results.

Table 4: All deaths and venous thromboembolic events (including those in first 30 days) during the 6-month follow-up

TVP et AVC: CLOTS 3

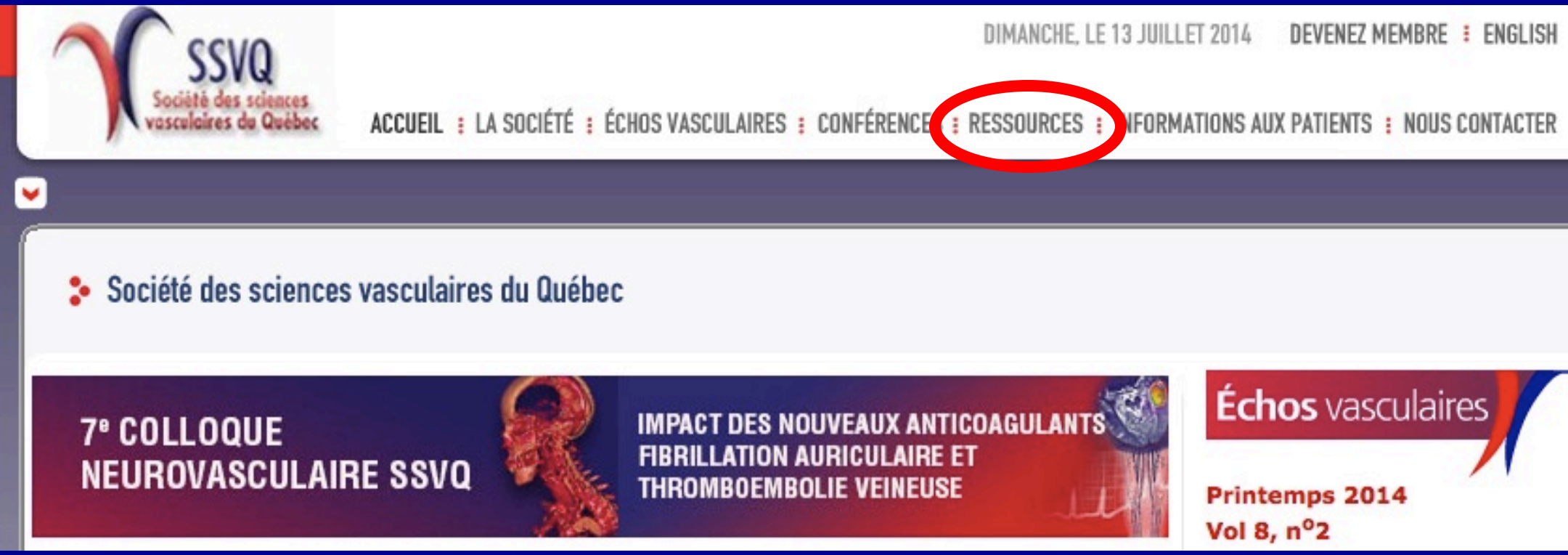
Mortalité à 6 mois, après ajustement



Mortalité réduite de 14% à 6 mois, p=0.042

Figure 3: Cumulative hazard of death during the 6 months after randomisation in the two treatment groups

Référence québécoise



Référence québécoise

SSVQ
Société des sciences vasculaires du Québec

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G.T. TEV

Protocoles

1. Protocole de prophylaxie de la thromboembolie veineuse pour population médicale:
Version Daltéparine
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2.Protocole de prophylaxie de la thromboembolie veineuse pour population médicale:
Version Enoxaparine
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www.thrombosiscanada.ca

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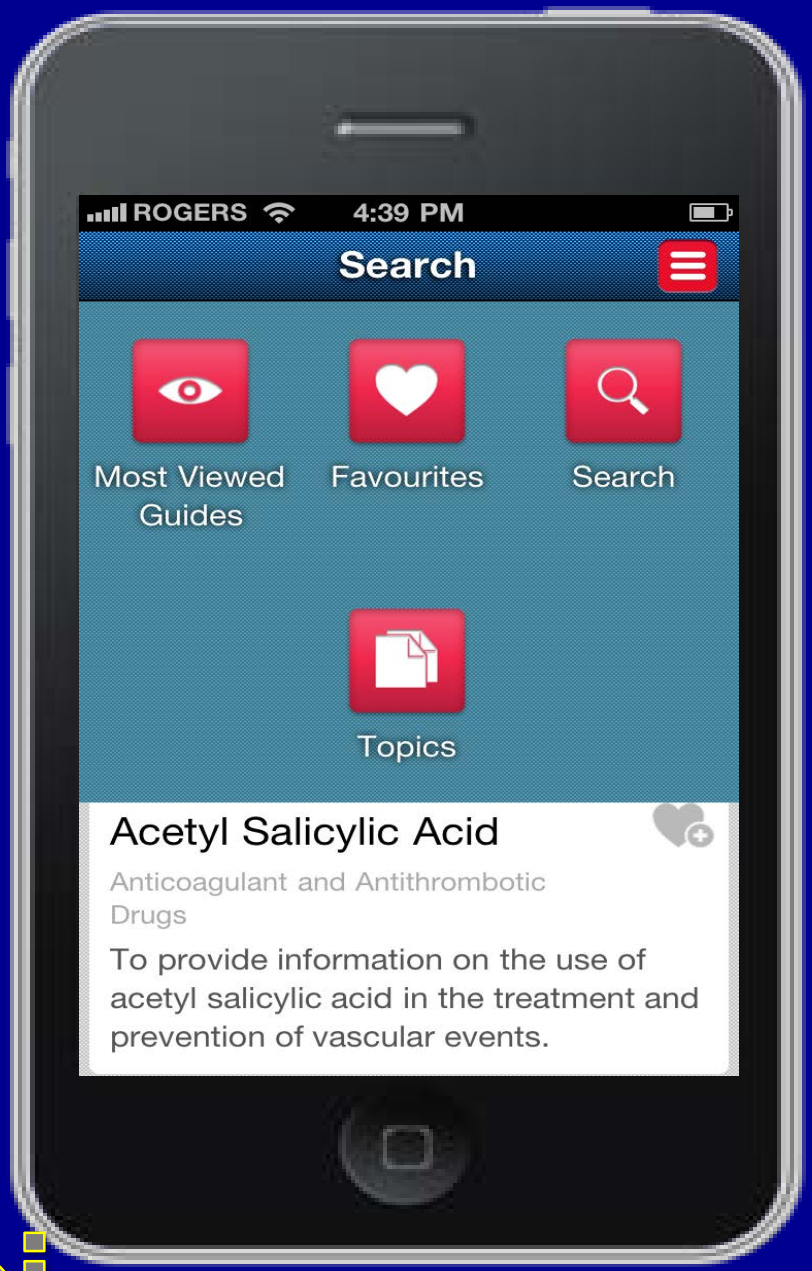
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Topics
Acetyl Salicylic Acid
Anticoagulant and Antithrombotic Drugs
To provide information on the use of acetyl salicylic acid in the treatment and prevention of vascular events.

Merci