







How to create and international thromboprophylaxis guideline?

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KariTikkinen

#clueworkinggroup

#eauguidelines

Lecțio Magistralis at the Dipartimento di Scienze Clinico Chirurgiche, Diagnostiche e Pediațiche, Universită di Pavia, invited by Professors Richard Naspro, Luca Ansaloni and Gian Luigi Marseglia



Conflict of Interest Disclosure

I have no financial conflicts of interest

Guideline work (related to this lecture)

EAU *ad hoc* Guideline 2017 on Thromboprophylaxis in Urological Surgery (chair)

American Society of Hematology 2019 Guideline on Prevention of Venous Thromboembolism in Surgical Hospitalized Patients (panel member)

European Society of Anaesthesiology and Intensive Care Task

Introduction

Serious complications of surgery include deep vein thrombosis (DVT) and pulmonary embolism (PE) - together referred to as venous thromboembolism (VTE) - and major bleeding

Substantial practice variation in the use of thromboprophylaxis, both within and between countries

Uro: Violețțe eț al. *Eur Urol Focus* 2020

Gyne: Hopkins et al. J Obstet Gynaecol

Can 2012

Gyne: Petch et al. Thromb Res 2016

General/Gyne: Pourjamal et al. BJS Open 2022

No procedure-specific guidance

No consensus on the use of thromboprophylaxis

No procedure-specific guidance for general abdominal or gynecologic surgery

Risks known to vary between procedures, but magnitude uncertain

The only procedure-specific guideline in any surgery is in urology, EAU Lavikainen et al. Syst Rev 20

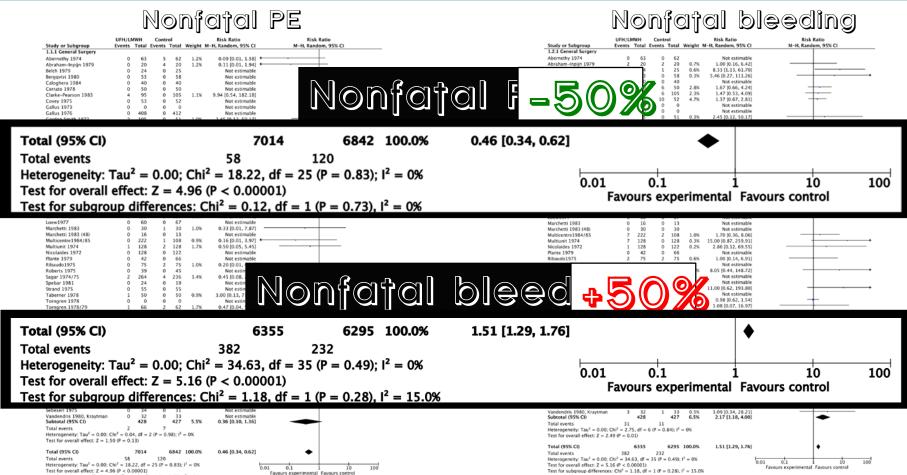
e 1 Major guidelines on the use of thromboprophylaxis for abdominal and/or pelvic surgery

Guideline association or guideline group	Year	Type of surgery	Stratification by procedure (Yes/No)	Number (percentage of procedure specifi recommendations for abdominal and/or pelvic surgery ^a
Enhanced Recovery After Surgery Society (ERAS)	2020	Vulvar and vaginal	No	0
American Society of Clinical Oncology (ASCO)	2019	Major cancer	No	0
American Society of Hematology (ASH)	2019	All	Partly ^b	3 (60%)
International Initiative on Thrombosis and Cancer (ITAC-CME)	2019	Cancer	No	0
Enhanced Recovery After Surgery (ERAS) Society	2018	Elective colorectal	No	0
National Institute for Health and Care Excellence (NICE) (of the United Kingdom)	2018	All	No ^c	0
Southern African Society of Thrombosis and Hemostasis	2018	Obstetrics and gynecology	No	0
The American Society of Colon and Rectal Surgeons	2018	Colorectal	No	0
Asian Venous Thrombosis Forum (AVTF) working group	2017	All	No	0
European Association of Urology (EAU)	2017	Urology	Yes	23 (100%)
European Society of Anesthesiology (ESA)	2017	All	No ^d	0
Enhanced Recovery After Surgery Society (ERAS)	2016	Gynecologic oncology	No	0
Enhanced Recovery After Surgery Society (ERAS)	2016	Liver surgery	No	0
Thrombosis Canada	2016	Non-orthopedic	No	0
The Scottish Intercollegiate Guidelines Network (SIGN)	2014	General abdominal Gynecologic Bariatric	Noe	0
Enhanced Recovery After Surgery Society (ERAS)	2013	Pancreaticoduodenectomy	Yes ^f	1 (100%)
Enhanced Recovery After Surgery Society (ERAS)	2013	Radical cystectomy	Yes ^f	1 (100%)
Enhanced Recovery After Surgery Society (ERAS)	2013	Elective rectal/pelvic	No	0
American College of Chest Physicians (ACCP)	2012	Non-orthopedic	No	0
National Health and Medical Research Council (NHMRC) (of Australia)	2012	All	No ^g	0
American Urological Association (AUA)	2009 (reviewed 2011)	Urologic	No	0
Phelican College of Obstetricians and Gynecologists (ACOG)	2007	Gynecologic	No	0

What should be considered when recommending (or not recommending) thromboprophylaxis?

- 1. Effect of treatment (prophylaxis)
 - Systematic review and meta-analysis of randomized trials
- 2. Baseline risk ('natural history') of outcomes
 - 'Best contemporary, observational evidence' including lowest risk of bias (or median value) identified through systematic review
- 3. Patient-related risk (and protective) factors

Effect of TP: Heparin vs. no prophylaxis



Test for subgroup differences: $Chi^2 = 0.12$, df = 1 (P = 0.73), $I^2 = 0\%$

Effect of TP: Antiplatelets (aspirin) vs. placebo



Study	Trea Yes	atment No	Co Yes	ontrol No	
PEP-trial, hip fracture-group	87	6,592	122	6,555	•
PEP-trial, arthroplasty-group	22	2,025	28	2,013	
POISE-2-trial	45	4,953	53	4,959	
STRATAGEM-trial	1	144	1	145	
Overall					



Table 2. Effects of Aspirin on 30-Day Outc	comes.*			
Outcome	Aspirin (N = 4998)	Placebo (N = 5012)	Hazard Ratio (95% CI)†	P Value
Safety outcomes				
Life-threatening bleeding	87 (1.7)	73 (1.5)	1.19 (0.88-1.63)	0.26
Major bleeding	230 (4.6)	188 (3.8)	1.23 (1.01–1.49)	0.04

- 1. Devereaux PJ, Mrkobrada M, Sessler DI, et al. Aspirin in patients undergoing noncardiac surgery. N Engl J Med. 2014;370(16):1494-1503. doi:10.1056/NEJMoa1401105
- 2. Prevention of pulmonary embolism and deep vein thrombosis with low dose aspirin: Pulmonary Embolism Prevention (PEP) trial. Lancet. 2000;355(9212):1295-1302.
- Columbo JA, Lambour AJ, Sundling RA, et al. A Meta-analysis of the Impact of Aspirin, Clopidogrel, and Dual Antiplatelet Therapy on Bleeding Complications in Noncardiac Surgery. Ann Surg. 2018;267(1):1-10. d

Intervention	Symptomatic VTE	Symptomatic PE	Symptomatic proximal DVT	Symptomatic DVT (any extension)	Major bleeding
Low dose low molecular weight heparin	0.33 (0.16 to 0.67)	0.68 (0.37 to 1.25)	0.43 (0.14 to 1.33)	0.47 (0.26 to 0.85)	2.04 (1.28 to 3.22)*
High dose low molecular weight heparin	0.19 (0.07 to 0.54)	0.63 (0.28 to 1.39)	NA	0,36 (0.11 to 1,20)	3.07 (1.39 to 6.77)
Direct oral anticoagulants	0.17 (0.07 to 0.41)	0.71 (0.34 to 1.43)	0.23 (0.06 to 0.86)	0.33 (0.16 to 0.68)	2.01 (1.08 to 3.73)

RESEARCH

Benefits and harms of direct oral anticoagulation and low molecular weight heparin for thromboprophylaxis in patients undergoing non-cardiac surgery: systematic review and network meta-analysis of randomised trials

Maura Marcucci, ^{1,2,3} Itziar Etxeandia-Ikobaltzeta, ¹ Stephen Yang, ⁴ Federico Germini, ^{1,2} Shyla Gupta, ⁵ Arnav Agarwal, ^{2,6} Matthew Ventresca, ¹ Shaowen Tang, ⁷ Gian Paolo Morgano, ¹ Mengxiao Wang, ^{8,9} Muhammad Muneeb Ahmed, ² Ignacio Neumann, ¹⁰ Ariel Izcovich, ¹¹ Juan Criniti, ¹¹ Federico Popoff, ¹¹ P J Devereaux, ^{1,2,3} Philipp Dahm, ^{12,13} David Anderson, ¹⁴ Lauri I Lavikainen, ¹⁵ Kari A O Tikkinen, ^{16,17} Gordon H Guyatt, ^{1,2} Holger J Schünemann, ^{1,18} Philippe D Violette^{1,19}

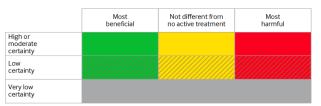


Fig 4 | Network meta-analysis results (network odds ratio (95% confidence interval)) based on GRADE (grading of recommendations, assessment, development, and evaluation) assessment of certainty of evidence, and treatment benefit and harm, with no active treatment as reference. PE=pulmonary embolism; VTE=venous thromboembolism; DVT=deep vein thrombosis; NA=not available. *Based on direct comparison

ARTS Trial —

A Large, Pragmatic, International Trial of Thromboprophylaxis in Intra-abdominal, Gynecologic, and Urologic Surgery



STUDY DESIGN AND ELIGIBILITY

- Pragmatic trial of 5,300 patients
- Randomized, open-label
- Adult patients undergoing abdominal or pelvic surgery at similar risk of VTE and bleeding
- Centers able to choose from which eligible procedures they recruit patients

RANDOMIZATION

- Randomization
 (1:1) to a direct
 oral anticoagulant
 (apixaban) or no
 anticoagulant using
 online randomization
 system
- Performed at earliest 12 hours post-surgery or at latest next morning on postoperative day

FOLLOW-UP

- No extraneous data collection
- 30 days follow-up

Comparator Arm

Standard of care

Experimental Arm Standard of care +

Apixaban 2.5 mg orally twice daily for 4 weeks

PRIMARY OUTCOMES

- Efficacy outcome
 Symptomatic
 VTE, including
 symptomatic DVT
 and symptomatic PE
- Safety outcome
 Major bleeding,
 defined as
 bleeding leading
 to a postoperative
 hemoglobin <70 g/L,
 transfusion of ≥1 unit
 of red blood cells,
 or bleeding that was
 judged to be the
 immediate cause of
 death

If interested in becoming an ARTS

Investigator, please welcome to the ARTS introductory meeting during the Annual Congress of the EAU on Sat 11th March 2023 at 12:30 CET in Meeting Room 6. Amber 3.



Contact: Global Principal Investigator, Professor Kari Tikkinen, email: kari.tikkinen@helsinki.fi available at www.sciencedirect.com
journal homepage: www.europeanurology.com/eufocus





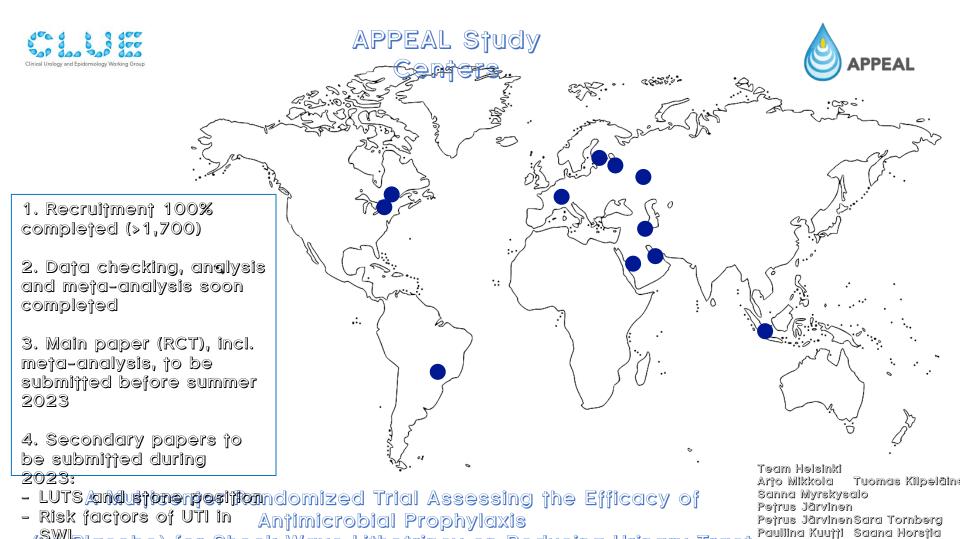
Clinical Studies Update

ARTS: A Large, International Trial of Thromboprophylaxis in Intra-abdominal, Gynecologic, and Urologic Surgery

Philippe D. Violette ^{a,b}, Rufus Cartwright ^{c,d}, P.J. Devereaux ^{a,e,f}, Peter L. Gross ^{e,g}, Kirsi-Maija Kaukonen ^{h,i}, Per Morten Sandset ^j, Tuomas P. Kilpeläinen ^k, Lauri I. Lavikainen ^l, Ville Sallinen ^{m,n}, Saana Horstia ^{l,o}, Gordon H. Guyatt ^{a,e}, Kari A.O. Tikkinen ^{k,p,*}

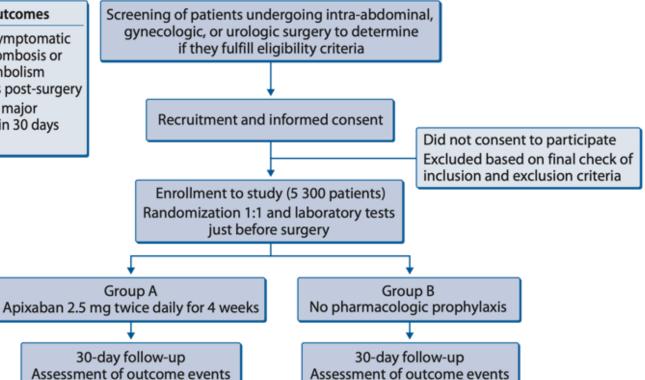
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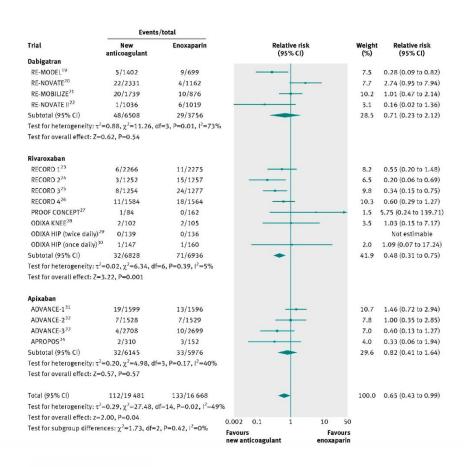
Primary outcomes

- Incidence of symptomatic deep vein thrombosis or pulmonary embolism within 30 days post-surgery
- 2. Incidence of a major bleeding within 30 days post-surgery



Symptomatic venous thrombosis

Clinically relevant bleeding



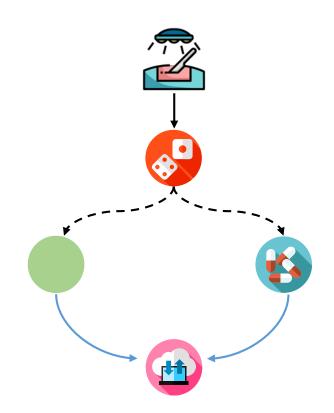
	Events	/total			
Trial	New anticoagulant	Enoxaparin	Relative r (95% CI		ight Relative risk %) (95% CI)
Dabigatran	untreougutaire		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,	(7270 CI)
RE-MODEL ¹⁹	107/1402	46/699	+	9	.0 1.16 (0.83 to 1.62)
RE-NOVATE ²⁰	141/2331	58/1162	-	10	0.0 1.21 (0.90 to 1.63)
RE-MOBILIZE ²¹	55/1739	33/876		6	.9 0.84 (0.55 to 1.28)
RE-NOVATE II ²²	37/1036	29/1019	-	_ 5	.9 1.25 (0.78 to 2.02)
Subtotal (95% CI)	340/6508	166/3756	•	31	1.8 1.12 (0.94 to 1.35)
Test for heterogeneity: τ²=	=0.00, χ^2 =2.30, df=	=3, P=0.51, I ² =0%			
est for overall effect: Z=1	1.26, P=0.21				
Rivaroxaban					
RECORD 1 ²³	105/2266	87/2275	-	10	0.6 1.21 (0.92 to 1.60)
RECORD 2 ²⁴	63/1252	52/1257	-	. 8	.3 1.22 (0.85 to 1.74)
RECORD 3 ²⁵	54/1254	45/1277	-	- 7	.7 1.22 (0.83 to 1.80)
RECORD 4 ²⁶	66/1584	46/1564	-	- 8	.1 1.42 (0.98 to 2.05)
PROOF CONCEPT ²⁷	3/84	3/162			.8 1.93 (0.40 to 9.35)
ODIXA KNEE ²⁸	3/102	5/105		_ 1	.0 0.62 (0.15 to 2.52)
ODIXA HIP (twice daily)25	11/139	2/136	, <u> </u>	o	.9 5.38 (1.22 to 23.83
ODIXA HIP (once daily)30	4/147	8/60		. 1	.3 0.54 (0.17 to 1.77)
Subtotal (95% CI)	309/6828	248/6936	•	38	3.6 1.25 (1.05 to 1.49)
est for heterogeneity: τ ² -	=0.00, γ^2 =7.40, df=	=7, P=0.39, I ² =5%	SSG		7 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)
est for overall effect: Z=2					
Apixaban					
ADVANCE-1 ³¹	46/1599	69/1596		8	.2 0.67 (0.46 to 0.96)
ADVANCE-232	53/1528	72/1529		8	.6 0.74 (0.52 to 1.04)
ADVANCE-3 ³³	131/2708	138/2699	4	12	2.1 0.95 (0.75 to 1.19)
APROPOS ³⁴	4/310	2/152			.7 0.98 (0.18 to 5.29)
Subtotal (95% CI)	234/6145	281/5976	•	25	9.5 0.82 (0.69 to 0.98)
est for heterogeneity: τ ² -	-0.00, χ ² -3.10, df-	=3, P=0.38, I ² =3%			
est for overall effect: Z=2	2.17, P=0.03				
Total (95% CI)	883/19 481	695/16 668		10	0.0 1.06 (0.92 to 1.22)
Test for heterogeneity: τ²=	$=0.03, \chi^2=25.27, d$	f=15, P=0.05, I ² =419	6		
est for overall effect: z=0	0.75, P=0.45		0.05 0.2 1	5 20	
Test for subgroup differen	ices: χ ² =11.78, df=	=2, P=0.003, ² =83%	Favours	Favours	
			new anticoagulant	enoxaparin	

Pragmatic trial

Broad and simple inclusion criteria

Central randomization

No extraneous data collection



Simple pragmatic trial
5,300 patients
Apixaban vs no
VTE/bleeding post
6p far interested
>100 departments
>80 centers
>20 countries

Drug regulator (Fimea) & Ethics (Tukija) under review

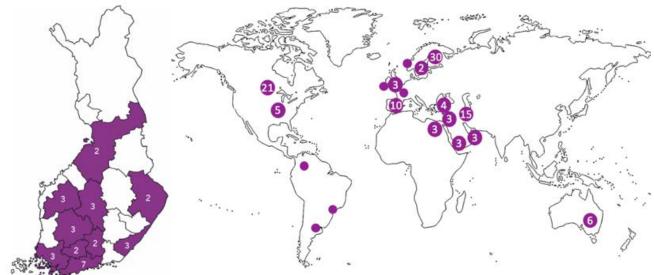
Applying for approvals; start during 2023

FİN: Həlsinki, Tampərə, Turku Lappəənranta, Jyvāskylā, ...

Tenjajive agreemenj of participation
Fin: Turku, Tampere, Lohja, Hyvinkää, Joensuu,
Jyväskylä, Hämeenlinna, Oulu; CAN: Hamiljon,
Toronjo, Sherbrooke, London, Monjreal,
Saskajoon, Vancouver, Thunder Bay, Calgary,
Ojjawa, Quebec Cijy; ESP: Malaga, Coruña,
Sanjander, Madrid; USA: Cleveland, WinsjonSalem, Philadelphia; AUS: Sydney, Melbourne;
NOR: Oslo; SWE: Sjockholm; UK: London; IR:
Dublin; BE: Leuven; FRA: Tours;

ARTS Study Centers
General, gyne and/or urologic surgery
departments







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Team effort





Great chance to contribute and learn from large, pragmatic trials

Potentially practice changing

Thromboprophylaxis policy of your hospitals – several per country!

Made as easy as possible to be implemented in busy clinical practice

Flexible inclusion of general abdominal, gynecologic and urologic surgery patients with similar risk of thrombosis and bleeding

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What should be considered when recommending (or not recommending) thromboprophylaxis?

- 1. Effect of treatment (prophylaxis)
 - Systematic review and meta-analysis of randomized trials
- 2. Baseline risk ('natural history') of outcomes
 - 'Best contemporary, observational evidence' including lowest risk of bias (or median value) identified through systematic review
- 3. Patient-related risk (and protective) factors

Evidence summaries for baseline risks of VTE and bleeding in urology (ROTBUS)



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Platinum Priority - Review - Kidney Cancer

Editorial by Malte Rieken and Alexander Bachmann on pp. 252-253 of this issue

Procedure-specific Risks of Thrombosis and Bleeding in Urological Cancer Surgery: Systematic Review and Meta-analysis

Kari A.O. Tikkinen a.*, Samantha Craigie b.c, Arnav Agarwal b.d, Philippe D. Violette d. Giacomo Novara⁵, Rufus Cartwright h.i., Richard Naspro¹, Reed A.C. Siemieniuk b.k., Bassel Ali b., Leyla Eryuzlu b.d., Johanna Geraci b., Judi Winkup b., Daniel Yoo b.d., Michael K. Gould l. Per Morten Sandset m,n, Gordon H. Guyatt b,o

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Article info

Article history: Accepted March 3, 2017

Associate Editor Christian Gratzke

Baseline risk Bleeding Modeling Reporting Risk of bias

Urology

Thromboprophylaxis Venous thromboembolism

Context: Pharmacological thromboprophylaxis involves balancing a lower risk of venous thromboembolism (VTE) against a higher risk of bleeding, a trade-off that critically depends on the risks of VTE and bleeding in the absence of prophylaxis (baseline risk) Objective: To provide estimates of the baseline risk of symptomatic VTE and bleeding requiring reoperation in urological cancer surgery.

Evidence acquisition: We identified contemporary observational studies reporting symptomatic VTE or bleeding after urological procedures. We used studies with the owest risk of bias and accounted for use of thromboprophylaxis and length of follow-u to derive best estimates of the baseline risks within 4 wk of surgery. We used the GRADE approach to assess the quality of the evidence. Evidence synthesis: We included 71 studies reporting on 14 urological cancer proce

dures. The quality of the evidence was generally moderate for prostatectomy and cystectomy, and low or very low for other procedures. The duration of thrombops laxis was highly variable. The risk of VTE in cystectomies was high (2.6-11.6% across risk groups) whereas the risk of bleeding was low (0.3%). The risk of VTE in prostatectomies varied by procedure, from 0.2-0.9% in robotic prostatectomy without pelvic lymph node dissection (PLND) to 3.9-15.7% in open prostatectomy with extended PLND. The risk of bleeding was 0.1-1.0%. The risk of VTE following renal procedures was 0.7-2.9% for lowrisk patients and 2.6-11.6% for high-risk patients; the risk of bleeding was 0.1-2.0%. Conclusions: Extended thromboprophylaxis is warranted in some procedures (eg. open and robotic cystectomy) but not others (eg, robotic prostatectomy without PLND in

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Platinum Priority - Review - Kidney Cancer

Editorial by Malte Rieken and Alexander Bachmann on pp. 252-253 of this issue

Procedure-specific Risks of Thrombosis and Bleeding in Urological Non-cancer Surgery: Systematic Review and Meta-analysis

Kari A.O. Tikkinen ^{a.e}, Samantha Craigie ^{b.e}, Arnav Agarwal ^{b.d}, Reed A.C. Siemieniuk ^{b.e}, Rufus Cartwright ^{f.e}, Philippe D. Violette ^{b.q}, Giacomo Novara ^f, Richard Naspro ^f, Chika Agbassi ^k, Bassel Ali b. Maha Imam b.l. Nofisat Ismaila b. Denise Kam k. Michael K. Gould m. Per Morten Sandset n.o, Gordon H. Guyatt b.p

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Article info

Keywords:

Article history: Accepted February 15, 2017

Associate Editor Christian Gratzke

Baseline risk Bleeding Modeling Reporting Risk of bias Thromboprophylaxis Urology Venous thromboembolism

Context: Pharmacological thromboprophylaxis involves a trade-off between a reduction in venous thromboembolism (VTE) and increased bleeding. No guidance specific for procedure and patient factors exists in urology. Objective: To inform estimates of absolute risk of symptomatic VTE and bleeding

requiring reoperation in urological non-cancer surgery. Evidence acquisition: We searched for contemporary observational studies and esti-mated the risk of symptomatic VTE or bleeding requiring reoperation in the 4 wk after urological surgery. We used the GRADE approach to assess the quality of the evidence. Evidence synthesis: The 37 eligible studies reported on 11 urological non-cancer procedures. The duration of prophylaxis varied widely both within and between procedures; for example, the median was 12.3 d (interquartile range [IQR] 3.1-55) for oper recipient nephrectomy (kidney transplantation) studies and 1 d (IOR 0-1.3) for percutaneous nephrolithotomy, open prolapse surgery, and reconstructive pelvic surgery studies. Studies of open recipient nephrectomy reported the highest risks of VTE and bleeding (1.8-7.4% depending on patient characteristics and 2.4% for bleeding). The risk of VTE was low for 8/11 procedures (0.2–0.7% for patients with low/medium risk; 0.8– 1.4% for high risk) and the risk of bleeding was low for 6/7 procedures (<0.5%; no bleeding estimates for 4 procedures). The quality of the evidence supporting these

Conclusions: Although inferences are limited owing to low-quality evidence our results suggest that extended prophylaxis is warranted for some procedures (eg. kidney transplantation procedures in high-risk patients) but not others (transurethral resection of the prostate and reconstructive female pelvic surgery in low-risk patients).

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EAU Guidelines on Thromboprophylaxis in Urological Surgery

K.A.O. Tikkinen (Chair), R. Cartwright, M.K. Gould, R. Naspro, G. Novara, P.M. Sandset, P.D. Violette, G.H. Guyatt



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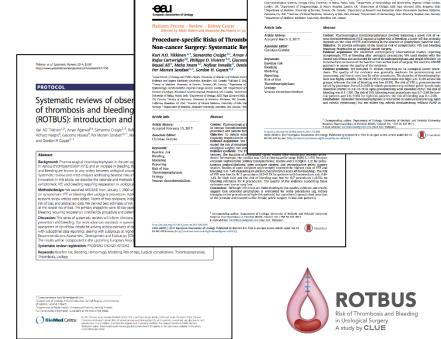
Evidence summaries for baseline risks of VTE and bleeding in urology available - ROTBUS____

14 different types of urological cancer procedures based on 71 studies

11 uro(gyneco)logical noncancer procedures based on 38 studies

Much of the evidence regarding baseline risk is (very) low quality

• Old search was until 01 Jan



available at www.selencedirect.com

Platinum Priority - Review - Kidney Cancer

Procedure-specific Risks of Thrombosis and Bleeding in Urological

Eur Urol 2017

Cancer Surgery: Systematic Review and Meta-analysis

Karl A.D. Hikima **, Samoutha Cruigie**, Arnav Agarus**, Philippe D. Volette **,
Giocono Noram **, Bugin Carverigie**, Philaret Napovi, Read A.C. Semieniak***, Bassel Air*,
Leyla Ezyata***, Johanna Cerad **, Judi Winkup **, Daniel Yoo **, Michael K. Could **,
Per Merter Samdert**, Genfra H. Ologuet**

***Openment All States University of Methods of Methods (Methods All States University of Methods (Methods (Metho

Big variation in the risk of symptomatic VTE

2.9-11.6

2.6-10.3

0.2-0.9

0.9-3.7

1.0-3.9

3.9-15.7

0.3 - 1.0

0.2-0.8

0.3 - 1.1

0.2 - 0.7

0.1 - 0.5

0.3

0.3

0.4

0.8

0.1

0.2

0.4

0.3

	pelween ine	procedures	
Procedure		Risk of VTE (low-high patient strata), %	Risk of bleeding,

Open radical cystectomy

RALP with extended PLND

Artificial urinary sphincter

Prolapse surgery (open)

Open radical prostatectomy without PLND

Reconstructive pelvic surgery (including

female SUI and vaginal prolapse)

Open radical prostatectomy with ext'd PLND

RALP without PLND

TURP or equivalent

Urethroplasty

Robotic radical cystectomy

Evidence summaries for baseline risks of VTE and bleeding soon available for general abdominal and gynecologic surgeries

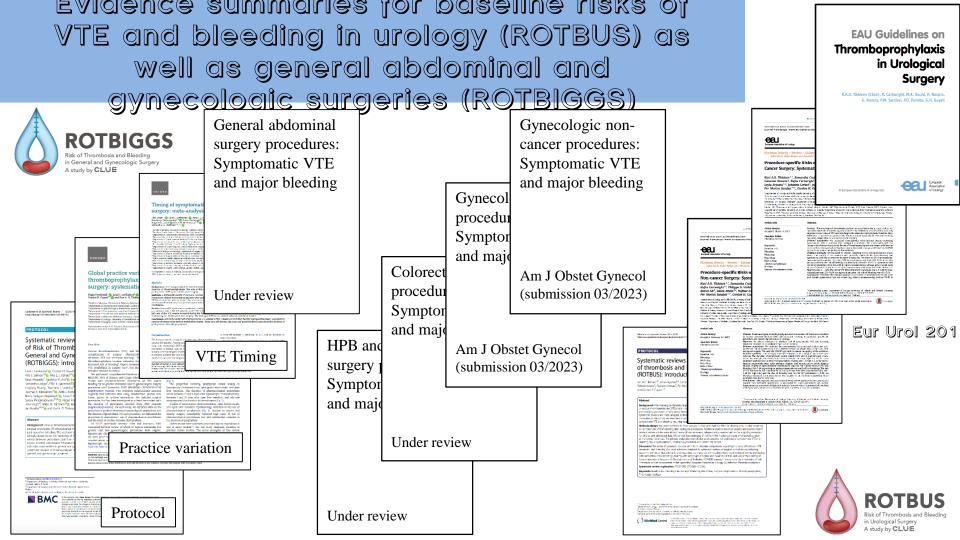
- General abdominal: 25,000 T&A and 2,600 full texts screened
- Gynecologic: 7,500 T&A and 1,600 full texts screened
- 581 studies included (282+299)
- >100 general abdominal surgery procedures
- >80 gynecologic surgery procedures
- Series of 5 articles to be published in 2023
 - General Abdominal, Colorectal, HPB & Upper Gl
 - Cancer and Non-Cancer Gynecology



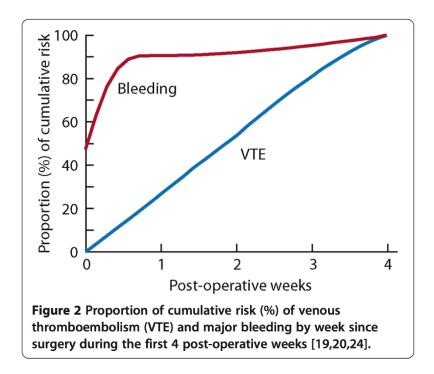
ROTBIGGS

Risk of Thrombosis and Bleeding in General and Gynecologic Surgery A study by **CLUE**

Projocol OpenAccess from PubMed or from https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s1



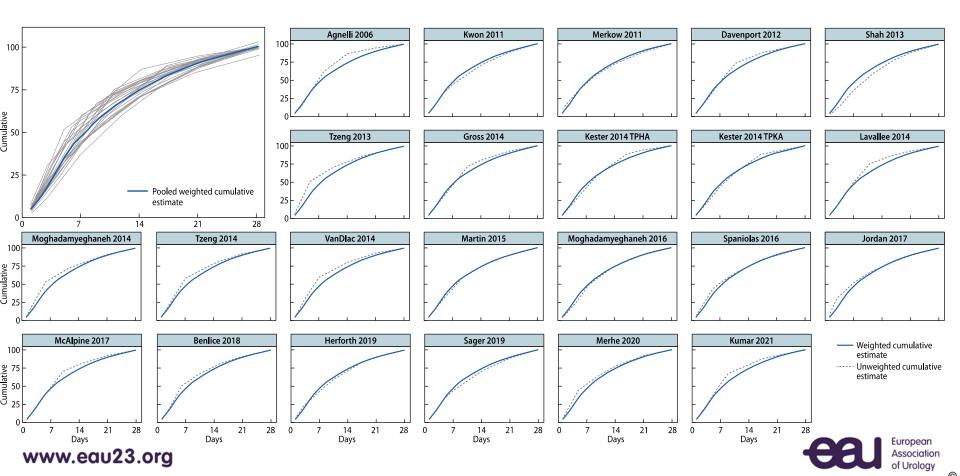
HOW IOUGI "Extended" (4 Weeks) thromboprophylaxis? When to start? Beginning next morning after surgery?



Tikkinen et al. Syst Rev 2014 Sweetland et al. BMJ 2009 Amin et al. J Tromb Haemost 2007

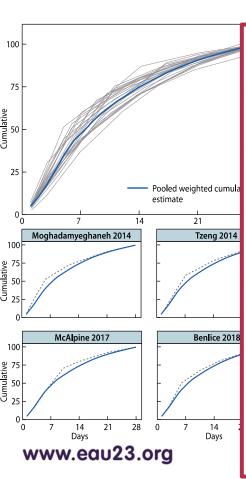
EAU23 | MILAN, ITALY 10-13 March 2023

EAU23 - A1009: Singh et al. Timing of symptomatic venous thromboembolism after surgery: A systematic review and meta-analysis





EAU23 - A1009: Singh et al. Timing of symptomatic venous thromboembolism after surgery: A systematic review and meta-analysis Published today in the BJS!



OXFORD

BJS, 2023, 1-9 https://doi.org/10.1093/bjs/znad035 Systematic Review

Timing of symptomatic venous thromboembolism after surgery: meta-analysis

Tino Singh^{1,2} [b], Lauri I. Lavikainen¹ [b], Alex L. E. Halme¹ [b], Riikka Aaltonen³ [b], Arnav Agarwal^{4,5} [b], Marco H. Blanker⁶ [b], Kostiantyn Bolsunovskyi^{1,7} [b], Rufus Cartwright^{8,9} [b], Herney García-Perdomo¹⁰ [b], Rachel Gutschon^{5,11} [b], Yung Lee¹² [b], Negar Pourjamal¹ [b], Robin W. M. Vernooij^{13,14} [b], Philippe D. Violette^{5,11} [b], Jari Haukka¹ [b], Gordon H. Guyatt^{5,15} [b] and Kari A. O. Tikkinen 1,16,17,*

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¹⁵Department of Medicine, McMaster University, Hamilton, Ontario, Canada

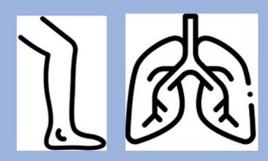
¹⁶Department of Urology, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

¹⁷Department of Surgery, South Karelian Central Hospital, Lappeenranta, Finland

Timing of Perioperative Pharmacological Thromboprophylaxis Initiation and Its Effect on Venous Thromboembolism and Bleeding Outcomes: A Systematic Review and Meta-Analysis

22 randomized trials (n=17,124)

Starting thromboprophylaxis before surgery compared to after surgery may decrease any VTE



5.1% before vs. 6.6% after Number Needed to Treat = 67

Starting thromboprophylaxis before surgery compared to after surgery may increase bleeding



31% before vs. 26% after Number Needed to Harm = 20

RCTs needed for thromboprophylaxis timing on VTE and bleeding risk in non-orthopedic surgery



No statistically significant differences





2019

Cochrane Database of Systematic Reviews

Felder S, Rasmussen MS, King R, Sklow B, Kwaan M, Madoff R, Jensen C

- Seven RCTs (1728 participants) were identified evaluating extended prophylaxis with LMWH for ≥14 days vs in-hospital period only after abdominal or pelvic surgery
- Any VTE: 5.3% in the extended vs. 13.2% in the hospital only (OR 0.38, 95% Cl 0.26-0.54; l²=28%; moderate-quality)
- Sympt. VTE: 0.1% in the extended vs. 1.0% the hospital only (OR 0.30, 95% Cl 0.1-1.1;

What should be considered when recommending (or not recommending) thromboprophylaxis?

- 1. Effect of treatment (prophylaxis)
 - Systematic review and meta-analysis of randomized trials
- 2. Baseline risk ('natural history') of outcomes
 - 'Best contemporary, observational evidence' including lowest risk of bias (or median value) identified through systematic review
- 3. Patient-related risk (and protective) factors

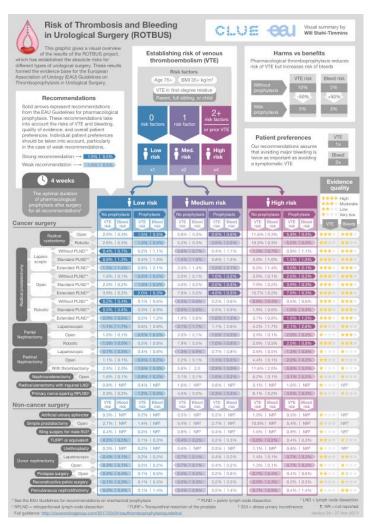
Stratifying the risk of VTE according to patient risk factors

Based on literature search, we developed a very simple model for risk of VTE but not for risk of bleeding

	letent endeleneel	
VTE risk		Risk
Low	No risk factors	1 🕱
Medium	Any one of the following:	2%
	Age 75 years or more	
	Body mass index 35 or more	
	VTE in 1st degree relative (parent, full sibling, or child)	
High	Prior VTE	4×
	Patients with any combination of two or more risk factors	

What should be considered when recommending (or not) thromboprophylaxis?

- 4. Quality of evidence / certainty in estimates
- 5. Relative value of different (good and bad) outcomes
- 6. Burden and other effects of treatment (prophylaxis)
- 7. Patients' values and preferences
- 8. Costs



Thromboprophylaxis in Urological Surgery

K.A.O. Tikkinen (Chair), R. Cartwright, M.K. Gould, R. Naspro, G. Novara, P.M. Sandset, P.D. Violette, G.H. Guyatt

© European Association of Urology 2017



Available at:

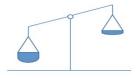
hjjps://jwijjer.com/KariTikkinen/sjajus/936532034817847 hjjp://clueworkinggroup.com/2017/12/01/jhromboprophyl

Strength of recommendation



Strong recommendation

- benefits clearly outweigh risks/hassle/cost
- risk/hassle/cost clearly outweighs benefit



What can downgrade strength?

- low confidence in estimates
- close balance between upsides and downsides



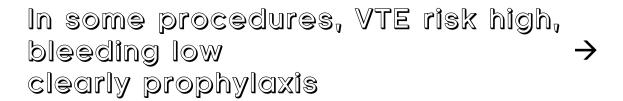
Relative value of different outcomes

- We considered DVT and PE as equally problematic and assigned them a single weighting: "any symptomatic VTE"
- We defined "major bleeding" as bleeding requiring re-operation/re-exploration (including angioembolization)
 - Also transfusion rates to be provided in ROTBIGGS

We assigned twice the weight for major bleeding as

Take home messages

VTE and bleeding risks unknown, ROTBIGGS publications available next year



In some, VTE risk is low, bleeding high > clearly no prophylaxis







ORIGINAL ARTICLE

Tranexamic Acid in Patients Undergoing Noncardiac Surgery

P.J. Devereaux, M. Marcucci, T.W. Painter, D. Conen, V. Lomivorotov, D.I. Sessler, M.T.V. Chan, F.K. Borges, M.J. Martínez-Zapata, C.-Y. Wang, D. Xavier, S.N. Ofori, M.K. Wang, S. Efremov, G. Landoni, Y.V. Kleinlugtenbelt, W. Szczeklik, D. Schmartz, A.X. Garg, T.G. Short, M. Wittmann, C.S. Meyhoff, M. Amir, D. Torres, A. Patel, E. Duceppe, K. Ruetzler, J.L. Parlow, V. Tandon, E. Fleischmann, C.A. Polanczyk, A. Lamy, S.V. Astrakov, M. Rao, W.K.K. Wu, K. Bhatt, M. de Nadal, V.V. Likhvantsev, P. Paniagua, H.J. Aguado, R.P. Whitlock, M.H. McGillion, M. Prystajecky, J. Vincent, J. Eikelboom, I. Copland, K. Balasubramanian, A. Turan, S.I. Bangdiwala, D. Stillo, P.L. Gross, T. Cafaro, P. Alfonsi, P.S. Roshanov, E.P. Belley-Côté, J. Spence, T. Richards, T. VanHelder, W. McIntyre, G. Guyatt, S. Yusuf, and K. Leslie, for the POISE-3 Investigators*

Patients

- Recruited patients 06/2018 07/2021 at 114 hospitals in 22 countries
- Inclusion
 - 45 years of age or older
 - Inpatient noncardiac surgery
 - At risk for bleeding & cardiovascular complications
- Exclusion
 - Cardiac surgery or intracranial neurosurgery
 - If a physician planned to administer systemic tranexamic acid during surgery
 - Creatinine clearance of <30 ml/minute or longterm dialysis

Characteristics	Tranexamic Acid (N=4757)	Placebo (N = 4778)
Surgery — no./total no. (%)		
Any procedure	4729/4757 (99.4)	4740/4778 (99.2)
General:	1769/4729 (37.4)	1773/4740 (37.4)
Orthopedic	1083/4729 (22.9)	1063/4740 (22.4)
Vascular	699/4729 (14.8)	700/4740 (14.8)
Urologic	598/4729 (12.6)	624/4740 (13.2)
Spinal	237/4729 (5.0)	206/4740 (4.3)
Gynecologic	162/4729 (3.4)	171/4740 (3.6)
Thoracic	127/4729 (2.7)	146/4740 (3.1)
Low-risk	39/4729 (0.8)	34/4740 (0.7)
Plastic	14/4729 (0.3)	23/4740 (0.5)
Data missing on type of procedure performed	1/4729 (<0.1)	0/4740
No procedure performed	27/4757 (0.6)	35/4778 (0.7)
Data missing on whether patient underwent surgery	1/4757 (<0.1)	3/4778 (0.1)
Medication taken within 24 hr before surgery — no. (%)		
Therapeutic-dose thrombin or factor Xa inhibitor	22 (0.5)	28 (0.6)
Therapeutic-dose vitamin K antagonist	6 (0.1)	8 (0.2)
Therapeutic-dose intravenous or subcutaneous antithrombotic agent	58 (1.2)	44 (0.9)
Prophylactic-dose anticoagulant	753 (15.8)	757 (15.8)

Interventions and Outcomes

Patients assigned in a 1:1 ratio to receive tranexamic acid (1-g intravenous bolus) or placebo at the start and end of surgery and, in a 1:1 ratio with the use of a partial factorial design, to a hypotension-avoidance strategy or a hypertension-avoidance strategy

The primary efficacy outcome (at 30 days)

A composite of life-threatening bleeding, major bleeding, and bleeding into a critical organ

The primary safety outcome (at 30 days)

A composite of myocardial injury (i.e., myocardial infarction or isolated ischemic troponin elevation), nonhemorrhagic stroke, peripheral arterial thrombosis, and symptomatic proximal venous thromboembolism

Table 2. Effects of Tranexamic Acid on 30-Day Outcomes.*					
Outcome	Tranexamic Acid (N=4757)	Placebo (N = 4778)	Hazard Ratio (95% CI)†	P Value	
Primary efficacy outcome: composite bleeding outcome — no. (%)‡	433 (9.1)	561 (11.7)	0.76 (0.67–0.87)	<0.001§	
Individual components of composite bleeding outcome — no. (%)					
Life-threatening bleeding¶	78 (1.6)	79 (1.7)	0.99 (0.73–1.36)		
Major bleeding¶	363 (7.6)	496 (10.4)	0.72 (0.63-0.83)		
Bleeding into a critical organ¶	12 (0.3)	21 (0.4)	0.57 (0.28–1.16)		
Primary safety outcome: composite cardiovascular outcome — no./total no. (%)	649/4581 (14.2)	639/4601 (13.9)	1.02 (0.92–1.14)	0.04**	
Individual components of composite cardiovascular outcome — no. (%)					
MINS¶	608 (12.8)	602 (12.6)	1.02 (0.91-1.14)		
Nonhemorrhagic stroke††	24 (0.5)	16 (0.3)	1.51 (0.80–2.84)		
Peripheral arterial thrombosis††	22 (0.5)	23 (0.5)	0.96 (0.53-1.72)		
Symptomatic proximal venous thromboembolism††	32 (0.7)	28 (0.6)	1.15 (0.69–1.91)		
Other secondary outcomes — no. (%)					
Bleeding independently associated with death after noncardiac surgery	416 (8.7)	541 (11.3)	0.76 (0.67–0.87)		
MINS not fulfilling the universal definition of myocardial infarction	549 (11.5)	549 (11.5)	1.01 (0.89–1.13)		
Myocardial infarction	67 (1.4)	53 (1.1)	1.27 (0.89–1.82)		
Net risk-benefit outcome‡‡	983 (20.7)	1046 (21.9)	0.94 (0.86–1.02)		

Shown is the two-sided P value for superiority.

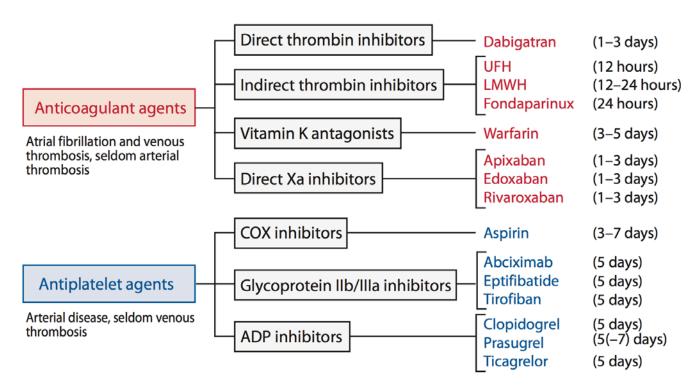
** Shown is the one-sided P value for noninferiority. To show statistical significance, this P value had to be less than 0.025.

Management of antithrombotic agents during perioperative period

In principle there are four options:

- 1. to defer surgery until antithrombotic agents are not anymore needed
- 2. stop antithrombotic agents prior to surgery and restart some time after surgery
- 3. confinue through the surgery
- 4. "bridge" antithrombotic agents

odys appropriate time to stop antiplatelet agents before surgery while the optimal time to stop varies across anticoagulants



Earlier major guidelines preceded major studies

- A large, rigorous randomized trial comparing aspirin
 to placebo showed that aspirin increases postoperative bleeding without reducing arterial
 thrombotic events
 Devereaux et al. NEJM 2014
 - Indirect evidence for antiplatelet agents other than aspirin
 - However, perioperative aspirin may be beneficial for patients with prior percutaneous coronary intervention (PCI) Graham et al. Ann Intern Med 2017

• Evidence has also demonstrated that bridging with LMWH increases bleeding without preventing

EAU Thromboprophlaxis guideline principles for peri-operative management of antithrombotic agents in urology

1. Discontinue antithrombotic therapy for the period around surgery

10

2. In those with a temporary very high risk of thrombosis, delay surgery until that risk decreases. If it is not possible to delay, continuing antithrombotic therapy or bridging through surgery may be advisable

Peri-operative management of antithrombotic agents: 7 recommendations out of 9 strong

In patients receiving antiplatelet agents, we recommend stopping antiplatelet agents before surgery and not initiating any alternative antithrombotic therapy

In patients in whom antiplatelet agents have been stopped before surgery, we recommend restarting when bleeding is no longer a serious risk - typically four days post-surgery - rather than longer periods of withholding

In patients with very high risk of thrombosis receiving antiplatelet agents in whom surgery can be delayed, we recommend delaying surgery

· drug-eluting stent placement within 6 months

Perioperative Management of Patients With Atrial Fibrillation Receiving a Direct Oral Anticoagulant

Conducted at 23 clinical centers in Canada, USt, and Europe (08/2014 - 07/2018)

3,007 participants with AF; long-term DOAC users; scheduled for elective surgery

DOAC omitted 1d before a low-; and 2d before a high-bleeding-risk procedure

	Major bleeding at 30 days	Arterial thromboembolism at 30 days
Apixaban	1.35% (0%-2.00%)	0.16% (0%-0.48%)
Dabigatr an	0.90% (0%-1.73%)	0.60% (0%-1.33%)
	1 25% 10%_2 85%)	

Peri-operative management of antithrombotic agents: 7 recommendations out of 9 strong

- In patients receiving anticoagulant agents, except those with very high risk of thrombosis, we recommend stopping drugs before surgery and not initiating any alternative antithrombotic therapy
- In patients with a new VTE, we recommend that surgery is delayed for at least 1 month, and if possible 3 months, to permit discontinuation of anticoagulation preparatively, rather than operating within 1 month of thrombosis
- In patients receiving any anticoagulant with a severe thrombophilia, such as antithrombin deficiency and

Exclusion criteria





- Active bleeding or major hemorrhage during the last 6 months
- Contraindication to anticoagulant prophylaxis
- Requiring ongoing anticoagulant/antiplatelet during previous 7 days preceding surgery or within 30 days post-surgery
- Known thrombophilia
- Known bleeding disorder
- Substantial liver impairment (for instance, INR 1.4 or more during last 60 days)
- Creatinine clearance <30ml/min
- Platelet count <50,000 × 10⁹/L
- Hb <70 g/L (= <7 g/dL)
- Known allergy to apixaban
- Taking strong inhibitors or inductors of both CYP 3A4 and P-glycoprotein, such as anti-seizure medications (e.g. phenytoin, fosphenytoin, carbamazepine), azole-antimycotics (e.g. ketoconazole, itraconazole), HIV-protease inhibitors (e.g. ritonavir, indinavir) and rifampicin
- Concomitant procedures with high risk of VTE/bleeding
- Emergency operation that needs to be performed within 24 hours
- · Pregnant or breast-feeding women
- Previous randomization in this trial
- Any reason why, in the opinion of the investigator(s), the patient should not participate

General Abdominal Surgery: Potential procedures to be included after careful consideration of patient's personal VTE and bleeding risk factors

General abdominal surgery

Cholecystectomy, open
Cholecystectomy, open, emergency
Groin hernia repair, open, emergency
Ventral hernia repair, open
Ventral hernia repair, laparoscopic, emergency
Ventral hernia repair, open, emergency
Ventral hernia repair, open, emergency
Small bowel resection, laparoscopic
Small bowel resection, laparoscopic, benign
Small bowel resection, laparoscopic, malignant
Small bowel resection, laparoscopic, IBD
Splenectomy, laparoscopic, elective
Splenectomy, open, elective

General colorectal surgery

Abdominoperineal resection, laparoscopic Anterior resection, minimally-invasive Anterior resection, robotic Anterior resection, open Anterior resection, laparoscopic, emergency Anterior resection, open, benign Anterior resection, open, malignant Anterior resection, open, IBD Colectomy, minimally-invasive Colectomy, laparoscopic Colectomy, robotic Colectomy, laparoscopic, malignant Colectomy, laparoscopic, IBD Colectomy, open, benign Colectomy, laparoscopic, left Colectomy, laparoscopic, right Colectomy, open, left Colectomy, open, right

General hepatobiliary and upper gastrointestinal surgery

Distal pancreatectomy, minimally-invasive
Distal pancreatectomy, laparoscopic
Distal pancreatectomy, laparoscopic, benign
Distal pancreatectomy, open, benign
Liver resection, minimally-invasive, minor
Liver resection, robotic
Liver resection, open
Liver resection, laparoscopic, minor
Liver resection, open, minor
Liver resection, open, major
Gastrectomy, robotic
Gastric bypass, robotic
Gastric bypass, open
Sleeve gastrectomy, robotic





Gynecologic Surgery: Potential procedures to be included after careful consideration of patient's personal VTE and bleeding risk factors

Gynecologic cancer surgery

Trachelectomy, radical, with laparoscopic pelvic lymphadenectomy, vaginal

Trachelectomy, radical, with pelvic lymphadenectomy, open

Surgery for ovarian cancer, any, minimally-invasive

Vulvectomy, any

Hysterectomy, any, vaginal

Hysterectomy, any, open

Supracervical hysterectomy, malign, laparoscopic

Supracervical hysterectomy, malign, open

Total hysterectomy, with or without lymphadenectomy, robotic

Total hysterectomy, with or without lymphadenectomy, vaginal

Total hysterectomy, with or without lymphadenectomy, open

Total hysterectomy, with lymphadenectomy, minimally-invasive

Total hysterectomy, with lymphadenectomy, laparoscopic

Total hysterectomy, with lymphadenectomy, robotic

Total hysterectomy, with lymphadenectomy, open

Radical hysterectomy, with lymphadenectomy, minimally-invasive

Radical hysterectomy, with lymphadenectomy, laparoscopic

Radical hysterectomy, with lymphadenectomy, open

Gynecologic non-cancer surgery

Deep endometriosis surgery, with bowel surgery, open

Oophorectomy, robotic

Sacrocolpopexy, robotic

Sacrocolpopexy, open

Sacrocolpopexy, with hysterectomy, minimally-invasive

Sacrocolpopexy, with hysterectomy, open

Sacrocolpopexy, without hysterectomy, minimally-invasive

Sacrocolpopexy, without hysterectomy, open

Uterosacral ligament suspension, laparoscopic

Vaginal obliterative POP surgery (colpocleisis)

Hysterectomy, any, open

Supracervical hysterectomy, benign, open

Total hysterectomy, benign, open





Urologic Surgery: Potential procedures to be included after careful consideration of patient's personal VTE and bleeding risk factors

Urologic cancer surgery

Laparoscopic radical prostatectomy without lymph node dissection
Laparoscopic radical prostatectomy with standard lymph node dissection
Laparoscopic radical prostatectomy with extended lymph node dissection
Open radical prostatectomy without lymph node dissection
Robotic radical prostatectomy with standard lymph node dissection
Robotic radical prostatectomy with extended lymph node dissection
Laparoscopic partial nephrectomy
Open partial nephrectomy
Robotic partial nephrectomy
Laparoscopic radical nephrectomy
Open radical nephrectomy
Open nephroureterectomy
Radical penectomy with inquinal lymph node dissection

<u>Urologic non-cancer surgery</u>
Sling surgery for male stress urinary incontinence
Recipient nephrectomy, open



