

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Complications of Factor V Leiden in Adults Undergoing Major Non-Cardiac Surgical Procedures: A systematic review and meta-analysis

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Review question / Objective: To determine the association of factor V Leiden and post-operative complications in adult patients undergoing non-cardiac surgery.

Eligibility criteria: We searched for published articles in Embase and Medline. We excluded animal studies and non-English articles. Additionally, we will review the reference lists of eligible articles for any potential articles that fit our inclusion criteria that may have been missed in the original search. The search strategy included MeSH words such as factor V Leiden, postoperative complications, and perioperative outcomes.

Information sources: Embase and Medline.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 May 2022 and was last updated on 23 May 2022 (registration number INPLASY202250138).

INTRODUCTION

Review question / Objective: To determine the association of factor V Leiden and post-operative complications in adult patients undergoing non-cardiac surgery.

Rationale: Thromboembolic complications and associated adverse outcomes are a

serious morbidity and mortality concern in perioperative patient care. It is unclear what the impact of Factor V Leiden is on patient outcomes during surgery, and no specific anticoagulation regimen is currently recommended specifically for these patients. This review aims to assess the impact of Factor V Leiden on perioperative outcomes in patients with

this disorder undergoing surgery to better inform future patient management strategies.

Condition being studied: Factor V Leiden.

METHODS

Search strategy:

- 1 (open adj1 reduction?).mp,kw. 8512
- 2 adenectom*.mp,kw. 142
- 3 adrenalectom*.mp,kw. 8797
- 4 (aneurysm* adj2 repair*).mp,kw. 8610
- 5 angioplast*3.mp,kw. 59620
- 6 appendectom*.mp,kw. 9204
- 7 arthrectom*.mp,kw. 14
- 8 arthroplast???.mp,kw. 74201
- 9 atherectom*3.mp,kw. 2728
- 10 CABG.mp,kw. 15272
- 11 caesarean*.mp,kw. 15223
- 12 cardiac ablat*.mp,kw. 240
- 13 (cardiac adj2 catheter* adj2 ablat*).mp,kw. 101
- 14 cardiomyoplast*3.mp,kw. 669
- 15 (carotid adj2 endarterectom*3).mp,kw. 10255
- 16 cervicectom*.mp,kw. 5
- 17 cesarean*.mp,kw. 42023
- 18 cholecystectom*.mp,kw. 21478
- 19 colectom*.mp,kw. 17266
- 20 coronary artery bypass surger*.mp,kw. 5623
- 21 (coronary adj3 bypass*).mp,kw. 48432
- 22 (coronary adj2 catheter* adj2 ablat*).mp,kw. 6
- 23 (coronary adj3 catheter*).mp,kw. 1262
- 24 (coronary adj2 radiofrequenc* adj2 ablat*).mp,kw. 6
- 25 cystectom*.mp,kw. 12688
- 26 dissectom*.mp,kw. 5217
- 27 diskectom*.mp,kw. 6078
- 28 duodenectom*.mp,kw. 457
- 29 esophagectom*.mp,kw. 11864
- 30 fundectom*.mp,kw. 47
- 31 gastrectom*.mp,kw. 24309
- 32 glossectom*.mp,kw. 915
- 33 gonadectom*.mp,kw. 2101
- 34 (heart adj2 radiofrequenc* adj2 ablat*).mp,kw. 23
- 35 (heart adj2 valve? adj2 repair*).mp,kw. 86
- 36 (heart adj2 valve? adj2 replac*).mp,kw. 953
- 37 hemiarthroplast???.mp,kw. 2723
- 38 hemi-arthroplast???.mp,kw. 112
- 39 hemicolectom*.mp,kw. 2799
- 40 hemi-colectom*.mp,kw. 71
- 41 hepatectom*.mp,kw. 26952
- 42 (hybrid-maze adj2 procedure*).mp,kw. 3
- 43 hypophysectom*.mp,kw. 1779
- 44 iridectom*.mp,kw. 1053
- 45 jejunectom*.mp,kw. 44
- 46 laparoscop*.mp,kw. 113876
- 47 laparotom*.mp,kw. 36466
- 48 laryngectom*.mp,kw. 6201
- 49 lobectom*.mp,kw. 13859
- 50 lumpectom*.mp,kw. 2598
- 51 lymphadenectom*.mp,kw. 13351
- 52 lymph-adenectom*.mp,kw. 32
- 53 lymphectom*.mp,kw. 38
- 54 mandibulectom*.mp,kw. 667
- 55 mastectom*.mp,kw. 27734
- 56 mastoidectom*.mp,kw. 1795
- 57 maxillectom*.mp,kw. 1098
- 58 mesohepatectom*.mp,kw. 59
- 59 meso-hepatectom*.mp,kw. 2
- 60 metastasectom*.mp,kw. 2396
- 61 MIDCAB.mp,kw. 388
- 62 (minimal* adj3 invasiv*).mp. 73227
- 63 (mitral valve? adj2 repair*).mp,kw. 4645
- 64 (mitral valve? adj2 reparat*).mp,kw. 11
- 65 myectom*.mp,kw. 1224
- 66 myomectom*.mp,kw. 2891
- 67 necrosectom*.mp,kw. 808
- 68 nephrectom*.mp,kw. 29034
- 69 neurosurg*.mp,kw. 58409
- 70 obstetr*.mp,in,kw,kf. 315433
- 71 oesophagectom*.mp,kw. 1193
- 72 oncosurg*.mp. 150
- 73 onco-surg*.mp. 33
- 74 oophorectom*.mp,kw. 6696
- 75 operati*.mp,kw. 627841
- 76 orchidectom*.mp,kw. 1757
- 77 orchiectom*.mp,kw. 10747
- 78 p*ectom*.mp. 95401
- 79 p*ostom*.mp. 5076
- 80 p*otom*.mp. 29977
- 81 pancreatectom*.mp,kw. 11712
- 82 pancreaticoduodenectom*.mp,kw. 9424
- 83 pancreatico-duodenectom*.mp,kw. 149
- 84 parathyroidectom*.mp,kw. 6115
- 85 para-thyroidectom*.mp,kw. 5
- 86 pharyngectom*.mp,kw. 912
- 87 pharyngolaryngoesophagectom*.mp,kw. 65
- 88 pharyng*esophagectom*.mp,kw. 85
- 89 pneumonectom*.mp,kw. 17952
- 90 pneumonectom*.mp,kw. 17952
- 91 post-an?esth*.mp. 1564
- 92 postan?esth*.mp. 3282
- 93 postoperat*.mp,kw. 578298
- 94 post-operat*.mp,kw. 51040
- 95 postprocedur*.mp,kw. 6542
- 96 post-procedur*.mp,kw. 5847
- 97 postsurg*.mp,kw. 15494
- 98 post-surg*.mp,kw. 14195
- 99 proctocolectom*.mp,kw. 3509
- 100 prostatect*.mp,kw. 28161
- 101 quadrantectom*.mp,kw. 375

- 102 reoperat*.mp,kw. 86661
 103 reresect*.mp,kw. 112
 104 resect*.mp,kw. 253542
 105 rhinectom*.mp,kw. 79
 106 salpingectom*.mp,kw. 2119
 107 salpingo-oophorectom*.mp,kw. 3736
 108 segmentectom*.mp,kw. 2766
 109 segmentectom*.mp,kw. 2766
 110 splenectom*.mp,kw. 13757
 111 subsegmentectom*.mp,kw. 164
 112 sub-segmentectom*.mp,kw. 9
 113 surgeon*.mp,kw. 157250
 114 surger*.mp,kw. 1751851
 115 surgical*.mp,kw. 946406
 116 thymectom*.mp,kw. 3714
 117 thyroidectom*.mp,kw. 17778
 118 tonsillectom*.mp,kw. 7043
 119 transfusion*.mp,kw. 88743
 120 (transmyocardia* adj5 ablat*).mp,kw. 4
 121 (transmyocardia* adj3 revasculari*).mp,kw. 586
 122 transplant*.mp,kw. 514607
 123 trauma*.mp,kw. 284295
 124 trisegmentectom*.mp,kw. 254
 125 tri-segmentectom*.mp,kw. 6
 126 tumorectom*.mp,kw. 594
 127 uretecto*.mp,kw. 6
 128 uvulectom*.mp,kw. 45
 129 vaginectom*.mp,kw. 182
 130 vulvectom*.mp,kw. 494
 131 exp Surgical Procedures, Operative/ 2206182
 132 su.fs. [Surgery floating subheading] 1366661
 133 tr.fs. [Transplant floating subheading] 92111
 134 exp Specialties, Surgical/ 99826
 135 exp Surgeons/ 9624
 136 exp "Anesthesia and Analgesia"/ 121442
 137 exp Anesthetics/ 126137
 138 exp Analgesics/ 331640
 139 an?esthe*.mp,jw. 299638
 140 analges*.mp,jw. 153276
 141 exp Postoperative Care/ 29086
 142 exp Postoperative Period/ 41489
 143 exp Postoperative Complications/ 388052
 144 or/1-143 [Perioperative or Surgical] 4197297
 145 factor v/ or factor va/ 5039
 146 Factor V Leiden.mp. 4576
 147 Factor 5 Leiden.mp. 7
 148 fvl.mp. 637
 149 or/145-148 6251
 150 144 and 149 1422
 Embase
<https://libaccess.mcmaster.ca/login?url=http://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=7103zW1Sbe74igAyKoRg0hK66bk5ZvWuVgWR9afw2ipt6un2PMyuqUAKLLRAXNGDo>
 1 (open adj1 reduction?).mp,kw. 19335
 2 adenectom*.mp,kw. 475
 3 adrenalectom*.mp,kw. 26137
 4 (aneurysm* adj2 repair*).mp,kw. 23858
 5 angioplast*3.mp,kw. 102088
 6 appendectom*.mp,kw. 24257
 7 arthrectom*.mp,kw. 51
 8 arthroplast???.mp,kw. 111582
 9 atherectom*3.mp,kw. 6950
 10 CABG.mp,kw. 35360
 11 caesarean*.mp,kw. 36753
 12 cardiac ablat*.mp,kw. 607
 13 (cardiac adj2 catheter* adj2 ablat*).mp,kw. 174
 14 cardiomyoplast*3.mp,kw. 1396
 15 (carotid adj2 endarterectom*3).mp,kw. 21539
 16 cervicectom*.mp,kw. 733
 17 cesarean*.mp,kw. 116034
 18 cholecystectom*.mp,kw. 58534
 19 colectom*.mp,kw. 22287
 20 coronary artery bypass surger*.mp,kw. 22677
 21 (coronary adj3 bypass*).mp,kw. 107347
 22 (coronary adj2 catheter* adj2 ablat*).mp,kw. 23
 23 (coronary adj3 catheteri*).mp,kw. 3642
 24 (coronary adj2 radiofrequenc* adj2 ablat*).mp,kw. 14
 25 cystectom*.mp,kw. 35617
 26 dissectom*.mp,kw. 11538
 27 diskectom*.mp,kw. 8328
 28 duodenectom*.mp,kw. 1286
 29 esophagectom*.mp,kw. 16157
 30 fundectom*.mp,kw. 144
 31 gastrectom*.mp,kw. 63253
 32 glossectom*.mp,kw. 2436
 33 gonadectom*.mp,kw. 5335
 34 (heart adj2 radiofrequenc* adj2 ablat*).mp,kw. 35
 35 (heart adj2 valve? adj2 repair*).mp,kw. 175
 36 (heart adj2 valve? adj2 replac*).mp,kw. 15295
 37 hemiarthroplast???.mp,kw. 5014
 38 hemi-arthroplast???.mp,kw. 244
 39 hemicolectom*.mp,kw. 11840
 40 hemi-colectom*.mp,kw. 311
 41 hepatectom*.mp,kw. 34965
 42 (hybrid-maze adj2 procedure*).mp,kw. 9
 43 hypophysectom*.mp,kw. 10022
 44 iridectom*.mp,kw. 2283
 45 jejunectom*.mp,kw. 131
 46 laparoscop*.mp,kw. 257452
 47 laparotom*.mp,kw. 109678
 48 laryngectom*.mp,kw. 13145
 49 lobectom*.mp,kw. 44273
 50 lumpectom*.mp,kw. 8142
 51 lymphadenectom*.mp,kw. 42484
 52 lymph-adenectom*.mp,kw. 126

53 lymphectom*.mp,kw. 68
54 mandibulectom*.mp,kw. 1222
55 mastectom*.mp,kw. 68617.

Participant or population: - Adult patients (≥ 18 years of age) with a diagnosis of Factor V Leiden (heterozygous or homozygous)- Inclusion criteria: 1) Adult patients (≥ 18 years of age); 2) A preoperative diagnosis of Factor V Leiden; 3) Patients undergoing non-cardiac surgery; 4) At least one postoperative complication reported; 6) Comparator group with no factor V Leiden should be present; and 7) English language articles- Exclusion criteria: 1) Surgical patients < 18 years; 2) Pregnant patients; 2) no non-cardiac surgical procedure; 3) Factor V Leiden was not assessed 4) No postoperative complications reported.

Intervention: None.

Comparator: Patients with factor V Leiden compared to those without.

Study designs to be included: We will include randomized controlled trials and observational studies (case control, retrospective/prospective cohorts) that have reported at least one postoperative complication. Narrative case series, case reports, books, chapters, conference abstracts, and dissertations will be excluded.

Eligibility criteria: We searched for published articles in Embase and Medline. We excluded animal studies and non-English articles. Additionally, we will review the reference lists of eligible articles for any potential articles that fit our inclusion criteria that may have been missed in the original search. The search strategy included MeSH words such as factor V Leiden, postoperative complications, and perioperative outcomes.

Information sources: Embase and Medline.

Main outcome(s): The primary outcome will be any postoperative complication (including thrombotic events, graft survival)

in adult patients with a diagnosis of Factor V Leiden undergoing non-cardiac surgery.

Data management: Covidence, Excel, Google Documents and Google Sheets will be used to organize the review.

Quality assessment / Risk of bias analysis: Studies that meet the inclusion criteria will be assessed independently and in duplicate using the Cochrane Version 2 for RCTs, and for non-randomized studies the CLARITY tools from McMaster.

Strategy of data synthesis: We will present study demographics, characteristics, postoperative outcomes of all included studies using a table format. Additional tables will be created for quality assessment of included studies. If A meta-analysis will be conducted if there are an adequate number of studies.

Subgroup analysis: Subgroups consisting of heterozygous vs. homozygous patients with Factor V Leiden, as well as subgroups for specific surgery types (orthopedic, transplant, general surgical, vascular) will be considered.

Sensitivity analysis: N/A.

Language: English.

Country(ies) involved: Canada.

Keywords: Factor V Leiden, Perioperative Outcomes, Surgery, Prognosis.

Dissemination plans: We plan to publish the results of our review in a peer-reviewed journal relevant to the care of perioperative patients.

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