CHEST Online Supplement

Incidence of VTE and Bleeding Among Hospitalized Patients With Coronavirus Disease 2019

A Systematic Review and Meta-analysis

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e-Appendix 1. PROSPERO protocol registration

PROSPERO
International prospective register of systematic reviews

NHS National Institute for Health Research

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Incidence of venous thromboembolism and bleeding among hospitalized patients with COVID-19: a systematic review and meta-analysis

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

31/07/2020

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/08/2020

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.
Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.
This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

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Review stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

David Jimenez

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Dr Jimenez

7. * Named contact email.

Give the electronic mail address of the named contact.

djimenez.hrc@ gmail.com

8. Named contact address

Give the full postal address for the named contact.

Colmenar Road\r\nKm. 9,100\r\n28034 Madrid (Spain)

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+34669461858

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

Hospital Ramon y Cajal. Universidad de Alcalá. CIBER Enfermedades Respiratorias.

Organisation web address:

https://www.comunidad.madrid/hospital/ramonycajal/

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are**

now mandatory fields for each person.

Dr David Jimenez. Hospital Ramon y Cajal
Dr Parth Rali. Temple University Hospital
Dr Alfonso Muriel. Hospital Ramon y Cajal
Dr Raquel Morillo. Hospital Ramon y Cajal
Dr Behnood Bikdeli. Brigham and Women´s Hospital, Harvard Medical School
Dr Pedro Ruiz-Artacho. Clinica Universidad de Navarra
Dr Raphael Le Mao. Université Européenne de Bretagne
Dr Carmen Rodriguez. Hospital Ramon y Cajal
Dr Beverley Hunt. Guys & St Thomas' NHS Foundation Trust
Dr Manuel Monreal. Hospital Germans Trias i Pujol

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

None

Grant number(s)

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

What is the overall incidence of venous thromboembolism (VTE) and bleeding among hospitalized patients with COVID-19?

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

Sources: We will search MEDLINE (using the Ovid platform), PubMed, Embase, CINAHL (using the Ovid platform), the Cochrane Library, COVID-19 Open Research Dataset Challenge, COVID-19 Research Database (WHO), Epistemonikos (COVID-19 Living Overview of the Evidence platform), EPPI Centre living systematic map of the evidence, and reference lists of included papers, We will hand search (up to July 31, 2020) preprint servers (bioRxiv, medRxiv, and Social Science Research Network First Look) and coronavirus resource centres of The Lancet, JAMA, and N Engl J Med.

Search dates: From January 1, 2020 to July 31, 2020.

Restrictions: None.

17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy.Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/198864_STRATEGY_20200730.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

COVID-19 may predispose patients to venous thromboembolic events (deep vein thrombosis [DVT] and/or pulmonary embolism [PE]), due to hypoxia, excessive inflammation, platelet activation, endothelial dysfunction, and stasis. Accumulating evidence suggests that hospitalized patients with COVID-19 may have a high incidence of venous thromboembolism (VTE), despite receiving standard thromboprophylaxis according to guidelines for acutely ill medical patients. However, an accurate estimate of the incidence of VTE in hospitalized patients diagnosed with COVID-19 remains unclear, with incidence rates reported between 4.8% and 85%. This variability might have been influenced by the type of events counted, the type of testing for VTE, assessment setting, and the use and type of thromboprophylaxis. Furthermore, the assessment of PE in patients with COVID-19 is conflated by the presence of immunothrombosis. Local inflammation in the lungs with subsequent endothelial inflammation, complement activation, thrombin generation, platelet and leukocyte recruitment, and the initiation of immune responses culminate in small pulmonary vessel thrombosis.

In addition to an increased risk of thrombosis, patients with COVID-19 might be at risk of excess bleeding due to factors such as imbalances in platelet production and destruction, coagulation factor consumption in the setting of severe inflammation, and use of antiplatelet or anticoagulant agents

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

INCLUSION CRITERIA

VTE and/or major bleeding among hospitalized patients with WHO-defined confirmed or probable COVID-19.

EXCLUSION CRITERIA

Studies enrolling 10 consecutive patients initially hospitalized for COVID-19.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

Patients hospitalized for COVID-19 who are diagnosed of VTE and/or bleeding during hospitalization.

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Patients hospitalized for COVID-19 who are not diagnosed of VTE or bleeding during hospitalization.

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

Observational studies such as cohort (prospective or retrospective) and cross-sectional studies.

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

The primary outcome will be the incidence of VTE during hospitalization among patients hospitalized for COVID-19, expressed as the proportion of patients with a diagnosis of VTE. VTE includes upper and lower limb deep vein thrombosis (DVT) and pulmonary embolism (PE) diagnosed by accepted imaging tests, either after clinical suspicion or by routine screening. The secondary outcome will be the incidence of major bleeding during hospitalization among patients hospitalized for COVID-19. Definitions of major bleeding will be according to definitions in the individual studies. The outcomes data from the first available time point identified as a primary endpoint from each study will be incorporated into our primary analysis.

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Proportion of patients.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main

outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

None.

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

Not applicable.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Two authors will screen titles and abstracts, review full texts, extract data, and assess risk of bias independently, using standardized prepiloted forms. We will resolve disagreements by consensus. We will extract data for study design, setting, population characteristics, quantitative outcomes, study limitations, and other important comments. Two independent researchers (DJ and RLM) will perform the screening and data extraction with disagreements resolved by discussion within the wider team (PR, BB and MM).

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

We will use the Newcastle-Ottawa scale to rate risk of bias for comparative non-randomised studies corresponding to every study's design (cohort or cross-sectional). This assesses the representativeness of the sample, sample size, response rate, ascertainment of the exposure, control of confounding variables, assessment of preventability, and appropriate statistical analysis, which provides a score ranging from 0 (lowest grade) to 9 (highest grade). A higher grade indicates a lower risk of bias. The Begg rank correlation method will assess for publication bias.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

We will analyze pooled data on the incidence of VTE and major bleeding using a random-effects model approach. We will measure statistical heterogeneity between groups using the Cochran's Q statistic and the Higgins I^2 statistic. Conventionally, I^2 values of 25%, 50%, and 75% indicate low, moderate, and high heterogeneity, respectively.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

We will analyze data for subgroup effects by VTE type (i.e. DVT vs. PE), as well as setting (ward vs.

intensive care unit [ICU]), type of assessment for VTE (i.e. screening vs. clinical diagnosis), intensity of pharmacological thromboprophylaxis (no pharmacological thromboprophylaxis vs. standard-dose thromboprophylaxis vs. intermediate-dose thromboprophylaxis vs. therapeutic anticoagulation), and geographical area (North America vs. Europe vs. Rest of the World). A priori, another planned exploratory analysis will involve the incidence of outcomes in studies with a prospective design.The clinical significance of immunothrombosis in patients with COVID-19 is not yet clear. We, therefore, will also analyze the incidence of PE after excluding episodes of subsegmental PE.

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review

Cost effectiveness
No

Diagnostic
No

Epidemiologic
Yes

Individual patient data (IPD) meta-analysis
No

Intervention
No

Meta-analysis
Yes

Methodology
No

Narrative synthesis
No

Network meta-analysis
No

Pre-clinical
No

Prevention
No

Prognostic
No

Prospective meta-analysis (PMA)
No

Review of reviews
No

Service delivery
No

Synthesis of qualitative studies
No

Systematic review
Yes

Other

No

Health area of the review

Alcohol/substance misuse/abuse
No

Blood and immune system
No

Cancer
No

Cardiovascular
Yes

Care of the elderly
No

Child health
No

Complementary therapies
No

COVID-19
Yes

Crime and justice
No

Dental
No

Digestive system
No

Ear, nose and throat
No

Education
No

Endocrine and metabolic disorders
No

Eye disorders
No

General interest
No

Genetics
No

Health inequalities/health equity
No

Infections and infestations
No

International development
No

Mental health and behavioural conditions
No

Musculoskeletal
No

Neurological
No

Nursing

No

Obstetrics and gynaecology
No

Oral health
No

Palliative care
No

Perioperative care
No

Physiotherapy
No

Pregnancy and childbirth
No

Public health (including social determinants of health)
No

Rehabilitation
No

Respiratory disorders
No

Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Spain

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with

The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

COVID-19; coronavirus; venous thromboembolism; bleeding.

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.
Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

Comprehensive assessment of the thrombotic and hemorrhagic event rates is critical in thorough

assessment of the disease course for COVID-19 and for considering strategies to mitigate patient outcomes.

40. Details of final report/publication(s) or preprints if available.

This field should be left empty until details of the completed review are available OR you have a link to a preprint.

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International prospective register of systematic reviews

NHS
National Institute for
Health Research

Give the link to the published review.

e-Table 1. MOOSE checklist for meta-analyses of observational studies (50)

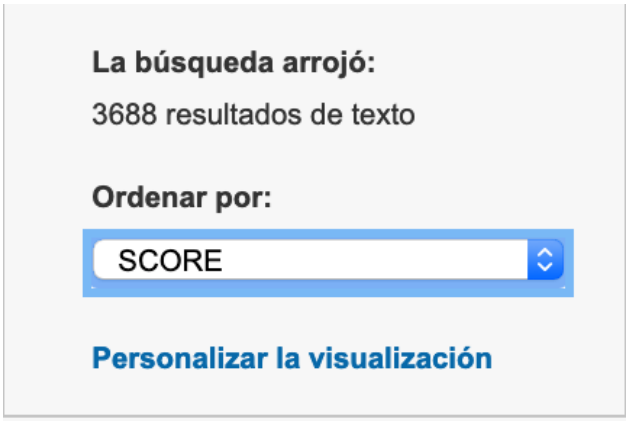
Item No	Recommendation	Reported on Page No
Reporting of background should include		
1	Problem definition	6, 7
2	Hypothesis statement	-
3	Description of study outcome(s)	6, 7
4	Type of exposure or intervention used	6, 7
5	Type of study designs used	6, 7
6	Study population	6, 7
Reporting of search strategy should include		
7	Qualifications of searchers (eg, librarians and investigators)	7
8	Search strategy, including time period included in the synthesis and key words	7
9	Effort to include all available studies, including contact with authors	7
10	Databases and registries searched	7
11	Search software used, name and version, including special features used (eg, explosion)	-
12	Use of hand searching (eg, reference lists of obtained articles)	7
13	List of citations located and those excluded, including justification	9 Fig 1
14	Method of addressing articles published in languages other than English	-
15	Method of handling abstracts and unpublished studies	7
16	Description of any contact with authors	7
Reporting of methods should include		
17	Description of relevance or appropriateness of studies assembled for assessing the hypothesis to be tested	7, 8
18	Rationale for the selection and coding of data (eg, sound clinical principles or convenience)	7, 8
19	Documentation of how data were classified and coded (eg, multiple raters, blinding and interrater reliability)	7, 8
20	Assessment of confounding (eg, comparability of cases and controls in studies where appropriate)	-
21	Assessment of study quality, including blinding of quality assessors, stratification or regression on possible predictors of study results	8
22	Assessment of heterogeneity	8
23	Description of statistical methods (eg, complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose-response models, or cumulative meta-analysis) in sufficient detail to be replicated	8, 9
24	Provision of appropriate tables and graphics	Tables 1-2, Figs 1-3

Reporting of results should include		
25	Graphic summarizing individual study estimates and overall estimate	Figs 2, 3 Appendixes 7, 9
26	Table giving descriptive information for each study included	Table 2 Appendix 4
27	Results of sensitivity testing (eg, subgroup analysis)	11-13 Appendixes 7-9
28	Indication of statistical uncertainty of findings	10-13

e-Appendix 2. Search strategies

MEDLINE

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND (2019/12[PDAT]:2030[PDAT]) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))



Pubmed

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND (2019/12[PDAT]:2030[PDAT]) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))

History and Search Details

Download Delete

Search	Actions	Details	Query	Results	Time
#6	···	›	Search: **#1 OR #2 OR #3 AND #4 AND #5** Sort by: **Most Recent**	3,691	00:50:14
#5	···	›	Search: **((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))** Sort by: **Most Recent**	5,265,486	00:49:02
#4	···	›	Search: **2019/12[PDAT]:2030[PDAT]** Sort by: **Most Recent**	1,059,872	00:48:19
#3	···	›	Search: **((2019) AND (novel)) AND (coronavirus)** Sort by: **Most Recent**	3,043	00:47:38
#2	···	›	Search: **(wuhan) AND (coronavirus)** Sort by: **Most Recent**	2,951	00:46:54
#1	···	›	Search: **(((2019-nCoV) OR (2019-nCoV)) OR (COVID-19)) OR (SARS-CoV-2)** Sort by: **Most Recent**	36,312	00:46:19

EMBASE

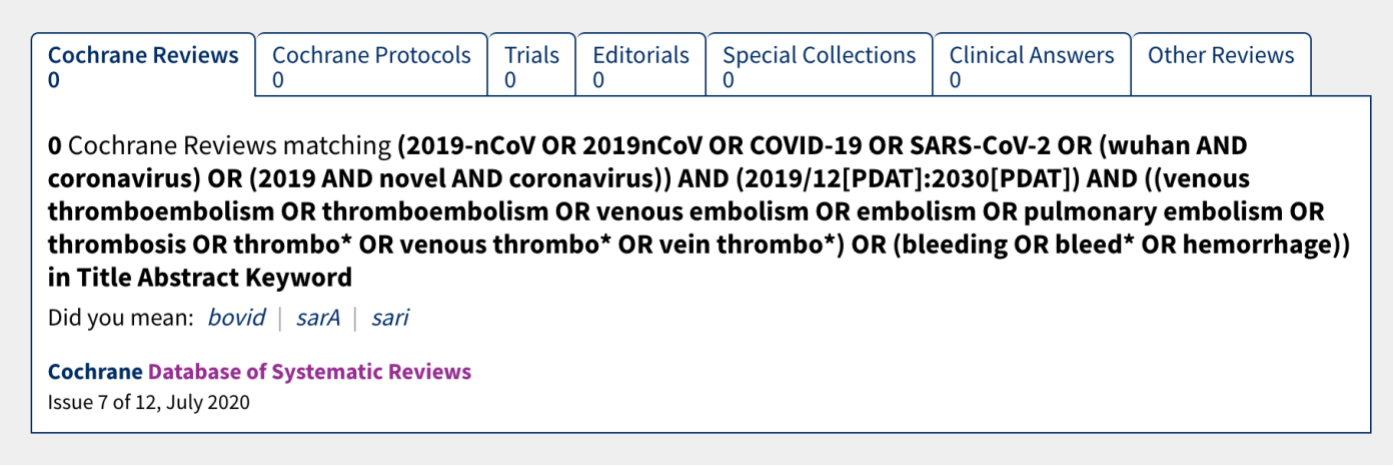
(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))

CINAHL

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))

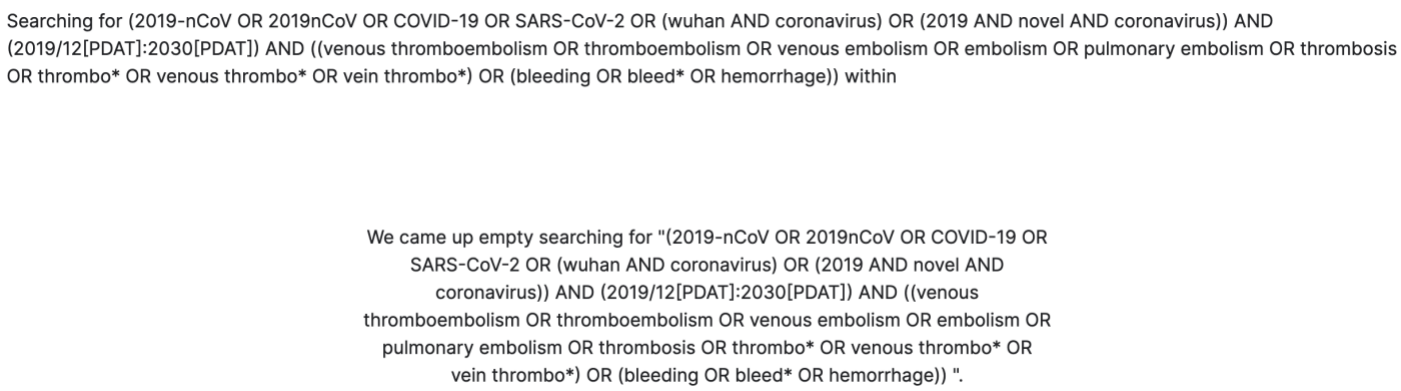
Cochrane Library

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND (2019/12[PDAT]:2030[PDAT]) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))



COVID-19 Open Research Dataset Challenge

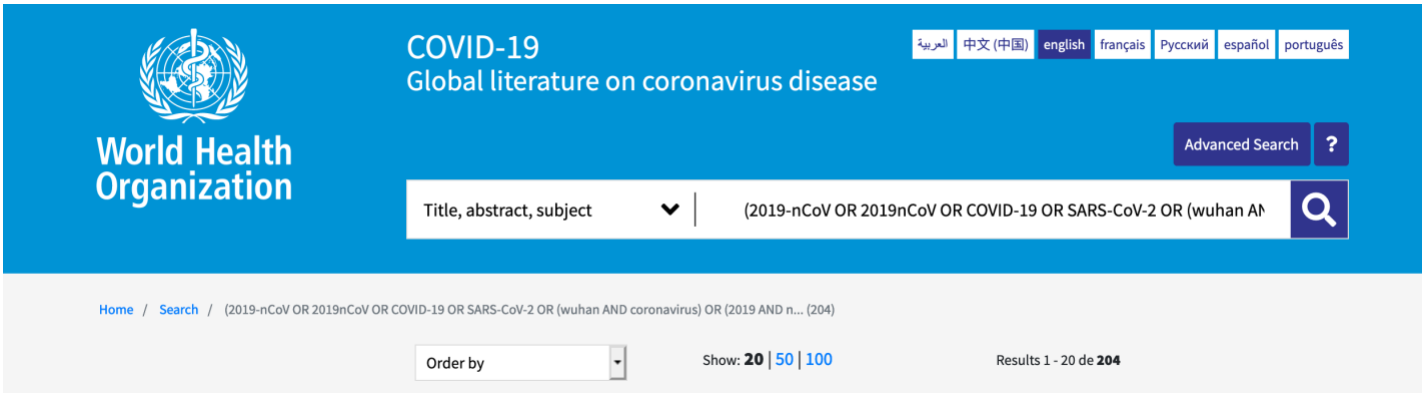
(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND (2019/12[PDAT]:2030[PDAT]) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))



CHEST™ Online Supplement

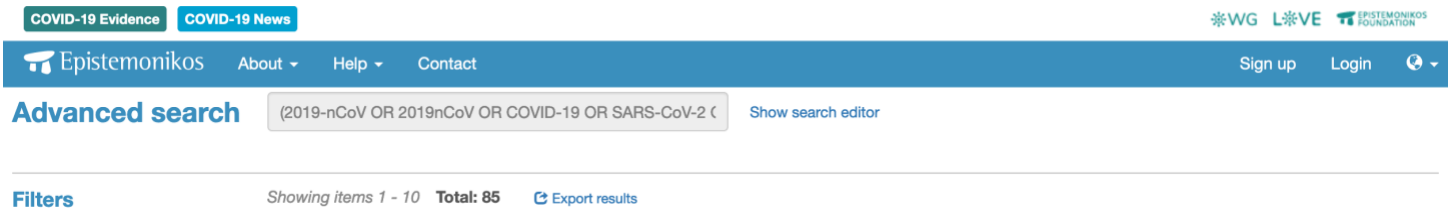
COVID-19 Research Database (WHO)

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND (2019/12[PDAT]:2030[PDAT]) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))



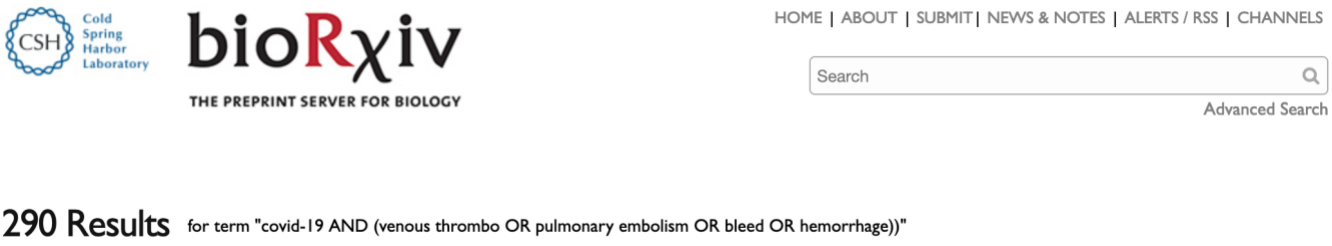
Epistemonikos (COVID-19 Living Overview of the Evidence platform)

(2019-nCoV OR 2019nCoV OR COVID-19 OR SARS-CoV-2 OR (wuhan AND coronavirus) OR (2019 AND novel AND coronavirus)) AND ((venous thromboembolism OR thromboembolism OR venous embolism OR embolism OR pulmonary embolism OR thrombosis OR thrombo* OR venous thrombo* OR vein thrombo*) OR (bleeding OR bleed* OR hemorrhage))



bioRxiv

COVID-19 AND (venous thrombo OR pulmonary embolism OR bleed OR hemorrhage)



e-Table 2. Detailed characteristics of included studies

Study	Continent	n	Age, y	Cancer, %	History of VTE, %	Follow-up, d	VTE, n (%)	Incidence of DVT, % (% of IDDVT/CAT)	Incidence of PE, % (% of ISSPE)	Bleeding, n (%)	Major bleeding, n (%)
Al-Samkari et al (1)	North America	400 Male: 228 Female:172	Ward: 60 (23-99) ICU: 65 (32-97)	-	-	6-9	19 (4.8)	2.3 (22.2)	2.5 (10.0)	19 (4.8)	9 (2.3)
Artifoni et al (2)	Europe	71 Male: 43 Female: 28	64 (46-75)	6	7	13	16 (22.5)	12.7 (77.8)	9.9	-	-
Beun et al (3)	Europe	75 Male: - Female: -	61 (53-68)	-	-	-	23 (30.7)	4.0	26.7 (80.0)	-	-
Bilaloglu et al (4)	North America	3334 Male: 2014 Female: 1320	64 (51-75)	-	-	-	235 (7.0)	3.9	3.2	-	-
Cattaneo et al (5)	Europe	388 Male: - Female: -	70 (58-78)	10.0	0	-	0 (0)	0	-	-	-
Chen J et al (6)	Asia	1008 Male: - Female: -	-	-	-	-	10 (1.0)	-	1.0	-	-
Chen S et al (7)	Asia	88 Male: 54 Female: 34	63 (55-71)	6	-	>7	40 (45.5)	45.5 (80.0)	-	-	-
Criel et al (8)	Europe	82 Male: 48 Female: 34	Ward: 63.6 ± 14.4 ICU: 64.5 ± 11.8	-	-	-	6 (7.3)	7.3	-	-	-
Cui et al (9)	Asia	81 Male: 37 Female: 44	59.9 ± 14.1	-	-	-	20 (24.7)	24.7	0	-	-

Demelo-Rodriguez et al (10)	Europe	156 Male: 102 Female: 54	68.1 ± 14.5	10.3	1.3	9	23 (14.7)	14.7 (95.7)	-	-	-
Desborough et al (11)	Europe	66 Male: 48 Female: 18	59 (49-66)	7.6	-	9	11 (16.7)	9.1 (100)	7.6 (20.0)	-	-
Dubois-Silva et al (12)	Europe	171 Male: - Female: -	-	-	-	-	8 (4.7)	-	4.7 (37.5)	-	-
Fauvel et al (13)	Europe	2878 Male: - Female: -	-	-	-	-	103 (3.6)	-	3.6	-	-
Fraisse et al (14)	Europe	92 Male: 73 Female: 19	61 (55-70)	-	5	9	31 (33.7)	6.5	27.2	-	-
Grandmaison et al (15)	Europe	58 Male: - Female: -	-	-	-	-	23 (39.7)	32.8 (21.1)	6.9	-	-
Grillet et al (16)	Europe	280 Male: - Female: -	-	-	-	-	23 (8.2)	-	8.2	-	-
Hekimian et al (17)	Europe	51 Male: - Female: -	-	-	-	-	8 (15.7)	-	15.7	-	-
Helms et al (18)	Europe	150 Male: 122 Female: 28	63 (53-71)	6.0	5.3	7-30	28 (18.7)	2.0	16.7 (12.0)	4 (2.7)	4 (2.7)
Hippensteel et al (19)	United States	91 Male: 53 Female: 38	-	3.3	-	-	24 (26.4)	20.9 (42.1)	5.5	-	-
Klok et al (20)	Europe	184 Male: 140 Female: 44	64 ± 12	2.7	-	7	28 (15.2)	1.6 (66.7)	13.6 (28.0)	-	-
Klok et al (21)	Europe	184 Male: 140 Female: 44	64 ± 12	2.7	-	14	68 (37.0)	1.6	35.3	-	-

Koleilat et al (22)	United States	3404 Male: - Female: -	-	-	-	-	18 (0.5)	0.5	-	-	-
Llitjos et al (23)	Europe	26 Male: 20 Female: 6	68 (52-75)	0	4	-	18 (69.2)	69.2	-	-	-
Lodigiani et al (24)	Europe	388 Male: 264 Female: 124	66 (55-75)	6.4	3.1	18	16 (4.1)	1.5 (16.7)	2.6 (10.0)	-	-
Longchamp et al (25)	Europe	25 Male: 16 Female: 9	68 ± 11	8	0	5-10	14 (56.0)	24.0	32.0	-	-
Maatman et al (26)	North America	109 Male: 62 Female: 47	61 ± 16	-	-	36-55	29 (26.6)	23.9 (3.8)	2.8	-	-
Mazzaccaro et al (27)	Europe	32 Male: 23 Female: 9	68.6 ± 12	-	-	-	21 (65.6)	0	65.6 (34.5)	-	-
Mei et al (28)	Asia	256 Male: 131 Female: 125	55.5 (0.5-87)	1.6	0	28	5 (2.0)	1.6	0.4	-	-
Mestre-Gomez et al (29)	Europe	452 Male: - Female: -	-	-	-	-	29 (6.4)	-	6.4 (69.0)	-	-
Middeldorp et al (30)	Europe	198 Male: 130 Female: 68	61 ± 14	3.5	5.6	7	39 (19.7)	13.1 (42.3)	6.6 (15.4)	-	-
Minuz et al (31)	Europe	10 Male: - Female: -	-	-	-	7	6 (60.0)	-	60.0	-	-
Moll et al (32)	North America	210 Male: 101 Female: 109	62.2 ± 16.2	24.2	4.3	7	9 (4.3)	3.3	1.0	-	-

Nahum et al (33)	Europe	34 Male: 25 Female: 9	62.2 ± 8.6	3	-	2	22 (64.7)	64.7 (63.6)	-	-	-
Patell et al (34)	North America	399 Male: 210 Female: 189	-	-	-	9	22 (5.5)	3.8 (40.0)	1.8	86 (21.6)	45 (11.3)
Pesavento et al (35)	Europe	324 Male: 181 Female: 143	71 (59-82)	-	-	12-17	-	-	-	33 (10.2)	16 (4.9)
Poissy et al (36)	Europe	107 Male: - Female: -	-	-	-	6	22 (20.6)	-	20.6	-	-
Ren et al (37)	Asia	48 Male: 26 Female: 22	70 (62-80)	-	-	-	41 (85.4)	85.4 (90.2)	-	-	-
Rieder et al (38)	Europe	49 Male: 30 Female: 19	60 ± 23	22.4	12.2	10	2 (4.1)	-	4.1	-	-
Santoliquido et al (39)	Europe	84 Male: 61 Female: 23	67.6 ± 13.5	16.7	3.6	24	10 (11.9)	11.9 (80.0)	-	-	-
Stoneham et al (40)	Europe	274 Male: - Female: -	-	-	-	-	21 (7.7)	1.8	5.8	-	-
Tavazzi et al (41)	Europe	54 Male: - Female: -	-	-	-	-	10 (18.5)	14.8 (75.0)	3.7 (100)	-	-
Thomas et al (42)	Europe	63 Male: 44 Female: 19	-	2	2	8	6 (9.5)	1.6 (100)	7.9 (20.0)	-	-
Trimaille et al (43)	Europe	289 Male: 171 Female: 118	62.2 ± 17	-	-	12	49 (17.0)	4.2	14.5*	-	-

Voicu et al (44)	Europe	56 Male: 42 Female: 14	-	-	0	14	20 (35.7)	35.7 (45.0)	-	-	-
Whyte et al (45)	Europe	1477 Male: - Female: -	-	-	-	-	80 (5.4)	-	5.4	-	-
Wright et al (46)	North America	44 Male: 28 Female: 16	54 (42-59)	-	-	-	11 (25.0)	-	-	-	-
Xu et al (47)	Asia	138 Male: 81 Female: 57	52.4 ± 16.7	2.9	-	18	4 (2.9)	2.9	0	6 (4.3)	1 (0.7)
Zerwes et al (48)	Europe	20 Male: 14 Female: 6	63.7 ± 14.3	-	-	-	4 (20.0)	20.0	-	-	-
Zhang et al (49)	Asia	143 Male: 74 Female: 69	63 ± 14	4.9	0.7	-	66 (46.2)	46.2	-	-	-

*Five patients had pulmonary embolism and concomitant deep vein thrombosis.

Abbreviations: ICU, intensive care unit; NA, VTE, venous thromboembolism; DVT, deep vein thrombosis; PE, pulmonary embolism; IDDVT, isolated distal deep vein thrombosis; CAT, catheter-associated thrombosis; ISSPE, isolated subsegmental pulmonary embolism.

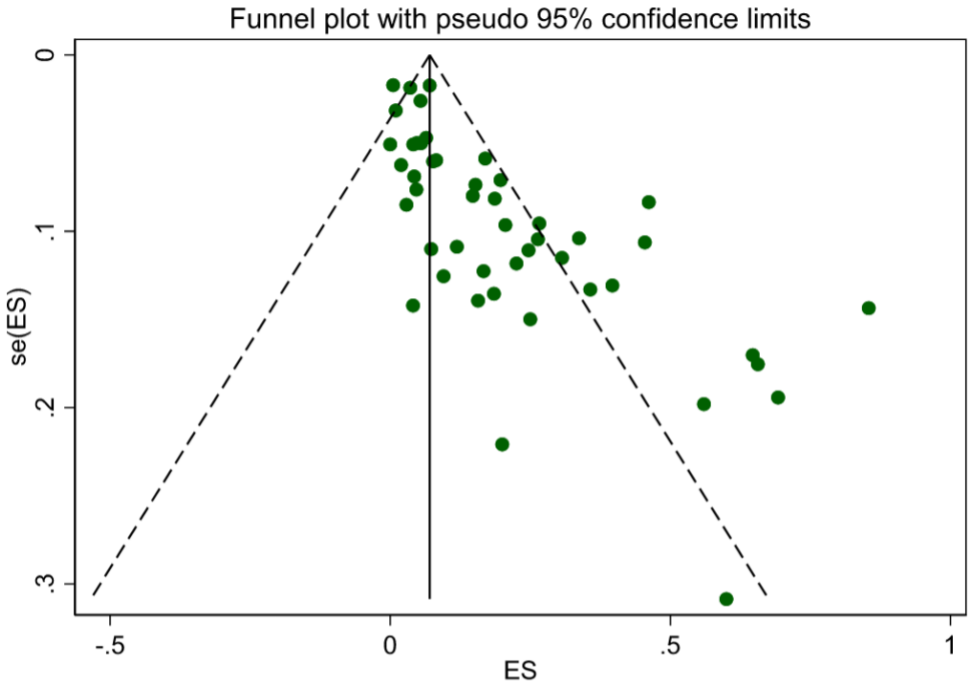
e-Table 3. Risk of bias assessment (Newcastle-Ottawa for non-randomized studies)

Study	Selection	Comparability	Outcome	Total score
Al-Samkari et al (1)	3	2	3	8
Artifoni et al (2)	4	2	3	9
Beun et al (3)	3	1	2	6
Bilaloglu et al (4)	3	2	2	7
Cattaneo et al (5)	4	2	2	8
Chen J et al (6)	3	2	2	7
Chen S et al (7)	3	2	3	8
Criel et al (8)	3	1	3	7
Cui et al (9)	3	1	2	6
Demelo-Rodriguez et al (10)	3	2	3	8
Desborough et al (11)	3	2	3	8
Dubois-Silva et al (12)	4	2	3	9
Fauvel et al (13)	4	2	2	8
Fraisse et al (14)	3	2	3	8
Grandmaison et al (15)	3	2	3	8
Grillet et al (16)	3	1	2	6
Hekimian et al (17)	3	0	2	5
Helms et al (18)	4	2	3	9
Hippensteel et al (19)	3	2	2	7
Klok et al (20)	3	1	3	7
Klok et al (21)	3	1	3	7
Koleilat et al (22)	3	2	2	7
Llitjos et al (23)	4	2	2	8
Lodigiani et al (24)	4	2	3	9
Longchamp et al (25)	4	2	3	9
Maatman et al (26)	4	2	3	9
Mazzaccaro et al (27)	4	1	2	7
Mei et al (28)	4	2	3	9

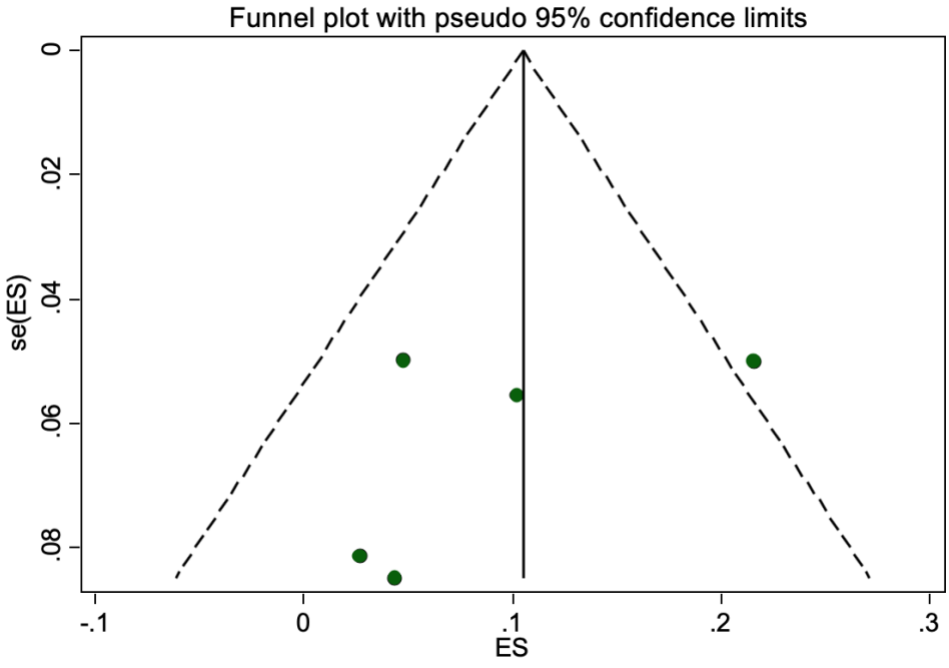
Mestre-Gomez et al (29)	3	0	2	5
Middeldorp et al (30)	4	2	3	9
Minuz et al (31)	3	1	3	7
Moll et al (32)	3	2	3	8
Nahum et al (33)	4	2	2	8
Patell et al (34)	4	2	3	9
Pesavento et al (35)	4	2	3	9
Poissy et al (36)	3	0	3	6
Ren et al (37)	3	1	3	7
Rieder et al (38)	3	2	3	8
Santoliquido et al (39)	4	2	3	9
Stoneham et al (40)	3	0	2	5
Tavazzi et al (41)	3	0	2	5
Thomas et al (42)	3	2	3	8
Trimaille et al (43)	4	1	3	8
Voicu et al (44)	4	1	3	8
Whyte et al (45)	3	2	2	7
Wright et al (46)	2	0	2	4
Xu et al (47)	3	2	3	8
Zerwes et al (48)	3	1	2	6
Zhang et al (49)	3	2	3	8

e-Figure 1. Funnel plots

a) VTE

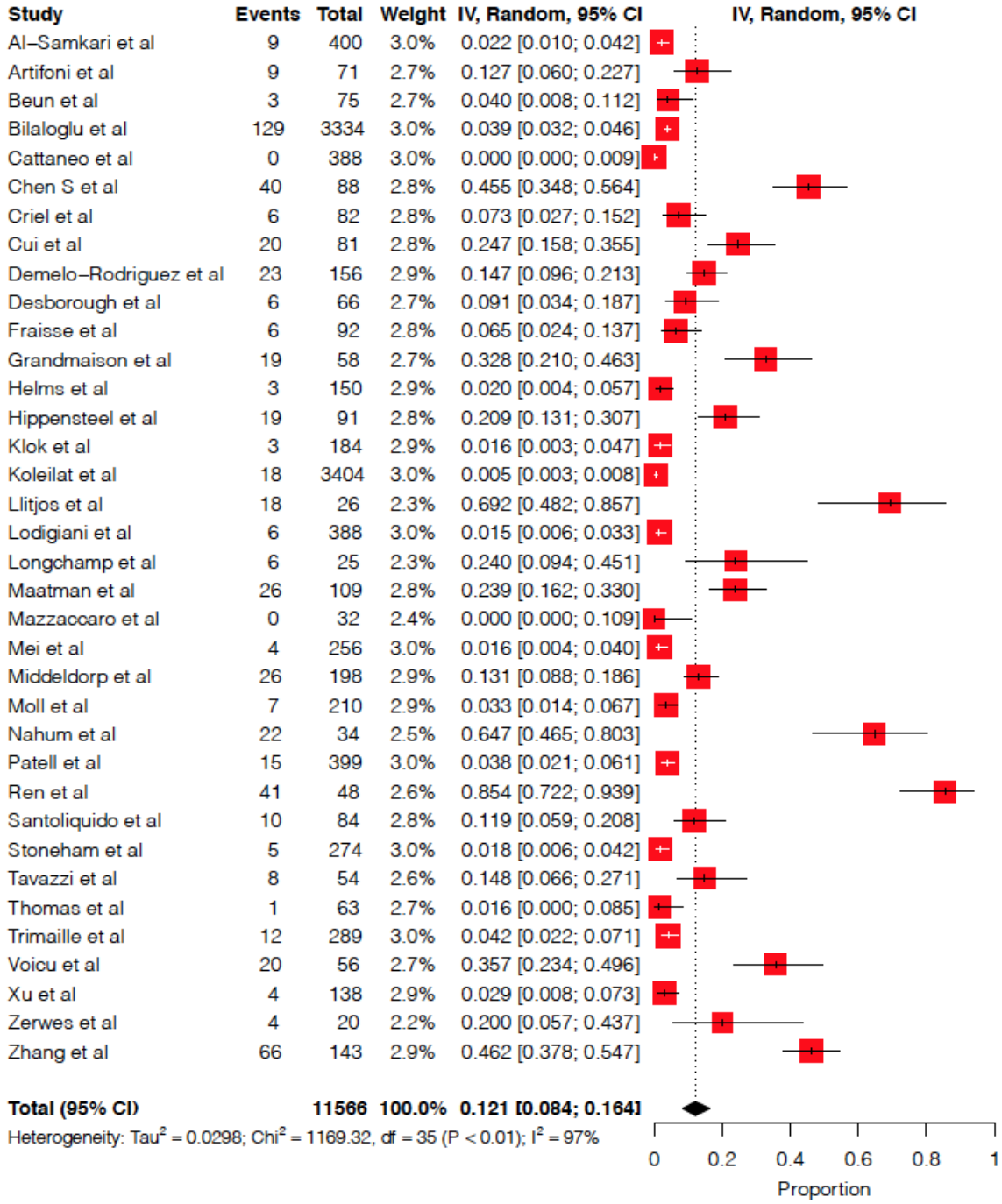


b) Bleeding

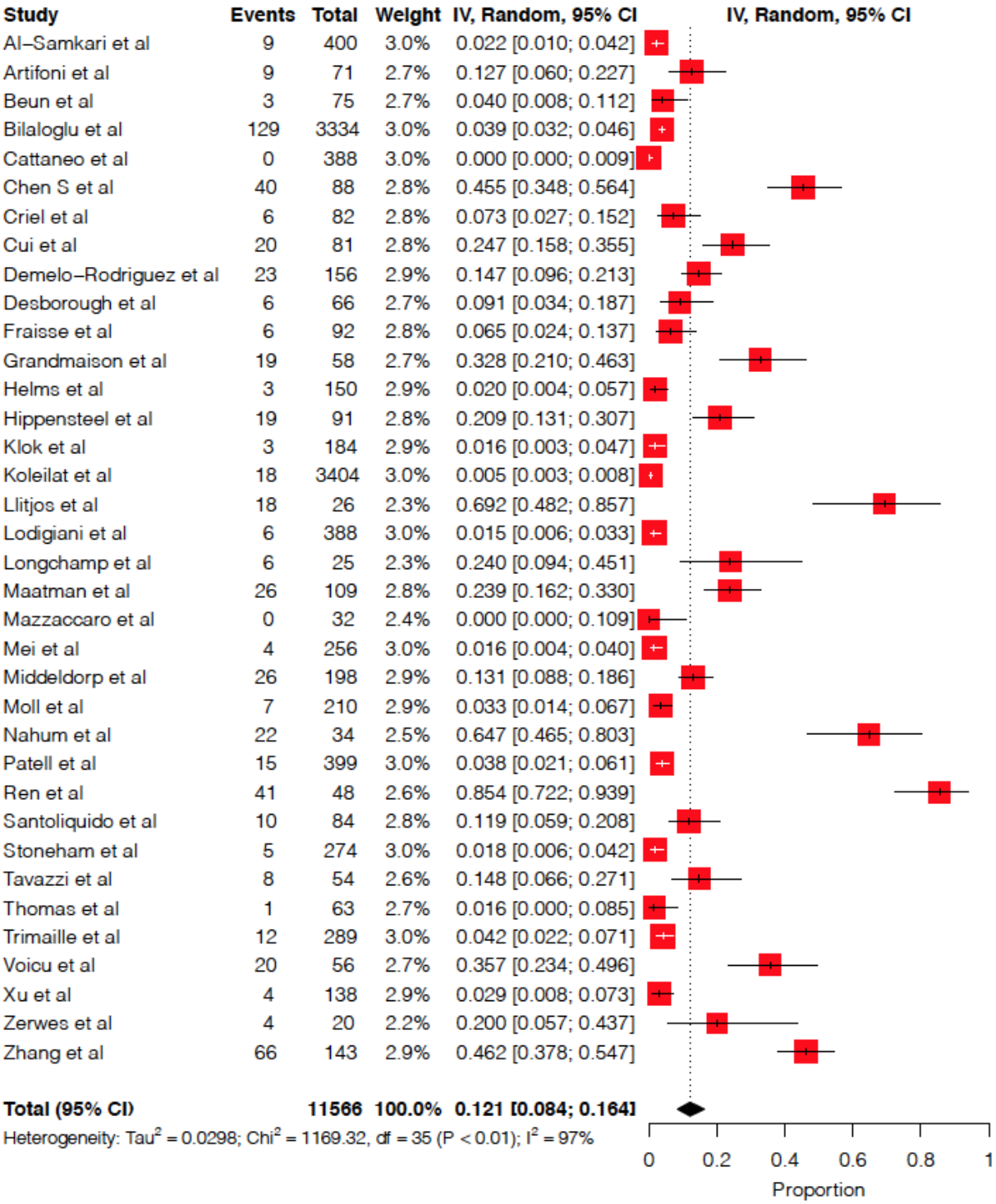


e-Figure 2. Forest plots for additional analyses
a) VTE: type

DVT

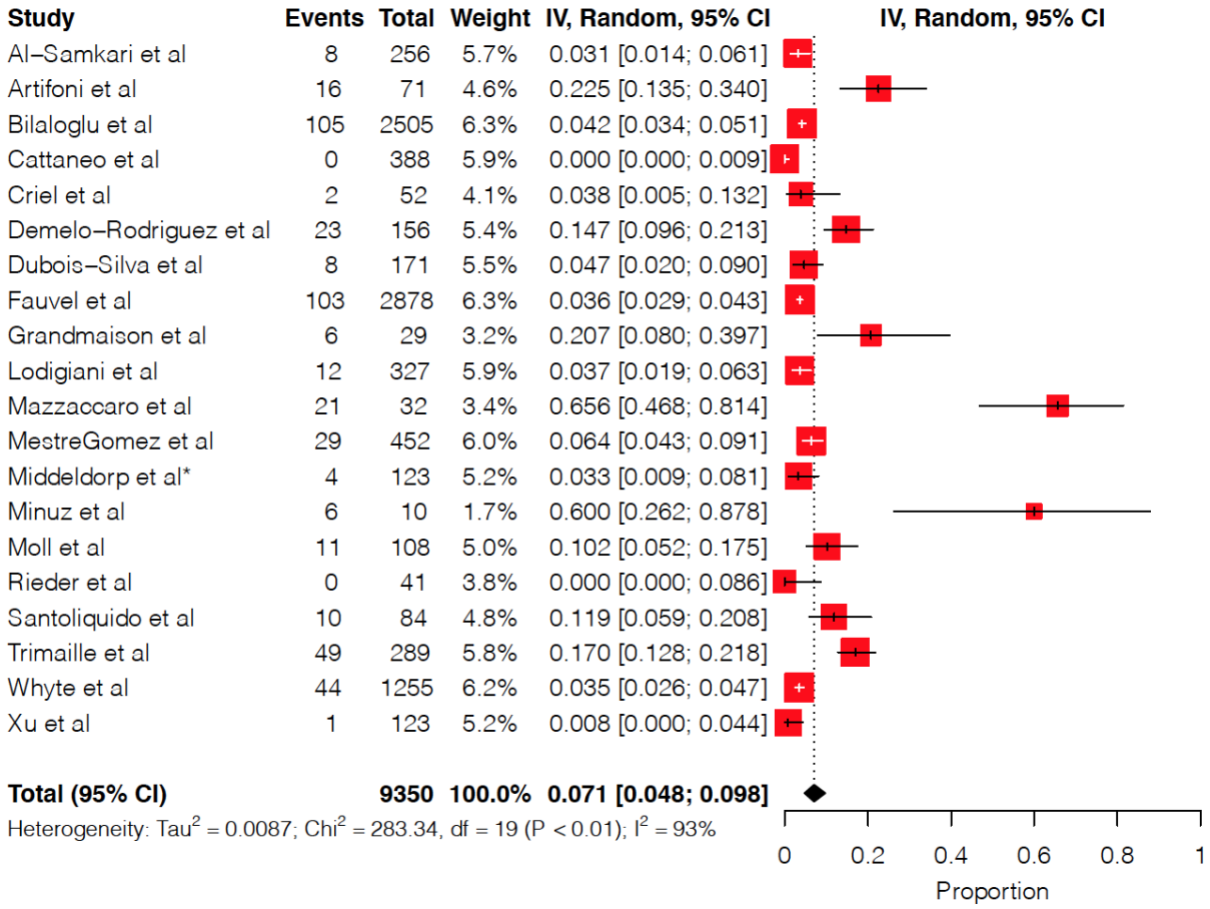


PE



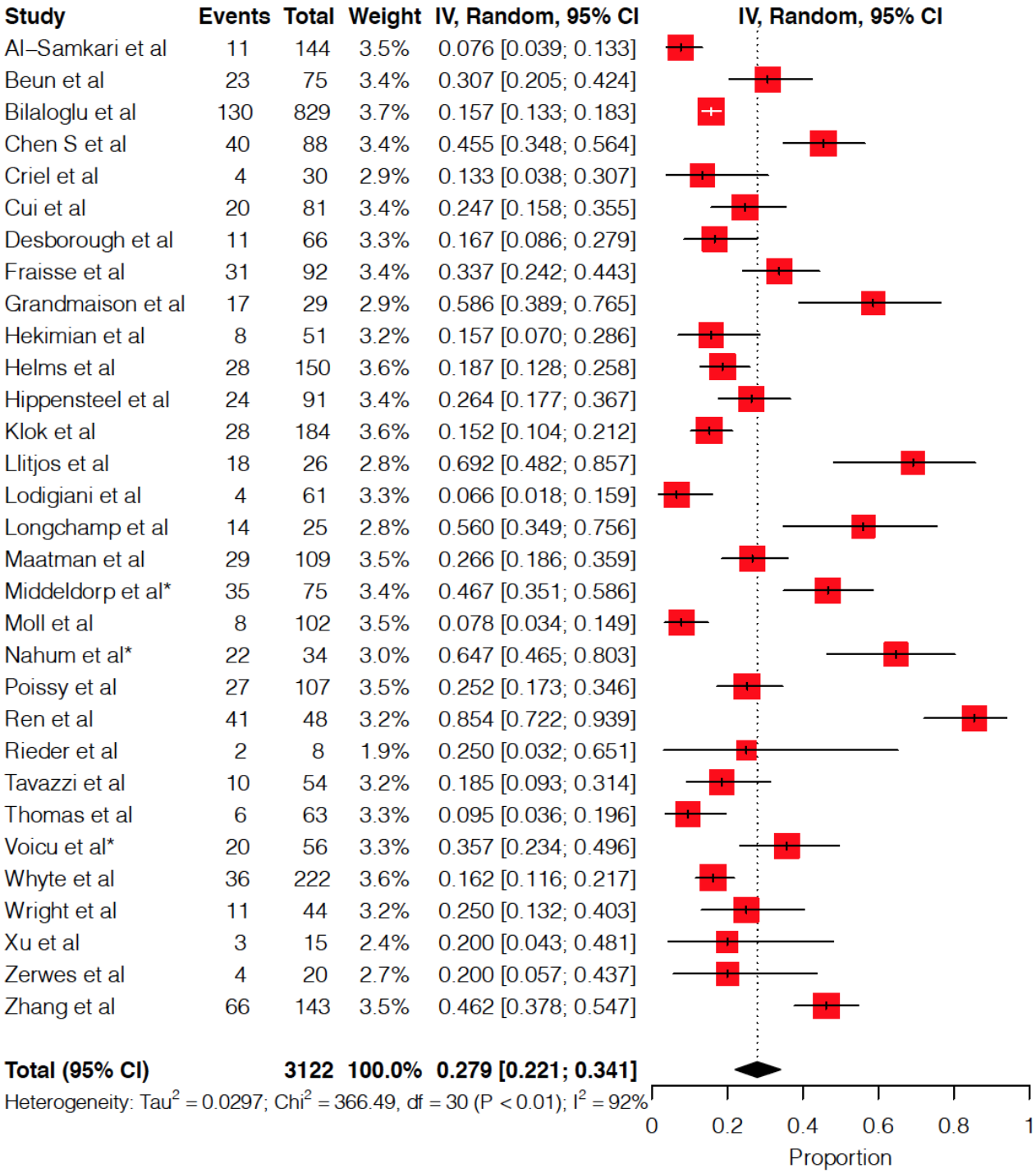
b) VTE: Setting

Ward



*Shortest assessment period.

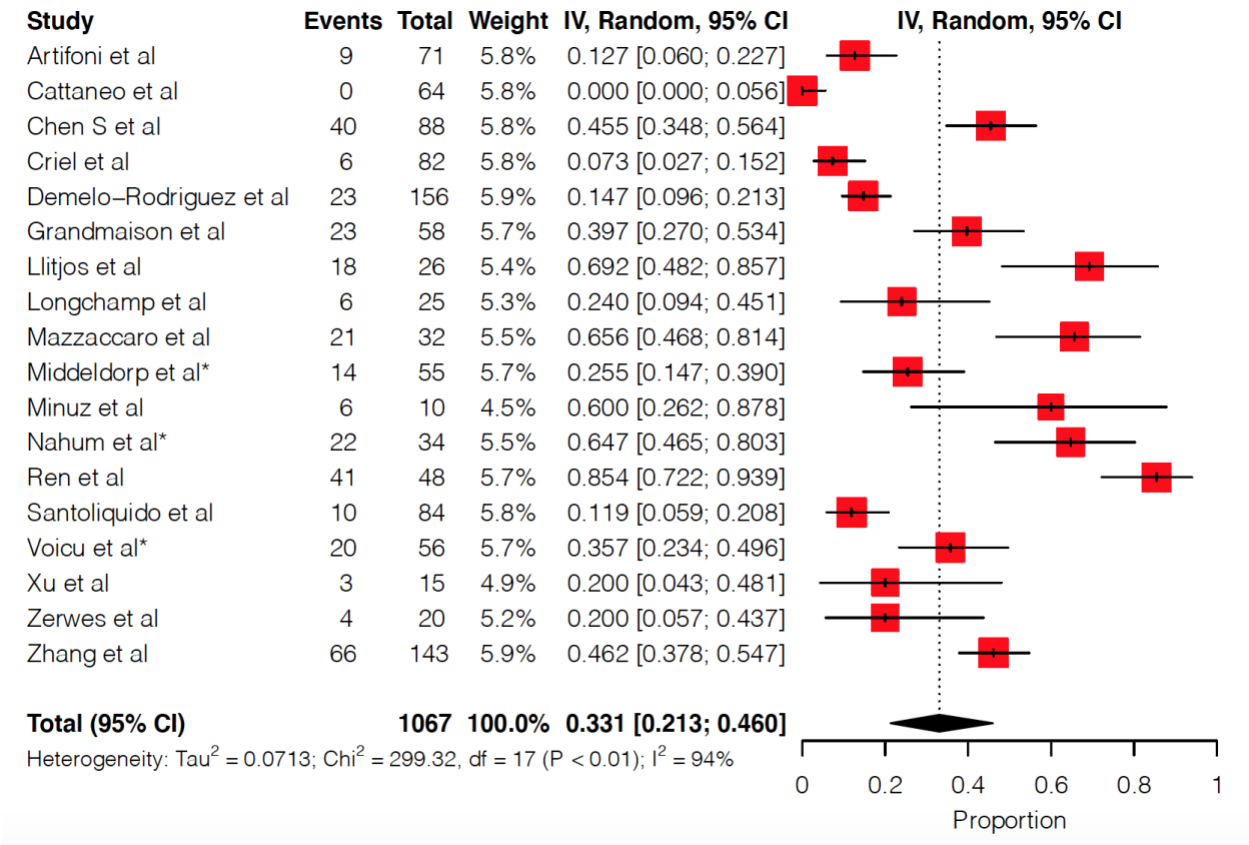
ICU



*Shortest assessment period.

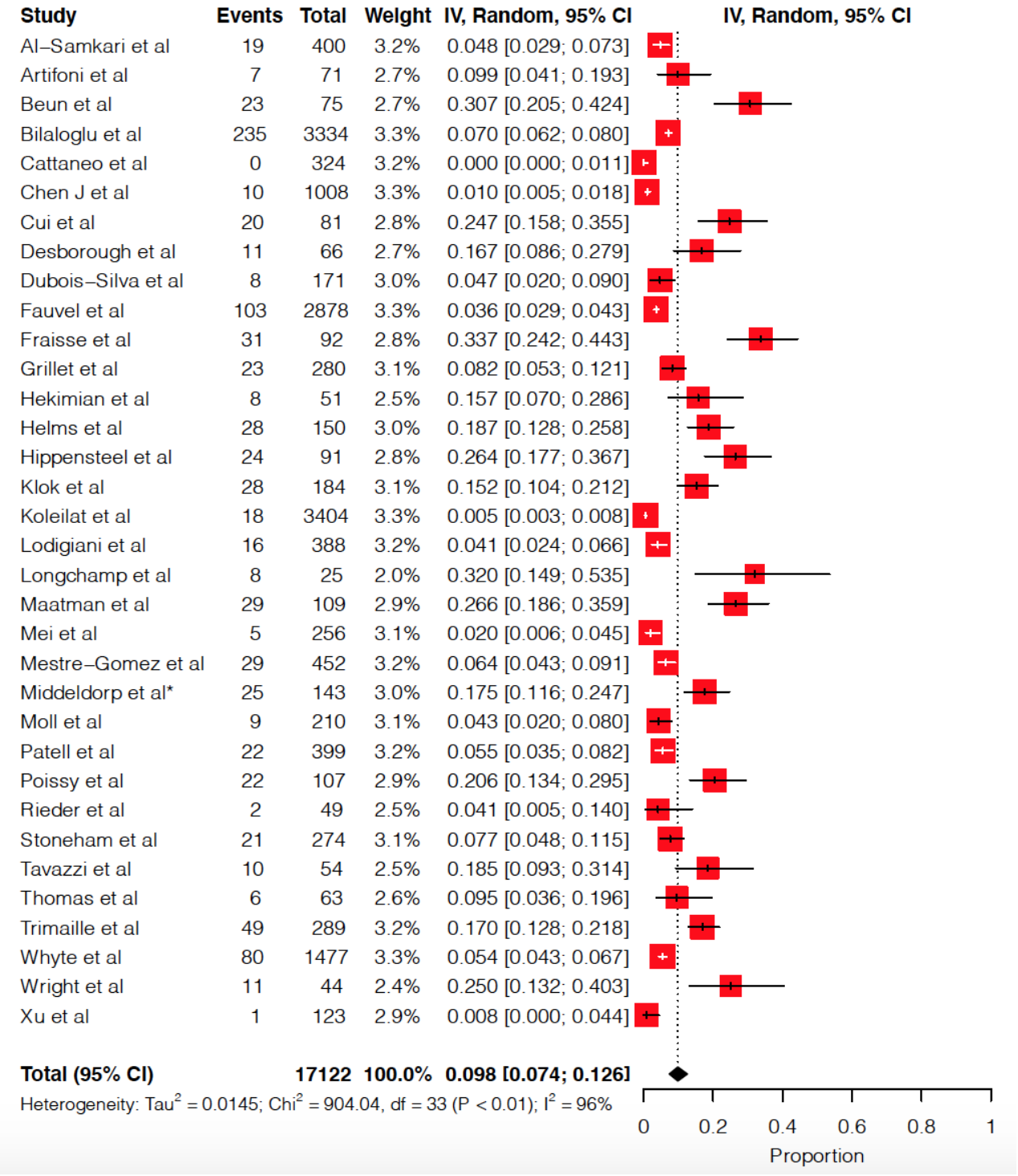
c) VTE: Type of assessment

Screening



*Shortest assessment period.

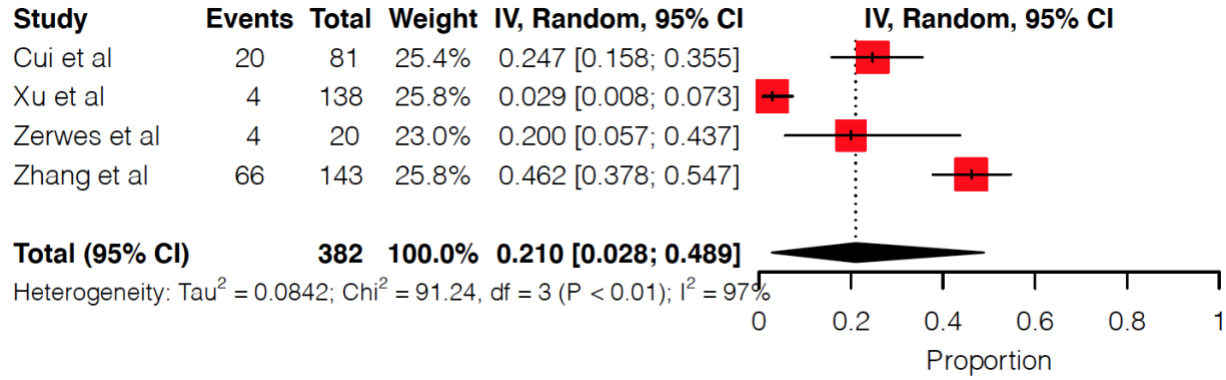
Clinical diagnosis



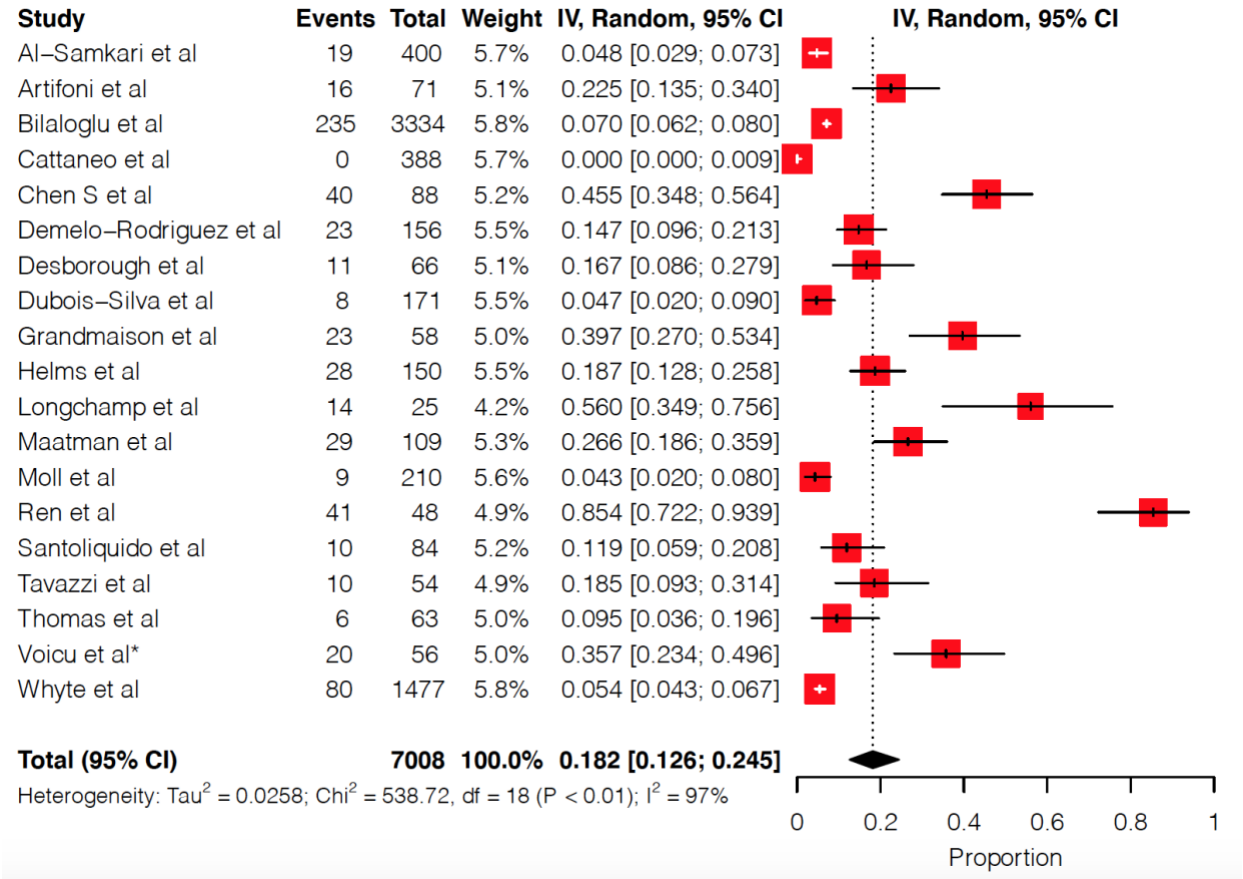
*Shortest assessment period.

d) VTE: Intensity of pharmacological thromboprophylaxis

No prophylaxis

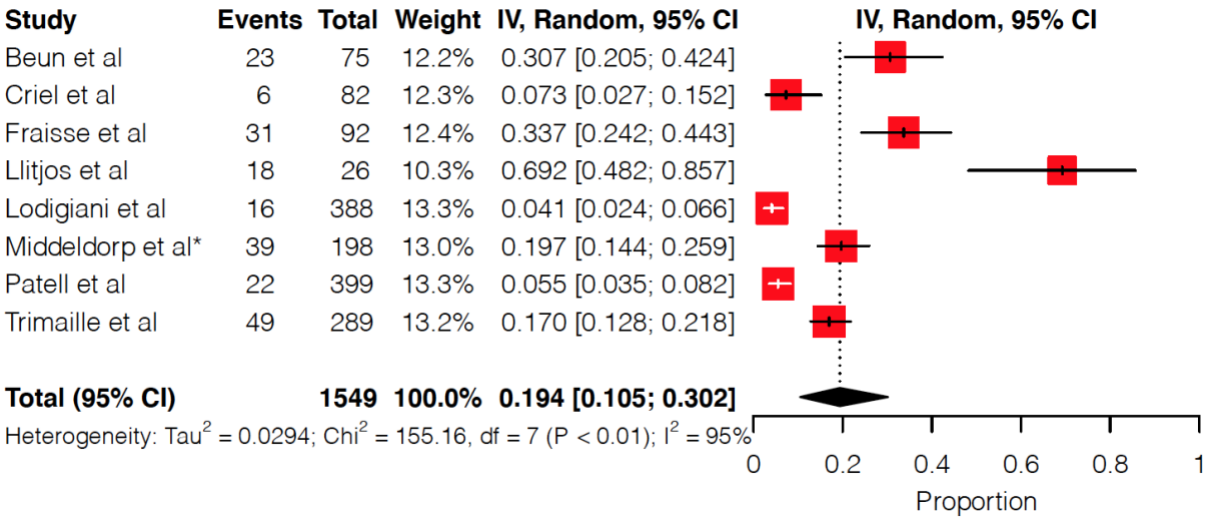


Standard dose prophylaxis



*Shortest assessment period.

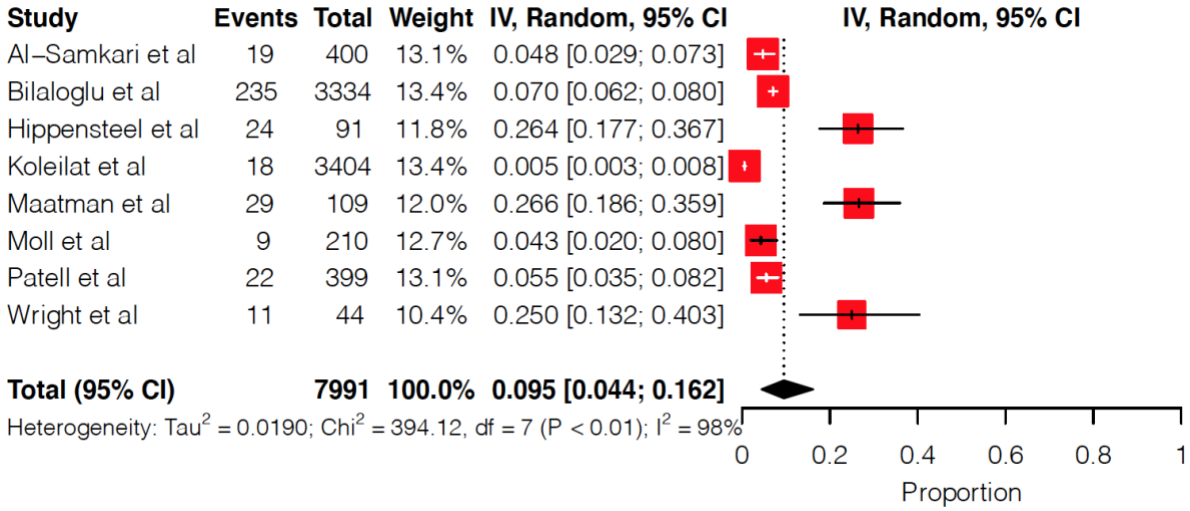
Intermediate dose or full anticoagulation



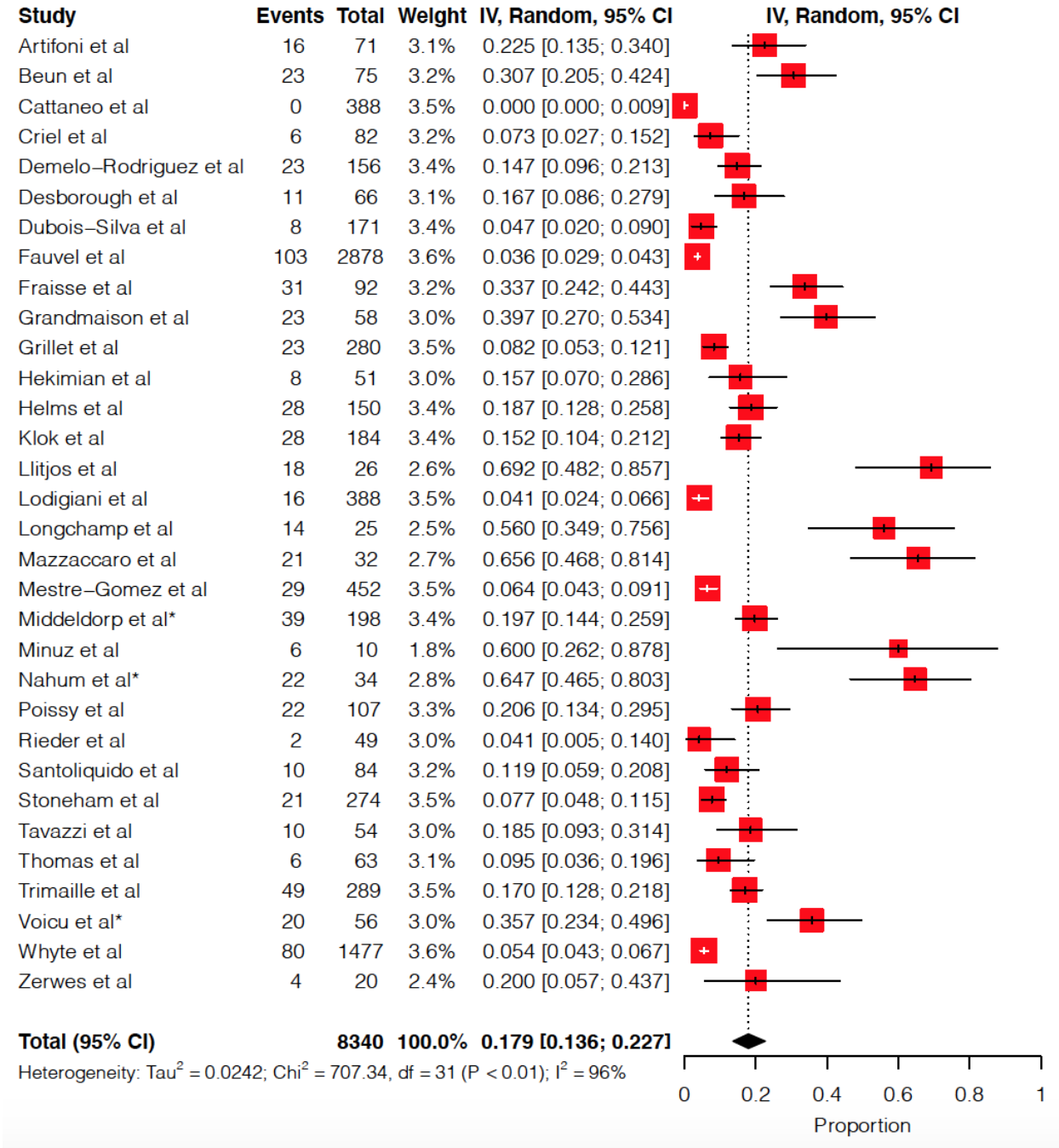
*Shortest assessment period.

e) VTE: Geographical area

North America

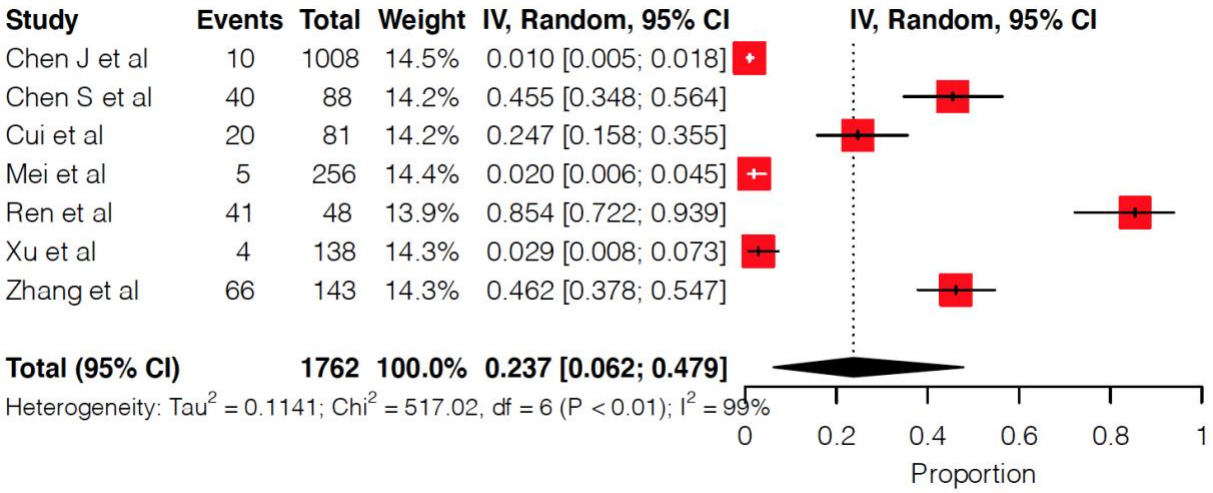


Europe



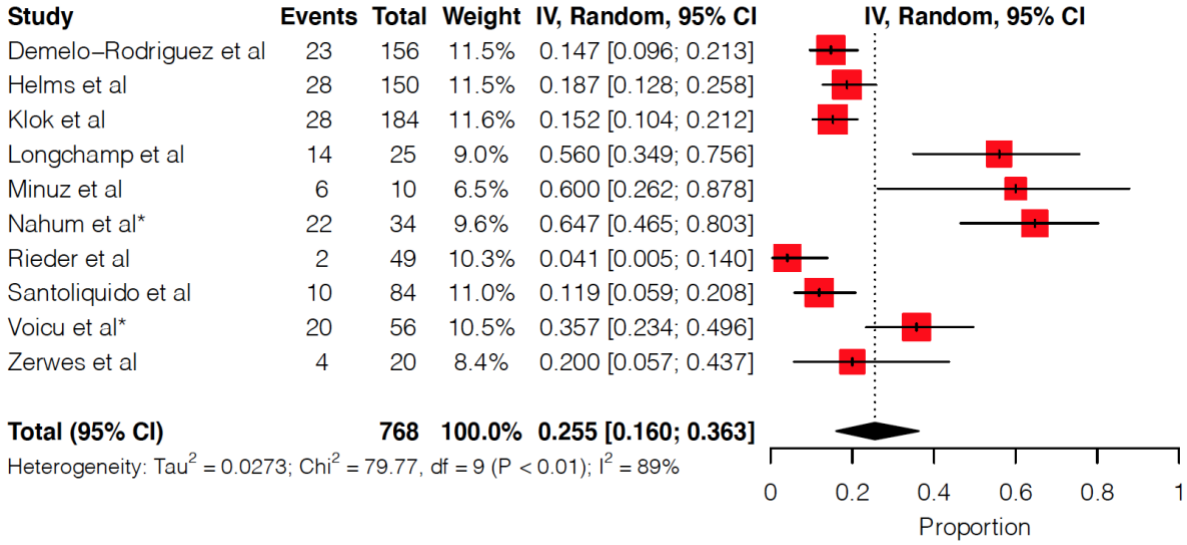
*Shortest assessment period.

Rest of World



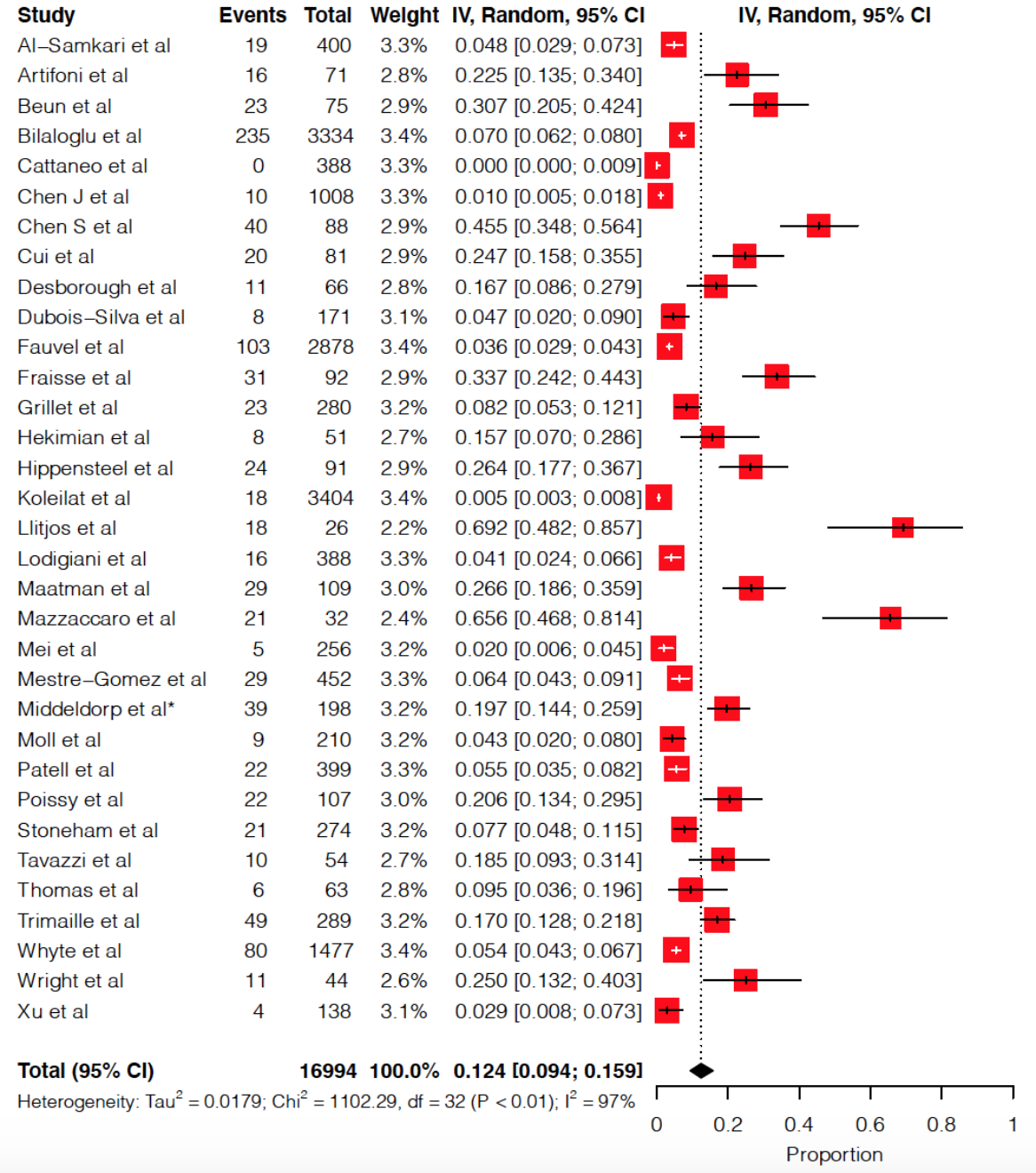
f) VTE: Design

Prospective



*Shortest assessment period.

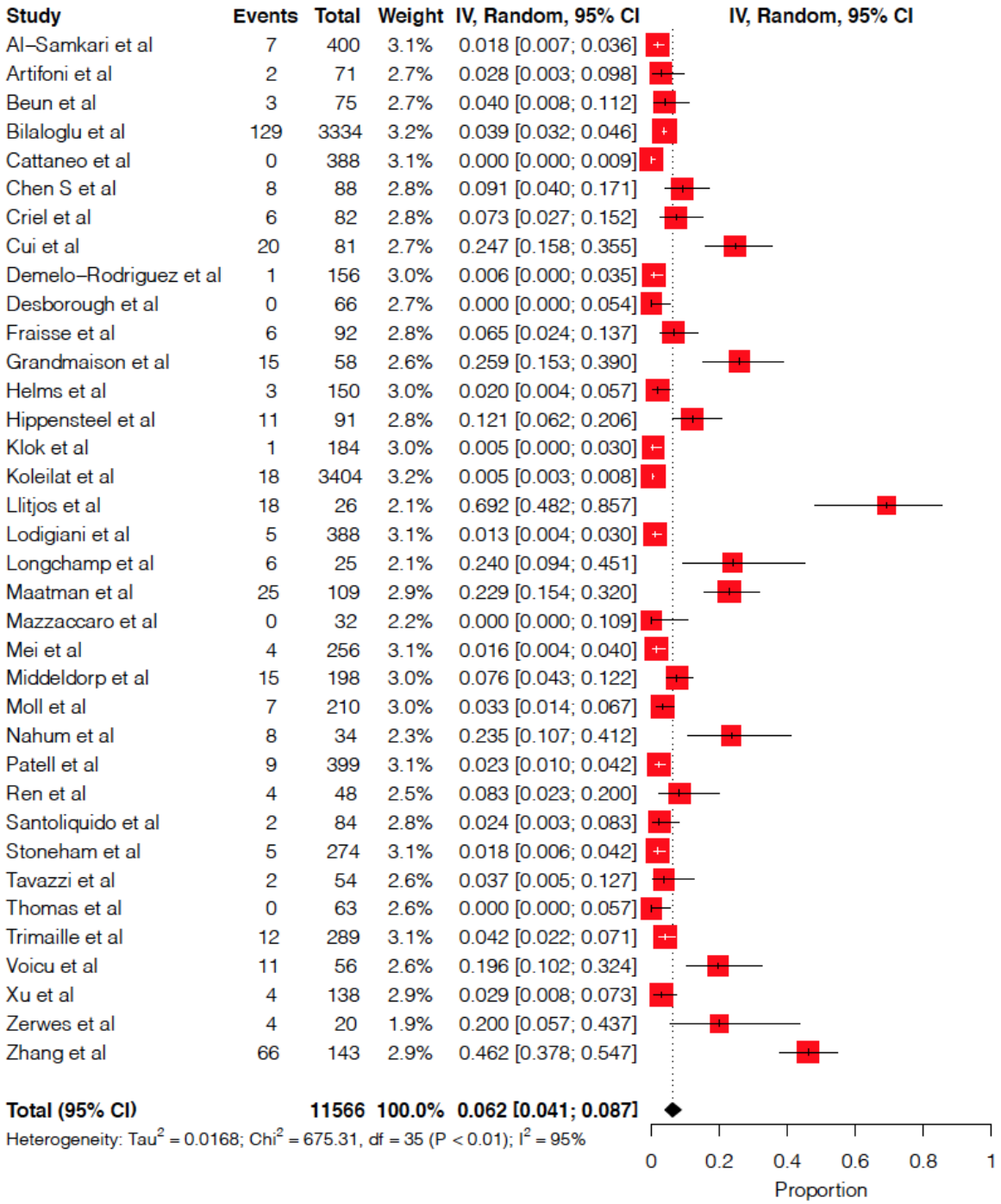
Retrospective



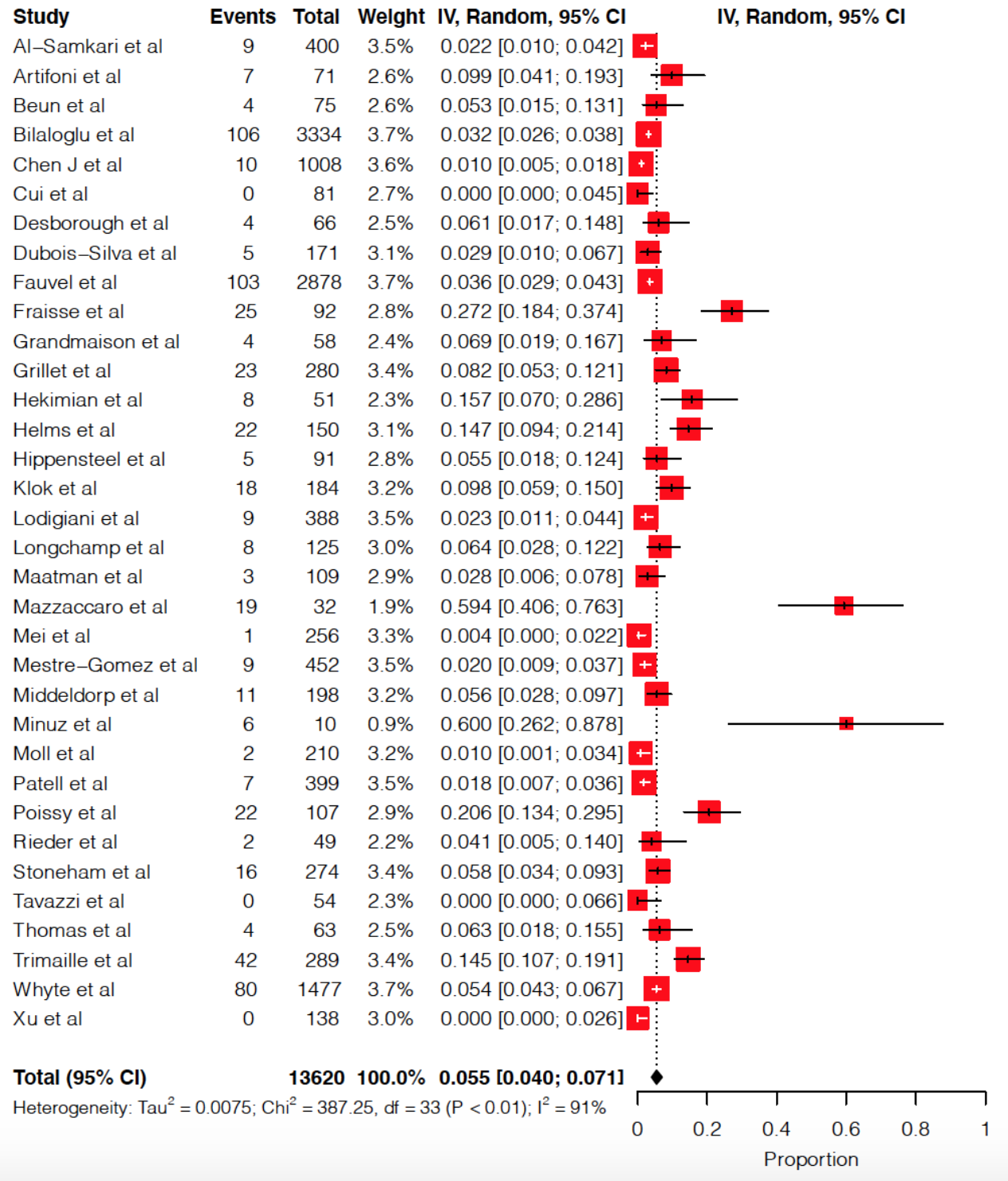
*Shortest assessment period.

g) VTE: After exclusion catheter-related thrombosis/isolated distal DVT and isolated subsegmental PE

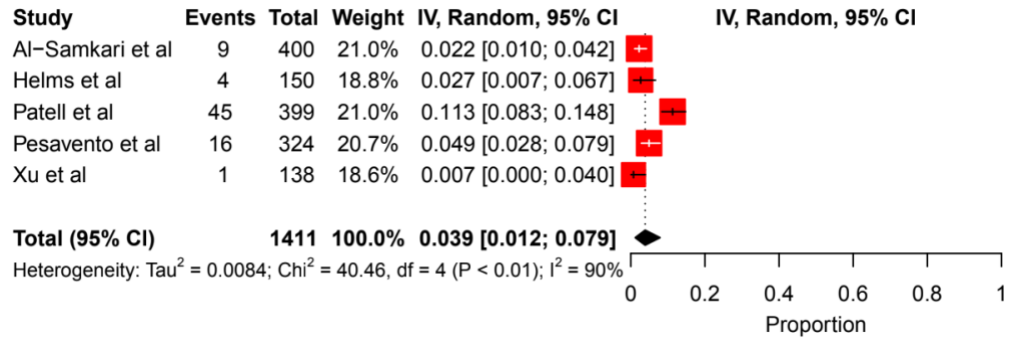
DVT without catheter-related thrombosis/isolated distal DVT



PE without isolated subsegmental episodes

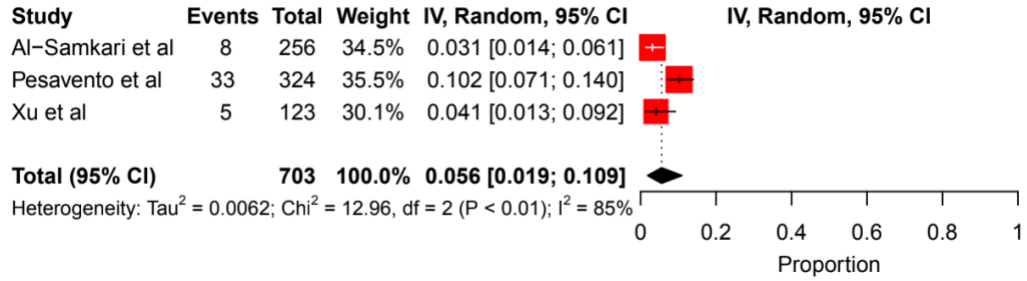


h) Bleeding: Major bleeding events

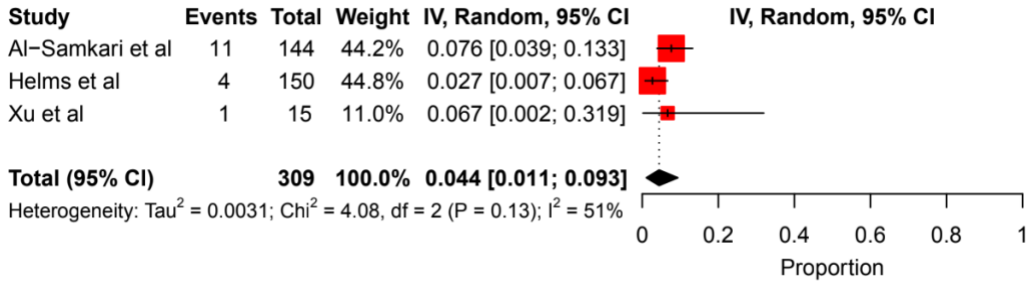


i) Bleeding: Setting

Ward



ICU

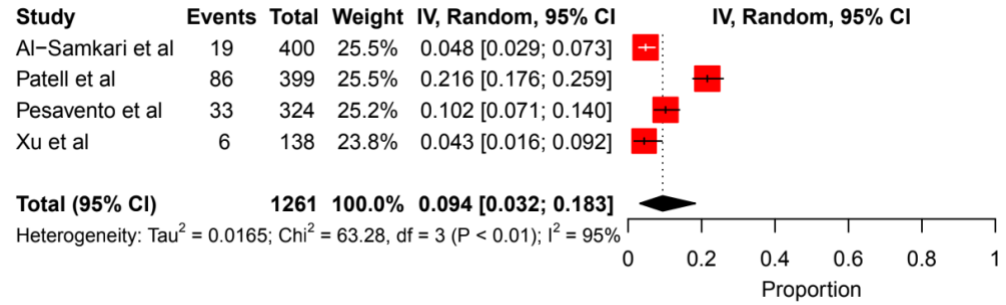


j) Bleeding: Design

Prospective

Only one study.

Retrospective

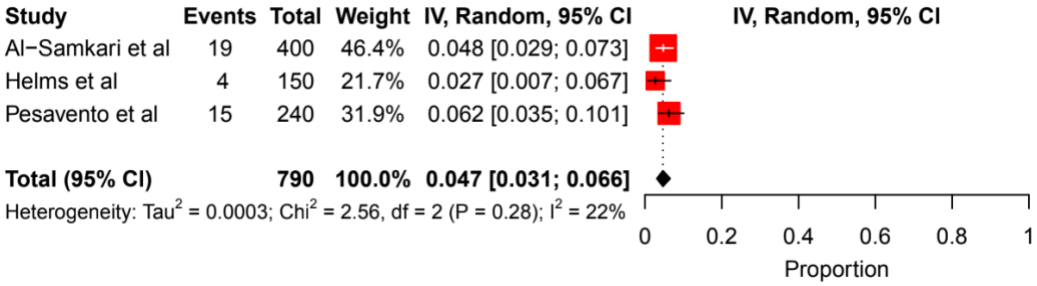


j) Bleeding: Intensity of pharmacological thromboprophylaxis

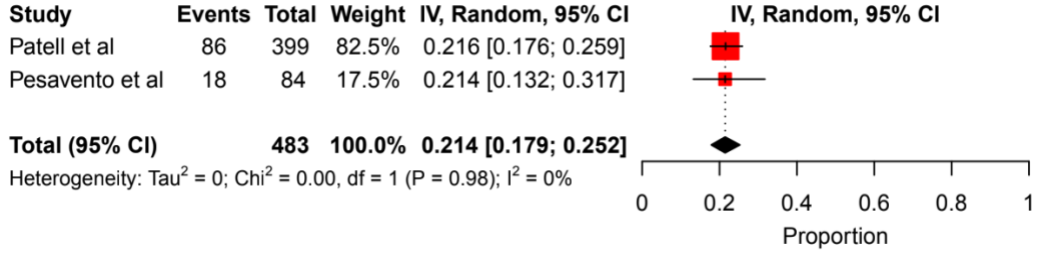
No prophylaxis

Only one study.

Standard dose prophylaxis



Intermediate dose prophylaxis or full (therapeutic) anticoagulation



e-Table 4. Subgroup meta-analyses according to the geographical area

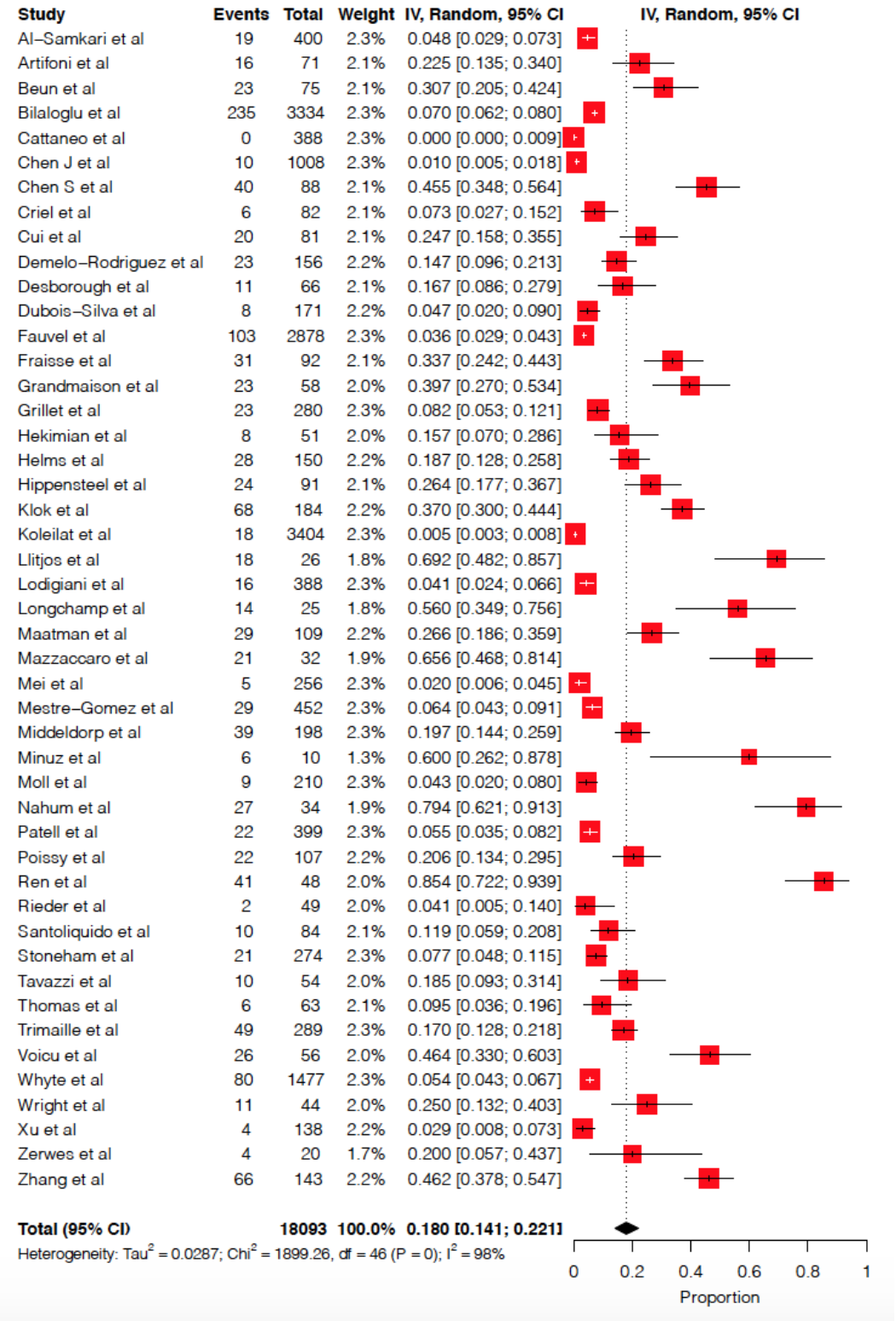
a) VTE

Geographical area	VTE	DVT	PE	Ward	ICU	Screening	Clinical diagnosis	Prospective studies	Retrospective studies
North America	9.5 (4.4-16.2)	5.8 (2.8-10.0)	2.4 (1.6-3.4)	4.8 (2.5-7.8)	16.9 (10.9-23.7)	-	9.5 (4.4-16.2)	-	9.5 (4.4-16.2)
Europe	17.9 (13.6-22.7)	10.8 (6.2-16.3)	10.8 (8.0-14.0)	8.7 (5.3-12.8)	27.4 (20.7-34.7)	28.0 (16.6-41.0)	11.3 (8.1-14.9)	25.5 (16.0-36.3)	14.5 (10.2-19.4)
Rest Of World	23.7 (6.2-47.9)	30.0 (7.8-59.0)	0.8 (0.4-1.3)	0.8 (0.0-4.5)	45.5 (26.6-65.1)	51.3 (30.3-72.0)	4.5 (0.6-11.7)	-	10.8 (1.8-25.8)

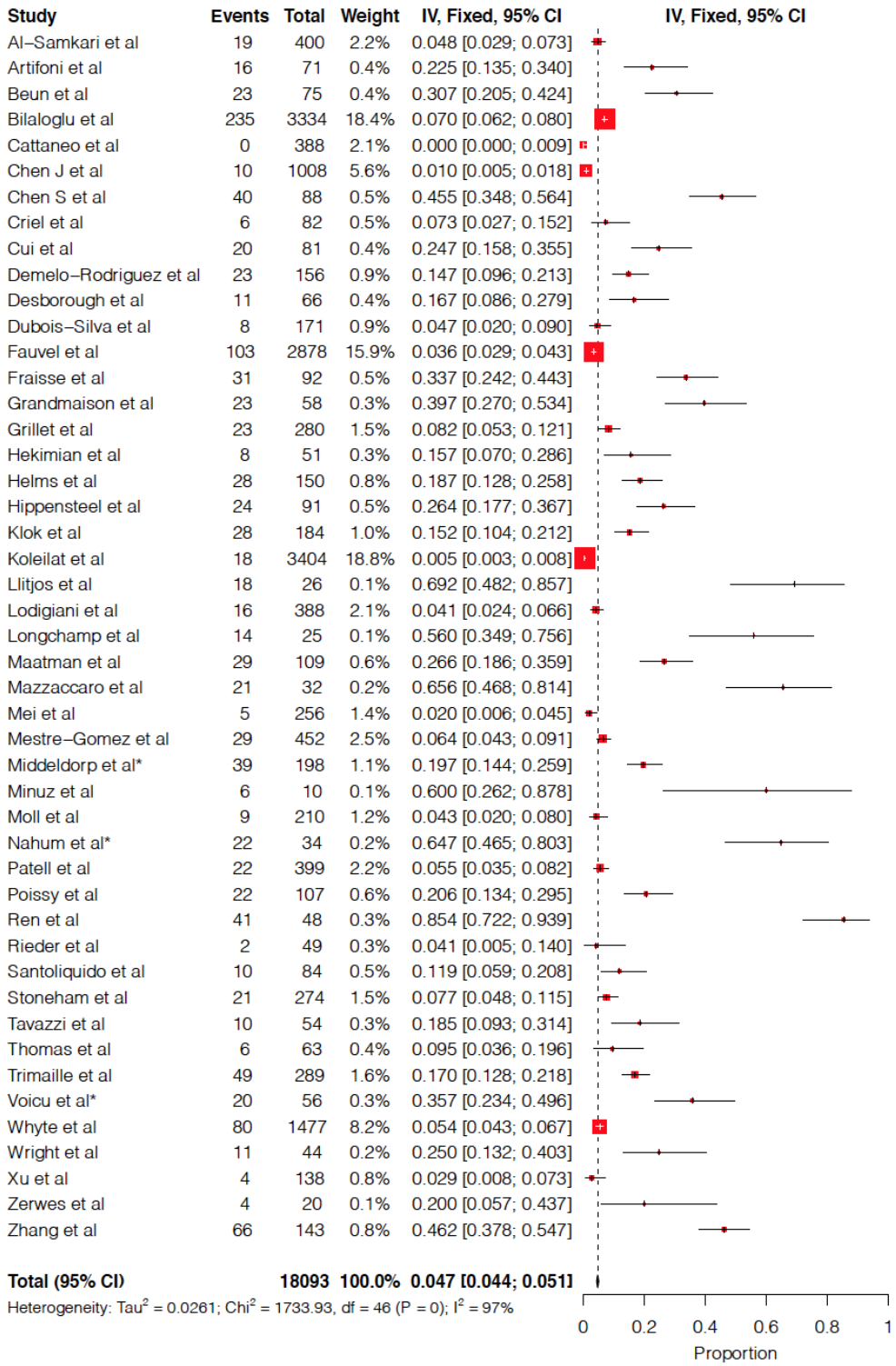
b) Bleeding

Geographical area	Bleeding	Major bleeding	Ward	ICU	Prospective studies	Retrospective studies	No prophylaxis	Standard-dose prophylaxis	Intermediate-dose prophylaxis or therapeutic anticoagulation
North America	12.0 (0.9-32.7)	6.1 (0.4-17.8)	3.1 (1.4-6.1)	7.6 (3.9-13.3)	-	12.0 (0.9-32.7)	-	4.8 (2.9-7.3)	21.6 (17.6-25.9)
Europe	6.3 (1.0-15.4)	4.3 (2.5-6.6)	10.2 (7.1-14.0)	2.7 (0.7-6.7)	2.7 (0.7-6.7)	10.2 (7.1-14.0)	-	4.7 (1.9-8.7)	21.4 (13.2-31.7)
Rest Of World	4.4 (1.6-9.2)	0.7 (0.0-4.0)	4.1 (1.3-9.2)	6.7 (0.2-32.0)	-	4.4 (1.6-9.2)	4.4 (1.6-9.2)	-	-

e-Figure 3. Sensitivity analyses
a) Outcomes from the longest available follow-up points in studies reporting outcomes at multiple time points

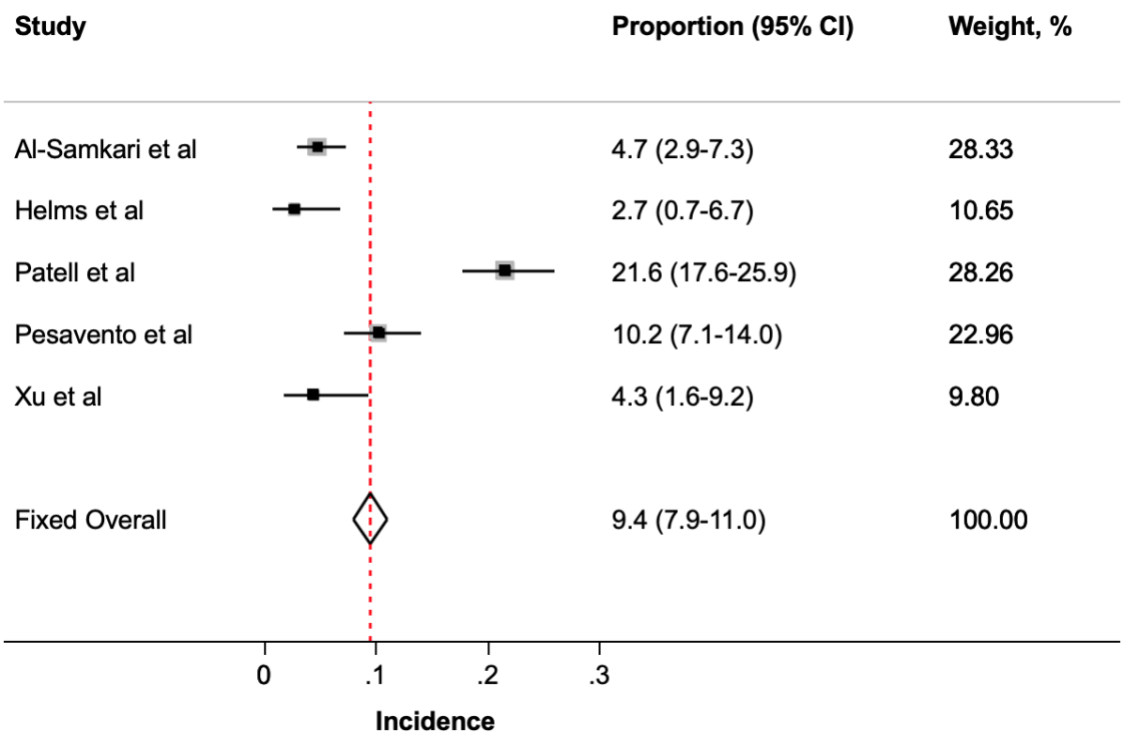


b) VTE: inverse variance fixed-effects models.



*Shortest assessment period.

c) Bleeding: inverse variance fixed-effects models.



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