



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE



R ADAMS COWLEY
SHOCK TRAUMA CENTER
UNIVERSITY OF MARYLAND



PREVENT CLOT: Is Aspirin Ok for Ortho Trauma Patients?

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Industry Conflicts

Consultant

Stryker, Lincotek, Imagen

Research Support

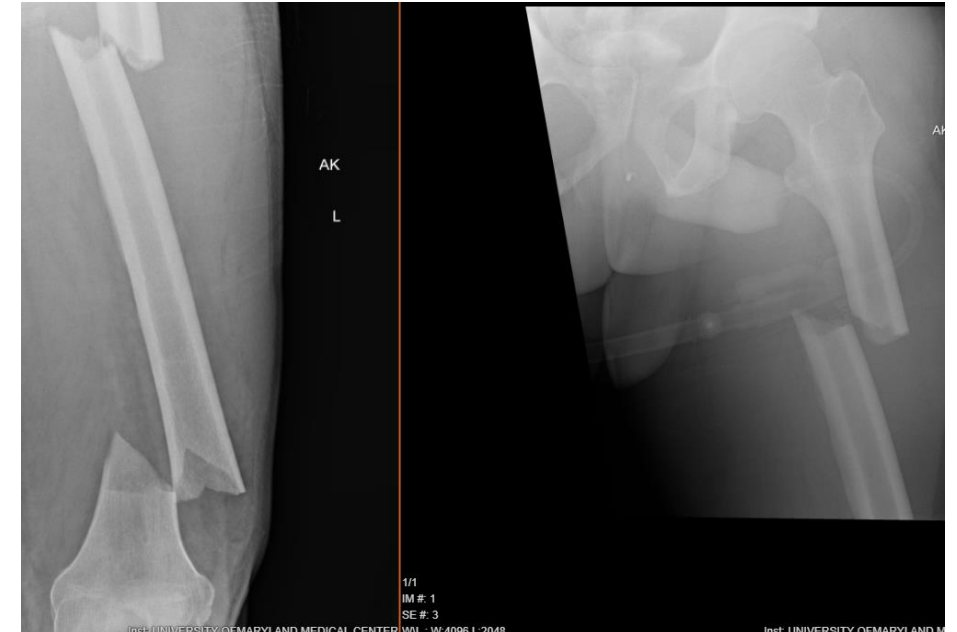
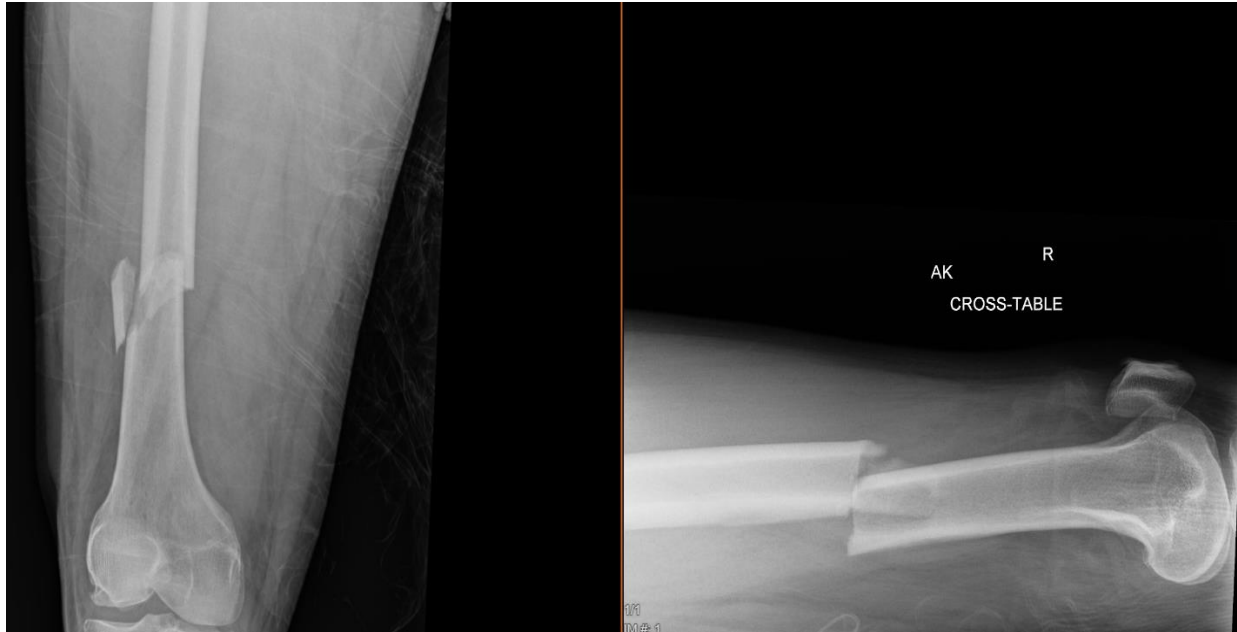
PCORI, DOD, AO

Acknowledgments

Nathan O'Hara, PhD, MHA

METRC team

Partners



Case 1: Young, MVC, Bilateral Femurs- Hypoxia in OR – Large PE

Case 2: Young, MVC, Bilateral Femurs- Arrest in OR – Large PE

The NEW ENGLAND
JOURNAL *of* MEDICINE

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Aspirin or Low-Molecular-Weight Heparin
for Thromboprophylaxis after a Fracture

Major Extremity Trauma Research Consortium (METRC)*

PREVENT CLOT

- 1. VTE in Ortho Trauma**
- 2. Initial Work**
- 3. PCLOT Design**
- 4. Main Results**
- 5. What's next?**

1. VTE in Ortho Trauma

VTE in Ortho Trauma

Trauma is a risk factor for VTE ~ 100 years

1934: Lower extremity injury = Risk Factor¹

1967: 35% by venogram²

- Injured and uninjured limbs
- Observed within 24 hours
- Most asymptomatic

1. McCartney et al. Am J Pathol 1934

2. Freerk et al Arch Surg 1967

VTE in Ortho Trauma

Volume 331

DECEMBER 15, 1994

Number 24

A PROSPECTIVE STUDY OF VENOUS THROMBOEMBOLISM AFTER MAJOR TRAUMA

**WILLIAM H. GEERTS, M.D., KAREN I. CODE, R.N., RICHARD M. JAY, M.D., ERLUO CHEN, M.B., M.P.H.,
AND JOHN PAUL SZALAI, PH.D.**

VTE Common After Trauma³

349 patients (no prophylaxis, venography)

58% DVT (18% proximal)

3. Geerts et al. NEJM 1994

VTE in Ortho Trauma

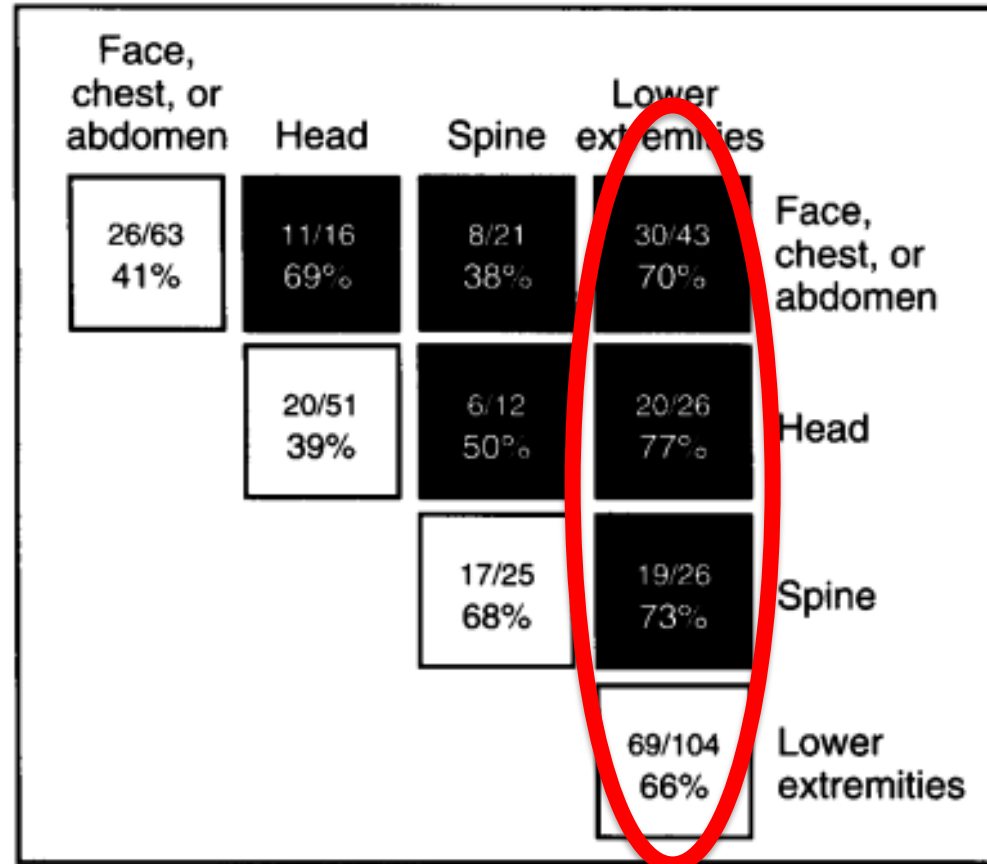


Figure 1. The Frequency of Deep-Vein Thrombosis among 349 Patients with One or More Major Injuries.

VTE in Ortho Trauma

Risk Factors for VTE in Trauma (n=450,375)⁴

- Age > 40
- LE Fracture AIS >2
- Head injury
- Venous injury
- Major Surgery

VTE in Ortho Trauma

Reported Event Rate Varies⁵

DVT: 0.36%⁴ to 58%³

Why?

Diagnostic protocols

Different patient populations

Type of prophylaxis

5. Haut et al. J Trauma 2009

4. Knudson et al. Annals Surg 2004

3. Geerts et al. NEJM 1994

Mechanical and/or Chemical Prophylaxis

VTE Trauma: Cochrane Review (2013)⁶

DVT:

Prophylaxis (chemical or mechanical) Reduces DVT (RR ~0.50)

LMWH better than UH (RR 0.68)

Chemical AND mechanical better (RR 0.34)

6. Barrera et al. Cochrane 2013

Mechanical and/or Chemical Prophylaxis

VTE Trauma: Cochrane Review (2013)⁶

PE & Death

Effect Less Clear (lower event rate, less precision)

Trend the Same

VTE in Ortho Trauma



CHEST

Supplement

ANTITHROMBOTIC THERAPY AND PREVENTION OF THROMBOSIS, 9TH ED: ACCP GUIDELINES

Prevention of VTE in Orthopedic Surgery Patients

Antithrombotic Therapy and Prevention of Thrombosis,
9th ed: American College of Chest Physicians
Evidence-Based Clinical Practice Guidelines

Yngve Falck-Ytter, MD; Charles W. Francis, MD; Norman A. Johanson, MD;
Catherine Curley, MD; Ola E. Dahl, MD; Sam Schulman, MD, PhD;
Thomas L. Ortel, MD, PhD; Stephen G. Pauker, MD; and Clifford W. Colwell Jr, MD

CLINICAL
MANAGEMENT
UPDATE

The Journal of TRAUMA® Injury, Infection, and Critical Care

Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group

Frederick B. Rogers, MD, Mark D. Cipolle, MD, PhD, George Velmahos, MD, PhD, Grace Rozycki, MD, and Fred A. Luchette, MD

J Trauma. 2002;53:142-164.

Venous Thromboembolism Prophylaxis in Orthopaedic Trauma Patients: A Survey of OTA Member Practice Patterns and OTA Expert Panel Recommendations

H. Claude Sagi, MD, FACS,* Jaimo Ahn, MD, PhD,‡ David Ciesla, MD,† Cory Collinge, MD,§ Cesar Molina, MD,|| William T. Obrebsky, MD,§ and Oscar Guillamondegui, MD||, the Orthopaedic Trauma Association Evidence Based Quality Value and Safety Committee

- VTE: well-recognized, potentially fatal complication after orthopaedic trauma
- Guidelines recommend LMWH for VTE prophylaxis

Aspirin in Arthroplasty

THA/TJR: High risk for VTE

(DVT up to 57% despite prophylaxis⁸)

Aspirin: Now most common VTE prophylaxis⁷

2009-2019 (70,000+ THA, 35,000+ TKR)

Overall: 42% (THA) 50% (TKR)

High Risk: 35% (THA) 47% (TKR)

7. Singh et al. J Arthrop 2023

8. Singh et al. JBJS 1984

Aspirin in Arthroplasty

ASA vs. LMWH: Acceptable Risk

Meta-Analyses: Aspirin Acceptable

13 RCT, 6000 patients⁷

Large Propensity Matched Studies: Aspirin Acceptable & Safe

100,000+ THA/TJA

7. Singh et al. J Arthrop 2023

8. Matharu JAMA Int Med 2020

What about Aspirin in Ortho Trauma?

Aspirin in Trauma?

Appealing Re Cost (high proportion uninsured)

Appealing re PO vs SC

Concerning because you can't "turn it off"

Does it prevent VTE in this population?

Are there bleeding/safety risks?

Aspirin in Trauma?

No modern high-quality comparison of ASA vs LMWH in orthopaedic trauma patients

2. Initial Work

P-CLOT Origins: STC

Idea: Deb Stein & Ted Manson



Pilot Data

P-CLOT PILOT

Complication Profile of LMWH

AO Grant 2014 (PI: Johal, \$15K) ^{9,10}

- 9. Johal et al. OTA 2015
- 10. Johal et al. AAOS 2016

P-CLOT PILOT

ADAPT trial (Bryce Haac MD)

Single site, RCT (n=329)⁸

Primary outcome:

Composite: Bleeding, SSI, DVT, PE, and Death

8. Haac et al. PLOS One 2020

P-CLOT PILOT

ADAPT Trial

Primary Outcome:

LMWH:

50.4% (95%CI: 48-53%) probability of superiority

“... evaluation of ... clinical endpoints will require a considerably larger sample”

P-CLOT PILOT

Demonstrated feasibility

Similar inpatient compliance¹¹

Similar post-discharge adherence¹²

11. Haac et al. OTA Int 2021

12. Haac et al. J Trauma 2018

Patient Centered Outcomes Research

PCOR

Focus Groups

DCE⁹

13. Haac BE, O'Hara NN, et al. BMJ Open 2017

Discrete Choice Experiment (DCE)


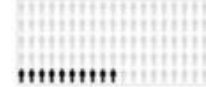

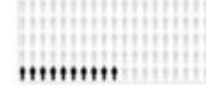





Quantitative technique measure patient preferences

Surveys: chose the best option

Relative importance of attributes

Quantify: willingness to pay

Which med would you prefer?

	Medication A	Medication B
Type of daily medication	Oral pill	Needle injection
What will it cost you	\$100	\$50
Possible side effect	None	Bruising on leg
Chance that you will have a bleeding complication and need a blood transfusion	10 out of 1000 	100 out of 1000 
Chance that you will have wound complication and need another operation	50 out of 1000 	100 out of 1000 
Chance that you will have a blood clot and have to take medications for 6 months	20 out of 1000 	10 out of 1000 
Chance of death due to a pulmonary embolism	1 out of 1000 	1 out of 1000 
Check one 	Prefer Medication A <input type="checkbox"/>	Prefer Medication B <input type="checkbox"/>

13. Haac BE, O'Hara NN, Mullins CD, et al.. BMJ Open 2017

Discrete Choice Experiment (DCE)

Patients prefer PO

Switch to SC w/ Absolute Risk Reduction of

Bleeding: 7%

Wound complication: 4.5%

VTE: 1.2%

Death from PE: 0.07%

13. Haac BE, O'Hara NN, Mullins CD, et al.. BMJ Open 2017

Patients Don't Want to Die

DCE Changed PCLOT

Patients strongly prefer ASA^{1,2} (pill and cost) if acceptable performance re death

Changed primary outcome

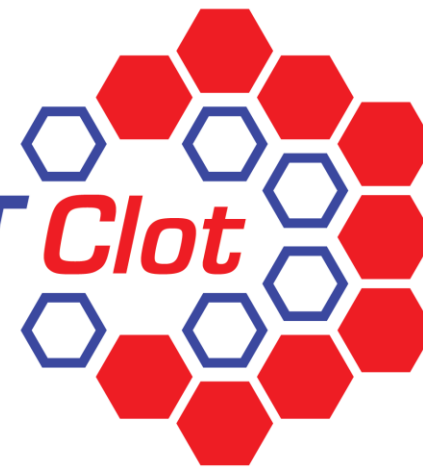
13. Haac BE, O'Hara NN, Mullins CD, et al.. BMJ Open 2017

14. Wong A, Kraus PS, Lau BD, et al. J Hosp Med 2015

3. PCLOT DESIGN



PREVENT *Clot*



Aspirin vs Low Molecular Weight Heparin for Thromboprophylaxis:
A Randomized Clinical Trial of Over 12,000 Orthopaedic Trauma Patients

Robert V. O'Toole for METRC

What is METRC?

Research Infrastructure at JHU + 80 sites

Founded 2009

Director: Ellen MacKenzie PhD

Clinical Chair: Mike Bosse, MD

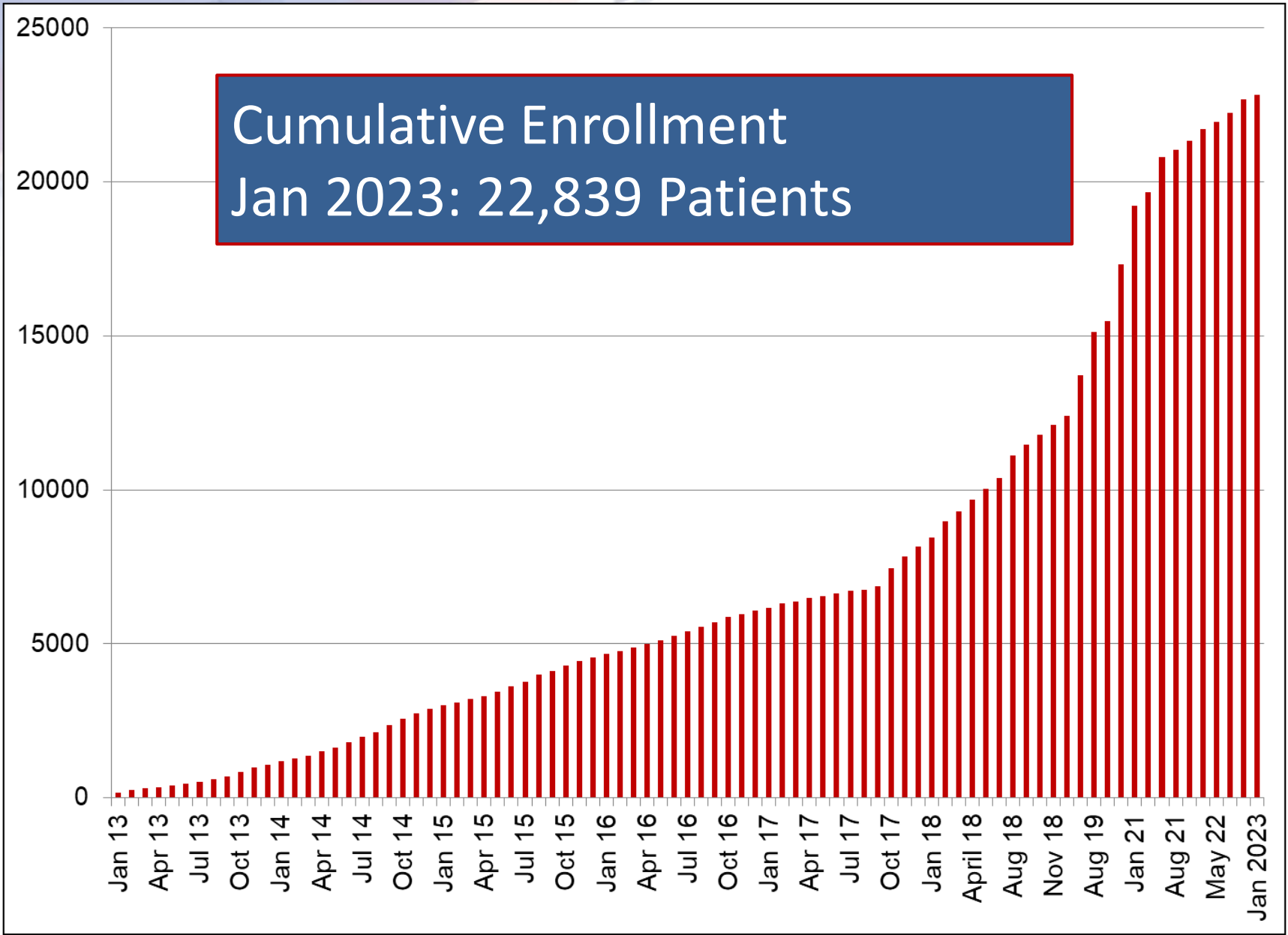


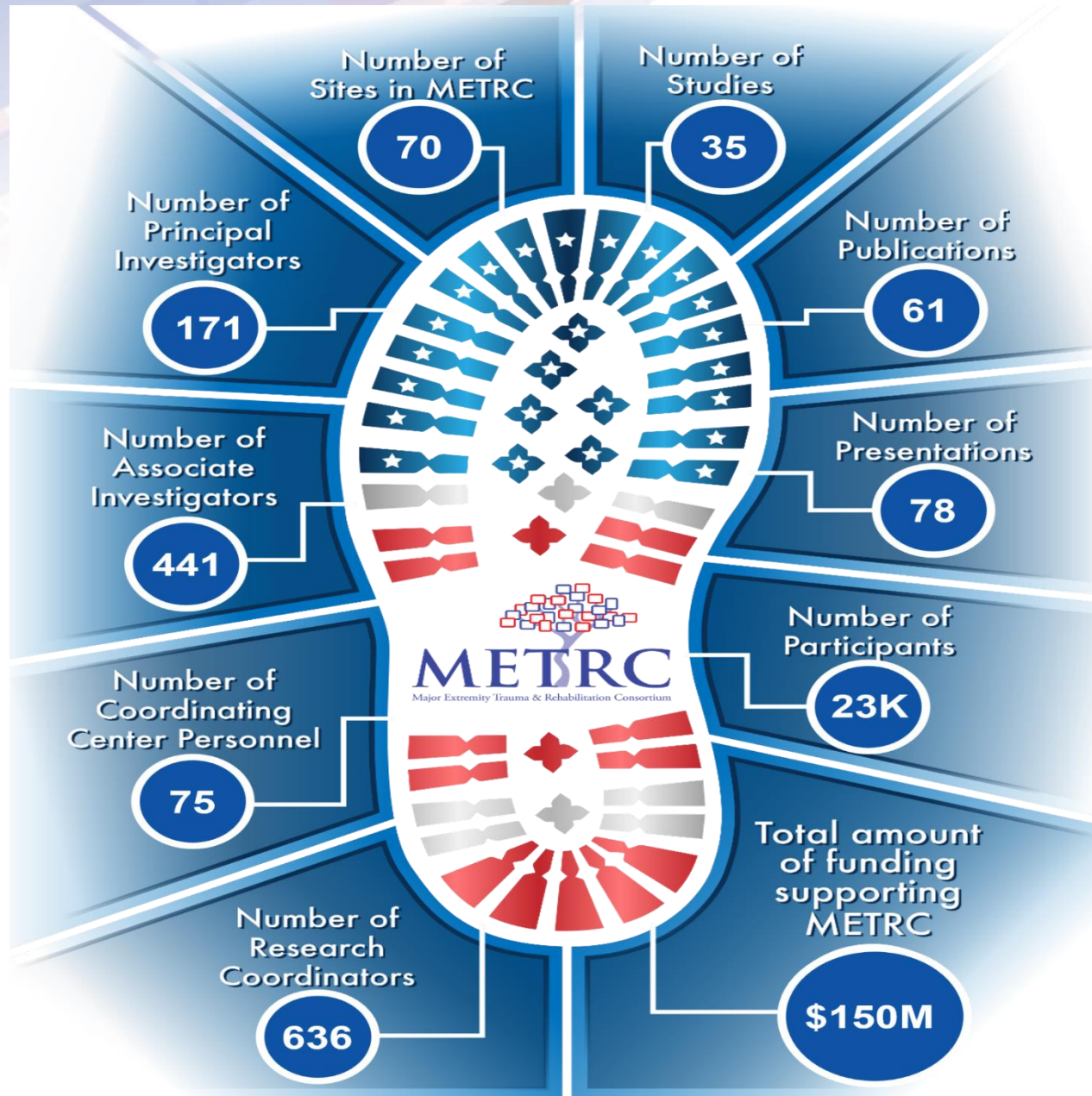
METRC Accomplishments

- **34** Prospective Studies
 - 21 “done”
 - 14 ongoing
- **4** Retrospective Studies
- **0** Failed Studies
 - All studies have yielded publishable results
 - High quality and high value

Cumulative Enrollment

Jan 2023: 22,839 Patients





P-CLOT DESIGN

Funding



PCS-1511-32745



Study Management Team

UMD

- Robert O'Toole
- Deborah Stein
- Nathan O'Hara
- Yasmin Degani

• METRC CC

- Renan Castillo
- Katherine Frey
- Tara Taylor
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- Kuladeep Sudini
- Elias Weston-Farber
- Brianna Fowler

Protocol Committee

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- Leah Gitajn
- Conor Kleweno
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- Jessica Rivera
- Gerard Slobogean
- Heather Vallier

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- Andres Rodrigue

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- Jeffrey Claridge
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- Oscar Guillamondegui
- Bryce Haac
- Elliott Haut
- Bellal Joseph
- Stephanie Savage
- Deborah Stein

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- Stephen Fisher
- Debra Marvel
- Daniel Mullins
- Stephen Wegener

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- Nathan O'Hara
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- Rachel Seymour

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- Lucas Marchand
- Christopher Lee

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- Eileen Flores
- Steven Herndon
- Katherine Joseph
- Jeremy Palmer
- Peter Thomas
- Dave Wells
- Sara Wyen
- Larry Cutsail
- Stephen Fisher
- Randolph Fenninger
- Kevin Bozic
- Nicole Stassen
- Breazeale Stephen

21 Participating Centers

- Carolinas Medical Center
- Dartmouth-Hitchcock Medical
- Foothills Medical Center
- Hamilton General Hospital
- Harborview Medical Center
- Indiana University Health Methodist Hospital
- Harvard Orthopaedic Trauma Service
- The MetroHealth System
- R Adams Cowley Shock Trauma
- Rhode Island Hospital
- Ryder Trauma Center
- San Antonio Military Medical Center
- University of Arizona Tucson
- University of Mississippi Medical Center
- University of Tennessee Health Sciences Center
- University of Texas Health Sciences Center
- Vanderbilt Medical Center
- Wake Forest Health Sciences
- Allegheny General Hospital
- Inova Fairfax Hospital Falls Church
- University of Wisconsin

Participating Centers

21 Centers

120+ Ortho & Trauma Investigators

175+ Research Coordinators

12,000+ patients

PREVENT CLOT

PREVENT CLOT:

Effectiveness and ***safety*** of ASA vs LMWH for thromboprophylaxis in ortho trauma



PREVENT CLOT Study Hypothesis

Primary Hypothesis:

All cause mortality is non-inferior with ASA compared to LMWH in ortho trauma patients.

Methods

FDA Status

FDA: IND Exempt 133628

Aspirin is not FDA approved for this indication

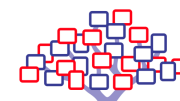
Study Design

Pragmatic RCT

Designed from hospital policy perspective

Protocol Paper¹

1. O'Toole RV, Stein DM, Frey KP, *et al.* BMJ Open 2021



Study Design: Inclusion/Exclusion Criteria

Inclusion Criteria

- Adult trauma patients (18+)
- Plan for prophylaxis
- Operative extremity fracture proximal to metatarsal or carpal bones
or
- pelvis or acetabulum fracture, treated operatively or non-operatively

Exclusion Criteria

- >48 hrs to trauma center
- 3+ doses of thromboprophylaxis prior to consent
- Dx of venous thromboprophylaxis in prior 6 m
- On therapeutic anticoag or had a chronic blood clotting disorder
- COVID + patients

Study Design

- Randomization on 1:1 ratio, stratified by treatment site
- Open label (Patients, clinicians NOT blinded)
- Treatments:
 - LMWH: 30 mg subcutaneously, 2x day
 - ASA: 81 mg orally, 2x day
- Duration/Indication based on hospital protocols

Study Design: Outcomes

Outcomes evaluated up to 90 days after randomization

Primary outcome: All cause mortality

Secondary Outcomes:

PE related death

Non-fatal PE

DVT

Secondary Safety Outcomes:

Bleeding events

Wound complications

Surgical site infections

Study Design: Outcomes

Changed Primary Outcome:

Death Due to PE → All Cause Mortality

Study Design: Analysis

Statistical Analysis Plan

Primary outcome: Intent to treat (ITT)

Treatment-specific Kaplan-Meier estimators

Assess non-inferiority with a 2-sided confidence interval

2 analysts wrote independent code all results

Secondary outcomes: Cumulative incidence function w death as a competing risk

Participants censored at last known clinical encounter.

Report risk differences and 95% CI, no hypothesis testing

Study Design

Primary Outcome:

Sensitivity analysis: per protocol

Adherence:

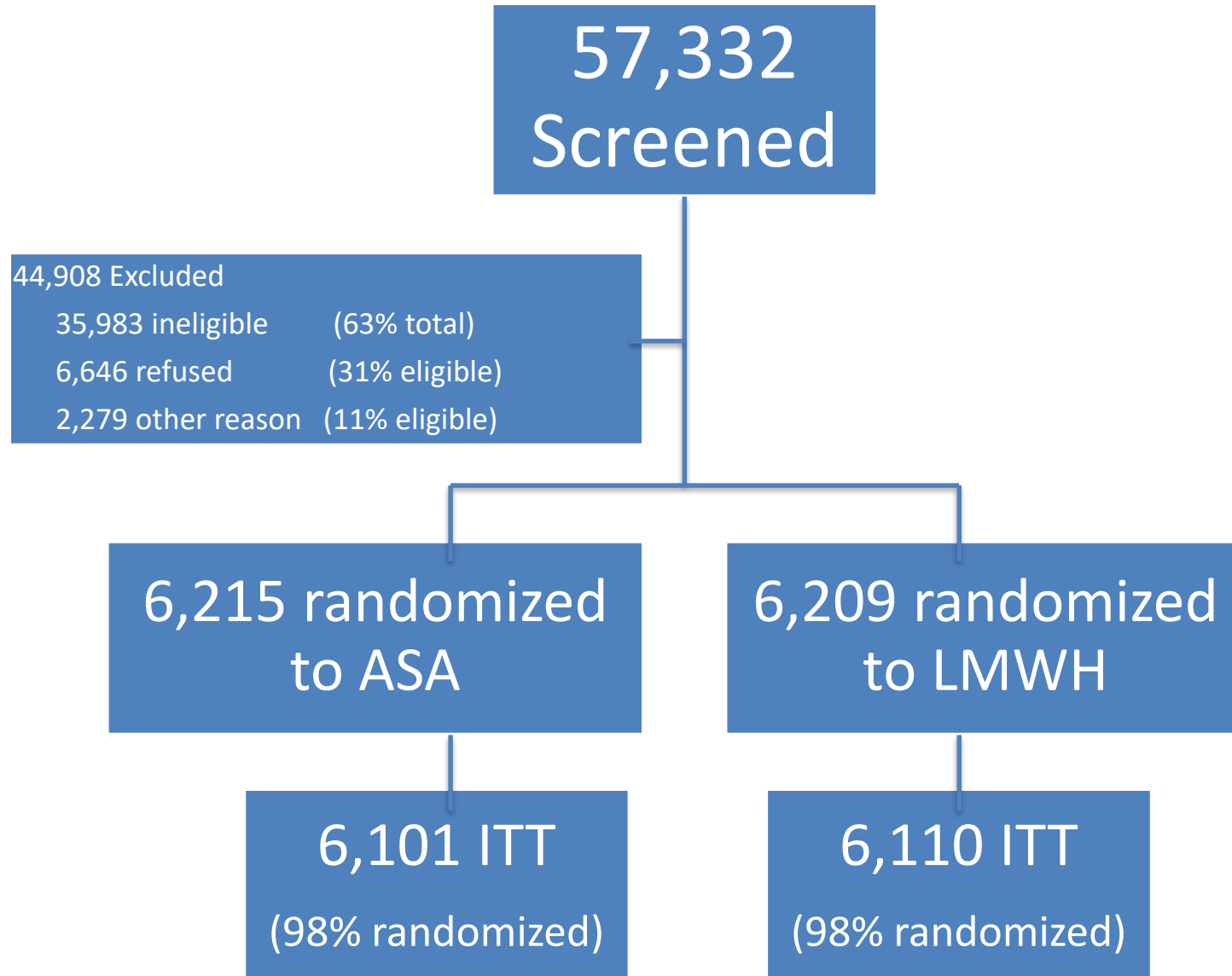
1) receipt of 80% of in-hospital doses

AND

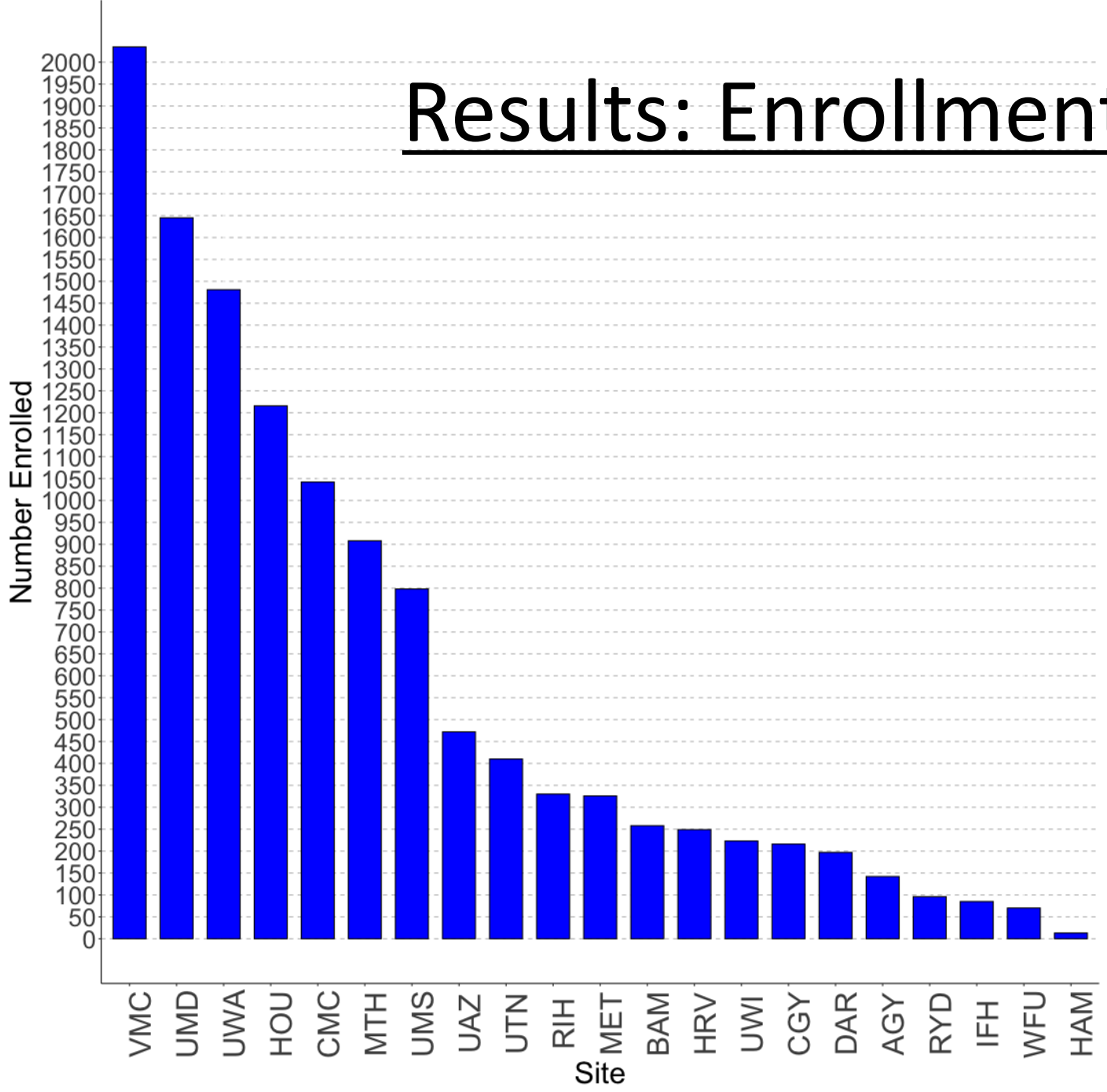
2) discharged on allocated medication (if applicable)

4. MAIN RESULTS

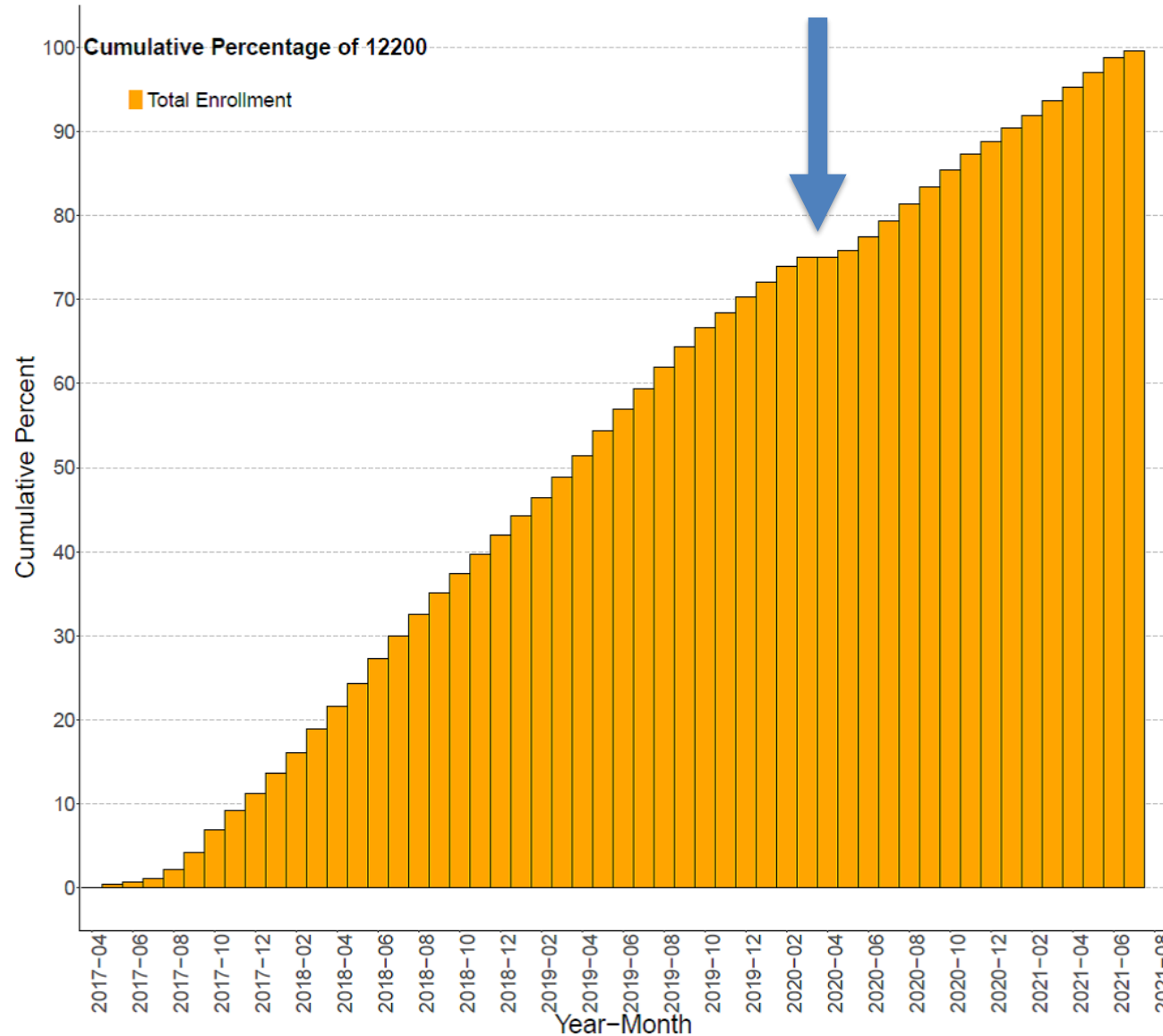
Results: Enrollment and Follow-up



Results: Enrollment by Site



Results: Enrollment Over Time



**Enrollment: Apr 2017-Aug 2021
(~4.5 Years)**

Final follow-up: Jan 2022

Results: Balance Between Groups

	ASA (N = 6101)	LMWH (N = 6110)
Male	63%	62%
Age (yrs)	44.5	44.7
ISS - median (IQR)	9 (4-10)	9 (4-10)
>15	13.7%	14.2%
Injury Region		
LE fx only	67.4%	66.6%
UE fx only	11.9%	12.2%
UE & LE fx	20.6%	21.1%

Primary Result: All Cause Mortality (ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality			

Primary Result: All Cause Mortality (ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality	0.73% (n=45)		

Primary Result: All Cause Mortality (ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality	0.73% (n=45)	0.78% (n=47)	

Primary Result: All Cause Mortality (ITT)

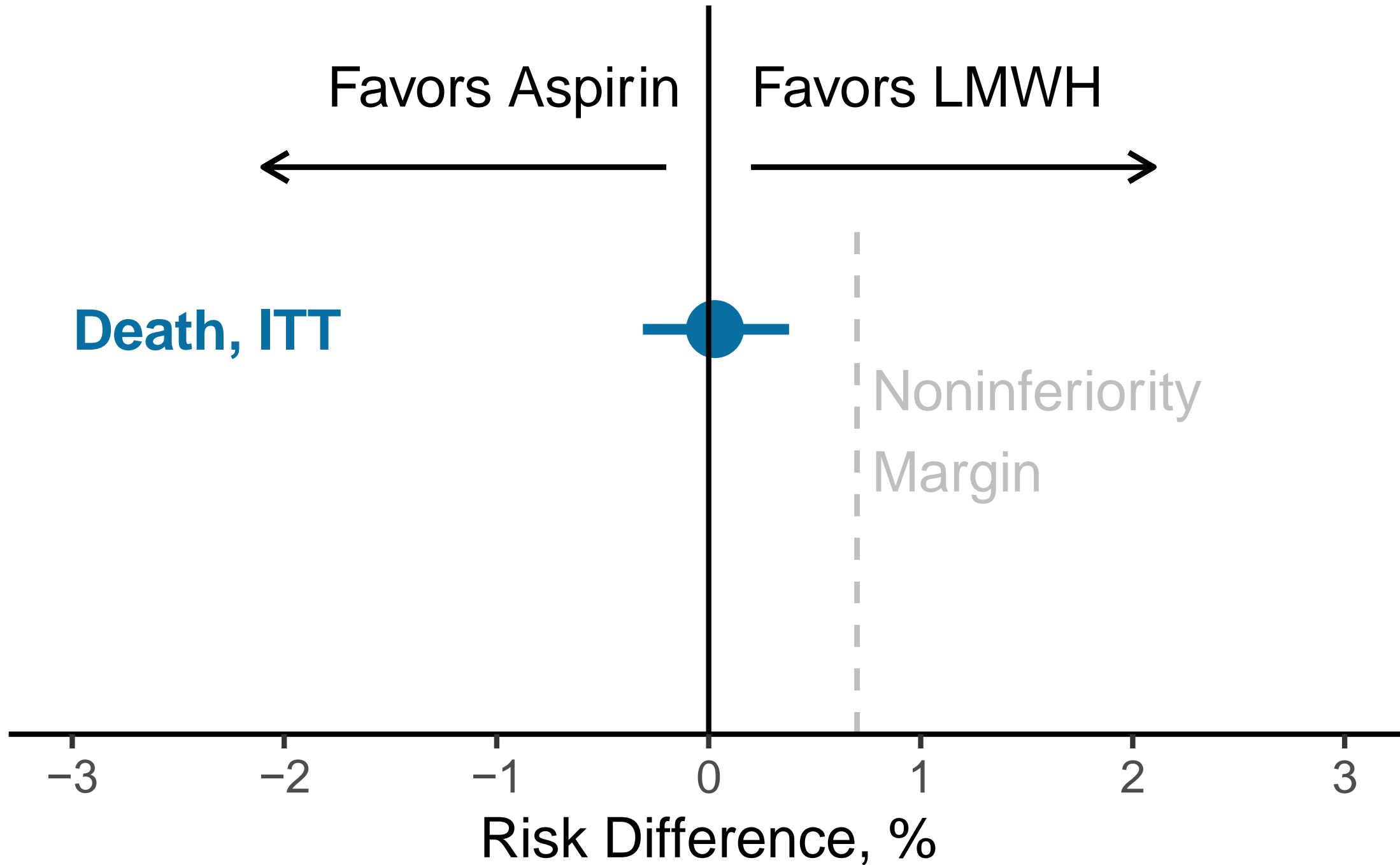
	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality	0.73% (n=45)	0.78% (n=47)	0.05% (-0.27 to 0.38%) P-value <0.001

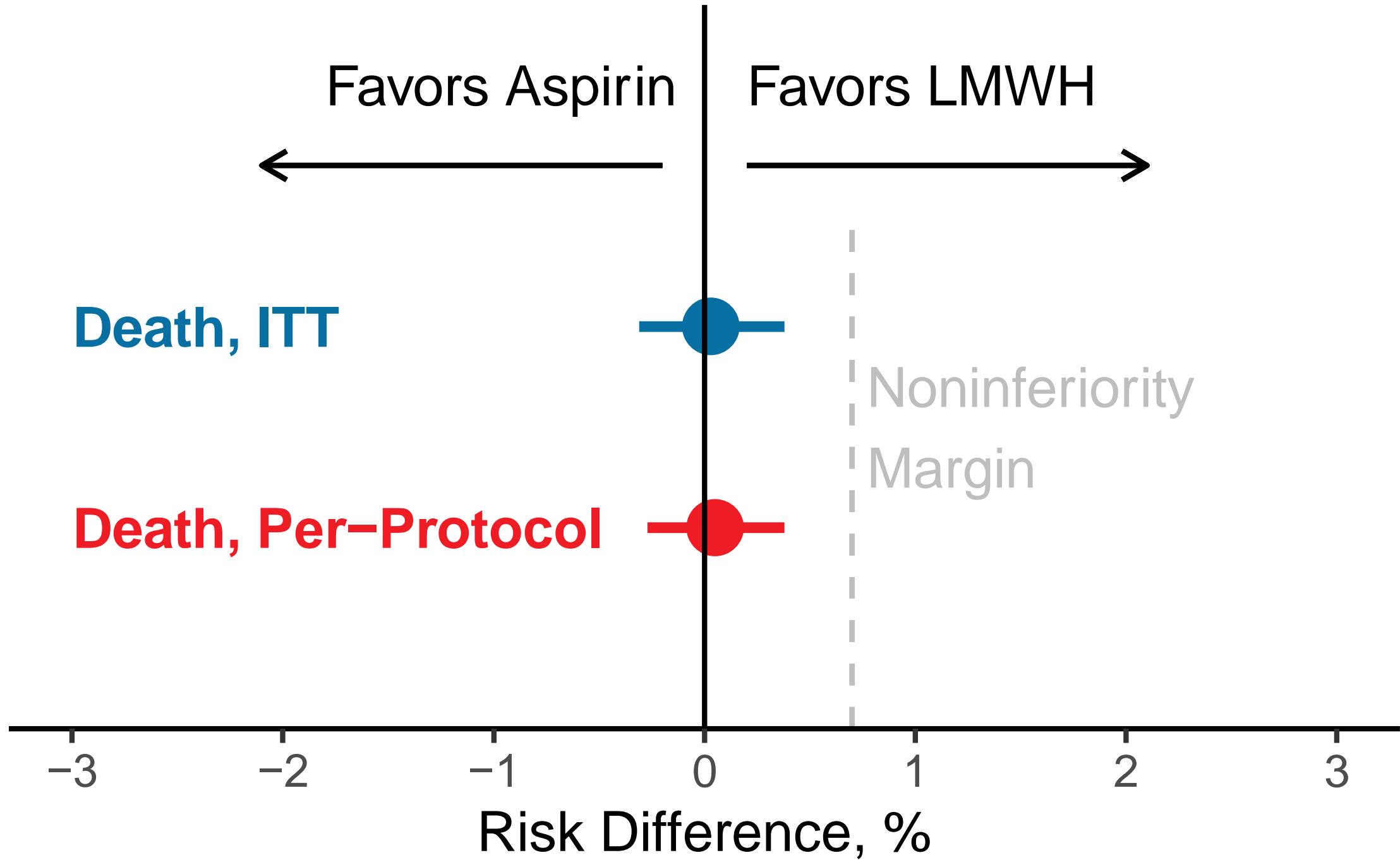
Primary Result: All Cause Mortality (per protocol)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality			

Primary Result: All Cause Mortality (per protocol)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
all cause mortality	0.72% (n=38)	0.75% (n=41)	0.03% (-0.31 to 0.38%)





Favors Aspirin

Favors LMWH

Death, ITT

Death, Per-Protocol

Noninferiority Margin

Risk Difference, %

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
death due to PE			
PE			
DVT			

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

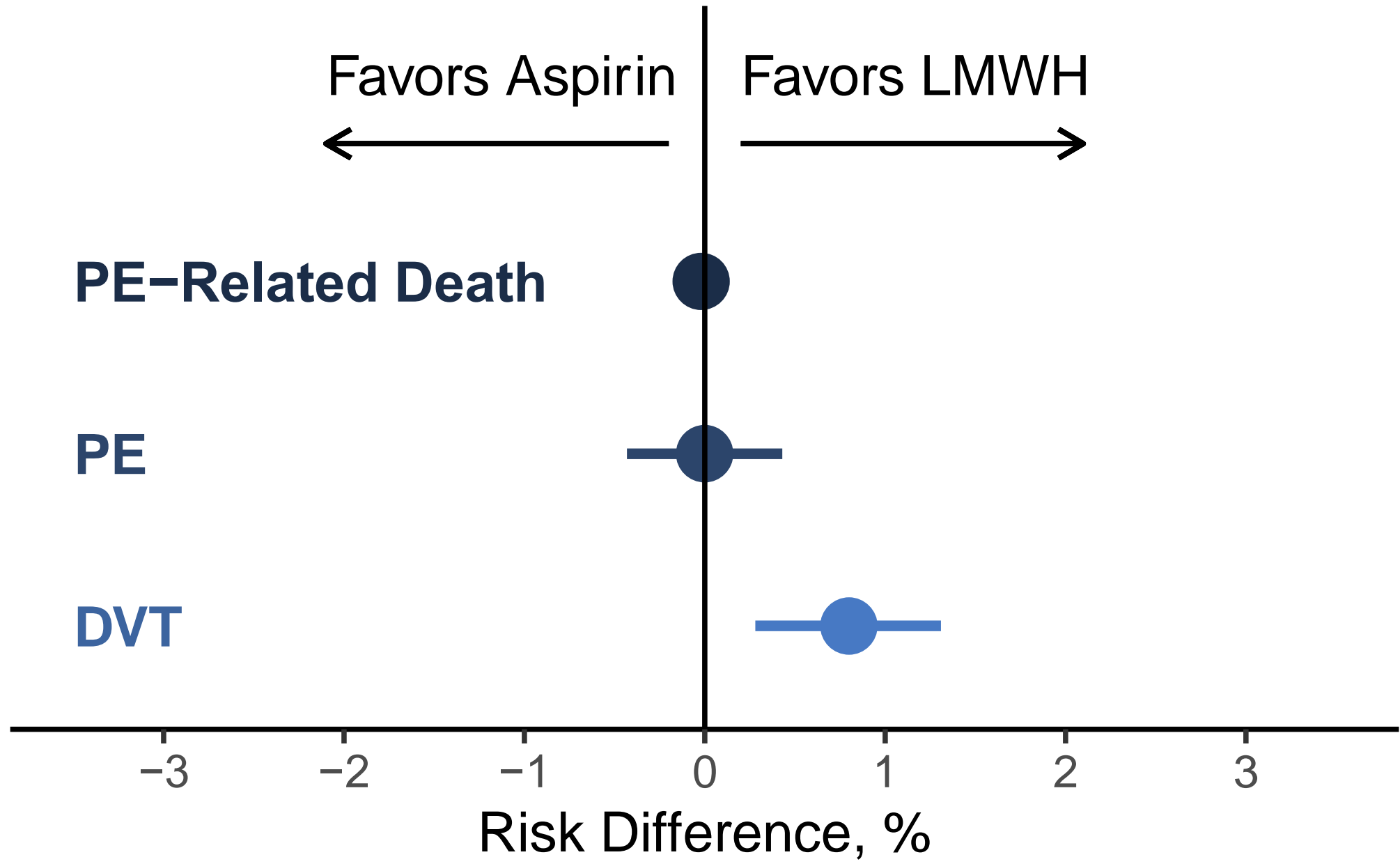
	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
death due to PE	0.08% (n=5)	0.07% (n=4)	-0.02% (-0.12% to 0.08%)
PE			
DVT			

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
death due to PE	0.08% (n=5)	0.07% (n=4)	-0.02% (-0.12% to 0.08%)
PE	1.49% (n=90)	1.49% (n=90)	0.0% (-0.43% to 0.43%)
DVT			

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
death due to PE	0.08% (n=5)	0.07% (n=4)	-0.02% (-0.12% to 0.08%)
PE	1.49% (n=90)	1.49% (n=90)	0.0% (-0.43% to 0.43%)
DVT	1.71% (n=103)	2.51% (n=151)	0.8% (0.28% to 1.31%)



Favors Aspirin

Favors LMWH

PE-Related Death

PE

DVT

Risk Difference, %

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

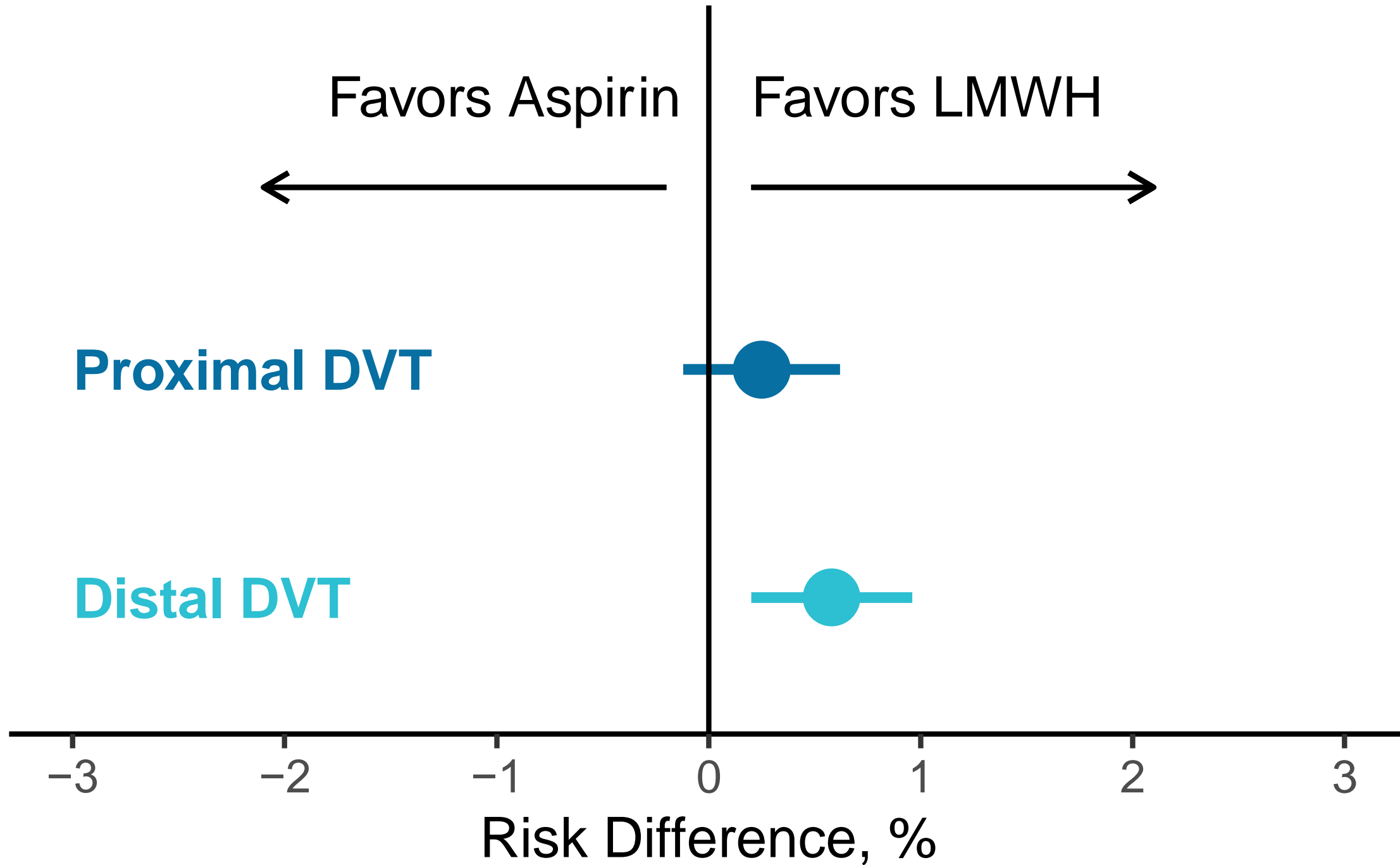
	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
DVT	1.7% (n=103)	2.5% (n=151)	0.8% (0.3% to 1.3%)
Proximal DVT			
Distal DVT			

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
DVT	1.7% (n=103)	2.5% (n=151)	0.8% (0.3% to 1.3%)
Proximal DVT	1.0% (n=59)	1.2% (n=74)	0.3% (-0.1% to 0.6%)
Distal DVT			

Secondary Efficacy Outcomes (ITT): PE related death, PE and DVT

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
DVT	1.7% (n=103)	2.5% (n=151)	0.8% (0.3% to 1.3%)
Proximal DVT	1.0% (n=59)	1.2% (n=74)	0.3% (-0.1% to 0.6%)
Distal DVT	0.9% (n=52)	1.5% (n=87)	0.6% (0.2% to 1.0%)



Secondary Safety Outcomes(ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
Bleeding Complication			
Wound Complication			
Infection			

Secondary Safety Outcomes(ITT)

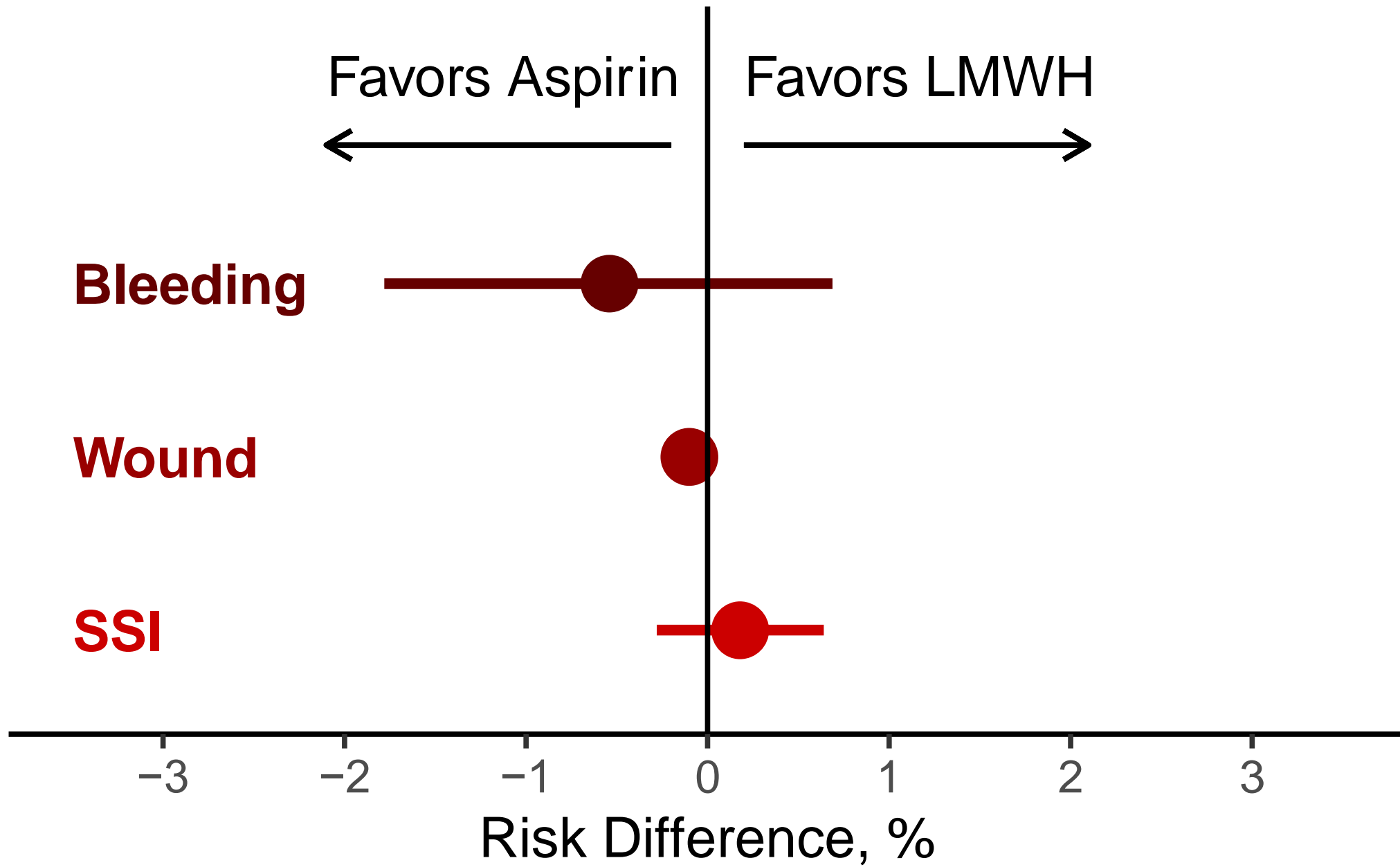
	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
Bleeding Complication	14.3% (n=869)	13.7% (n=834)	-0.5% (-1.8% to 0.7%)
Wound Complication			
Infection			

Secondary Safety Outcomes(ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
Bleeding Complication	14.3% (n=869)	13.7% (n=834)	-0.5% (-1.8% to 0.7%)
Wound Complication	0.23% (n=14)	0.13% (n=8)	-0.10% (-0.3% to 0.1%)
Infection			

Secondary Safety Outcomes(ITT)

	LMWH (N = 6110)	ASA (N = 6101)	Difference (95% CI)
Bleeding Complication	14.3% (n=869)	13.7% (n=834)	-0.5% (-1.8% to 0.7%)
Wound Complication	0.23% (n=14)	0.13% (n=8)	-0.10% (-0.3% to 0.1%)
Infection	1.6% (n=93)	1.7% (n=103)	0.18% (-0.3% to 0.6%)



Favors Aspirin

Favors LMWH

Bleeding

Wound

SSI

Risk Difference, %

Discussion

Discussion

Primary Result:

ASA is non-inferior to LMWH in preventing all-cause mortality after ortho trauma

-per protocol analysis consistent

Discussion

Secondary/Safety results similar:

- PE-related death
- PE
- Proximal DVT
- Bleeding
- Wound issues
- Infection

Discussion

- LMWH fewer DVT (1.7% vs 2.5%)

Similar proximal DVT (1.0% vs 1.2%)

Different distal DVT (0.9% vs 1.5%)

Difference of clinical importance?

Discussion

Strengths

- RCT
- 21 centers = generalizable results
- High follow-up (96.8%) and adherence (87.4%)
- Blinded outcome adjudication panel
- Large - adequate statistical power even for rare outcome

Discussion

Limitations

- Open label (no signs of testing bias)
- Up to 2 doses ppx prior to enrollment
- Little data on postop adherence – not aim of the study
- Changed primary outcome from PE-related mortality to all cause mortality
 - (prior to SAP, protocol paper, looking at any data)

Main Results: Conclusions

Conclusion

12,000+ patient RCT:

ASA is an **acceptable** thromboprophylaxis agent in orthopaedic trauma patients

Non inferior for all cause mortality

Conclusion

No difference:

Death due to PE, PE

Bleeding, wound dehiscence, infection, proximal DVT

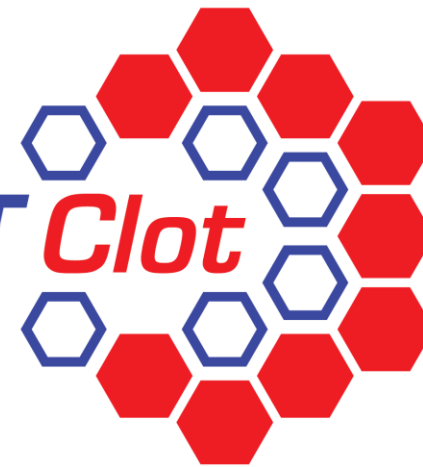
Difference:

Signal: favors LMWH in distal DVT (0.9% vs 1.5%, 95%CI: 0.2 – 1.0)

Clinicians, Patients, Hospitals Consider These Data



PREVENT Clot



Aspirin vs Low Molecular Weight Heparin for Thromboprophylaxis:
A Randomized Clinical Trial of Over 12,000 Orthopaedic Trauma Patients
METRC

5. WHAT'S NEXT?

Is ASA ok in “high risk” ortho
trauma patients?

Subgroup Analyses

Old People with Fractures

Hip Fractures (PEP Trial¹⁵: 13,000+ asa vs placebo)

Pelvis/Acetabulum

ICU Patients

Head Injury

15. PEP Trial Lancet 2000

Subgroup Analyses

Old People with Fractures

Only Subgroup analysis – Age > 60 years

All cause mortality, n=2602 patients

No change in effect: 0.16% [95%CI: -0.94-1.25]

New Results!

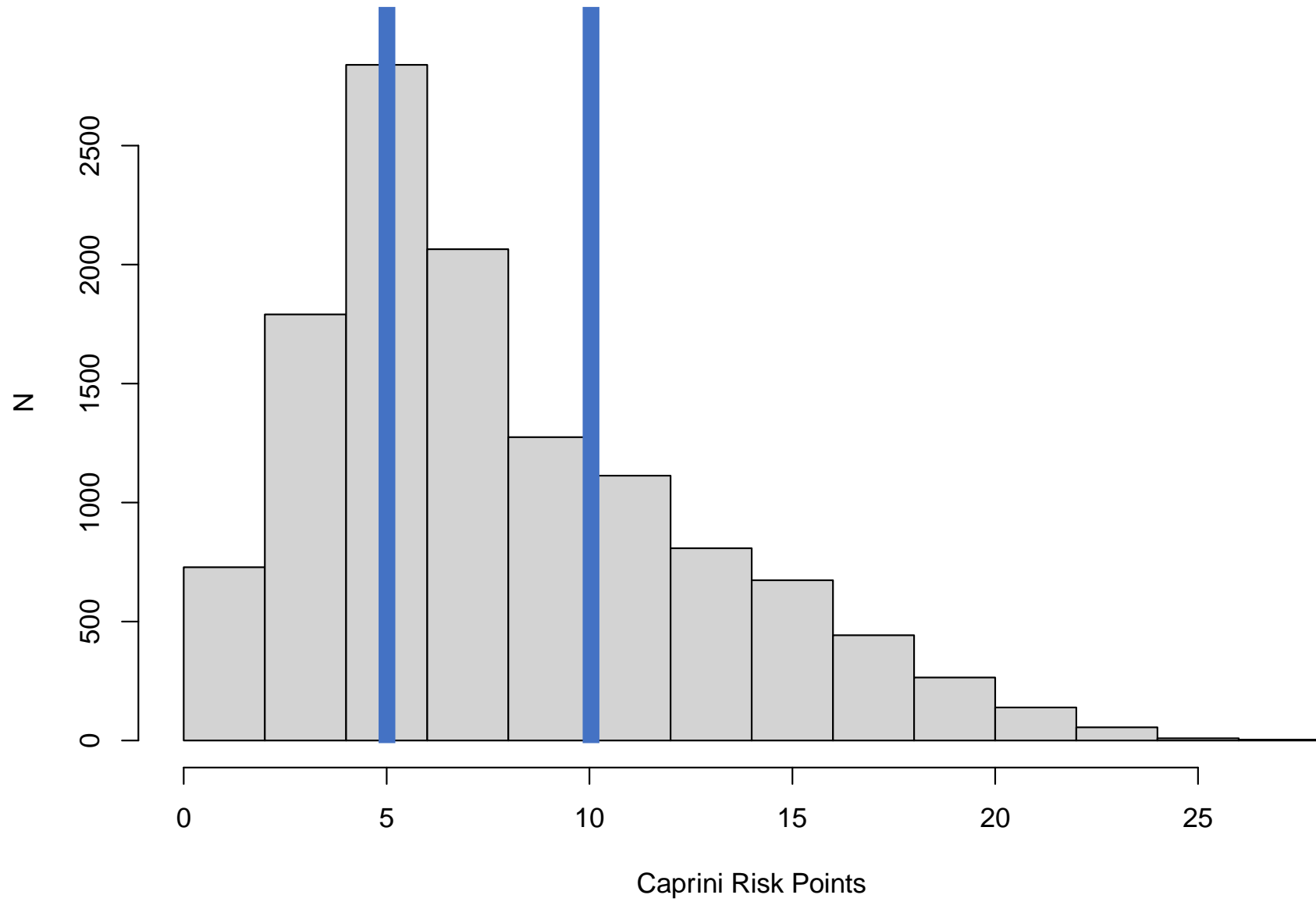
(Prelim: Not peer reviewed)

Nathan O'Hara, PhD, MHA

Characteristic	Overall, (N = 12,211)
Age, years	
40 or less	5,690 (47%)
41-60	3,918 (32%)
61-74	2,001 (16%)
75 or more	602 (4.9%)
Obese, > 30 kg/m ²	4,238 (35%)
Diabetes	1,002 (8.2%)
History of VTE	89 (0.7%)
History of cancer	306 (2.5%)
History of MI	98 (0.8%)
History of CHF	88 (0.7%)
History of CVD	96 (0.8%)
Estrogen medication	219 (1.8%)
Discharge weightbearing status	
As tolerated	4,512 (37%)
Protected	535 (4.4%)
Non-weightbearing	5,448 (45%)
Touchdown	1,716 (14%)
Humerus fracture	1,131 (9.3%)
Radius or ulna fracture	1,611 (13%)
Femur fracture	3,916 (32%)
Tibia fracture	5,935 (49%)
Pelvis or acetabulum fracture	2,591 (21%)
Foot fracture	1,253 (11%)
Head injury	1,569 (13%)
Spinal injury	1,268 (10%)
Thorax injury	2,253 (18%)
Abdominal injury	1,573 (13%)

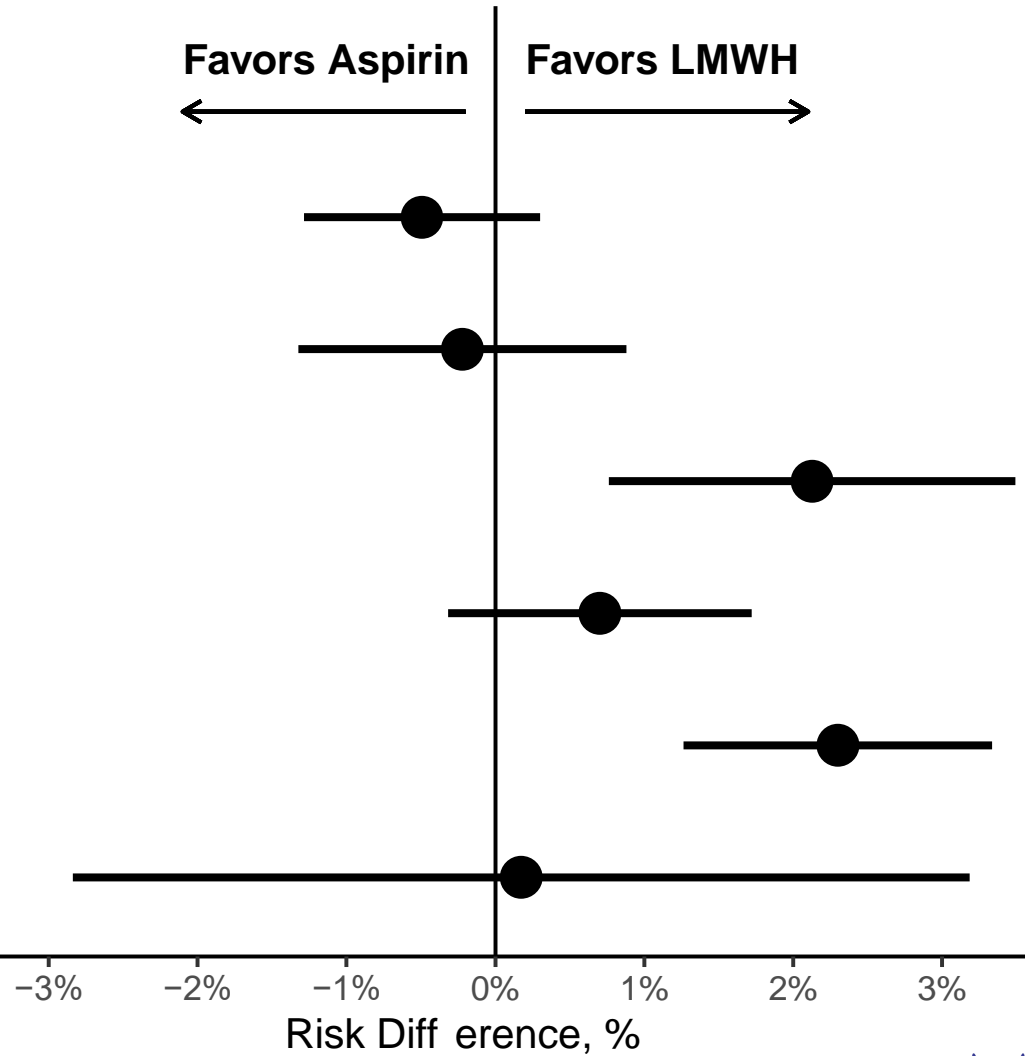
Caprini Score Value	Risk Factor
1 point	Age 41 – 60 years Body mass index > 30 kg/m ² History of myocardial infarction Congestive heart failure Cerebrovascular disease Diabetes Oral contraceptives or hormone replacement therapy Abdominal injury Thoracic injury
2 points	Age, 61 – 74 years Prior cancer diagnosis Immobilization due to restricted weight bearing Fracture of the tibia Head injury
3 points	Age, ≥ 75 years Previous venous thromboembolism
5 points	Multi-trauma (Injury severity score ≥ 16) Fracture of the femur, pelvis, or acetabulum Spine injury

Distribution of VTE Risk



Highest Risk Quartile

	ASA	LMWH
Death	1.0%	1.5%
PE	2.3%	2.6%
Any DVT	4.8%	2.7%
Proximal DVT	2.4%	1.7%
Distal DVT	3.3%	2.3%
Bleeding	23.6%	23.4%



Combining outcomes to tell the whole story:

Patient Satisfaction & The “win ratio”

Nathan O’Hara, PhD, MHA

The Win Ratio

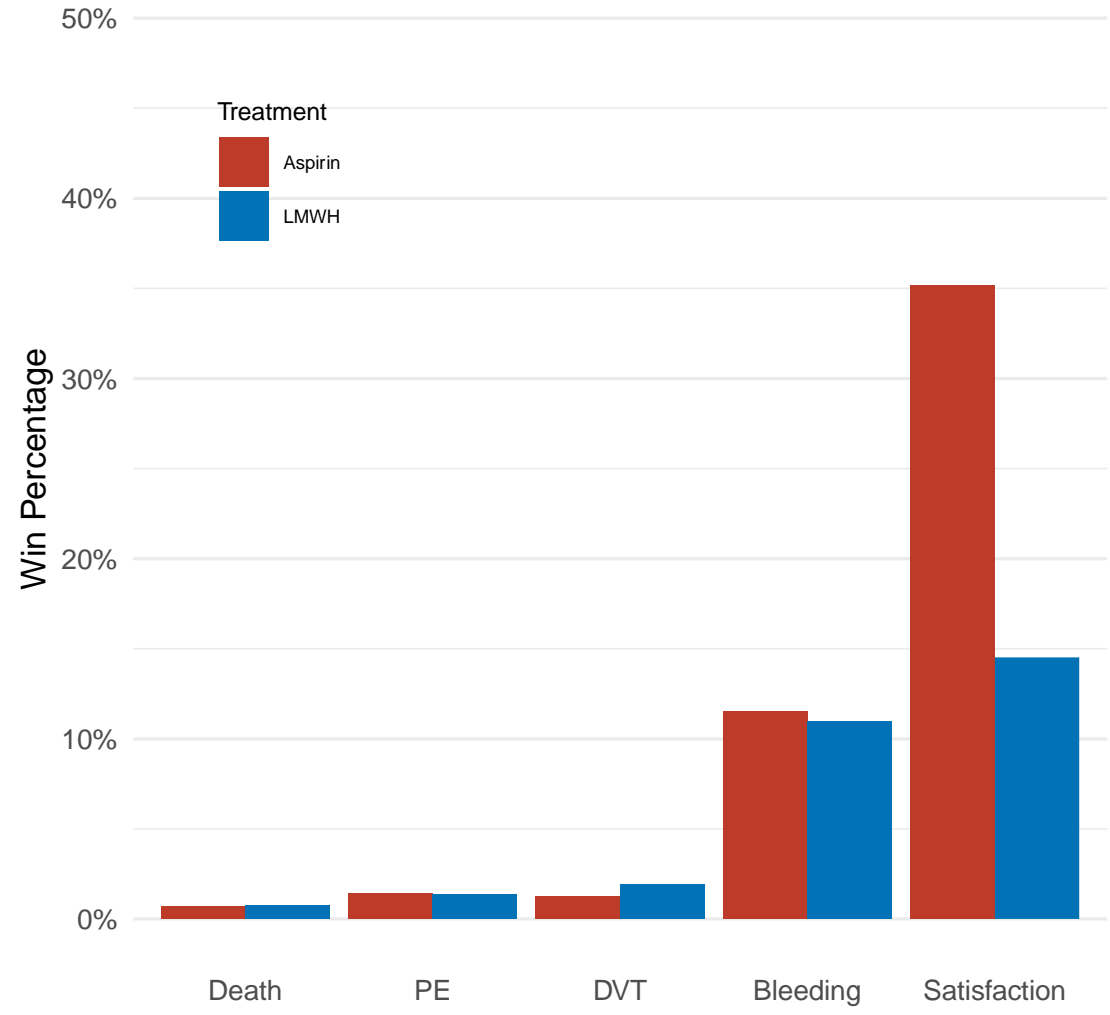
Ranked comparison of every patient to every other patient in the study

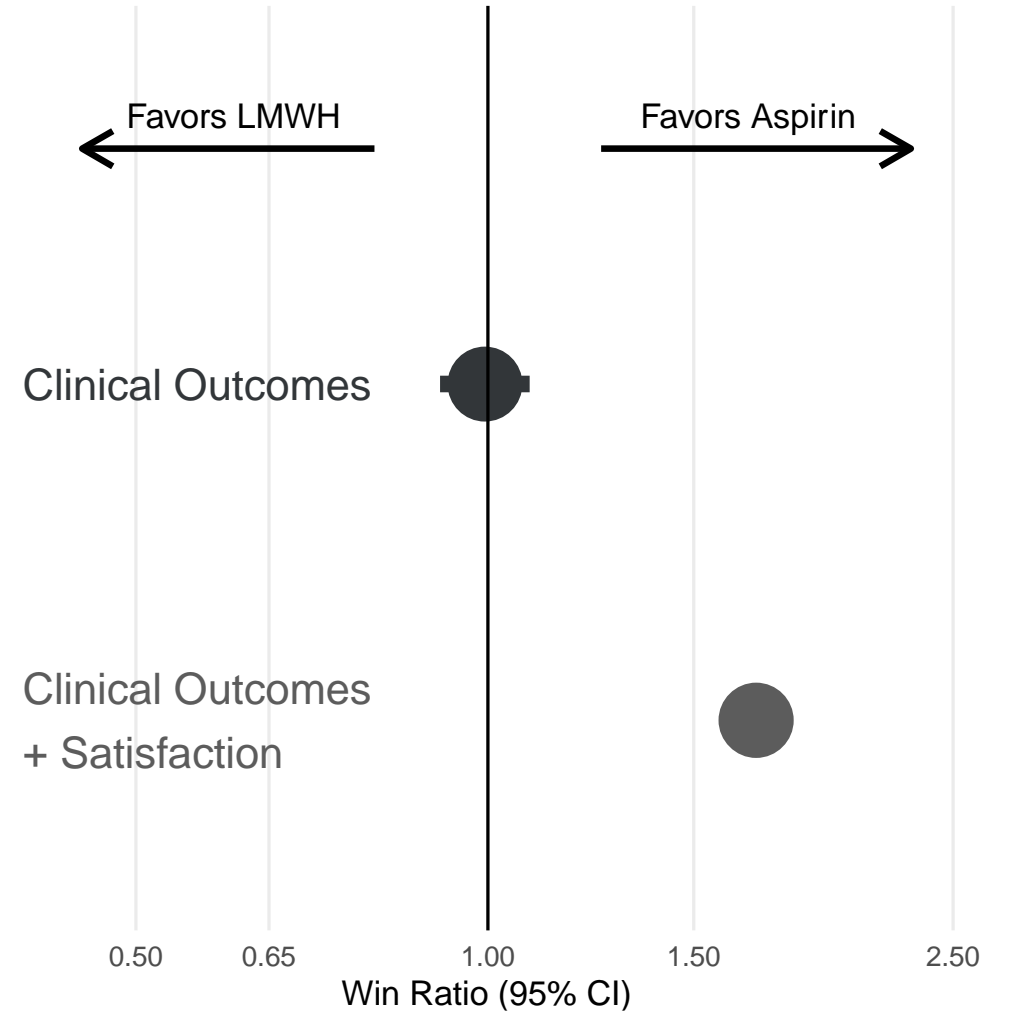
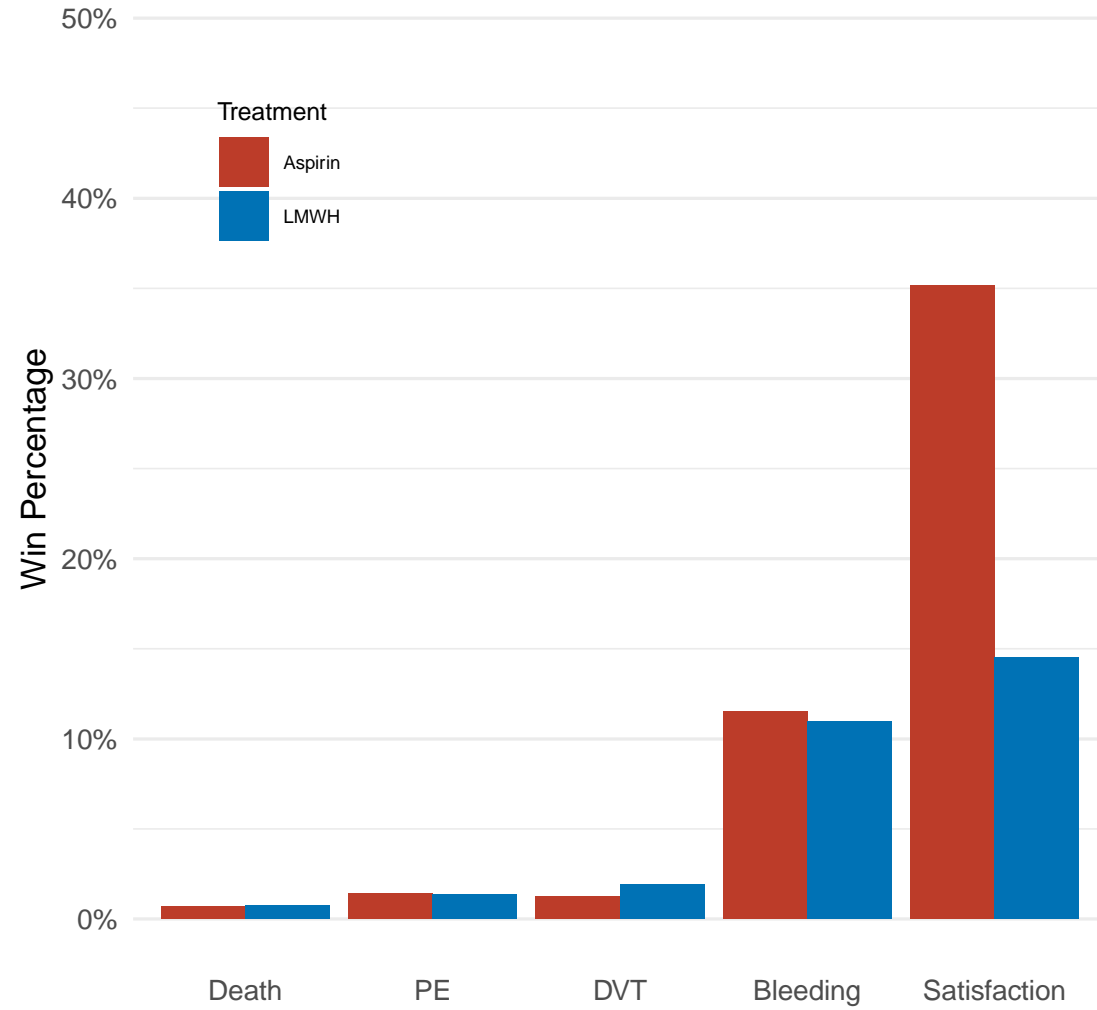
Rank the outcomes in order of importance:

Death, PE, DVT, Bleeding, Satisfaction

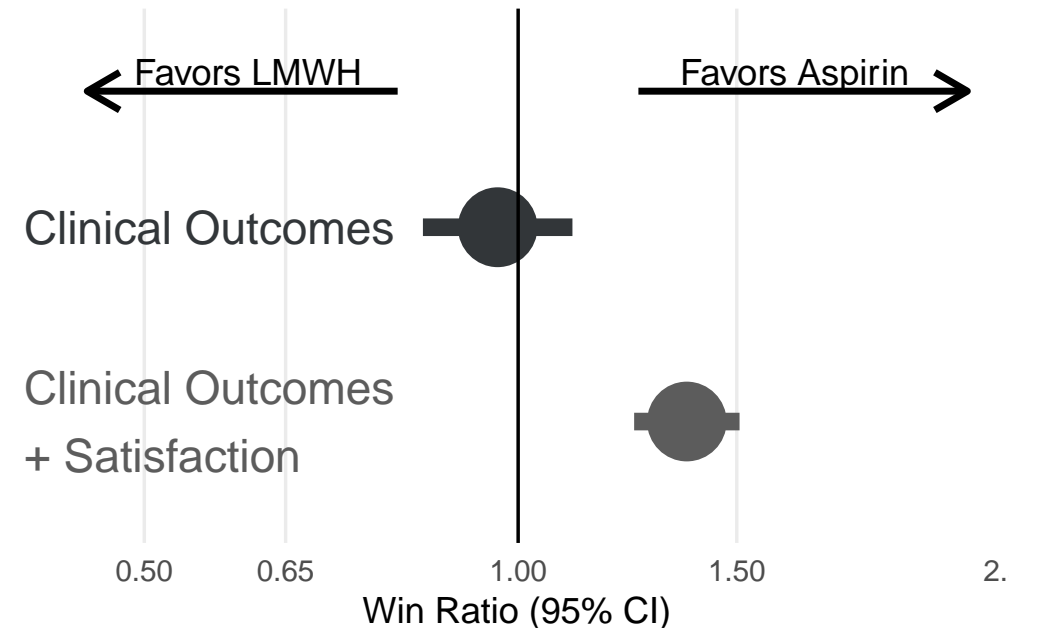
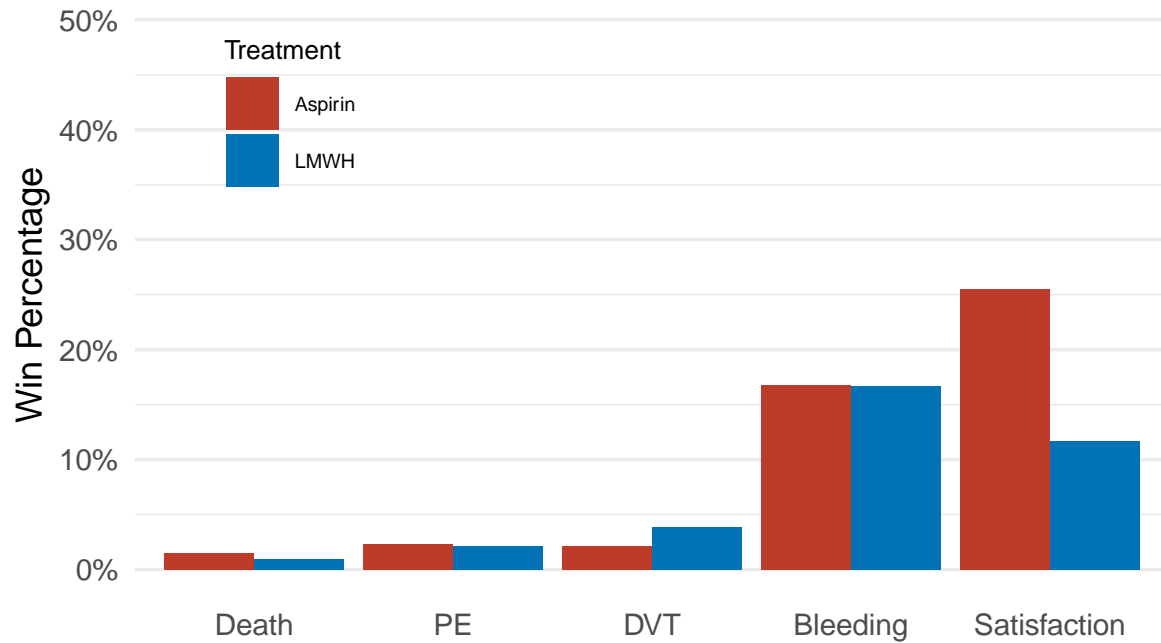
Compare each patient and see which patient “wins”

Sum up the wins for each treatment

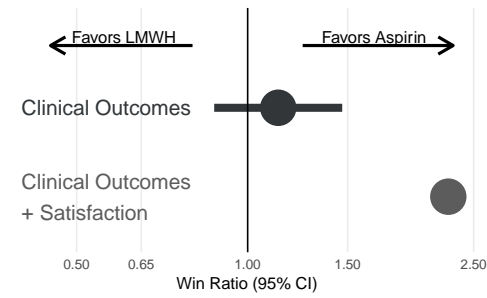
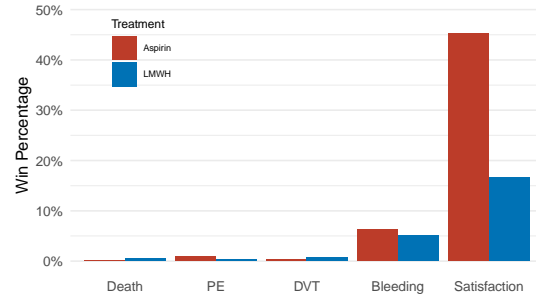




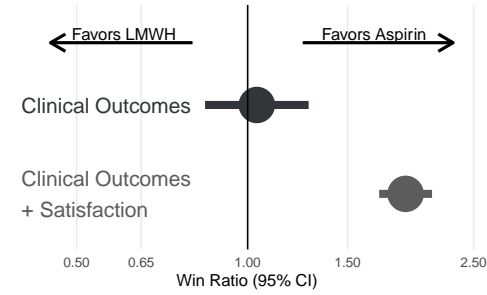
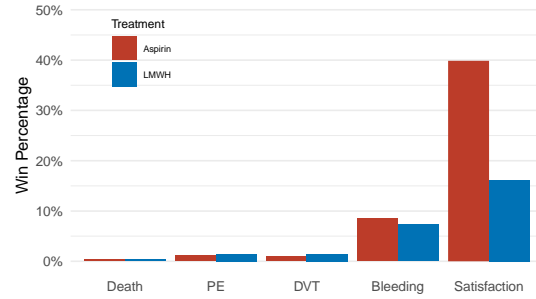
Highest Risk Quartile



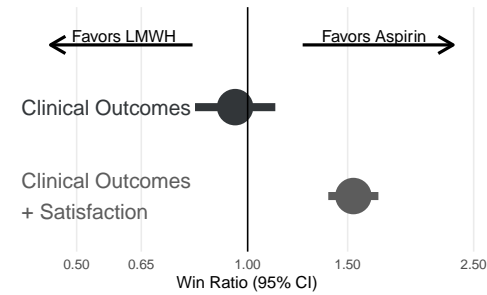
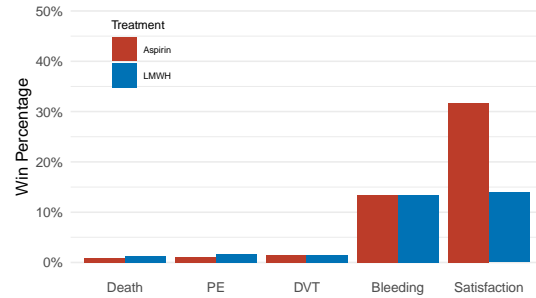
Lowest Risk Quartile



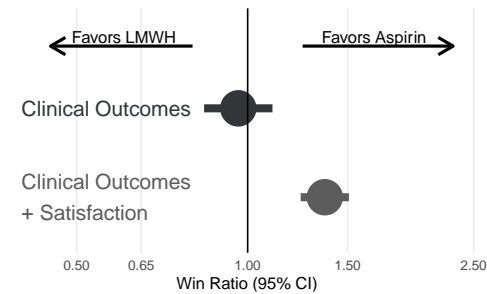
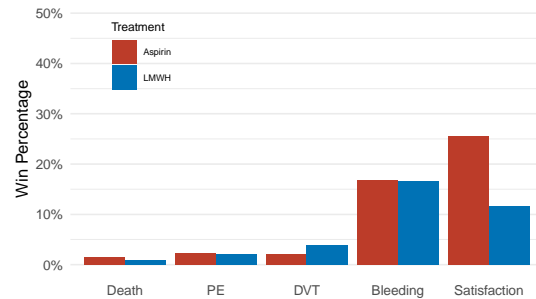
Second Lowest Risk Quartile



Second Highest Risk Quartile



Highest Risk Quartile



Future Questions

PCLOT FUTURE QUESTIONS

Heterogeneity of Treatment Effect (HTE)

Cost

Trauma w/o Fractures?

CONCLUSIONS

Conclusions

Large, 12,000+ patient RCT

ASA: Acceptable performance (Distal DVT?)

Difference:

Signal: favors LMWH in distal DVT (0.9% vs 1.5%, 95%CI: 0.2 – 1.0)

More work coming

Will this change practice?



Aspirin vs Low Molecular Weight Heparin for Thromboprophylaxis:
A Randomized Clinical Trial of Over 12,000 Orthopaedic Trauma Patients
METRC