

# Patient Demographics and Reported Outcomes in Funded versus Non-funded Studies Assessing Thromboprophylaxis after Total Joint Arthroplasty: A Systematic Review

### INTRODUCTION

There are numerous studies discussing thromboprophylaxis after total joint arthroplasty (TJA), which have varying conclusions. The patient inclusion criteria may be different for each study, which may lead to selection bias and misrepresenting data.

The purpose of this study was to investigate if industry funding impacted patient demographics and overall reported outcomes of studies analyzing venous thromboembolism (VTE) prevention after TJA.

### **MATERIALS & METHODS**

Electronic searches were completed for Ovid, PubMed, and Embase. Studies were included if:

- published in the English language between 2000 and 2016 (1)
- including patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (2)(TKA)
- evaluating prevention and control of postoperative VTE with at least one of the following thromboprophylactic agents: aspirin, enoxaparin, deltaparin, dabigatran, apixaban, rivaroxaban, dabigatran, ximelagatran, fondaparinux or coumadin. Data was extracted and analyzed via mixed-effect logistic regression.



Figure 1. Screening and selection for this systematic review.

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TABLES 1-3		

Table 1. Patient Demographics and study information of funded vs. non-funded studies.

	Funded Studies (n=29)	Non-funded Studies (n=28)	p-value
<b>Conflict of Interest</b>	23	9	<u>0.000</u>
<b>Excluded Revisions</b>	15	12	0.512
Retrospective	4	14	<u>0.013</u>
<b>Male (%)</b>	39.41%	31.09%	<u>0.019</u>
Age (mean)	66.7	66.7	1.000
BMI (mean)	29.0	28.8	0.729

Table 2. Number of funded and non-funded studies including each drug category.

	Funded Studies	Non-funded Studies		
Aspirin +/- foot				
pump	4	8		
Enoxaparin	18	18		
Foot pump only	1	3		
Oral anticoagulants*	20	11		
Other LMWH <sup>&amp;</sup>	5	6		
Warfarin	7	9		
*: İncluding dahigatran anixahan riyaroxahan ximelgatran				

&: İncluding fondaparinux and daltaparin

Table 3. Outcomes of funded vs. non-funded studies.

	Funded Studies	Non-funded Studies	p-value
PE % (95% CI)	0.29% (0.19 - 0.42)	0.72% (0.47 - 1.12)	<u>0.001</u>
DVT % (95% CI)	3.78% (2.09 - 6.72)	3.27% (1.84-5.73)	0.728
Major Bleeding % (95% CI)	0.75% (0.52 - 1.11)	1.4% (0.84 - 2.33)	0.046
Mortality % (95% CI)	0.12% (0.09 - 0.16)	0.38% (0.25 - 0.57)	0.000

There was no overall drug effect between reporting outcomes, patient demographics, and level of funding.

There were no significant differences between patient age, BMI, or revision exclusions between funded and non-funded studies.

However, funded studies reported less pulmonary embolisms (PE) (0.29%, 95% CI 0.19-0.42) compared to non-funded studies (0.72%, 95% CI; 0.47-1.12) (p=0.001).

Funded studies also **reported fewer events of major bleeding** (0.75%, 95% CI; 0.52-1.11) than non-funded studies (1.4%, 95% CI; 0.84-2.33) (p=0.046).

Funded studies also reported significantly less 90-day mortality (0.12% (95% CI; 0.09-0.16) than non-funded studies (0.38%, 95% CI; 0.25-0.57) (p=0.000).

Industry-funded studies reported less PE, major bleeding, and mortality compared to non-funded studies. There were no differences in patient demographics or drug effect.

It is important to investigate the underlining reason how funded studies are reporting fewer poor outcomes than non-funded studies. In addition, our data suggests careful examination of data from funded studies when applying results to a clinical basis.

Future studies should further investigate patient demographics, study design, and additional forms of bias that may arise in orthopedic research.

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## RESULTS

There were 57 studies included in this systematic review; 29 studies were industry funded and 28 were non-funded

## DISCUSSION

## REFERENCES

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