TRANSFORMING A PROJECT INTO A PUBLISHABLE MANUSCRIPT

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LEARNING OBJECTIVES

After completion of the presentation, learners will be able to:

1. List the components of the methods, results, and discussion sections of a project manuscript
2. Identify aspects of figures and tables for publication
3. Describe common pitfalls in manuscript writing and how to avoid them

OUTLINE OF A MANUSCRIPT

Section of manuscript	Element	Purpose	Related vocabulary
Background	Research question(s)	What are the study questions?	Objectives, aims
	Background	Why is the research important?	Relevance

OUTLINE OF A MANUSCRIPT

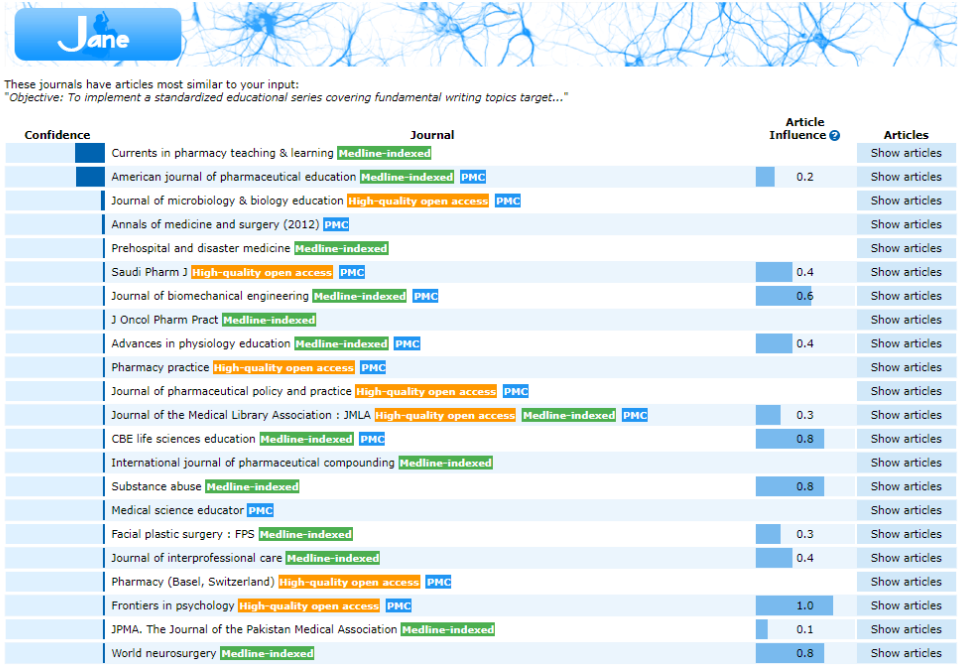
Section of manuscript	Element	Purpose	Related vocabulary
Methods	Design	How is the study structured?	Observational, prospective, randomized, descriptive
	Subjects	Who are the subjects and how are they selected?	Inclusion/exclusion criteria, recruitment/enrollment
	Variables	What measurements are made?	Nominal, ordinal, continuous, outcome
	Statistics	Study size/how analyzed?	Hypothesis, sample size, significance, confidence intervals

OUTLINE OF A MANUSCRIPT

Section of manuscript	Element	Purpose	Related vocabulary
Results	Results	Summarize what happened in the study	Table 1, relative change, absolute change, number needed to treat
Discussion/ Conclusion	Conclusions	Interpret and discuss results	Limitations, weaknesses, strengths

BEGIN WITH THE END IN MIND

- Journal / Author Name Estimator (JANE)
- Insert title, abstract, or key words to find matching journal
- Read example articles from journal that match your type

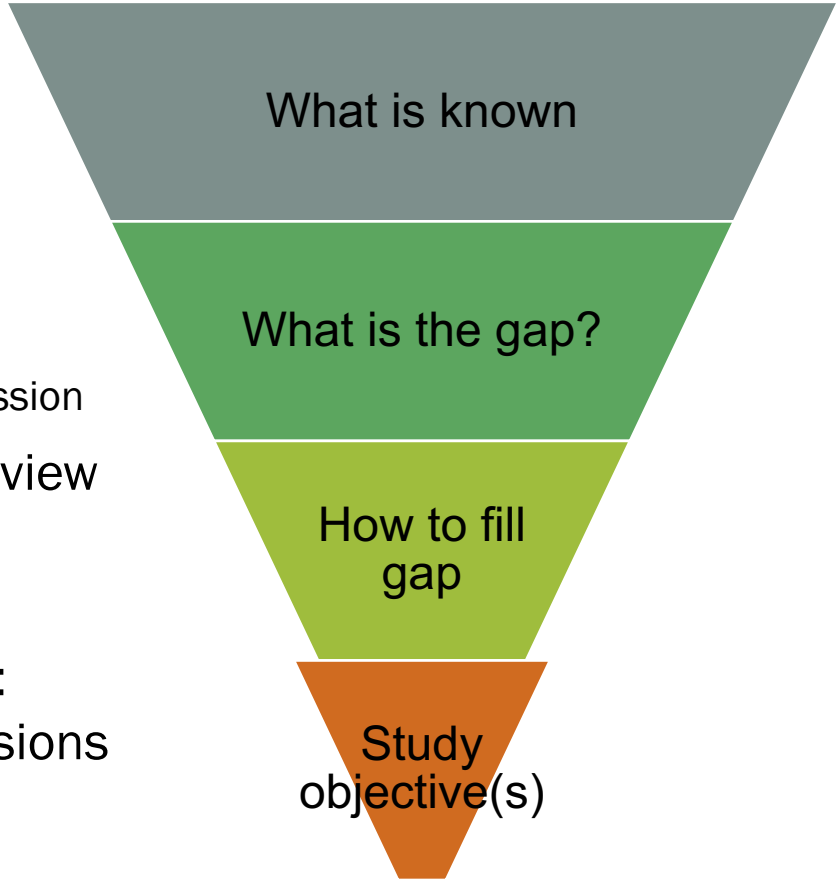


URL: https://jane.biosemantics.org/

INTRODUCTION

- Structured like a funnel
- Brief is better
  - Detailed comparison to literature in discussion
- Leverage initial proposal/literature review
- End introduction with study objective

- Module 4 of Emerging Writers Series: Structuring Introductions and Conclusions



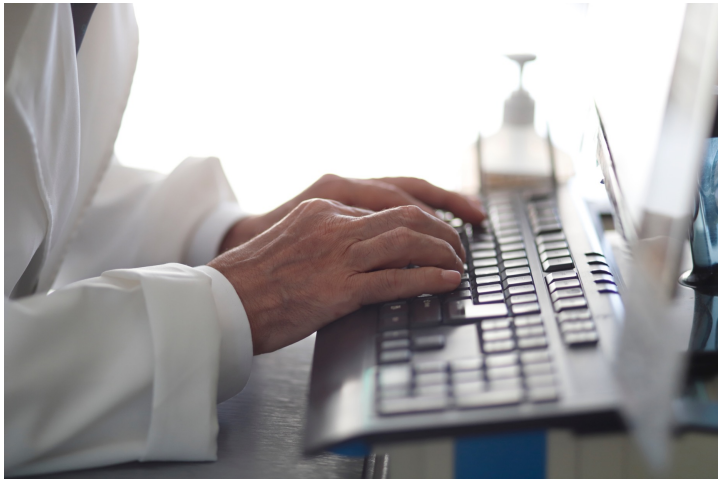
https://blog.wordvice.com/how-to-draft-a-compelling-introduction-for-your-journal-article/

METHODS - GENERAL OUTLINE

1. Describe the study design
2. Describe the setting
3. Describe the intervention
4. Describe the population
    1. i.e. inclusion/exclusion criteria
5. Describe the variables
6. Describe the analysis

METHODS CONSIDERATIONS

- Methods needs to be described in enough detail to be reproducible
  - If a specific lab test, program, etc was used, cite it
  - Describe what was done
- List IRB approval



METHODS - STUDY DESIGN

- Cohort, RCT, prospective, retrospective, etc
- Gives a preview of the overall design
- Often in the first paragraph of methods section

Methods

This single-arm, prospective cohort study evaluated the feasibility and safety of a protocol to extend the INR interval up to 12 weeks over 2 years. A detailed explanation of the study methods is described in Porter et al. [14]. The study took place in a pharmacist-managed anticoagulation clinic under the guidance of a hematologist medical director. In this clinic, pharmacists have prescriptive authority under a scope of practice where they assess patients independently and manage anticoagulant therapy. This study was approved by the University of Wisconsin-Madison Health Sciences Institutional Review Board (IRB) and the William S. Middleton Memorial Veterans Hospital Research and Development Committee. An independent Data Monitoring Committee (DMC) monitored the safety of the study.

Porter A, et al. *J Thromb Thrombolysis*. 2019;47(2):200-208. doi: 10.1007/s11239-018-1760-9.

METHODS - SETTING

- Inpatient, outpatient
- Rural, urban
- Number of sites
- Specialists
- Patients
  - Veterans
  - Pediatrics
- General geography
- Unique aspects of site

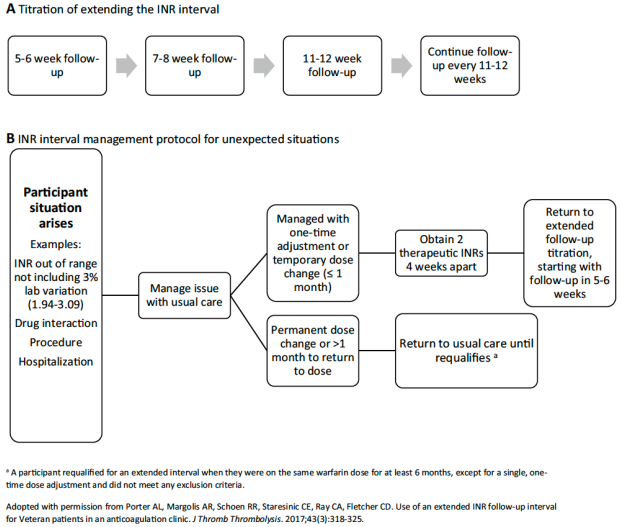
Practice description

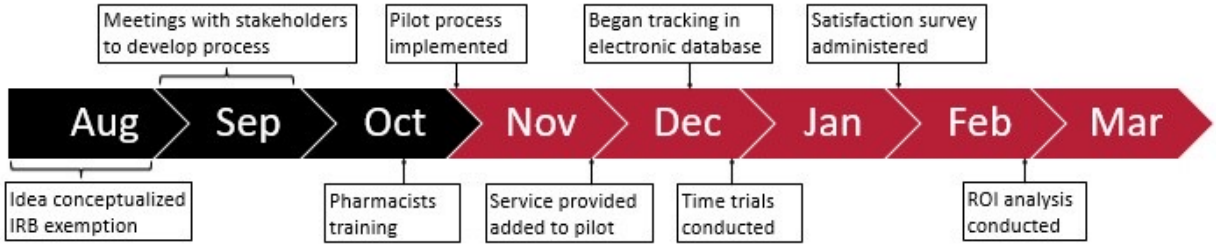
The Madison VA provides care for 130,000 veterans living in the Wisconsin and upper Illinois area and is the specialty care referral center for 57,000 Veterans who reside in the Tomah VA Medical Center primary service area. The VHA does not have a dedicated specialty pharmacy. Medications that are reviewed and verified are mailed directly to the patient from the health system or a central mail outpatient pharmacy.

Albright T, et al. *J Am Pharm Assoc (2003).* 2022;S1544-3191(22) doi: 10.1016/j.japh.2022.05.004

METHODS - INTERVENTION

- What was done?
- Who was involved?
- What kind of resources used?
- Steps to offer intervention
- Timeline





Porter A, et al. *J Thromb Thrombolysis*. 2019;47(2):200-208. doi: 10.1007/s11239-018-1760-9.
Brown A, et al. WPRC 2022.

METHODS - POPULATION

- List inclusion and exclusion criteria
- Be as specific as you can
- Try to remove subjectivity

Porter A, et al. *J Thromb Thrombolysis*. 2019;47(2):200-208. doi: 10.1007/s11239-018-1760-9.

The following inclusion criteria was used: 18 years of age or older, on indefinite warfarin therapy, a target INR goal of 2.0–3.0, a patient of the anticoagulation clinic for the previous 12 months, and a stable weekly warfarin dose for the prior 6 months, with no more than a single, one-time adjustment [14]. A planned interruption for a procedure or surgery with INRs out-of-range during that time would not exclude a patient from the study. Patients were excluded if they had: at least one episode of consumption of 4 or more alcoholic beverages in 24 h in the previous 6 months, diagnosis of cancer and on active chemotherapy or radiotherapy in the previous 3 months, life expectancy of less than 1 year, enrolled in other investigational drug protocols, only received care in the Anticoagulation Clinic for part of the year (i.e. patients who are managed by another clinic for the winter), received visiting nurse services for INR monitoring, thrombocytopenia with platelet count of less than 100 K/μL in the previous 12 months, history of bleeding or thromboembolism requiring medical intervention within the previous 6 months, treatment for active liver disease, diagnosis or documentation in the electronic health record suggesting cognitive impairment, activated power of attorney, inability to provide informed consent, non-English speaking, an unstable mental health disorder that impairs judgment which had specific criteria and was flagged in the electronic medical record, or a history of nonadherence to anticoagulation clinic policies and procedures, such as missed appointments, self-adjustment of warfarin dose, or noncompliance. Eligible patients were invited by a pharmacist staff member and interested patients underwent informed consent.

METHODS - VARIABLES

- What was measured?
- When was it measured?
- How was it measured?
  - If validated survey – describe and cite
  - If scale used – describe anchors

> *Study Outcomes.* The primary outcome of this analysis was measured using the Duke Anticoagulation Satisfaction Scale (DASS).[16] The DASS is a validated tool to assess patient satisfaction with anticoagulation therapy. The DASS was validated with 3 subscales: (1) limitations to daily activities, (2) hassles of anticlot treatment, and (3) positive psychological impact of anticoagulation. When interpreting the DASS, higher numbers indicate worsening satisfaction, ranging from 25 to 175. The DASS contains 25 questions on a 7-point ordinal scale (*not at all* = 1, *very much* = 7). Of the 25 questions, 6 were positive-type questions and subsequently coded inversely.

Schoen R, et al. *Ann Pharmacother.* 2020;54(5):442-449. doi: 10.1177/1060028019889414

METHODS - ANALYSIS

- Be specific in how the data is assessed
  - What tests are used?
  - How many investigators reviewed the data?
  - Describe and cite software used (unless Excel)
- Describe the theory or framework used for behavior/system changes

METHODS - COMMON PITFALLS

Not enough detail, esp scales	Ask a colleague to report back methods and results to you
All results need to be described in methods	Cross check results with methods
Missing specific analysis conducted	Whoever conducted the statistical analysis should draft
Missing IRB statement	Use of checklist to ensure included

RESULTS

- Describe sample size and demographics
- Objectively summarize key findings
  - Present outcomes in the same order used in the introduction and methods
- Utilize both text and visual aids

Clin Spine Surg. 2019;32(7):295-296. doi:10.1097/BSD.0000000000000845

RESULTS - DEMOGRAPHICS

- Overview of number of participants and overview of baseline characteristics

A total of 5988 patients were randomly assigned to placebo (n=2991) or to empagliflozin (n=2997). As previously reported,[25] the 2 groups had clinical features typical of patients with HFpEF and they were well-balanced with respect to baseline characteristics.

Circulation. 2021 Oct 19;144(16):1284-1294. doi: 10.1161/CIRCULATIONAHA.121.056824.

- May reference baseline characteristics table

Participant demographics and smoking-related variables appear in **Table 1**. Among 1251 patients who were randomized (mean [SD] age, 49.1 [11.9] years; 675 [54.0%] women), 751 (60.0%) completed treatment and 881 (70.4%) provided final follow-up.

JAMA. 2021;326(15):1485-1493. doi:10.1001/jama.2021.15333

Table 1. Demographic Characteristics and Baseline Smoking-Related Variables

	Treatment duration of 12 wk		Treatment duration of 24 wk	
	Varenicline monotherapy (n = 315)	Varenicline plus nicotine patch (n = 314)	Varenicline monotherapy (n = 311)	Varenicline plus nicotine patch (n = 311)
Sex, No. (%)				
Female	171 (54.3)	171 (54.5)	167 (53.7)	166 (53.4)
Male	144 (45.7)	143 (45.5)	144 (46.3)	145 (46.6)
Race, No. (%)[a]				
Asian	2 (0.6)	2 (0.6)	1 (0.3)	3 (1.0)
Black/African American	70 (22.2)	71 (22.6)	78 (25.2)	68 (21.9)
Native American/Alaska Native	5 (1.6)	3 (1.0)	2 (0.6)	4 (1.3)
Native Hawaiian/Pacific Islander	1 (0.3)	0	2 (0.6)	0
White	219 (69.5)	221 (70.4)	214 (69.0)	213 (68.5)
Other	12 (3.8)	12 (3.8)	6 (1.9)	14 (4.5)
>1	6 (1.9)	5 (1.6)	7 (2.3)	9 (2.9)
Hispanic ethnicity, No. (%)	10 (3.3)	14 (4.7)	5 (1.7)	12 (4.0)
Age, mean (SD), y	48.9 (12.4)	48.6 (11.4)	48.9 (12.3)	49.9 (11.5)
Income ≥$35 000, No. (%)	166 (56.3)	182 (61.7)	162 (54.5)	159 (55.4)
Education level of at least some college, No. (%)	208 (66.7)	195 (62.3)	227 (73.5)	212 (68.6)
Cigarettes per day, mean (SD)	15.9 (7.6)	16.0 (7.3)	16.2 (7.4)	16.0 (7.7)
Smoking history, mean (SD), y	28.7 (12.8)	27.5 (12.3)	28.9 (12.8)	28.7 (12.1)
(Fagerström Test of Cigarette Dependence score, mean (SD)[b]	5.1 (2.0)	4.9 (2.0)	4.9 (2.0)	5.0 (2.1)
Heaviness of Smoking Index, mean (SD)[c]	3.0 (1.2)	3.0 (1.2)	3.0 (1.3)	3.1 (1.3)
Exhaled carbon monoxide level, mean (SD), ppm	16.9 (9.6)	16.5 (9.0)	16.9 (9.6)	16.4 (9.7)
Smokes menthol cigarettes, No. (%)	181 (57.5)	164 (52.2)	179 (57.7)	158 (50.8)
Prior use of cessation medication, No. (%)[d]	244 (77.5)	248 (79.0)	245 (79.0)	255 (82.0)
Prior use of varenicline, No. (%)	124 (39.4)	136 (43.3)	149 (48.1)	133 (42.8)
Lives with another person who smokes, No. (%)	134 (42.5)	109 (34.7)	125 (40.3)	112 (36.0)
Motivation to quit score, mean (SD)[e]	6.4 (0.9)	6.4 (0.9)	6.4 (0.8)	6.4 (0.9)
Confidence in quitting score, mean (SD)[e]	5.5 (1.4)	5.5 (1.3)	5.5 (1.3)	5.5 (1.3)

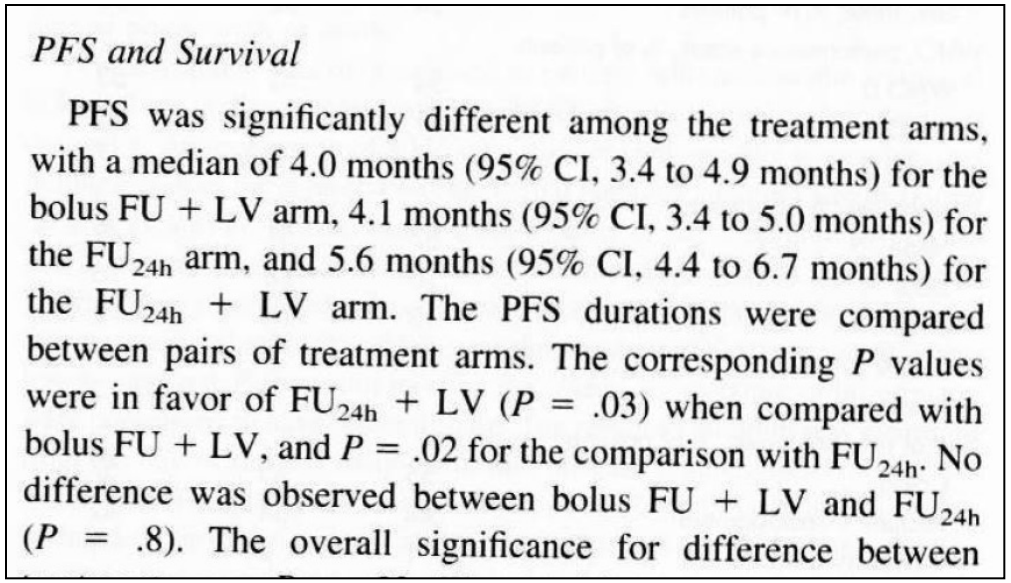
JAMA. 2021;326(15):1485-1493. doi:10.1001/jama.2021.15333

RESULTS – KEY FINDINGS

- Use subheadings to separate outcomes
  - Primary outcome
  - Secondary outcomes
  - Post Hoc outcomes
- **Not everything collected needs to be incorporated**
- Highlight points from the visuals

THINK PAIR SHARE

- Identify some pitfalls within this results section
- How could this results section be improved?



PFS and Survival

PFS was significantly different among the treatment arms, with a median of 4.0 months (95% CI, 3.4 to 4.9 months) for the bolus FU + LV arm, 4.1 months (95% CI, 3.4 to 5.0 months) for the FU_{24h} arm, and 5.6 months (95% CI, 4.4 to 6.7 months) for the FU_{24h} + LV arm. The PFS durations were compared between pairs of treatment arms. The corresponding *P* values were in favor of FU_{24h} + LV ($P = .03$) when compared with bolus FU + LV, and $P = .02$ for the comparison with FU_{24h}. No difference was observed between bolus FU + LV and FU_{24h} ($P = .8$). The overall significance for difference between

J Clin Oncol. 2003;21(20):3721-3728. doi: 10.1200/JCO.2003.11.122.

RESULTS – FIGURES AND TABLES

- Used when results cannot be easily described in text
- Improve readability and understanding of results
- Footnotes should be used for clarification

- Module 3: Plagiarism and Appropriate use of Figures and Tables

RESULTS – FIGURES AND TABLES

- Components of figures
  - Caption (figure number, title, description)
  - Axis labels and titles
  - Image (graph, image, etc.)
  - Results
  - Definitions

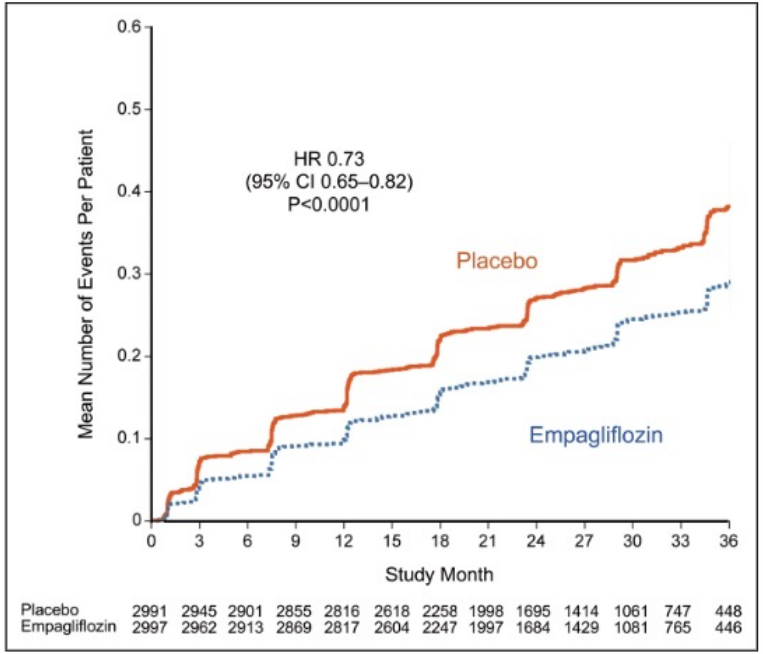


Figure 4. Total number of outpatient visits reporting interval intensification of diuretics for worsening heart failure.
Shown are mean cumulative function curves for placebo (shown in red) and for empagliflozin (shown in blue). HR indicates hazard ratio.

Circulation. 2021 Oct 19;144(16):1284-1294. doi: 10.1161/CIRCULATIONAHA.121.056824.

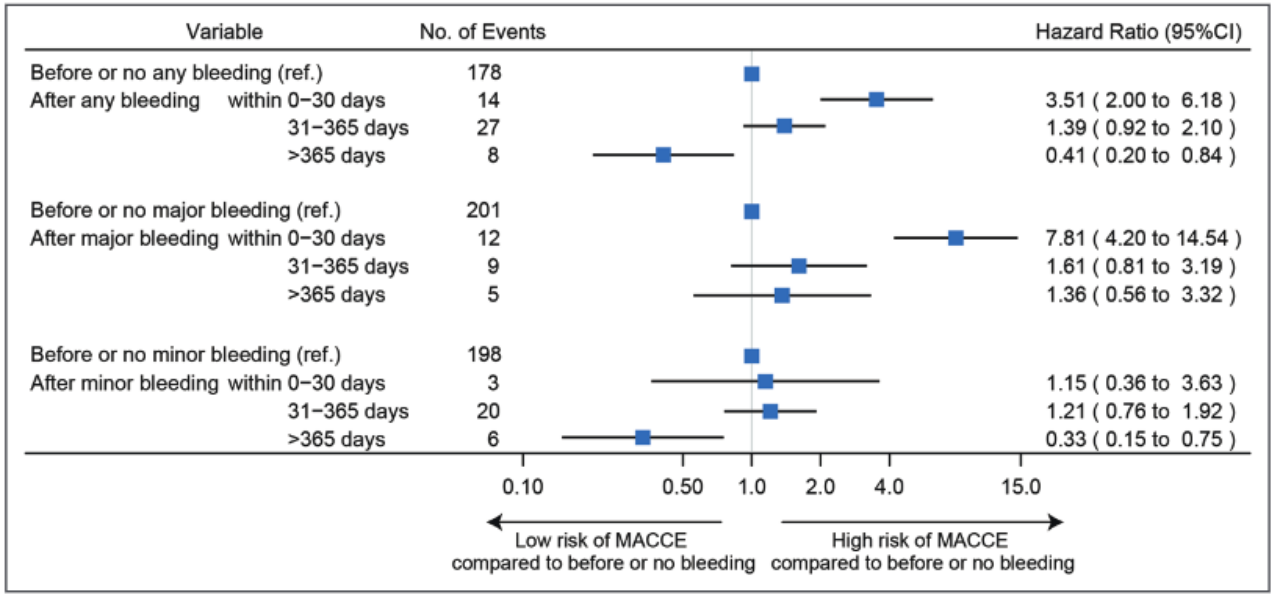


Figure 3. Hazard ratios for major adverse cardiac and cerebrovascular events (MACCE) in the time-adjusted multivariate analysis. Hazard ratios for MACCE in the Cox multivariate analysis with bleeding as a time-adjusted binary covariate. We used a multivariate model with the following variates: time intervals, the assigned treatment group in the AFIRE trial (Atrial Fibrillation and Ischemic Events With Rivaroxaban in Patients With Stable Coronary Artery Disease), age, sex, type of atrial fibrillation, diabetes, heart failure, hypertension, stroke history, previous percutaneous coronary intervention or coronary artery bypass grafting, creatinine clearance, body mass index, drinking habit, and concomitant drugs (proton pump inhibitor and nonsteroidal anti-inflammatory drugs). Overall, 123 patients without creatinine clearance data were excluded from this analysis. In the time-adjusted multivariate analysis, first and recurring MACCE and bleeding were considered; if multiple bleeding episodes occurred, the association between the most recent one and MACCE was examined.

Circ Cardiovasc Interv. 2021;14(11):e010476. doi: 10.1161/CIRCINTERVENTIONS.120.010476..

RESULTS – FIGURES AND TABLES

- Components of tables
  - Caption (table number, title, description)
  - Column titles
  - Table body
  - Results
  - Footnotes

Table 2. Adverse Events That Emerged during the Intervention Period (Safety Population).*

Event	Placebo, 1.14 ml (N=313)	Dupilumab, 200 mg (N=631)	Placebo, 2.00 ml (N=321)	Dupilumab, 300 mg (N=632)	Combined Placebo (N=634)	Combined Dupilumab (N=1263)
	number of patients (percent)					
Any adverse event	257 (82.1)	508 (80.5)	270 (84.1)	515 (81.5)	527 (83.1)	1023 (81.0)
Any serious adverse event	26 (8.3)	49 (7.8)	27 (8.4)	55 (8.7)	53 (8.4)	104 (8.2)
Any adverse event leading to death†	3 (1.0)	1 (0.2)	0	4 (0.6)	3 (0.5)	5 (0.4)
Any adverse event leading to permanent discontinuation of the intervention	19 (6.1)	19 (3.0)	10 (3.1)	44 (7.0)	29 (4.6)	63 (5.0)
Adverse events occurring in ≥5% of patients in any group‡						
Viral upper respiratory tract infection	60 (19.2)	119 (18.9)	64 (19.9)	111 (17.6)	124 (19.6)	230 (18.2)
Upper respiratory tract infection	37 (11.8)	69 (10.9)	49 (15.3)	77 (12.2)	86 (13.6)	146 (11.6)
Bronchitis	47 (15.0)	73 (11.6)	42 (13.1)	71 (11.2)	89 (14.0)	144 (11.4)
Influenza	29 (9.3)	36 (5.7)	22 (6.9)	38 (6.0)	51 (8.0)	74 (5.9)
Sinusitis	27 (8.6)	36 (5.7)	29 (9.0)	26 (4.1)	56 (8.8)	62 (4.9)
Urinary tract infection	17 (5.4)	17 (2.7)	12 (3.7)	19 (3.0)	29 (4.6)	36 (2.9)
Headache	26 (8.3)	46 (7.3)	25 (7.8)	40 (6.3)	51 (8.0)	86 (6.8)
Rhinitis allergic	16 (5.1)	21 (3.3)	15 (4.7)	18 (2.8)	31 (4.9)	39 (3.1)
Back pain	16 (5.1)	30 (4.8)	7 (2.2)	25 (4.0)	23 (3.6)	55 (4.4)
Accidental overdose§	16 (5.1)	33 (5.2)	16 (5.0)	33 (5.2)	32 (5.0)	66 (5.2)
Injection-site reaction¶	17 (5.4)	96 (15.2)	33 (10.3)	116 (18.4)	50 (7.9)	212 (16.8)

N Engl J Med. 2021;384(11):989-1002.
doi: 10.1056/NEJMoa2032183.

RESULTS – COMMON PITFALLS

- Using a table or figure when information can be written clearly and succinctly in text format (or vice versa)
- Separating data from statistical significance
- Repeating data in a table or figure and in text
- Using misleading tables and/or figures
- Not referencing tables or figures in text

DISCUSSION

- General outline for an original project
  - Identify the key findings
  - Interpret the work for the audience
    - How would the work be or can they be extrapolated to other locations
    - How does this relate to prior literature***
  - Critical appraisal (strengths & limitations)
  - Future directions
    - Unanswered or new questions found

DISCUSSION – KEY FINDINGS

- The first paragraph of the discussion section
- Should **NOT** simply restate the results data!
- Goal is to identify the significance of the results for target audience

DISCUSSION – INTERPRETATION

- The bulk of the discussion section (2 or more paragraphs)
- How or could this project be extrapolated externally?
- How do key findings relate to prior literature?
  - Heavy on citations
- Goal is to interpret the significance of the results for target audience
  - Connect the dots to past literature, institutional or regulatory goals

DISCUSSION – CRITICAL APPRAISAL

- One or two paragraphs
- Authors strengths with explanation
- Authors limitations with explanation and interpretation
  - Why are they limitations and how do they impact the findings?
- Goal is to appraise the quality of the results for target audience

TAKE A MINUTE…

How can you improve this limitations section?

“There are multiple limitations to this study. First, we used the Duke Anticoagulation Satisfaction Scale (DASS) to capture patient satisfaction. There was a low number of participants with the vast majority being male and white. Finally, the results were not adjusted for multiple testing.”

There are limitations to the interpretation of these data, including the use of the DASS to capture patient satisfaction. Short-term events around the time of the periodic DASS assessments may have affected the participants' responses, but the similar findings of the post hoc analysis with highly stable patients and consistent trends of the subscales support the overall findings. Although the DASS is a validated tool for measuring satisfaction with anticoagulation therapy, quantifying the impact of an extended INR follow-up interval was not its original validated use.[16] Because this was a pilot study for the health system's clinic, the number of participants is relatively small, so a potential difference may not be adequately captured. Although the homogeneity in race and sex of the participants studied is reflective of the institution's patient population, this aspect may limit the generalizability to other patient populations. Finally, because results were not adjusted for multiple testing, potentially spurious results are possible.

DISCUSSION – FUTURE DIRECTION

- The last paragraph before the conclusion
- Highlights what has been done or will be done with the results
- Could also share with how this work may be disseminated

DISCUSSION – OTHER

- Many journals have unique requests for discussion sections
  - Implications for practice
  - Key takeaways (often in bulleted format)
  - Formatting to fit standards

- Remember use JANE or similar tool to identify initial target journal and review the requirements before writing

DISCUSSION SECTION TIPS/TRICKS

- Go back to the original project proposal and literature review
- Consider presenting interim/initial results as a poster and collect feedback to add to discussion section
- Send to colleague at an arms-reach to review prior to submission
  - Editing Tips: Read it out loud; take a break and come back to your work

DISCUSSION – COMMON PITFALLS

- Restating results without truly providing analysis
- Lack of interpretation
- Surface-level critical appraisal of limitations and strengths
- Overgeneralizing findings

CONCLUSION

- What was the main pragmatic takeaway(s) from the project
  - Common issue is overstating or overgeneralizing the findings
- Suggest **AGAINST** restating results or adding new information
- Module 4 of Emerging Writers Course: Structuring Introductions and Conclusions

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