Writing up Research: Abstracts and Manuscripts

Frank Friedenberg MD
Chief, Gastroenterology
Spring, 2019

Abstracts

- Follow directions – word count, font, etc.
- Check if table/figure will reduce allowed word count
- Pick an accurate title – must reflect main theme (i.e. specific aim) of abstract
- Clarity – avoid uncommon abbreviations
- Simplicity – discuss main results
- Too many analyses becomes confusing
  - Consider more than one abstract

Example Abstract Titles

- “Colorectal Cancer Screening in African Americans Age 45-49”
- “Measurement of Fractional Exhaled Nitric Oxide as a Marker of Disease Activity in IBD”
- “The Impact of Pre-Procedure Blood Pressure on Cardiopulmonary Status During Colonoscopy”

Abstracts

- Write abstract long before deadline
- Revise multiple times before submission
- Involve colleagues in writing and editing

Statistics

- Should be addressed before study begins
- Get results early; contemplate additional analyses

Submission

- Pick a category very carefully
- look at previous year's abstracts to determine fit

Esophageal, Gastric and Duodenal Disorders

Subcategories:

Barrett's Esophagus: Diagnosis and Management
Barrett's Esophagus: Pathogenesis
Barrett's-Related Esophageal Adenocarcinoma
Clinical Acid-Peptic (Non-GERD) and Other Gastroduodenal Disorders
Dyspepsia
EGD: Gastroduodenal Neuroendocrine Secretion: Neural, Hormonal, Intracellular and Molecular Regulation of Gastrin, Histamine, Somatostatin and Other Peptides
EGD: Gastroduodenal Exocrine Secretion: Neural, Hormonal, Intracellular and Molecular Regulation of Acid, Pepsinogen, Bicarbonate, Mucus and Other
EGD: Mucosal Defense: Pre-Epithelial, Epithelial and Post-Epithelial
EGD: Mucosal Injury, Repair and Healing
EGD: NSAIDs: Clinical Studies: Epidemiology, Diagnosis and Management
EGD: NSAIDs: Mechanisms of Injury and Repair
Endoscopic Detection of Premalignant Lesions in the UGI Tract
GERD: Diagnostic Testing
GERD: Pathogenesis
GERD: Pharmacological Treatment
GERD: Complications and Extra-Esophageal Presentations
GERD: Surgical, Intraluminal and Non-Pharmacologic Treatment
Helicobacter pylori: Diagnosis
Helicobacter pylori: Treatment and Antimicrobial Resistance

Authors and Speakers

- Senior responsible faculty member is final author.
- First author – most responsible for completing, organizing work.
- Carefully choose speaker – consider background, language skills.

ABSTRACT FINAL ID: T1053;

TITLE: GERD Prevalence: A Population-Based Survey of an African American Community

AUTHORS (FIRST NAME, LAST NAME): Jitha Rai[1], Vishwas Vanar[1], Charles A. Bongiorno[1], Mayur Parepally[1], Arashdeep Poonia[1], Joel Richter[1], Frank K. Friedenberg[1]

ABSTRACT BODY: Background: The prevalence of GERD is increasing in Western Societies. Changes in diet, the decline in prevalence of H. pylori, and the obesity epidemic are thought to be major contributors. Prior studies have primarily examined Caucasian subjects with respect to GERD prevalence and risk factors. We sought to study the prevalence and risk factors for GERD in a primarily African American (AA) population.

Methods: During the summer of 2008, adults entering or passing by a retail pharmacy near Temple Hospital were eligible to participate. Included subjects were self-selected and produced identification verifying their age and residence within the hospital's zip code. A researcher assisted subjects as necessary to read and interpret questions. The bilingual survey queried demographic information, lifestyle habits, medical history, medications, frequency and severity of GERD symptoms, and diet. Subjects underwent measurement of BMI and waist-to-hip ratio (WHR). GERD was defined as ≥ 2 days per week of heartburn, regurgitation, antacid treatment for heartburn, or an impact on QOL ⊏ 3 on a 1-5 scale.

Results: 413 subjects were interviewed; 60.3% ♀, 88.5% AA. Most participants graduated high school (80.2 %), had health insurance (74.9 %), drank alcohol ≥ 1 time per week (51.5%), and were current or former smokers (58.2%). The prevalence of GERD was 36.6%. Older age (45.6 ± 16.6 vs. 42.1 ± 17.3 years; P=0.05) and larger waist circumference (38.7 ± 6.2 vs. 36.8 ± 6.8 in; P=0.002), but not WHR were associated with GERD. There was a significant association between GERD and increasing BMI quartile even after adjusting for age and gender (OR=2.01, 95% CI 1.13-3.61; P= 0.02). Additionally, weight gained since age 18 was associated with prevalent GERD (OR=2.16,95% CI 1.09-4.28; P=0.03). There was no association between GERD and gender, smoking, or alcohol status. There was no relationship between dietary servings per week of meat, vegetables, sweets, soda, coffee, or tea and the presence of GERD. There was no relationship between dining out and GERD, however the frequency of eating "fast food" was inversely associated with GERD (P=0.014). This was due to the strong inverse relationship between "fast food" consumption and age (P<0.001). In regression analysis, waist circumference (OR=1.05, 95% CI 1.01-1.10; P=0.04) but not BMI or age was associated with GERD.

Conclusions: In this cross-sectional study of primarily AA subjects, waist circumference was the strongest risk factor for GERD. This finding has been seen in non-AA populations and is likely due to raised intragastric pressure. Adverse lifestyle and dietary practices were not associated with GERD.

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Poster Presentation

- Same principles apply
- Follow directions
- Make it: Clear, Simple, and Attractive
- Choose color combinations carefully
- Also make figures simple and attractive
- Visibility: make font large enough to read from 4 to 6 feet.

Poster Presentation

- Use figures and tables to summarize data to avoid crammed text
- Using photomicrographs, results from gels, etc. encouraged (if they add meaning)

Poorly Done Poster

Socioeconomic Disparities in the use of Catheter-Free Esophageal pH Testing

Eva Sum, MD, Sesha Uppalapati, MD, Joseph Kim, MD, Joel E. Richter, MD and Frank K Friedenberg, MD, MS (Epi),
Digestive Disease Center, Temple University School of Medicine, Philadelphia, PA.

Purpose

- There is a paucity of literature on Gastroesophageal Reflux Disease in African Americans
- Temple Hospital is unique in that we serve not only a local community which is predominantly AA and impoverished, but also a large tertiary care referral population that is primarily affluent and white
- This study's purpose was to: (1) compare the presentation and evaluation of white and AA patients with chronic GERD.
  (2) To identify predictor variables associated with erosive esophagitis.

Methods

- Data from consecutive patients evaluated for chronic reflux between 1/06 and 8/07 at Temple.
- Identified individuals without erosions to determine whether they subsequently underwent a Bravo® pH capsule (Medtronics) study (off PPI) to clarify their reflux status. Our unit now rarely orders catheter-based pH studies (~5 per year)
- Established pH criteria were used to determine the study's result. Patients were thus classified as either: Erosive esophagitis (EE); pH Negative (PN); or pH Positive (PP).
- The patient's zip code was used to estimate median household income.

Table 1. Characteristics of 429 patients with chronic reflux symptoms divided by test results.

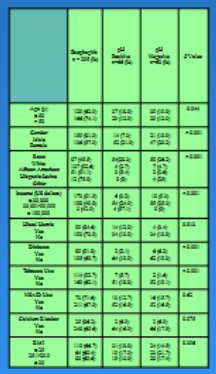


Table 1 Univariate Analysis
Patients with EE were significantly older, poorer (median income 32,600 USD), far more likely to be male (82% vs. 58%). Beta blockers, diabetes, black race and tobacco were also associated with EE.

Results (n=550)

Table 2. Erosive Esophagitis Parameter estimates from ordinal logistic regression model

Variable	β Estimate*	*P* Value	95% Confidence Interval Lower Bound	Upper Bound
Smoking	5.23	< 0.001	2.27	12.06
Diabetes	4.95	< 0.001	2.07	11.88
Male Gender	2.81	< 0.001	1.61	4.92
Black Race	5.41	0.014	1.41	20.66

Displayed β estimate values (and associated 95% confidence intervals) are the proportional-odds ratios. The value is the original β coefficient exponentiated, using e^{β}.

Table 2. Regression Analysis
- Tobacco use, AA race, diabetes, and male gender were associated with having presence of EE.
- Overall, 83.9% of pH studies were performed in whites while only 7.4% of AA underwent pH testing. The income of those who underwent pH testing was nearly double those who did not (52,700 USD vs. 26,700 USD; $P<0.001$). Only 13.6% of patients who underwent pH testing did not have commercial insurance. No patient without insurance or city-supplied insurance underwent this test.

Conclusions

- Tobacco use, diabetes, male gender, and AA race were strongly associated with erosive esophagitis.
- Study suggests an access limitation to catheter-free esophageal pH testing in the AA community.
- In the past payment for the capsule is usually out-of-pocket and not covered by most health insurance policies (however, the EGD portion usually is covered).
- This limitation precludes it's widespread use for patients living in poverty.

A Little Better

Diabetes is an Independent Risk for GERD in African Americans
Results from TRIAGE

Jake Natalini BS, Amiya Palit MD, Frank K. Friedenberg, MD, MS (Epi)
Section of Gastroenterology. Temple University School of Medicine. Philadelphia, PA

Background

-Previous studies have identified an association between diabetes mellitus (DM) and the prevalence of GERD
-Mechanisms may include delayed gastric emptying and/or disordered esophageal motility due to autonomic neuropathy.

Objectives

-Purpose: to determine if there is an independent association between DM and GERD after adjusting for potential confounders

Methods

- TRIAGE (Temple Registry for Investigation of African American Gastrointestinal Disease Epidemiology) is an ongoing NIH-funded registry of AA's from a single zip code in North Philadelphia.
- Complex sampling of the community was performed. Weighted data is in close agreement with published census and demographic data.
- All participants completed a validated, computer-based interview assisted by a research coordinator. GERD was defined as heartburn and/or regurgitation > 3 days/wk
- All patients had measurement of height, weight, and waist : hip ratio
- Subjects with DM completed the Diabetes Complications Index and recorded the duration of DM, fasting blood sugar, and latest HgbA1C.

Results

- 419 subjects recruited corresponding to a weighted population of N = 21,264; 56.9% female, mean age 44.2 ± 2.1 y.
- Prevalence of GERD = 23.7% , and DM = 14.9%. The prevalence of GERD for individuals with and without DM was 41.5 vs. 20.6% ;P< 0.001.
- Logistic regression identified DM, Age > 40 , BMI > 30, harmful drinking , and high smoking dependence as independent risks for GERD.
- substituting waist; hip ratio for BMI had little impact on adjusted risk.
- Gender was an important effect modifier.: for males, the risk of GERD in those with DM was substantial (OR=4.63;3.96-5.40) while in females the risk was significant but far less (1.79;1.61-2.00).
- We found no relationship between GERD and the number of years of DM, the patient's fasting glucose, or DCI score.

	Overall		Men		Women	
	Weighted N	Odds Ratio 95% CI	Weighted N	Odds Ratio 95% CI	Weighted N	Odds Ratio 95% CI
Age						
≤40	8,931	1.0	4,261	1.0	4,670	1.0
>40	12,333	1.25 (1.17-1.35)	4,901	1.57	7,432	1.03 (0.95-1.12)
BMI Kg/m²						
>25	7,362	1.0	3,932	1.0	3,430	1.0
>25.1-30	5,612	0.93 (0.82-1.02)	2,839	0.67 (0.57-0.79)	2,773	1.06 (0.95-1.19)
≤30.1	7,937	1.49 (1.37-1.62)	2,293	1.86 (1.59-2.17)	5,644	1.06 (0.96-1.18)
Harmful Drinking						
No	18,608	1.0	7,704	1.0	10,904	1.0
Yes	2,559	1.58 (1.44-1.75)	1,389	1.30 (1.09-1.55)	1,170	2.15 (1.88-2.45)
Smoking Dependence						
Non-Smoker	8,753	1.0	8,048	1.0	10,036	1.0
Low	6,408	1.11 (1.02-1.20)	2,841	1.04 (0.90-1.22)	3,567	1.10 (0.99-1.22)
Medium	5,011	1.18 (1.08-1.29)	2,233	1.04 (0.88-1.23)	2,778	1.29 (1.16-1.43)
High	1,092	2.11 (1.83-2.43)	580	1.45 (1.07-1.97)	512	3.57 (2.95-4.31)
Diabetes						
No	18,084	1.0	8,048	1.0	10,036	1.0
Yes	3,180	2.38 (2.18-2.59)	1,115	4.63 (3.96-5.40)	2,066	1.79 (1.61-2.00)

Conclusions

-In our registry we found a high prevalence of GERD and confirmed that DM was an important, independent risk factor.
-This effect was most pronounced in males.
-There was no evidence that duration of DM, glucose control, or autonomic dysfunction modified this relationship.
-Future studies focused on the mechanism of this relationship are needed.

GERD Prevalence: A Population-Based Survey of an African American Community

Jitha Rai MD, Vishwas Vanar MD, Charles Bongiorno MD, Mayur Parepally BS, Arashdeep Poonia BS,
Joel Richter MD, Frank K Friedenberg MD, MS (Epi)
Digestive Disease Center, Temple University School of Medicine, Philadelphia PA

Background

- The prevalence of GERD is increasing in Western Societies.
- Prior studies have identified the decline in prevalence of *H.pylori*, changes in diet, and the obesity epidemic as major contributors to GERD.
- Most studies have examined primarily Caucasian patient populations. There has been few studies investigating the risk factors for GERD in African Americans.

Aim

To identify the prevalence and risk factors of GERD in a primarily African American population.

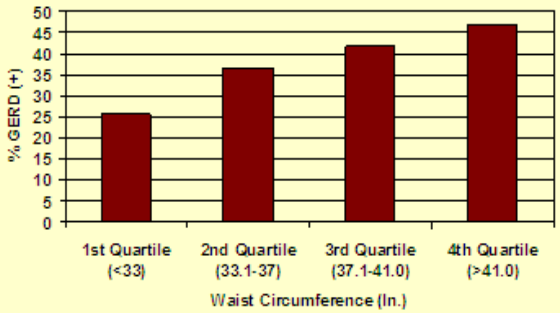
Methods

- Convenience sample: Adult subjects were selected based on their residence within the hospital's zip code.
- Interviewed at a local pharmacy
- Subjects participated in a bilingual survey that queried demographic information, lifestyle habits, medical history, medications, frequency and severity of GERD symptoms.
- Participants underwent measurements of BMI and waist-to-hip ratio (WHR). GERD was defined as ≥ 2 days per week of heartburn, regurgitation, or medication treatment for heartburn.

Results

- 413 subjects were interviewed; 60.3% ♀, 88.5% AA. Most graduated high school (80.2 %), had health insurance (74.9 %), drank alcohol ≥ 1 time per week (51.5%), and were current or former smokers (58.2%).
- The prevalence of GERD was 36.6%. Older age (45.6 ± 16.6 vs. 42.1 ± 17.3 years; P=0.05) and larger waist circumference (38.7 ± 6.2 vs. 36.8 ± 6.8 in; P=0.002), but not WHR were associated with GERD.
- GERD was associated with increasing BMI quartile even after adjusting for age and gender (OR=2.01, 95% CI 1.13-3.61; P= 0.02). Additionally, weight gained since age 18 was associated with prevalent GERD (OR=2.16,95% CI 1.09-4.28; P=0.03).
- In regression analysis, only waist circumference (OR=1.05, 95% CI 1.01-1.10; P=0.04) but not WHR, BMI, or age was associated with GERD.
- There was no association between GERD and gender, smoking, alcohol status, dietary servings per week of meat, vegetables, sweets, soda, coffee, or tea.

Relationship Between Waist Circumference and GERD Prevalence



Conclusions

- In this cross-sectional study of primarily AA subjects, waist circumference was the strongest risk factor for GERD. It was a stronger risk than BMI or Waist:Hip Ratio. A 5% increased risk for GERD was seen with each inch increase in waist circumference.
- This finding has been seen in non-AA populations and is likely due to raised intragastric pressure.
- Adverse lifestyle and dietary practices were not associated with GERD in our study.

Outcomes For Severe Complicated *Clostridium difficile* Infection Treated With Vancomycin Enema

Mark Malamood, MD; Eric Nellis, MD; Frank Friedenberg, MD, MS Epi
Digestive Disease Center, Temple University School of Medicine, Philadelphia PA

Background

- Prevalence of Clostridium difficile infection (CDI) is increasing.[1]
- Serious, complicated infections have been linked to a virulent strain (BI/NAP1) which produces elevated levels of toxin and can lead to colectomy or death.[1]
- For these patients, standard of care is now concomitant treatment with IV metronidazole (IVM) and per oral vancomycin (POV).[2,3]
- Some institutions use add-on therapy with vancomycin per rectum (VPR) to increase colonic drug delivery.
- Only two, small case series have previously been reported concerning the use of VPR in the setting of severe, complicated CDI.[4,5]

Aim

- Our purpose was to look at clinical outcomes of consecutive patients with CDI treated with VPR at our hospital.

Methods

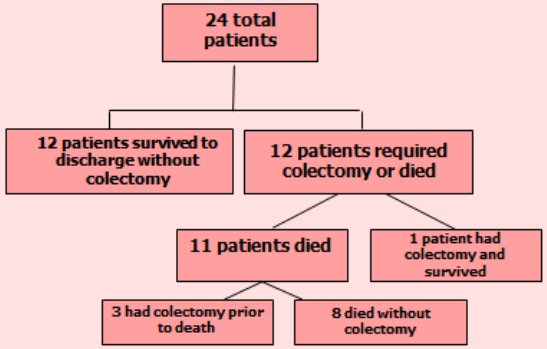
- Retrospective electronic chart and pharmacy review.
- We identified inpatients prescribed VPR at our urban tertiary care academic medical center from 1/2003 to 12/2013.
- Patients must have been in ICU at initiation of VPR treatment, have had a positive stool test for C. difficile toxin by ELISA or pseudomembrane on endoscopy, and have received 4 or more doses of VPR
- Patients were followed to discharge or death
- Our primary endpoint was the combined endpoint of colectomy and/or death

Results

Variable	All (n=24)	Survived with no surgery (n=12)	Required Colectomy and/or died (n=12)*	P-value
Average age (SD),years	61.8(15.9)	64.5(16.7)	59.1(15.3)	0.42
Male Gender(%)	11(45.8)	5(45.5)	6(54.5)	0.68
Mean VPR doses**(SD)	20.8(13.8	22.3(6.9)	19.3(19.4)	0.62
Median days of abx prior to initiation of VPR (IQR)	6 (1.5-16.5)	3.5 (1-15.25)	8.5 (2-19.5)	0.47

*11 of 12 patients in this group died (91.6%) while one required colectomy but survived to discharge (8.4%). Three of the 11 patients that died had a colectomy prior to death

**Most patients received concomitant therapy with POV (n=17) and/or IVM (n=20)



Discussion

- Our study, while modest in size, is one of only three case series' reported to date on the use of VPR for severe complicated *Clostrodium difficile* infection
- 50% of patients who received VPR in our study survived to discharge without colectomy while 50% required colectomy and/or died
- There were no statistically significant differences in age, gender, or mean number of VPR doses between the group that survived without colectomy and the group that required colectomy and/or died.
- Our finding that VPR did not improve outcomes in severe, complicated CDI contradicts findings of previously reported case studies.[4,5]
- While not statistically significant (P=0.47), there was a noticeably larger median days of antibiotic treatment prior to initiation of VPR in the group that required colectomy and/or died compared to the group that survived without colectomy.

Conclusion

- Based on our modest sample size and high rate of morbidity and mortality, we cannot advocate for the use of VPR in severe complicated CDI.
- Controlled trials are needed to better assess this therapy.

References

1. Barlett, JG. Narrative review: the new epidemic of Clostridium difficile-associated enteric disease. Annals of Internal Medicine. 2006;145 (10): 758.
2. Cohen SH, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults: 2010 Update by Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infec Control Hosp Epidemiology. 2010 May; 31 (5):431-55.
3. Debast SB, et al. European Society of Microbiology and Infectious Diseases: Update of The Treatment Guidance Document For Clostridium difficile Infection. Clin Microbiol Infec. 2014 March; 20 Supol 2: 1-26.
4. Apisarnthanarak, A, et al. Adjunctive Intracolonic Vancomycin For Severe Clostridium difficile Colitis: Case Series and Review of The Literature. Clin Infect Dis. 2002 Sep 15; 35 (6): 690-6.
5. Kim PK, et al. Intracolonic Vancomycin For Severe Clostridium difficile Colitis. Surg Infect (Larchmt) 2013 Dec; 14 (6): 532-9.

Administrative Database Research May Overestimate the Rate of Interval Colon Cancer

Jonathan Gotfried, MD; Marc Bernstein, MD; Adam Ehrlich, MD, MPH; Frank Friedenberg, MD, MS Epi
Digestive Disease Center, Temple University School of Medicine, Philadelphia PA

Background

- Colorectal cancer (CRC) is the 3rd most common cancer and 2nd leading cause of cancer-related deaths in North America. Defining optimum screen intervals is important.
- Interval Colorectal Cancers (ICC) are defined as CRC's occurring 6-36 months after a colonoscopy that is negative for malignancy.
- Population-based studies have estimated the rate to be 3-6% of all colorectal cancer's[1,2,3].
- Studies have utilized linkage of insurance databases with cancer registries to study ICC rates.

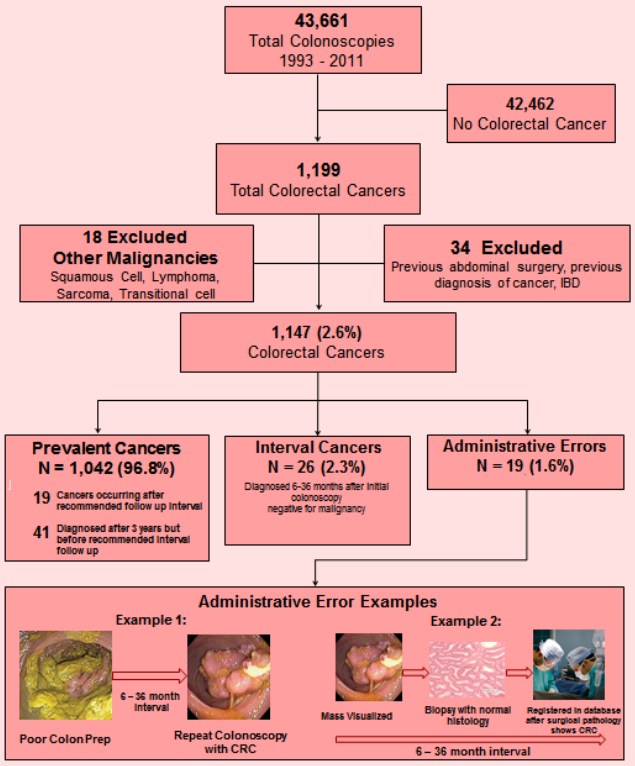
Aim

- Determine ICC rate in our urban, tertiary care hospital.
- Perform manual chart review to identify administrative errors that may falsely increase the ICC rate.

Methods

- Retrospective electronic chart review.
- Identified all colonoscopy exams performed at Temple University Hospital in Philadelphia from 1993-2011 using CPT coding.
- Linked data to the Pennsylvania Cancer Registry for the same time period.
- Following database linkage, we identified all "prevalent" colorectal cancers (defined as CRC found at first colonoscopy).
- All other cancers were grouped as "interval" and "non-interval" based on length of time from last colonoscopy.
- Within the "interval" group, we identified cases of "administrative errors" which could falsely increase the ICC rate.

Results



Discussion

- Due to errors unique to merging administrative databases, the rate of interval CRC reported in the literature may be falsely elevated.
- The ICC rate at Temple is lower than quoted rates of 3-6% in current literature.
- At our institution the rate was 41% lower after removing cases of administrative errors.
- We expected results to be higher given predominantly African American population based on:
  - Increased rate of right side malignancies and higher miss rates of right sided malignancies[4]
  - AA known to have more aggressive phenotypes[5].
- Exams performed for all indications including bleeding and therefore prevalence of CRC higher than in screening populations.
- Suboptimal colon preps contributed to most of the administrative errors.

Conclusion

- Published ICC rates are likely higher than true rates due to misclassification resulting from administrative errors.
- Future publications which link administrative databases need to account for these potential errors. The new standard for publication in the field of ICC rates requires manual confirmation of potential cases.

References

1 Singh H, Nugent Z, Demers AA, Bernstein CN. Rate and predictors of early/missed colorectal cancers after colonoscopy in Manitoba: a population-based study. Am J Gastroenterol. 2010;105(12):2588-96.

2 Singh A, Kuo YF, Riall TS, Raju GS, Goodwin JS. Predictors of colorectal cancer following a negative colonoscopy in the Medicare population. Dig Dis Sci. 2011;56(11):3122-8.

3 Brenner H, Chang-Claude J, Seiler CM, Hoffmeister M. Interval cancers after negative colonoscopy: population-based case-control study. Gut. 2012;61(11):1576-82.

4 Bressler B, Paszat LF, Vinden C, Li C, He J, Rabeneck L. Colonoscopic miss rates of right-sided colon cancer: a population-based analysis. Gastroenterology. 2004;127(2):452-6.

5 Hoffmann LJ, Lee S, Waddell B, Davis K. Effect of Race on Colon Cancer Treatment and outcomes in the Department of Defense Healthcare System. Diseases of the Colon & Rectum. 2010;53(1):9-15.

Principles of Manuscript Preparation

Manuscript Preparation

- Introduction – should be done before experiment started (this is the background justifying the study)

  -Intro final sentence: “Our purpose was to….”
- Methods
  - Population/material studied
  - Techniques/interventions applied
  - IRB approval
  - Clinicaltrials.gov registration

ClinicalTrials.gov

ClinicalTrials.gov is a service of the National Institutes of Health.

Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017[1] (NOT FOR SUBMISSION[2])

Instructions: Answer the following questions to evaluate whether the study is an applicable clinical trial (ACT). Use the accompanying "Elaboration" for additional information to help answer the questions.

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)?	☐	☐
a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."		
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

Manuscript Preparation - Statistics

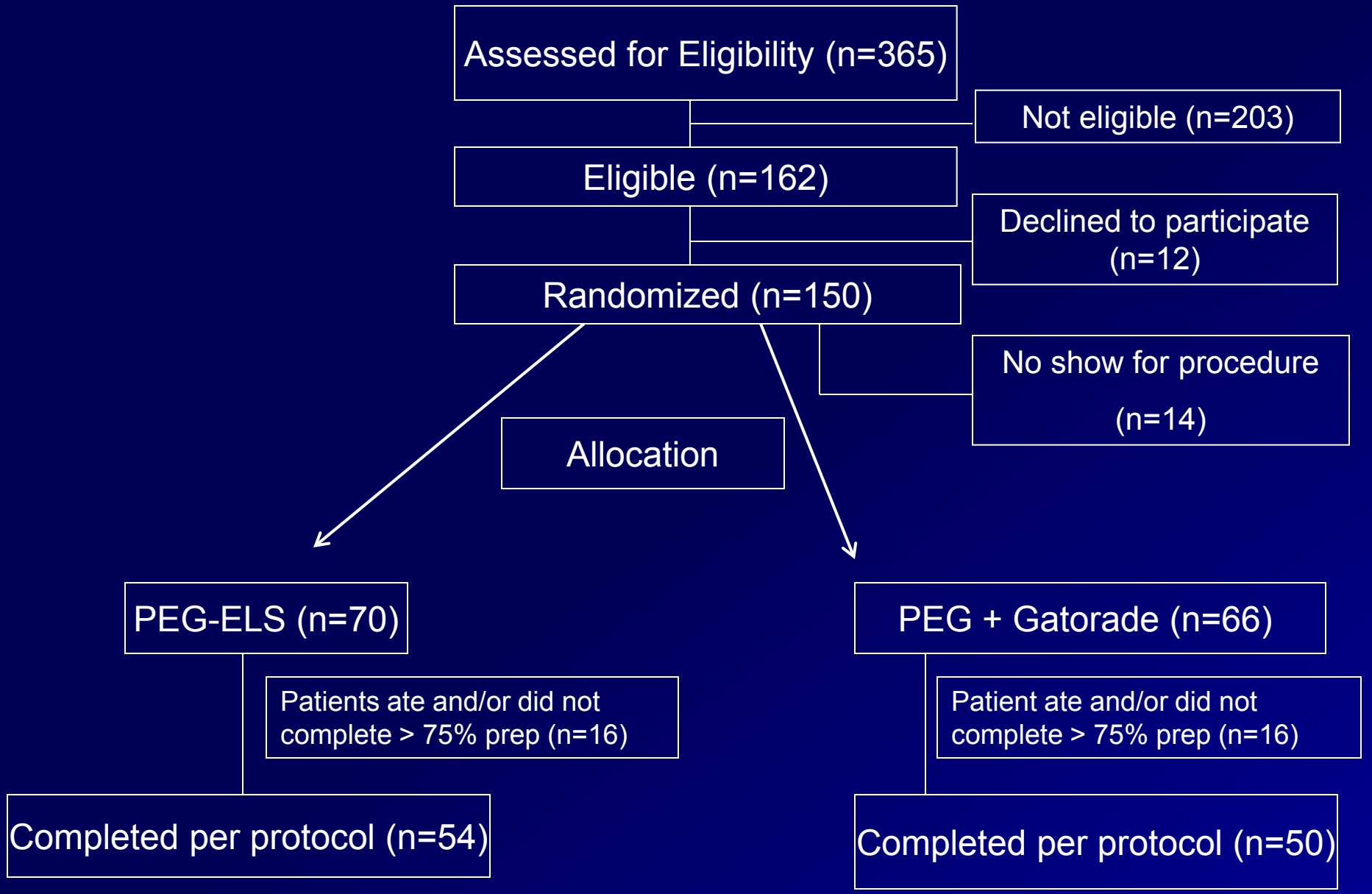
- Planned Descriptive Analysis - term given to the analysis of data that helps describe, show or summarize data in a meaningful way (e.g. means)
- Planned Inferential Analysis – t-test, χ^2 etc.
- Sample size/Power calculation
  - Clearly state primary endpoint
  - Reference literature used to determine calculation
  - Assume dropouts if applies

Results

Manuscript Preparation - Results

- Figure 1 – flow diagram of patients eligible and not eligible for the primary outcome

(CONSORT diagram- CONsolidated Standards Of Reporting Trials)


Assessed for Eligibility (n=365)
Not eligible (n=203)
Eligible (n=162)
Declined to participate (n=12)
Randomized (n=150)
No show for procedure (n=14)
Allocation
PEG-ELS (n=70)
PEG + Gatorade (n=66)
Patients ate and/or did not complete > 75% prep (n=16)
Patient ate and/or did not complete > 75% prep (n=16)
Completed per protocol (n=54)
Completed per protocol (n=50)

Manuscript Preparation - Results

- Population characteristics usually highlighted in Table 1 which may also include Inferential Analysis data output.

Sample Table 1

Procedure & post-procedure

During colonoscopy, total doses of fentanyl and midazolam were documented. Intravenous normal saline was co-administered with sedation and subsequently run at a rate of 150 mL per hour throughout the examination. Procedure vital signs were all readings between the beginning of sedation and the "scope out" time documented by the nurse. Post-procedure vital signs were all readings after the colonoscope had been withdrawn until the patient was discharged from the recovery area.

Hypotension & adverse events

The mean of the vital sign readings for the pre-, peri-, and post-procedure periods were used for analysis. Hypotension was defined as a systolic blood pressure <90 mmHg and/or a diastolic blood pressure <60 mmHg. These parameters were selected because other authors have used these in the past when studying physiologic changes during colonoscopy with conscious sedation [16, 17]. There is otherwise no standard definition for intraoperative hypotension [18]. Adverse cardiopulmonary events were instances in which either the patient became symptomatic (e.g. chest pain, palpitations, shortness of breath) or required medical intervention (e.g. early termination of the procedure, pharmacotherapy) in the judgment of the attending physician.

Statistical analysis

Univariate comparisons of categorical and continuous predictor variables were accomplished using the chi-square test or independent samples *t*-test respectively. We performed binary logistic regression analyses to look for variables

Table 1. Characteristics of 626 study patients.

Demographics / Pre-Procedure Variables	
Age (mean years ± SD)	56.0 ± 10.4
Body Mass Index (kg/m² ± SD)	28.9 ± 5.3
n (%)	
Males	338 (54.0)
Ethnicity	
White	114 (18.2)
Black	373 (59.6)
Hispanic	110 (17.6)
Asian	21 (3.4)
Other	8 (1.3)
ASA Physical Status Class	
I	84 (13.4)
II	525 (83.9)
III	12 (1.9)
IV	0 (0.0)
Blood Pressure Medication Class	
≥1 Medication	158 (25.2)
Multiple (≥2 Medications)	133 (21.2)
ACE inhibitor	78 (12.5)
CCB	69 (11.0)
Diuretic	69 (11.0)
BB	47 (7.5)
ARB	28 (4.5)
Co-Morbidities	
Asthma / COPD	45 (7.2)
Coronary Artery Disease	12 (1.9)
Congestive Heart Failure	6 (1.0)

ACE – angiotensin converting enzyme; ARB – angiotensin receptor blocker; ASA - American Society of Anesthesiologists; BB – beta blocker; CCB – calcium channel blocker; COPD – chronic obstructive pulmonary disease; SD – standard deviation

Table 1. Characteristics of 200 in-patients diagnosed with first episode of *Clostridium difficile* infection stratified by complication status

	Complication* n = 32 mean (s.d.)	No complication n = 168 mean (s.d.)	95% Confidence interval of difference	P Value
Age (year)	68.8 (12.9)	65.9 (17.2)	−9.2–3.4	0.37
Creatinine increase (%)†	106.7 (132.9)	27.4 (70.2)	30.3–128.2	0.002
Temperature (°F)	99.5 (2.2)	99.4 (1.9)	−0.82–0.65	0.82
WBC ($10^3/\mu$L)	27.3 (19.9)	16.7 (9.6)	3.3–17.9	0.006
Albumin (g/dL)	2.1 (0.7)	2.3 (1.5)	−0.33–0.75	0.45
ALT (U/L)	51.7 (50.6)	34.0 (38.0)	−36.8–1.5	0.07
Total bilirubin (mg/dL)	0.92 (0.53)	0.83 (0.76)	−0.37–0.19	0.54
Haemoglobin (gm/dL)	10.9 (2.0)	10.2 (1.8)	0.1–1.5	0.02
Body mass index (kg/m^2)	29.5 (9.4)	26.7 (10.3)	−6.9–1.2	0.17
	n (%)	n (%)	Risk estimate (95% CI)	P Value
Gender				0.98
Female	18 (15.9)	95 (84.1)		
Male	14 (16.1)	73 (83.9)	1.01 (0.47–2.17)	
Race				0.83
White	11 (18.5)	48 (81.4)		
Black	17 (17.0)	83 (83.0)		
Hispanic	3 (11.5)	23 (88.5)		
Immune status				0.36
Immunosuppressed (−)	10 (13.0)	67 (87)		
Immunosuppressed (+)	22 (17.9)	101 (82.1)	1.46 (0.65–3.28)	
Pseudomembranes				0.053
No	0 (0)	4 (100)		
Yes	11 (52.4)	10 (47.6)	2.1 (1.0–3.3)	
Severe CT findings				0.003
No	2 (5.0)	38 (95.0)		
Yes	12 (30.0)	28 (70.0)	8.1 (1.7–39.3)	

Manuscript Preparation - Results

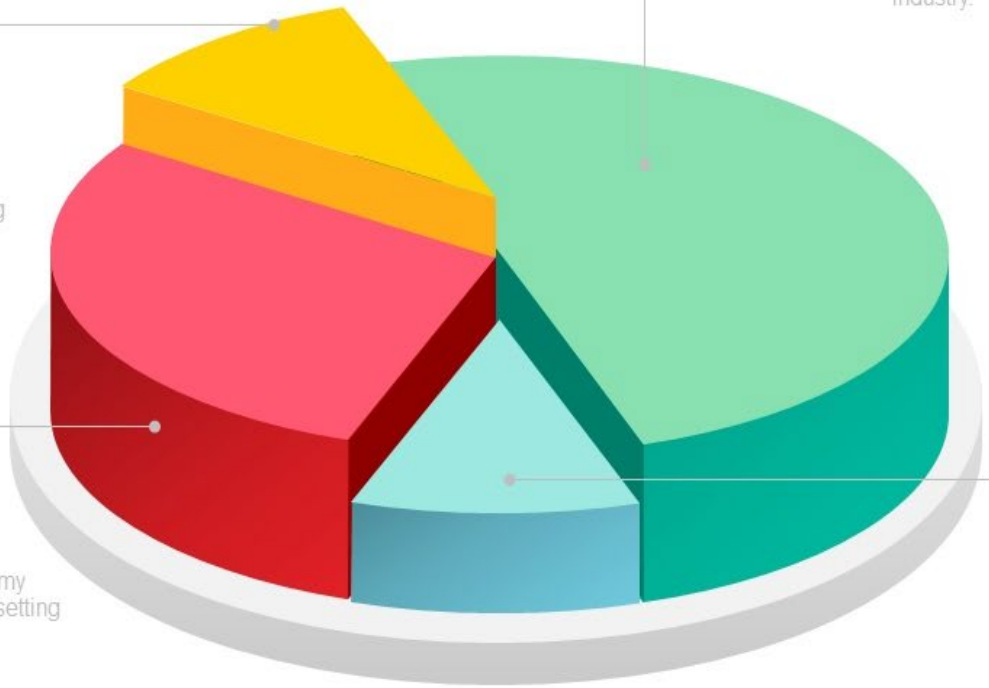
- Subsequent paragraphs highlight important statistical findings
- For complex data use figures and tables (avoid redundancy)
- Use subheadings liberally if possible – easier for reader to focus for additional sets of important findings

Sample Methods to Display Results

About Company

3d Pie Chart

This slide is perfect for long text descriptions



50%

Mobile App Design

Lorem Ipsum is simply dummy text of the printing and typesetting industry.

16%

Creative Design

Lorem Ipsum is simply dummy text of the printing and typesetting industry.

24%

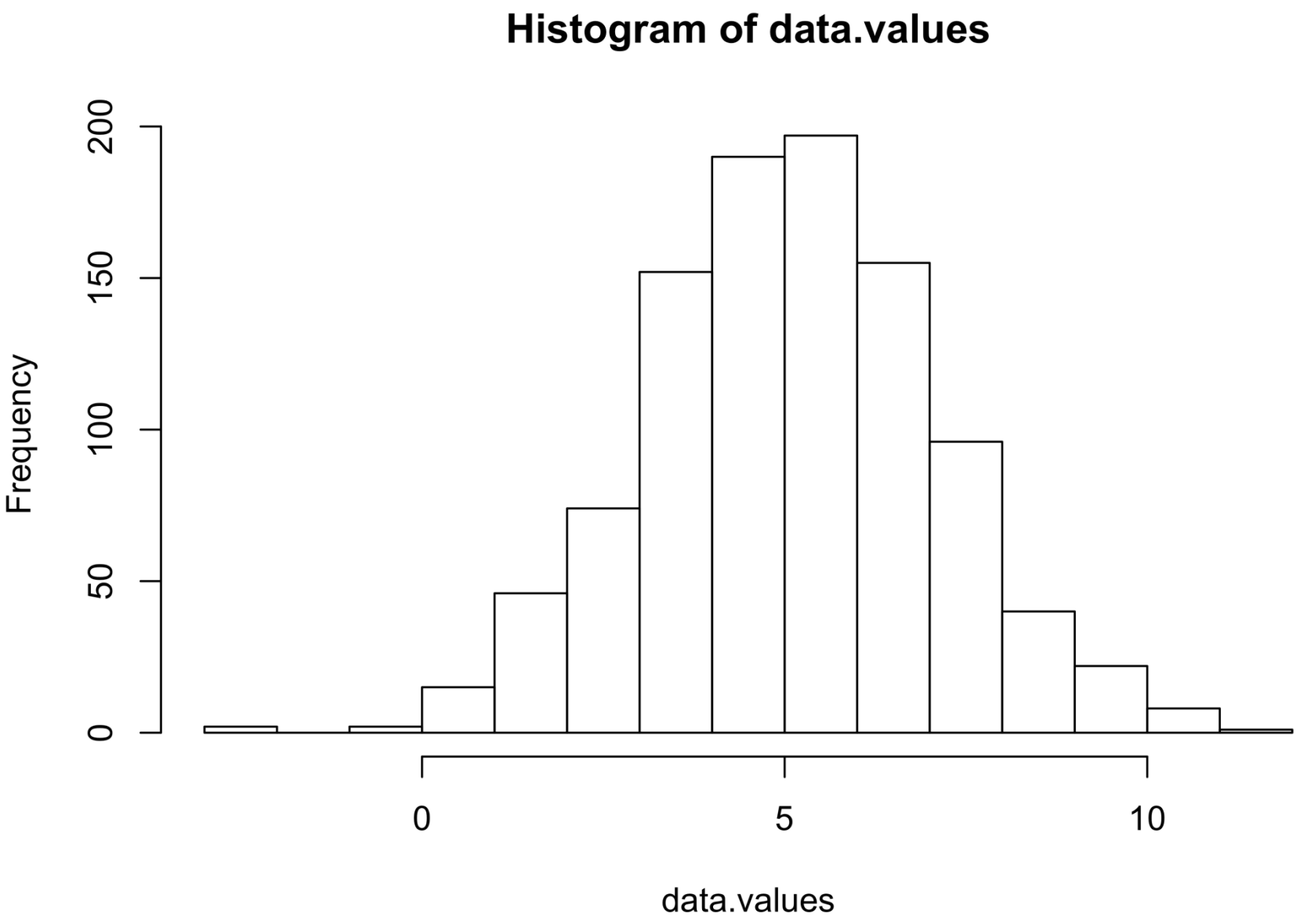
Desktop Application

Lorem Ipsum is simply dummy text of the printing and typesetting industry.

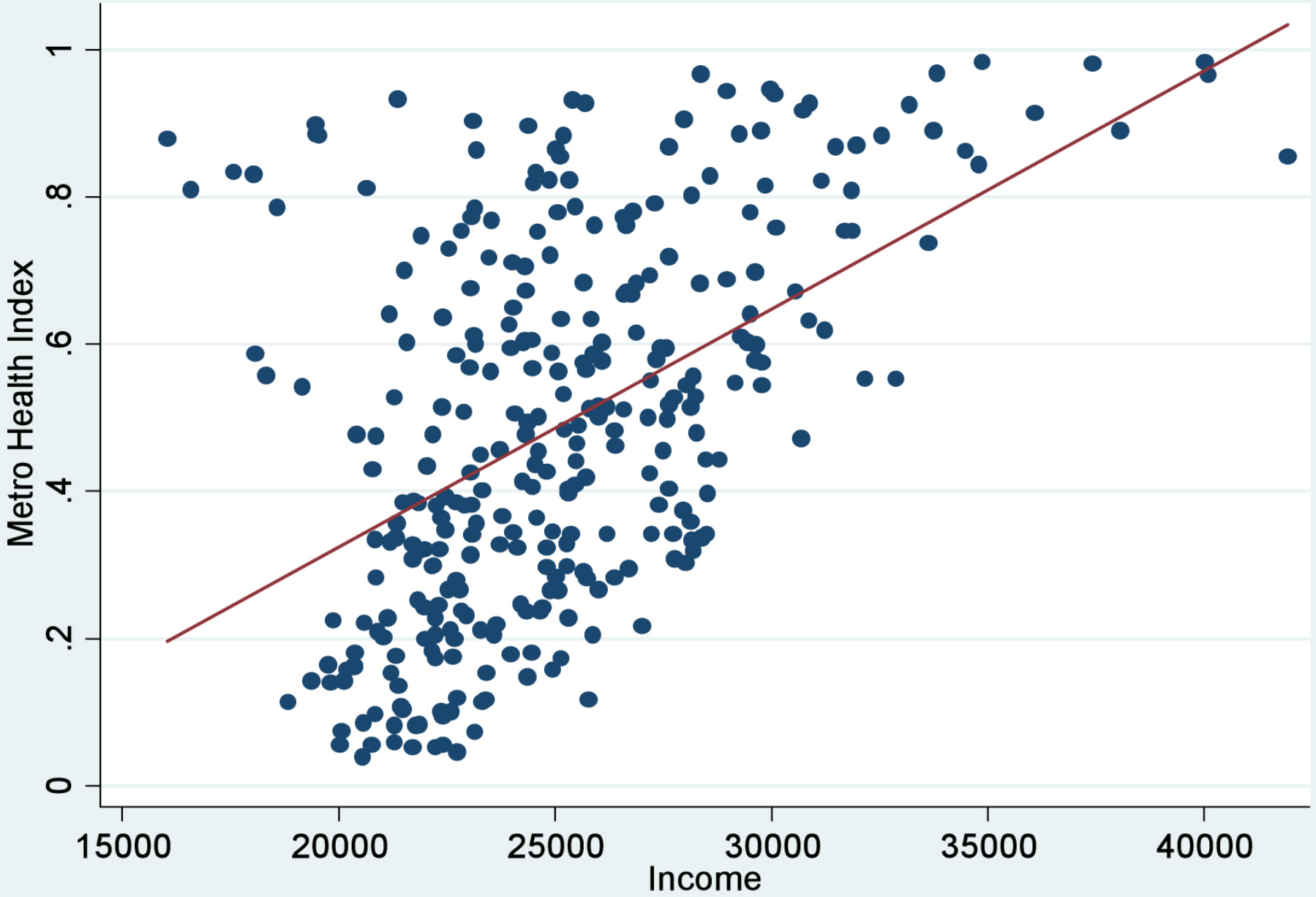
10%

Commercial Print Ad

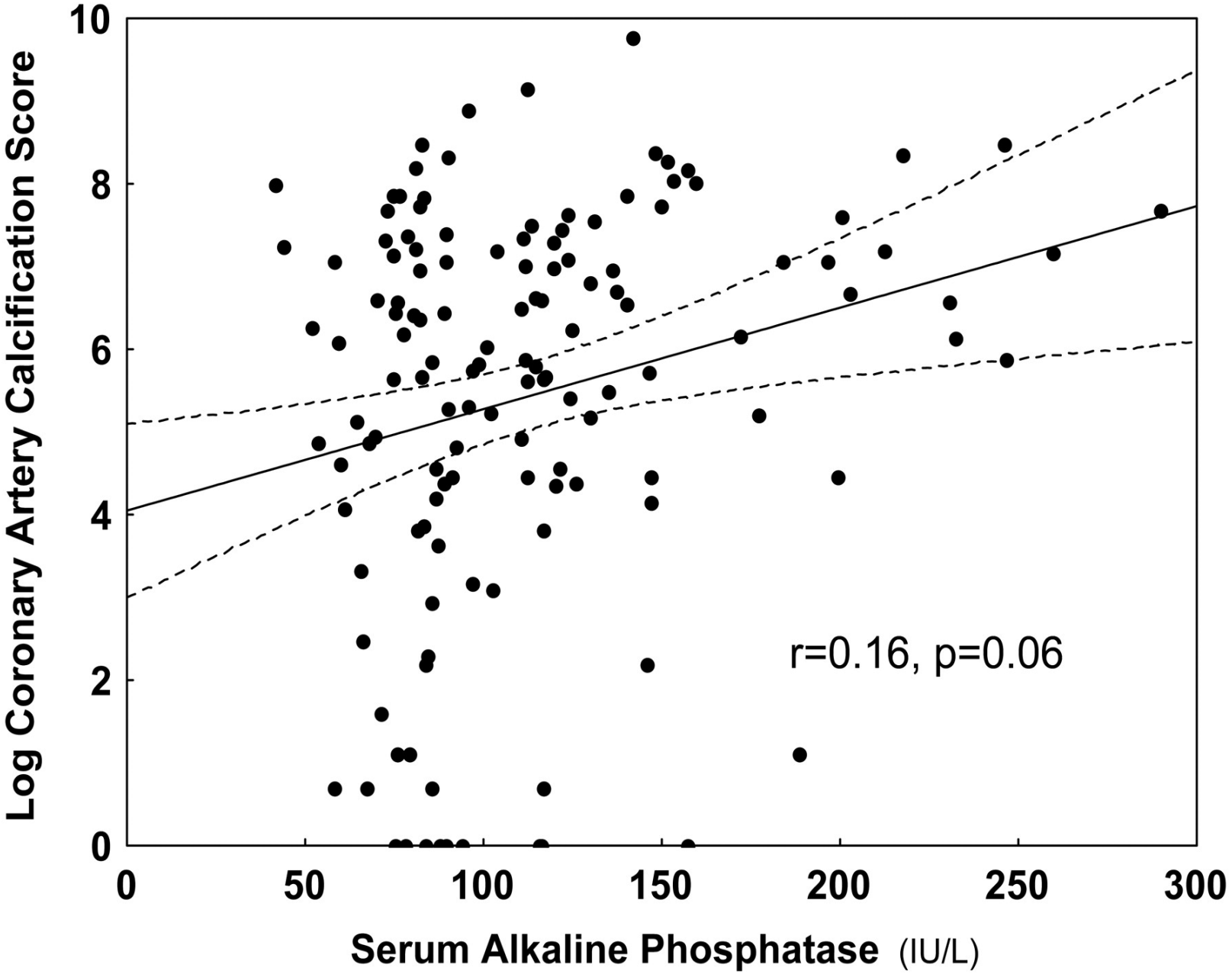
Lorem Ipsum is simply dummy text of the printing and typesetting industry.


Histogram of data.values
Frequency
0
50
100
150
200
0
5
10
data.values

Scatterplot

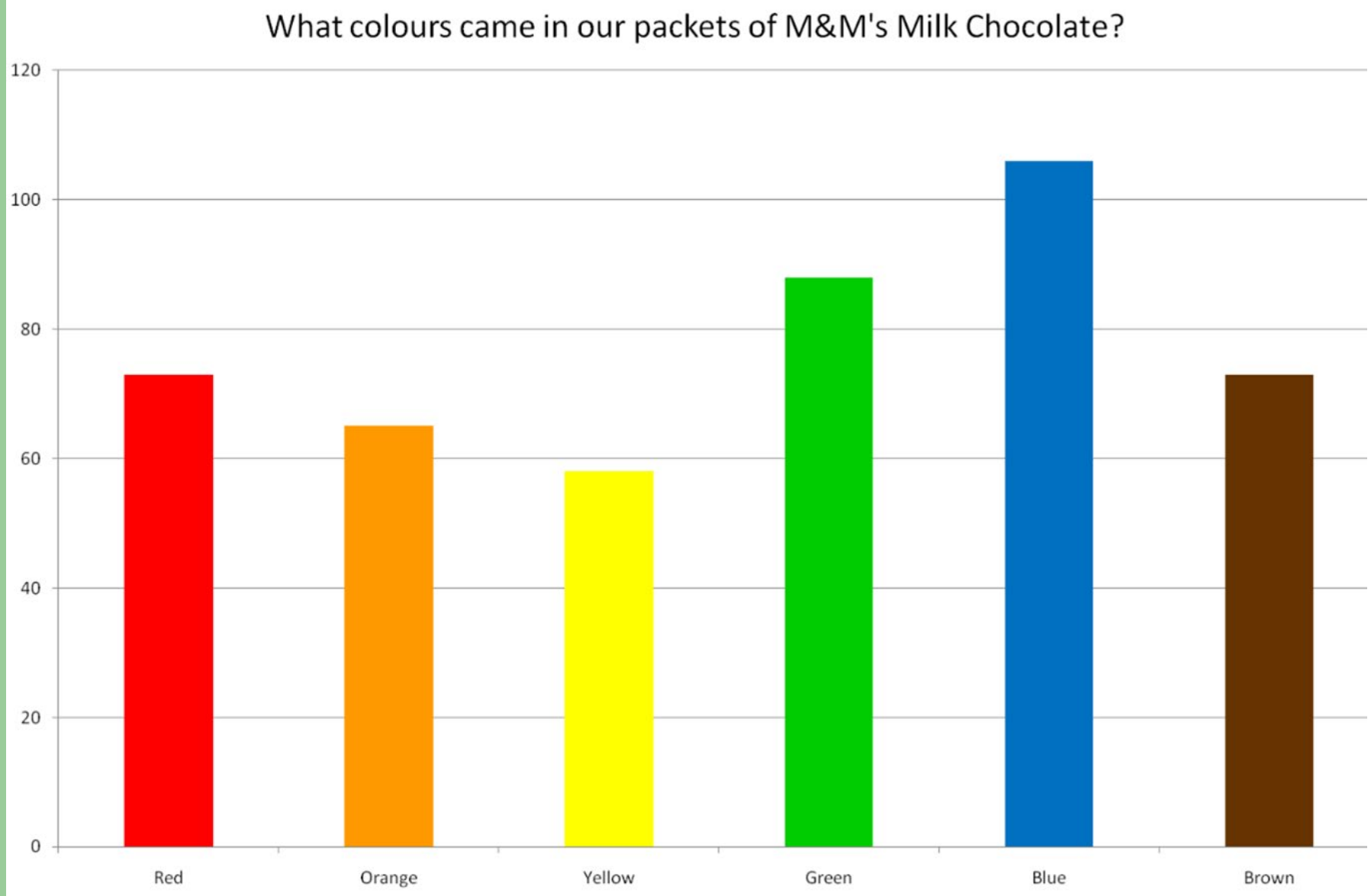


Scatterplot with 95% CI

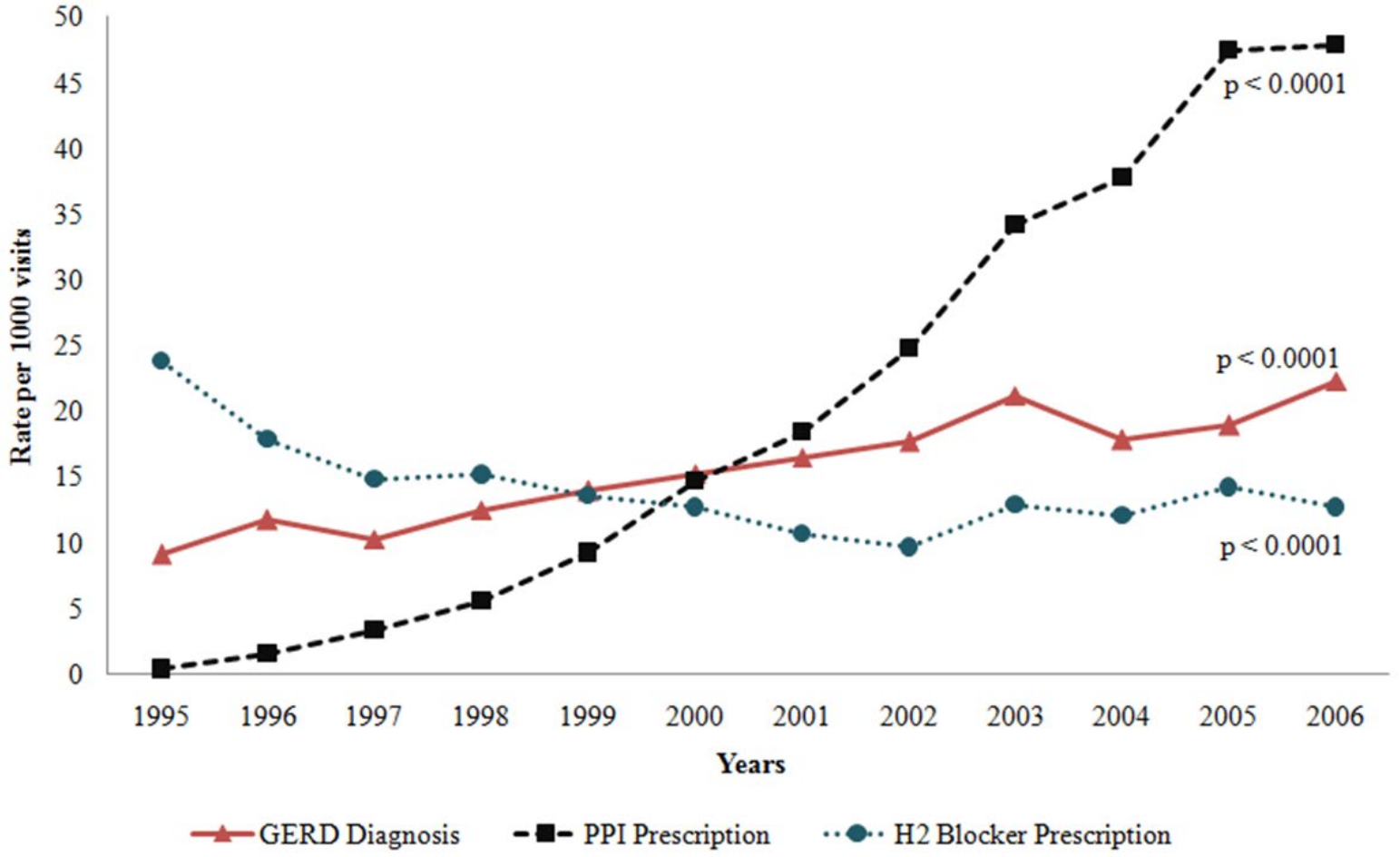


Bar Graphs

- May be vertical or horizontal
- Choose Y-axis scale carefully
- Useful to compare groups across a categorical variable (e.g. time, symptoms)
- Use a line graph when x-axis has >9 categories


What colours came in our packets of M&M's Milk Chocolate?
120
100
80
60
40
20
0
Red
Orange
Yellow
Green
Blue
Brown

Line Graph

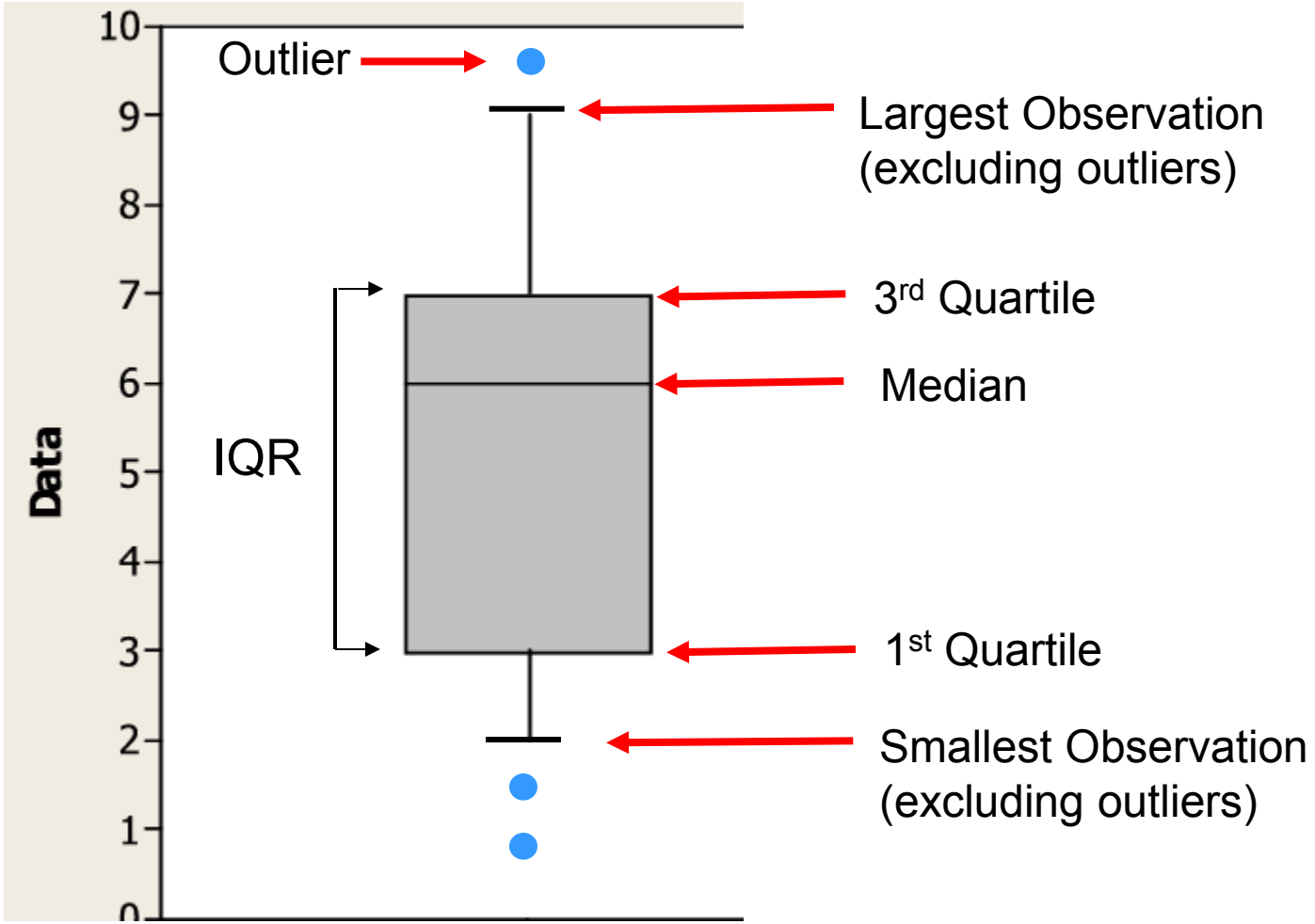


Friedenberg, et al.Trends in Gastroesophageal Reflux Disease as Measured by the National Ambulatory Medical Care Survey. Dig Dis Sci. 2009 Oct 15.

Boxplots

- Appropriate when displaying medians rather than means
- Spacing between the different parts of the box help indicate variance, skewness and identify outliers.
- 5 point summary: the smallest observation, lower quartile (Q1), median, upper quartile (Q3), and largest observation
- Can be horizontal or vertical

Boxplots ("Box and Whisker")
5-Point Data Summary



Manuscript Preparation

- Results
- Finish with adverse events if relevant
- Often see per protocol vs. modified ITT vs. ITT results explored

Manuscript Preparation

- Conclusions
- 1st paragraph highlights main results
- 1-2 paragraphs putting results in context of known data
- Additional paragraphs to discuss unusual findings, potential study strengths and limitations, directions for future research
- Final paragraph is summary - restates conclusions and mentions direction for future studies.

Abstract – goes first, do last

- Select key lines from introduction, methods, results, and conclusion
- Be mindful of word limits
- Other data needed (put on face page) will be: word count, potential conflicts, 4-6 key words, and funding source.

Thank You