Nicole K. Cates, DPM, AACFAS

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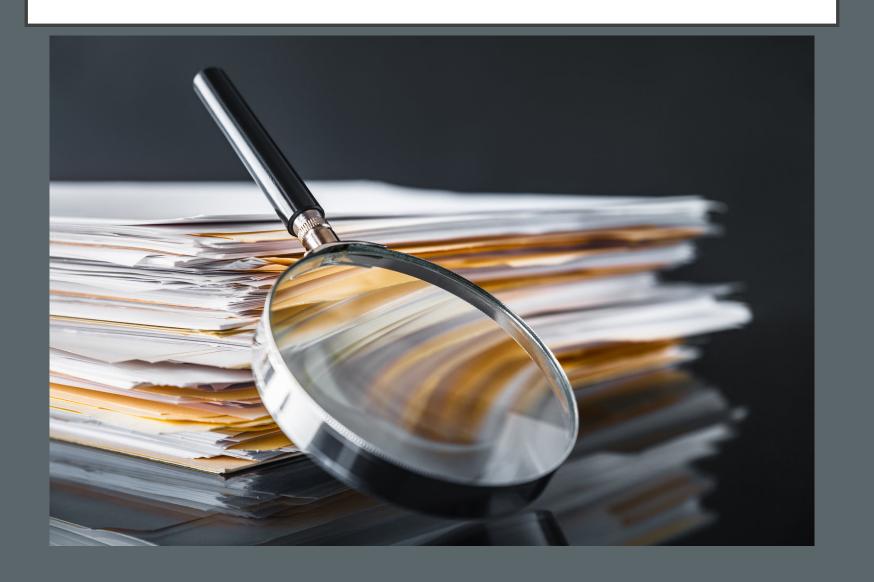
Conducting a Retrospective Study



OVERVIEW

- · Form an Idea
- IRB
- Datamining
- Statistical analysis
- Evaluating the results
- Writing the manuscript

FORM AN IDEA



FORM AN IDEA

- Cohort: What group are you evaluating?
- Comparison: What are you comparing?
- Factors: What factors are you comparing for?
- Review existing literature to see if study exists:
 Database like pubmed

EXAMPLE FORM AN IDEA

- Cohort: Charcot patients that underwent reconstructive surgery
- Comparison: Comparing Charcot patients with and without diabetes
- Factors:
 - Preoperative risk factors: age, BMI, HTN, PAD, renal disease, smoking history, location of preoperative ulcer, etc.
 - Postoperative outcomes: delayed union, dehiscence, amputation,
 Charcot recurrence, postoperative ambulation, etc.

IRB

Institutional Review Board (IRB)

IRB

ACFAS Research Committee Meeting: IRB Processes and Ethics

PROTOCOL IDENT	IFICATION NUMBER:	
PROTOCOL VERSI	ON NUMBER:	
PROTOCOL PREPA	RATION DATE:	
SPONSOR:		
Authorized By:		
	Signature	Date
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PROTOCOL AUTHO	OR:	
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PRINCIPAL INVEST	TIGATORS:	

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2. Protocol Summary

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1	MRN	Age at repair		Diabetes 1=yes 0=no	CKD 1=yes 0=no		1=yes	Smoker hx or current 1=yes 0=no	Preop ulcer 1=yes 0=no	Forefoot 1=yes 0=no	Midfoot 1=yes 0=no	Hindfoot 1=yes 0=no	Ankle 1=yes 0=no	Preopeative Soft tissue infection 1=yes 0=no	Preoperative Osteomyelitis 1=yes 0=no	CN forefoot 1=yes 0=no	CN midfoot (TMTJ+CNJ) 1=yes 0=no	CENTLE COLL C	CN rearfoot (AJ+calcane us) 1=yes 0=no
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26	418301	62	37.11	0	0		1	0	0	0			0 0						0
27	6507640	31			0	0	1	1	0	0			0 0	0	0	0		1 7	1

- Cohort: Define cohort and determine how to find the patients
 - ICD-10's: If cohort based on diagnosis can pull patients by diagnostic codes
 - CPTs: If surgical patients can pull patients by surgical codes
 - Determine if you want single surgeon or multiple surgeons
 - Ex) Dr Bradley Lamm's patients who had multiplanar external fixator devices. "Dr Bradley Lamm's patients for CPT 20692"

- Inclusion Criteria:
 - Cohort: defined as X
 - Underwent X surgery, surgery defined as
- Exclusion Criteria:
 - <18 years old
 - < I year follow up postoperatively

EXAMPLE DATAMINING

- Inclusion Criteria:
 - Cohort: Charcot joint involvement defined as joint subluxation, dislocation, presence of small osseous fragments, or osseous fracturing consistent with Charcot neuroarthropathy
 - Underwent: Charcot reconstructive surgery which included arthrodesis, osteotomies, or deformity correction of the ankle / hindfoot.
- Exclusion Criteria:
 - <18 years old</p>
 - < I year follow up postoperatively

- Define Each Factors:
 - Age: defined as age at time of surgery
 - PAD: defined as non-triphasic doppler signal
 - Renal disease: defined as either CKD or ESRD in medical records
 - Amputation
 - Minor amputation: toe, ray, TMA, symes, choparts amputation
 - Major amputation: below the knee or above the knee amputation
 - Postoperative ambulation: defined as non-ambulatory (wheelchair bound), partially ambulatory (transfers only or assistive devices and fully ambulatory (unassisted ambulation)

- Factors:
 - Continuous variable: value is obtained by measuring
 - Example: age, BMI, AIC
 - Categorical variable: variable that can take on one of a limited, and usually fixed, number of possible values
 - Example diabetes yes = I, no = 0
 - Example postoperative ambulatory status, non=0, partial=1, full=3

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1	MRN	Age at repair		1=yes	CKD 1=yes 0=no	1=yes	HTN 1=yes 0=no	Smoker hx or current 1=yes 0=no	Preop ulcer 1=yes 0=no	Forefoot 1=yes 0=no	Midfoot 1=yes 0=no	Hindfoot 1=yes 0=no	Ankle 1=yes 0=no	Preopeative Soft tissue infection 1=yes 0=no	Preoperative Osteomyelitis 1=yes 0=no	CN forefoot 1=yes 0=no	(TMTJ+CNJ) 1=yes	1=yes	CN rearfoot (AJ+calcane us) 1=yes 0=no
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19	6547008	60		0	(-	-	0	1	1	(0	0	1	0	-	0	0	0
20	7122523	82	29.33	0	(0	1	1	1	1	(0	0	0	0	1	0	0	0
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MRN	Age at		BMI va time of repair		Diabete 1=yes 0=no	s	CKD 1=yes 0=no		ESRD 1=yes 0=no		HTN 1=yes 0=no	Smoker has or current 1=yes 0=no	
Preop 1=ye 0=no		Forefo 1=yes 0=no		Midfo 1=yes 0=no		Hindf 1=yes 0=no		Ankle 1=yes 0=no		Preop Soft to infect 1=yes 0=no	ion		

CN forefoot 1=yes 0=no

CN midfoot (TMTJ+CNJ) TJ) 1=yes 0=no

CN hindfoot | CN rearfoot (TNJ+CCJ+S (AJ+calcane 1=yes 0=no

us) 1=yes 0=no

Descriptive Statistics for Non-diabetic versus Diabetic Charcot Neuroarthropathy (Bivariate Analysis)

Post Reconstructive Outcomes	Non Diabetic CN (N=25)	Diabetic CN (N=50)	P-value
Delayed healing	52.0% (13/25)	34.0% (17/50)	0.1336
Dehiscence	36.0% (9/25)	16.0% (8/50)	0.0512
Major lower extremity amputation	16.0% (4/25)	26.0% (13/50)	0.3933
Delayed osseous union	28.0% (7/25)	4.0% (2/50)	0.0051
Recurrence of Charcot	16.0% (4/25)	12.0% (6/50)	0.7186
New Charcot location collapse	0% (0/25)	6.0% (3/50)	0.5481
Return to ambulation	85.7% (18/25)	29.8% (14/50)	<0.0001

- What to ask the statistician to get p-values
 - "X had statistically higher rates of Y and Z" (p=0.002)
- What to ask the statistician to get odds ratios
 - "X was 8 times more likely to develop Y than Z
 [OR 8.01 (95% CI (3.5-87.6)]

- P-values
 - Bivariate analysis: comparing two different groups for a factors
 - Two groups: Charcot patients <u>WITH</u> and <u>WITHOUT</u> diabetes
 - Factor I: comparing for Age at time of reconstruction
 - Factor 2: comparing for BMI at time of reconstruction
 - Factor 3: comparing for preoperative diagnosis of renal disease
 - Etc, etc

- Odds ratios: Multivariate logistic regression
 - A model that is used to predict the probabilities of the different possible outcomes of a variable, given a set of independent variables
 - Need to run separate regressions for preoperative factors and postoperative outcomes
 - Comparing all statistically significant preoperative factors to see which have the biggest impact

Charcot Etiology: Diabetic vs non Diabetic

Comparing Charcot Neuroathropathy with Diabetic vs Non-Diabetic Etiology for preoperative infection, anatomic location of Charcot breakdown, and outcomes

- a. Pre-operative Infection
 - i. Bivariate analysis comparing "CN DM" and "CN non DM" for:
 - 1. Pre-op ulcer (column AH)
 - 2. Forefoot (column AI)
 - Midfoot (column AJ)
 - Hindfoot (column AK)
 - 5. Ankle (column AL)
 - 6. Medial (column AM)
 - 7. Lateral (column AN)
 - 8. Soft tissue infection (column AO)
 - 9. Osteomyelitis (column AP)
 - Multivariate logistic regression for the statistically significant factors from above
- b. CN by anatomic location
 - i. Bivariate analysis comparing "CN DM" and "CN non DM" for
 - 1. Forefoot collapse (column AQ)
 - 2. Midfoot collapse (column AR)
 - 3. Hindfoot collapse (column AS)
 - 4. Rearfoot collapse (column AT)
 - Multivariate logistic regression for the statistically significant factors from above
- c. Outcomes
 - i. Bivariate analysis comparing "CN DM" and "CN non DM" for
 - 1. Delayed/non healing (column BI)
 - 2. Dehiscence (column BJ)
 - 3. Major lower extremity amputation (column BK)
 - 4. Non union (column BL)
 - 5. Recurrence of Charcot (column BM)
 - New Charcot location collapse (column BN)
 - 7. Return to ambulation (column N)
 - Multivariate logistic regression for the statistically significant factors from above

EVALUATING THE RESULTS

Characteristics	Non Diabetic N=25	Diabetic N=50	P value
Delayed healing	13(52.0)	17(34.0)	0.1336
Dehiscence	9(36.0)	8(16.0)	0.0512
Major lower extremity amputation	4(16.0)	13(26.0)	0.3933
Non union	7(28.0)	2(4.0)	0.0051
Recurrence of Charcot	4(16.0)	6(12.0)	0.7186
New Charcot location collapse	0(0.0)	3(6.0)	0.5481
Return to ambulation	18(85.7)	14(29.8)	<.0001

Multivariate logistic regression for the statistically significant factors from above

Effect	DF	Chi-Square	Pr > ChiSq
osseous delayed non	1	6.5560	0.0105
Ambulator_1_yes	1	12.2075	0.0005

Odds Ratio 95% Confidence Limits

Osseous delayed non 1 vs 0 16.4 1.9 139.6 Ambulator 1 vs 0 17.6 3.5 87.6

EVALUATING THE RESULTS

- What values are statically significant
- What do the these values being statically significant mean?
- Understand the results and what they mean clinically

WRITING THE MANUSCRIPT

Sections of the paper

- Title page
- Abstract
- Introduction
- Methods
- Results
- Discussion
- References
- Tables / Figures

WRITING THE MANUSCRIPT

Order in which I write

- I. Title page
- 2. Methods
- 3. Tables
- 4. Results
- 5. Abstract
- 6. Introduction
- 7. Discussion
- 8. References
- 9. Figures

WRITING THE MANUSCRIPT TITLE PAGE

- Title
 - Charcot Reconstruction: Outcomes in Patients With and Without Diabetes
- Authors
 - Nicole K. Cates, DPM¹....Christopher E. Attinger, MD²
 - First author: author who wrote majority of the manuscript
 - Last author: most senior author
- Affiliations
 - ²Attending Physician, Department of Plastic Surgery, MedStar Georgetown University Hospital, 3800 Reservoir Rd NW, Washington DC, 20007
- Corresponding author
 - Name, title, affiliation, email, Phone, Fax
- Financial disclosure statement
 - Financial disclosures of all authors

WRITING THE MANUSCRIPT METHODS

- Methods: this helps me define my cohort, and factors
 - IRB approval board
 - How you identified patients for the study (cohort, icd-102 or CPTs, for X surgeons, time frame Y-Z)
 - Inclusion / exclusion criteria
 - Datamining: all factors evaluated: preoperative factors and postoperative outcomes (how each was defined)
 - Any study specific equation / concept (fully define)
 - Statistical analysis (Statistician typically writes this paragraph)

- **Tables**: puts all the results in one area in a clean format
 - Fill in the tables with the data from the statistician
 - Need tables citations (Table I) in the paper to appear in the order they appear at the end of the manuscript
 - Table I: always demographics
 - Following tables: bivariate analysis, multivariate regression, etc.

Tables: Demographics

Tables

Table 1: Demographics of Patients Included in the CN Osseous Reconstruction Cohort

	Number % (N=75), Median
Age at repair	56 (31-86)
	Median: 58
Body Mass Index (BMI)	32.4 (20.7-45.6)
	Median: 31.6
Glycosylated hemoglobin A1c (HbA1c)	8.5 (5.0-14.6)
	Median: 7.4

Tables: Bivariate

Table 2: Descriptive Statistics for Non-diabetic versus Diabetic Charcot

Neuroarthropathy (Bivariate Analysis)

+	÷			
	Characteristics	Non Diabetic	Diabetic	P value
		(cases)	(Matched controls)	
		N=25	N=50	
	Age at repair	56 (31-82)	56 (31-86)	0.9886
		Median: 57	Median: 58	
	Body Mass Index (BMI)	30.4 (20.7-41.3)	33.4 (21.3-45.6)	0.1098
		Median: 29.8	Median: 33.8	
	Hypertension	64.0% (16/25)	64.0% (32/50)	1.0000

Tables: Multivariate Regression

Table 4: Multivariate Logistic Regression, for risk outcome Osseous Delayed Union and

Return to Ambulation

Effect	Odds Ratio	95% Wald Confidence Limits	
Return to Ambulation	17.6	3.5	87.6
Osseous Delayed Union	16.4	1.9	139.6

WRITING THE MANUSCRIPT RESULTS

- Results: Use the tables section to write the results section
 - List out all the demographic data
 - Bivariate analysis: solely include statistically significant results (p-values)
 - Multivariate regression solely include statistically significant results (odds ratios

- Abstract: Helps think through the overall message of the paper
 - Primary & secondary aims of the study
 - Methods: what statistical analysis did you perform (bivariate analysis, multivariate regression)
 - Results: only statistically significant variables
 - Conclusion: summarizing clinical significance and meaning of the results

Abstract

- Primary & secondary aims of the study sentance
 - The objective of this study is to compare risk adjusted matched cohorts of Charcot neuroarthropathy patients who underwent osseous reconstruction with and without diabetes.
- Methods sentance
 - Bivariate analysis was performed for preoperative infection, location of Charcot breakdown, and post reconstruction outcomes, in patients with a minimum of I year follow-up period.

Abstract

- Results sentance
 - Through bivariate analysis, presence of preoperative ulceration (p=0.0499) was found to be statistically more likely in the patients with diabetes; whereas, delayed osseous union (p=0.0050) and return to ambulation ($p\le0.0001$) was statistically more likely in patients without diabetes.
 - The non-diabetic Charcot patients were 17.6 folds more likely to return to ambulation [OR 17.6 (95% CI (3.5-87.6)], and 16.4 folds more likely to have delayed union [OR 16.4 (95% CI (1.9-139.6)].

Abstract

- Conclusion sentence
 - Our results demonstrate that DM CN patients are more likely to present with preoperative ulcerations compared to non DM CN patients. Though the non DM CN patients show higher rates of delayed union after CN reconstruction, they are more likely to return to ambulation compared to patients with DM.

WRITING THE MANUSCRIPT INTRODUCTION

Introduction

- Ist paragraph: Generally introduce the topic
- 2nd paragraph: Overview of current literature on the topic
- 3rd paragraph: Why this research is relevant. Primary / secondary aims of the study

WRITING THE MANUSCRIPT DISCUSSION

Discussion

- Overview paragraph: Generally overview the topic. Want to explain why this concept is important
- Results Paragraph: Paragraphs explaining each statistically significant results with literature to back up hypothesis of why it is statistically significant
- Limitations paragraph: review all the limitations to the study,
 and how future studies can improve on this study
- Conclusion paragraph: overview of the results with a clear take home message for the reading

WRITING THE MANUSCRIPT RESULTS

References

- Fill in as you go, even if you don't completely format the references put
 a skeleton list for yourself to work off later
- Within the manuscript don't number until after attending edits, keep citations as (author) or (author-year) if there are duplicates of the same author
 - After final attending edits number in order they appear in the manuscript (1).... Blah blah (2).
 - Have reference citations match order they appear in the manuscripts

WRITING THE MANUSCRIPT FIGURES

Figures

- Clinical or radiographic figures that highlight and demonstrate key concepts from the paper
- Can also include algorithms, decision trees, radiographic measurements, etc
- *Need figure citations (Figure 1) in the paper to appear in the order they appear at the end of the manuscript

THANK YOU!

Nicole K. Cates, DPM, AACFAS

FootSurgerySF.com
@FootSurgerySF