RESIDENT CLINICAL PEARLS

May 2023 AAIP CE Program

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EMORY HEALTHCARE

Dalbavancin utilization in the emergency department and impact on hospital admission for acute bacterial skin and skin structure infections

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Conflict of Interest Disclosure

Disclosure statement: These individuals have the following to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation.

- **Resident**: Ruchi Shah, PharmD (nothing to disclose)
- **Co-investigators**: Kristen Paciullo, PharmD, BCIDP; Raphaelle Lombardo, PharmD, BCPS; Ronald Trible, MD, PhD (nothing to disclose)

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Background

- ABSSSIs are commonly caused by beta hemolytic Streptococcus or *Staphylococcus aureus*, including MRSA
- The MRSA rate of infection is approximately 50% for ABSSSIs that present to the ED
- According to the IDSA guidelines, IV antibiotics are indicated for patients with moderate to severe ABSSSIs

ABSSSIs = Acute bacterial skin and skin structure infections
IDSA = Infectious Diseases Society of America
IV = Intravenous
ED = Emergency Department
MRSA = methicillin-resistant Staphylococcus aureus

Weng QY, Raff AB, Cohen JM, et al. Costs and Consequences Associated With Misdiagnosed Lower Extremity Cellulitis. JAMA Dermatol. 2017;153(2):141-146.

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Treatment for ABSSSIs

- **Vancomycin**
  - Historically, the gold standard for empiric coverage of moderate to severe MRSA infections
  - Requires patient specific dosing and close monitoring for safety and efficacy
- **Dalbavancin**
  - Newer IV anti-MRSA antibiotic with approximately 15-day half-life
  - Allows for the treatment of ABSSSIs with a single dose

Study	Primary Endpoint	Inclusion	Clinical Impact
DISCOVER 1 DISCOVER 2 (2014)	• Early clinical response: cessation of spread of infection-related erythema and absence of fever at 48 – 72 hours	• Adults who required at least 3 days of IV antibiotic therapy and had one or more systemic signs of infection	• Dalbavancin found non-inferior to vancomycin • Lead to FDA approval for ABSSSIs

FDA = Food and Drug Administration

1. Boucher HW, Wilcox M, Talbot GH, Puttagunta S, Das AF, Dunne MW. Once-weekly dalbavancin versus daily conventional therapy for skin infection. N Engl J Med. 2014;370(23):2169-2179. doi:10.1056/NEJMoa1310480

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Dalbavancin in the ED

Study	Intervention	Clinical Impact
Talan et. al (2015)	• Preintervention vs. postintervention • Standard of care vs. single dose dalbavancin	• Dalbavancin showed decrease in hospital admission
Koziatek et. al (2018)	• Retrospective cohort • Included patients diagnosed with cellulitis and treated with dalbavancin in the ED • Primary outcome: cellulitis-related return to the ED within one week of initial ED arrival	• Decreased hospital length of stay • None of the patients who received dalbavancin required hospitalization

1. Talan DA, Salhi BA, Moran GJ, et al. Factors associated with decision to hospitalize emergency department patients with skin and soft tissue infection. West J Emerg Med. 2015;16:89-97
2. Koziatek C, Mohan S, Caspers C, Swaminathan A, Swartz J. Experience with dalbavancin for cellulitis in the emergency department and emergency observation unit. Am J Emerg Med. 2018;36(7):1312-1314.

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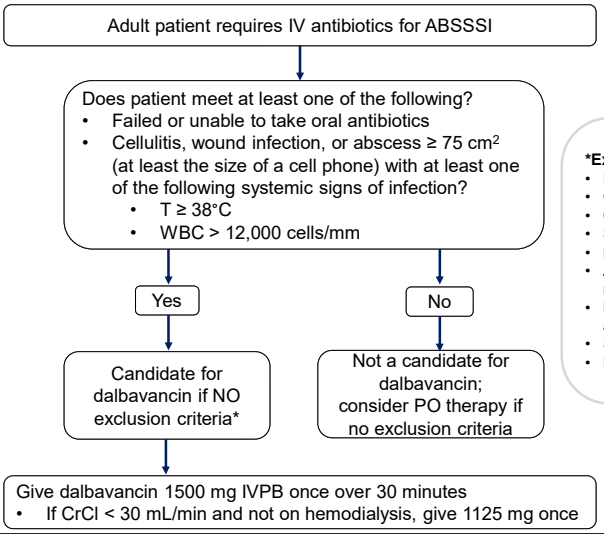
Dalbavancin Algorithm



***Exclusion Criteria:**
- Hemodynamic instability
- Concern for sepsis
- Co-morbidity requiring hospital admission
- Significantly immunocompromised
- Bilateral lower extremity involvement
- ABSSSI associated with concern for gram negative or mixed infection
- Known or suspected osteomyelitis, septic arthritis, or endocarditis
- Severe allergy to glycopeptide antibiotics
- Pregnant

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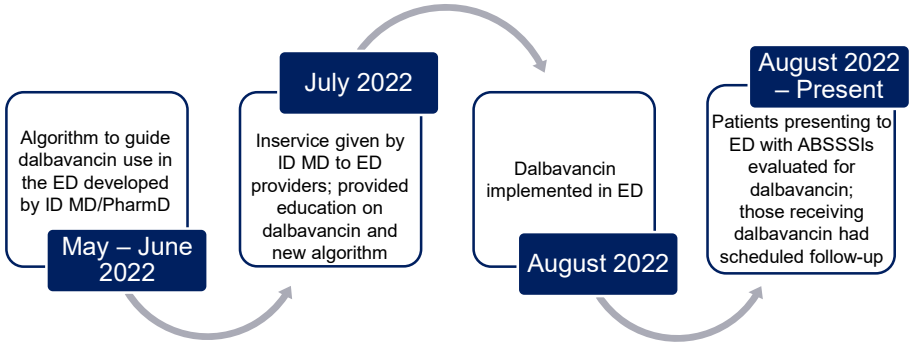
Dalbavancin Implementation



ID = Infectious Diseases

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Study Purpose

Evaluate the impact of the implementation of the dalbavancin algorithm in the ED on the length of hospital stay in patients with ABSSSIs

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Study Site

- Emory Saint Joseph's Hospital (ESJH)
- Atlanta, Georgia
- 410-bed acute-care facility
- 194 patients admitted to ESJH with primary diagnosis of ABSSSIs in 2021

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Objectives

Primary objective: compare length of hospital stay in patients with ABSSSI prior to and post implementation of dalbavancin algorithm in the ED

Secondary objectives:

- Acute kidney injury
- Readmission for the treatment of ABSSSI
- Hospital and drug costs

AKI= Acute Kidney Injury

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Methods

IRB-approved, single center, retrospective chart review

↓

Presented to ESJH ED with ABSSSI between 8/01/2021 - 12/31/2021 and 8/01/2022 - 12/31/2022

Inclusion Criteria

- Patients ≥ 18 years old
- Patients with moderate to severe ABSSSI who require IV antibiotics

Exclusion Criteria

Same as dalbavancin algorithm

IV = Intravenous

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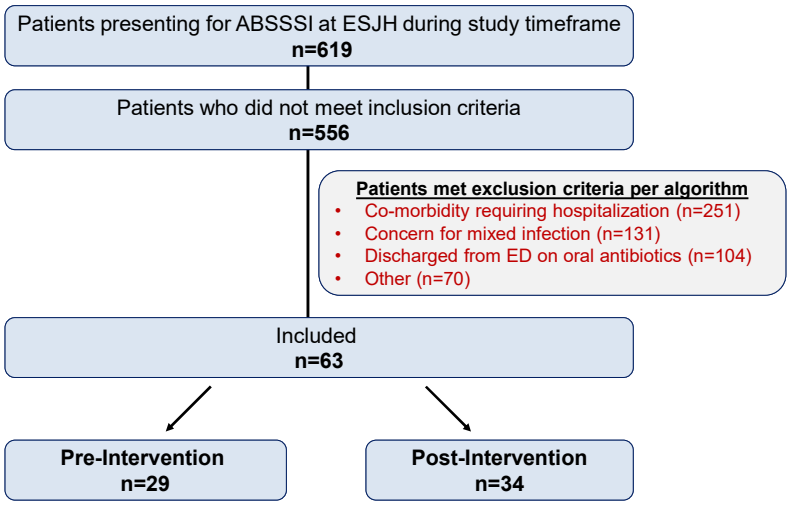
Methods



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Statistics

Continuous data: Two-sample independent t-test

Nominal data: Chi-square or Fisher's exact test

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Results: Demographics

Characteristic	Pre-Intervention (n=29)	Post-Intervention (n=34)	P-value
Sex (male), n (%)	18 (62.1)	14 (41.2)	0.16
Age (years), mean (SD)	62.4 (18.5)	83.4 (124.6)	0.37
BMI (kg/m^2), mean (SD)	29.8 (7.6)	28.0 (6.1)	0.32
Weight (kg), mean (SD)	91.4 (33.5)	82.4 (22.7)	0.23
SCr (mg/dL) on admission, mean (SD)	1.3 (1.4)	1.0 (0.4)	0.27
Heart Failure, n (%)	3 (10.3)	1 (2.9)	0.33
CKD, n (%)	4 (13.8)	3 (8.8)	0.69
Diabetes, n (%)	3 (10.3)	4 (11.8)	0.99
Dalbavancin (n)	**1**	**5**	

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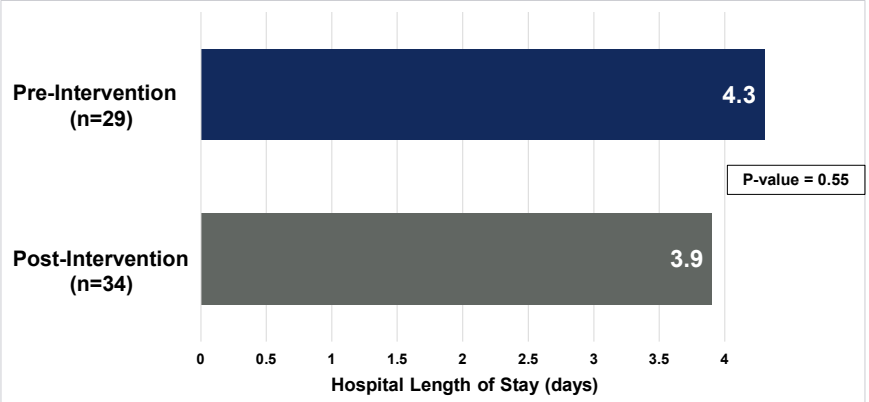
Results: Primary Outcome



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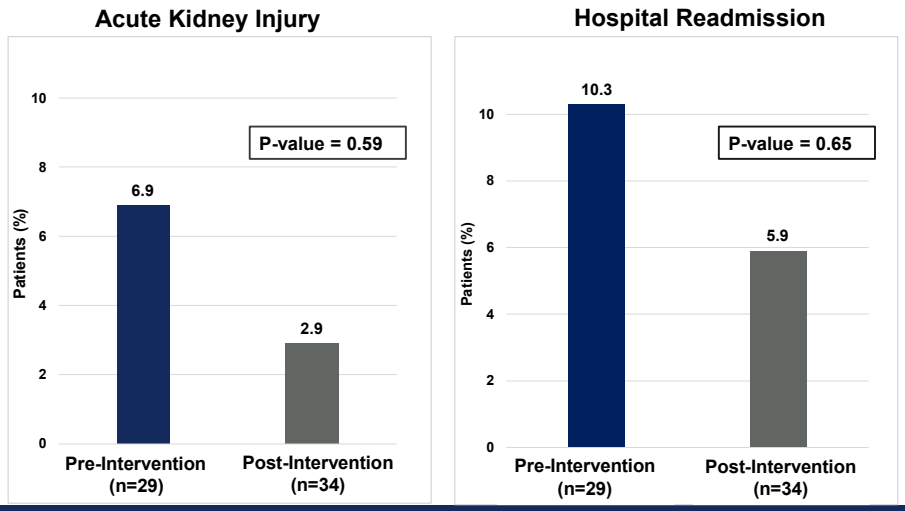
Results: Secondary Outcomes



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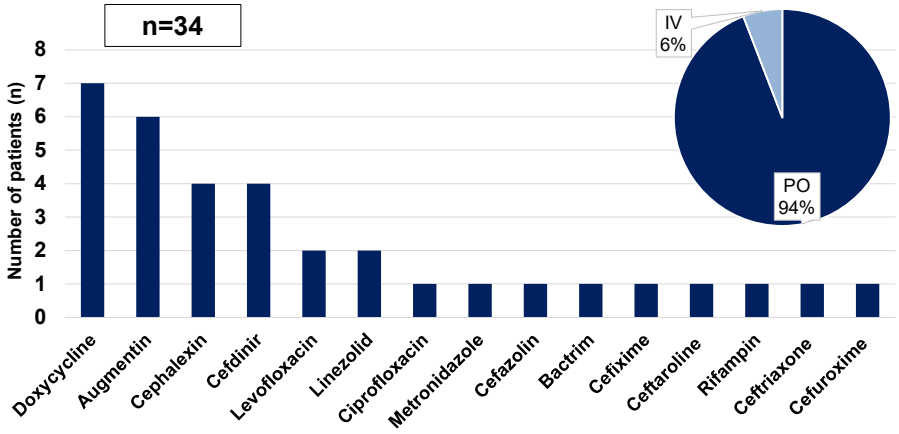
Post-Intervention Discharge Antibiotics



IV = Intravenous
PO= Oral

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Cost Implications

Average cost per admission for cellulitis at ESJH

- $7092.08

Dalbavancin cost and reimbursement

- $2072.77 (AWP) x 3 = $6218.31
- Majority of insurance companies provide reimbursement
- Patient assistance program for uninsured

AWP = Average Wholesale Price

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Limitations

- Single center
- Small sample size
- Retrospective chart review
- EMR transition
- Dalbavancin shortage
- Lack of 24/7 ER pharmacist

EMR = Electronic Medical Record

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Discussion

- Implementation of the dalbavancin algorithm in the ED did not appear to significantly impact hospital length of stay, readmissions, or ADRs
- Impact on hospital length of stay was limited due to the small number of patients who received dalbavancin
- EMR transition during implementation of dalbavancin algorithm was a barrier to change in practice

ESJH = Emory Saint Joseph's Hospital
LOS = Length of Stay
ADRs = Adverse Drug Reactions

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Future Steps

- Share results to pertinent hospital committees
- Further education to ED providers with the goal to assist in identifying patients that would qualify for dalbavancin
- Dalbavancin use in the ED is being expanded to all hospitals in the Emory Healthcare system – opportunity to look at impact in a larger patient population

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Self Assessment

What are the potential benefits of utilizing dalbavancin in the emergency department for ABSSSIs?

A. Decreased length of hospital stay
B. Decreased hospital costs
C. Lower risk of adverse events
D. All of the above

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Acknowledgements

- Dr. Kristen Paciullo, PharmD, BCIDP
- Dr. Raphaelle Lombardo, PharmD, BCPS
- Dr. Ronald Trible, MD, PhD

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Dalbavancin utilization in the emergency department and impact on hospital admission for acute bacterial skin and skin structure infections

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Persistence of Biologics in the Treatment of Psoriasis

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Disclosure Statement

The following individuals have nothing to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation

- Connor Lockridge, PharmD
- Nathalie See, PharmD
- Dylan Wallace, PharmD
- Ah Lim Yoo, PharmD
- John Thomas Menchaca, MD

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Grady Health System (GHS)

- Academic Medical Center
  - 953 licensed beds
  - Various specialized outpatient clinics
- 12 ambulatory care pharmacists in a variety of outpatient clinics

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Background

- Chronic auto-inflammatory skin disorder affects 3.2% of U.S population
- 2019 AAD guidelines state individuals with moderate to severe disease, or with insufficient response to alternative therapy may require biologics
- **Biologic persistence:** the difference in time from treatment initiation to treatment discontinuation
- Common reasons for discontinuation are insufficient response and adverse drug reactions

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AAD: American Academy of Dermatology *J Am Acad Dermatol.* 2019

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Previous Literature

Mourad et al.

- Obesity and female sex predicted earlier biologic discontinuation
- Concomitant psoriatic arthritis improved treatment persistence

Murage et al.

- Experienced biologic users had increased adherence and persistence
- Younger age, female gender, greater disease severity, and more comorbidities were associated with decreased adherence and persistence

Grady

Br J Dermatol. 2019 *Patient Prefer Adherence.* 2018

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Slide 29

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0 I think you need to reorganize the background points a little to make it flow better. I'd have to hear you speak to say for sure.
, 2023-03-23T12:50:56.757

Purpose

Evaluate biologic drug persistence and the potential impact of patient specific factors in the treatment of psoriasis

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Study Design

- Single-center, retrospective chart review
- January 2019 to September 2022
- Statistical analysis:
  - Fisher's Exact, Wilcoxon Rank Sum, Student's t-Test, ANOVA

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ANOVA: Analysis of variance

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Methodology

- Terminology:
  - **Identification period:** period to identify and enroll patients (January 2019 to September 2021)
  - **Index date:** date of first biologic prescription during identification period
  - **Follow-up period:** duration that each patient was followed from index date (max 365 days)
  - **Treatment persistence:** duration of time from index date to treatment discontinuation

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Methodology

Inclusion criteria	Exclusion criteria
• Adults ≥ 18 years of age • Prescribed subcutaneous biologic for treatment of psoriasis • Biologic filled at a Grady pharmacy	• Concomitant diagnosis of another auto-inflammatory disease, other than psoriatic arthritis

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Outcomes

Primary:

- Median number of days to biologic discontinuation

Secondary:

- Adherence to biologic therapy
- Completion of induction dose
- Cause of biologic discontinuation

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Baseline Characteristics

Variable	Persistence < 180 days (n=20)	Persistence ≥ 180 days (n=71)	*P*-value
Age (years), mean (SD)	52.4 (11.6)	51.0 (12.0)	0.63
BMI (kg/m2), median (IQR)	32.8 (25.7, 36.6)	30.1 (26.3, 37.8)	0.72
Male, n (%)	9 (45.0)	36 (50.7)	0.80
Race/ethnicity, n (%)			
Black	11 (55.0)	39 (54.9)	1
Hispanic	5 (25.0)	16 (22.5)	0.77
White	3 (15.0)	11 (15.5)	1
Asian	1 (5.0)	5 (7.0)	1

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BMI: Body mass index IQR: Interquartile range SD: Standard deviation

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Baseline Characteristics

Comorbidities, n (%)	Persistence < 180 days (n=20)	Persistence ≥ 180 days (n=71)	*P*-value
Hypertension	11 (55.0)	39 (54.9)	1
Hyperlipidemia	10 (50.0)	16 (22.5)	0.03
Diabetes	6 (30.0)	19 (26.8)	0.78
Psoriatic arthritis	5 (25.0)	13 (18.3)	0.53
History of CVA/TIA	1 (5.0)	9 (12.7)	0.45
History of MI	0 (0.0)	6 (8.5)	0.33

CVA: Cerebrovascular accident TIA: Transient ischemic attack MI: Myocardial infarction

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Baseline Characteristics

Variable	Persistence < 180 days (n=20)	Persistence ≥ 180 days (n=71)	*P*-value
Tobacco use, n (%)			
Current	3 (15.0)	13 (18.3)	1
Treatment status, n (%)			
Experienced	8 (40.0)	37 (52.1)	0.45
Primary insurance, n (%)			
Uninsured	12 (60.0)	47 (66.2)	0.61
Medicare	7 (35.0)	12 (16.9)	0.12
Medicaid	1 (5.0)	9 (12.7)	0.45
Commercial	0 (0)	3 (4.2)	1

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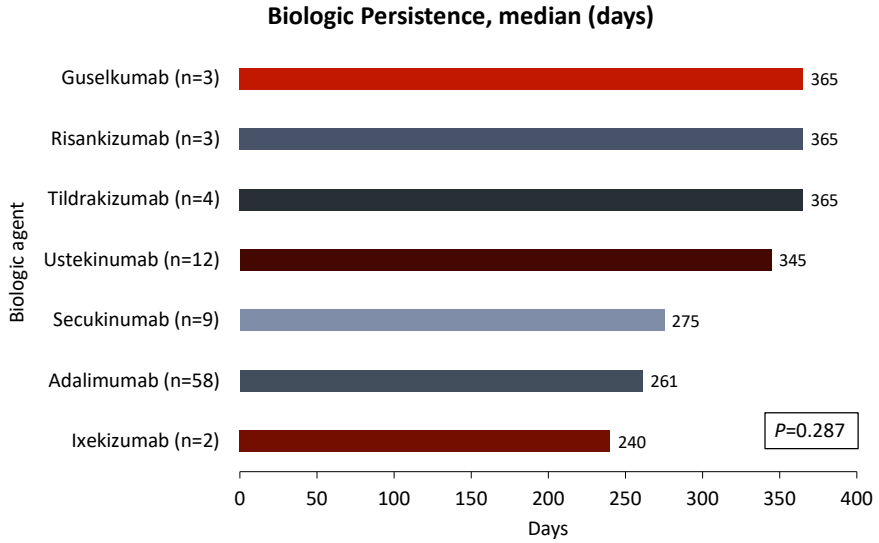
Primary Outcome



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Secondary Outcomes

Variable	Persistence < 180 days (n=20)	Persistence ≥ 180 days (n=71)	*P*-value
Adherence (PDC), n (%)			
PDC ≥ 80%	12 (60)	41 (57.7)	1
Completion of induction dose, n (%)			
Yes	18 (90.0)	64 (90.1)	1
Cause of biologic discontinuation, n (%)			
Treatment failure	10 (50)	6 (8.5)	<0.001
Adverse effect(s)	2 (10)	2 (2.8)	0.21
Other	8 (40)	30 (42.3)	1

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PDC: Proportion of days covered

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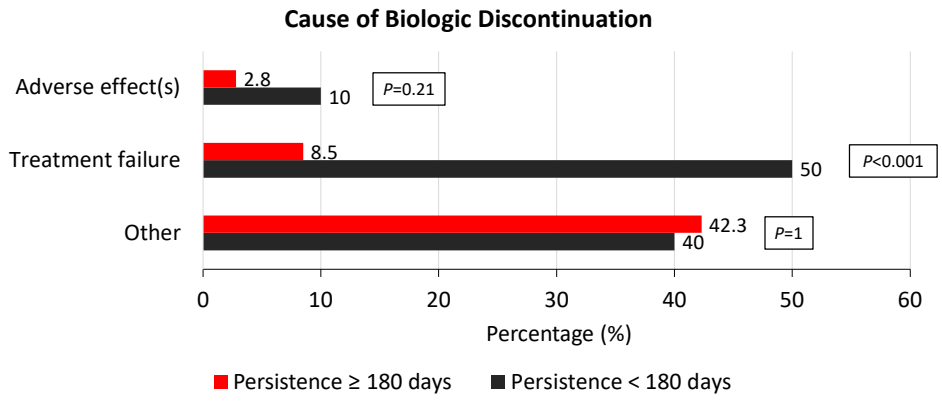
Secondary Outcomes



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Discussion

- Individuals who persisted for less than 180 days were more likely to have concomitant hyperlipidemia, and more likely to discontinue biologic therapy due to treatment failure
- Duration of biologic persistence did not differ with age, BMI, race, gender, insurance, comorbidities, treatment status, or smoking status
- Social/economical challenges and health literacy may influence biologic persistence in ethnic minorities

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BMI: Body mass index

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Limitations

- Retrospective, single-center nature of the study
- Small sample size
- Short study duration
- Institutional formulary restrictions

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Conclusion

- Biologic persistence does not appear to be influenced by patient specific factors
- Duration of biologic therapy does not appear to differ between individual biologic agents
- Hyperlipidemia may predict decreased biologic persistence for the treatment of psoriasis

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BMI: Body mass index

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Acknowledgements

I would like to thank my advisors for their guidance, support, and expertise throughout the development of this presentation

- Nathalie See, PharmD
- Dylan Wallace, PharmD

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Learning Assessment Question

- What patient specific factors may impact the persistence of biologics in the treatment of psoriasis?
  - A. Obesity
  - B. Female sex
  - C. Younger age
  - D. More comorbidities
  - E. All of the above

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Persistence of Biologics in the Treatment of Psoriasis

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EFFICACY OF PARENTERAL HALOPERIDOL FOR NAUSEA IN THE EMERGENCY DEPARTMENT

Southeastern Residency Conference
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DISCLOSURES

- The following investigators have nothing to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation:
  - Presenter: Gabby Mendoza, PharmD
  - Advisors: Dora Hall, PharmD, BCPS and Sarah Cullen, PharmD, BCPS

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OBJECTIVES

- Evaluate the use of rescue antiemetics after parenteral haloperidol administration for nausea in the emergency department
- Determine the route of administration and dose of haloperidol being administered for nausea in the emergency department
- Analyze the safety of parenteral haloperidol based on incidence of QTc prolongation

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BACKGROUND

- Nausea and vomiting are some of the most common reasons for emergency department visits
- Haloperidol, a butyrophenone, acts as a potent dopamine antagonist in the chemoreceptor trigger zone of the brain and has been used to treat nausea and vomiting
- The efficacy of parenteral haloperidol for nausea in the emergency department has not been extensively studied

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CDC. *FastStats – emergency department visits*, 2022.

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BACKGROUND

Title	Haloperidol Use in the Emergency Department for Gastrointestinal Symptoms: Nausea, Vomiting, and Abdominal Pain
Design	Retrospective chart review
Inclusion	• Patients ≥18 years in the ED • Patients with ICD-10 codes for any of the following: nausea, vomiting, abdominal pain, epigastric pain, abdominal tenderness, gastroparesis, cyclical vomiting, functional dyspepsia
Results	• 56.6% discharged home vs. 43.2% admitted to hospital • Receiving haloperidol as the only medication in the ED led to lower hospital admission (OR = 0.25, P <0.005) • Approximately 4.4% of patients developed side effects
Conclusion	• Most patients successfully treated and discharged home • Haloperidol seemed safe and led to less frequent hospital admissions

ED – emergency department
OR – odds ratio

Shahsavari et al. *Clinical and Translational Gastroenterology*, 2021;12(6).

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BACKGROUND

Title	Intravenous Haloperidol for the Treatment of Intractable Vomiting, Cyclical Vomiting, and Gastroparesis
Design	Retrospective, case-control, cross-over study
Inclusion	• Patients with 2+ ED visits for the treatment of intractable vomiting, cyclical vomiting, or gastroparesis that did not receive haloperidol for one visit but did receive it during a previous or subsequent visit
Results	• Reduced hospitalization rate in the haloperidol group (OR 0.083, 95% CI, P = 0.004) • No adverse effects were documented in the haloperidol group
Conclusion	• Haloperidol seems to be an effective adjunctive treatment in the ED for intractable vomiting, cyclical vomiting, and gastroparesis • Haloperidol is more effective than traditional care in reducing hospitalization rate
Notes	• Most common dose was 5 mg and was typically given as a secondary agent • Haloperidol has a long half-life and adverse effects may not be immediately apparent

CI – confidence interval

Schwartz et al. *World journal of emergency medicine* 2021;12(3):228-231

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PURPOSE

To assess the efficacy of parenteral haloperidol for nausea in the emergency department by determining the rate of rescue antiemetics needed after utilizing haloperidol

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451-bed community hospital

ED: 31 licensed beds
Average ED visits: 65,000 per year

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PRIMARY OUTCOME

Parenteral haloperidol for nausea

Did not receive additional rescue antiemetic

Received additional rescue antiemetic

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SECONDARY OUTCOMES

- Route of administration
- Dose administered
- Safety: QTc prolongation

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METHODOLOGY

Design

- Single center
- Retrospective chart review

Timeline

- January 2022 to June 2022

Statistics

- Descriptive data

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POPULATION

Inclusion	Exclusion

• Adults ≥18 years of age
• Patients receiving IM or IV haloperidol
• ED patients with the ICD-10 codes for:
  • nausea and vomiting
  • gastroparesis
  • cannabis use without complication
  • cyclic vomiting syndrome
  • cannabis use with other disorder
  • cannabis use with unspecified cannabis-induced disorder
	• Patients <18 years of age
	• Patients receiving haloperidol decanoate
	• Pregnant patients
	• Prisoners
	• Patients with cognitive disabilities

IM – intramuscular
IV - intravenous

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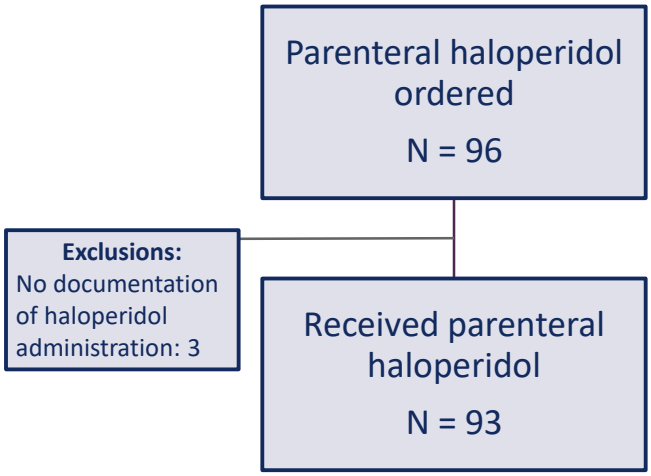
ENROLLMENT



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BASELINE CHARACTERISTICS

Characteristics	N = 93
Mean age	35 (17-85)
Gender (male)	30 (30.3%)
Race	
African American	80 (86.0%)
Caucasian	11 (11.8%)
Hispanic	1 (1.1%)
Other	1 (1.1%)
Antiemetics Given Before Haloperidol	
None	32 (34.4%)
1	33 (35.5%)
2	28 (30.1%)

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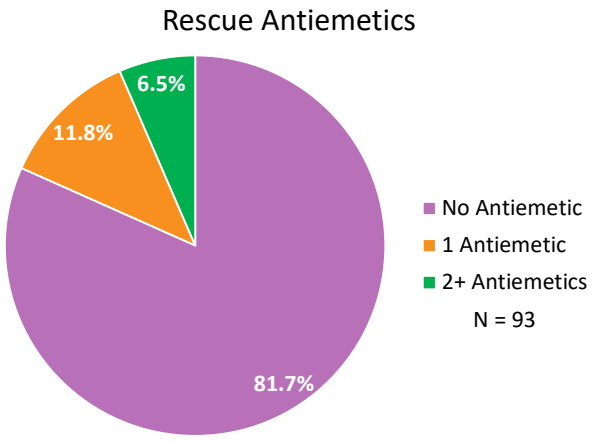
PRIMARY OUTCOME



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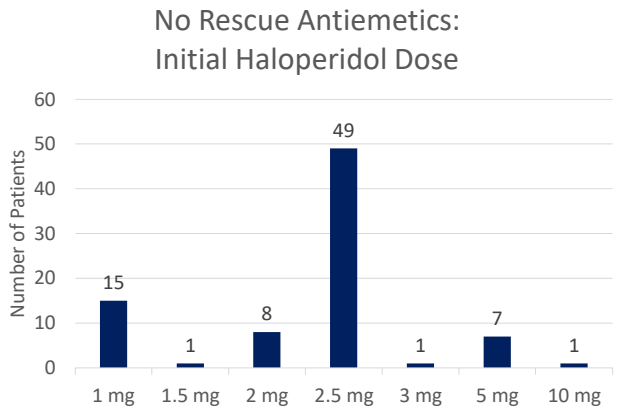
PRIMARY OUTCOME



N = 82

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PRIMARY OUTCOME

Number of Rescue Antiemetics Given

Initial Haloperidol Dose	1	2+
2 mg	0	1
2.5 mg	6	2
5 mg	5	3

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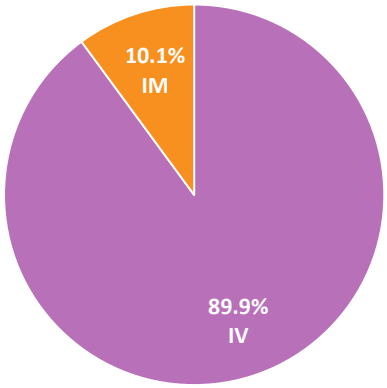
SECONDARY OUTCOMES

Route of Administration



IV – intravenous
IM – intramuscular

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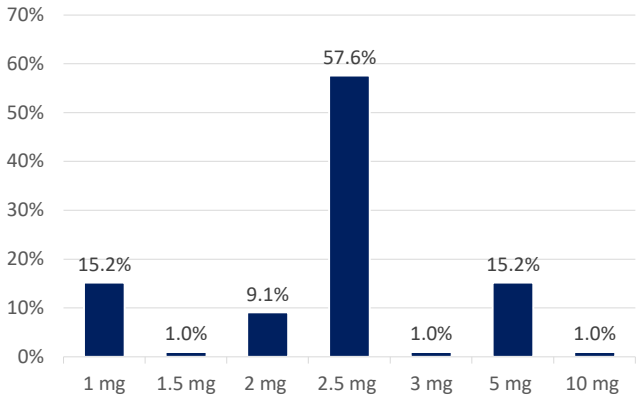
SECONDARY OUTCOMES

Dose of Parenteral Haloperidol



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SECONDARY OUTCOMES

Number of Doses of Parenteral Haloperidol Administered	N = 93
1	87 (93.5%)
2	6 (6.5%)

6 patients received an initial dose of 2.5 mg haloperidol → 6 patients received a second dose of 2.5 mg haloperidol

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SAFETY

- 10 patients had an EKG done after receiving haloperidol
  - 1 patient had prolonged QTc interval

Vent. rate	113	BPM
PR interval	166	ms
QRS duration	66	ms
QT/QTc-Baz	344/471	ms
P-R-T axes	83 75 55	

Sinus tachycardia
Right atrial enlargement
Borderline ECG

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DISCUSSION

- Majority of patients had resolution of symptoms after the administration of parenteral haloperidol
  - Over half of the patients received one single IV dose of 2.5 mg
- Patients needing rescue antiemetics after parenteral haloperidol received between 2-5 mg haloperidol
- Unclear if administration of antiemetic(s) prior to haloperidol affected outcomes

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LIMITATIONS

- Retrospective
- Single-center
- Relies on provider & nurse entry
- Small sample size
- Lack of follow-up documentation

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CONCLUSION

- Haloperidol seems to be an effective treatment for nausea in the emergency department
- Additional studies would be beneficial to analyze the effect of antiemetics given before parenteral haloperidol and safety

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ASSESSMENT QUESTION

True or false:
The majority of patients in this study required a single IV dose of 2.5 mg haloperidol to treat their nausea in the ED.

A. True
B. False

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ACKNOWLEDGEMENTS

Dora Hall, PharmD, BCPS
Sarah Cullen, PharmD, BCPS
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EFFICACY OF PARENTERAL HALOPERIDOL FOR NAUSEA IN THE EMERGENCY DEPARTMENT

Southeastern Residency Conference
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A retrospective comparison of warfarin versus direct oral anticoagulants (DOACs) for treatment of intracardiac thrombus in hospitalized patients

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The investigators declare that there are no relevant or material financial interests that relate to the research described here.

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Reena Patel, PharmD, BCPS

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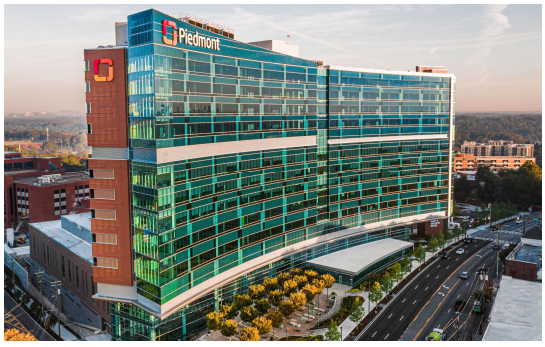
Piedmont Atlanta Hospital (PAH)

- 600+ bed quaternary care hospital
- Affiliated with Piedmont Healthcare
- Cardiac care:
  - Heart transplantation
  - Left ventricular assist device (LVAD)
  - Extracorporeal membrane oxygenation (ECMO)
  - Level 1 cardiovascular emergency program
  - Advanced electrophysiology and cardiovascular imaging



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Intracardiac Thrombus

- Known complication in patients with cardiac impairment, atrial fibrillation, and after myocardial infarction
- Standard of care for intracardiac thrombus is treatment with warfarin for prevention of embolic events
- Recommended treatment duration:
  - ≥ 3 months for LV thrombus
  - 4-12 weeks for LAA thrombus

Cruz Rodriguez JB, Okajima K, Greenberg BH. Management of left ventricular thrombus: a narrative review. *Ann Transl Med*. 2021;9(6):520. doi:10.21037/atm-20-7839
Lip GYH, Banerjee A, Boriani G, et al. Antithrombotic Therapy for Atrial Fibrillation: CHEST Guideline and Expert Panel Report. *Chest*. 2018;154(5):1121-1201. doi:10.1016/j.chest.2018.07.040

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Therapy Comparison

	DOACs	Warfarin
Monitoring	Regular monitoring not required	Frequent INR monitoring
Food and Drug Interactions	Fewer drug and food interactions	Many drug and food interactions
Dosing	Fixed dosing	Variable dosing
PK Considerations	Rapid onset (hours) Caution in renal impairment	Slow onset (5-7 days) No renal dosing

DOAC = direct oral anticoagulant; INR = international normalized ratio; PK = pharmacokinetic

Xarelto (rivaroxaban) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; February 2023.; Eliquis (apixaban) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2021.
Warfarin [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2017.

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DOAC Landmark Trials (Atrial Fibrillation)

	ROCKET AF	ARISTOTLE
Drug studied	Rivaroxaban	Apixaban
Mean CHADS2	3.5	2.1
Treatment Groups	Rivaroxaban Warfarin	Apixaban Warfarin
Primary Efficacy Endpoint	Rivaroxaban noninferior to warfarin	Apixaban superior to warfarin
Safety	Major bleeding similar Increased risk of GI bleeding with rivaroxaban	Major bleeding significantly lower with apixaban

Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. N Engl J Med. 2011;365(10):883-891. doi:10.1056/NEJMoa1009638
Granger CB, Alexander JH, McMurray JJ, et al. Apixaban versus warfarin in patients with atrial fibrillation. N Engl J Med. 2011;365(11):981-992. doi:10.1056/NEJMoa1107039

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DOACs for Intracardiac Thrombus

- DOACs do not have an FDA-approved indication for treating intracardiac thrombus, but they are widely used in practice
- No randomized controlled clinical trials have compared the efficacy of DOACs versus warfarin

FDA = Food and Drug Administration

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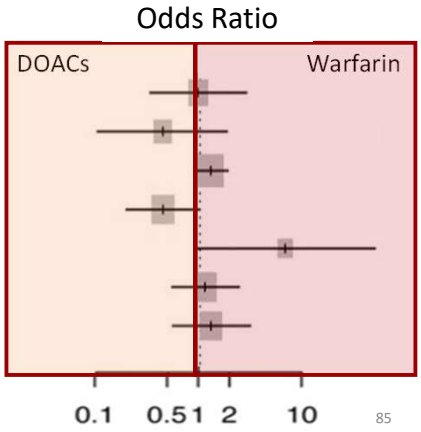
Warfarin versus DOACs for treating left ventricular thrombus: a systematic review and meta-analysis

	DOAC Group		Warfarin Group	
Study	Thrombus resolution	Total	Thrombus resolution	Total
Daher et al	12	17	30	42
Jaidka et al	10	12	25	37
Robinson et al	56	121	131	236
Jones et al	33	41	38	60
Yunis et al	62	64	200	200
Ali et al	18	32	37	60
Iqbal et al	13	22	42	62

OR = 1.11 (95% CI 0.51-2.39)
p = 0.76



Dalia T, Lahan S, Ranka S, et al. Warfarin versus direct oral anticoagulants for treating left ventricular thrombus: a systematic review and meta-analysis. *Thromb J*. 2021;19(1):7. Published 2021 Feb 1. doi:10.1186/s12959-021-00259-w

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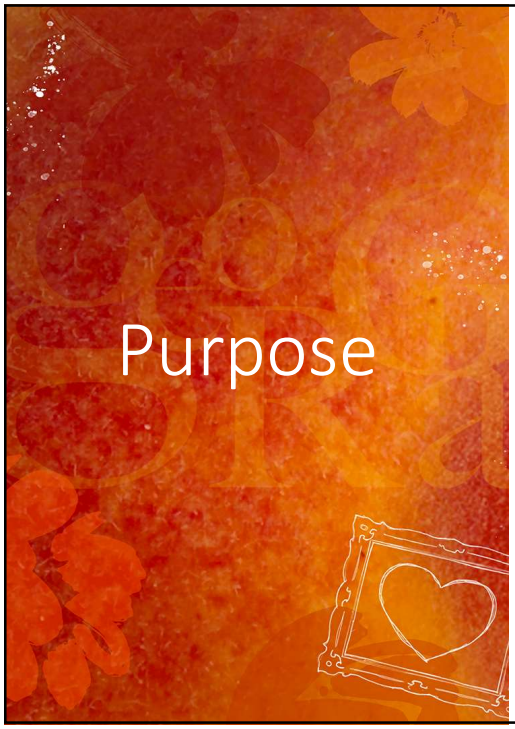

Compare the efficacy of warfarin versus DOACs for the treatment of LV and LAA thrombus and to characterize their safety profiles

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Methodology

- Single-center
- Retrospective chart review
- January 1, 2018 – February 1, 2023
- Statistical analysis
  - Continuous variables: two-sided Student's t-test
  - Categorical variables: Fisher's exact test

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Methodology

Inclusion	Exclusion
• Adults age ≥ 18 years • Patients with LV or LAA thrombus diagnosed by imaging who were treated with warfarin, apixaban, or rivaroxaban	• No repeat imaging* within 1 year of diagnosis • Patients who switched or discontinued anticoagulants • Surgical thrombectomy • Left ventricular assist device (LVAD), mechanical valve(s), or moderate to severe mitral stenosis

* echocardiogram, cardiac magnetic resonance imaging (CMR), or cardiac computed tomography angiography (CCTA)

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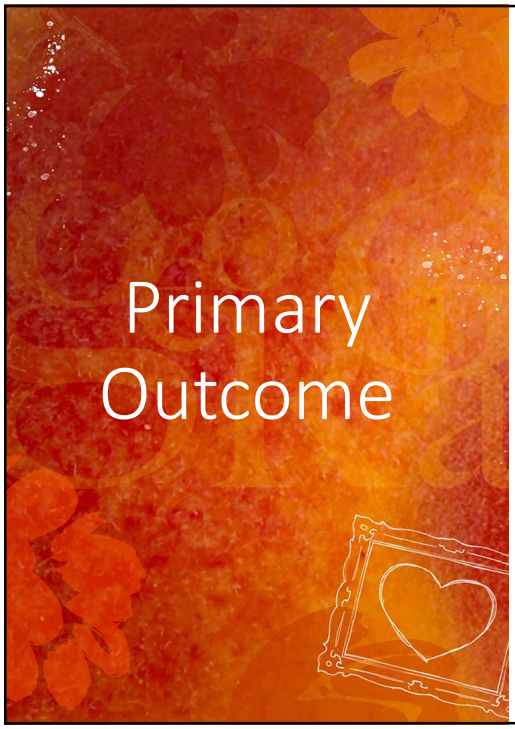

Resolution of LV or LAA thrombus confirmed by repeat imaging at six months

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Secondary Outcomes

- Length of hospital stay
- Incidence of ischemic stroke*
- Incidence of systemic embolic events*
- Incidence of major bleeding as defined by the ISTH*
- Incidence of clinically relevant non-major bleeding as defined by the ISTH*
- All-cause mortality at 12 months
- Resolution of thrombus within 6 to 12 months

*While on therapy and within 12 months of starting anticoagulation

ISTH = International Society on Thrombosis and Haemostasis

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ISTH Definitions

Major Bleeding

- Fatal bleeding
- Bleeding in critical area or organ (intracranial, intraspinal, retroperitoneal, pericardial, etc.)
- Bleeding causing fall in hemoglobin of ≥ 2 g/dL or leading to transfusion of ≥ 2 units of blood

Clinically relevant non-major bleeding

- Medical intervention by a healthcare professional
- Hospitalization or increased level of care
- Face to face evaluation

Kaatz, S, Ahmad, D, Spyropoulos, AC, Schulman, S, for the Subcommittee on Control of Anticoagulation. Definition of clinically relevant non-major bleeding in studies of anticoagulants in atrial fibrillation and venous thromboembolic disease in non-surgical patients: communication from the SSC of the ISTH. *J Thromb Haemost* 2015; 13: 2119– 26.

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Patient Demographics

	DOACs N = 35	Warfarin N = 20	P-value
Male	29 (83%)	15 (75%)	0.49
Age, years	61.7	60	0.68
LAA thrombus	16 (46%)	2 (10%)	**0.006**
LV thrombus	19 (54%)	18 (90%)	**0.006**
Comorbidities			
Myocardial infarction	11 (31%)	9 (45%)	0.32
HFrEF	22 (63%)	15 (75%)	0.37
Atrial fibrillation	18 (51%)	4 (20%)	**0.022**
Stroke or TIA	7 (20%)	5 (25%)	0.67

HFrEF = Heart failure with reduced ejection fraction; TIA = transient ischemic event

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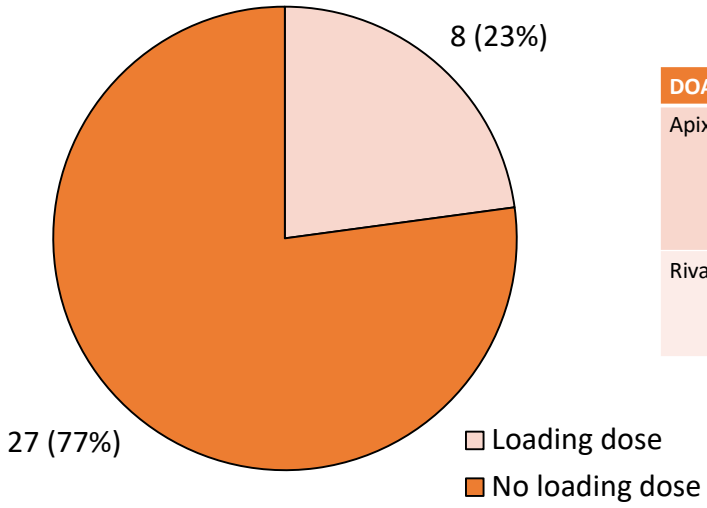
DOAC Dosing



DOAC	Dose	Patients
Apixaban	10 mg BID x 7 days → 5 mg BID	5
	5 mg BID	22
	2.5 mg BID	1
Rivaroxaban	15 mg BID x 21 days → 20 mg daily	3
	20 mg daily	4

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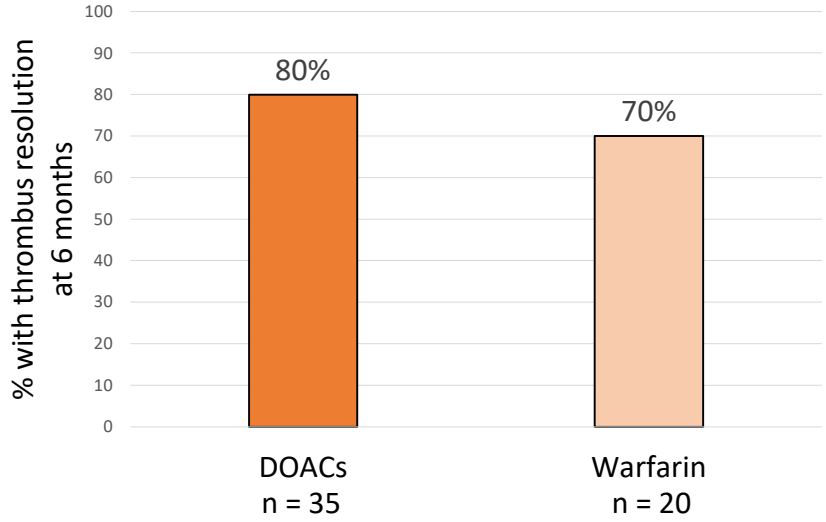
Primary Endpoint



p = 0.41

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Secondary Endpoints

	DOACs N = 35	Warfarin N = 20	P-value
Average length of hospital stay	5 days	8.2 days	0.13
Ischemic stroke*	1 (3%)	0 (0%)	0.45
Embolic events*	1 (3%)	1 (5%)	0.69
Major bleeding*	0 (0%)	2 (10%)	0.19
Clinically relevant non-major bleeding*	1 (3%)	2 (10%)	0.11
All-cause mortality at 12 months	4 (11%)	2 (10%)	0.87
Thrombus resolution at 6-12 months	4 (11%)	1 (5%)	0.43

*While on therapy and within 12 months of starting anticoagulation

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Conclusions

DOACs

- Higher percentage of resolution of thrombus at 6 months
- Higher percentage of resolution of thrombus between 6 and 12 months
- One incidence of ischemic stroke

Warfarin

- Longer length of stay
- Higher incidences of major and clinically relevant nonmajor bleeding

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Discussion

- One patient in DOAC group with ischemic stroke
  - Cardioembolic stroke 4 days after starting DOAC
  - Attributed to large apical LV thrombus
  - Loading dose used
- Longer length of hospital stay in warfarin group
  - Affected by time to reach therapeutic INR
- Both major bleeding events in warfarin group
  - Two gastrointestinal bleeds requiring readmission

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Limitations

- Single-center, retrospective chart review
- Limited sample size
- Lack of quantifiable documentation of size of thrombus
- Lack of standardized timing for follow-up imaging
- Variability in DOAC dosing
- Lack of documented time in therapeutic range for warfarin
- Variability in type of imaging used

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Future Directions

- A randomized controlled trial is needed to evaluate the efficacy and safety profiles of DOACs versus warfarin for treatment of intracardiac thrombus
- Present results to cardiology/electrophysiology team
  - Work with cardiology team to arrange follow-up imaging at predetermined times in future studies

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Self Assessment Question

True or False:
DOACs are as effective as warfarin for resolution of intracardiac thrombus.

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- NaaDede Badger-Plange, PharmD, BCPS
- Chelsea Moran, PhamD, BCPS
- Reena Patel, PharmD, BCPS
- Nassim Najafisales, PharmD, BCPS
- Kristin Fernandes, PharmD, BCPS

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A retrospective comparison of warfarin versus direct oral anticoagulants (DOACs) for treatment of intracardiac thrombus in hospitalized patients

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AFE? It's A-OK!: A Review of Amniotic Fluid Embolism and Treatment

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Disclosures

NO CONFLICTS OF INTEREST TO DISCLOSE

OFF-LABEL MEDICATION USE

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Abbreviations

ACLS	Advanced Cardiac Life Support
AFE	Amniotic Fluid Embolism
CPR	Cardiopulmonary Resuscitation
DIC	Disseminated Intravascular Coagulopathy
DVT	Deep Vein Thrombosis
ECMO	Extracorporeal Membrane Oxygenation
FFP	Fresh Frozen Plasma
G	Gravidity
INR	International Normalized Ratio
MI	Myocardial Infarction
P	Parity
PE	Pulmonary Embolism
PLT	Platelets
PRBC	Packed Red Blood Cells
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
ROSC	Return of Spontaneous Circulation

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Objective

Identify factors that may require early, aggressive intervention in amniotic fluid embolism

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What is Amniotic Fluid Embolism?

- Complication of pregnancy characterized by sudden catastrophic cardiovascular collapse with a cascade of symptoms
- First case report from 1926
- Rare complication that occurs in ~1:50,000
  - ~100 cases annually in the US
  - Incidence increasing
- 2nd leading cause of maternal death in the US and Europe
  - Mortality rate 60%

Mutchler, C. (2021, July 4). *What is amniotic fluid embolism?* Verywell Health.

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AFE Risk Factors

- AFE can not be predicted, but risk may increase due to:
  - Cesarean delivery
  - Amnioinfusion
  - Blunt force trauma
  - Rapid labor
  - Induction
  - Antepartum hemorrhage

Mutchler, C. (2021, July 4). *What is amniotic fluid embolism?* Verywell Health.

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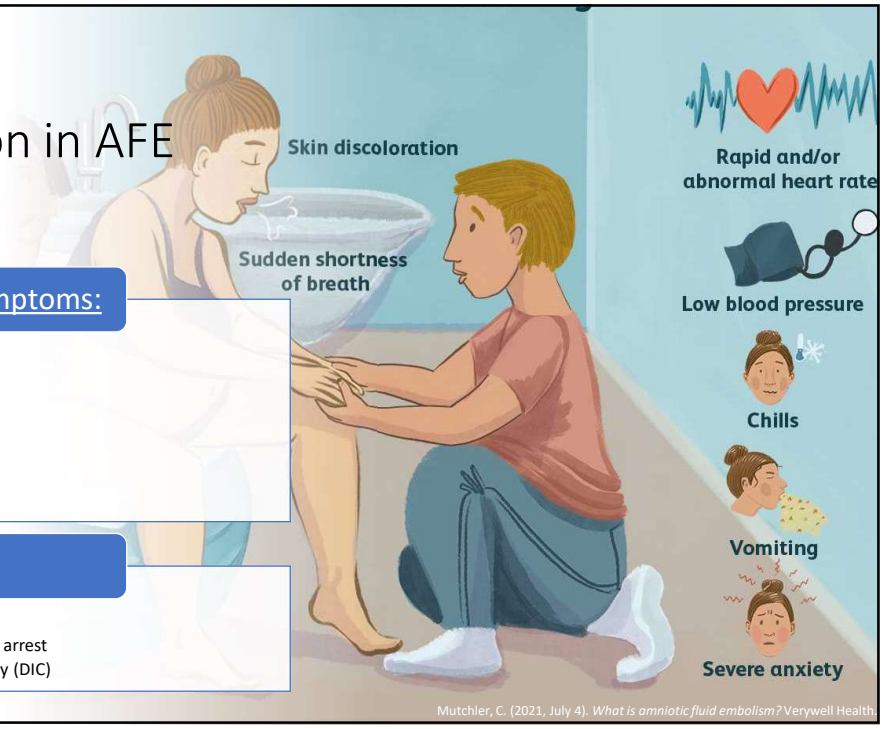
Initial Presentation in AFE



Commonly reported symptoms:

- Altered Mental Status
- Headache
- Nausea
- Fetal distress
- Decorticate posturing
- Seizures
- Cyanosis

Hallmark symptoms:

- Sudden onset of hypoxia
- Sudden onset of hypotension or cardiac arrest
- Disseminated Intravascular coagulopathy (DIC)

Mutchler, C. (2021, July 4). *What is amniotic fluid embolism?* Verywell Health.

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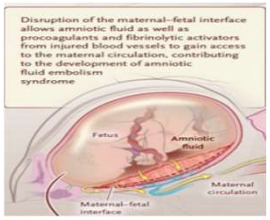
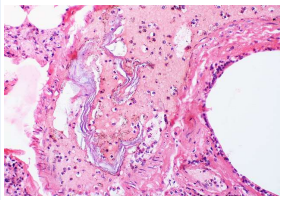
Pathophysiology of AFE

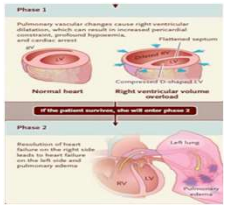


1.)Disruption of the maternal-fetal barrier

Amniotic fluid and contents are introduced into the maternal circulation



2.) Debris and antigens in the amniotic fluid produce an intense immunologic response in the mother



3.) Two phased response:

Phase 1: Cardiorespiratory failure

Phase 2: Disseminated intravascular coagulopathy (DIC)

Case 33-2019: A woman with cardiopulmonary arrest during cesarean section. (2020). *New England Journal of Medicine*

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Particulate matter from the amniotic fluid causes acute pulmonary vascular obstruction

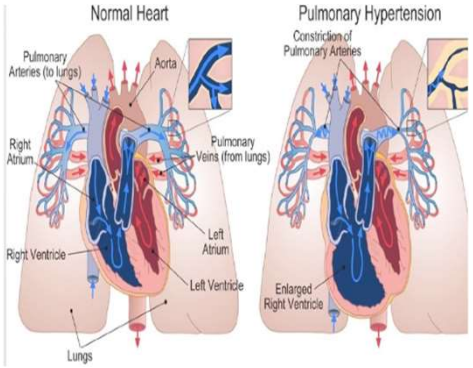
- fetal cells/mucin block pulmonary capillaries
- *Steiner and Lushbaugh-1941*

Vasoactive substances such as serotonin cause pulmonary vasoconstriction

- Leads to pulmonary hypertension
- Triggers immediate right ventricular failure
- *Attwood-1956*

Right ventricular failure will further decompensate and lead to left ventricular failure

- Cardiogenic shock



Phase 1: Cardiorespiratory Failure

Pulmonary hypertension. ACHA. (n.d.)

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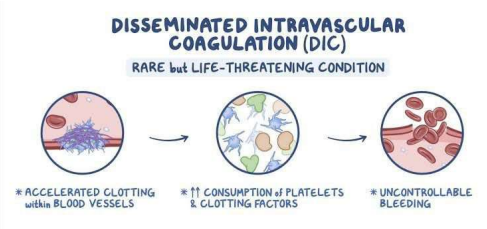
Widespread microthrombi → Consumptive coagulopathy
- Platelets consumed
- Fibrinogen consumed
- Prolonged PT and APTT

→ Uncontrollable bleeding → Thromboxane A2 → Multi-Organ Damage



Laboratory Findings in Acute DIC

- Platelet Count	↓
- Fibrinogen	↓
- PT (INR)	↑
- PTT	↑
- D-dimer	↑

Phase 2-DIC

Disseminated intravascular coagulation (DIC). Mount Sinai Health System. (n.d.).

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Diagnosing AFE

Clinical diagnosis of exclusion
- Often diagnosed retrospectively or misdiagnosed entirely

Differential:
- Pulmonary Embolism
- Myocardial infarction
- Air Embolism
- Sepsis
- Drug induced anaphylaxis
- High spinal block

The Society of Maternal-Fetal Medicine (SMFM) endorses diagnostic criteria:
- Hypoxemia
  - O_2 saturation <90%
- Hypotension
  - SBP<90mmHg or sudden cardiac arrest
- DIC:
  - PLT<100k
  - >25% increase in PTT
  - Fibrinogen <200mg/L

Society for Maternal-Fetal Medicine

Combs, C. A. (2022). Amniotic fluid embolism: Management using a checklist. *OBG Management*, *34*(7).

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Survivability

- Dependent upon several factors:
  - Variability in immune response
  - Delivery location (home, birth center, hospital)
  - Type of hospital and level of services (critical care, NICU, OB, etc.)
  - Timing of event-before or after delivery
  - **Immediacy of recognition and aggressive treatment**

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Treatment of AFE

Initial treatment is focused on early recognition and resuscitation

Multidisciplinary approach

Cardiac arrest	Hemodynamic support	Respiratory Support	Controlling coagulopathy	Pulmonary Vasodilators	A-OK

Combs, C. A. (2022). Amniotic fluid embolism: Management using a checklist. *OBG Management*, *34*(7).

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Cardiac Arrest

High quality CPR

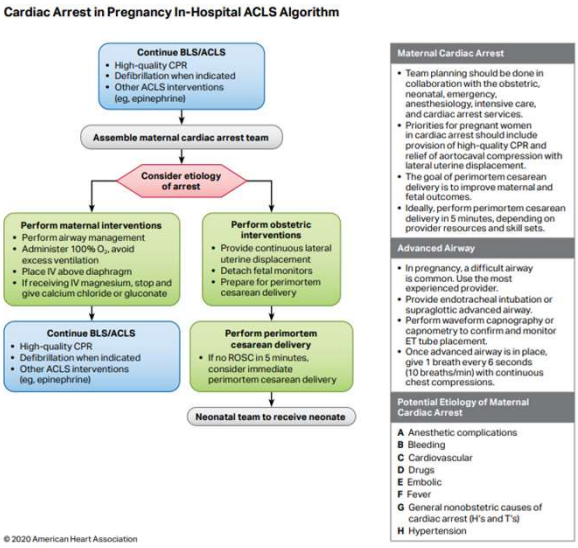
- Continuous lateral displacement

Consider delivery if viable

- 23 weeks gestational age

Deliver via emergent c-section if no ROSC in 4-5 minutes

- Improves maternal hemodynamics



American Heart Association CPR & First Aid. (n.d.).

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Hemodynamic Stability

- Vasopressors
  - Norepinephrine
- Inotropes
  - Dobutamine
  - Milrinone
- Avoid excessive fluid administration

Combs, C. A. (2022). Amniotic fluid embolism: Management using a checklist. *OBG Management*, *34*(7).

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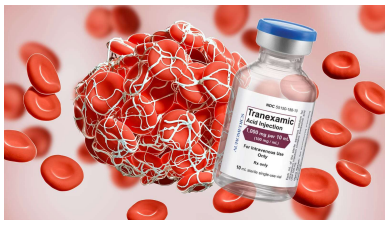
Controlling Coagulopathy

- PLT>50,000
- Normalize PT and INR
  - PRBCs
  - FFP or cryoprecipitate
  - Tranexamic Acid
- Uterine atony
  - Oxytocin
  - Ergot derivatives
    - Methylergonovine
  - Prostaglandins
    - Misoprostol
    - Carboprost



Combs, C. A. (2022). Amniotic fluid embolism: Management using a checklist. *OBG Management*, *34*(7).

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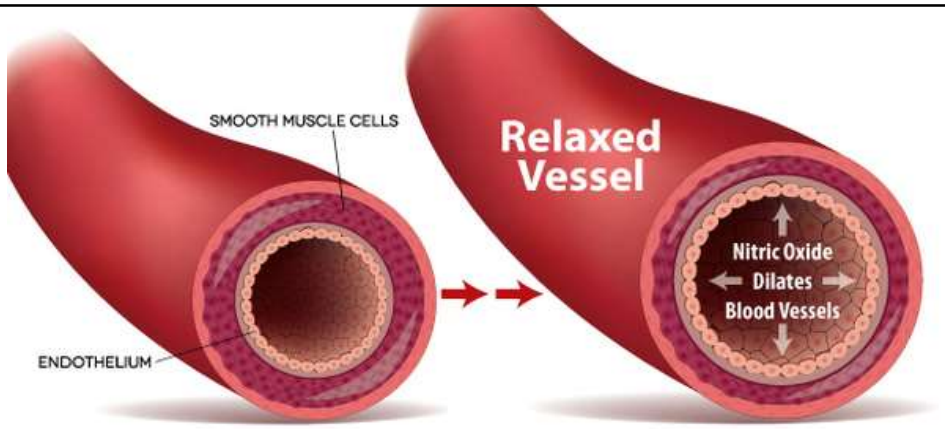

Pulmonary Vasodilators

- Prostacyclins
  - Epoprostenol
  - Treprostinil
- Sildenafil
- Inhaled Nitric oxide

Combs, C. A. (2022). Amniotic fluid embolism: Management using a checklist. *OBG Management*, *34*(7).

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What is A-OK?

A-OK medication regimen [3]

Atropine 1 mg (vagolytic)

Ondansetron 8 mg (5-HT3 antagonist)

Ketorolac 30 mg (cyclooxygenase inhibitor)

Rezai, Shadi, et al. "Atypical Amniotic Fluid Embolism Managed with a Novel Therapeutic Regimen." *Case Reports For Medical Practitioners*, 2020

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A-OK Protocol

Atropine 1mg IV

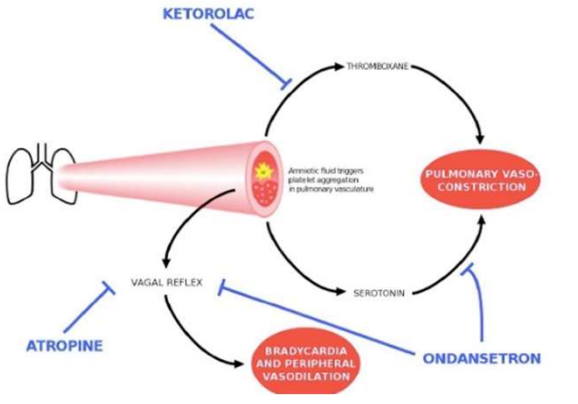
- Competitive muscarinic antagonist
- Blocks vagal stimulation and reverses parasympathetic activity
- Decreased vasoconstriction in the pulmonary vasculature

Ondansetron 8mg IV

- 5-HT3 receptor antagonist
- Blocks serotonin receptors in the heart and lungs
- Combats pulmonary hypertension and cardiovascular collapse

Ketorolac 30mg IV

- NSAID that inhibits prostaglandin release
- Halt the coagulation cascade



Long, M., Martin, J., & Biggio, J. (2022). Atropine, Ondansetron, and Ketorolac. *Ochsner Journal*, *22*(3), 253–257.

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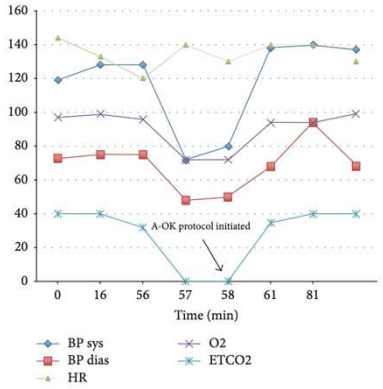
Case Study 1

- 26 yo G2P1001 at 38+1, BMI 41, gestational diabetes
- Presented to ED with SOB, T: 39 fever-O2 sats 97%, normal BP
  - Started on fluids and ABX for suspected sepsis
- Underwent stat primary low transverse c-section
- BP dropped to 72/48 and O_2 dropped to 72%
  - End tidal CO2 fell from 32 to 0
- The anesthesia team initiated A-OK protocol within 1 min of the listed symptoms
- EBL: 2L; Uterine atony/hemorrhage treated with oxytocin, carboprost, 3 units PRBC, 1 unit of FFP, and 3.5L IV fluids
- Within 3 minutes sats recovered to 97% and BP to 138/68
- Once stabilized, she remained intubated and transferred to the ICU
- No evidence of PE, DVT, or DIC-no changes in PT, PTT, INR
  - The patient was extubated postop day 1 and discharged postop day 3



Rezai, S., C Hughes, A., B Larsen, T., N Fuller, P., & E Henderson, C. (2020). Atypical amniotic fluid embolism managed with a novel therapeutic regimen. *Case Reports For Medical Practitioners.*

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Case Study 2

41 yo G8P3 presents at 39 weeks for induction of labor

Patient complains of shortness of breath during induction and Sp02 dropped to 80%

Less than 1 minute later the patient arrested

ACLS initiated and baby was delivered via forceps

The patients was still pulseless after 40 minutes of ACLS

A-OK administered and pulse was regained and stabilized after 2 minutes.

1 hour later the patient developed DIC requiring 13 units PRBC, 6 units FFP, 2 units PLT, 30 units cryo, 2 doses of recombinant factor VIIa

Required hemodialysis for 5 days post arrest due to acute tubular necrosis

Patient discharged on hospital day 13 with neurological deficits that still persist

Copper, P.L., Otto, M.P. & Leighton, B.L. (2013). "Successful management of cardiac arrest from amniotic fluid embolism with ondansetron, metoclopramide, atropine, and ketorolac: a case report," SOAP.

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A-OK Kits

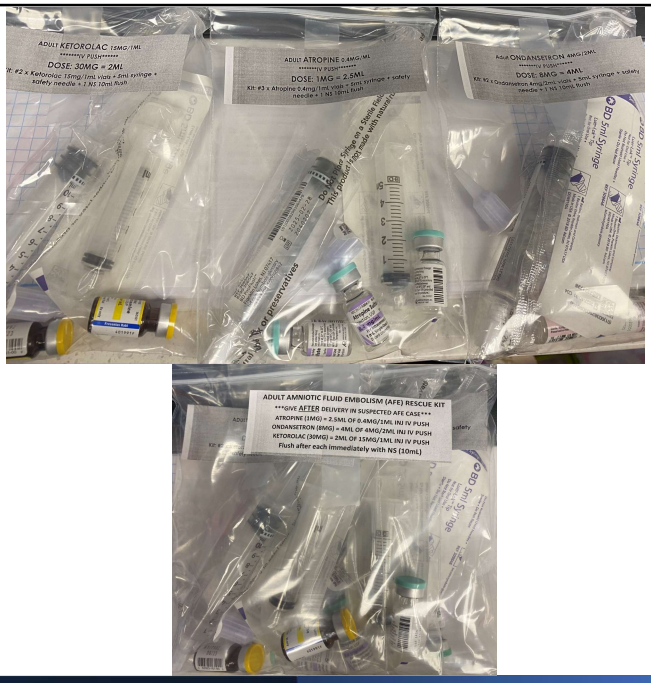
ADULT AMNIOTIC FLUID EMBOLISM (AFE) RESCUE KIT
GIVE AFTER DELIVERY IN SUSPECTED AFE CASE
ATROPINE (1MG) = 2.5ML OF 0.4MG/1ML INJ IV PUSH
ONDANSETRON (8MG) = 4ML OF 4MG/2ML INJ IV PUSH
KETOROLAC (30MG) = 2ML OF 15MG/1ML INJ IV PUSH
Flush after each immediately with NS (10mL)
Exp Date _____

ADULT **ATROPINE** 0.4MG/ML
*******IV PUSH*******
DOSE: 1MG = 2.5ML
Kit: #3 x Atropine 0.4mg/1mL vials + 5mL syringe + safety needle + 1 NS 10mL flush
Exp Date_____

Adult **ONDANSETRON** 4MG/2ML
********IV PUSH******
DOSE: 8MG = 4ML
Kit: #2 x Ondansetron 4mg/2mL vials + 5mL syringe + safety needle + 1 NS 10mL flush
Exp Date_____

ADULT **KETOROLAC** 15MG/1ML
*******IV PUSH******
DOSE: 30MG = 2ML
Kit: #2 x Ketorolac 15mg/1mL vials + 5mL syringe + safety needle + 1 NS 10mL flush
Exp Date _____

COST: <$10



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Conclusion

- AFE is a rare, but catastrophic complication of pregnancy
- Difficult to diagnose
- Requires early recognition and immediate action
- AWARNESS IS KEY
- A-OK shows potential benefit with low risk and low cost

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Learning Assessment Questions

What are the two phases of AFE?

A. Cardiorespiratory failure and DIC
B. Sepsis and shock
C. DIC and PE
D. Cardiorespiratory failure and renal failure

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AFE? It's A-OK!: A Review of Amniotic Fluid Embolism and Treatment

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