

# Comparative Analysis of Reintervention Rates in Mesh versus No Mesh Hernia Repair Using Electronic Health Records

Grishma KC; John Norys; Emily Krause; Kevin Sexton, MD; Laura E Gressler, MS, PhD  
University of Arkansas for Medical Sciences, Little Rock, AR



## BACKGROUND

Hernia is a condition where an organ, such as the intestine or abdominal tissue, protrudes through an opening or weakness in the muscle or tissue that contains it.<sup>1</sup>

Hernias can result in pain, discomfort, and potential complications if left untreated.<sup>1</sup>

The most common treatment for hernias is through surgical repair. In the United States, more than 1 million hernia repairs are performed annually.<sup>2</sup>

Hernia repair procedures can differ based on type (open vs. laparoscopic), approach, and use of mesh.<sup>1,2</sup>

While abdominal hernia repair is generally a safe procedure, there is some risk of complications.<sup>1,2</sup>

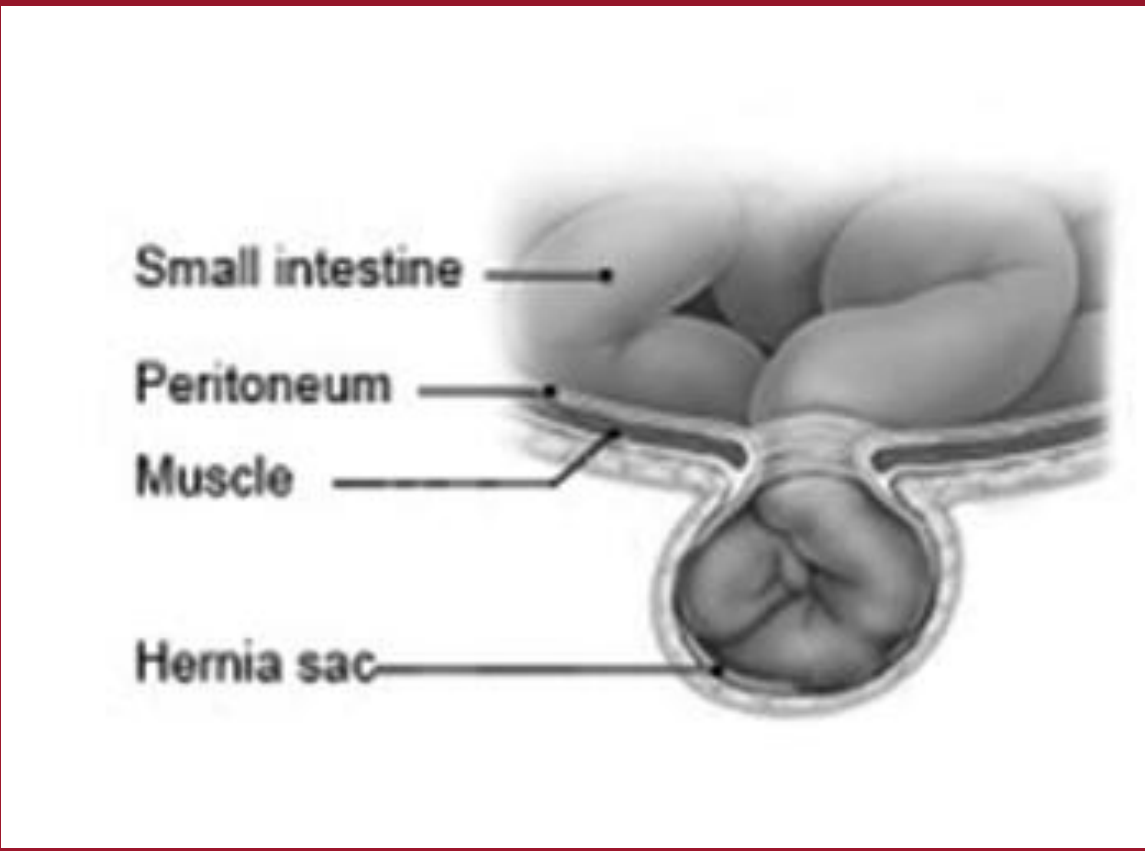
The Food and Drug Administration’s (FDA) spontaneous reporting systems may not represent the true rate of adverse events related to devices used within hernia repair due to potential under-reporting.<sup>4,5</sup>

Electronic health records (EHR) data can be a valuable source of information otherwise missing or underreported in other real-world data (RWD) such as claims data.<sup>6</sup>

Moreover, unstructured data extracted from EHR can give further insight into medical device-, procedure-, and patient-characteristics, as well as experienced outcomes.<sup>7</sup>

Thus, RWD derived from electronic health records EHRs has emerged as a complementary approach for safety signal detection.<sup>4,6,7</sup>

Figure 1: Hernia and Hernia repair<sup>8</sup>



## OBJECTIVES

- This study delves into the impact of mesh usage and procedural and device characteristics on hernia repair reinterventions, leveraging unstructured clinical notes from EHR

## METHODS

- Study design:** A retrospective cohort study
- Data source:** EHR Data from Arkansas Clinical Data Repository (AR-CDR)
- Cohort:** 18 years or older who underwent inguinal repair at UAMS between 10/1/2015 and 7/1/2023 identified through CPT codes. Patients with a concurrent procedure were excluded to restrict the procedures to hernia repairs.
- Exposure:** Mesh versus no mesh device during hernia repair
- Index data:** Date of the initial hernia repair
- Primary outcome:** Reintervention rates between mesh and no mesh procedures identified using CPT-4 codes

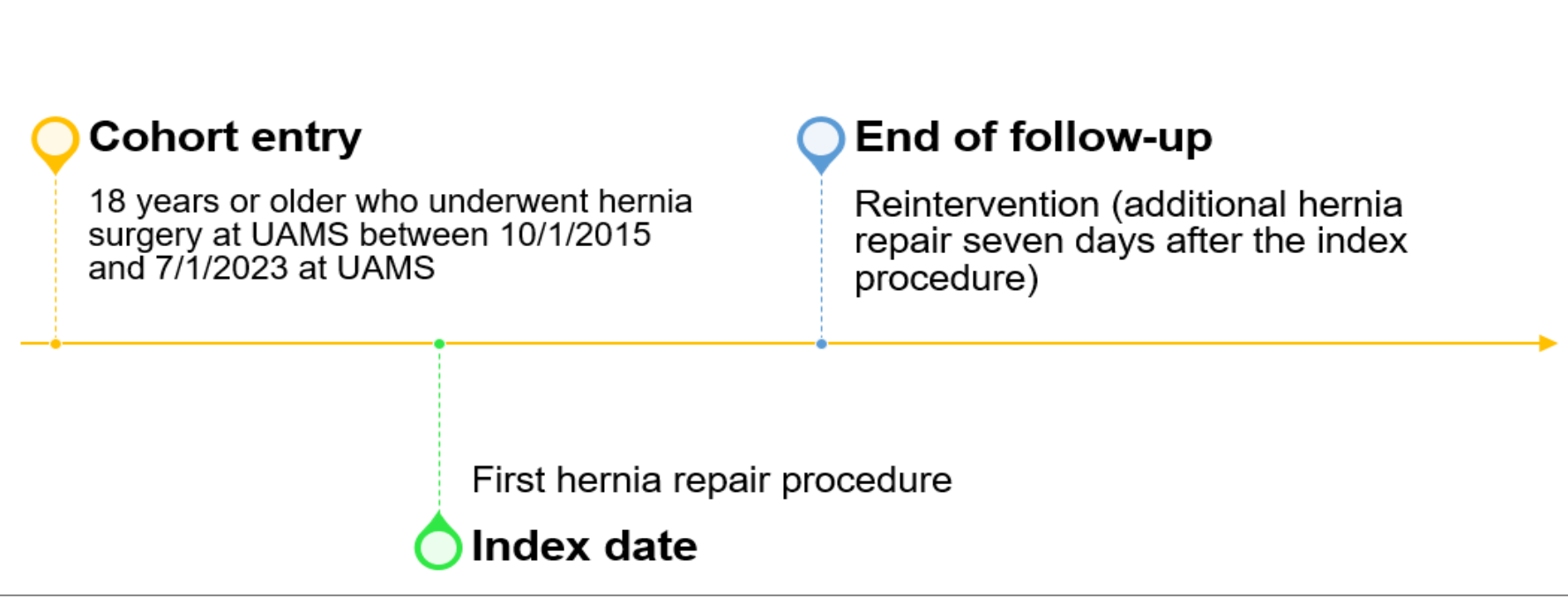
### Data extraction:

- Structured data like diagnoses, medications, procedures, demographics, etc. were extracted.
- Unstructured features that provide a more detailed understanding of device and procedure-related characteristics like surgical approach note, anesthesia type, device item name, procedure name, manufacturers etc. were extracted from clinical notes.
- Unigrams, bigrams, trigrams, and tetragrams were extracted and their frequencies were recorded to identify various structures of device and procedure-related characteristics.

### Statistical analysis:

- Chi-square tests and t-tests
- Unadjusted logistic regression
- Adjusted logistic controlling for structured data
- Adjusted logistic controlling for structured data and unstructured data

Figure 2: Timeline of cohort entry



## RESULTS

A total of 1838 patients underwent hernia repair at UAMS between 10/1/2015 to 7/1/2023.

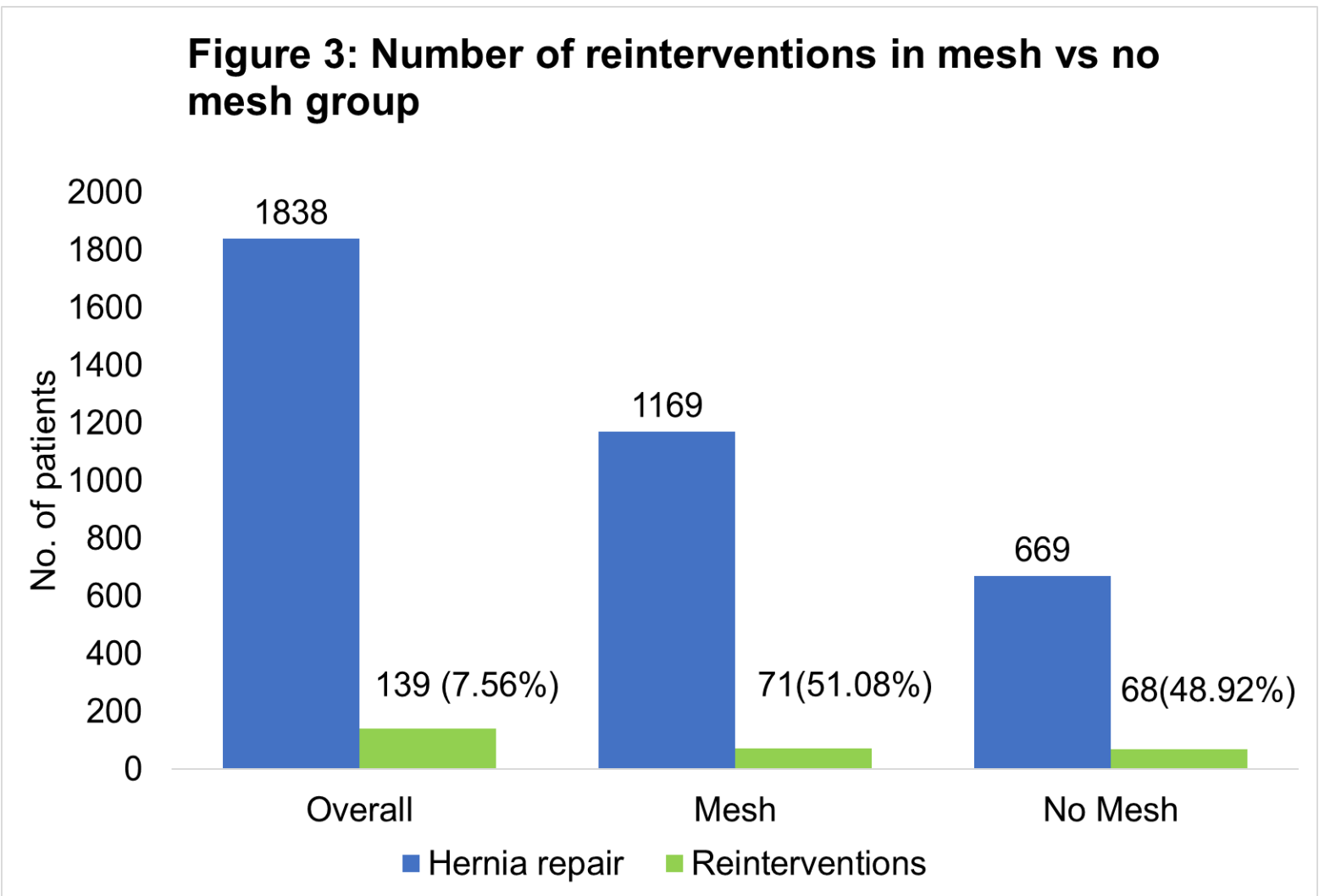
- 35.85% in 50-64 age group
- Mean age of 54.33(14.95)
- 60.72% males
- 56.31% had open surgical approach

## RESULTS

Table 1: Patient Demographics

Characteristics		Overall (n%)	No Mesh (n%)	Mesh n(%)	P(<0.005)
Total Patients (n)		1838	669 (36.40)	1169 (63.40)	
Reinterventions		139 (7.56)	68 (48.92)	71 (51.08)	0.0014
Age	Mean (SD)	54.33 (14.95)	52.72 (15.01)	55.24 (14.84)	0.0005
Sex	Male	1116 (60.72)	296 (44.25)	820(70.15)	<0.0001
	Female	722(39.28)	373 (55.75)	349(29.85)	
Surgical Approach	Open	1035 (56.31)	321(47.98)	714(61.08)	<0.0001
	Null	603 (32.81)	285 (42.60)	318 (27.20)	
	Robotic	70 (3.81)	14 (2.09)	56 (4.79)	
Comorbidity score	Mean (SD)	4.27(3.58)	4.86(3.54)	3.94(3.56)	<0.0001

- A **chi-square analysis** found that the rates of reinterventions, sex, item name, surgical approach were significantly different between the mesh vs no mesh group.
- Additionally, **t-tests** found that the two groups had substantially different age and comorbidity scores.



- The **first logistic regression** that only controlled for structured data variables showed 1.603 (95% CI: 1.116-2.189) higher odds of reintervention with mesh than without mesh.
- The **second logistic model**, which incorporated both unstructured and structured data, indicated an odds ratio of 1.519 (95% CI:1.054-2.198).

Table 2: Odds ratio estimates for Mesh vs No Mesh

Model	Point Estimate	95% Wald Confidence Limits
Unadjusted model	1.75	1.237 2.476
Adjusted model 1 (structured data)	1.603	1.116 2.303
Adjusted model 2 (structured + unstructured data)	1.519	1.054 2.189

## DISCUSSION

### CONCLUSION

- ❖ Patients receiving mesh during their hernia repair exhibited significantly higher odds of reintervention.
- ❖ The difference between the two adjusted logistic regression results indicates that unstructured variables can be influential factors in this analysis.
- ❖ EHR data can be leveraged to potentially provide more granular information regarding device performance and aid in post-market surveillance of medical device-based procedures.
- ❖ Extraction and integration of unstructured clinical notes is feasible and can be used to enhance these kinds of analyses.

### STRENGTHS

- Unstructured clinical notes were used that provided valuable information regarding medical devices, procedures, and outcome characteristics that are otherwise underreported or absent in other RWD sources.

### LIMITATIONS

- Patients who received medical care at different hospital systems or relocated following a procedure yet experienced an outcome are not captured in the analysis.
- While the unstructured EHR data extraction method shows promising potential, validation and the comprehensive assessment of clinical notes are necessary.

## FUTURE WORKS

- Test the feasibility of EHR data enhanced with clinical notes in providing sufficient information for health outcomes research in other patient populations, medical devices, and procedures.
- Develop and apply dynamic algorithms that continuously extract unstructured data to monitor elevated reintervention rates among other procedures and devices.

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