

Real-World Outcomes and Healthcare Burden: Claims Analysis of IV Ibuprofen vs Ketorolac in Pediatrics

Mosadoluwa Afolabi¹, Jensy Rodriguez-Silva¹, Ishveen Chopra¹, Ines Macias-Perez², Jason Makii², Emily Durr², Theresa Human²

¹STATinMED, LLC, Dallas, TX, ²Cumberland Pharmaceuticals Inc., Nashville, TN

INTRODUCTION

- Adverse drug reactions (ADRs) have considerable clinical and economic costs, particularly in the pediatric population:
 - The incidence of ADRs in hospitalized children ranges from 0.4-17.7%¹
 - Up to \$136 billion spent on ADRs annually in the US²
- While both IV ibuprofen (IVIB) and ketorolac are non-selective cyclooxygenase (COX) inhibitors, they vary in their selectivity levels for COX-1 and COX-2 enzymes. This difference affects their relative risks of GI toxicity, nephrotoxicity, and bleeding^{3,4}

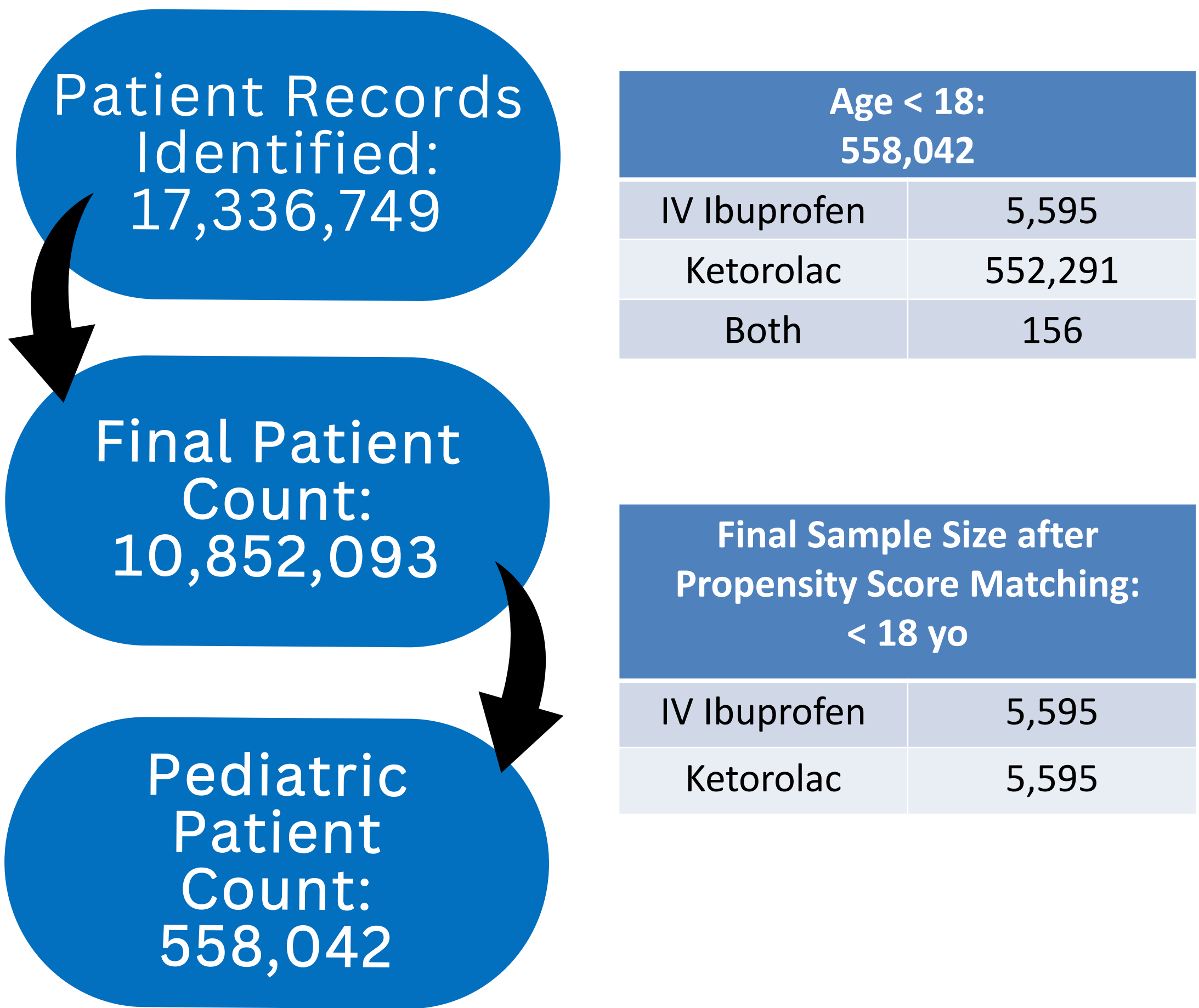
OBJECTIVE

Compare ADR profiles of IVIB and ketorolac in pediatric patients, while evaluating their economic impact using real-world claims data

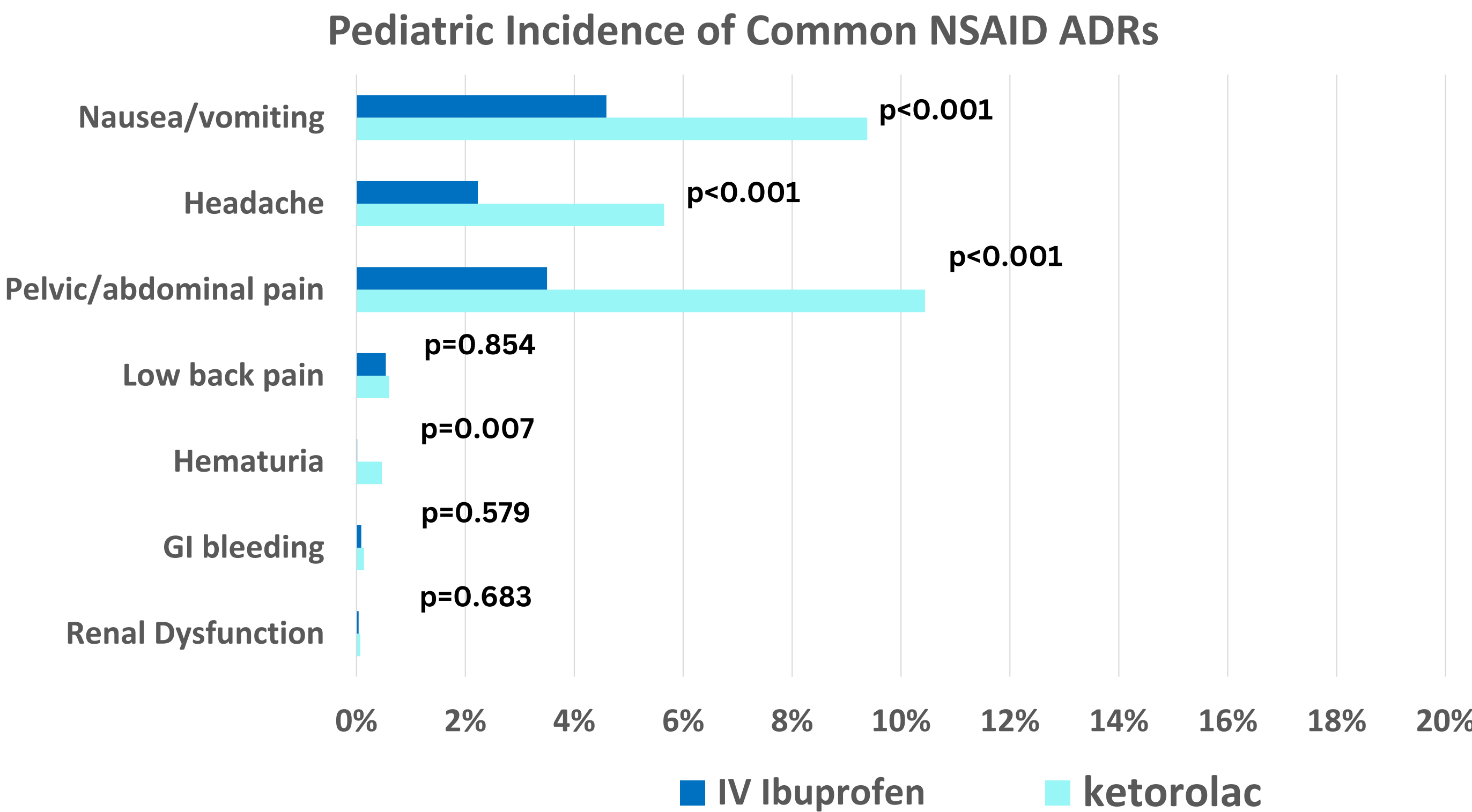
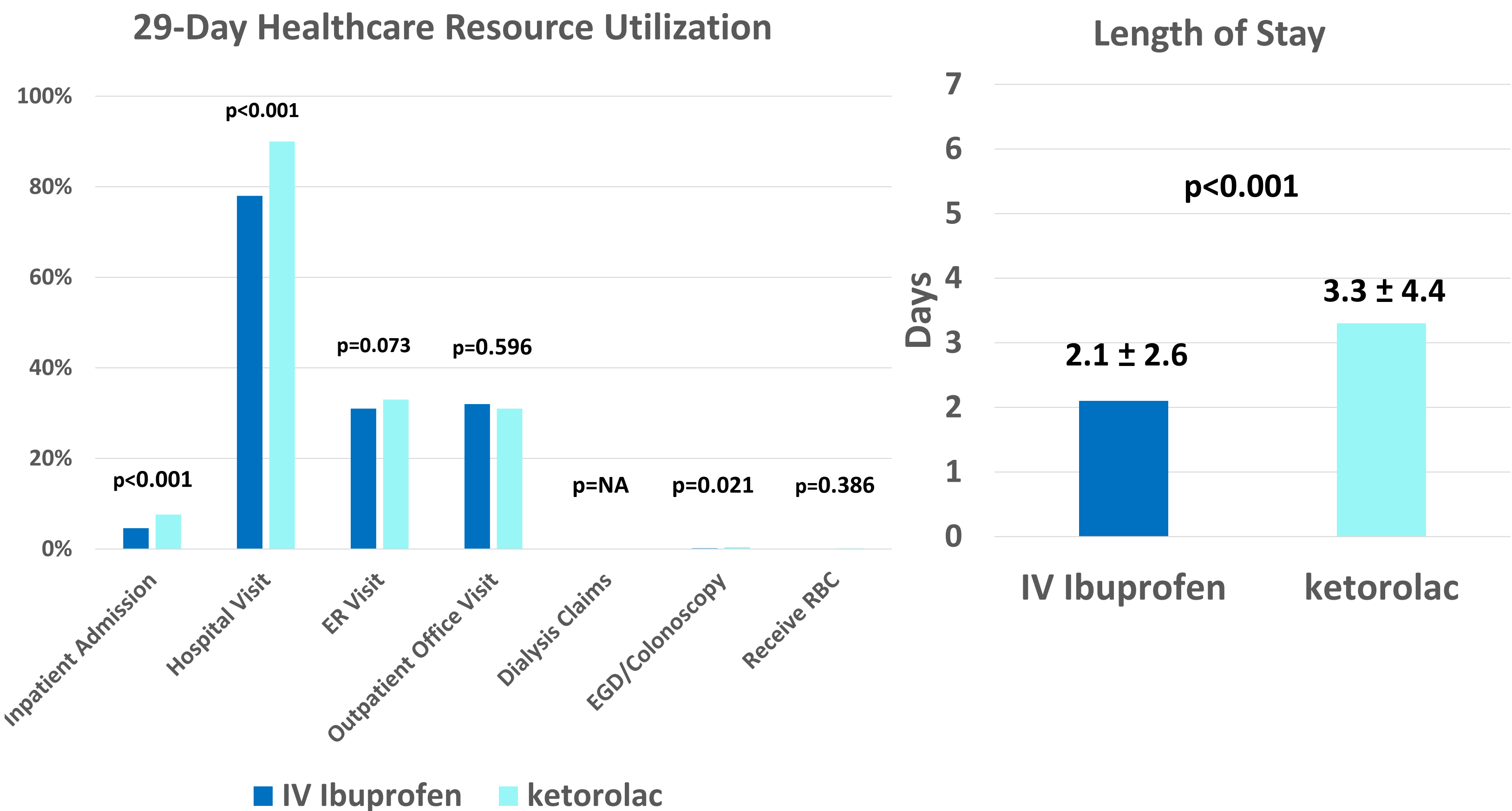
METHODS

- Retrospective, longitudinal, observational, all-payer database assessing patients between January 1, 2014 to June 20, 2023
- Common ADRs identified a priori and assessed within 72 hours from the last dose of the index drug administered
- Inpatient and outpatient HCRU were evaluated 29 days after the last dose of the index drug administered
- Propensity score matching 1:1 (IVIB:ketorolac)
 - Variables included age, sex, reason for administration (surgical, fever, other), number of doses administered.
- Inclusion criteria:** <18 years old, received one or more doses of IVIB or IV/IM ketorolac, baseline records available for ≥12 months prior to drug administration
- Exclusion criteria:** Claim for renal dysfunction, GI or general bleeding disorders, low back pain, headache, abdominal pain, nausea/vomiting, or throat pain during 12-month baseline period, received oral/ophthalmic/nasal formulations, or received both medications.

RESULTS



Demographics after Propensity Score Matching		
	Pediatric IV ibuprofen N=5,579	Pediatric Ketorolac N=5,579
Mean Age, yrs	8 ± 5	8 ± 5
Gender, %		
Male	51.9	51.9
Mean Dose, mg	429 ± 340	25 ± 12
Number of Doses, %		
1	97.9	97.9
2	1.97	1.97
Reason for drug administration, %		
Surgery	44.5	44.5
Fever	18.5	18.5
Other	35.6	35.6
Payer Channel		
Medicaid	61.2	59
Private/Commercial	33.6	36.3



DISCUSSION

- Reduction in major ADRs and HCRU observed in pediatric patients that received IVIB compared to ketorolac
- LOS was significantly shortened by 1.2 days in pediatric patients that received IVIB vs ketorolac
- The incidence in ADRs when comparing IVIB vs ketorolac may be attributable to the variations in selectivity of inhibition of COX-1 relative to COX-2. Ketorolac is the most potent inhibitor of COX-1 isoenzymes among all NSAIDs.
- There were statistically higher rates of EGDs/colonoscopy claims in pediatric patients that received ketorolac. Potential reasons may be that pediatricians are identifying risks of using NSAIDs, particularly when prescribing ketorolac in pediatric patients and following up to ensure no ADRs. Given the lack of indication in the pediatric population, clinicians may be ordering more GI testing in this population.

CONCLUSION

- This first-of-its-kind analysis of real-world pediatric claims data suggests IV ibuprofen may provide a more favorable safety profile compared to ketorolac in children. These findings have significant implications for pediatric pain management, providing an opportunity to enhance both patient safety and healthcare efficiency in this sensitive population where medication safety is paramount.

REFERENCES

- Robles, A, et al., Averting ADRs in Pediatric Inpatients, US Pharmacist, Aug 2023: p. HS-11-16
- Johnson JA, et al. Drug-related morbidity and mortality: a cost-of-illness model. Arch Intern Med 1995; 155: 1949-1956
- Lucas, G.N.C., et al., Pathophysiological aspects of nephropathy caused by non-steroidal anti-inflammatory drugs. J Bras Nefrol, 2019. 41(1): p. 124-130.
- Laine, L., GI risk and risk factors of NSAIDs. J Cardiovasc Pharmacol, 2006. 47 Suppl 1: p. S60-6.