

# Safety and Efficacy of Preoperative Meloxicam IV in Colorectal Surgery

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**BACKGROUND:** Intravenous (IV) meloxicam (Meloxicam IV; Anjeso™) is approved for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. Limitation of Use - Because of delayed onset of analgesia, meloxicam IV alone is not recommended for use when rapid onset of analgesia is required. Clinical studies supporting approval were conducted in the postoperative setting. This study involves dosing preoperatively in subjects undergoing colorectal procedures.

## METHODS

- Phase 3b, placebo controlled (1:1) study in subjects undergoing bowel resection and/or anastomosis.
- Subjects randomized to meloxicam IV 30 mg or placebo with first dose 30 minutes before start of surgery, then every 24 hours on top of a Standardized Enhanced Recovery After Surgery (ERAS) protocol.
- Preoperative hydration, gabapentin, acetaminophen.
- Alvimopan prohibited
- Opioid rescue available on request

## RESULTS

Table 1: Summary of Adverse Events

	Meloxicam IV 30 mg N=27	Placebo N=28
Category / Term	n (%)	n (%)
Any TEAE	23 (85.2)	26 (92.9)
Any SAE	3 (11.1)	4 (14.3)
Withdrawn due to AE	0	0
Deaths	0	0
<b>Most Common AEs</b>		
Nausea	9 (33.3)	14 (50.0)
Vomiting	5 (18.5)	5 (17.9)
Hypokalemia	2 (7.4)	7 (25.0)
Hypophosphatemia	2 (7.4)	6 (21.4)
Ileus	1 (3.7)	5 (17.9)
Hypertension	2 (7.4)	3 (10.7)

TEAE= Treatment-Emergent Adverse Event; SAE = Serious Adverse Event; AE=Adverse Event

Safety assessments comparable between meloxicam IV 30 mg once daily and placebo.<sup>Table 1</sup>

Inpatient opioid use reduced by 35.3% in meloxicam IV group.<sup>Fig 1</sup>

Significant reduction in time to:

first bowel sounds (↓58.9%)<sup>Fig 2</sup>,

first bowel movement (↓17.5%)<sup>Fig 2</sup>, and

hospital discharge (↓27.0%)<sup>Fig 3</sup>

for meloxicam IV vs. placebo group (p<0.05)

Figure 1: Opioid Consumption: End of Surgery through Discharge

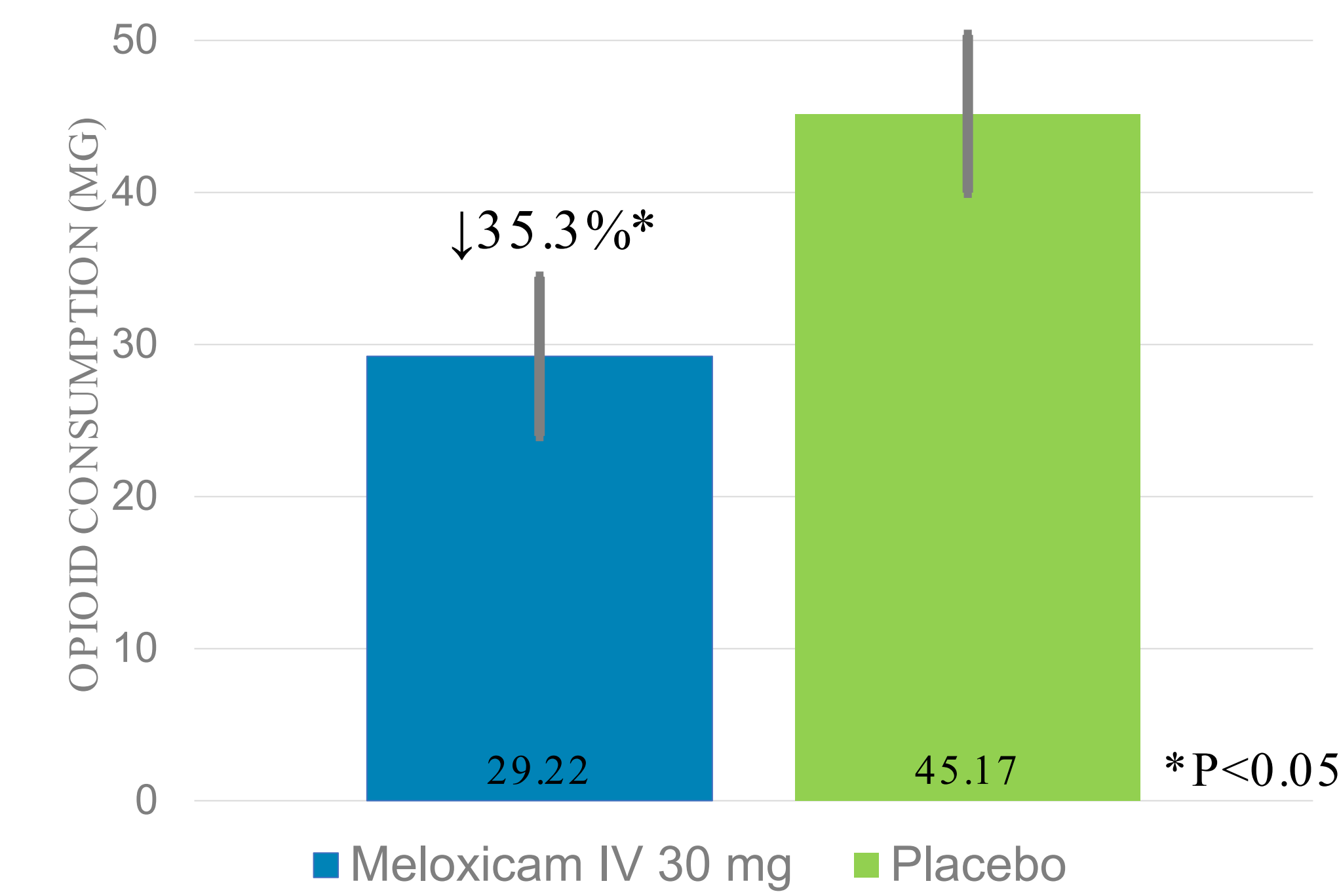


Figure 2: Time to Bowel Function Recovery

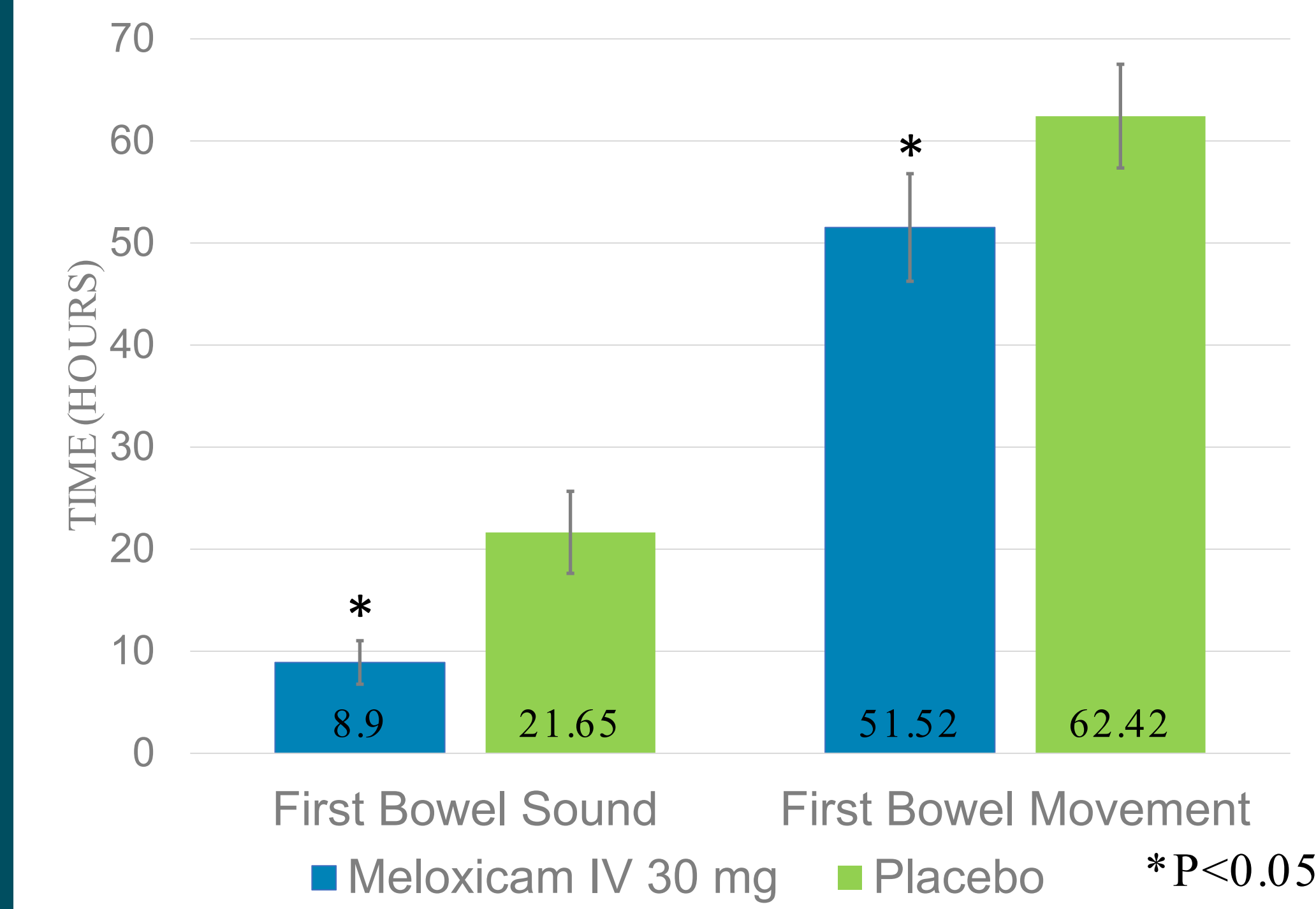
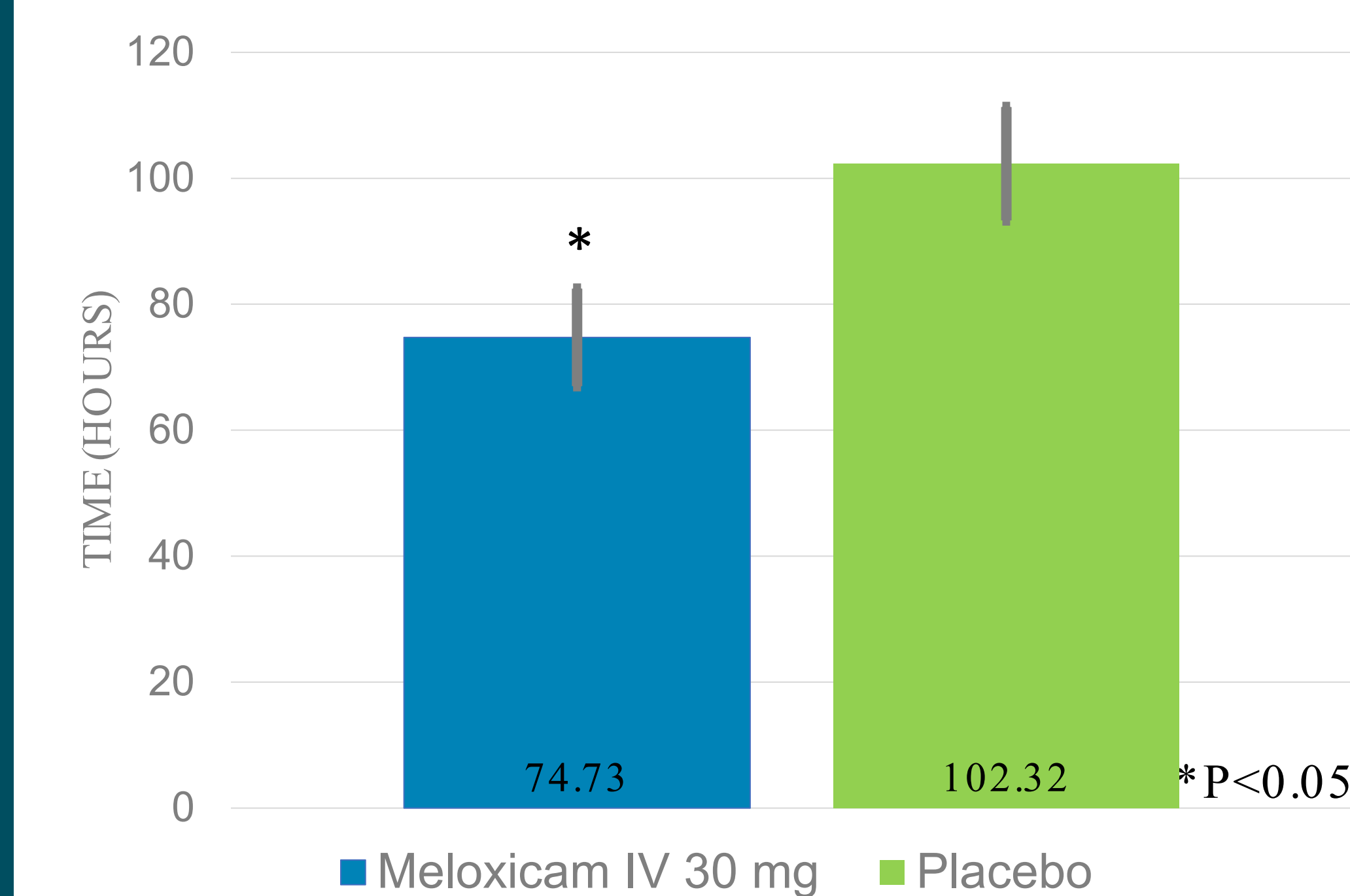


Figure 3: Time to Hospital Discharge Order



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