Efficacy of MR-107A-02 in Acute Moderate and Severe Postoperative Pain: A Post-Hoc Subgroup Analysis of two Phase III Trials

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BACKGROUND

- MR-107A-02, a novel, fast-absorbing meloxicam, demonstrated efficacy, acceptable safety profile, and reduction in opioid use in Phase III trials.
- This post-hoc analysis evaluated the efficacy of MR-107A-02 vs placebo in patient subgroups presenting with moderate or severe pain.

METHODS

- **Study design**: Two multi-center, randomized, double-blind phase III studies, bunionectomy and herniorrhaphy were conducted.
- **Study inclusion**: Participants with baseline pain intensity scores of numeric rating scale (NRS) at rest (NRS-R)/ with activity (NRS-A) ≥4 were enrolled. This post-hoc analysis is based on the following subgroups:
  - Moderate pain: NRS 4–6 (baseline mean 5.2 to 5.5)
  - Severe pain: NRS 7–10 (baseline mean 8.2 to 8.5)
- **Statistical analysis**: Least squares (LS) means, and standard errors (SEs) were estimated for MR-107A-02 vs placebo in the full analysis set (FAS).

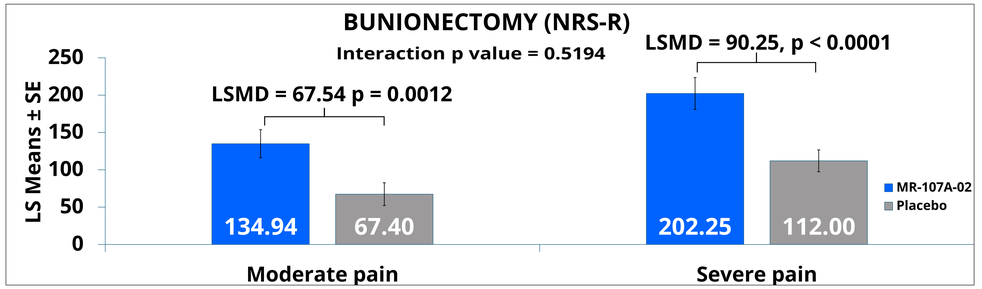
Table 1: Primary Endpoint ($SPID_{0-48}$) in pain severity levels

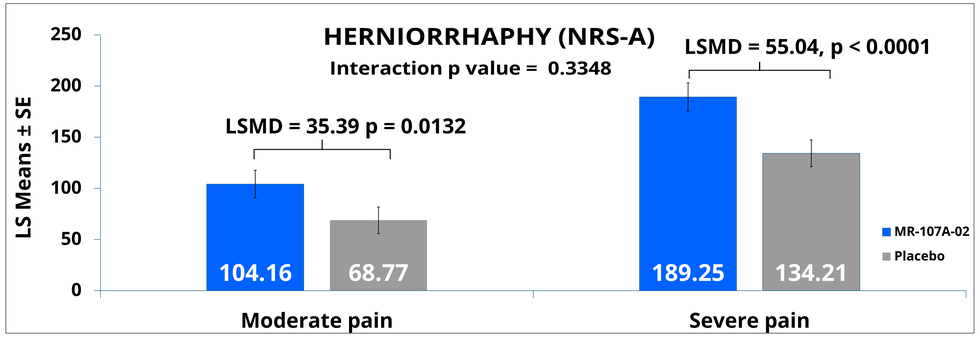
Studies	Pain levels	MR-107A-02		Placebo		LS mean difference (LSMD)
		N	LS means	N	LS means	
Bunionectomy	Moderate	48	134.94	35	67.40	67.54 (p=0.0012)
	Severe	88	202.25	101	112.00	90.25 (p<0.0001)
Herniorrhaphy	Moderate	53	104.16	56	68.77	35.39 (p=0.0132)
	Severe	176	189.25	171	134.21	55.04 (p<0.0001)

RESULTS

- Across both studies, the number of participants at baseline for MR-107A-02 vs placebo shown in **Tab.1**.
- MR-107A-02 demonstrated statistically significant improvements versus placebo across moderate and severe baseline pain subgroups (**Fig. 1-2**).

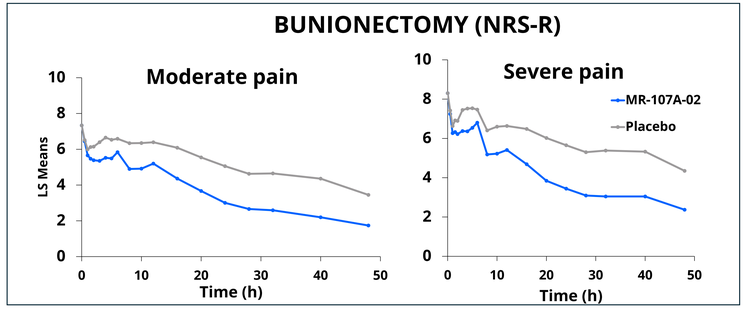
Figure 1: Summary of Pain Intensity Difference 0-48 hours ($SPID_{0-48}$) - FAS

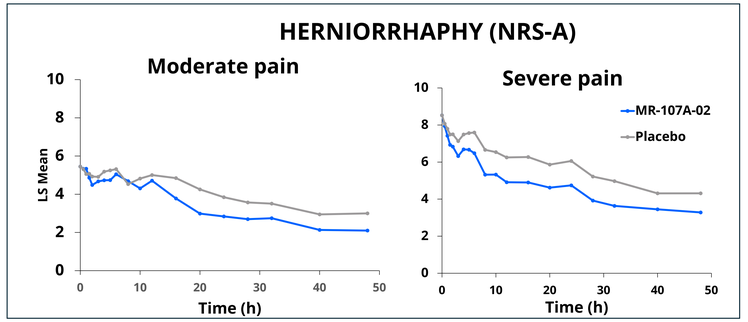




FAS, full analysis set; LSMD, least squares mean difference; NRS-A, numeric rating scale with activity; NRS-R, numeric rating scale at rest; SE, standard error

Figure 2: NRS pain score vs. time by pain severity – FAS





CONCLUSIONS

MR-107A-02 demonstrated analgesic efficacy across both surgical models and baseline pain-severity subgroups.

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