Safety and Efficacy of the Sufentanil Sublingual Tablet 30 mcg for Management of Acute Traumatic Pain

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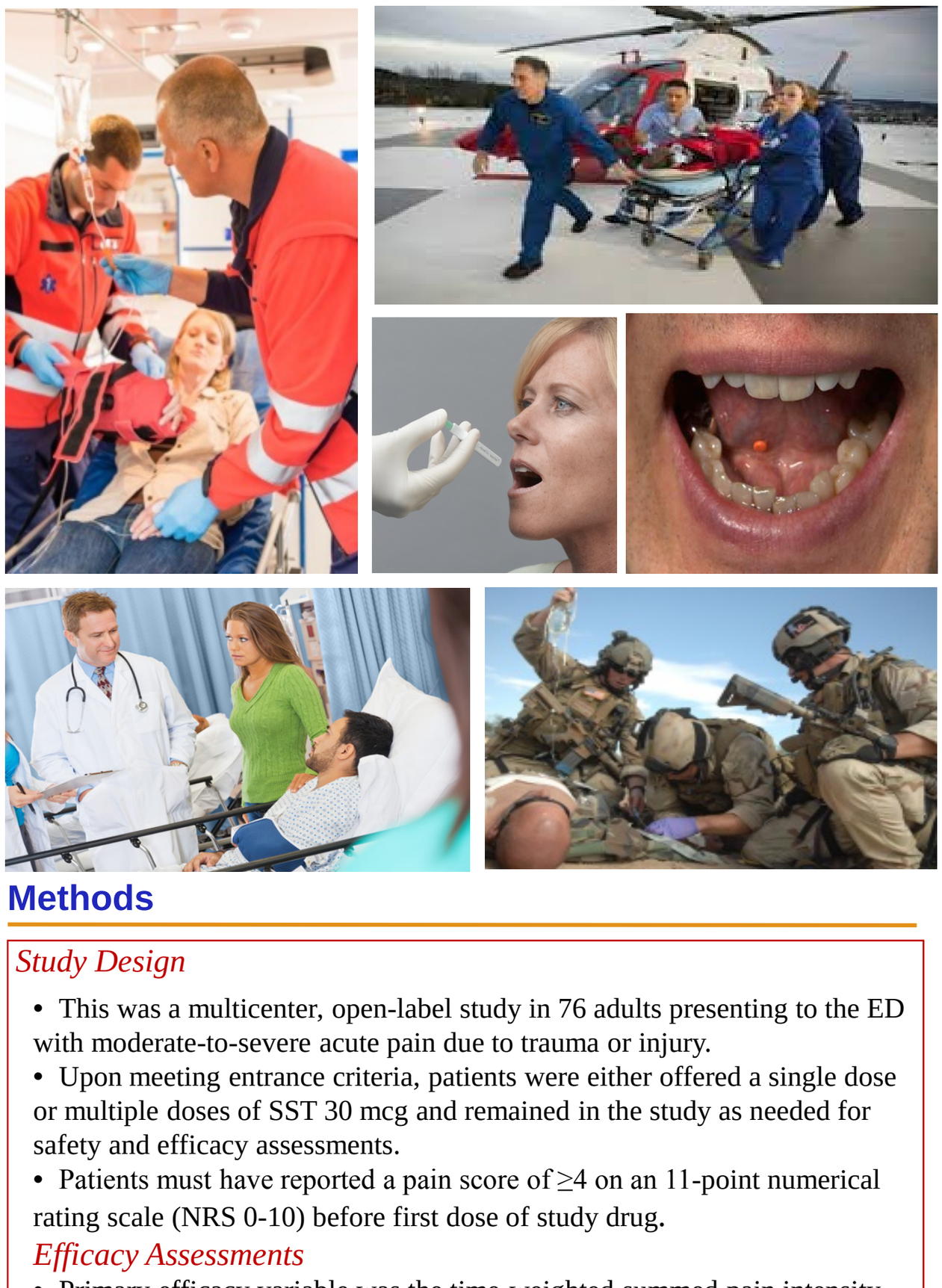
Background

Pain is the most common reason people visit the Emergency Department (ED). Studies indicate however, that the provision of adequate analgesia in the ED remains a challenge.[1] Overcrowding as well as difficulty in gaining IV access have been linked to delays in pain relief.[2] A potent and easy to administer analgesic might help facilitate adequate and prompt pain relief in the ED. The Sufentanil Sublingual Tablet 30 mcg (SST 30 mcg) is in phase 3 development for treatment of moderate-to-severe acute pain in emergency medicine and battlefield trauma (**Figure 1**). The product is designed to leverage sufentanil's unique pharmacokinetic and pharmacodynamic properties and could offer potential analgesic advantages in challenging venues.[3-5] The primary objective of this study was to evaluate the safety and efficacy of SST 30 mcg for management of pain in an ED setting.

Figure 1. Sufentanil Sublingual Tablet 30mcg



Methods

Study Design

- This was a multicenter, open-label study in 76 adults presenting to the ED with moderate-to-severe acute pain due to trauma or injury.
- Upon meeting entrance criteria, patients were either offered a single dose or multiple doses of SST 30 mcg and remained in the study as needed for safety and efficacy assessments.
- Patients must have reported a pain score of ≥4 on an 11-point numerical rating scale (NRS 0-10) before first dose of study drug.

Efficacy Assessments

- Primary efficacy variable was the time-weighted summed pain intensity difference to baseline over the 1-hour study period (SPID1)

Safety Assessments

- Safety assessments included spontaneously reported adverse events (AEs), vital signs, oxygen saturation, and a Six-Item Screener (SIS)
  - The Six-Item Screener was administered pre and post dose to assess for potential cognitive impairment.[6]

Results

Baseline Demographics

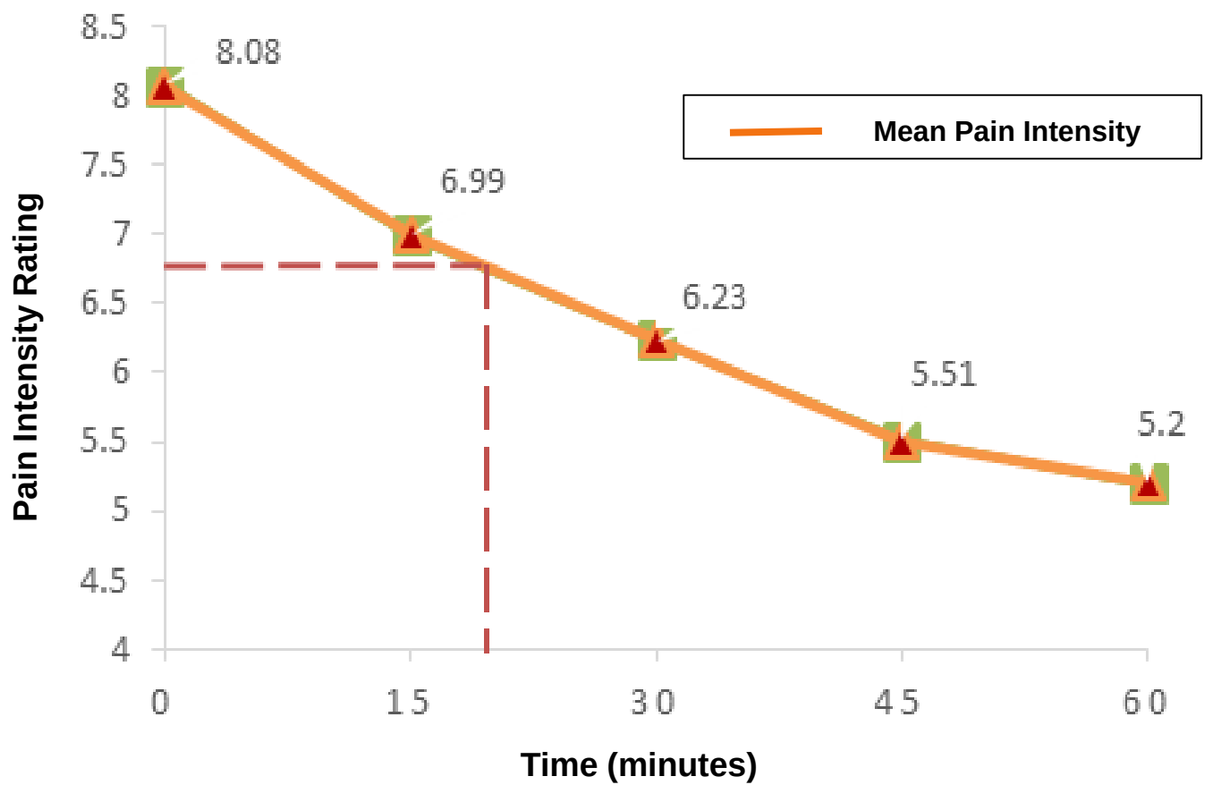
- Forty patients were enrolled in the single-dose cohort and 36 in the multi-dose cohort; mean age 42 years, 61% were male
- Baseline pain intensity (mean) 8.1/10 ("severe" pain)

Results (Cont)

Efficacy

- Reductions in Pain Intensity (mean 2.9/10) within the first hour were observed (**Figure 2)**
  - Literature has identified 1.3 as the minimum clinically significant change in Pain Intensity when administering an 11-pt NRS in the ED[7]
- Mean PI decreases of 1.3 occurred within 15-20 minutes of administering one dose of SST 30 mcg
- Only 4 patients in total terminated early (within the first 2 hours of the study) due to inadequate analgesia.

Figure 2. Pain Intensity Over First Hour



Safety

- No adverse events were reported in 60/79 (79%) patients.
- Observed AEs occurring in > 1 patient are listed in **Table 1.**
- AEs in general were mild to moderate in severity with nausea (9.2%) and somnolence (5.5%) the most common
- SIS results suggest no cognitive impairment caused by sublingual sufentanil 30mcg
  - Mean pre-dose score was 5.8/6 vs 5.9/6 post-dose

Table 1. Adverse Events Occurring in >1 patient

Adverse Events n (%)	Sufentanil Sublingual Tablet 30 mcg	Severity Rating
Nausea	7 (9.2%)	6 mild, 1 moderate
Somnolence	4 (5.5%)	All mild
Vomiting	3 (3.9%)	All mild
O_2 Saturation Decreased	2 (2.6%)	All mild

Conclusion

- **Efficacy and tolerability results from this study suggest that SST 30 mcg dispensed sublingually may offer an alternative to IM or IV analgesia in emergency department situations**
- **Nausea, somnolence and dizziness were the most common AEs**
- **Additional, multi-dose studies are indicated to more accurately characterize the safety and efficacy profile of this therapy in the ED**

References

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