Safety and efficacy of Sufentanil Sublingual Tablet System for postoperative pain relief after laparotomic hysterectomy

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Background and aims:

Hysterectomy is one of the most frequently performed major surgical interventions. In the industrialized world about 20% of women can be expected to have a hysterectomy by age 60. Chronic pain after surgery remains an issue, being reported by 4.7–31.9% after hysterectomy. The intensity of postoperative pain is considered a significant risk factor for the development of chronic pain.¹ For this reason an effective postoperative pain control becomes even more necessary.

Sufentanil Sublingual Tablet System (SSTS) (Zalviso®) was recently approved in Europe for treatment of moderate-to-severe acute postoperative pain in hospitalized patients. This handheld PCA device delivers a fixed dose of 15 mcg sufentanil tablets on a PRN basis, allowing patients to self-titrate to their own comfort level.²

We performed an analysis to evaluate clinical application of SSTS for postoperative pain relief after hysterectomy, assessing effectiveness, safety, and patient satisfaction.

Results and Discussion:

Average patient age was 52 years (range 38-74), BMI was 26.5 (range 18.3-34.8).

Mean number of doses was 19 (range 4-51) over 72 hours, with inter-dosing intervals of 165 minutes.

Median NRS was 1 (range 0-4) at rest, and 2 (range 0-6) during movement.

No desaturation ($SpO_2 < 92\%$) was found.

Nausea and vomiting were the most common adverse events (Aes).

PGA scores were positive, with a success rate of 91%.

Materials and Methods:

Observational case series on 20 patients who underwent laparotomic hysterectomy under general anesthesia, between July 2016 and September 2016. Postoperative pain was managed by the exclusive use of SSTS.

Prior to the end of surgery, paracetamol 1 g, morphine 0.1 mg/kg, ondansetron 4 mg were administered. Efficacy was assessed by patient reports of pain intensity on an 11-point numerical rating scale (NRS).

Safety assessments included vital signs, and adverse events (AEs). Patient satisfaction was assessed via the Patient Global Assessment (PGA) of method of pain control, with "success" defined as the proportion of patients responding "good" or "excellent".

Conclusions:

In our clinical experience, SSTS has proved an effective and safe device for postoperative pain relief after laparotomic hysterectomy.

References:

- 1 Brandsborg B et al. Chronic pain after hysterectomy. Acta Anaesthesiol Scand. 2008 Mar;52(3):327-3.
- 2 Minkowitz HS. A review of sufentanil and the sufentanil sublingual tablet system for acute moderate to severe pain. Pain Manag. 2015;5(4):237-50.

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