Sublingual Sufentanil PCA in Orthopedic Surgery: A Case Series

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Introduction

The sufentanil sublingual tablet system (SSTS; Zalviso®) is a novel patient-controlled analgesia (PCA) device intended to overcome some of the drawbacks of opioid-based intravenous PCA (IV-PCA). Based on the results of three phase III studies, the SSTS has been approved in the EU for the management of acute moderate to severe postoperative pain in adults in a hospital setting.

This case series presents the experience with the SSTS in 50 patients, from May to October 2017, 23 after total knee arthroplasty (TKA), 10 total hip arthroplasty (THA) and 17 anterior cruciate ligament reconstructions (ACLR).

Materials and Methods

All patients received a spinal anesthesia with bupivacaine 10-12.5mg for knee surgery and levobupivacaine 10-12.5mg for hip surgery. After surgery, the first dose of sublingual sufentanil was administered before reversion of the sensory block. Patients also received a combination of paracetamol plus non-steroidal antiinflammatory drug (NSAID). The SSTS was maintained up to 72h and adverse events were recorded.

Data were downloaded from the devices and patients were contacted 1 to 3 months after discharge, to evaluate the degree of satisfaction with the SSTS, in a 0 to 5 scale (0 – totally unsatisfied; 1 – very unsatisfied; 2 – unsatisfied; 3 – satisfied; 4 – very satisfied; 5 – totally satisfied).

Patient profile

- Age ≥18 years
- ASA 1-3
- No pulmonary disease, obstructive sleep apnea or cognitive dysfunction

Therapeutic protocol

- Sublingual sufentanil PCA
- Paracetamol 1000mg iv 8/8h (first 24h, then po)
- Cetorolac 30mg iv 8/8h (first 24h, then diclofenac 50mg po 8/8h)
- Omeprazole 40mg po id
- Ondansetrom 4mg iv (if needed)
- Clemastine 2mg iv (if needed)

Results and Discussion

- Incidence of adverse events
 - pruritus – 6%
 - dizziness – 6%
 - nausea without vomiting – 2%
 - nausea with vomiting – 2%
 - cumulative incidence - 8%.
 - All events were mild to moderate and controlled with rescue therapy. No other adverse events were recorded
- Average treatment duration - 48,4 hours [Standard Deviation (SD) 20,7]
- Average consumption - 17,7 tablets (SD 10,8)
- Average interval between tablets - 204,8 minutes
 - First day - 126,4 minutes
 - Second day - 290,9 minutes
 - Third day - 391,6 minutes
- Average requests in lockout period – 0,98
- **Average patient global satisfaction - 4,3** (ranging from 2 to 5)

Patients	Treatment duration (hours)	Tablets consumption	Average interval between tablets (minutes)				Lockout period requests	Surgery	Adverse events	Satisfaction	Age	ASA score
			Total	1st day	2nd day	3rd day						
1	58	14	258,6	143	231	516	0	TKA	0	4	71	3
2	61	14	271,5	140,2	294	483,7	0	TKA	0	4	65	2
3	59	16	234,6	87,8	173	550	0	TKA	0	5	63	3
4	59	16	223,5	82,3	114,5	563,8	0	TKA	0	4	68	3
5	72	16	284,4	177	291,8	422,5	0	TKA	0	5	69	3
6	45	13	220,8	104,3	383,8		0	TKA	0	5	63	2
7	53,2	12	221,1	77,4	265,3	542	0	TKA	0	5	65	3
8	71,2	11	351,9	113	337	620,7	0	TKA	0	5	77	3
9	57	25	136,7	65,9	151,2	287	6	TKA	0	3	71	3
10	64	24	174,9	179,3	110,6	279,8	5	TKA	0	3	58	3
11	57	13	369,3	168	582,4	370	0	TKA	0	4	56	2
12	0,68	2	41	41			1	TKA	0	4	76	3
13	48	13	271	220,7	151,4	441	0	TKA	0	5	67	2
14	72,5	16	273,3	223,5	293,8	299,3	0	TKA	0	5	78	2
15	63	6	509,7	179,5	1140	1200	0	TKA	0	5	73	2
16	56	15	205,4	110,4	1440		1	TKA	0	4	66	3
17	54	14	267,6	148	272	496	1	TKA	0	4	78	2
18	41	13	223,8	109,3	393,8		1	TKA	0	4	63	2
19	25	8	216,4	115,4	398		1	TKA	0	4	69	3
20	67	40	117,9	92,8	95,1	135,3	1	TKA	0	3	73	2
21	71,2	11	372,9	118	387	630,7	1	TKA	0	5	68	2
22	64,5	29	157,6	70,9	181,2	287	1	TKA	0	4	77	2
23	69,5	31	165,4	67,6	184,8	198,9	1	TKA	0	4	72	3
24	27	40	48,6	46,4	35,96		0	THA	Pruritus	4	77	2
25	30	29	75,7	59,7	81,4		0	THA	0	4	74	3
26	65,5	19	201,7	134,3	168	306,7	1	THA	0	4	81	3
27	22	8	189,3	186	197,5		0	THA	0	4	71	2
28	34	8	251,7	163,8	398		7	THA	0	4	67	3
29	47	17	294,3	117	297	514,8	2	THA	0	4	69	3
30	60,5	11	332	107,3	464,8	516	0	THA	0	4	50	2
31	63	24	194,7	184,3	150,6	289,8	1	THA	0	5	68	3
32	22	8	198,3	191	197,5		1	THA	0	5	75	2
33	39	11	271,5	168,8	421		1	THA	0	5	72	3
34	0,35	2	21				0	ACLR	0	4	24	1
35	70	28	143,8	107	159,1	199,3	0	ACLR	0	4	31	1
36	20	40	28,9	24,4	36,86		1	ACLR	Dizziness + Pruritus	4	44	1
37	15	5	223	223			0	ACLR	0	5	27	1
38	46	8	186,7	144	243,4		0	ACLR	0	5	21	1
39	65,5	32	131	117,4	163,7	178,5	2	ACLR	0	3	33	2
40	69,5	31	144,5	62,6	164,8	198,9	2	ACLR	PON + Dizziness + Pruritus	3	21	1
41	70	31	149,1	81,6	130,5	265,8	1	ACLR	0	5	31	1
42	46	6	556	218,5	781		0	ACLR	0	3	39	1
43	55	30	107,4	93,9	71,7	521	0	ACLR	PONV + Dizziness	2	18	1
44	29	8	234,3	160,6	438,2		7	ACLR	0	5	28	2
45	69,2	40	106,9	87,8	94,1	125,3	0	ACLR	0	5	19	1
46	71	33	130,9	113,3	160,7	167,6	2	ACLR	0	5	24	2
47	30	10	198,1	168,3	222		0	ACLR	0	5	39	1
48	10	9	65,8				0	ACLR	0	5	39	2
49	46,5	19	125,7	145,3	138,7	141,5	0	ACLR	0	4	29	1
50	10	8	67,3				1	ACLR	0	5	27	1
Average	48,4366	17,74	204,79	126,4170213	290,8715556	391,63	0,98			4,26	55,68	
Standard Deviation	20,71139582	10,77565283										

Data also showed a higher consumption in younger patients, with a higher incidence of nausea and vomiting in this subgroup. The other adverse events had no relevant tendency.

Conclusions

The sufentanil sublingual tablet system is a valid alternative for postoperative pain control in major orthopedic surgery, with a high patient global satisfaction and low incidence of adverse events.