

Table E1. Demographic Characteristics for Intent-to-Treat Population

Characteristic	Intravenous Patient-Controlled Analgesia with Morphine	Single-Dose DepoDur		Total	P Value
		20 mg	30 mg		
Patients, number	55	51	58	164	
Mean age, years (standard deviation)	68.0 (9.2)	66.5 (8.9)	66.0 (10.2)	66.8 (9.4)	Not significant
Gender, number (%)					Not significant
Men	25 (45)	20 (39)	23 (40)	68 (41)	
Women	30 (55)	31 (61)	35 (60)	96 (59)	
Mean body mass index, kg/m ² (standard deviation)	30.7 (5.6)	30.6 (5.0)	31.6 (4.6)	31.0 (5.1)	Not significant
Physical status, number (%)					Not significant
1	4 (7)	2 (4)	2 (3)	8 (5)	
2	35 (64)	36 (71)	40 (69)	111 (68)	
3	16 (29)	13 (26)	16 (28)	45 (27)	

Table E2. Adverse Events, Days 1 to 7

	Intravenous Patient- Controlled Analgesia		Single-Dose DepoDur				P Value
	Morphine (n=55)		20 mg (n=51)		30 mg (n=56)		
	number	(%)	number	(%)	number	(%)	
Nausea	42	(76)	39	(77)	46	(82)	0.70
Hypotension	16	(29)	20	(39)	22	(39)	0.45
Vomiting	19	(35)	21	(41)	30	(54)	0.13
Pruritus	9	(16)	28	(55)	33	(59)	<0.001
Urinary retention	6	(11)	9	(18)	9	(16)	0.62
Hypoxia	5	(9)	2	(4)	5	(9)	0.56
Bradycardia	3	(5)	1	(2)	2	(4)	0.78
Somnolence	5	(9)	3	(6)	10	(18)	0.14
Respiratory depression*	0	(0)	4	(8)	5	(9)	0.13
Hypercapnia	0	(0)	1	(2)	2	(4)	0.53
Pyrexia	17	(31)	25	(49)	32	(57)	<0.02
Decreased oxygen saturation	20	(36)	14	(27)	18	(32)	0.63

*1 additional case of respiratory depression was recorded at each dose level that was not treated with an opioid antagonist. However, these 2 cases were included in calculating the reported p value.

P values were determined with the Fisher exact test.

Table E3. Respiratory Depression

Treatment	Opioid Antagonist	Age (years)	Gender	Weight (kg)	BMI	ASA
DepoDur 20 mg	Naloxone	81	M	89	28	2
DepoDur 20 mg	Naloxone	66	F	100	39	2
DepoDur 20 mg	Naloxone	74	F	94	33	2
DepoDur 20 mg [*]	Naloxone	73	F	84	36	2
DepoDur 30 mg	Naloxone	66	F	81	35	2
DepoDur 30 mg	Naloxone	69	F	68	25	2
DepoDur 30 mg [*]	Naloxone	68	F	79	28	2
DepoDur 30 mg [*]	Naloxone	75	F	85	33	2
DepoDur 30 mg [*]	Naloxone	72	M	90	28	2

ASA=Physical status according to American Society of Anesthesiologists class; BMI=body mass index.

^{*}Serious adverse event.