The effects of nefopam with fentanyl in intravenous patient-controlled analgesia after arthroscopic orthopedic surgery: a prospective double-blind randomized trial

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BACKGROUND: Although nefopam has been used as an analgesic in Patient-controlled analgesia (PCA), combination use of nefopam and fentanyl through PCA has not been performed. Therefore, we carried out this prospective randomized, double-blind study to assess the effects of nefopam compared with ketorolac in intravenous fentanyl based patient-controlled analgesia after shoulder arthroscopic orthopedic surgery.

METHODS: 92 patients were randomly divided into two groups to receive intravenous PCA, which were nefopam group (nefopam 120 mg and fentanyl 20 µg/kg in total 100 ml) and ketorolac group (ketorolac 2 mg/kg and fentanyl 20 µg/kg in total 100 ml). Pain assessment was assessed by a visual analog scale (VAS) and numeric rating scale (NRS). Additionally, patient satisfaction, adverse events and vital sign were observed.

RESULTS: There were no significant differences in VAS score (P=0.48), NRS score (P = 0.15). Patient satisfaction did not differ between groups [8.5 (0.8) vs 8.2 (1.0), P = 0.14]. There were no significant statistical differences in incidences of nausea (P=0.72), vomiting (P = 0.46), urinary retention (P = 0.82), pruritus (P = 1.00), shivering (P = 1.00), sweating (P = 0.49), and dizziness (P = 0.45) between the both groups. There were also no differences in heart rate [78.2 (7.7) vs 75.2 (6.5), P = 0.18], SpO₂ [98.4 (1.8) vs 98.5 (1.9), P = 0.83].

Table 1. Patients demographic data

	Nefopam group (n = 46)	Ketorolac group (n = 46)	P value
Age	53.3 ± 12.8	51.9 ± 11.5	0.59
Sex (M/F)	25/21	21/25	0.53
Height (cm)	162.6 ± 11.7	162.8 ± 7.9	0.93
Weight (kg)	65.3 ± 9.7	66.7 ± 9.7	0.48
Aneth. time (min)	135.9 ± 39.0	128.5 ± 29.3	0.31
Op. time (min)	87.5 ± 36.8	80.8 ± 26.4	0.32
ASA class (1/2)	23/23	25/21	0.84

Table 2. Total PCA infusion volume (ml) and the number of pressed bolus button during 24 hr after the operation.

	N group (n=46)	K group (n=46)	P value
Total PCA infusion volume (ml)			
10 minute	0.84 (0.47)	1.00 (0.69)	0.22
20 minute	1.74 (0.71)	2.00 (0.85)	0.12
1 hour	3.28 (0.99)	3.58 (1.16)	0.18
4 hour	8.50 (2.74)	9.13 (3.05)	0.30
8 hour	13.66 (3.64)	14.57 (4.82)	0.31
12 hour	18.69 (4.51)	19.76 (6.10)	0.34
24 hour	32.84 (7.17)	34.44 (8.02)	0.32
The number of pressed bolus button			
10 minute	1.50 (1.97)	2.26 (2.51)	0.11
20 minute	3.59 (5.04)	5.17 (5.84)	0.17
1 hour	6.17 (8.38)	8.04 (7.44)	0.26
4 hour	5.43 (6.07)	7.59 (7.32)	0.13
8 hour	1.71 (3.15)	2.88 (5.47)	0.21
12 hour	1.59 (3.09)	1.87 (3.19)	0.67
24 hour	3.65 (9.48)	3.24 (4.69)	0.79

Table 3. Incidence of adverse events and requirement of additional treatment during 48 hours after the operation.

		N group (n=46)	K group (n=46)	P-value
Adverse events				
Nausea	PACU	2 (4)	3 (7)	0.50
	1- 4 hours	7 (15)	7 (15)	1.00
	4 - 12 hours	12 (26)	11 (24)	0.50
	12 - 24 hours	2 (4)	1 (2)	0.50
	24 - 48 hours	2 (4)	1 (2)	0.50
Vomiting	PACU	0	0	1.00
	1- 4 hours	3 (7)	3 (7)	1.00
	4 - 12 hours	3 (7)	0	0.24
	12 - 24 hours	0	0	1.00
	24 - 48 hours	0	0	1.00
Urine retention	PACU	1 (2)	0	1.00
	1- 4 hours	3 (7)	1 (2)	0.62
	4 - 12 hours	9 (20)	3 (7)	0.12
	12 - 24 hours	6 (13)	2 (4)	0.27
	24 - 48 hours	4 (9)	1 (2)	0.36
Dizziness	PACU	6 (13)	1 (2)	0.11
	1- 4 hours	6 (13)	6 (13)	1.00
	4 - 12 hours	5 (11)	7 (15)	0.76
	12 - 24 hours	3 (7)	3 (7)	1.00
	24 - 48 hours	3 (7)	0	0.24
Sweating		2 (4)	0	0.49
Shivering		0	0	1.00
Pruritus		0	0	1.00
Additional treatment				
Analgesics		19 (41)	18 (39)	1.00
Antiemetics		7 (15)	6 (13)	1.00
Urinary catheter insertion		6 (13)	1 (2)	0.11

CONCLUSIONS: The combinatory use of nefopam and fentanyl in PCA provided similar analgesic effects of ketorolac and fentanyl without increased adverse effects. Consequently, nefopam is considered to be an appropriate alternative drug to be co-administered with fentanyl based PCA for patients who have difficulty using Non-steroidal anti-inflammatory drugs.