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Pharmacist educational intervention in intravenous patient controlled analgesia in associated with decreased postoperative pain

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ABSTRACT

Education may be provided by any healthcare professional who has undertaken appropriate training education, education on patient communication and education is usually included in the healthcare professional's training. One of the most obvious problems a person has to deal with after surgery is pain. There are many reasons why it is important to treat pain after surgery adequately and promptly. This study was conducted to compare the clinical efficacy and adverse effects of multimodal analgesic regimen of morphine and Ibuprofen combined with ketorolac using IV PCA, and to study the effect of structured preoperative educational program on analgesic efficacy, incidence of adverse effects, and patients` satisfaction. Categorical data and proportions were analyzed using the $\chi 2$ test or the Fisher's exact test as required. Student's t test was used to compare the Physician-Pharmacist Co management of Postoperative means of the 2 groups with normal distributions, and the Mann-Whitney U test was used to compare variables with non-normal distributions. All tests were 2-tailed, P value < 0.05 was considered statistically significant. Morphine provides more effective postoperative analgesia than Ibuprofen when coadministered with ketorolac. The combination of ketorolac allowed more pronounced synergistic effect with morphine than that with Ibuprofen. Preoperative patient and nurse education improved analgesia and overall patient satisfaction with their pain treatment protocol; the patient can treat pain more in a more timely and individualized manner, thus, increasing pain-management satisfaction.

Keywords: Ketorolac, Mann-Whitney U test, Physician-Pharmacist

INTRODUCTION

Health education is also a tool used by managed care plans, and may include both general preventive education or health promotion and disease or condition specific education. [2] Important elements of patient education are skill building and responsibility: patients need to know when, how, and why they need to make a lifestyle change. Group effort is equally important: each member of the patient's health care team needs to be involved. One of the most obvious problems a person has to deal with after surgery is pain. There are many reasons why it is important to treat pain after surgery adequately and promptly.

This study was conducted to compare the clinical efficacy and adverse effects of multimodal analgesic regimen of morphine and Ibuprofen combined with ketorolac using IV PCA, and to study the effect of structured preoperative educational program on analgesic efficacy, incidence of adverse effects, and patients` satisfaction.

MATERIALS AND METHODS

Patient Selection

The study was, after full history taking, physical examination and complete investigations, from those patients who were admitted for different types of surgical procedures during the period between July December 2016 and March 2017. The study was conducted according to the Declaration of Helsinki and the guidelines for Good Clinical Practice. The local ethics committees approved the protocol, and informed consent was obtained from all patients before study entry. Recruitment included patients with physical status of an American Society of Anesthesiologists (ASA) I and II, aged between 33 - 68 years. Exclusion criteria included: history of allergy to the study drugs, contraindication to the study drugs, refuse of using PCA as a pain management method, history of hepatic, cardiopulmonary or renal disease, hemodynamic instability, history of any chronic pain or drug history of analgesics, administration of opioid in the last 4 hours, history of substance abuse and psychiatric disorder.

Study Design

The study was prospective randomized double blinded, in which patients were randomized either to receive morphine for postoperative analgesia using PCA disposable infusion device (group M), or receive PCA Ibuprofen for postoperative analgesia (group N). The study was double blinded using opaque sealed envelope; both patients and the anesthesiologists managing postoperative pain were blinded to knowledge of the group to which they belonged. Patients were selected randomly from either morphine or Ibuprofen group to attend additional structured preoperative educational program provided by the pharmacist. Accordingly, patients in morphine group were randomly sub classified into either morphine control group (group M1) or morphine intervention group (group M2); both groups received the usual hospital routine care for pain management. Similarly patients in Ibuprofen group were randomly sub classified into either Ibuprofen control group (group I1) or Ibuprofen intervention group (group I2); both groups received the usual hospital routine care for pain management. The intervention subgroups were subjected to an additional pharmacist care for pain management through patients and nurse counseling provided by the clinical pharmacist. Patient Counseling Education was provided to patients in the intervention subgroups of each morphine and Ibuprofen ;(groupM2 and group N2). A structured preoperative educational program consisted of 15 minute session of verbal education on safe use of PCA was provided to patients. Also patients were instructed about the use of the visual analogue scales (VAS)[14], this consists of an ungraduated, straight 10-cm line marked at one end with the term " no pain" and at the other end "the worst possible pain". The patient is instructed to mark the line with a pencil slash at the point that corresponds best to the present level of pain intensity. A printed instruction sheet was given to reinforce the given information: (Appendix A).Instruction sheet were modified, adapted after Lam et al and Macintyre et al [15, 16], then translationinto Arabic language was carried out to facilitate communication and understanding. Also patients in the intervention groups were interviewed the day before the operation to be instructed in filling-in the revised American pain society patient outcome questionnaire (APS-POQ-R)[17]. It was designed to determine patients' satisfaction with their pain management with PCA and the incidence of adverse effects such as nausea, itching, dizziness, drowsiness or constipation. A validated Arabic translated form of questionnaire was downloaded from the American pain society website [18] tobe suitable for the studied patients.

Statistical Analysis

The SPSS version 22 software (copy right IBM Corporation and other(s), 1989, 2013) and Microsoft office excel 2010 were used for statistical analysis. Results are presented as means ± standard deviations (SD) for continuous data, median and range for ordinal data, and as frequencies and percentages for categorical data. Analysis of normality was performed using the Kolmogorov-Smirnov test. Categorical data and

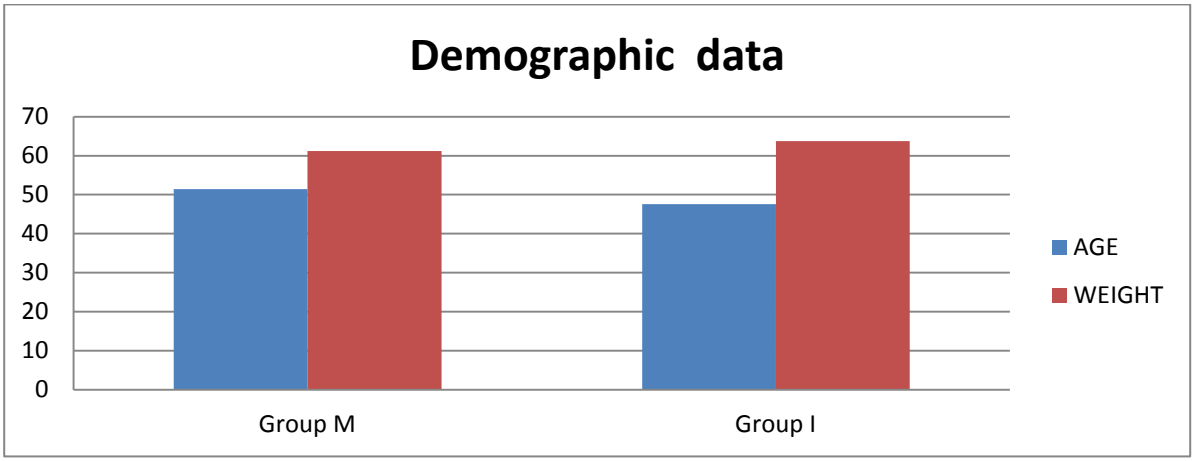
proportions were analyzed using the $\chi 2$ test or the Fisher's exact test as required. Student's t test was used to compare the Physician-Pharmacist Comanagement of Postoperative means of the 2 groups with normal distributions, and the Mann-Whitney U test was used to compare variables with non-normal distributions. All tests were 2-tailed, P value < 0.05 was considered statistically significant.

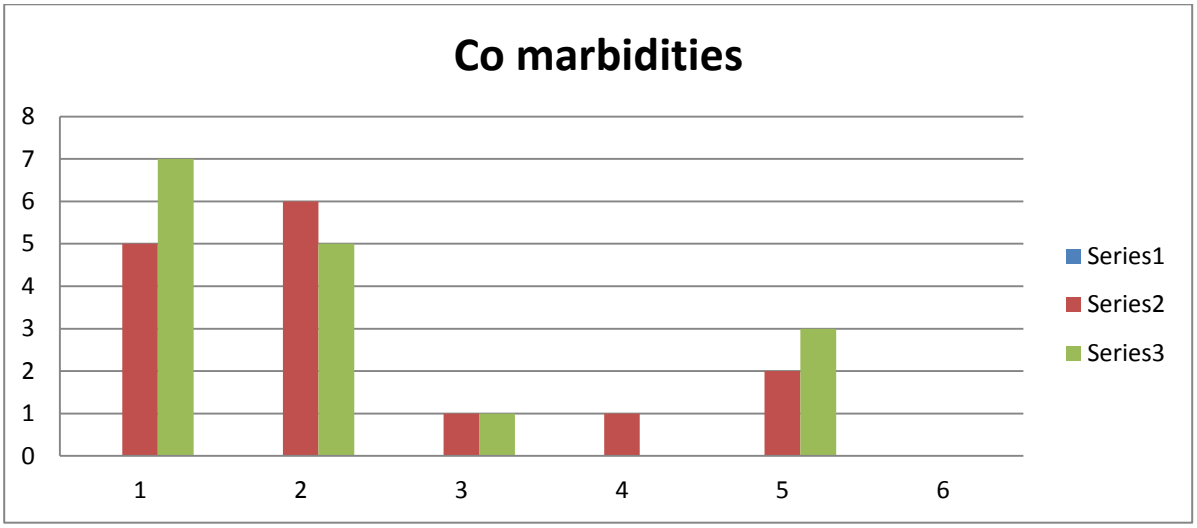
RESULTS AND DISCUSSION

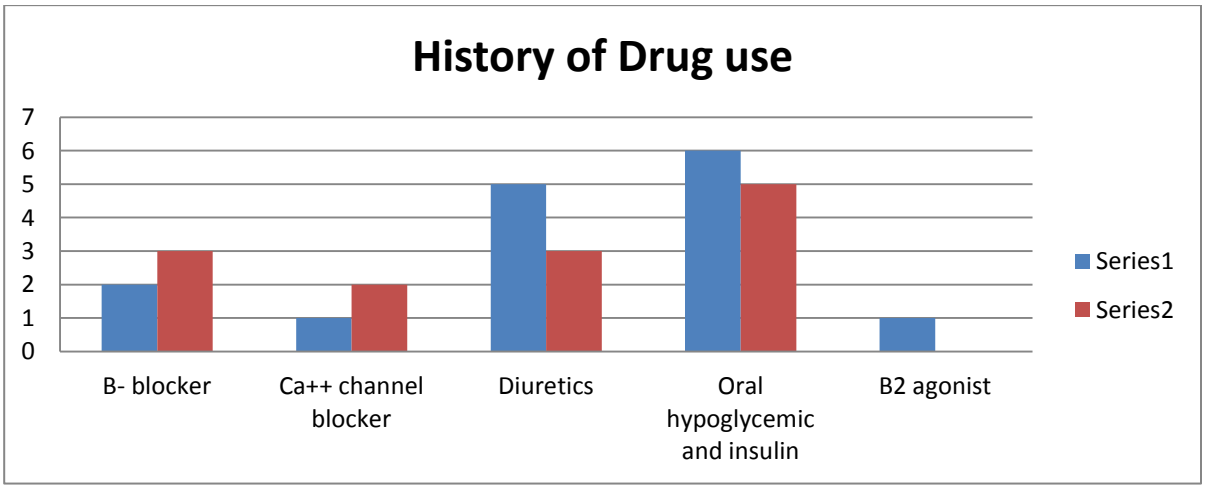
Patient Enrollment and Baseline Characteristics A total of 60 patients were enrolled and screened to be eligible for the study according to the inclusion and exclusion criteria. Ten patients were excluded; therefore 50 patients with a mean age of 49.5 ± 10.7 years (CV% 21.7) were consented and randomized into two groups. Five patients were withdrawn after randomization while45 patients completed the study: 22 patients for morphine group (M) and 23 for lbuprofen group (I).Flow chart of patient enrollment, reasons for exclusion and withdrawal are summarized Forty five patients who completed the study comprised 21 males (47%) and 24 females (53%), with mean age of 49.4 ±10.8 (CV%:21.9%). Baseline demographics of the analyzed groups are summarized in

Table 1: The two drug groups were comparable with respect to sex, age, weight, ASA, comorbidities, drug history and type of surgery.

PARAMETERS	Group M	Group I	P value
SEX M/F	9/13	12/11	0.45
AGE	51.4±11.6	47.6±11.7	0.36
WEIGHT	61.2±7.4	63.7±10.0	0.35
ASA physical status classification 1/2N	12/10	12/11	0.61
Type of surgery: abdominal/thoracic N	17/5	15/8	0.37
Abdominal(N): HIPEC/ Gastric pull p/ whipple/ Hystrectomy/ gastrectomy/ Radical cyctectomy/ Abdominal exploration	3/4/2/2/3/2/1	5/2/2/1/2/1/2	
Thoracic(N): Lung lobectomy/ chest wall mass	2/3	5/3	
Co morbidities			
Hypertension	5	7	0.50
DM	6	5	0.73
Ischemic heart disease	1	1	1.00
Bronchial Asthma	1	0	0.30
Smoking	2	3	0.80
Drug History:			
B- blocker	2	3	0.80
Ca++ channel blocker	1	2	1.00
Diuretics	5	3	0.40
Oral hypoglycemic and insulin	6	5	0.73
B2 agonist	1	0	0.30







ASA: American society of anesthesiologists, HIPEC: hyperthermicintraperitoneal chemotherapy, P*<0.05 Morphine control group; M1, and morphine intervention group; M2, each comprised eleven patients. On the other hand ibuprofen control group; I1, comprised eleven patients while Ibiprofen intervention group; I2, comprised twelve patients. Regarding baseline, there was no significant difference in sex, age, weight, ASA, and type of surgery between each of control and intervention group“Table2”.

POSTOPERATIVE ASSESSMENT

Primary Patients` Outcomes

Pain Intensity Median visual analogue score during the 48 postoperative hours in both drug groups presented in Figure 2. It revealed a statistically significant lower VAS score, for patients in group M, at0.5, 6, 8, 10, 12, 14, 16, 18, 22, 26, 28, 32, 34, 36, 38, 42, 44, 46, and 48 hour when compared with those patients in group I. Adequate analgesia (VAS ≤ 4) was reached 1.5 hour after surgery for group M, while after 2 hours in group I.

Parameters	Group M1	Group M2	P value	Group I1	Group I2	P value
Sex male/female	4/7	5/6	0.67	8/3	4/8	0.06
Age(Mean ±SD)	51.9±9.1	49.9±12.8	0.42	51.2±9.3	44.9±11.4	0.17
Weight	61.5±7.5	60.9±7.7	0.84	60.1±9.1	66.9±10.0	0.11
ASA physical status ½	6/5	6/5	1.00	5/6	7/5	0.54
Type of surgery:	9/2	8/3	\0.61	6/5	9/3	0.30

Hemodynamic Parameters

Mean SBP values were significantly lower for patients in group M when compared with group I at certain time points(0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 16, and 18 hour)as shown in Figure 3. Similarly, significantly lower mean DBP values were clear for patients in group M when compared with those patients in group N at0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 8, 14, 16, 18, 20, 30, 34, 36, and 40 hour after surgery "Fig 4". With respect to HR, findings in Figure 5 revealed significantly higher values, only during the early postoperative hours (0, 0.5, 1, and 1.5), in group I as compared with group M. Although mean RR values were significantly lower in group M at certain time points(1.5, 2, 2.5, 3, 3.5, 4, 6, 10, 12, 14, 16, 18, 20 , 22, 24, 26, 28, 34, 38, 40, 44, 46, and 48 hour)as compared with group I" Fig 6", no patients had any episodes of respiratory depression (RR< 8 breaths/min).

Secondary patients` outcome

Arterial Blood Gases PaCO2 levels were significantly lower in group I when compared with group M at each of 36 and 48 postoperative hours. However, no patient in the 2 drug groups had any episode of respiratory depression (PaCO2 > 50 mmHg). The corresponding mean values, at the 36 hour, were (34.5 ± 4.4) mmHg and (36.8 ± 1.3) mmHg for groups I and M, respectively (P: 0.02*). Similarly, the corresponding mean values, at the 48 hour, were (32.2 ± 4.2) mmHg and (37.1 ± 1.8) mmHg for groups I and M, respectively (P < 0.01*). With respect to SaO2 levels, postoperative data were similar in both drug groups "Table 3", no patient had any episode of hypoxemia (SaO2<90%)

Table 3: No patient had any episode of hypoxemia

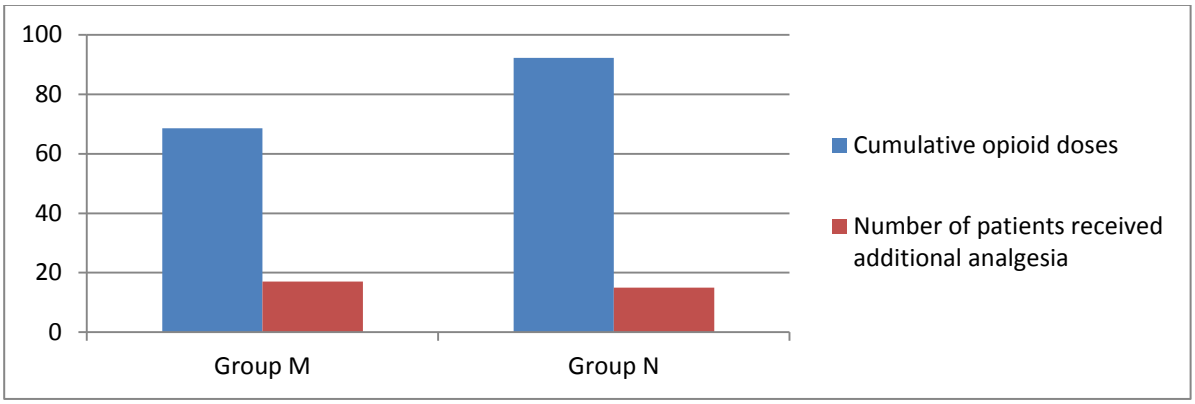
Time	PaCO2 group M	PaCO2 group I	P value	SaO2 group M	SaO2 group I	P value
0	36.5±6.1	37.5±9.7	0.49	95.2±7.8	95.4±1.9	0.92
12	36.1±3.0	38.3±8.1	0.27	95.9±8.7	95.4±1.7	0.64
24	37.3±2.0	38.0±11.2	0.76	95.1±4.6	96.2±2.1	0.40
36	36.8±1.3	34.5±4.4	0.02	91.8±9.9	95.7±2.3	0.11
48	37.1±1.8	32.2±4.2	<0.01	95.8±5.2	95.9±1.9	0.97

Opioid Requirement

Postoperative results revealed a statistically significant higher cumulative opioid doses consumption "Table 4" for patients in group I compared with those in group M (as morphine equivalents; on basis of that 1mg Ibuprofin =0.7 mg morphine). On the other hand, numbers of patients that required additional analgesic doses (additional dose of the study opioid drug) were not statistically different in the two drug groups (P: 0.37).

Table 4: For patients in group I compared with those in group M (as morphine equivalents; on basis of that 1mg Ibuprofin =0.7 mg morphine).

Parameters	Group M	Group i	P value
Cumulative opioid doses	68.6±6.2	92.2±6.8	<0.01
Number of patients received additional analgesia	17	15	0.37



Opioid doses (in morphine equivalent mg; 1mg Ibuprofen=0.7 mg morphine) [21], P*<0.05

Sedation Median Ramsey scores were significantly lower for patients in group Nwhen compared with those in group M at 0, 0.5, 1, 20, 22, 24, 26, and 28 hours after surgery "Fig 7"

INCIDENCE AND SEVERITY OF ADVERSE EFFECTS

Regarding incidence and severity of adverse effect postoperatively "Table 5",Median score of itching measured using APS-POQ-R questionnaire, ranged from 0 no itching to 10 severe itching, was lower in group I than group M (P: 0.03*). Incidences of postoperative nausea, drowsiness, dizziness were not statistically different in the two drug groups.

Table 5: Median score of itching measured using APS-POQ-R questionnaire

Incidence and severity of adverse effects	Group M	Group I	P value
Nausea	0(0-4)	0(0-2)	0.22
Drowsiness	0(0-2)	0(0-2)	0.68
Itching	0(0-2)	0(0-2)	0.03
Dizziness	0(0-2)	0(0-2)	0.27

Patient satisfaction with pain management Median score of the least pain in the first 24 postoperative hours was significantly lower in group M than in group I (P<0.01*) as shown in Table 6. Also patients in group I experienced a significantly higher percentage of time experience of severe pain during the first 24 hours than those patients in group M (P: 0.02*). While other scores of satisfaction were similar between morphine and Iburofen group.

EFFECT OF STRUCTURE PREOPERATIVE EDUCATION ON PATIENTS' OUTCOMES

Visual Analogue Scale Patients in group M2 showed a significant lower median VAS score than those patients in group M1 at 1.5, 2, 2.5, 3, 3.5, 4, 6, and 8 postoperative hours "Table 7", while patients in group I2 showed a significant lower scores only at 0, 0.5, 1postoperative hours compared to patients in group I1.

Table 6: Incidence and Severity of Adverse Effects

Item of APS-POQ-R	GroupM	GroupI	Pvalue
Least pain the first 24 hrs	2	4.5	<0.01
Worst pain in the first 24 hrs	4	4	0.98
% of times experience of severe pain during the first 24 hrs	20%	30%	0.02
Pain interfered or prevented from doing activites in bed	3	3	0.20
Pain interfered or prevented doing activities out of bed	4	4	1.00
Pain interfered or prevented from falling asleep	3.5	4	0.50
Pain interefered or prevented from staying asleep	3	4	0.50
Feeling anxious	2	1	0.49
Feeling depressed0	0	0	0.49
Feeling frightened	0	0	0.12
Feeling helpless	0	0	0.72
One % that best showed how much relief they have received from all of paintreatment	80%	90%	0.87
Participation in decisious about pain treatment	0	4	0.07
Satisifaction with the results of pain treatment while in the hospital	9	7	0.92
How helpful the information about pain treatment options	6	7	0.73
No.of patients that received non medicine mehods used to relieve pain	10	12	0.65
How often a nurse did or doctors encourage to use non medicine methods to control pain N(%)	9	8	0.30
	5	1	
	8	5	
No.of patient received help in filling in questionnaire N(%)	7	8	0.83

Time	VAS group M1	VAS group M2	P value	VAS group I1	VAS group I2	P value
0	7	5	0.18	8	5	<0.01
0.5	6	5	0.12	8	5	<0.01
1	6	4	0.12	6	4	0.01
1.5	6	3	0.02	5	4	0.23
2	5	3	0.04	4	4	0.28
2.5	5	3	0.04	4	4	0.28
3	5	3	0.04	8	5	0.93
3.5	5	3	0.04	4	4	0.79
4	4	2	0.04	4	4	0.10
6	3	2	0.04	4	4	0.19
8	4	2	0.04	4	4	0.61

Adverse effect	Group M1	Group M2	P value	Group I1	Group I2	P value
Nausea	0	0	0.54	0	0	0.49
Drowsiness	0	0	1.00	0	0.5	0.38
Itching	0	0	1.00	0	0	1.00
Dizziness	0	0	0.92	0	0	0.26

ADDITIONAL ANALGESIA AND CUMULATIVE OPIOID DOSES

Numbers of patients that required additional analgesic doses (additional opioid doses) and the cumulative opioid doses (as morphine equivalents) were comparable in the intervention and control groups “Table 9”.

Parameters	GroupM1	GroupM2	Pvalue	GroupI1	GroupI2	Pvalue
Cumulative opiod doses	67.3 ± 4.1	70.0 ±7.7	0.32	92.3±7.4	92.2±6.6	0.97
No.of patients received additional opioid doses	10	7	0.46	7	8	0.88

Patient Satisfaction The median score of the least pain, worst pain, and the percentage of time experience of severe pain in the first 24 hours were significantly lower in group M2 as compared with group M1(P: <0.01*, <0.01* and 0.03*, respectively). Similarly, scores of patients in group I1were significantly higher than those patients in group I2(P: <0.01*, <0.01* and 0.01*, respectively) "Table 10". Satisfaction scores with the results of pain treatment and the percentages of pain relief from pain treatment were significantly higher for patients in group M2 and group I2 compared with those patients in either group M1 or group I1 (P<0.01*). Patients in the intervention groups (M2 and I2) noted that, the given information about pain management options were helpful, while patients in the control groups (M1 and I1) didn't see that (P<0.01*). Seven patients in group M1 received help in filing in the questionnaire, while two patients only in group M2 did not fill the questionnaires themselves (P: 0.03*). Also eight patients in group I1 required nurse help for filing in the questionnaire and nine patients in group I2 Filled in the questionnaire themselves (P :0.02*).

Item of APS-POQ-R	GroupM1	GroupM2	Pvalue	GroupI1	GroupI2	Pvalue
Least pain the first 24 hrs	3	1	<0.01	5	2	<0.01
Worst pain in the first 24 hrs	7	2	<0.01	7	3	<0.01
% of times experience of severe pain during the first 24 hrs	30%	0%	0.03	50%	20%	0.01
Pain interfered or prevented from doing activites in bed	3	3	0.25	3	3	0.78
Pain interfered or prevented doing activities out of bed	5	4	0.18	4	4	0.10
Pain interfered or prevented from falling asleep	2	3	0.54	4	4	0.41
Pain interefered or prevented from staying asleep	2	3	0.23	4	4	0.19
Feeling anxious	1	2	0.20	2	1	0.15
Feeling depressed0	0	0	0.2	0	0	0.21
Feeling frightened	0	0	072	0	0	0.24
Feeling helpless	0	0	.92	0	0	0.29
One % that best showed how much relief they have received from all of pain treatment	60%	100%	<0.01	80%	100%	0.01
Participation in decisious about pain treatment	0	0	0.49	5	2.5	0.52
Satisifaction with the results of pain treatment while in the hospital	7	9	<0.01	5	8.5	<0.01
How helpful the information about pain treatment options	0	10	<0.01	1	9	<0.01
No.of patients that received non medicine mehods used to relieve pain	6	5	0.67	5	7	0.53
How often a nurse did or doctors encourage to use non medicine methods to	3	2	0.69	4	4	0.75
	3	2		4	6	

control pain N(%)	5	7		3	2	
No.of patient received help in filling in questionnaire N(%)	7	2	0.03	8	3	0.02

The present study was performed to compare the clinical efficacy and adverse effects of PCA morphine and Ibuprofen combined with ketorolac in postoperative setting and evaluate the effectiveness of a constructed educational program for pain management on patients `outcomes. To accomplish the goal, a combination of opioid analgesics, either morphine (morphine group) or nalbuphine (nalbuphine group), and non-opioid analgesic ketorolac was used for PCA administration. Groups were subdivided into control and intervention groups. Patient and nurse education on safe and effective use of PCA was provided to the intervention groups. No available data in literature compared the effect of morphine ketorolac combination versus Ibuprofen ketorolac on postoperative pain management using PCA. Ketorolac is a NSAID with analgesic and antipyretic properties [27]. A further study conducted by Gear et al compared the analgesic effect of Ibuprofen in males versus females after bone-impacted third molar extraction, they found prolonged effect of analgesia in females compared with males using a predominately kappa agonist butorphanol and ibuprofen [36]. The unexpected anti-analgesic effect in males receiving ibuprofen then females.

CONCLUSION

Morphine provides more effective postoperative analgesia than Ibuprofen when coadministerd with ketorolac. The combination of ketorolac allowed more pronounced synergistic effect with morphine than that with Ibuprofen. Preoperative patient and nurse education improved analgesia and overall patient satisfaction with their pain treatment protocol; the patient can treat pain more in a more timely and individualized manner, thus, increasing pain-management satisfaction. Preoperative PCA education avoids patient's confusion between PCA button and the nurse call button, allows patients to be familiar with PCA technique and reduces fear of addiction from frequent use of PCA. Also education may allow patients to balance between administration of analgesics and adverse events by self-adjusting the dose of analgesic used. Limitation of the study: Pain intensity is not estimated during rest and at movement/coughing which is important to judge the analgesic efficacy.

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