Comparative study between palonosetron and ondansetron in the profilaxia of postoperative nausea and vomiting in women with 60 years or older, submitted to laparoscopic colecistectomies

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Background and Goal of Study

-Cholelithiasis is the most common abdominal surgical disease in the elderly and Laparoscopic cholecystectomy is considered the gold standard treatment of this condition.

-In this double-blind, randomized clinical trial we compared the efficacy of palonosetron with ondansetron to prevent postoperative nausea and vomiting (PONV) in women with 60 years or older.

-This is the first study in the world that contemplates the prevention of PONV in elderly patients.

Materials and Methods:

-Total of 82 non smoker female patients, ASA I to III, were randomized and allocated to one of the groups containing 41 individuals in each group.

-Group P received 75 mcg I.V of Palonosetron in the induction of anesthesia, whereas the O group received 4 mg I.V of Ondansetron in the induction and followed with regular administration of 8 / 8H of 4 mg I.V of Ondansetron.

-Patients received the same dosage of drugs during anesthesia.

- One patient in each group was excluded.

-The incidence and intensity of nausea and vomiting, as well as presence of adverse effects, need for rescue medication (Metoclopramide) were evaluated during clinical postoperative visits with 2,6,24 and 48 hours.

-The intensity was measured by numerical scale of 0-10. A score> 5 of intensity was considered severe.

Results and Discussion

-The groups were also homogeneous in the clinical numerical variables: Age, weight, height, body mass index, anesthesia time, surgery time, pneumoperitoneum time, fentanyl dose, remifentanil dose, morphine dose and volume of crystalloids administered .

-There was no difference between the frequency and intensity of PONV and the frequency of adverse events between all the periods analyzed (Table 1).

-There was also no difference in the total frequency of PONV, the frequency of rescue medication use, the need for postoperative morphine and the degree of satisfaction with one of the drugs used. (Table 2 and 3).

Table 1. Episode and intensity of nausea and vomiting in the five periods analyzed.

Variable	Palonosetron		Ondansetron		p value
	n	%	N	%	
Postoperative 0-2h					
Nausea	6	15,0	11	27,5	0,17
Intensity of nausea					
Not severe	4	10,0	6	15,0	0.38
Severe	2	5,0	5	12,5	
Vomiting	2	5,0	5	12,5	0,43
Intensity of vomiting					
Not severe	1	2,5	2	5,0	0.51
Severe	1	2,5	3	7,5	
Post-operative 2-6h					
Nausea	14	35,0	14	35,0	1
Intensity of nausea					
Not severe	7	17,5	10	25,0	0.51
Severe	7	17,5	4	10,0	
Vomiting	8	20	6	15	0,56
Intensity of vomiting					
Not severe	3	7,5	4	10,0	0,68
Severe	5	12,5	2	5,0	
Postoperative 6-24h					
Nausea	16	40,0	11	27,5	0,24
Intensity of nausea					
Not severe	10	25,0	8	20,0	0.44
severe	6	15,0	3	7,5	
Vomiting	9	22,5	6	15	0,39
Intensity of vomiting					
Not severe	4	10,0	6	15,0	0.062
Severe	5	12,5	0	0,0	
Posoperative 24-48h					
Náusea	5	12,5	3	7,5	0,71
Intensity of nausea					
Not severe	3	7,5	1	2,5	0.85
severe	2	5,0	2	5,0	
Vomiting	2	5	1	2,5	0,99
Intensity of vomiting					
Not severe	1	2,5	1	2,5	1
Severe	1	2,5	0	0,0	
Postoperative 0-48h					
Nausea	24	60,0	22	55,0	0,65
Vomiting	14	35,0	10	25,0	0,33

Chi square test or Exact Fisher test

Table 2. Postoperative side effects 0-48h.

Variable	Palonosetron		Ondansetron		p value
	n	%	N	%	
Postoperative 0-48h					
Headache	4	10,0	5	12,5	0,99
Dizziness	4	10,0	6	15,0	0,50
Somnolence	11	27,5	18	45,0	0,10
Other	6	15,0	7	17,5	0,76

Chi Square test or Exact Fischer test

Table 3. Variables of the final evaluation according to the treatment group.

Variable	Palonosetron		Ondansetron		p value
	n	%	N	%	
Rescue Medication					
Yes	11	27,5	12	30,0	0,80
No	29	72,5	28	71,3	
Morphine postoperative					
Yes	2	5,0	1	2,5	0,99
No	38	95,0	39	97,5	
Degree of satisfaction					
Unsatisfied	3	7,5	4	10,0	0,80
Satisfied	18	45,0	15	37,5	
Very satisfied	19	47,5	21	52,5	

Chi Square test or Exact Fisher test

Conclusion:

-Single-dose administration of palonosetron in induction of anaesthesia was as effective as regular administration of ondansetron at induction of anaesthesia, followed by regular 8/8-hour use in prophylaxis of PONV in women with 60 years of age or older who underwent laparoscopic cholecystectomy.

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