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Original article

Low Doses of Haloperidol Combined With Ondansetron Are not Effective for Prophylaxis of Postoperative Nausea and Vomiting in Susceptible Patients☆,☆☆

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ABSTRACT

Background: In this observational study we reviewed the efficacy and side effects of different antiemetic combinations used in our hospital for postoperative nausea and vomiting (PONV) prophylaxis in high-risk women undergoing highly emetogenic surgery.

Methods: After reviewing retrospectively the medical records of patients undergoing highly emetogenic elective surgeries under general anaesthesia, we selected 368 women whose Apfel risk score was ≥ 3 and receiving a combination of 2 antiemetics for PONV prophylaxis. We analysed the incidence of PONV at 2, 6, 12 and 24 h after surgery, antiemetic rescue requirements, pattern of occurrence of PONV, side effects and level of sedation were also assessed. The main goal was complete response defined as no PONV within 24 h after surgery.

Results: Ondansetron 4 mg i.v. plus dexamethasone 8 mg i.v. (O&Dex), haloperidol 1 mg i.v. (O&Hal1), haloperidol 2 mg i.v. (O&Hal2) or droperidol 1.25 mg i.v. (O&Dro) were the combinations most frequently used. The complete response was better in groups O&Dex: 68.5% (CI: 58–78), O&Hal2: 64.1% (CI: 53–74) and O&Dro 63% (CI: 52–73) than in group O&Hal1: 41.3% (CI: 31–52) ($P<.01$). Peak incidence of PONV occurred within the 2–6 h period. The incidence of side effects was higher in group O&Hal2.

Conclusion: In high risk patients for PONV who underwent highly emetogenic surgeries, the efficacy of low-dose haloperidol (1 mg) in combination is limited. Higher doses (2 mg) are more effective but its use is associated with a high incidence of side effects.

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Dosis bajas de haloperidol en combinación con ondansetrón no son eficaces para la profilaxis de náuseas y vómitos postoperatorios en pacientes propicios a esta complicación

Palabras clave:
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Náuseas y vómitos postoperatorios
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RESUMEN

Introducción: El objetivo de este estudio fue evaluar la eficacia y los efectos secundarios de distintas combinaciones de antieméticos para la profilaxis de náuseas y vómitos postoperatorios (NVPO) en pacientes propicios a presentarlos tras cirugía muy emetógena.
Métodos: Tras revisar retrospectivamente las historias clínicas de pacientes sometidos a cirugía electiva muy emetógena bajo anestesia general durante el periodo 2009 a 2011, seleccionamos 368 mujeres con puntuación de Apfel $\geq$3 y que recibieron una combinación de 2 antieméticos como profilaxis. Analizamos la incidencia de NVPO a las 2, 6, 12 y 24 h del postoperatorio, rescates antieméticos, patrón de aparición de NVPO, efectos secundarios y nivel de sedación. Valoramos la respuesta completa como ausencia de NVPO en las primeras 24 h.
Resultados: Ondansetrón 4 mg i.v. en combinación con dexametasona 8 mg i.v. (O&Dex), haloperidol 1 mg i.v. (O&Hal1), haloperidol 2 mg i.v. (O&Hal2) o droperidol 1,25 mg i.v. (O&Dro) fueron las combinaciones más empleadas. La respuesta completa fue mayor en los grupos O&Dex: 68,5% (IC: 58-78); O&Hal2: 64,1% (IC: 53-74) y O&Dro 63% (IC: 52-73) que en el grupo O&Hal1: 41,3% (IC: 31-52) ($P < 0,01$). La máxima incidencia de NVPO ocurrió entre las 2 y 6 h del postoperatorio. La incidencia de efectos secundarios fue mayor en el grupo O&Hal2.
Conclusiones: En pacientes con elevado riesgo de NVPO sometidos a cirugía muy emetógena, la eficacia de dosis bajas de haloperidol (1 mg) en combinación con ondansetrón es escasa. Dosis mayores (2 mg) son altamente eficaces, pero se asocian a una alta incidencia de efectos secundarios.

Introduction

Despite the development of new antiemetics with a stronger and safer profile, postoperative nausea and vomiting (PONV) continues to be a problem for surgical patients, primarily for those with an increased risk of developing this complication; among whom the incidence rate can reach 80%, even after prophylactic administration of antiemetics.[1–3] Good control of PONV increases patient satisfaction, reduces postoperative complications and allows for the development of outpatient and fast-track surgery.[4–7] Clinical guidelines recommend an antiemetic prophylaxis that is proportional to the patient's risk, using combinations of antiemetics with different mechanisms of action in high-risk patients.[8]

The effectiveness and safety of ondansetron, dexamethasone and droperidol, alone and in combination, have been demonstrated in several studies.[9–12] Droperidol has been used in anaesthesia for many years, but since the FDA released an alert in 2001 regarding the risk of arrhythmia associated with its use, haloperidol has been increasingly used as an alternative, as it also belongs to the butyrophenone group and shares a mechanism of action (blocks D2 receptors).[13,14] It has been used as an antiemetic since its approval as an antipsychotic in 1967 and its use is recommended by current clinical guidelines.[8,15]

Considering these criteria, we studied the effectiveness and safety of the combinations of antiemetics that were most commonly used in our normal clinical practice for prophylaxis of PONV in patients with an increased risk of presenting these symptoms. The primary hypothesis was that all combinations of antiemetics are equally effective, without any noticeable side effects.

Patients and Methods

The study, approved by the Navarra Ethics Committee, was designed as a retrospective cohort study.[16] All patients were selected using our digitised clinical record. Starting in September 2009 and working in chronological order, we revised all the patients that had undergone surgical interventions with an increased risk of postoperative vomiting (colorectal, gynaecological, breast, thyroid, and cholecystectomies), performed on women older than 18 and whose score on the Apfel scale was $\geq$ 3 (woman, non-smoker, previous history of PONV/kinetosis, postoperative use of opioids). We chose patients who had received a combination of 2 antiemetics during surgery as prophylaxis for PONV. We excluded patients who had undergone outpatient surgery or emergency surgery, as well as those who had received loco regional anaesthesia or total intravenous anaesthesia (TIVA).

Once the patient was approved for inclusion in the study, we contacted her to obtain informed consent. As we will explain later, we needed 92 patients per prophylactic group, and so we included in each group the first 92 patients that we reviewed who met the eligibility criteria and gave consent. The most recent patient underwent surgery in December 2011.

We obtained all the variables needed to complete the database through the digitised clinical record, in which variables related to PONV were recorded daily, and so it was possible to access a reliable source of data. During surgery, the