

XXIX jornada

Serveis de farmàcia d'hospitals comarcals

8 de novembre de 2019

Organitzen



Fundació Hospital
de l'Esperit Sant



ATENCIÓN FARMACÉUTICA AL PACIENTE ONCO-HEMATOLÓGICO: PREVENCIÓN DE LAS NÁUSEAS Y VÓMITOS POST- QUIMIOTERAPIA

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**PREVALENCIA DE N/V DE HASTA UN 70-80%
DE LOS PACIENTES SIN EL ADECUADO TTO
PROFILÁCTICO**





Prevención de las náuseas y
vómitos post-quimioterapia



Consulta de atención
farmacéutica en las náuseas y
vómitos



Experiencia profesional, futuros
retos



INTRODUCCIÓN

- ▶ Las N/V inducidos por la QT → EA desagradable que reduce la calidad de vida de los pacientes
- ▶ Pueden conllevar anorexia, malnutrición, deshidratación y ansiedad.
- ▶ Principal factor de riesgo asociado al desarrollo de N/V: potencial emetógeno de los citostáticos que conforman el esquema antineoplásico. La combinación de citostáticos presenta normalmente mayor poder emetógeno que la monoterapia.
- ▶ 4 niveles de emetogenicidad:
 - ▶ altamente emetógeno (>90% de riesgo de emésis)
 - ▶ moderadamente emetógeno (30-90% de riesgo)
 - ▶ bajo riesgo emetógeno (10-30% de riesgo)
 - ▶ mínimo riesgo emetógeno (<10% de riesgo)

NCCN National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2019

Antiemesis

[NCCN Guidelines Index](#)
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[Discussion](#)

EMETOGENIC POTENTIAL OF PARENTERAL ANTICANCER AGENTS³

LEVEL	AGENT
High emetic risk (>90% frequency of emesis) ^{b,c}	<ul style="list-style-type: none"> • AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide • Carboplatin AUC ≥4 • Camustine >250 mg/m² • Cisplatin • Cyclophosphamide >1,500 mg/m² • Dacarbazine • Doxorubicin ≥60 mg/m² • Epirubicin >90 mg/m² • Ifosfamide ≥2 g/m² per dose • Mechlorethamine • Streptozocin
Moderate emetic risk (30%-90% frequency of emesis) ^{b,c}	<ul style="list-style-type: none"> • Aldesleukin >12-15 million IU/m² • Amifostine >300 mg/m² • Arsenic trioxide • Azacitidine • Bendamustine • Busulfan • Carboplatin AUC <4^d • Camustine^d ≤250 mg/m² • Clofarabine • Cyclophosphamide ≤1500 mg/m² • Cytarabine >200 mg/m² • Dactinomycin^d • Daunorubicin^d • Dual-drug liposomal encapsulation of cytarabine and daunorubicin • Dinutuximab • Doxorubicin^d <60 mg/m² • Epirubicin^d ≤90 mg/m² • Idarubicin • Ifosfamide^d <2 g/m² per dose • Interferon alfa ≥10 million IU/m² • Irinotecan^d • Irinotecan (liposomal) • Melphalan • Methotrexate^d ≥250 mg/m² • Oxaliplatin^d • Temozolomide • Trabectedin^d





RECOMEDACIONES DE PROFILAXIS ANTIEMETICA SEGÚN LAS PRINCIPALES GUÍAS

		ASCO 2018	NCCN 2019	ESMO 2016
Altamente emetógena	Con cisplatino	NK1+5HT ₃ +DEXA+OLA → DEXA + OLA días 2-4	NK1+5HT ₃ +DEXA → DEXA días 2-4	NK1+5HT ₃ +DEXA → DEXA días 2-4
	AC	NK1+5HT ₃ +DEXA+OLA → OLA días 2-4	OLA+PALO+DEXA → OLA días 2-4 NK1+5HT ₃ +DEXA+OLA → DEXA + OLA días 2-4	NK1+5HT ₃ +DEXA → DEXA o nada días 2-4
Moderadamente emetógena		Si tto con fcos con riesgo de N/V retardados 5HT ₃ +DEXA → DEXA días 2-3 o nada	5HT ₃ +DEXA → DEXA ú 5HT ₃ días 2-3 OLA+PALO+DEXA → OLA días 2-3 NK1+5HT ₃ +DEXA → DEXA días 2-3	Si tto con fcos con riesgo de N/V retardados 5HT ₃ +DEXA → DEXA días 2-3 o nada
	Carboplatino AUC>4	NK1+5HT ₃ +DEXA		NK1+5HT ₃ +DEXA
Bajo riesgo emetógeno		5HT ₃ ó DEXA día 1	5HT ₃ ó DEXA día 1	5HT ₃ ó DEXA día 1
Mínimo riesgo emetógeno		NADA	NADA	NADA



FACTORES DEL PACIENTE QUE PUEDEN INFLUIR EN LA INCIDENCIA DE N/V

- ▶ Experiencias anteriores con la QT
- ▶ Mal control de las N/V en ciclos de QT previos
- ▶ Factores psicosociales (ansiedad, estrés..)
- ▶ Depresión
- ▶ Horas de sueño la noche anterior al tratamiento (mayor relación con las N/V retardados. <7h más incidencia de N/V).
- ▶ Edad (los jóvenes tienen más riesgo)
- ▶ Sexo (las mujeres tienen más N/V que los hombres)
- ▶ Historia de N/V durante el embarazo.
- ▶ Historia de vértigos, mareos...
- ▶ El alcohol es un factor protector (5 o más bebidas alcohólicas/semana)



<http://www.riskcinv.org/>



Chemotherapy Emetogenicity Level

A) Please select the type of chemotherapy the patient is scheduled to receive. Select up to 4 agents (scroll or start typing to search the list).

MASCC/ESMO Guideline
Emetogenicity Level*

Select Type ...

Chemotherapy Emetogenicity Level

A) Please select the type of chemotherapy the patient is scheduled to receive. Select up to 4 agents (scroll or start typing to search the list).

Anthracycline/cyclophos. combination

B) Current Cycle Number:

B) Current Cycle Number:

MASCC/ESMO Guideline
Emetogenicity Level*

High Emetogenic
Chemotherapy > 90%

Your
Selections:

Your Selections: • Anthracycline/cyclophos. combination



Patient Emetogenicity Risk Profile

Tell us about your patient and their chemotherapy.

1. What is the patient's gender?

Female ▼

2. What is the patient's age?

35

3. Does the patient expect to develop CINV?

No ▼

4. Did the patient have morning sickness during a prior pregnancy?

No ▼

5. Did the patient sleep 7 or more hours the night before chemotherapy?

Yes ▼

6. After the previous cycle of chemotherapy (if applicable), did the patient take non-prescribed antiemetics at home? i

No ▼

7. Has the patient had any nausea or a vomiting episode in the prior cycle?

No ▼

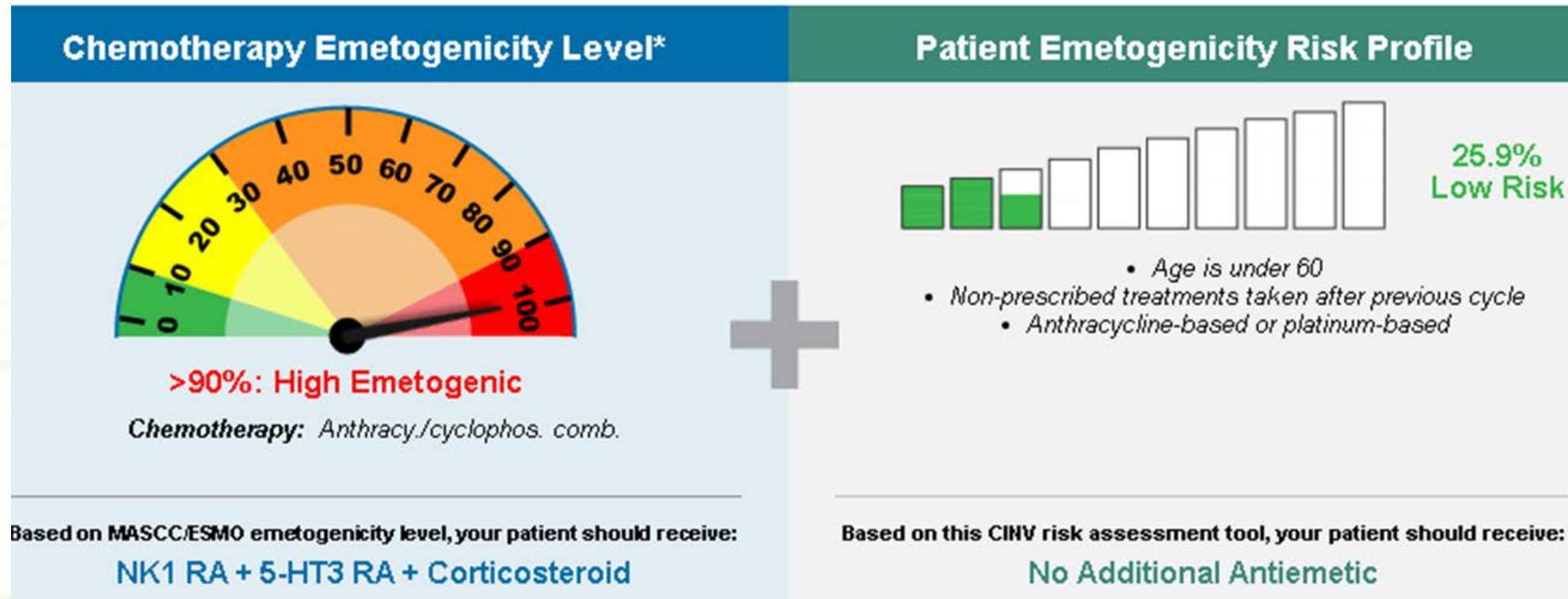
8. Is the chemotherapy Anthracycline or Platinum based?

Yes ▼

- Dranitsaris G et al. The development of a prediction tool to identify cancer patients at high risk for chemotherapy-induced nausea and vomiting



RECOMMENDATION: Based on MASCC/ESMO emetogenicity level & CINV risk assessment tool, your patient should receive:
NK1 RA + 5-HT3 RA + Corticosteroid + No Additional Antiemetic





MEDIDA DE LOS RESULTADOS EN SALUD PERCIBIDOS POR EL PACIENTE: PROs vs CRITERIOS DE TERMINOLOGIA DE EA

9. PRO-CTCAE™ Symptom Term: Nausea				
NÁUSEAS				
a. En los últimos 7 días, ¿con qué FRECUENCIA tuvo NÁUSEAS?				
<input type="radio"/> Nunca	<input type="radio"/> Rara vez	<input type="radio"/> A veces	<input type="radio"/> A menudo	<input type="radio"/> Casi siempre
b. En los últimos 7 días, ¿cuál fue la INTENSIDAD de las NÁUSEAS en su PEOR momento?				
<input type="radio"/> Ninguna	<input type="radio"/> Leve	<input type="radio"/> Moderada	<input type="radio"/> Intensa	<input type="radio"/> Muy intensa

Common Terminology Criteria for Adverse Events (CTCAE)

Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-	-
Definition: A disorder characterized by a queasy sensation and/or the urge to vomit.				CTCAE V5	
Navigational Note: -					

Náuseas	Hiporexia sin alteraciones del hábito alimentario	Menor ingesta por VO, sin pérdida de peso significativa, deshidratación o desnutrición; necesidad de hidratación IV por menos de 24 horas	Inadecuada ingesta de calorías o líquidos por VO; necesidad de hidratación IV, NE o NPT por más de 24 horas	Consecuencias potencialmente mortales	†
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MEDIDA DE LOS RESULTADOS EN SALUD PERCIBIDOS POR EL PACIENTE: PROs

Vomiting	Intervention not indicated	Outpatient IV hydration; medical intervention indicated	Tube feeding, TPN, or hospitalization indicated	Life-threatening consequences	Death
<p>Definition: A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth.</p> <p>Navigational Note: -</p>					

CTCAE V5

10. PRO-CTCAE™ Symptom Term: Vomiting				
VÓMITOS				
a. En los últimos 7 días, ¿con qué FRECUENCIA tuvo VÓMITOS?				
<input type="radio"/> Nunca	<input type="radio"/> Rara vez	<input type="radio"/> A veces	<input type="radio"/> A menudo	<input type="radio"/> Casi siempre
b. En los últimos 7 días, ¿cuál fue la INTENSIDAD de los VÓMITOS en su PEOR momento?				
<input type="radio"/> Ninguna	<input type="radio"/> Leve	<input type="radio"/> Moderada	<input type="radio"/> Intensa	<input type="radio"/> Muy intensa





CONSULTA DE ATENCION FARMACEÚTICA



PNT DE TRABAJO

EQUIPO MULTIDISCIPLINAR





ENTREVISTA FARMACÈUTICA

- ▶ Disponer de despacho para la atención farmacéutica individualizada
- ▶ Agenda para la citación de pacientes
- ▶ Visitas de inicio
- ▶ Visitas de seguimiento
- ▶ Llamadas telefónicas





ENTREVISTA FARMACÉUTICA



Conocer el potencial emetógeno del esquema de QT prescrito



Antecedentes personales del paciente (factores de riesgo: mareos, vértigos, horas de sueño, consumo alcohólico...)



Explicar el esquema de tratamiento profiláctico para las N/V



Explicar el tratamiento de rescate



Dar información escrita



Registro de los PROs



Seguimiento



Teléfono de contacto si dudas



EXPERIENCIA PROFESIONAL





Elaboración y actualización de **Protocolos** de profilaxis antiemética

Valoración del paciente y **dispensación** del tratamiento

Evaluación y **adecuación** del tratamiento

Medida de **resultados**

SUPPORTIVE CARE

16810 Evaluation of practice patterns for prevention of chemotherapy (CT)-induced nausea and vomiting (CINV) and antiemetic guidelines (GLs) adherence based on real-world prescribing data

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Background: GLs-recommended antiemetic treatment improves emesis in most patients (pts) receiving CT. Non-adherence to GLs leads to suboptimal CINV control. MASCC/ESMO GLs recommend prophylaxis with a neurokinin-1 receptor antagonist (NK₁RA), a 5-hydroxytryptamine-3 (5-HT₃) RA, and dexamethasone (DEX) for pts receiving highly emetogenic CT (HEC, including anthracycline-cyclophosphamide [AC]) and carboplatin-based regimens. Here, we analyse use of NK₁RA + 5-HT₃RA + DEX for antiemetic prophylaxis prior to HEC and carboplatin (considered moderately EC [MEC]).

Methods: The data source was the Global Oncology Monitor (Ipsos Healthcare). Geographically representative physicians from France, Germany, Italy, Spain, and UK were screened for treatment involvement and number of pts treated/month. Pts' data from Jan–Dec 2017 were collected and extrapolated based on a doctor universe; projected estimates are shown here. The emetic risk of CT was classified per MASCC/ESMO GLs.

Results: Antiemetic treatment use is shown (Table). Data from 46,503 pts treated with CT were collected, which represents a total prevalence of 1,468,522 CT-treated pts included in the analysis. NK₁RAs were used in 39%/36%/23% of pts receiving cisplatin-/AC-/carboplatin-based CT, respectively; 18%/20%/11% received the GLs-recommended NK₁RA + 5-HT₃RA + DEX combination; 17% of all HEC-/MEC-treated pts received no antiemetics. Physicians' perception of the emetic risk of CT did not follow MASCC/ESMO GLs classification for 48%/48%/43% of cisplatin-/AC-/carboplatin-based regimens.

Conclusions: EU practice patterns revealed very low adherence to antiemetic GLs in clinical practice, with 16% of all pts (HEC/AC/carboplatin) receiving an NK₁RA + 5-HT₃RA + DEX, and 17% of HEC-/MEC-treated pts receiving no antiemetics. New strategies to improve GLs adherence are critically needed.

Table: 16810 Use of NK₁RA-based prophylactic antiemetic treatments for CINV by emetic risk of chemotherapy according to the MASCC/ESMO guidelines classification

Chemotherapy regimen	Total patients,* %, n	Patients with NK ₁ RAs,* % n	NK ₁ RA + 5-HT ₃ RA + DEX, %	NK ₁ RA + 5-HT ₃ RA, %	NK ₁ RA + DEX, %	NK ₁ RA monotherapy, %	NK ₁ RA + other antiemetics, %
HEC – cisplatin based	55% of HEC 211,600	39% 81,827	18% 38,804	16% 33,363	2% 4,935	2% 4,554	0% 172
HEC – AC based	39% of HEC 151,185	36% 54,724	20% 30,955	12% 18,601	2% 3,497	1% 1,419	0% 252
HEC – other	6% of HEC 22,219	17% 3,803	2% 515	13% 2,894	1% 144	1% 234	0% 15
MEC – carboplatin based	30% of MEC 177,027	23% 40,317	11% 18,839	10% 17,484	1% 1,995	1% 1,656	0% 343
Total (all HEC + carboplatin based)	38% of all patients 562,032	32% 180,671	16% 89,114	13% 72,342	2% 10,571	1% 7,862	0% 783

5-HT₃RA, 5-hydroxytryptamine-3 receptor antagonist; AC, anthracycline-cyclophosphamide; CINV, chemotherapy-induced nausea and vomiting; DEX, dexamethasone; HEC, highly emetogenic chemotherapy; MASCC/ESMO, Multinational Association of Supportive Care in Cancer/European Society for Medical Oncology; MEC, moderately emetogenic chemotherapy; NK₁RA, neurokinin-1 receptor antagonist.
*Estimate of total number of patients is based on the projected prevalence of total 1,468,522 patients being treated with chemotherapy. A sample of 46,503 patients was used for the projections.

- 39% / 36% pacientes en tratamiento con Cisplatino/AC reciben antagonistas NK-1
- Un 17% de los pacientes tratados con esquemas de riesgo emetógeno alto o moderado **NO reciben tratamiento antiemético**



¿Cómo está
estructurada
la consulta
de AF en
relación a
NVIQ?

1ª Consulta
(inicio tratamiento)



Selección del tratamiento de profilaxis
antiemética más adecuado al paciente

Resto Consultas
(seguimiento)



Optimizar el tratamiento

- Modificar si no se consigue buen control (añadir, sustituir)
- Simplificar/reducir si buen control
- Modificar si efectos adversos no tolerables



1ª Consulta...

... Selección del tratamiento antiemético

✓ Factores relacionados con el tratamiento: esquema, dosis, vía administración, duración

✓ Factores relacionados con el paciente

- Edad, sexo
- Tratamiento quimioterápico previo y concomitante
- Emesis gravídica, antecedentes cinéticos
- Factores psicológicos (estrés, ansiedad, etc...)
- Tratamiento concomitante (opioides, antibióticos...)
- Interacciones / ajustes dosis
- Otros factores: alteraciones gastrointestinales (gastroparesia, estreñimiento, obstrucción...), metabólicas (hipercalcemia...), dolor, patología (ca pancreas, vías biliares, carcinomatosis peritoneal, diabetes)

Ondansetron	Granisetron
<p>-Alerta AEMPS:</p> <ul style="list-style-type: none"> -Dosis: 8 mg antes QT (16 mg dosis única máxima); después 8 mg c/12 h max 5 días -Vida media: 3.5 h (8 h en ancianos) -Pac >75 años la dosis inicial iv no debe exceder 8 mg -Adm con precaución en pacientes con factores de riesgo de prolongación Q-T o arritmias cardiacas. No usar en pac con sdme de QT largo congénito -No exceder 8 mg/día en pac con insuficiencia hepática moderada o grave -Estudios publicados de reducción niveles de ciclofosfamida y cisplatino (Uptodate) -Interacciones (amiodarona, enzalutamida, mitotano, dabrafenib, antiarrítmicos clase Ia, III, etc...) 	<ul style="list-style-type: none"> -Dosis: 1-2 mg c/24 -Adm con precaución en pacientes con factores de riesgo de prolongación Q-T o arritmias cardiacas -No ajustes en función de la edad -No precisa ajuste en IH -Mejor perfil interacciones ¿?



Diferencias en profilaxis antiemética con esquemas altamente emetógenos

Pacientes alto riesgo emetógeno, tratamiento inmunoterapia, baja tolerancia a corticoides

Propuesta tratamiento antiemético

Adaptación de la presentación Dr Gralla, XXI Simposio de revisiones en cáncer

Riesgo emetogeno	Emesis Aguda	Emesis Retardada
Alto (Cispt)	5-HT3 + Dexa + NK1 (± Olanzapina)	Dexa + NK1 (no si nepa)
Moderadamente-alto	5-HT3 + Dexa + NK1 (± Olanzapina)	NK1 (no si nepa) ± Dexa
Moderado	5-HT3 + Dexa	± Dexa
Bajo	Dexa o 5-HT3 o ARDopamina	No profilaxis rutina
Mínimo	No profilaxis rutina	No profilaxis rutina

Considerar olanzapina en los grupos de mayor riesgo (cispt/AC especialmente en mujeres jóvenes y aquellas sin buen control con tratamiento inicial)





Pacientes con intolerancia a corticoides, pacientes en tratamiento con quimio-inmunoterapia

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JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

The Oncologist®

Symptom Management and Supportive Care

One-Day Versus Three-Day Dexamethasone in Combination with Palonosetron for the Prevention of Chemotherapy-Induced Nausea and Vomiting: A Systematic Review and Individual Patient Data-Based Meta-Analysis

YUKI OKADA,^{a,b,*} KOJI OBA,^{c,d,*} NAOTO FURUKAWA,^e YOSHIMASA KOSAKA,^f KENJI OKITA,^g SATOSHI YUKI,^h YOSHITO KOMATSU,ⁱ LUIGI CELIO,^j MATTI AAPRO^k

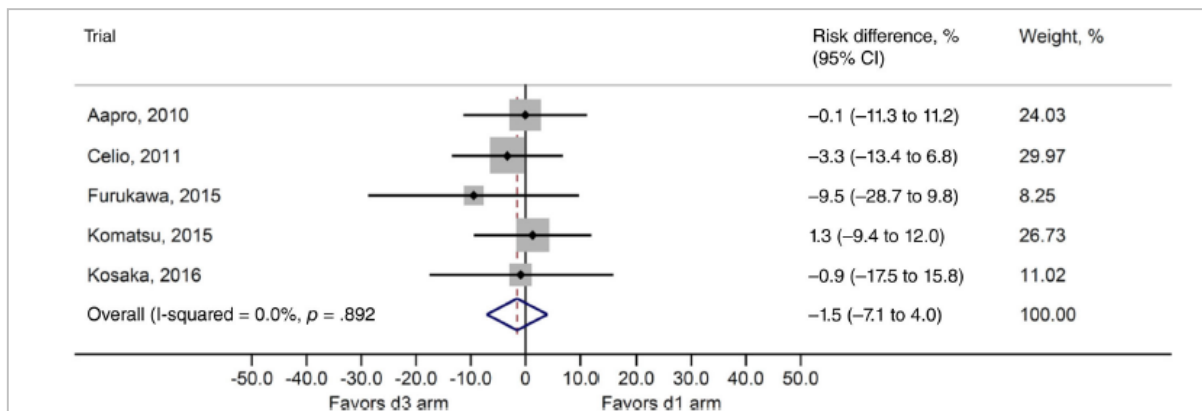


Figure 2. Risk difference for complete response rate: overall* and by study. d3 arm: Palonosetron plus 3-day dexamethasone. d1 arm: Palonosetron plus 1-day dexamethasone. *Overall combined (pooled) result with fixed-effect model. Abbreviation: CI, confidence interval.

Aprepitant Versus Dexamethasone for Preventing Chemotherapy-Induced Delayed Emesis in Patients With Breast Cancer: A Randomized Double-Blind Study

Fausto Roila, Benedetta Ruggeri, Enzo Ballatori, Albano Del Favero, and Maurizio Tonato

ABSTRACT

Purpose

A combination of aprepitant, a 5-HT₃ receptor antagonist, and dexamethasone is recommended for the prophylaxis of acute or delayed emesis induced by chemotherapy containing anthracyclines plus cyclophosphamide in patients with breast cancer. The aim of this study was to verify whether dexamethasone is superior to aprepitant in preventing delayed emesis in patients receiving the same prophylaxis for acute emesis.

Patients and Methods

A randomized double-blind study comparing aprepitant versus dexamethasone was completed in chemotherapy-naïve patients with breast cancer treated with anthracyclines plus cyclophosphamide. Before chemotherapy, all patients were treated with intravenous palonosetron 0.25 mg, dexamethasone 8 mg, and oral aprepitant 125 mg. On days 2 and 3, patients randomly received oral dexamethasone 4 mg twice per day or aprepitant 80 mg once per day. Primary end point was rate of complete response (ie, no vomiting or rescue treatment) from days 2 to 5 after chemotherapy.

Results

Of 580 enrolled patients, 551 were evaluable: 273 received dexamethasone, and 278 received aprepitant. Day 1 complete response rates were similar: 87.6% for dexamethasone and 84.9% for aprepitant ($P < .39$). From days 2 to 5, complete response rates were the same with both antiemetic prophylaxes (79.5%; $P < 1.00$), as were results of secondary end points (ie, complete protection, total control, no vomiting, no nausea, score of Functional Living Index-Emesis; $P < .24$). Incidences of insomnia (2.9% v 0.4%; $P < .02$) and heartburn (8.1% v 3.6%; $P < .03$) were significantly greater with dexamethasone on days 2 to 5.

Conclusion

In patients with breast cancer treated with anthracycline plus cyclophosphamide chemotherapy and receiving the same antiemetic prophylaxis for acute emesis, dexamethasone was not superior to aprepitant but instead had similar efficacy and toxicity in preventing delayed emesis.

Fausto Roila, "S. Maria" Hospital, Terni; Benedetta Ruggeri, Azienda Sanitaria Unica Regionale Marche, Ascoli Piceno; Enzo Ballatori, University of L'Aquila, L'Aquila; Albano Del Favero, University of Perugia; and Maurizio Tonato, Umbria Regional Cancer Network, Perugia, Italy.

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Written on behalf of the Italian Group for Antiemetic Research.

Supported by the Italian Minister of Health (Progetto di Ricerca Finalizzata, No. RFP5-2006-6-341766). Palonosetron and dexamethasone as well as grant for preparation of the double-blind trial provided by Helsinn Health Care, Lugano, Switzerland, and Italfarmaco, Milano, Italy.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Clinical trial information: NCT00689973.

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Alternativa en pacientes con tumores germinales en tratamiento con esquemas multidia con cisplatino

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Randomized, Double-Blind, Placebo-Controlled, Phase III Cross-Over Study Evaluating the Oral Neurokinin-1 Antagonist Aprepitant in Combination With a 5HT3 Receptor Antagonist and Dexamethasone in Patients With Germ Cell Tumors Receiving 5-Day Cisplatin Combination Chemotherapy Regimens: A Hoosier Oncology Group Study

Días 1-2	Día 3	Días 4-5	Días 6-7	Día 8
Dexa 20 mg + Granisetron 1 mg	Aprepitant 125 mg + Granisetron 1 mg	Aprepitant 80 mg + Granisetron 1 mg	Aprepitant 80 mg + Dexa 4 mg/12 h	Dexa 4 mg/12h





Resto Ciclos...

... Evaluación de respuesta y adecuación del tratamiento

**Imprescindible
conocer...**

- ✓ Vómitos? Nauseas?
- ✓ Momento aparición N/V (día??)
- ✓ Duración
- ✓ Intensidad
- ✓ Adherencia al tratamiento
- ✓ Visitas Urgencias
- ✓ Otros motivos posibles





1. Pacientes SIN buen control antiemético

➤ Añadir fármaco

- Antagonista AR-NK-1
- Primperan / Domperidona
- IBP
- Lorazepam
- Olanzapina



➤ Sustituir fármaco

- Ondasetron/Granisetron por Palonosetron (plantear en esquemas tipo Folfox, Folfiri... por efecto sobre N/V agudos)

Original Article

Effect of olanzapine for breast cancer patients resistant to triplet antiemetic therapy with nausea due to anthracycline-containing adjuvant chemotherapy

Junya Sato^{1,2,†}, Masahiro Kashiwaba^{3,†,*}, Hideaki Komatsu³, Kazushige Ishida³, S

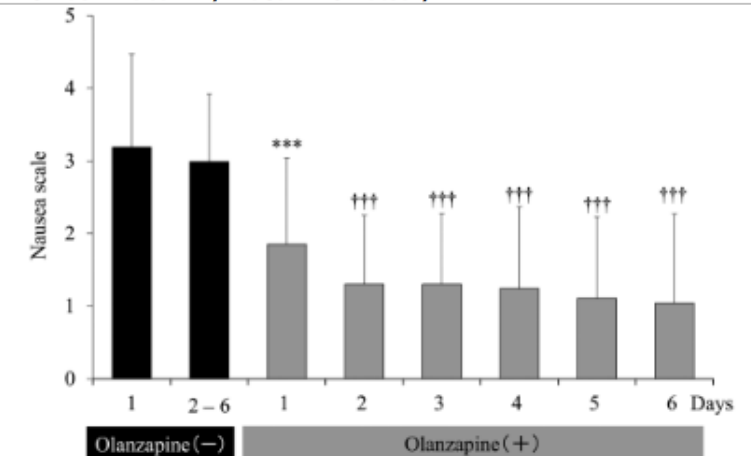


Figure 2. Change in nausea scale evaluated by patient self-writing scale with or without olanzapine application ($n = 45$). *** $P < 0.001$ vs. Day 1 in the first cycle [olanzapine (-)] by paired t -test. ††† $P < 0.001$ vs. average value in Days 2-6 in the first cycle [olanzapine (-)] by Dunnett t -test.



2. Pacientes CON buen control antiemético



- Simplificar/Reducir tratamiento → Reducir corticoides

3. Pacientes con EA no tolerables, independientemente del control antiemético

- Cambiar tratamiento (por ej. pac con hipo incontrolable, diabetes descontrolada)





*Medir
Resultados*





- Evaluar **eficacia antiemètica** en pacientes con cáncer de mama tratadas con esquema AC
→ Respuesta Completa y Control Completo
- Evaluar **PROs** en los distintos ciclos de QT (Pro-CTCAE)
- Evaluar impacto de **factores de riesgo** N/V inducidos por quimioterapia (Score Dranitsaris)





ORIGINAL ARTICLE

The development of a prediction tool to identify cancer patients at high risk for chemotherapy-induced nausea and vomiting

Respuesta Completa

- No emesis, no necesidad medicación de rescate

Control Completo

- No emesis, no necesidad rescate, no nauseas (more than mild")

NCI- PRO-CTCAE™ ITEMS-SPANISH

Item Library Version 1.0

10. PRO-CTCAE™ Symptom Term: Vomiting				
VÓMITOS				
a. En los últimos 7 días, ¿con qué FRECUENCIA tuvo VÓMITOS?				
O Nunca	O Rara vez	O A veces	O A menudo	O Casi siempre
b. En los últimos 7 días, ¿cuál fue la INTENSIDAD de los VÓMITOS en su PEOR momento?				
O Ninguna	O Leve	O Moderada	O Intensa	O Muy intensa

9. PRO-CTCAE™ Symptom Term: Nausea				
NÁUSEAS				
a. En los últimos 7 días, ¿con qué FRECUENCIA tuvo NÁUSEAS?				
O Nunca	O Rara vez	O A veces	O A menudo	O Casi siempre
b. En los últimos 7 días, ¿cuál fue la INTENSIDAD de las NÁUSEAS en su PEOR momento?				
O Ninguna	O Leve	O Moderada	O Intensa	O Muy intensa

Table 2. Predictive factors for nausea and vomiting from days 0 to 5

Predictive factor ^a	Odds ratio ^b	(95% CI)	Impact on risk
Age <60 years	1.41	(1.12–1.77)	↑ by 41%
Anticipatory nausea and vomiting	1.41	(1.13–1.77)	↑ by 41%
Sleep <7 h	1.34	(1.10–1.48)	↑ by 34%
History of morning sickness	1.30	(1.04–1.64)	↑ by 30%
Use of non-prescribed antiemetics at home	2.70	(1.45–2.60)	↑ 2.7 times
Platinum- or anthracycline-based chemotherapy	1.94	(1.45–2.60)	↑ by 94%
Nausea or vomiting in the prior cycle	5.17	(3.72–7.18)	↑ 5.17 times
Cycle number (vs. cycle 1)			
Cycle 2	0.17	(0.12–0.24)	↓ by 83%
≥Cycle 3	0.15	(0.10–0.24)	↓ by 85%

developed.

Patients and methods: Data from 1198 patients enrolled in one of the five non-interventional CINV prospective studies were pooled. Generalized estimating equations were used in a backwards elimination process with the *P*-value set at <0.05 to identify the relevant predictive factors. A risk scoring algorithm (range 0–32) was then derived from the final model coefficients. Finally, a receiver-operating characteristic curve (ROCC) analysis was done to measure the predictive accuracy of the scoring algorithm.

Results: Over 4197 chemotherapy cycles, 42.2% of patients experienced ≥grade 2 CINV. Eight risk factors were identified: patient age <60 years, the first two cycles of chemotherapy, anticipatory nausea and vomiting, history of morning sickness, hours of sleep the night before chemotherapy, CINV in the prior cycle, patient self-medication with non-prescribed treatments, and the use of platinum or anthracycline-based regimens. The ROC analysis indicated good predictive accuracy with an area-under-the-curve of 0.69 (95% CI: 0.67–0.70). Before to each cycle of therapy, patients with risk scores ≥16 units would be considered at high risk for developing ≥grade 2 CINV.

Conclusions: The clinical application of this prediction tool will be an important source of individual patient risk information for the oncology clinician and may enhance patient care by optimizing the use of the antiemetics in a proactive manner.

Key words: emesis, nausea, risk, prediction, cancer, CINV





➤ TRIPLE TERAPIA

- 14 pacientes
- 38 ciclos evaluados
- Requieren ajuste tratamiento → 3 pac (21%)
- RC total (días 1-5) → 81,6%
- CC total (días 1-5) → 73,7%

➤ DOBLE TERAPIA

- 37 pacientes
- 92 ciclos evaluados
- Requieren ajuste tratamiento → 7 pac (19%)
- RC total (días 1-5) → 82,6%
- CC total (días 1-5) → 75%

Patient Emetogenicity Risk Profile

Tell us about your patient and their chemotherapy.

1. What is the patient's gender?	Female	5. Did the patient sleep 7 or more hours the night before chemotherapy?	Yes
2. What is the patient's age?	35	6. After the previous cycle of chemotherapy (if applicable), did the patient take non-prescribed antiemetics at home?	No
3. Does the patient expect to develop CINV?	No	7. Has the patient had any nausea or a vomiting episode in the prior cycle?	No
4. Did the patient have morning sickness during a prior pregnancy?	No	8. Is the chemotherapy Anthracycline or Platinum based?	Yes

- Aproximadamente 30% pacientes de alto riesgo según score



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Pràctiques innovadores d'atenció al pacient



Thank you!

