Palonosetron-based antiemetic prophylaxis in breast cancer patients receiving AC chemotherapy – registry data from German gynaeco-oncology practices

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Updated Abstract

Introduction: Anthracycline/cyclophosphamide (AC)-based chemotherapy (CT) in women with breast cancer (BC) is considered a situation with high risk for nausea and vomiting. International antiemetic guidelines recommend a triplet antiemetic prophylaxis with 5-HT_3-receptor-antagonist (5HT3RA), neurokinin1-receptorantagonist (NK1A) and dexamethasone (DEX). Palonosetron (PAL), a 5HT3RA with longer half-life and stronger receptor binding affinity than older compounds, has demonstrated its efficacy as 5HT3RA in moderately (MEC) and highly (HEC) emetogenic CT and has proven high efficacy in the triplet prophylaxis in recent clinical trials. Gynaecologists who are associated in the BNGO document all patients by using an online registry in order to control, maintain and improve treatment quality and measure outcome. The objective of this analysis was to evaluate the efficacy of PAL-based antiemetic prophylaxis with or without the NK1A aprepitant (APR) in BC patients (pts) receiving AC-based chemotherapy in BNGO practices.

Methods: From 11/2008 until 3/2015, 2,986 BC patients receiving AC-containing chemotherapy and antiemetic prophylaxis based on PAL have been documented using the ODM Quasi® GYN online documentation system. Severity, frequency, duration and onset of nausea (N) and vomiting (V) were assessed after the 4th antiemetic treatment cycle. Efficacy criteria were complete control (CC: no V, no rescue medication (RM), only mild N); complete response (CR: no V, no RM) and RM.

Results: 2,986 pts with a median age of 55 years received a PAL-based antiemetic prophylaxis and were documented in 49 practices. In 79.6 % of pts the A component of the CT schedule was epirubicin. Response was evaluated after cycle 4. Efficacy of all PAL-based antiemetic regimens (n=2,986): CC: 63.0 %, CR 77.9 %. Rescue Medication was applied in 8.9 % of pts. Efficacy of the triplet therapy of PAL plus APR plus DEX (n=716): CC 73.2 %, CR 84.5% %, RM 7.7 %. 76.2 % of pts had no or only mild N in the overall risk phase, 79.2 % of pts had no N in the delayed phase. Only 5.1 % of all pts had severe N during the overall phase. No additional side effects were observed with the triplet therapy.

Conclusions: Antiemetic prophylaxis based on the 5HT3-RA PAL is effective in breast cancer pts receiving AC chemotherapy. The addition of APR to PAL enhances the efficacy in the reduction of vomiting and nausea in the acute and the delayed phase. The triplet therapy is well tolerated.

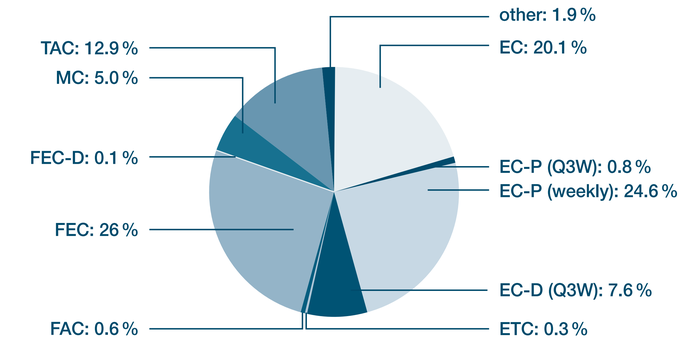
Background

Since 2008, the efficacy of palonosetron-based antiemetic prophylactic regimens has been recorded via the online documentation system of the BNGO. Current guidelines recommend a three drug combination consisting of 5-HT3-receptor-antagonist (5HT3RA), neurokinin1-receptorantagonist (NK1RA) and dexamethasone (DEX). This retrospective analysis of data from 49 BNGO-practices evaluated the efficacy of a palonosetron-based antiemetic regimens with or without NK1-RA after 4 cycles of an anthracycline/cyclophosphamide (AC)-containing chemotherapy in breast cancer patients. In clinical studies palonosetron proved to be highly effective within a three drug combination in patients receiving HEC and AC.

Material and Methods

This retrospective analysis evaluated the data of 2,986 breast cancer patients after 4 cycles of AC-containing chemotherapy who had received palonosetron as a two drug combination with dexamethasone or as a three drug combination with additional NK1RA. For documentation, 49 practices used the specialized ODM Quasi®GYN online documentation system. Severity, frequency, duration, and onset of nausea (N) and vomiting (V) were recorded in a patient diary. Efficacy criteria were: Complete control (CC: no V, no rescue medication, mild N), complete response (CR: no V, no rescue medication) and rescue medication. Response was evaluated after cycle 4.

AC Chemotherapy Regimens



A = Doxorubicin, D = Docetaxel, C = Cyclophosphamid, E = Epirubicin, F = 5-Fluorouracil, M = Mitoxantron, P = Paclitaxel, Q3W = repeated every three weeks

Results

2,986 patients treated with AC-containing chemotherapy received a palonosetron-based antiemetic prophylaxis. In 79.6 % of patients the anthracycline was epirubicin. Median patient age was 55 years.

All Palonosetron-based antiemetic regimens: 63.4 % of patients reached complete control and 77.9 % reported complete response after cycle 4. 8.9 % of patients needed rescue medication.

Triplet antiemetic prophylaxis: In total, 716 patients (24.0 %) of all breast cancer patients receiving AC-based chemotherapy have been treated with the triplet antiemetic prophylaxis consisting of palonosetron/dexamethasone/NK1RA (P-N-Dex). The use of P-N-Dex has increased since 2013:

	2008–2010	2011	2012	2013	2014	Jan–March 2015
P-N-Dex	24.3 %	21.0 %	20.9 %	24.4 %	27.1 %	29.0 %

Efficacy of P-N-Dex after 4 cycles of AC-based chemotherapy: complete control 73.2 %, complete response 84.5 %, rescue medication 7.7 %

Nausea control: 51.5 % had no nausea during the overall risk phase (day 1–5) and 76.2 % had no or only mild nausea. Only 5.2 % of patients reported severe nausea in the overall risk phase. In the delayed phase (day 2–5), 79.2 % of patients reported no or only mild nausea.

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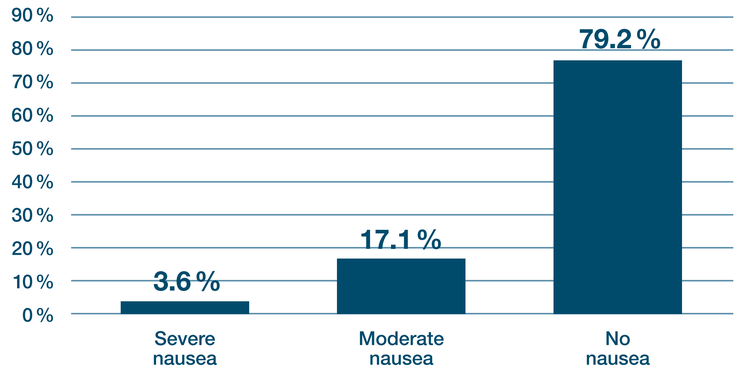
Efficacy of Palonosetron Regimens

	Patients (n)	%
All palonosetron-based regimens	**2,986**	
Complete Control	1,894	63.0
Complete Response	2,327	77.9
Rescue Medication	267	8.9
Palonosetron plus NK1RA plus DEX	**716**	
Complete Control	524	73.2
Complete Response	605	84.5
Rescue Medication	55	7.7
Delayed nausea (days 2–5), all palonosetron-based regimens	**2,986**	
No or only mild nausea	2,365	79.2
Moderate nausea	424	18.2
Severe nausea	108	3.6
Nausea in the overall risk phase (days 1–5), all palonosetron-based regimens	**2,986**	
No or only mild nausea	2,276	76.2
Moderate nausea	556	18.6
Severe nausea	154	5.2

Delayed nausea, all Palonosetron-based regimens



Conclusion

Palonosetron-based antiemetic prophylaxis proved to be effective in these comparatively young breast cancer patients receiving AC chemotherapy. The addition of the NK1-RA aprepitant increases the efficacy in the reduction of vomiting and nausea even further. Delayed nausea was well controlled. Efficacy was maintained over all 4 cycles of chemotherapy applied.

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