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

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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 A-based chemotherapy in BNGO practices.

Methods: From 11/2008 until 3/2014, 2,329 BC patients receiving A-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: 2,329 pts with a median age of 55 years received a PAL-based antiemetic prophylaxis and were documented in 47 practices. In 78 % 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= 2,329): CC: 64.6 %, CR 79.4 %. Rescue Medication was needed in 6.3 % of pts. Efficacy of the triplet therapy of PAL plus APR plus DEX (n=544): CC 73.3 %, CR 84.9 %, RM 6,6 %. 75 % of pts had no or only mild N in the overall risk phase, 78.2 % of pts had no nausea in the delayed phase. Only 5.2 % 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 47 BNGO-practices evaluated the efficacy of a palonosetron-based antiemetic regimens with or without NK1-RA after 4 cycles of an anthracycline (A)-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.

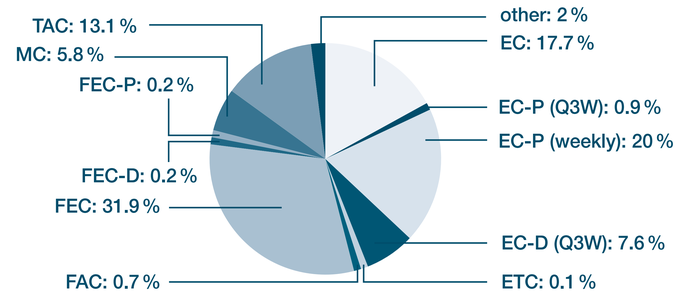
Material and Methods

This retrospective analysis evaluated the data of 2,329 breast cancer patients after 4 cycles of A-containing chemotherapy who had received palonosetron as a two drug combination with dexamethasone or as a three drug combination with additional NK1RA. For documentation, 47 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.

Patients

Age	Number of patients
1–19	0
20–29	21
30–39	167
40–49	552
50–59	715
60–69	598
70–79	263
>79	13

Chemotherapy Regimens



Results

2,329 patients treated with A-containing chemotherapy received a palonosetron-based antiemetic prophylaxis. In 78 % of patients the anthracycline was epirubicin. Median patient age was 55 years.

Considering all palonosetron-based antiemetic regimens, 64.4 % of patients reached complete control and 79.4 % reported complete response after cycle 4. 6.3 % of patients needed rescue medication.

544 patients received the triplet antiemetic therapy consisting of palonosetron/dexamethasone/NK1RA (P-N-DEX).

Efficacy after 4 cycles of A-based chemotherapy: CC 73.3 %, CR 84.9 %, rescue medication: 6.6 %.

Nausea control: Half of the patients had no nausea during the overall risk phase (day 0–4) and 74.2 % had no or only mild nausea. Only 5.2 % of patients reported severe nausea in the overall risk phase. In the delayed phase (day 1–4), 78. 2 % of patients reported no or only mild nausea.

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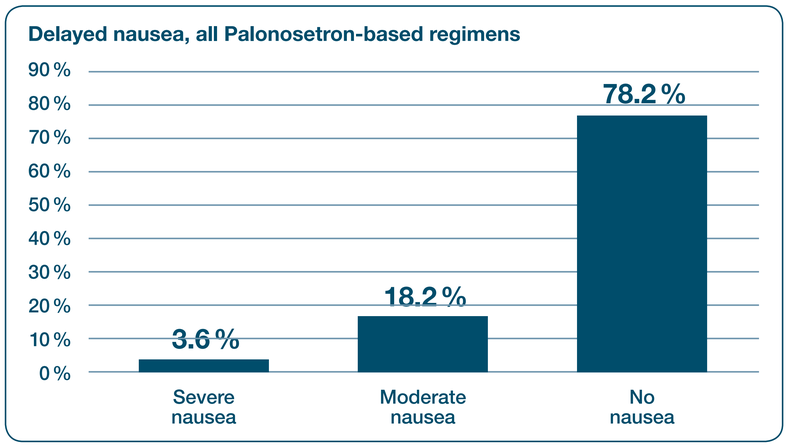
Efficacy of Palonosetron Regimens

	Patients (n)	%
All palonosetron-based regimens	**2,329**	**100**
Complete control	1,505	64.6
Complete response	1,849	79.4
Rescue medication	147	6.3
Palonosetron plus NK1RA plus DEX	**544**	**100**
Complete control	399	73.3
Complete response	339	84.9
Rescue medication	36	6.6
Delayed nausea (days 1–4), all palonosetron-based regimens	**2,329**	**100**
No or mild nausea	1,822	78.2
Moderate nausea	424	18.2
Severe nausea	83	3.6
Nausea in the overall risk phase (days 0–4), all palonosetron-based regimens	**2,329**	**100**
No or only mild nausea	1,748	75
Moderate nausea	460	19.8
Severe nausea	121	5.2



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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