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Quality of life and efficacy of NEPA as CINV prophylaxis in highly or moderately emetogenic chemotherapy – interim results of a German non-interventional study

Jörg Schilling[1], Jacqueline Rauh[2], Dagmar Guth[3], Volker Heilmann[4], Meinolf Karthaus[5]

[1] Gynäko-onkologische Gemeinschaftspraxis Berlin, [2] Gemeinschaftspraxis Innere Medizin Witten, [3] Gynäkologische Praxis Plauen, [4] Praxis Günzburg, [5] Städtisches Klinikum München Neuperlach

Background

The combination of 5-HT_3- and NK_1-receptor-antagonists (RA) and dexamethasone is recommended by international antiemesis guidelines for patients receiving highly emetogenic chemotherapy (HEC) including anthracycline/cyclophosphamide (AC)-containing chemotherapy regimens as well as for patients receiving certain moderately emetogenic chemotherapies (MEC). The 2016 published updated antiemetic guideline of the Multinational Association of Supportive Care in Cancer (MASCC) and the European Society for Medical Oncology (ESMO) recommends the use of this triple combination also for carboplatin-based regimens. NEPA (Akynzeo®) is a fixed combination capsule combining the long lasting NK_1-RA netupitant and the pharmacologically distinct 5-HT_3-RA palonosetron. It has been approved by FDA and EMA for the prevention of acute and delayed CINV in adult cancer patients receiving cisplatin-based HEC or MEC. The AkyPRO study is a prospective non interventional study planned to evaluate quality of life in 2500 adult cancer patients receiving NEPA. Patients must receive single day or two day MEC or HEC. More than 100 German centers participate in the study.

Here we present an interim analysis of the AkyPRO study of the quality of life of patients as recorded in FLIE questionnaires and of the antiemetic efficacy of NEPA as documented by physicians and patients. Since September 2015, 1 959 patients have been included.

Methods

AkyPRO study

- Multi-center, prospective, open, non-interventional study (NIS)
- For CINV prevention NEPA is prescribed in accordance with the terms of the marketing authorisation
- Antiemetic prophylaxis with NEPA must be documented during 3 consecutive chemotherapy cycles per patient
- Efficacy ist documented by patient diaries (patients) and electronic case report forms (e-CRF) (physicians)
- Primary endpoint: Quality of life as recorded by FLIE questionnaires in 3 consecutive cycles of MEC or HEC
- Secondary endpoints: efficacy of NEPA, use of rescue medication, safety data and AEs

Documentation

Physicians: Efficacy is documented by physicians using an e-CRF. Efficacy is assessed at the end of each of 3 consecutive cycles using 4 efficacy categories: Very good, good, satisfactory, poor.

Patients: Patients used diaries for documenting the efficacy of the antiemetic prophylaxis with NEPA, the need for rescue medication as well as adverse events on days 1–5 (and up to day 6 for pts receiving a chemotherapy on two consecutive days) of 3 consecutive chemotherapy cycles. At the end of each of 3 consecutive cycles, patients gave an overall assessment of efficacy using 4 efficacy categories: Very good, good, satisfactory.

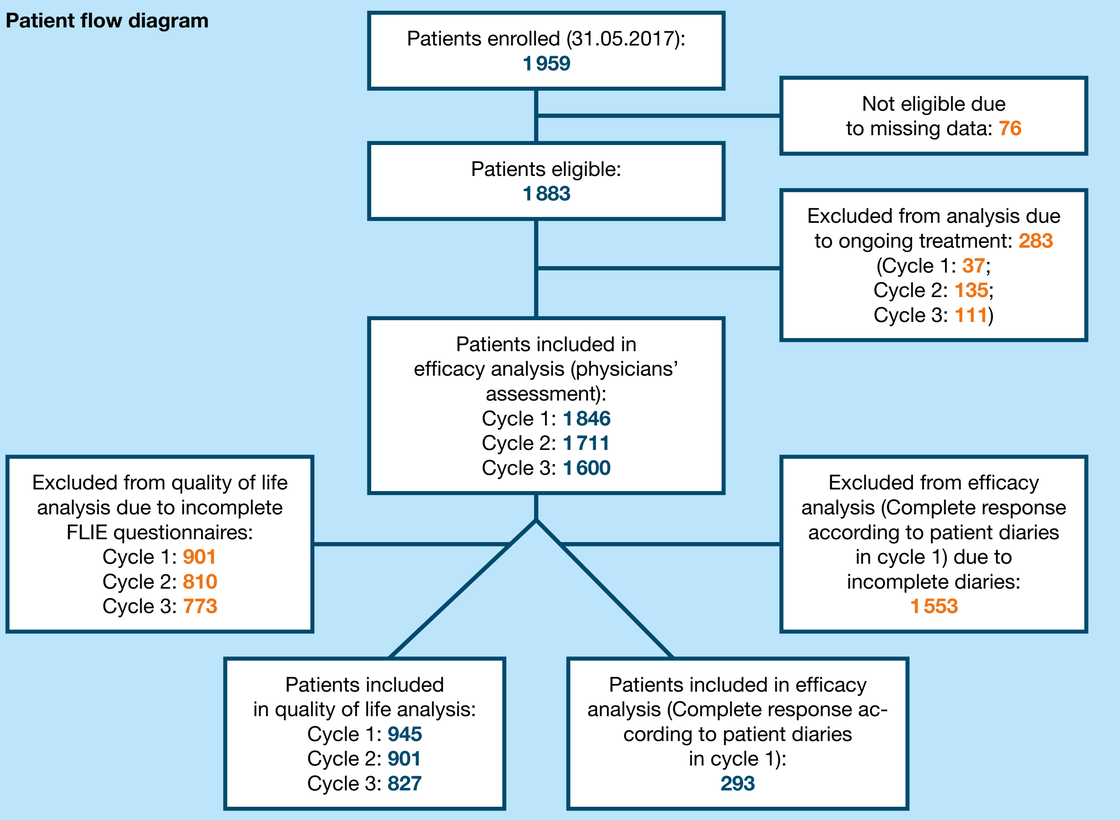
Patients receive FLIE questionaires on day 5 (day 6 for two day chemotherapies) of 3 consecutive cycles.

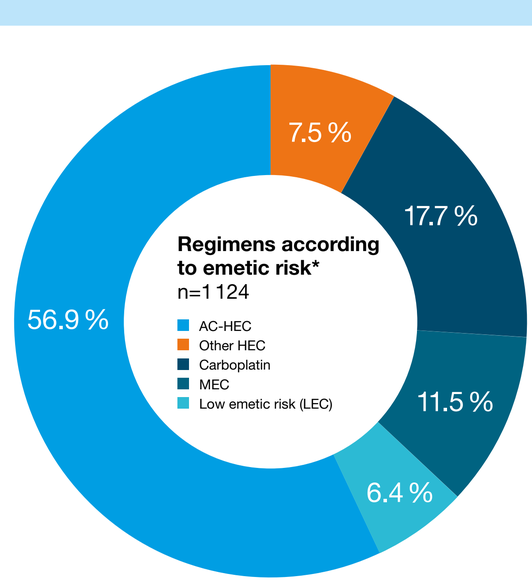
Results

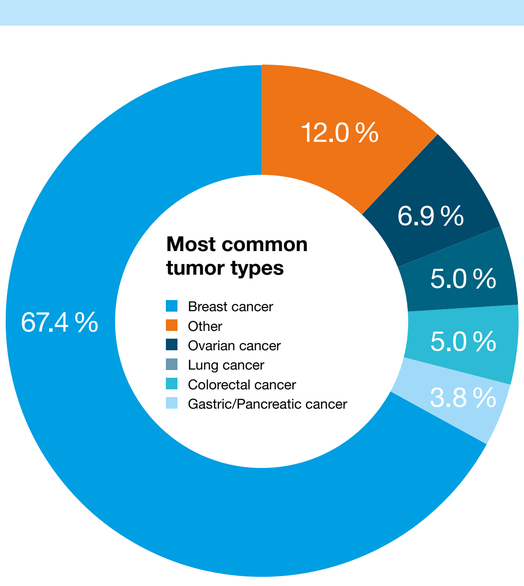
Patients

At the cut-off date 31.05.2017, 1 959 patients had been included in the study.

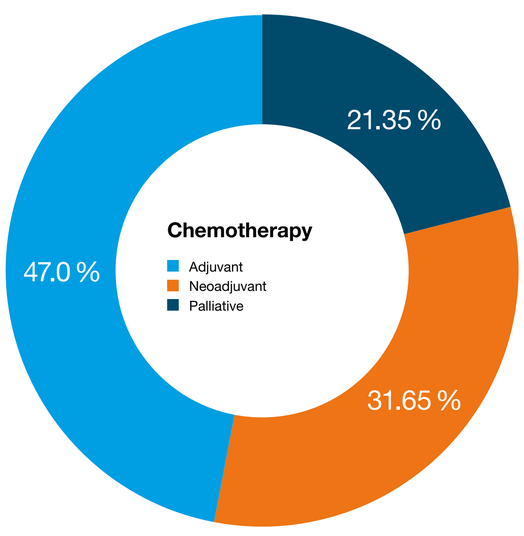
Patient flow diagram







According to MASCC/ESMO Roila F et al. MASCC and ESMO Consensus Guidelines for the Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting: ESMO Clinical Practice Guidelines. Ann Oncol 2016; 27(suppl 5):v119-v133

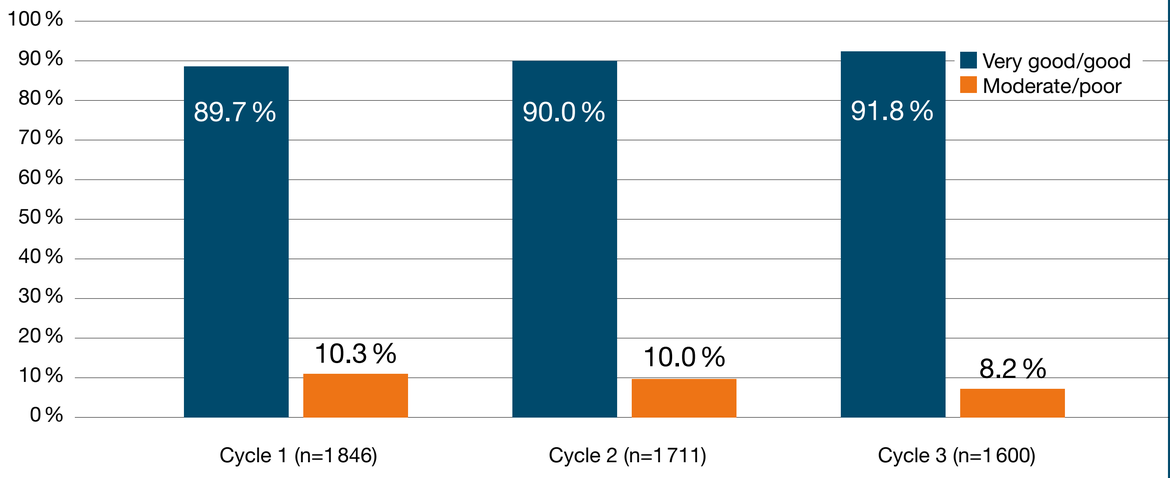


Patient details

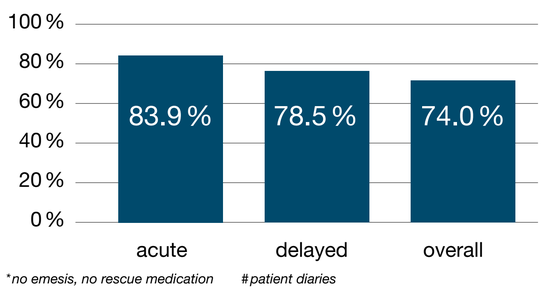
		October 2016, n=1 263	May 2017, n=1 959
Female, n (%)		1091 (86.4 %)	1 690 (86.3 %)
Male, n (%)		172 (13.6 %)	269 (13.7 %)
Age (years)	Median	57	57
	Range	28–89	27–89
Tumor Type (n; %)	Breast	869 (68.8 %)	1 320 (67.4 %)
	Other	71 (5.6 %)	169 (8.6 %)
	Ovarian	85 (6.7 %)	136 (6.9 %)
	Lung	68 (5.4 %)	97 (5.0 %)
	Colorectal	51 (4.0 %)	97 (5.0 %)
	Cervical Stomach	22 (1.7 %)	52 (2.7 %)
	Pancreatic	30 (2.4 %)	42 (2.1 %)
	Head & Neck	25 (2.0 %)	33 (1.7 %)
		13 (1.0 %)	13 (0.7 %)
ECOG-Status (%)	0	756 (59.9 %)	1 204 (61.5 %)
	1	414 (32.8 %)	640 (32.7 %)
	2	87 (6.9 %)	109 (5.6 %)
	3		6 (0.3 %)

Efficacy

Overall efficacy of antiemetic prophylaxis with NEPA during 3 consecutive cycles as assessed by physicians on a 4 point scale as recorded in eCRFS.

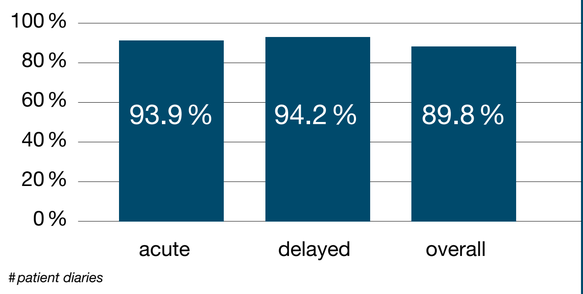


Complete Response* in Cycle 1 (n#=293)



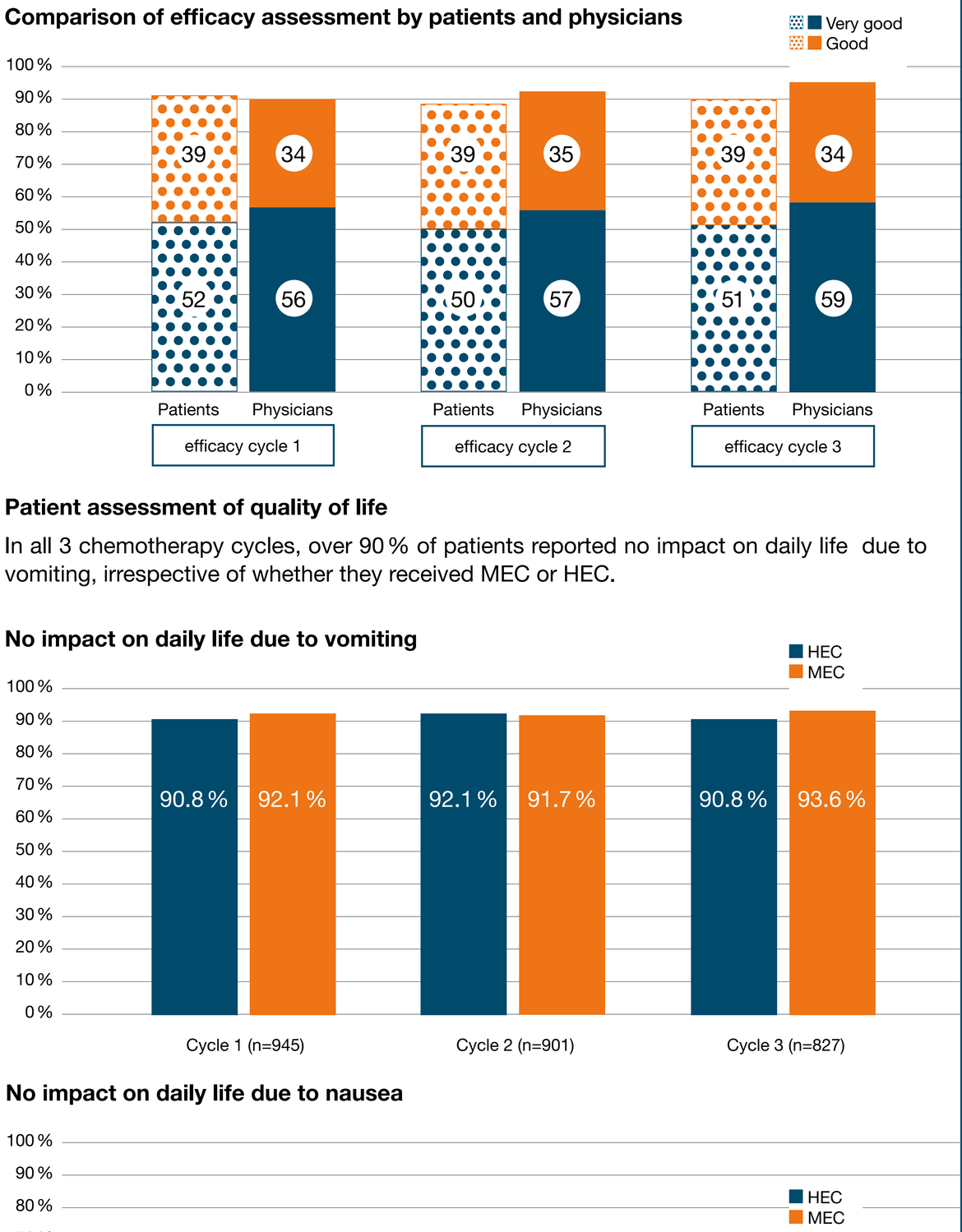
*no emesis, no rescue medication #patient diaries

No Emesis in Cycle 1 (n#=293)



#patient diaries

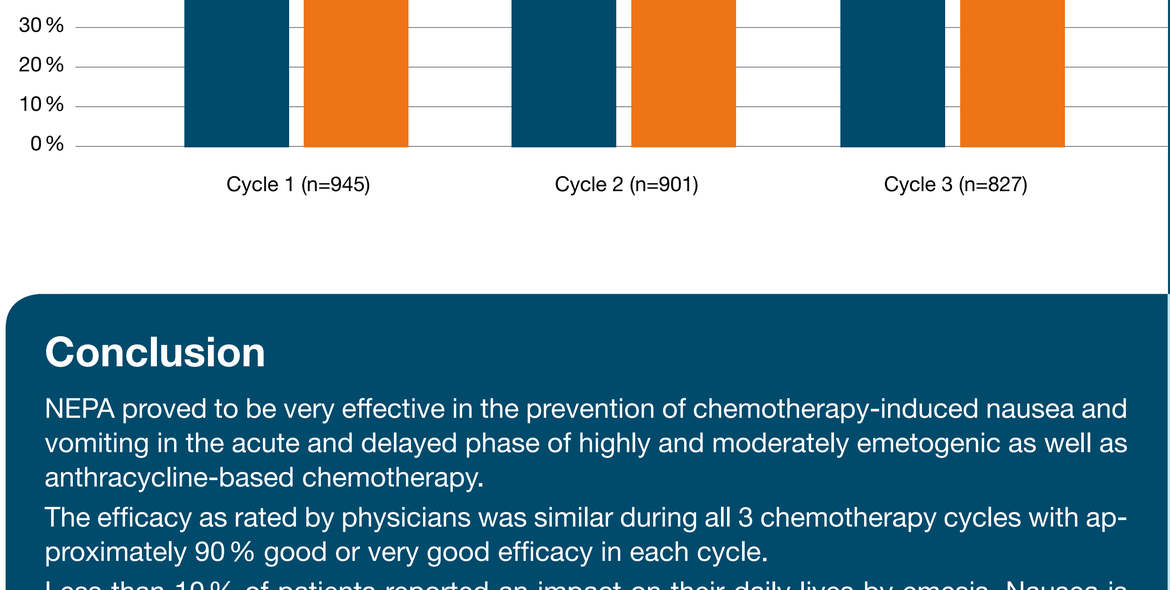
Comparison of efficacy assessment by patients and physicians



Patient assessment of quality of life

In all 3 chemotherapy cycles, over 90 % of patients reported no impact on daily life due to vomiting, irrespective of whether they received MEC or HEC.

No impact on daily life due to vomiting



No impact on daily life due to nausea

Conclusion

NEPA proved to be very effective in the prevention of chemotherapy-induced nausea and vomiting in the acute and delayed phase of highly and moderately emetogenic as well as anthracycline-based chemotherapy.

The efficacy as rated by physicians was similar during all 3 chemotherapy cycles with approximately 90 % good or very good efficacy in each cycle.

Less than 10 % of patients reported an impact on their daily lives by emesis. Nausea is more difficult to control with 62.1 %–65.2 % of patients reporting no impact on their daily lives by nausea. The study is ongoing.

Disclosures

Jörg Schilling: No financial relationship(s) with commercial interests to disclose.
Meinolf Karthaus: No financial relationship(s) with commercial interests to disclose.
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Dagmar Guth: No financial relationship(s) with commercial interests to disclose.
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