

Clinician-Reported Outcome Measure for Palonosetron Versus Standard of Care in Chemotherapy-Induced Nausea and Vomiting in Egypt

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Introduction:

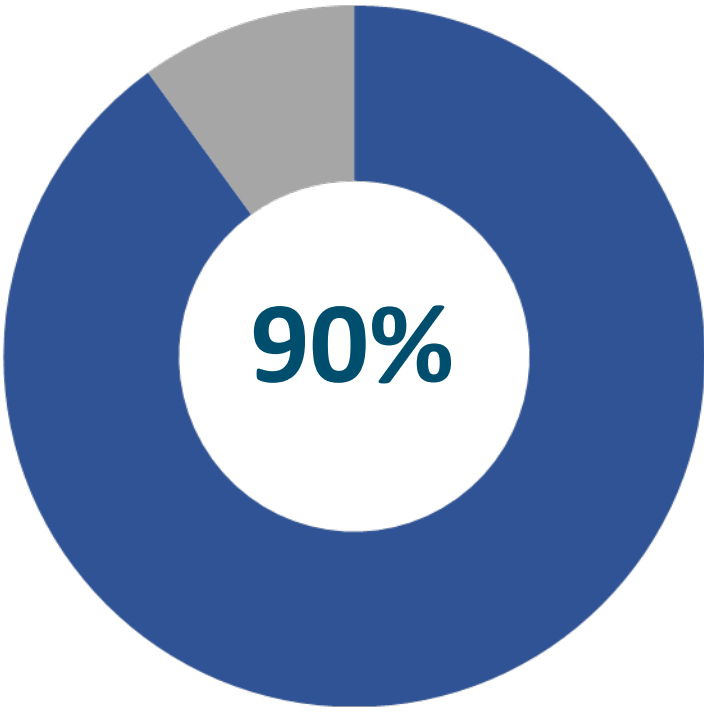
- Chemotherapy-induced nausea and vomiting (CINV) is considered to be the most stressful aspect of chemotherapy affecting patients’ quality of life (QoL)¹.
- The 1st generation of 5-hydroxytryptamine 3-receptor antagonists (5HT3RAs) are the standard of care (SoC) as anti-emetics in the management of high/moderate emetogenic chemotherapy (H/MEC) nausea and vomiting (N/V) but mainly for acute CINV².

Consequences of CINV:³⁻⁴



Treatment discontinuation as patients’ refusal to continue administration of anti-cancer medications

90%



Percentage of poorly managed CINV patients with a reduced daily functioning

- Our objective is to compare between palonosetron (a 2nd-generation 5-HT3RA with enhanced antiemetic effect for both acute and delayed CINV) and standard antiemetics in CINV in patients with different tumor types allocated on H/MEC using clinician reported outcome (ClinRO) measure. Statistical analyses were performed.

Methods:

- Study design

 - Four online-surveys were sent to 11 Egyptian reputable oncology experts from different representative institutions all over Egypt.
- Comparators:

 - Palonosetron and SoC (ondansetron, granisetron, aprepitant, or ondansetron/granisetron+dexamethasone) in patients completed at least three cycles of H/MEC within the last 6 months.

- Assessed outcomes

Health-related QoL (HRQoL) domains (1ry outcomes):

 - Performance of daily activities and being mentally and emotionally well
 - Appetite
 - Acceptance and trust toward anti-emetics
 - Effect of anti-emetic failure and discontinuation
- Secondary outcomes:

Adherence

 - Resources utilization
 - Use of rescue medications
 - Factors impact the physicians during prescription of prophylactic anti-emetic

- Measurement Tools and Assessment

 - The responses to the three-and four-point scales were weighted for a factor varying between (1 to 3) or (1 to 4) depending on the assessed HRQoL domain. The higher is the score, the better.
 - Scores of numeric rating scales (NRS) was categorized into 3-degrees: severe HRQoL deterioration (0-5), moderate deterioration of HRQoL (6-7), nearly normal HRQoL (8-10). The severe deterioration, moderate deterioration and nearly normal QoL would be scored as 1, 2 and 3, respectively.
 - Therefore, the sum of 8 components of 4 domains of primary outcome would generate an overall score of 27.

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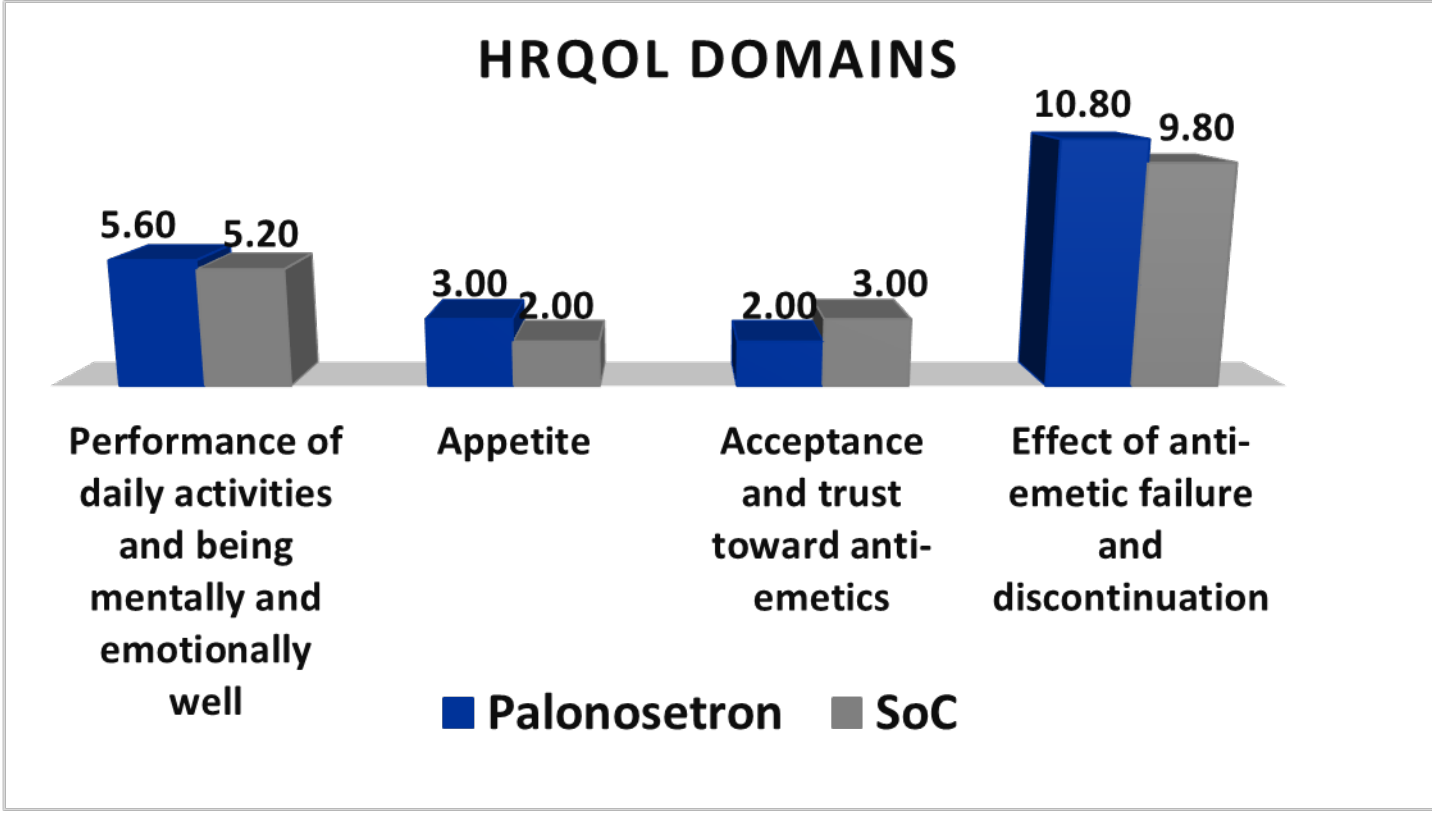
References:
1. Lindley, C. M., & Hirsch, J. D. (1992). Nausea and vomiting and cancer patients' quality of life: a discussion of Professor Selby's paper. The British journal of cancer. Supplement, 19, 526-529.
2. Paul, J., Hesketh, (2000) Clinical Science Review: Comparative Review of 5-HT3 Receptor Antagonists in the Treatment of Acute Chemotherapy-Induced Nausea and Vomiting, Cancer Investigation, 18:2, 163-173, DOI: 10.3109/07379000090938248
3. Cohen, L., de Moor, C.A., Eisenberg, P. et al. Chemotherapy-induced nausea and vomit-ing—incidence and impact on patient quality of life at community oncology set-tings. Support Care Cancer 15, 497–503 (2007). <https://doi.org/10.1007/s00520-006-0121-z>
4. Haiderali, A., Menditto, L., Good, M. et al. Impact on daily functioning and indi-rect/direct costs associated with chemotherapy-induced nausea and vomiting (CINV) in a US population. Support Care Cancer 19, 843–851 (2011). <https://doi.org/10.1007/s00520-010-0910-9>

Results:

ClinRO Results for MEC in CINV (10 respondents)

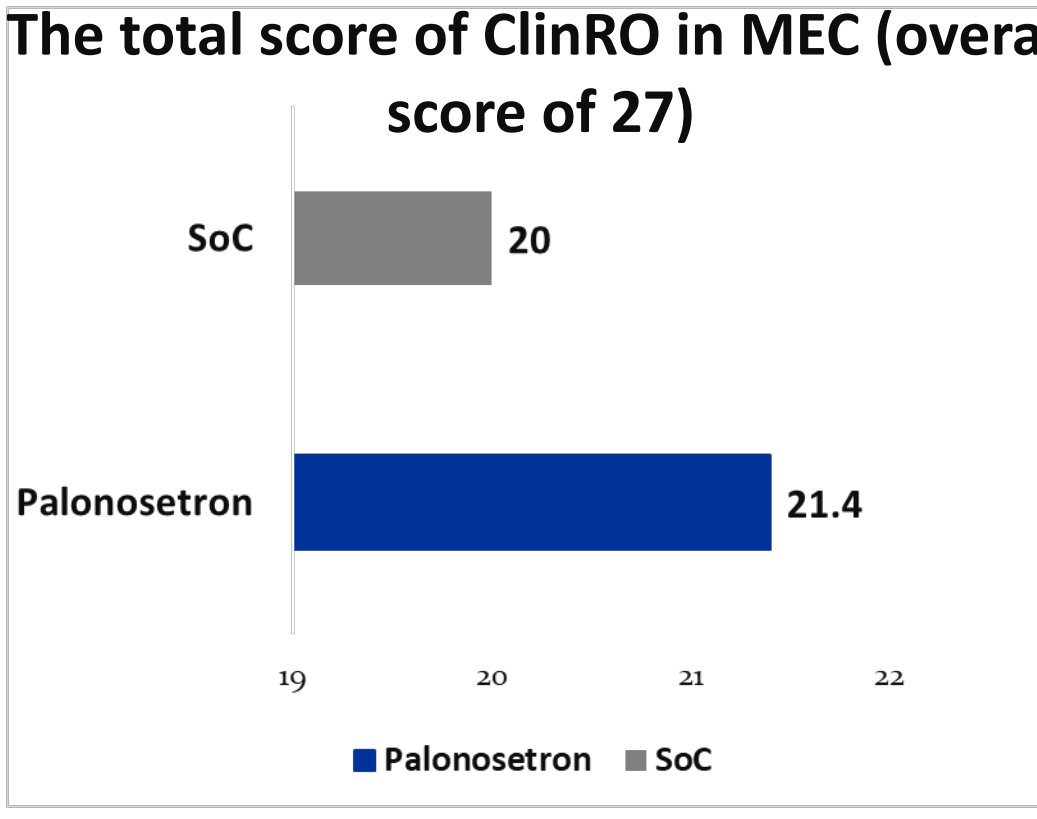
Primary outcomes:

HRQOL DOMAINS



Domain	Palonosetron	SoC
Performance of daily activities and being mentally and emotionally well	5.60	5.20
Appetite	3.00	2.00
Acceptance and trust toward anti-emetics	2.00	3.00
Effect of anti-emetic failure and discontinuation	10.80	9.80

The total score of ClinRO in MEC (overall score of 27)

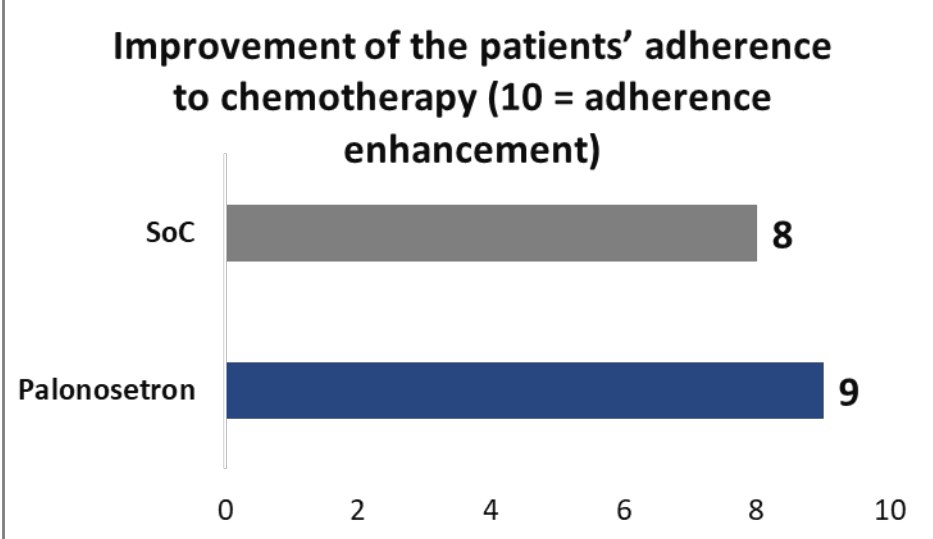


Group	Score
SoC	20
Palonosetron	21.4

Palonosetron has a better response in functioning capability and emotionally better, significant food tolerance and less severe hardship after treatment failure due to less severe N/V episodes

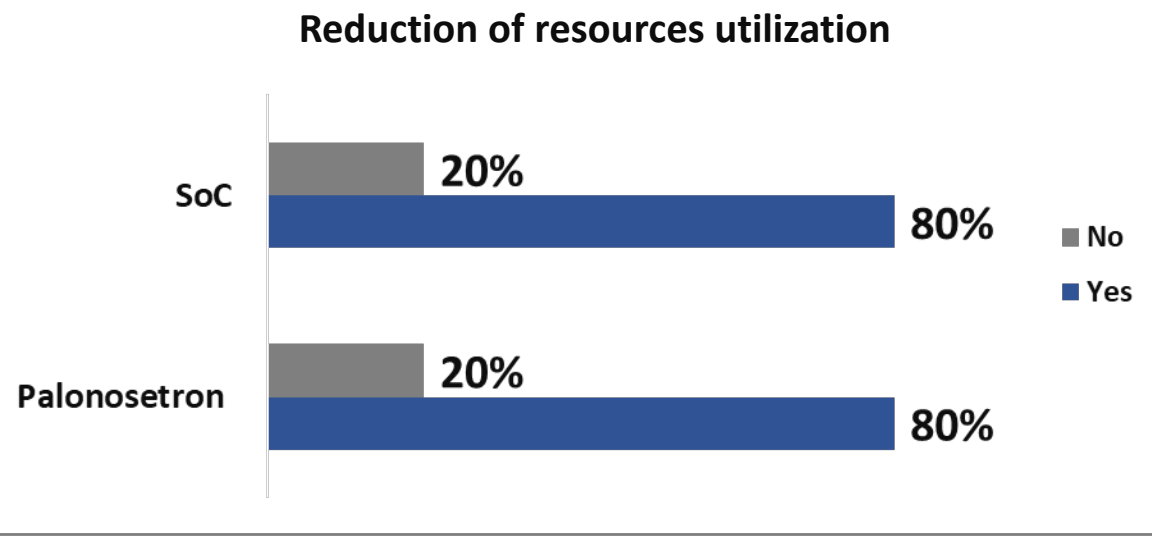
Secondary outcomes:

Improvement of the patients' adherence to chemotherapy (10 = adherence enhancement)



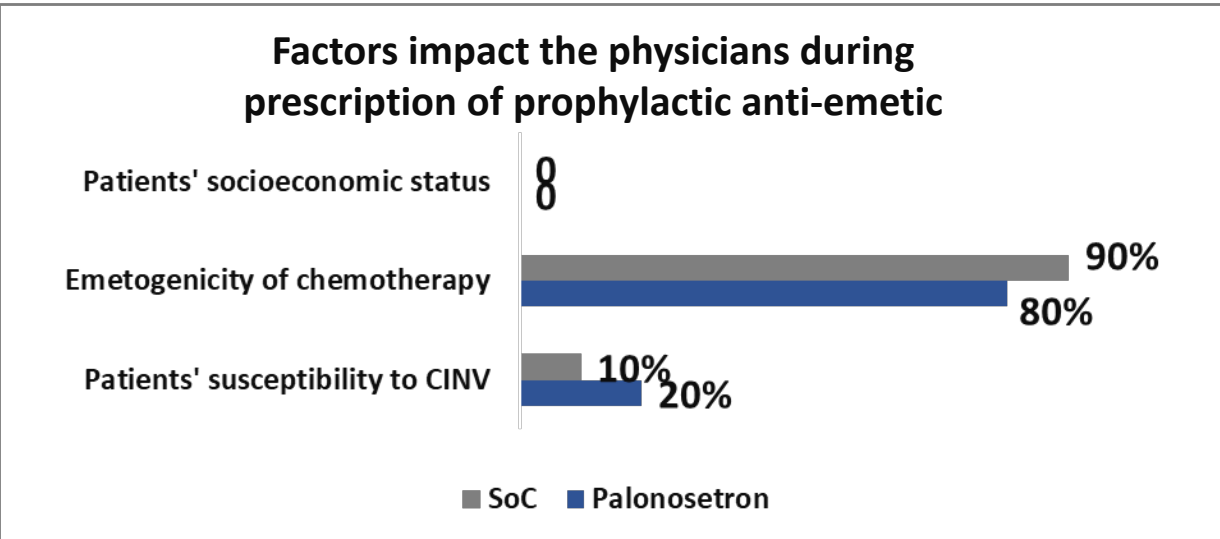
Group	Score
SoC	8
Palonosetron	9

Reduction of resources utilization



Group	Yes (%)	No (%)
SoC	20%	80%
Palonosetron	20%	80%

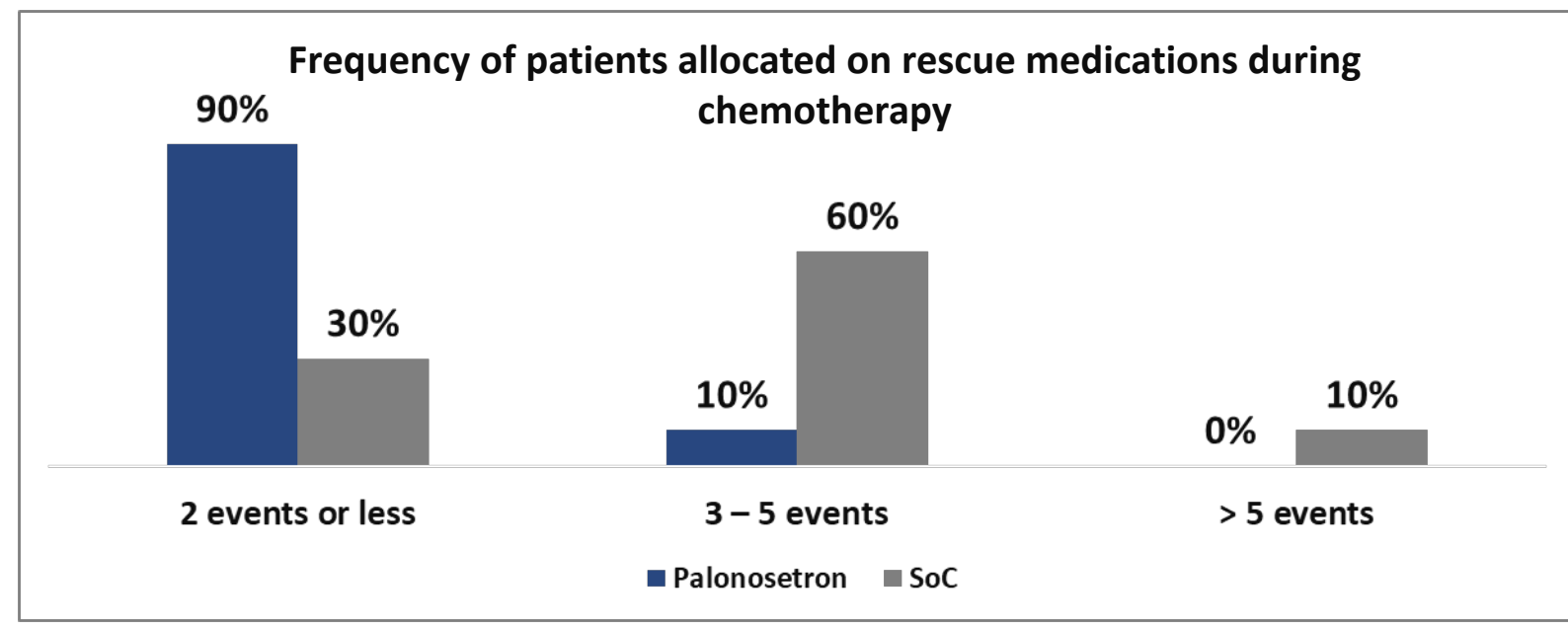
Factors impact the physicians during prescription of prophylactic anti-emetic



Factor	SoC (%)	Palonosetron (%)
Patients' socioeconomic status	8	8
Emetogenicity of chemotherapy	90%	80%
Patients' susceptibility to CINV	10%	20%

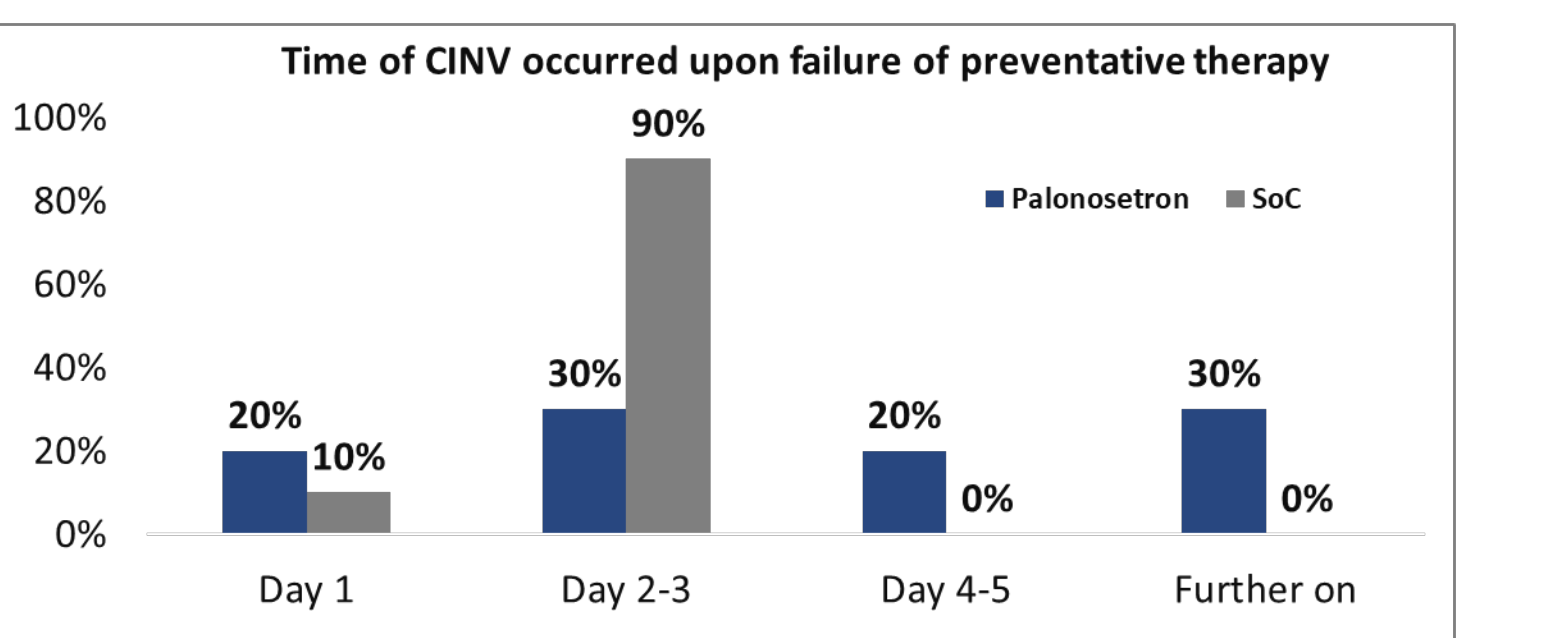
Use of rescue medications

Frequency of patients allocated on rescue medications during chemotherapy



Events	Palonosetron (%)	SoC (%)
2 events or less	90%	30%
3 - 5 events	10%	60%
> 5 events	0%	10%

Time of CINV occurred upon failure of preventative therapy

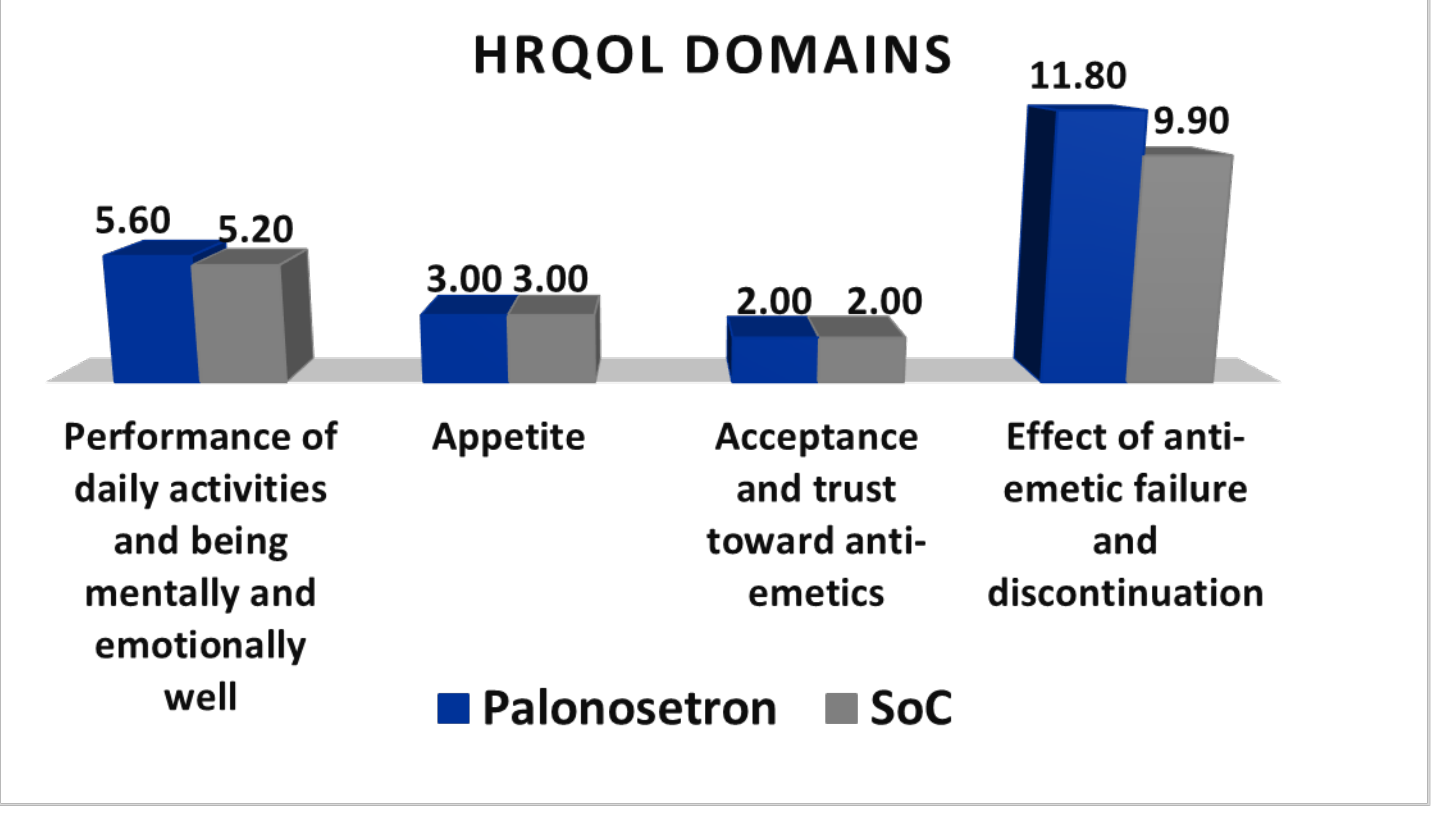


Time	Palonosetron (%)	SoC (%)
Day 1	20%	10%
Day 2-3	30%	90%
Day 4-5	20%	0%
Further on	30%	0%

ClinRO Results for HEC in CINV (11 respondents)

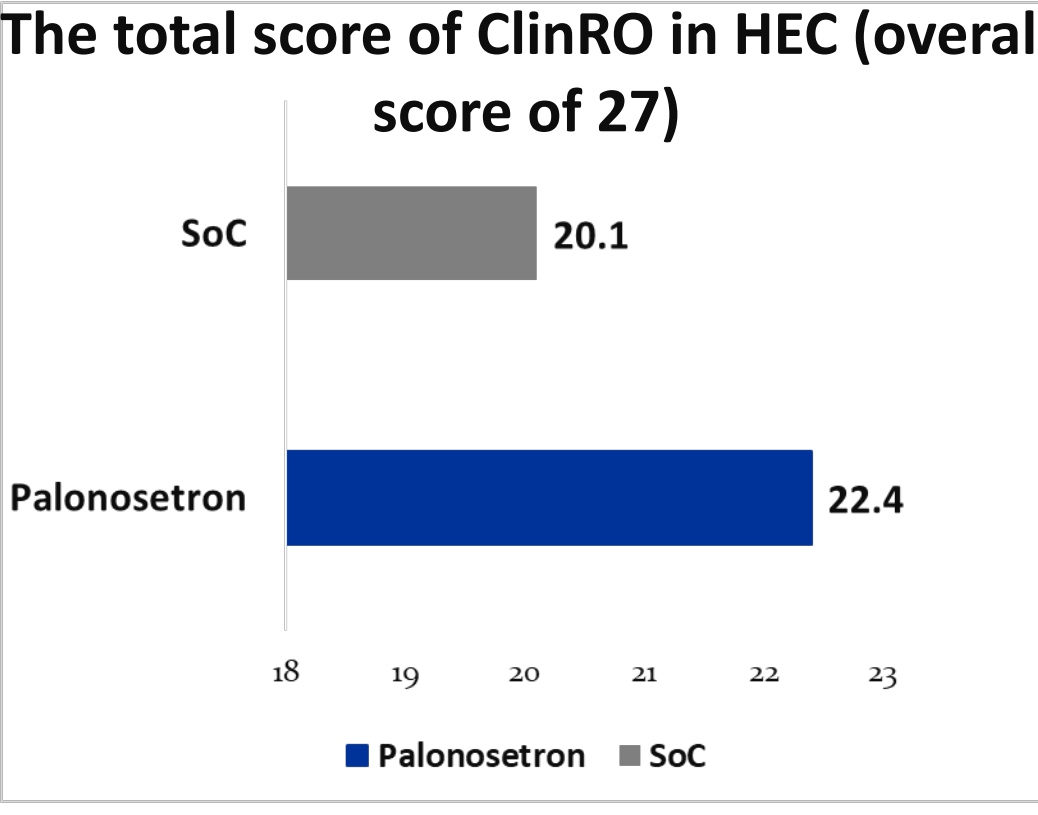
Primary outcomes:

HRQOL DOMAINS



Domain	Palonosetron	SoC
Performance of daily activities and being mentally and emotionally well	5.60	5.20
Appetite	3.00	3.00
Acceptance and trust toward anti-emetics	2.00	2.00
Effect of anti-emetic failure and discontinuation	11.80	9.90

The total score of ClinRO in HEC (overall score of 27)

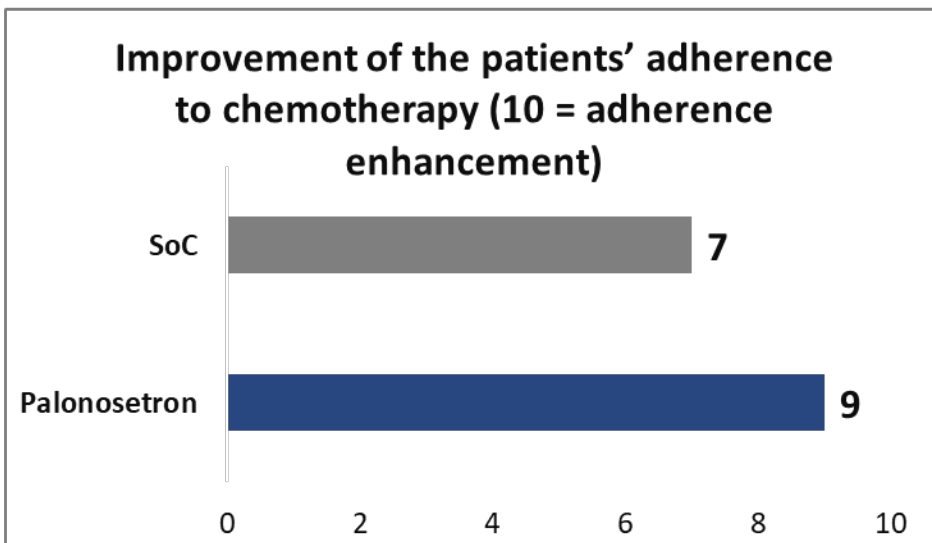


Group	Score
SoC	20.1
Palonosetron	22.4

Palonosetron has a better response in functioning capability and emotionally well-being, patient continuity on their anti-emetics, and less severe hardship after treatment failure due to less N/V episodes

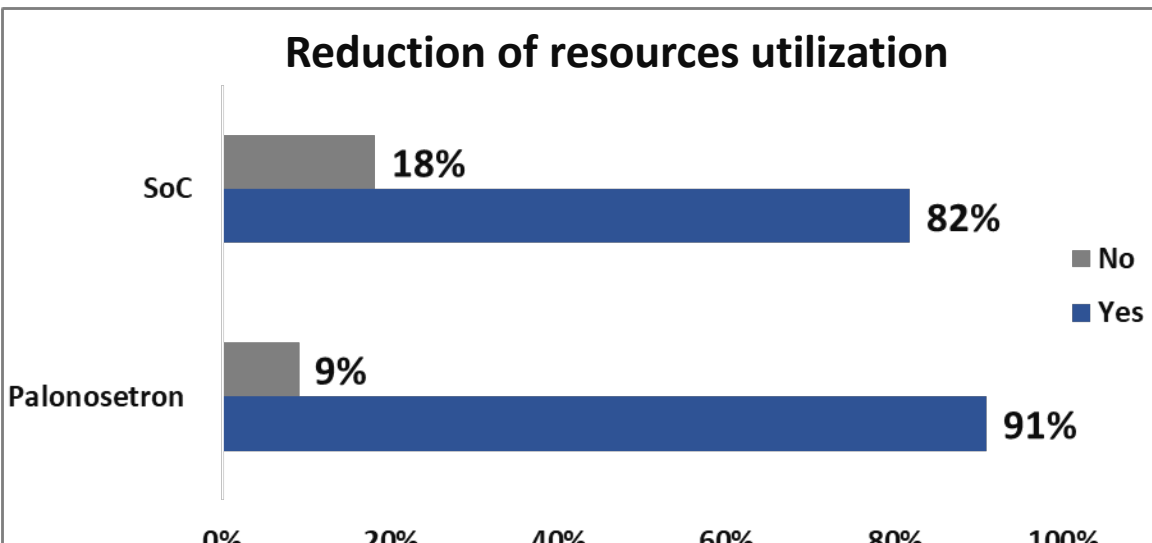
Secondary outcomes:

Improvement of the patients' adherence to chemotherapy (10 = adherence enhancement)



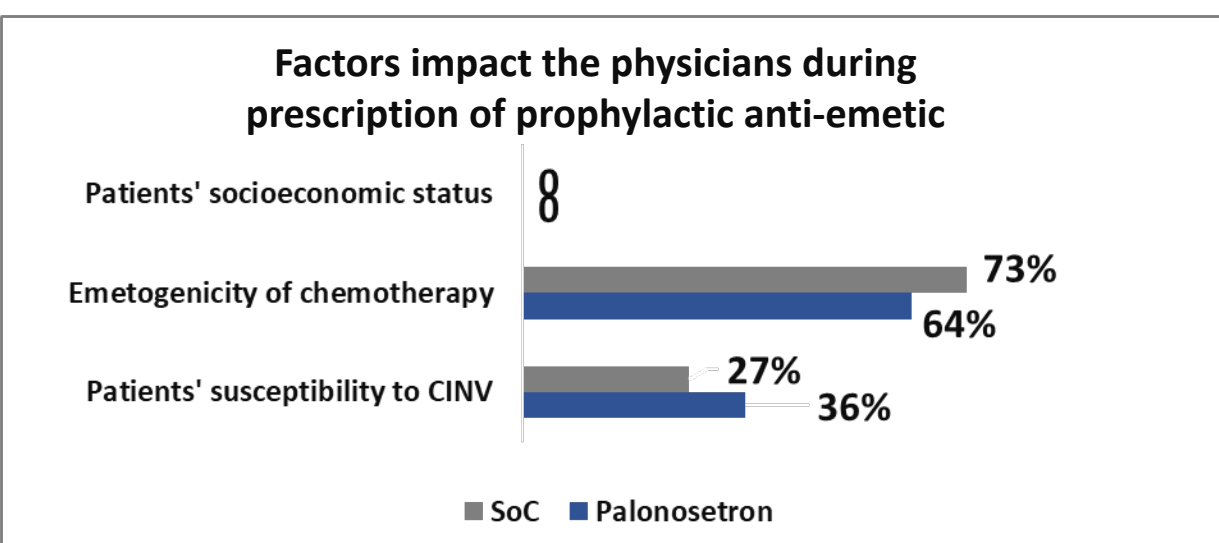
Group	Score
SoC	7
Palonosetron	9

Reduction of resources utilization



Group	Yes (%)	No (%)
SoC	18%	82%
Palonosetron	9%	91%

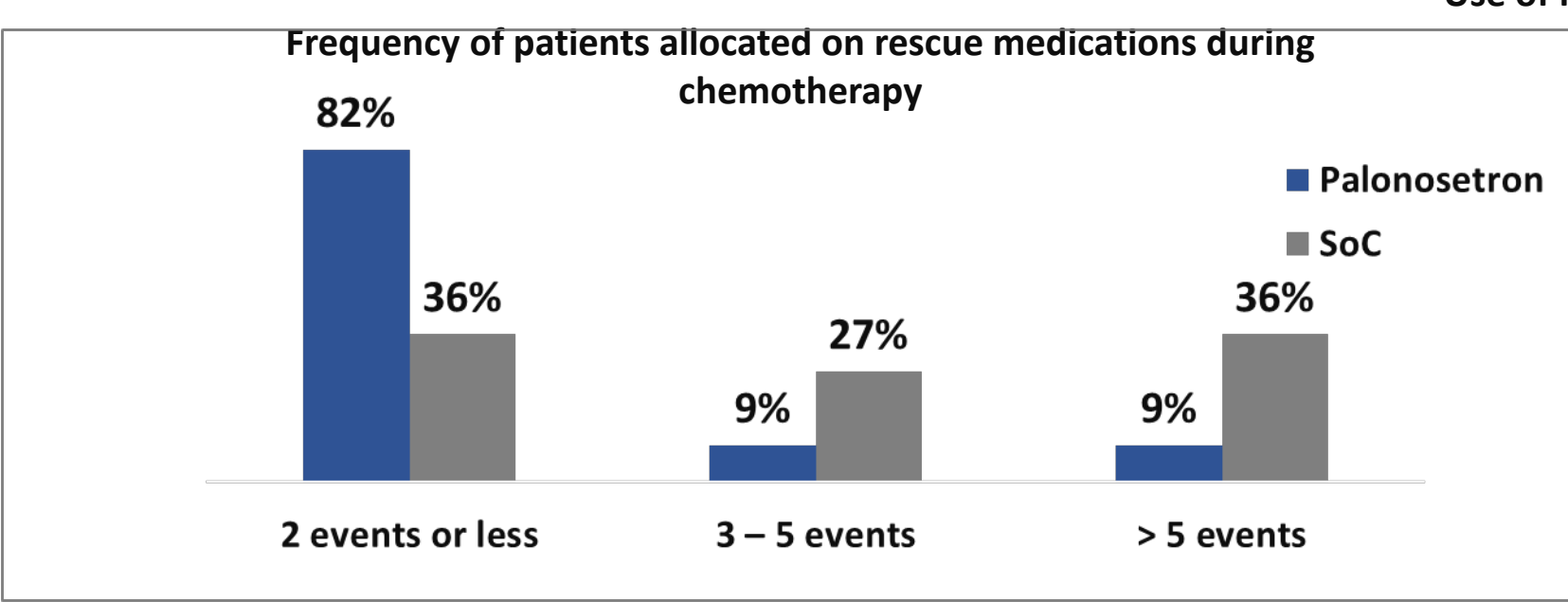
Factors impact the physicians during prescription of prophylactic anti-emetic



Factor	SoC (%)	Palonosetron (%)
Patients' socioeconomic status	8	8
Emetogenicity of chemotherapy	73%	64%
Patients' susceptibility to CINV	27%	36%

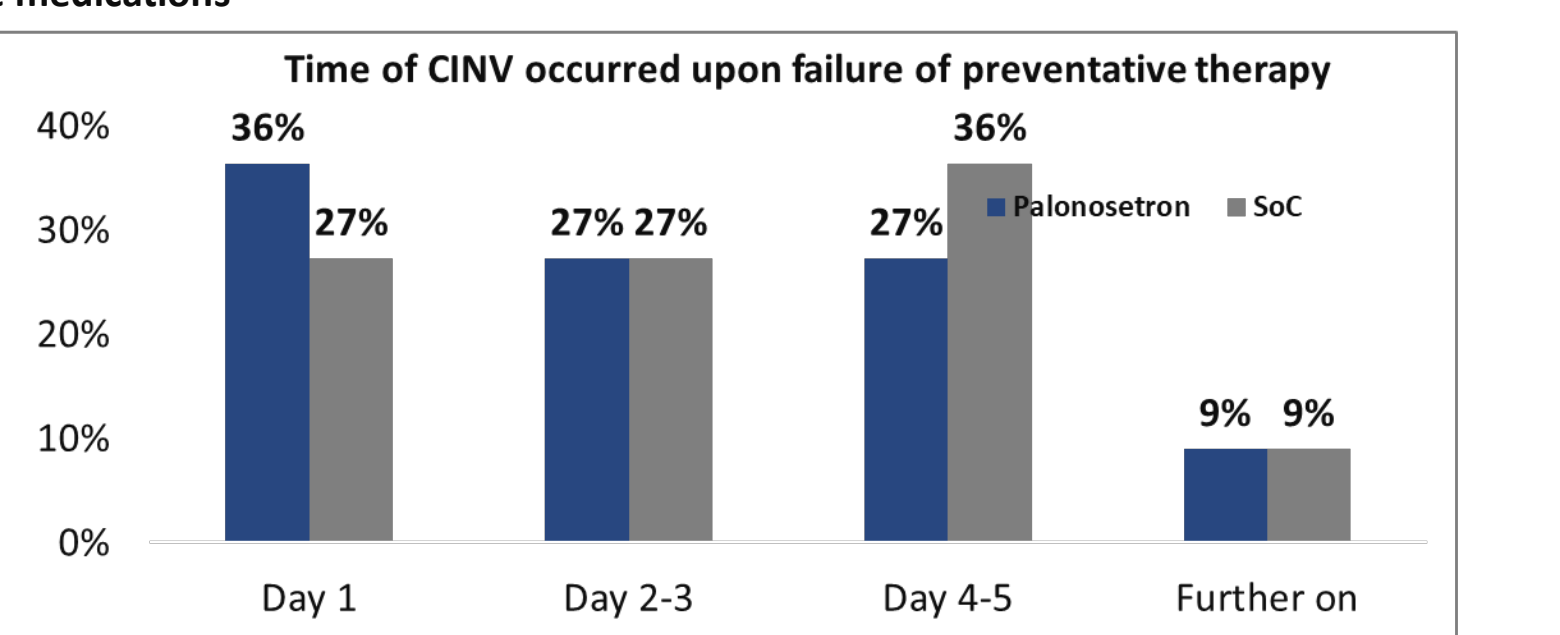
Use of rescue medications

Frequency of patients allocated on rescue medications during chemotherapy



Events	Palonosetron (%)	SoC (%)
2 events or less	82%	36%
3 - 5 events	9%	27%
> 5 events	9%	36%

Time of CINV occurred upon failure of preventative therapy



Time	Palonosetron (%)	SoC (%)
Day 1	36%	27%
Day 2-3	27%	27%
Day 4-5	27%	36%
Further on	9%	9%

Conclusion:

- The total score of ClinRO of palonosetron vs SoC in MEC were 21.4 vs 20 out of 27, respectively.
- In HEC, palonosetron compared to SoC generated a ClinRO score of 22.4 vs 20.1 out of 27, respectively.
- Administration of palonosetron as a prophylactic anti-emetic in ambulatory chemotherapy settings and assessment of its effect over specified HRQoL domains resulted in HRQoL improvement within H/MEC among different types of cancer compared to SoC in CINV.

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