High incidence of nausea during initial and repeated courses of intravenous chemotherapy in patients receiving guideline consistent anti-emetic prophylaxes – a prospective, observational, real-world study.

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Introduction

- Chemotherapy-induced nausea is now recognized as a specific clinical problem which is often not optimally treated [(1)]. It remains the most important unmet medical need regarding chemotherapy-induced nausea and vomiting (CINV) [(6)].
- For many years, CINV has been regarded as a single entity, however, there is a concern that vomiting have been the initial focus of anti-emetic research and nausea was perceived as a secondary endpoint [(2)].
- As one of the most serious treatment side effects in patients with cancer, CINV can significantly compromises patients' quality of life, but due to evidence-based research and guideline consistent CINV prophylaxis (GCCP), chemotherapy-induced vomiting can be prevented in the majority of patients [(3, 4)].
- Despite this, patients still experience nausea and its burden is often underestimated by the healthcare professionals [(3, 5)].

Materials & Methods

- This prospective, observational study included ninety-five patients receiving intravenous chemotherapy at a private oncology clinic.
- All subjects signed an informed consent document before commencing with the study.
- Chemo-naïve patients, as well as patients who have received prior chemotherapy, were allowed to take part. This broad inclusion of patients gave a review of 'real-life' experiences of patients.
- The study used visual analogue scales (VAS) and patient reported outcome measures (PROMs) to get data to resemble patients' experience as accurately as possible, and to ensure data was comparable between patients [(8)].
- This study focused on the incidence, intensity and duration of nausea in particular. The exact same format for the MASCC anti-emetic tool was used, but data was collected on a more frequent basis. By collecting the data in this way, it was expected that results seen, be as close to the real-life experience as possible.
- Patients were issued with standard antiemetic prophylactic therapy, and rescue medication was issued as per CINV guidelines [(7,9)].

Results

- One hundred subjects were enrolled over a seven-month period, of which 95 subjects' diaries were evaluable. The population consisted of 68 females (71.6%) and 27 males (28.4%). The median age of the group was 57 (ranging from 24 to 85) with a mean of age 57 years old. The emetogenicity of the chemotherapy received by the patients was 25 LEC patients (26.3%), 24 MEC (25.3%) patients and 46 HEC (48.4%) patients. The role of age, gender and motion sickness showed particular significance in the incidence of nausea, independently of the level of emetogenicity of chemotherapy received.

Table 1. The incidence, intensity, duration and time to first event of nausea during cycle 1, 2 and 3.

	Cycle 1	Cycle 2	Cycle 3
Incidence of nausea (overall phase) %	57,9	50,6	45,6
Time to first event of nausea (hours)	28,52	30,66	28,21
Intensity of nausea (VAS Score out of 10)	5,88	5,97	5,85
Intermittent nausea - Mean duration per episode (hours)	4,07	3,28	3,83
% Patients with Continuous Nausea	31,6	21,8	24,1

Incidence of nausea

- The incidence of nausea of the entire population was significantly higher than vomiting during all cycles of treatment.

Figure 1. The incidence of nausea vs the incidence of vomiting experienced by patients during cycle 1, 2 and 3.

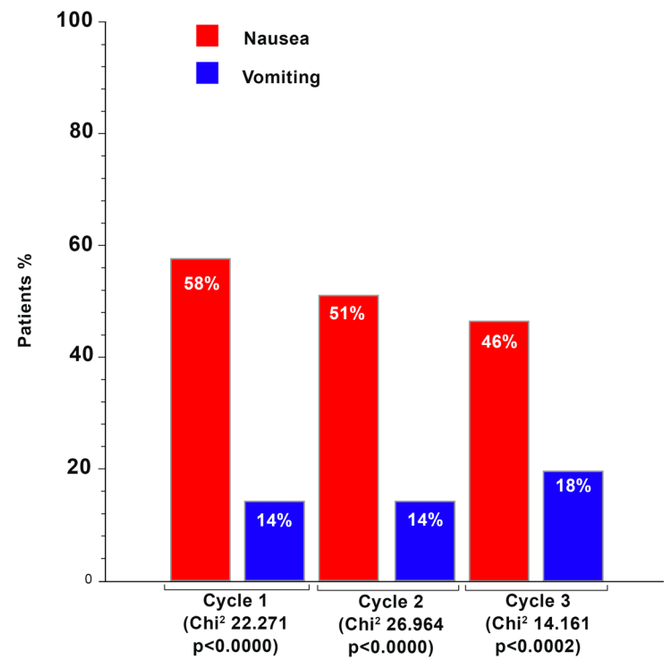
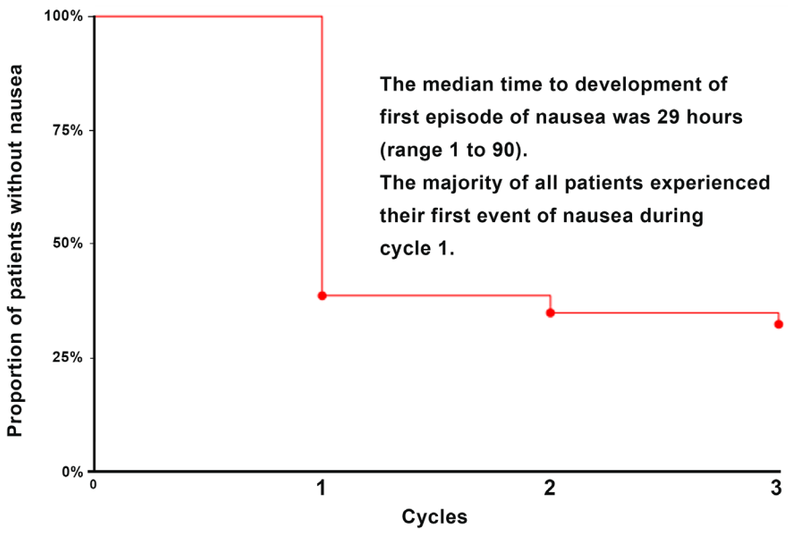


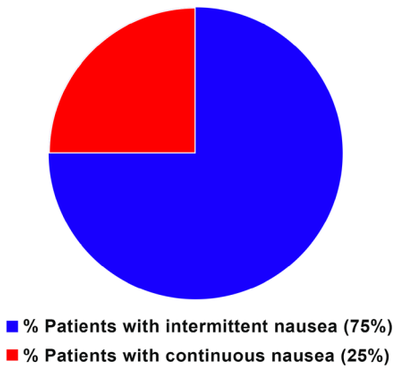
Figure 2. The proportion of patients without nausea during cycle 1, 2 and 3.



Continuous nausea vs intermittent nausea

- Nausea was continuous in 25% of the patients during all 3 cycles.

Figure 3. Proportion of patients with continuous nausea during treatment.

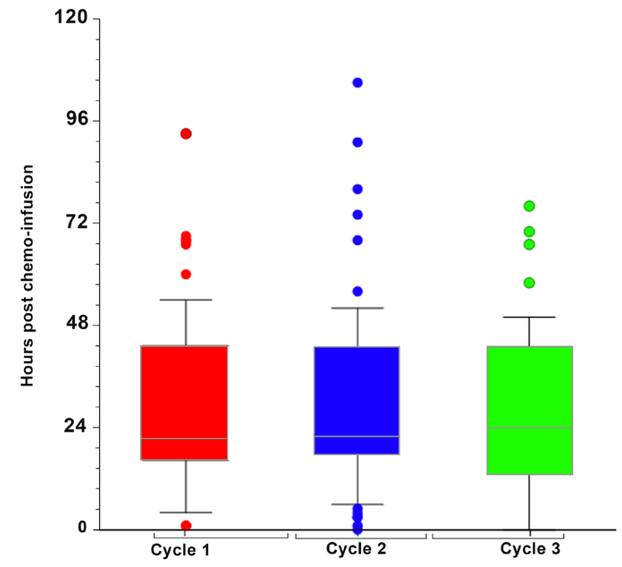


Duration and intensity of nausea

- For patients with documented intermittent nausea, the mean duration was 3.8 hours. The median maximum intensity of nausea was 6 (range 1-10) for all three cycles.

Time to first incident of nausea

Figure 4. Time to first incident of nausea experienced by patients during cycle 1, 2 and 3.



Risk factors impacting nausea

- Significant risk factors impacting nausea included age and history of motion sickness.

Figure 5. Age impacting the incidence of nausea during cycle 1, 2 and 3.

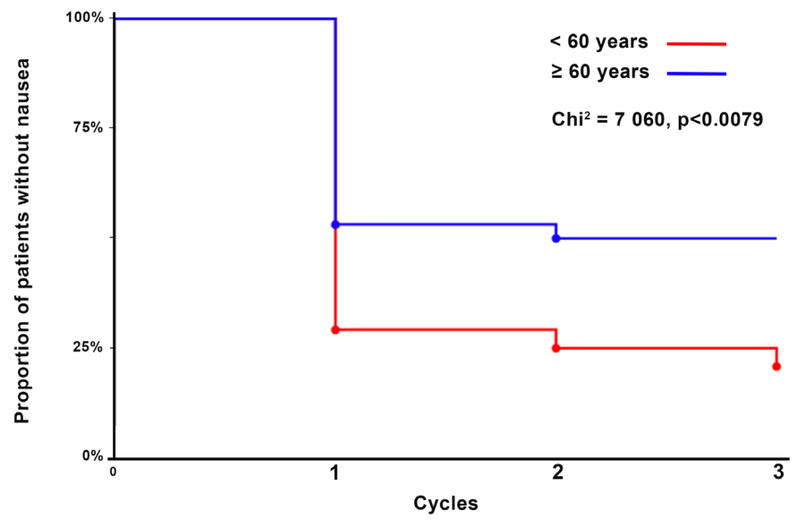


Figure 6. A history of motion sickness impacting the incidence of nausea during cycle 1, 2 and 3.

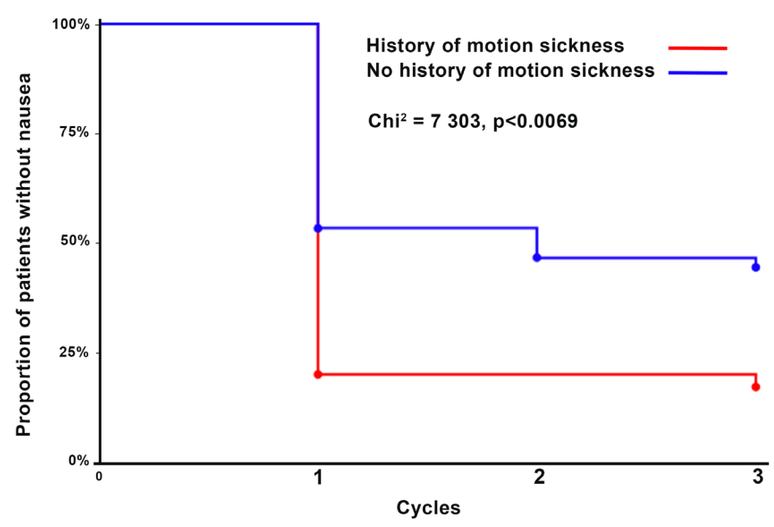
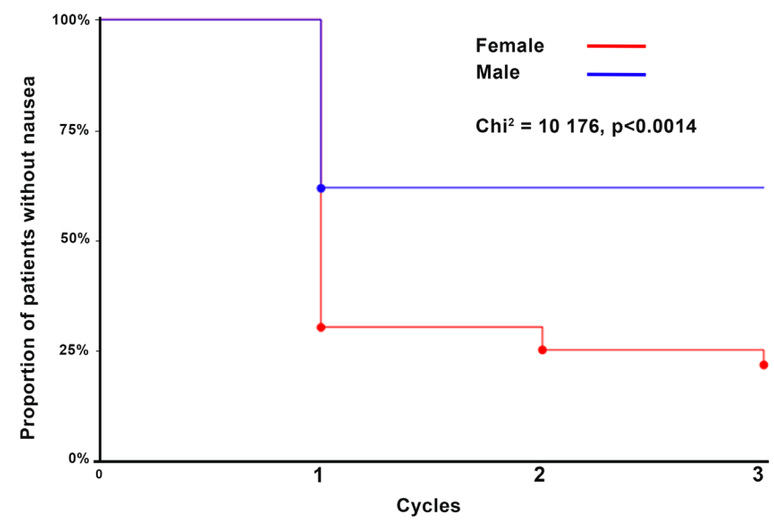


Figure 7. Gender impacting the incidence of nausea during cycle 1, 2 and 3.



Conclusion

- Despite the usage of guidelines consistent antiemetic prophylaxis, chemotherapy induced nausea remains a major unmet medical need in cancer patients. Further research should focus on treatment of nausea and patient's risk factors, as well as quality of life.

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