Dose Modification for Haematological Toxicity: A survey of Australian Medical Oncologists

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Abstract

Background: Evidence supporting *dose modifications to reduce serious* treatment-related adverse events *of antineoplastic therapy is limited and frequently based on clinical trial protocols*, which are not always generalisable to community patients. eviQ is an online resource with treatment protocols and recommendations for dose modification formulated by expert opinion and evidence-based review. Original recommended haematological thresholds to delay treatment were: neutrophil count $<1.5 \times 10^9/\text{L}$ and platelet count $<100 \times 10^9/\text{L}$.

Aim: To evaluate the current practices of Australian medical oncologists with regard to haematological dose modifications for antineoplastic treatments, and to determine rates of adherence to eviQ recommendations.

Methods: An online survey regarding haematological dose modifications was distributed to over 400 Medical Oncology Group of Australia members and eviQ medical oncology reference committee members via email. Responses were collated on 18 December 2017.

Results: 67% of 153 respondents indicated that they did not follow the eviQ haematological dose modification guidelines. 8% delayed curative intent treatment at neutrophil counts $<1.5 \times 10^9/\text{L}$, compared with 36% for palliative treatment; most delayed treatment at neutrophil counts $<1.0 \times 10^9/\text{L}$ (94% curative, 97% palliative respectively). 70% of clinicians delayed palliative treatment at platelet counts $<100 \times 10^9/\text{L}$, compared to 34% with curative treatment. No respondents indicated the original haematological cut off levels were too aggressive.

Conclusions: *The majority of responding medical oncologists indicated that they did not follow the eviQ haematological dose modification guidelines, which were viewed as too conservative. Subsequent to this survey, eviQ reviewed and updated haematological dose modification recommendations.*

Keywords

1. Antineoplastic agents
2. Drug prescriptions
3. Practice patterns, Physicians'
4. Neutropenia
5. Thrombocytopenia

Introduction

Dose modification of antineoplastic therapy is important to reduce treatment-related adverse events. The recommendations for dose modification vary across clinical trial protocols and different treatment regimens. Although clinical trial protocols have fixed thresholds for dose modification, these thresholds may not be best practice for the real-world patient population, who may have different characteristics to the trial patient population such as older age and more medical comorbidities. In practice, the balance between prevention of adverse events and reducing the therapeutic effect of treatment is not always clearly defined. There are no current internationally recognised guidelines for dose modification.

eviQ Cancer Treatments Online was established by the Cancer Institute of New South Wales (NSW), a NSW government agency, in 2009.¹ eviQ is a free online resource of evidence based, consensus driven cancer treatment protocols and information to be used at the point of care. Content is formulated by evidence-based review and expert opinion, and reviewed by practicing clinicians under a strict data governance framework.¹ eviQ includes information on antineoplastic drug administration, adverse effects and recommendations for dose modification.¹ Recommendations include dose modifications for haematological toxicity (table 1).

As attitudes to dose modifications have changed over time, this survey of Australian medical oncologists investigates clinicians' current attitudes and practice of dose modification in a real-world setting, and whether this is reflective of the eviQ recommendations. The primary intentions were for quality improvement and, if identified, to update eviQ guidance for dose modifications for haematological toxicity in line with current clinical practice.

Materials and Methods

eviQ content authors and the medical oncology reference committee chairs developed a survey using the online program "Survey Monkey". The survey was distributed to Medical Oncology Group of Australia (MOGA) members and eviQ reference committee members via email. The responses were collected between 1st December 2017 and 18th December 2017. Descriptive statistics were used. The significance of differences between respondents with different years of experience and title was determined by Fisher's exact test.

This study was approved by the Eastern Health Research and Ethics Committee.

Results

One hundred and fifty-three Australian medical oncologists participated in the survey, a response rate of approximately 25%. The respondents were consultant medical oncologists (86%) and medical oncology advanced trainees (14%) with varying years of experience (figure 1). The majority (71%) worked in public practice and 88% worked in a metropolitan setting. Oncologists from all Australian states and territories responded to the survey, except the Northern Territory. The majority of respondents were from New South Wales (36%), Victoria (30%), Queensland (12%) and South Australia (12%).

Sixty-seven percent of participants indicated that they did not follow the current eviQ haematological dose modification guidelines. The most common reasons for this stated in participant comments included overly conservative cut off levels (48%) and need to personalise modifications based on patient and treatment intent (23%). Participants were more willing to delay and/or dose reduce palliative treatment at a neutrophil threshold of less than $1.5 \times 10^9/L$ than curative treatment (36% and 8% respectively). The majority of clinicians delayed treatment at a neutrophil count of less than $1.0 \times 10^9/L$ (97% for palliative treatment, 94% for curative treatment). Thirty-four percent of clinicians delayed and/or dose reduced curative treatment at a platelet count of less than $100 \times 10^9/L$, compared to 70% for palliative treatment; whereas 98% of clinicians delayed and /or dose reduced treatment at a platelet count of less than $75 \times 10^9/L$ for both curative and palliative treatment (figure 2).

Respondents with 10 or less years of clinical experience were more likely to dose modify palliative treatment at a platelet count of less than $100 \times 10^9/L$ compared with those with more than 10 years

experience (81% vs 62%, $p = 0.02$). Similarly, trainees were also more likely to dose modify palliative treatment at a platelet count of less than $100 \times 10^9/L$ compared with consultants (95% vs 69%, $p = 0.02$). There were no differences in dose modification practices for neutrophil counts in the palliative setting or for curative treatment regimens (platelet and neutrophil counts) between respondents with different years of experience or title (table 2).

Discussion

Chemotherapy has a narrow therapeutic index.² The current method of treatment dosing using body surface area (BSA) is often inadequate as can readily be determined by drug levels and also unpredictable toxicities.^{2,3} BSA dosing does not account for inter-patient variation of drug metabolism and elimination processes, as well as potential interactions between concomitantly administered patient medications.^{2,3} The dose modification of antineoplastic therapy is integral to avoidance of morbidity and mortality in patients with cancer. However, dose intensity of antineoplastic therapy, defined as the amount of chemotherapy delivered per unit time, has been shown to have implications on long term patient outcomes such as disease-free survival and overall survival.⁴ This is particularly seen in curable cancers such as early breast cancer, where patients who received a lower dose intensity of chemotherapy have inferior disease-free survival⁵ and overall survival.⁶ Furthermore, prospective studies in early breast cancer have shown that dose dense chemotherapy, defined as a chemotherapy regimen in which drugs are given with less time between treatments than in a standard chemotherapy regimen,⁷ resulted in better overall and disease-free survival.^{8, 9, 10} This makes treatment dose modifications complex and individual nuances need to be considered.

Although there are international ¹¹ and Australian ¹² guidelines for safe prescribing, dispensing and administering antineoplastic therapy, these guidelines do not address when and how treatment should be dose modified. Currently, dose modification recommendations on eviQ reflect thresholds used in randomised control trial protocols, product information and reference committee consensus.¹ There is no universal agreement on what constitutes acceptable bone marrow function in clinical trials, with the treatment threshold for platelet and neutrophil count differing between clinical trials. As previously discussed, there is increasing evidence regarding the importance of maintaining dose density and dose intensity in the curative setting. Therefore, trial protocol thresholds have evolved over time. The availability of Granulocyte Colony Stimulating Factor (G-CSF) has also contributed to this change. In addition, clinical trials often include a select group of patients, with good performance status, which does not always reflect the real-world cancer patient population. Therefore, the incidence and severity of treatment induced toxicity reported in clinical trials may not reflect rates in routine clinical practice, and hence it is important to individualise dose modification to each patient. For example, an Australian retrospective study of 368 previously untreated women with early breast cancer, found that 24.3% of patients developed febrile neutropenia after one cycle of adjuvant docetaxel and cyclophosphamide (TC).¹³ This is compared to a much lower incidence of febrile neutropenia in the 2006 phase III trial comparing TC with doxorubicin plus cyclophosphamide (AC) in early breast cancer ¹⁴, and the 2013 phase II trial investigating adjuvant TC plus trastuzumab in HER2 amplified early breast cancer ¹⁵ (5% and 6.2% respectively). Supportive medications used in clinical trial protocols are not always reimbursed by the Australian pharmaceutical benefits scheme (PBS), contributing to further discrepancies in toxicity. However, the recent PBS reimbursement of Pegfilgrastim (G-CSF) for primary and secondary prophylaxis of febrile neutropenia in the patients

receiving chemotherapy with the intention of achieving a cure or substantial remission, may potentially now impact a clinician's decision to dose modify for neutropenia in this setting.¹⁶

The eviQ recommendations act as a resource to help aid decision making and are generally conservative with an emphasis on safety. These recommendations do not take into account the risk of administering treatment compared to the benefit of administering treatment for each individual patient. This survey demonstrates there are varying practices of dose modification of chemotherapy in Australia. More than half of the Australian oncologists who responded to the survey did not follow the eviQ recommendations.

This survey highlighted that clinicians felt the eviQ recommendations for haematological toxicity were too conservative, especially in curative settings. While many clinicians delayed palliative treatment at a neutrophil count of less than $1.5 \times 10^9/L$ and a platelet count of less than $100 \times 10^9/L$, fewer clinicians delayed curative treatment at these thresholds. This likely reflects the different goals of treatment between palliative antineoplastic therapy and curative antineoplastic therapy. In the setting of palliative antineoplastic therapy, where the goal of treatment is to prolong quality life but not cure, clinicians appear to place more emphasis on safety and avoidance of adverse events. Conversely, in the setting of curative antineoplastic therapy, clinicians appear to be more willing to accept the risk of treating patients at a lower haematological threshold if they are clinically well, to prevent compromising the therapeutic effect of their curative treatment.

As a result, the survey prompted the expert eviQ committees to discuss and review available evidence for dose modifications. This led to a significant change to the eviQ dose modification recommendations for haematological toxicity in the majority of the medical oncology treatment protocols, with the change taking effect on 8 May 2018.¹ The new recommendations aim to reflect

current clinical practice, and differ for curative treatment protocols and palliative treatment protocols (table 1).

For curative treatment protocols, the cut off level for treatment delay has remained at a neutrophil count of less than $1.0 \times 10^9/L$. However, for a platelet count of 75 to $100 \times 10^9/L$, it is now recommended to refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if the patient is clinically well. For a platelet count of less than $75 \times 10^9/L$, it is recommended to delay treatment until recovery. For palliative treatment protocols, the recommendation for a neutrophil count between 1.0 to $1.5 \times 10^9/L$ is to refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if the patient is clinically well. For a neutrophil count of less than $1.0 \times 10^9/L$, it is recommended to delay treatment. Similarly, for a platelet count of 75 to $100 \times 10^9/L$, the general recommendation is to delay, however if the patient is clinically well it may be appropriate to continue treatment; refer to treating team and/or local institutional guidelines. For a platelet count of less than $75 \times 10^9/L$, it is recommended to delay treatment until recovery.

While eviQ recommendations are a useful guide, they cannot account for individual patient, tumour and clinical factors. With advances in digital medicine and growing numbers of tumour-specific registries, the potential to measure outcomes compared to treatment dose in a real-world setting may become possible in the future, and thus provide a more accurate guide for dosing of anti-neoplastic treatment.

Conclusion

Prescribing and administering antineoplastic therapy requires a careful balance between the anti-cancer effect and treatment adverse effects. Evidence for dose modifications is limited, and often based on clinical trial protocols. Although eviQ provides a helpful guide, Australian oncologists are basing dose modifications on clinical judgement, and the situation of each individual patient. This survey demonstrated that clinicians felt the eviQ recommendations for haematological toxicity were too conservative. The survey has prompted a guideline review by the eviQ expert committee and a change to the eviQ dose modifications for haematological toxicity across a broad range medical oncology treatment protocols, implemented across the website.

Acknowledgments

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Figure 1. Clinical experience (years).

Figure 2. Neutrophil count and platelet count levels at which respondents delay or dose reduce treatment.

Table 1. EviQ recommendations for dose modification for haematological toxicity.

	CURATIVE		PALLIATIVE	
Level	Previous	Current	Previous	Current
Absolute neutrophil count (ANC) x 10⁹/L				
1.5 to 1.0	Continue treatment	Continue treatment	Delay until recovery	Refer to local guidelines. It is the view of the expert clinicians that treatment should proceed if the patient is clinically well
0.5 to 1.0	Delay until recovery	Delay until recovery	Delay until recovery	Delay until recovery
Less than 0.5	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction
Platelet count x 10⁹/L				

75 to 100	Delay until recovery	Refer to local guidelines. It is the view of the expert clinicians that treatment should proceed if the patient is clinically well	Delay until recovery	The general recommendation is to delay. However, if the patient is clinically well it may be appropriate to continue treatment; refer to treating team
50 to 75	Delay until recovery	Delay until recovery	Delay until recovery	Delay until recovery
Less than 50	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction	Delay until recovery Consider dose reduction

Table 2. Comparing responses by years of experience and title.

CURATIVE			
Absolute neutrophil count (ANC) x 10 ⁹ /L			
	1.5 to 1.0 % (n)	Less than 1.0 % (n)	P value
Years of experience			P = 1.0
0-10 years	8% (5)	92% (60)	
11 or more years	7% (4)	93% (57)	
Title			P = 0.15
Consultant	0% (0)	100% 106	
Trainee	5% (1)	95% (19)	
Platelet count x 10 ⁹ /L			
	75 to 100 % (n)	Less than 75 % (n)	P value
Years of experience			P = 0.46
0-10 years	29% (19)	71% (46)	
11 or more years	36% (23)	64% (41)	
Title			P = 0.79
Consultant	32% (38)	68% (80)	
Trainee	37% (7)	63% (12)	
PALLIATIVE			
Absolute neutrophil count (ANC) x 10 ⁹ /L			

	1.5 to 1.0	Less than 1.0	P value
	% (n)	% (n)	
Years of experience			P = 0.28
0-10 years	41% (27)	59% (39)	
11 or more years	31% (20)	69% (44)	
Title			P = 0.81
Consultant	37% (44)	63% (75)	
Trainee	40% (8)	60% (12)	
Platelet count x 10⁹/L			
	75 to 100	Less than 75	P value
	% (n)	% (n)	
Years of experience			P = 0.02
0-10 years	81% (52)	19% (12)	
11 or more years	62% (40)	38% (25)	
Title			P = 0.02
Consultant	69% (82)	31% (36)	
Trainee	95% (18)	5% (1)	

Figure 1. Clinical experience (years).

Figure 2. Neutrophil count and platelet count levels at which respondents delay or dose reduce treatment.

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