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Chemotherapy Safety Standards in the Developing World: is G CSF the Only Option?

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Editorial

The developing world poses a new set of challenges for the ever more demanding field of oncology. Not only that one has to cope with the concept of new treatments, there are different patient expectations and difficulties with compromised and limited services in remote areas. Issues such as language barriers, paucity of trained staff and lack of health educators are common and need to be kept in check before confirming any treatment options.

In this environment there are tough challenges like suitability for appropriate chemo regimen particularly in the palliative setting, safety of treatment delivery and monitoring. Furthermore there is little if any expertise available in remote areas that can cope with different treatment related toxicities. Combined with reluctance of people to travel considerable distances to reach medical facilities, problems are often overlooked and present at a stage too late for salvage. In this environment will it be safe to rely on measures such as G CSF only and a bigger question will this be enough?

In accordance with the available evidence, hematological toxicity from chemotherapy, neutropenic complications in particular are the most fearsome. This is counted to be the most common cause for serious events in chemotherapy related treatments as well as commonest reasons for hospital admissions as well as delay in subsequent chemotherapy cycles that can prove to be detrimental in patients overall outcome [1].

In line with the proposed guidelines NCCN as well as EORTC guidance updated in 2011, there are recommendations for prophylactic as well as therapeutic usage of G CSF. This is based on percentage risk of FN (febrile neutropenia) associated with a particular regimen. This has been classified as High risk based on the 20% or more incidence of FN with a known chemo regimen or Intermediate i.e. between 10-20% risks of FN. In addition there are identifiable patient related factors such as age and co morbidities that have also been suggested as important in decision algorithms for the use of G CSF [2-5]. Risk assessment dictates the approach to therapy, including the need for inpatient admission, IV antibiotics, and prolonged hospitalization Low-risk patients are defined as those who are expected to be neutropenic (absolute neutrophil count [ANC] <500 cells/microL) for ≤7 days and those with no comorbidities or evidence of significant hepatic or renal dysfunction. Most patients receiving chemotherapy for solid tumors are considered to be low-risk for complications requiring hospitalization or prolonging hospitalization.

High-risk patients are defines as those who are expected to be neutropenic (ANC <500 cells/microL) for >7 days. Patients with neutropenic fever who have ongoing comorbidities or evidence of significant hepatic or renal dysfunction are also considered to be high-risk, regardless of the duration of neutropenia. Along with Other criteria that confer a high-risk Some experts have defined high-risk patients as those expected to have profound neutropenia (ANC ≤100 cells/microL) for >7 days based on experience that such patients are the most likely to have life-threatening complications [2,3]. However, formal studies to clearly differentiate between patients with an ANC <500 cells/microL and ≤100 cells/microL are lacking An alternative to using the clinical criteria described above is to use the Multinational Association for Supportive Care in Cancer (MASCC) risk index, which is a validated tool for measuring the risk for neutropenic fever-related medical complications [5,6].

This is all well and good as far as prevention of hospital admissions and maintaining dose intensity is concerned, however, studies looking into the usefulness of the use of G CSF are clear on the fact that serious morbidity or deaths are not preventable by G CSF use. Under these circumstances, what factors will benefit the patients most of whom will be offered chemotherapy as palliative option for modest extension in life. It is difficult to ignore the fact that toxicities commonly related to chemotherapy leading to compromise in quality of life such as tiredness, nausea, poor taste, peripheral neuropathy etc will not benefit from G CSF intervention. Incidence of these common problems are far greater fear factors for the patients and a leading cause for declining or early discontinuation of chemotherapy. This begs the question, how do we improve on this particular predicament?

The answer is complex in its simplicity. Stating the obvious, education of the patients and monitoring of the effects with early intervention. This is a simple statement; however, its application to the practices in KSA will not be as simple. Recently, we undertook the task of auditing our prescribing practices for G CSF in patients attending our chemotherapy day unit as an outpatient. Purpose of this audit was to compare our prescribing practices in accordance with the published guidelines. Our finding were interesting and indicative of the concerns as outlined in this article. We found that more patients with intermediate to low risk of neutropenia, as defined by the NCCN and ESMO guidelines, irrespective of the co morbidities, age and factors such as use of polypharmacy as an indicator of their general health were prescribed G CSF. Duration of treatment varied between 3 to 7 days. This was dependent on the proximity of patient's residence to our center where a patient requiring longer travel are more likely to be prescribed longer duration of treatment.

Another factor identified that correlated well with over generous prescribing was the understanding and experience of the prescriber. Due to lack of available guidelines the prescribers, usually middle grade clinicians, would do so as a result of their personal views and perceptions which mainly revolved around medico legal issues and self-protectionism.

Another interesting revelation that emerged through the audit is that the dispensing of the G CSF injections was largely incorrect. Patients or the relatives who received the dispensed medications were provided these in plastic bags and not cool bags, in line with the product dispensing guidelines, where the correct temperature could be modulated. Otherwise in the usual 48-50 degrees Celsius summer temperatures viability of the medication cannot be guaranteed. It is perhaps due to this reason that despite generous prophylactic use of G CSF even in intermediate risk categories there was a slightly higher neutropenia rate.

As a model, Safer Chemotherapy guidelines as proposed by American Society of Clinical Oncology in association with Oncology Nursing society and National Health Service (NHS) National Chemotherapy Advisory Group (NCAG), have made specific recommendations [2]. This includes a team structure that will cater for all aspects of patients care at all levels of their treatment journey. This team should comprise of consultants, chemo nurses who are well versed in the management of cancer treatments, 24 hours accessible phone service manned by staff well experienced in chemotherapy treatments, primary care physicians who can be advised and can help manage patients concerns and last but not the least an acute oncology set up that can deal with complications arising as a consequence of treatments.

Suffice to say that only through these measures as well as setting of National standards and monitoring of outcomes from treatments offered can the safety goals be achieved. Question remains; how are we to achieve these targets in the developing systems?

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