10th Issue
July, 2018

# Onco News

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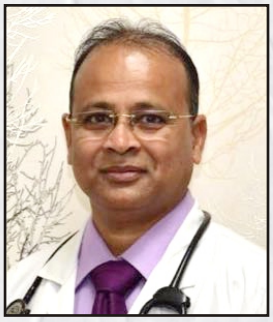
## *From the Desk of Editor*



Dear Readers,

Nowhere in the world, have technological advancements brought more relief than in the medical field Thanks to recent developments, diseases that were once considered fatal have now become more manageable, even curable, adding years to survival of the patients. One such disease that is now controllable is Multiple Myeloma (MM), the type of blood cancer that once instilled fear in mind of both doctors and patients alike but is now considered on par with any other chronic disease, with which the patient can survive for years with the effective treatment.

Putting in simple words, MM a heterogeneous, malignant plasma cell disorder characterized by renal insufficiency, anemia, bone lesions, skeletal destruction, and other systemic symptoms accounts for about 15% of all hematological malignancies and is the second most common hematological malignancy after Non-Hodgkins lymphoma. In India, every year about 6,800 new cases are reported with estimated 5,900 deaths per year. This issue will be focussed on current concepts in MM.

With regards
Dr. Naresh Somani
M.D., D.M.
Senior Medical Oncologist

**Introduction**

MM is a hematologic cancer characterized by clonal proliferation of plasma cells in the bone marrow, typically associated with a monoclonal component in the serum and/or urine. It is a slowly growing disease in most of the patients. Recent advances have made tremendous improvement in treatment.

**Pathobiology**

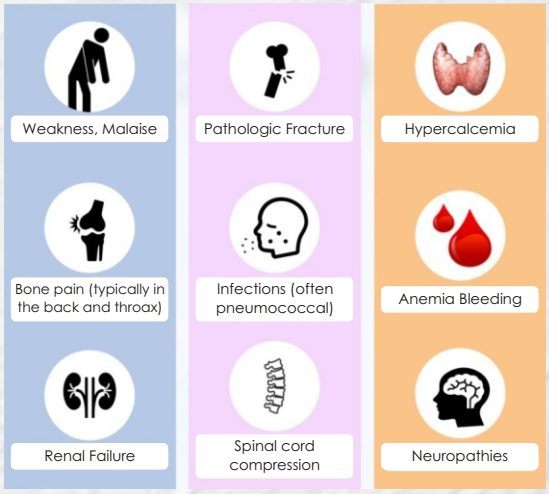
Although exact causes remain unknown, certain abnormalities and mutations in DNA cause plasma cells to become cancerous are known:

- In about half of all cases, chromosomal translocation turns on oncogenes;
- Another common finding is that parts of chromosome 13 are missing;
- In some patients interleukin-6 (IL-6) stimulates growth of plasma cells.

**Clinical features**

MM is difficult to diagnose early as there are no symptoms until at advanced stage:

- Bone involvement, causing pain, mainly in back, hips or skull; osteoporosis or plasmacytoma, or fracture.
- Low blood count, causing anemia, leukopenia or thrombocytopenia.
- Hypercalcemia, causing thirst, urinary problems, dehydration, constipation, abdominal pain, loss of appetite, weakness, drowsiness, confusion, coma.
- Kidney damage, causing weakness, shortness of breath, itching, or leg swelling.




**WHO SAID CANCER IS NOT CURABLE?**

P.T.O.

**Laboratory Tests**

When symptoms and clinical exam suggest MM, a number of tests are performed :

- **Blood and urine tests for monoclonal protein** An abnormal protein produced by the plasma cells, called a monoclonal (M) protein can be found in the blood or urine of almost all patients with MM, which helps establish the diagnosis.

  In some patients, "free light chains" (FLCs), which represent a small portion of the paraprotein, are secreted either in addition to the M protein or by itself. These can be measured by an assay called the free light chain assay. The assay measures the two types of free light chains, kappa and lambda, which are made by plasma cells, and provides a ratio of the two.
- **Bone marrow examination :** It shows that plasma cells comprise an abnormally high percentage of bone marrow cells (more than 10 percent).
- **Imaging:** This may include low-dose whole body computed tomography, positron emission tomography (PET)/CT, or magnetic resonance imaging (MRI). They are done at the time of diagnosis to look for bone changes.
- **Genetic and chromosomal tests :** Specialized tests may reveal genetic or chromosomal abnormalities of the plasma cells in individuals with MM. The results of these tests are helpful for predicting the response to treatment and survival.

**Diagnosis**

The diagnosis of MM requires the following:

A bone marrow aspirate or biopsy showing that at least 10 percent of the plasma cells or the presence of a plasma cell tumor (called a plasmacytoma), plus at least one of the following two features:

- **CRAB Signs:** Evidence of damage to the body as a result of the plasma cell growth, such as severe Bone damage, Kidney failure, Anemia, or high Calcium in the blood, and/or
- Detection of one of the following findings: ≥60 percent plasma cells in the bone marrow; free light chain ratio of 100 or more (provided involved FLC level is at least 100 mg/L); or MRI showing more than one lesion (involving bone or bone marrow).

**STAGING**

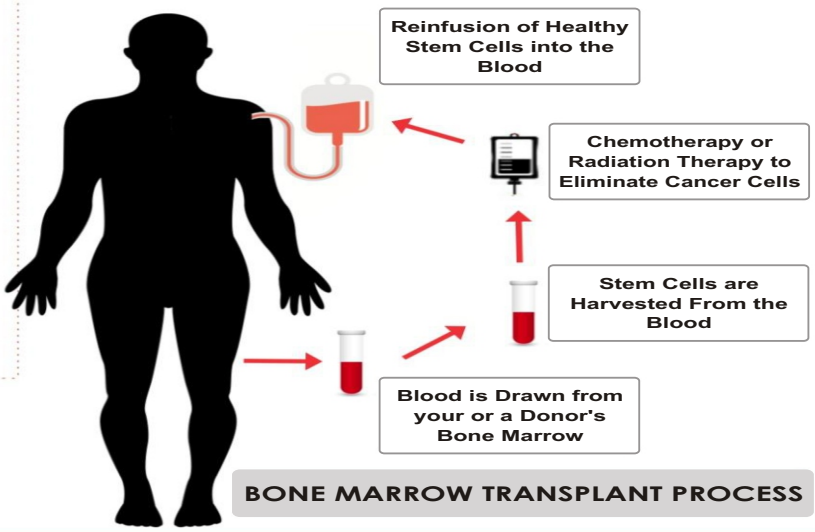
International Staging System for MM, which relies mainly on levels of albumin and beta-2 microglobulin in the blood, divides myeloma into three stages.

- Stage I: serum beta-2 microglobulin is less than 3.5 (mg/L) and the albumin level is 3.5 (g/dL) or greater;
- Stage II: neither Stage I or III, meaning either the beta-2 microglobulin level is between 3.5 and 5.5 (with any albumin level) or the albumin level is below 3.5 while the beta-2 microglobulin is less than 3.5;
- Stage III: serum beta-2 microglobulin is less than 5.5 (mg/L) or greater.

**Treatment**

While the disease till now has been considered incurable, stem-cell transplantation with high-dose chemotherapy has come as a boon to patients with its results in controlling the disease, stabilizing the malignant process and to extending survival, even by decades . Stem Cell Transplant provides a progression free survival of 50 months. Patients can undergo stem cell transplantation upto 65 years of age . Although for most patients, MM is never cured, appropriate treatment is based on staging. **Contd...**

**To a Multiple Myeloma Patient, SCT Provides a chance of improving progression free survival. Thus, turning a non-curable disorder into a curable disorder**




**In Lighter vain - Beware of reading health books ! You may die of misprint !!**

Contd.

Abbott

For the treatment of relapsed and refractory Multiple Myeloma,

℞ Pomahope

Pomalidomide Capsules 1 mg/2 mg/3 mg/4 mg

*Adding moments. Aiding lives.*

**More potent compared to Lenalidomide and Thalidomide[1]**

**Improved safety and convenience[2]**

**Deeper response[3]**

**Synergistic effect with Daratumumab (Anti CD38)[3]**


Page of Abridged Prescribing Information

**GENERIC NAME:** Pomalidomide capsule

**BRAND NAME:** Pomahope

**COMPOSITION:** Each capsule contains:
Pomalidomide ..... 1 mg/2mg/3mg/4 mg

**DOSAGE FORM:** Capsule

**INDICATIONS: Multiple myeloma**
Pomalidomide, in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

**DOSAGE AND ADMINISTRATION: Multiple Myeloma**
Females of reproductive potential must have negative pregnancy testing and use contraception methods before initiating Pomalidomide. The recommended starting dose of Pomalidomide is 4 mg once daily orally on Days 1-21 of repeated 28-day cycles until disease progression. Pomalidomide may be given in combination with dexamethasone. Pomalidomide may be taken with water. Inform patients not to break, chew, or open the capsules. Pomalidomide may be taken with or without food.

**CONTRAINDICATIONS: Pregnancy**
Pomalidomide can cause fetal harm when administered to a pregnant female. Pomalidomide is contraindicated in females who are pregnant. Pomalidomide is a thalidomide analogue, and is teratogenic in both rats and rabbits when administered during the period of organogenesis. If the drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

**WARNINGS AND PRECAUTIONS**
**Embryo-Fetal Toxicity:** Pomalidomide is a thalidomide analog as and is contraindicated for use during pregnancy. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. **Females of Reproductive Potential:** Females of reproductive potential must avoid pregnancy while taking Pomalidomide and for at least 4 weeks after completing therapy. Females must commit either to abstain continuously from heterosexual sexual intercourse or to use two methods of reliable birth control, beginning 4 weeks prior to initiating treatment with Pomalidomide, during therapy, during dose interruptions and continuing for 4 weeks following discontinuation of Pomalidomide therapy. Two negative pregnancy tests must be obtained prior to initiating therapy. The first test should be performed within 10-14 days and the second test within 24 hours prior to prescribing Pomalidomide therapy and then weekly during the first month, then monthly thereafter in women with regular menstrual cycles or every 2 weeks in women with irregular menstrual cycles. See Use in Specific Populations **Blood Donations:** Patients must not donate blood during treatment with Pomalidomide and for 1 month following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus runs a risk when exposed to Pomalidomide.
**Adverse drug reactions**
- Venous and Arterial Thromboembolism
- Hematologic
- Toxicity Hepatotoxicity
- Hypersensitivity Reactions
- Dizziness and Confusional State
- Neutropathy Cases of acute myelogenous leukemia
- Tumor Lysis Syndrome

**ISSUED ON:**
SOURCE: Prepared based on full prescribing information, Version 1.0 – dated 7th July, 2017

TM/ ™ Trademark of the Abbott Group of Companies.
For full prescribing information, please contact:
Abbott Healthcare Pvt. Ltd.
Angel Square, Bldg. No.04,
Gala No 1 to 5 & 11 to 15 Gr. Floor, 101 to 106 & 111 to 115, First Floor, 201 to 208 & 211 to 215, 2nd Floor, Pimpales Village, Shilvanadi, District Thane, Tal. Shilvanadi – 16 (Thane ZS).

For further information contact medical services division,
**Abbott Healthcare PVT. Limited,**
Floor 18, Godrej BKC, Plot No. C-68, BKC, Near MCA Club, Bandra (E), Mumbai - 400 051, India. Office: 022-38161757

INDPOM183117 18th June 2018 For the Use of an Oncologist only'


1. McCurdy AR, Lacy MQ. Pomalidomide and its clinical potential for relapsed or refractory multiple myeloma: an update for the hematologist. Ther Adv Hematol.2013;4(3):211–216. 2. Paludo J, et al. Blood. 2017;130(10):1198-1204.
3. Chari A, Suvannasankha A, Fay JW, et al.Daratumumab plus pomalidomide and dexamethasone in relapsed and/or refractory multiple myeloma. Blood. 2017;130(8):974-981

- Patients with solitary plasmacytoma may be treated with radiation or if it is not in the bone ,with surgery.
- Patients with early myeloma (smoldering or Stage I) may be watched closely, as early treatment does not seem to extend life. A bisphosphonate (e.g. zolidronic acid) or Denosumab may be prescribed if bone disease is present. Depending on other test results, patients with high risk of progressing to active myeloma may benefit for a time from lenalidomide and dexamethasone.
- Patients with active (symptomatic) myeloma (Stage II or III) or who have light chain amyloidosis are started on chemotherapy, often in combination with bisphosphonate treatment. Supportive treatment includes transfusions, antibiotics and all of which may relieve symptoms. Some patients receive stem cell transplant. Patients who undergo stem cell transplant often have consolidation treatment (additional cycles of chemotherapy). Some patients (with or without stem cell transplant) receive maintenance treatment to help delay the return of myeloma, but side effects should be considered.
- Today, we have 15 plus targeted chemotherapy drugs which tend to provide response to 90-92% of the myeloma patients. They are usually treated with combinations of drugs from two or three general classes like **immunomodulatory** drugs (lenalidomide, thalidomide, pomalidomide), **Proteasome inhibitors** (bortezomib, carfilzomib, ixazomib), **Steroids (**dexamethasone**), antibodies** that target myeloma cells (daratumumab or elotuzumab), **histone deacetylase inhibitor** (panobinostat) and **chemotherapy drugs** (melphalan, cyclophosphamide)

## Onco-Facts

1. Immuno-Oncology drugs have shown batter disease free survival than chemotherapy in first line treatment of the Non small cell lung cancer in certain subsets of patients.
2. 6 months of adjuvant trastuzumab is as effective as 12 months treatment in early stage breast cancer cutting cost and potential side effects.

## Nimotuzumab data Published in ASCO

**Dr. Somani's data gets International Presentation:**

Tumour response and survival of treatment naive head and neck cancer patients treated with nimotuzumab:

A systematic review and data analysis;

Get presentation in American Society of Clinical Oncology 2018. This is biggest platform of oncologists all over the world.

## *Upcoming conference of SoMex*

***2nd Annual Indian breast cancer conference***

***(International meeting ) on 5th to 7th October 2018.***

***For details log on www.ibccindia.com***

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## *Recent Activities of Somex Research & Health Pvt. Ltd.*

- SoMex will be organize CME on "Lung Cancer" on 20 July 2018.
- SoMex organized CME on "Epilepsy awareness talk for general public and felicitation of long term survivors of epilepsy" on 31 March 2018.
- CME and International speaker program on Management of metastatic Breast cancer on 17 th March 2018 .
- CME on "Immuno-oncology: Spreading Its Wings" on 4th March 2018.

**BOOK - POST**

To,_____

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*If undelivered please return to:*
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