



NewsLetter

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EDITORIAL

CAN WE PREVENT LITIGATION?

Rapid developments in the medical field in the last century have revolutionized the field of medical practice. Surgical treatment has moved towards less invasive modes of management with lesser morbidity and faster recovery. The medical fraternity is becoming more and more dependent on technology and market forces tend to influence decision making by the doctors. The fundamental values of medicine insist that the doctor's obligation is to keep the patients interest above everything else. The important issues of autonomy, confidentiality, justice, beneficence, and non maleficence are key factors that should guide the daily decision making by the doctor. There is also an allegation that the practice of modern medicine is becoming more impersonal, and with the increasing dependence on technology, the cost of treatment is rising. It is a fact that cannot be ignored that there is increasing dissatisfaction on the part of the patients who are expecting more and more from the doctors, leading to increasing incidence of litigation. The Medical Council of India has a redressal mechanism that can give punishment to the erring doctor after proper investigative procedures. The medical profession that was once considered noble is now considered along with other professions in the liability of paying for damages. The patients who want monetary compensation for the alleged medical negligence resort to the civil courts. However it has to be noted that the judicial bodies favor the patient who has suffered due to the negligent action of the doctors. All actions that are done in good faith may not stand legal testing. Malpractice claims against physicians are always initiated entirely by patients or their families. The patients who file against their doctors believe the physicians have caused them to suffer by performing injudiciously, ineptly, or negligently. Injured patients make an inexperienced, perhaps emotional judgment about the cause of their misery, and some respond by seeking legal redress. Most injured patients who contact CPA lawyers have had problematic relationships with their doctors. Many of them have high unpaid medical bills, and many have been advised by other health care professionals to seek lawyers.

Question is can we prevent litigation?
Answer is Yes!

Improvement in communication could avert a malpracticesuit. Postoperative surgeon's behavior perceived as insensitive or dismissive provokes a desire for retribution. While revenge is an immature emotional response, it is one of the most powerful personal motivations. Some litigants receive no explanation from their doctors for their injuries, and 85% of those who have been given explanations believe it is inadequate, or untrue and served only the doctor's interest. Seventy

percent of patients who file malpractice claims against their doctors say they did so because of bad interpersonal relationships with them. The perceived impressions include feelings of abandonment (32%), disrespect of patient and/or family views (29%), poorly delivered information (26%), or failure to understand the patient and/or family perspective (13%). Fifty four percent of malpractice suits are encouraged by other health professionals. The evidence is pretty clear in its consistent suggestion that a failure to establish reasonable rapport with patients and their families by meeting their emotional needs during a time of crisis and apprehension stimulates resentment and an impulse to lash out. Patients, not lawyers initiate medical malpractice actions. Poor physician communication skills are more likely than any other single factor, including actual bad medical practice, to precipitate a patient lawsuit. Surgeons are simply not among the most sensitive of doctors and are not well trained to recognize their patients' emotional needs. A recent study examined whether patients dropped hints about their anxieties during routine interactions with their doctors. Surgical patients averaged 1.9 indirect suggestions per visit that they wanted to more deeply discuss some aspect of their medical condition, but in only 38% of these cases were the clues adequately recognized and followed up. Most patients and their families are accepting, forgiving, and even consoling towards their physicians when faced with dreadful complications or the death of a loved one.

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ART OF TREATING MULTIPLE MYELOMA

Multiple myeloma is a clonal plasma cell malignancy that accounts for slightly > 10% of all hematologic cancer and 1% of all cancer. It usually evolves from an asymptomatic premalignant stage of clonal plasma cell proliferation termed “monoclonal gammopathy of undetermined significance” (MGUS) to intermediate asymptomatic but more advanced premalignant stage termed as Smoldering multiple myeloma (SMM).

The majority of patients with myeloma present with symptoms related to organ involvement (hypercalcemia, renal insufficiency, anemia, & bone lesions) (CRAB).

Overall survival in multiple myeloma is affected by host characteristics, tumor burden (stage), biology (cytogenetic abnormalities), and response to therapy. Tumor burden in multiple myeloma now is done by R-ISS staging. The Revised International Staging System (RISS) combines elements of tumor burden (ISS) and disease biology (presence of high risk cytogenetic abnormalities or elevated lactate dehydrogenase level), to create a unified prognostic index that helps in clinical care.

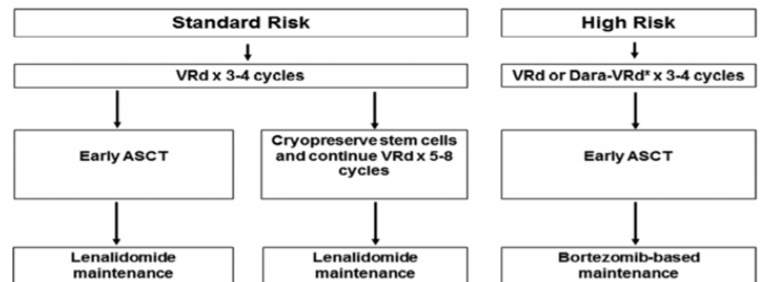
Treatment

The approach to treatment of symptomatic newly diagnosed multiple myeloma is dictated by eligibility for ASCT and risk-stratification

Initial treatment in patients eligible for ASCT

The optimal regimen & number of cycles remain unproven. However, at least three to four cycles of induction therapy including an immunomodulatory drug, proteasome inhibitor (PI), & steroids is advised prior to stem-cell collection. Chronologic age and renal function should not be the sole criteria used to determine eligibility for SCT. Up-front transplant should be offered to all transplant-eligible patients. Delayed initial SCT may be considered in select patients. Agents associated with stem-cell toxicity, such as melphalan and/or prolonged immunomodulatory drug exposure (more than four cycles), should be avoided in patients who are potential candidates for SCT. Ample stem-cell collection (sufficient for more than one SCT) should be considered upfront, due to concern for limited ability for future stem-cell collection after prolonged treatment exposure. The level of minimal response required to proceed to SCT is not established for patients receiving induction therapy—patients should be referred for SCT independent of depth of response. High-dose melphalan is the recommended conditioning regimen for ASCT. Tandem ASCT should not be routinely recommended. Lenalidomide maintenance therapy should be routinely offered to standard-risk patients starting at approximately day 90 to 110 at 10 to 15 mg daily until progression.

A minimum of 2 years of maintenance therapy is associated with improved survival, and efforts to maintain therapy for at least this duration are recommended. For high-risk patients, maintenance therapy with a PI with or without lenalidomide may be considered. The quality and depth of response should be assessed by International Myeloma Working Group (IMWG) criteria. Allogeneic transplant for multiple myeloma is not routinely recommended but may be considered in select high-risk patients or in the context of a clinical trial. The goal of initial therapy for transplant-eligible patients should be achievement of the best depth of remission. MRD-negative status has been associated with improved outcomes, but it should not be used to guide treatment goals outside the context of a clinical trial.



VRd- bortezomib, lenalidomide, dexamethasone
Drd- daratumumab, lenalidomide, dexamethasone

Initial treatment in patients ineligible for ASCT

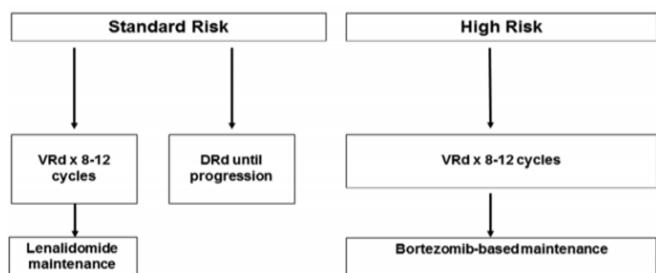
Initial treatment of patients with multiple myeloma who are transplant ineligible should include at minimum a novel agent (immunomodulatory drug or PI) and a steroid if possible. Triplet therapies for patients with multiple myeloma who are transplant ineligible, including bortezomib, lenalidomide, dexamethasone, should be considered. Daratumumab plus bortezomib plus melphalan plus prednisone may also be considered. Continuous therapy should be offered over fixed-duration therapy when initiating an immunomodulatory drug or PI-based regimen. The goal of initial therapy for transplant-ineligible patients should be achievement of the best quality and depth of remission. Depth of response for all patients should be assessed by IMWG criteria. It is recommended that patients be monitored closely with consideration of dose modifications based on levels of toxicity, neutropenia, fever/infection, tolerability of adverse effects, performance status, liver and kidney function, and in keeping with the goals of treatment.

Results of few randomized trial in newly diagnosed MM

Trial	Regimen	Patients (n)	ORR	CR+VGPR	PFS (in months)	P	OS (in months)	P
Durie et al	Rd VRd	229 242	72 82	32 43	31 43	0.002	64 75	0.025
Attal et al	VRd VRd-asct	350 350	97 98	77 88	36 50	<0.001	NR (82% at 4 year) NR (81% at 4 year)	0.87
Facon et al	Rd Drd	369 368	81 93	53 79	32 NR (71% at 30 mon)	<0.001	NR NR	N/A
Mourou et al	Vtd Dara-vtd	542 543	90 90	78 83	NR (85% at 30 mon) NR (93% at 30 mon)	<0.001	NR (90% at 30 mon) NR (96% at 30 mon)	<0.05

Result of few randomized studies in relapsed MM

Trial	Regimen	Patients (n)	ORR	CR+VGPR	PFS (in months)	P	OS (in months)	P
Stewart et al	Rd Ikd	396 396	67 87	14 32	18 26	<0.0001	40 48	0.04
Dimopoulos et al	Rd Drd	283 286	76 93	44 76	18.4 NR	<0.001	NA NA	NS
Palumbo et al	Vd Dvd	247 251	63 83	29 59	7.2 NR	<0.001	NA NA	0.3
Lonial et al	Rd Elo-rd	325 321	66 79	28 33	15 19	<0.001	40 44	NA
Moreau et al	Rd Ird	362 360	72 78	7 12	15 21	0.012	NA NA	NA
San Miguel et al	Vd Pano-vd	381 387	55 61	6 11	8.1 12	<0.0001	36 40	0.54
Attal et al	Pd Isa-Pd	153 154	35 60	9 32	6.5 11.5	<0.01	NR NR	0.06
Dimopoulos et al	Vd Ikd	465 464	63 77	6 13	9 19	<0.0001	40 48	0.01

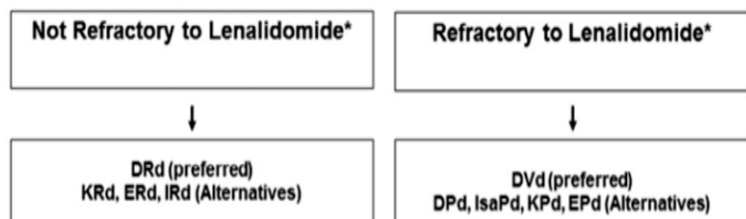


VRd - bortezomib, lenalidomide, dexamethasone
DRd - daratumumab, lenalidomide, dexamethasone

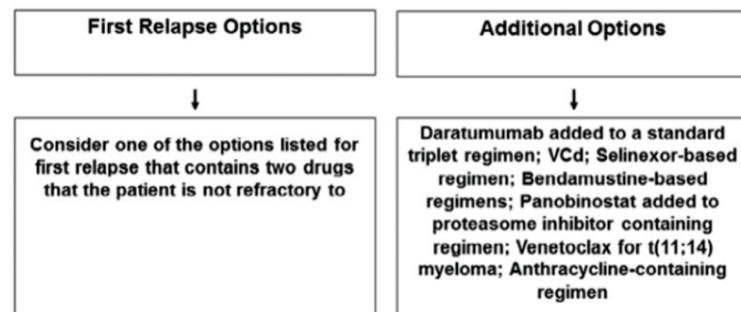
Treatment of relapsed disease

Treatment of biochemically relapsed myeloma should be individualized. Factors to consider include patient's tolerance of prior treatment, rate of rise of myeloma markers, cytogenetic risk, presence of comorbidities (ie, renal insufficiency), frailty, and patient preference. High-risk patients as defined by high-risk cytogenetics and early relapse post-transplant/initial therapy should be treated immediately. Close observation is appropriate for patients with slowly progressive and asymptomatic relapse. All clinically relapsed patients with symptoms due to myeloma should be treated immediately defined by high-risk cytogenetics and early relapse post-transplant/initial therapy should be treated immediately. Close observation is appropriate for patients with slowly progressive and asymptomatic relapse. Triplet therapy should be administered on first relapse, though the patient's tolerance for increased toxicity should be considered. Treatment of relapsed multiple myeloma may be continued until disease progression. ASCT, if not received after primary induction therapy, should be offered to transplant eligible patients with relapsed multiple myeloma. Repeat SCT may be considered in relapsed multiple myeloma if progression-free survival after first transplant is 18 months or greater.

First Relapse



Second and Subsequent Relapse



Emerging Options

There are several investigational approaches that are promising and patients should be considered for clinical trials investigating the se approaches. Two of the most exciting options include antigen receptor T cells (CAR-T) targeting B cell maturation antigen (BCMA) such as bb2121, 159 and belantamab mafodotin (a humanized anti-BCMA antibody that is conjugated to monomethyl auristatin-F, a microtubule disrupting agent). Another option that is promising is the use of bispecific T cell engager, such as AMG 701.

We at Rajiv Gandhi Cancer Institute and Research Centre has been doing autologous stem cell transplant since 2003 and till now we have done approximately 200 autologous stem cell transplant for multiple myeloma. Our results match international standard of care and we have published our data in journal of 'Clinical lymphoma myeloma & leukemia, February 2017'.

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XERODERMA PIGMENTOSUM



A 12 year old, bright, school going, active boy gave history of swelling over right cheek of 6 months' duration, parents also gave us classic history of child having normal skin till age of 2 years and noted the pigmentation problem thereafter.

There was no history of consanguinity, nor similar family history. On examination multiple small pigmented lesions were seen all over the exposed surface of skin of face, neck, upper chest, upper back and hands, he also had conjunctival lesions.

There was also a 3x3x6 cm polypoidal swelling in the right preauricular region with bleeding spots, with melanoma as primary diagnosis

Wide local excision with full thickness grafting was done under TIVA (Total Intravenous Anaesthesia) safeguarding the buccal, orbital branches of the facial nerve. Final histopathology was melanoma, all margins are free with multiple basal cell carcinoma lesions in the cuff of skin removed for wide excision

Xeroderma pigmentosum (XP) is an autosomal recessive, genetic disorder, in which there is a decreased ability to repair DNA damages. The basic defect in XP is a nucleotide excision repair (NER), leading to deficient repair of DNA damaged by UV radiation. Two types of NER exist: Global genome (GG-NER) and transcription coupled (TC-NER). These patients have high risk of skin cancer at an early age and Cataracts, which can all be treated in the usual way. They also have multiple anaesthetic complications related to gaseous General Anaesthetics, hence TIVA is the only choice

Treatment involves completely avoiding the sun, protective clothing, sunscreen, dark sun glasses, retinoids cream, Vitamin-D supplementation and genetic counselling.

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EDITORIAL

A study of 14,700 medical records in USA found that 97% of people who were negligently injured did not sue the responsible physician. The low rate of patients injured by medical errors who go on to sue is partially attributable to their not knowing how they were hurt. A physician's apology, when appropriate, was perceived as soothing and reassuring of integrity and beneficent intentions. We have all seen how many times a young surgeon, having borne the extraordinary intellectual and physical burdens of medical school and residency, has had his pride and self-assurance metastasize into arrogance. Unlike many of our colleagues in specialties like psychiatry and family medicine, surgeons seldom have an opportunity to establish extended relationships with their patients, and the trust they have in us is based largely upon confidence in our credentials and their respect for our profession. The limited opportunity to know our patients personally, and for them to know us, means that we must be more sensitive to their emotional needs, particularly because our invasive and usually painful therapies almost always mobilize more patient anxiety than the treatments offered by nonsurgical specialists. If some doctors are the best, there will inevitably be some who are among the worst. People who never mastered the communication craft but accumulated medical knowledge, create more problems for themselves and for their profession.

Message is communicate! Communicate! And Communicate. Let the Communication with patients be held by senior doctor and not juniors/residents. Senior doctor should have the patience to listen more than talk. Never argue with caregivers / relatives.

Dr. Thomas Percival (1740 to 1804), the father of modern medical ethics, argued that an essential component of the development of medicine as a profession should be the physician's acceptance of the healer's training and role as a social contract. Percival advocated removal from the profession of those who are unwilling or unable to work in a fiduciary capacity: "Let both the Physician and Surgeon never forget that their professions are public trusts. State medical boards, in their disciplinary roles, however focus and act upon physicians substance abuse, improper prescriptions, and sex with patients far more than upon demonstrable malpractice. These charges are much less defensible. The present dilemma provides an opportunity for professional medical associations to shift the balance from self-interest to the interests of patients, thereby regaining public support and influence". Let the professional bodies or medical community rather than judiciary (CPA) address medical negligence issues. Judging from recent trends, it is an opportunity for the professional associations and the state boards that they fulfill their mutual goals of protecting the public by insuring the integrity of the medical profession.



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