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Editorial

## Can we Afford not to Afford Treatment of Multiple Sclerosis in India?

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### Introduction

Multiple sclerosis (MS) is a chronic neurological disease which affects men and women in the prime of their youth. The disease can present in relapsing-remitting, secondary progressive, progressive relapsing and primary progressive forms and leads to increasing disability during the course of the patient's lifespan. Symptoms such as muscle weakness, gait and balance problems, coordination problems, visual impairment, diplopia, bladder and bowel disturbances, sensory symptoms, cognitive dysfunction and fatigue can be disabling at times and lead to poor health related quality of life, neurological disability and high health care costs. Progressive disease can be particularly disabling leading to a wheel chair dependent on caregivers for activities of daily living. In India; till a few years ago, MS was thought to be rare and a disease of the Western hemisphere. It is unclear why now we are seeing more and more MS patients in India. Is it because with advances in health care and diagnostics, we are diagnosing more cases which earlier remained undiagnosed or is the incidence of this disease actually increasing in the Indian population? This still needs to be determined and it would behoove us well to start a national MS registry and keep a track of MS cases and co-register with dietary and environmental variables. Many low and middle income countries such as India have a huge population with limited accessibility and affordability to health care facilities. About 70% of India's 1.3 billion population lives in rural areas with 30% living below the poverty line. In a country like India, a disease like MS can have a particularly devastating impact not just because of its chronicity and propensity to affect the young but also due to its high treatment cost burden.

A study published in April, 2015 found that the cost of first generation disease modifying medications for MS increased from between \$8000 to \$11000 annually in the 1990's too approximately between \$60000 to \$90000 per year currently. Newer disease modifying MS drugs cost even more. In the west, patients with MS commonly pay for their MS treatment in one of the following ways:

- I. Job (employer) based health insurance plan.
- II. Individual health insurance plan.
- III. Medicare.
- IV. Medicaid or state children's health insurance program.
- V. Other state and federal government funded programs for the uninsured and underinsured.

In India, where illiteracy, unemployment and poverty remain major social problems, state and federal supported health insurance schemes benefit only a small fraction of the population. As in India at present there is no National Health Insurance program, patients have to pay out of pocket for health care. The purpose of writing this commentary is to draw attention to the cost burden associated with a chronic disease like MS and start a discussion on treatment solutions that may benefit our MS population without causing unbearable financial burden. We calculated the average health care cost to a patient who is first time admitted for any demyelinating disease, in a corporate health care institution. A patient with spastic paraparesis was admitted to Sir Ganga Ram Hospital (SGRH) with provisional diagnosis of acute myelitis later confirmed as MS. We found that the entire hospitalization cost him around Rs.1.8 lac (\$2560).

### Breakdown of Costs

#### Investigations

- I. Contrast enhanced MRI brain and cervical spine (Rs. 26000/\$416).
- II. Visual evoked potential (VEP) (Rs. 2000/\$32).
- III. Lumbar puncture (CSF analysis) (Rs. 8000/\$128).
- IV. Ancillary investigations like autoimmune encephalitis panel (Rs. 40000/\$464).

#### Treatment Costs

Pulse IV steroid therapy x 5 days (Rs. 70000/\$1120).

#### Hospital Stay Costs

Room cost plus ancillary expenditure (Rs. 70000/\$1120).

It is important to remember that this is the financial burden borne out of pocket by an average middle class patient admitted to SGRH. Patients who live below the poverty line cannot afford such costs and the financial burden forces family members to take loans or at times sell their home and property to pay for the treatment. Unlike a case of post infectious myelitis, a patient with MS may suffer an acute exacerbation or relapse leading to another hospitalization and additional costs. The various MS disease modifying agents are so expensive that few patients in India can afford the drugs. Many as a result discontinue treatment regimens and self medicate with medications such as oral steroids.



We also calculated the average cost to the patient of various disease modifying agents available in India.

- I. Injectable DMT's like Avonex (beta interferon) given at a dose of 30mcgI/M once a week costs Rs. 30000/\$480 dollars monthly.
- II. Copaxone (glatiramer acetate) Rs. 20000/\$320 monthly.
- III. Mitoxantrone Rs. 400/\$5 per vial.
- IV. Tysabri (natalizumab) costs a whopping Rs. 1,40,800/\$2184 monthly.
- V. Oral DMTs like fingolimod costs around Rs. 3,00,000/\$4790 dollar for 30 capsules, teriflunomide Rs. 2,90,000/\$4500 for 1 month supply, and dimethyl fumarate Rs. 3,40,000/\$ 5300 for 1 month supply.
- VI. Azathioprine costs Rs. 600/\$9.6 per month.

The per capita income in India is estimated at just short of Rs. 6000 per month which equals \$90 per month. That means the per capita income for a family of 4 would be less than \$400 a month, but the reality is that most people live on much less than that and struggle to provide for the basic needs of food, clothing and shelter. Both the interferon's and the oral DMTs are accessible to only a few in India due to their exorbitant cost. As a result, many Indian MS patients cannot afford treatment and are left behind untreated with significant neurological disability impairing their quality of life. In India, where it is estimated that around 100,000-200,000 people have MS, finding cost effective treatment options is very important.

### What are the Solutions?

- i. Methylprednisolone (Solumedrol) is an effective drug used to treat an acute attack of MS. Once the diagnosis of MS is confirmed, and patient presents to the hospital with an acute exacerbation, first dose of methylprednisolone can be administered in the emergency department followed by rest of the doses at home. The outpatient administration can be carried out by trained nurses via patient outreach programs. This will greatly reduce the cost of treating an acute attack of MS without requiring admission.
- ii. An initial MS diagnostic and treatment package should be constituted, including all the necessary initial investigations and treatment. This shall help drive down the initial costs incurred by patients and family members.
- iii. A MRI package should be constituted. This should include the cost of MRI brain and cervical spine imaging at least once a year and help in reducing the diagnostic cost associated with repeated neuroimaging in patients with MS.
- iv. A National Health Insurance scheme geared towards chronic neurological diseases such as MS should be formulated. While many good insurance schemes have been recently launched by the government, unfortunately they remain on paper only.

- V. Pharmaceutical companies manufacturing and marketing MS drugs should be approached by the government and the cost of MS drugs should be negotiated so that more patients can afford these medications and avail their benefits. Recently 3 Indian pharmaceutical companies have launched generic versions of Tecfidera (dimethyl fumarate) costing under Rs.4000/month. Intas pharmaceuticals generic version of Aubagio (teriflunomide) costs only Rs. 2000/month.
- vi. There are various studies documenting the effectiveness of azathioprine in MS patients. A multicentre randomized non inferiority trial was conducted comparing azathioprine vs beta interferon's for relapsing remitting multiple sclerosis and it was found that efficacy of azathioprine is not inferior to that of beta interferon for patients with relapsing remitting multiple sclerosis. Massacesi et al. [1] conducted a study evaluating the efficacy of azathioprine therapy on new brain lesions evaluated using magnetic resonance imaging and concluded that azathioprine administered at lymphocyte suppressing doses, is effective in reducing MS new brain inflammatory lesions and is well tolerated [2]. In a study by Casetta et al.in 698 patients with MS, it was concluded that azathioprine is a fair alternative to interferon beta for treating MS patients [3]. In SGRH, we have around 20 patients with MS who are on azathioprine for the past 10 years, doing well and tolerating the medication well. Considering the convenience of oral administration, low cost and good efficacy, azathioprine may represent an alternative to interferon and oral DMTs. This should be studied further in the Indian context.

### Conclusion

In India, there is a large unmet disease burden of MS. We can't afford not to afford the treatment of MS in India as it affects our young population who are the backbone of our nation. To tailor to the requirements of the Indian population, drug trials with large sample size using cheaper drugs such as azathioprine are needed. Large academic medical centers in India should take the lead in this initiative and run head to head trials of azathioprine against more established injectable and oral DMT's.

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