INTRODUCTION

RA is a complex autoimmune inflammatory disorder with several articular and extra-articular manifestations. Despite several advances in the therapeutic management as a result of biologic response modifiers (biologic disease modifying antirheumatic drugs/DMARDs), RA continues to be difficult to treat disorder. Often progressive, it is a life long disease. If uncontrolled, it leads to disabling articular deformities and reduced quality of life and longevity. The global prevalence is considered to be 1% though WHO ILAR Bone and Joint Decade India COPCORD (community oriented program for control of rheumatic diseases) community surveys at multiple sites all over India covering a 55,000+ population demonstrated an overall pooled and standardized prevalence of 0.3%. This would still translate into about 5 million patients of RA which is an awesome burden.

RA is multi-causal and probably polygenic with a gene environment interaction. There is a hereditary pattern which is not always consistent. The web of causation model (see review of literature) demonstrates a complex array of etiological and aggravation factors which includes psychosocial.

It is predominantly a disease of women in perimenopausal age. Extremely painful when active, the disease is characteristically a polyarticular synovitis (swollen joints) effecting small joints of hands and feet. The arthritis is usually erosive and damaging. Overall, significant systemic complications are not too uncommon but almost any system can be effected- mostly skin, lungs, nerves and blood. Osteoporosis is invariably present.

Pain is an overarching symptom and a therapeutic target. RA is generally a chronic painful disease with acute painful flares and relapses. Though there is no dearth of analgesics and anti-inflammatory drugs and corticosteroids, pain management is often frustrating and interrupted by drug related toxicity. The pivotal drug is DMARD to control the core immune inflammation and methotrexate is considered to be the sheet anchor. Biologic DMARDs are powerful and targeted and produce early response (few weeks) as compared the slow effect (8-10 weeks) with the conventional DMARD. But
both conventional and biological DMARDS need careful screening to exclude infections and hepatic-renal disorders and further monitoring to detect early drug toxicity (mostly haematological and hepatic). Drug toxicity, including immunosuppression related infections, can be life threatening and fatal.

The community desires gentle and safe therapies. There are several non-pharmacological options which include diet and exercise. Though diet has been a central topic of discussion with community and patients, the data to support unequivocal evidence of effectiveness for diet is sparse. The number of published controlled dietary intervention studies in RA in peer reviewed literature is likely to less than two dozen and a Cochrane review of 2009 could only find 15 studies qualifying for an analysis. The maximum enthusiasm amongst dietary studies has been for Mediterranean diets with high extent of polyunsaturated fatty acids (PUFA). The diets have been largely fruits and vegetables but other than PUFA nothing much has been analysed for clinical benefit. It is generally agreed that diet can be a useful adjunct with appealing tolerability and safety profile. But the data supporting this contention is sparse.

Iron, calcium, zinc, copper and magnesium have been evaluated for etiological and therapeutic role in RA. Iron is critical to treating anaemia which is usually mixed (nutritional and chronic inflammation) in origin. Calcium and vitamin D are important for bone health. There is little if any data on the beneficial role of potassium (K+) in RA. Diets of RA patients are generally believed to be poor in nutrients and sparse data in literature suggests that the body K+ status is low in RA. This is compounded by the fact that patients of RA often follow several food fads and limitations based on anecdotal and hearsay evidence with a hope to control RA. Vegetables and fruits are the richest source of K+.

K+ plays critical physiological functions in generating voltage triggered nerve impulse (action potential) and several cellular functions that include cellular osmolality and integrity. It is critical to acid-base balance and along with calcium and sodium participates in several cytoplasmic signalling and enzymatic reactions. It has an array of vasogenic effects that are probably conducive to regulate blood pressure and blood flow. The benefits of dietary K+ in presence of modest sodium in prevention and treatment of
blood pressure and cardiovascular events has been endorsed by several elegant large scale epidemiological studies. Also K+ is shown to be antioxidant. Several of these processes are involved in the aetio-pathogenesis of disorders like RA. Premature mortality in RA can be due to accelerated atherosclerosis and coronary artery disease. Can dietary K+ be used to alleviate pain and swelling and improve disease control in RA? Oral K+ medicinal forms are fraught with gastrointestinal toxicity and poor tolerance. Normal serum K+ is maintained within a normal range by both renal and extra-renal mechanisms to avoid the life threatening situations arising from hyperkalaemia and hypokalaemia. Diet based K+ augmentation is likely to be more holistic and safe.

It is against this perspective that the current study was planned and carried out. Diet was principally used to augment K+ intake and a diet based mixed food K+ supplement provided an additional boost. A likely optimum oral diet based dose of K+ based on expert opinion and limited by safety concerns was evaluated in the current study. The primary goal was to reduce pain and thus patients with painful disease despite ongoing supervised standard of care therapy were chosen. There were several other secondary goals based on the known physiological role of K+ in health and clinical and experimental data described in literature.

Importance of Study:

As described above, there are several unmet needs in the management of RA with particular reference to safety of drugs. Also, pain is often difficult to treat because of several reasons including individual variability. It is prudent to add that RA is a difficult to treat disorder in the community and a cause of much disability and loss of productivity in the community. The current study focusses on the treatment aspects of RA.

The current study was planned to primarily target management of pain in patients who were otherwise on supervised standard drug therapy under care of a rheumatologist. Secondary goals include other disease activity measures.

A non-pharmacological intervention using diet as the medium to administer oral K+ is the key issue in the current study. K+ is considered to be a potentially toxic element when used as a drug. A dietary intervention approach is expected to provide a safe and
Effective adjunct treatment to current standard drugs used to treat RA. This should lead to better symptomatic management to begin with and a more disease control with prolonged intervention. All this should reduce the need for analgesics/NSAID and even DMARD in time.

As a holistic approach is being adopted with reference to a balanced healthy vegetarian diet with a rich source of K+ in particular, other clinical benefits, albeit modest, are likely with special reference to improved health. Such a diet is bound to have an overall influence on health and disease rather than confine to the putative clinical benefits of K+ intervention.

Being a dietary intervention, it is likely to be socioeconomically appealing to the patients and community.

Utility of this Study:

1) Diet based potassium intervention to reduce pain and improve disease control can be a useful adjunct to the standard of care for treating Rheumatoid arthritis
2) Potassium is potentially a toxic mineral when used as a medicine in clinical practice. However administration of potassium using a dietary augmentation is likely to be a safe option
3) The findings of the study can be used to educate doctors on proper nutrition