INTRODUCTION

The hepatitis B virus (HBV), discovered in 1966, infects more than 350 million people.\textsuperscript{1} Hepatitis B is a leading cause of chronic hepatitis and chronic infection with HBV is currently estimated to be the single most common cause of cirrhosis and hepatocellular carcinoma (HCC), accounting for 1 million deaths annually, worldwide.\textsuperscript{2}

World Health Organization estimated that the number of HBV carriers would reach 400 million by the year 2000 and that the numbers will continue to increase until neonatal vaccination and immunization are universally accepted.\textsuperscript{3}

The distribution of hepatitis B infection varies greatly throughout the world. In areas where the prevalence is high, such as Southeast Asia, China, and Africa, more than half the population is infected at some time in their lives, and more than 8.0 % are chronic carriers of the virus, the result of either neonatal transmission (vertical) or transmission from one child to another (horizontal). Areas with low levels of endemicity include North America, Western Europe, and Australia where only a minority of people come into contact with the virus, as a result of horizontal transmission among young adults.\textsuperscript{4}

Reports indicating the presence of immense community loads of chronic hepatitis B among Indian population are periodically published. In the absence of nation wide epidemiological infrastructure, these reports provide valuable insights into the ubiquitous presence of hepatitis B virus related disorders in India.
According to WHO data India falls in the intermediate zones for HBV chronic carrier prevalence. Although large studies representative for the vast country are yet to be conducted, periodically published data indicate prevalence of HBV is more or less in the range of 5 to 7%. Blood transfusion, vertical transmission and sexual transmission appear to be the major routes of spread. Chronic hepatitis B in India is associated with majority of cases of Hepatocellular carcinoma.

From when hemodialysis began, it was apparent that hepatitis due to HBV was a complication of maintenance dialysis and represented a serious threat to dialysis patients and staff. Controlling the spread of HBV infection in dialysis units has been one of the major advances in the management of patients with end-stage renal disease (ESRD). Patients with chronic HBV, however, continue to enter the population pool of dialysis patients and transplant candidates.

Hepatitis viruses are known to be associated with greater morbidity and mortality among the dialysis group. Chronic renal failure patients, by and large, are immunocompromised. They have greater risk of acquiring infections and due to poor immune status they fail to eliminate the infections efficiently.

Frequent vascular access for prolonged periods, during hemodialysis, places chronic renal failure patients at greater risk of acquiring Hepatitis B virus [HBV] and Hepatitis C virus [HCV] infection. High prevalence of HBV and HCV infections in hemodialysis patients is related to the duration of dialysis treatment and the number of blood
transfusion. Patient-to-patient contamination is also a contributing factor to the spread of these viruses.\textsuperscript{10}

Prevalence of HBV and HCV infections vary among hemodialysis patients in different countries. As a result of segregation, universal precautions, reduced blood transfusions, and vaccination the incidence of HBV infection in developed countries was brought under control.\textsuperscript{11} On the other hand, the little data available from less developed countries show that prevalence and incidence rates of HBV infection among patients undergoing long-term hemodialysis remain very high.

India had a total of more than 700,000 renal failure cases by the turn of the century.\textsuperscript{12} However, data on the prevalence of hepatitis viruses among that population are scanty. Furthermore, the data in this regard are complicated by the fact that there has been enormous variation in the data from various centers.\textsuperscript{13,14} The data regarding the prevalence of Hepatitis B among hemodialysis patients in Indian ranged from 3.4\% to 42\%\textsuperscript{15} and Mani et al have reported the prevalence to be as high as 77\%.\textsuperscript{16} Shreeprakash et al observed HBsAg prevalence of 7.5\% in Central India.\textsuperscript{17}

Hepatitis B vaccine has been recommended for both hemodialysis patients and staff members since the vaccine became available in 1982.\textsuperscript{18} Primary vaccination comprises three intramuscular doses of vaccine, with the second and third doses given 1 and 6 months, respectively, after the first. An alternative schedule of four doses given at 0, 1, 2, and 12 months to persons with normal immune status
or at 0, 1, 2, and 6 months to hemodialysis patients has been approved for Engerix-B®.

Worldwide data of HCV infections in dialysis patients varies from <5 % to 68 % in CRF\(^{19,20}\). Indian reports indicate 12 – 45 % range of HCV infection in CRF patients.\(^{21,22}\)

In a pilot study of forty patients we observed high prevalence of HCV among the ESRD patients on maintenance hemodialysis. So the work was extended to determine the prevalence of HCV and the association of HBV-HCV (Co-infection) among this population.

Several studies have been carried out separately on prevalence of HBV and HCV and that of vaccine response in patients on hemodialysis and staff members of the dialysis units.

A data regarding the prevalence of HBV, HCV and their co-infection [HBV-HCV] in vaccinated ESRD patients and Hepatitis B vaccine immunogenicity and efficacy are not available from India and many other countries.

Among the high risk groups, doctors and paramedical staff members working in the dialysis unit are an important target population for hepatitis B virus (HBV) exposure. So, therefore, the doctors and paramedical staff members working in the dialysis unit are selected as a control group in the present study. All the subjects in control group were also immunized by Hepatitis B vaccine.

The present work was undertaken with the following aims.
AIMS OF THE STUDY

1. To study and compare the prevalence of Hepatitis B [by presence of HBsAg and/or Anti-HBc (Total) antibodies] and Hepatitis C [by presence of Anti-HCV antibodies] in vaccinated ESRD patients on maintenance hemodialysis and Control group.

2. To study prevalence of HBV DNA in serum samples strongly positive for Anti-HBc antibodies.

3. Study the association between number of dialysis [duration of dialysis therapy] and prevalence of HBV & HCV infection rate in ESRD patients.

4. To evaluate the immunogenicity and efficacy of Hepatitis B vaccine in ESRD patients and Control group.