

CHAPTER -1



INTRODUCTION

High cholesterol is one of the top 10 risk factors that account for more than one-third of all deaths worldwide. It is an important risk factor for cardiovascular disease (CVD), estimated to cause 18% of cerebrovascular disease and 56% of Ischemic heart disease (Gaziano *et al.*, 2011). The prevalence of coronary artery disease in India increased from 1% to 9.7% in urban populations, and in rural populations it has almost doubled in the last decade (Gupta *et al.*, 2008).

In a cross sectional survey the prevalence of CHD is to be 3-4 % in rural areas and 8-10% in urban areas among individuals aged above 20 years. Based on these data it is estimated that there were approximately 29.8 million patients with CHD in the year 2003(Gupta *et al.*, 2008). Out of these 14.1 million resided in urban areas, while the remaining 15.7 million were rural residents (Sawanth *et al.*, 2008). One fifth of the deaths in India are influenced from coronary heart disease and by the year 2020, it will account for one third of all deaths (WHO, 2008).

The impact of hyperlipidemia related mortality and morbidity is very high in India and other countries (Setia *et al.*, 2012). Hospital admission due to hyperlipidemia increased from 5% to 30% in India (Kinra *et al.*, 2010). This increase in the mortality rate demands for prevention of atherogenic risk conditions which can be majorly achieved by reducing the elevated lipid levels of patient population through the lipid lowering drugs (Cholesterol Treatment Trial lists, 2005).

Lipid lowering medications (hypolipidemics) for the treatment of hyperlipidemia include statins, fibrates and anion-exchange resins. Statins, in particular, have been shown in large randomized controlled trials to be effective in preventing CAD events and in reducing overall mortality (Shepherd *et al.*, 1995; Sacks *et al.*, 1996; Athyros *et al.*, 2002; Collins R, 2003). Fibrates and anion-exchange resins achieved reductions in CAD events, but showed a non-significant increase in non-coronary mortality (Downs *et al.*, 1998). Statins are therefore recommended as first line therapy, whereas fibrates and anion-exchange resins can be considered as second line therapy and also in combination with statins (Mohammed K. Ali, 2010).

For primary prevention of CAD, lipid lowering medication is recommended in asymptomatic adults who have a 20% or greater risk of developing CAD in the next 10 years (Richard Kones, 2011). A combination of statins, anti-hypertensive's and low dose

aspirin is recommended by the World Health Report (2002) for secondary prevention of CAD, as this could cut death and disability rates from CAD by more than 50% (WHO Report, 2002).

Medication adherence has been recognized as a burning problem from past 35 years. Adherence is defined as the extent to which patients take medication as prescribed. Since the landmark publication by Sackett (Sackett *et al.*, 1976), it has been the focus of research over the last three decades (Vermeire *et al.*, 2001). Adherence can either be intentional or non-intentional and is determined by a variety of factors such as lack of knowledge, denial, poor memory and adverse attitudes to treatment. Reliable indicators of adherent behavior have not been found to date and demographic factors such as age, sex or social class have been shown to be poor predictors of adherence (Vermeire *et al.*, 2001).

The multilevel adherence challenge state that adherence is a complex behavioral pattern robustly influenced by the environments in which the patients live, healthcare providers and health care systems delivery care. The health care providers including pharmacists, nurses, psychologists etc who are involved in primary and secondary prevention play a role in enhancing adherence by interpreting recommendations, educating and motivating patients, monitoring responses to recommended behaviors and providing feedback. Maximum use of these services should be made patients to overcome non adherence to drugs (Patel *et al.*, 2005).

It has been identified that fear of side effects is of major concern to the patients. Moreover lack of information or understanding about the use of medication and disbelief in the action of medication are another identified reasons which might affect adherence to therapy (Gordon *et al.*, 2007). Patient education comprises 'all planned educational activities aimed at assisting patients in achieving voluntary health behavior changes (Burge *et al.*, 2005). Research has shown that patient education can bring about improvement in health status and improved adherence. Medication knowledge is highly correlated with medication adherence (Lipton *et al.*, 1994). Studies suggest that healthcare providers must assess the current knowledge about medications and enhance personal communication skills to increase patients' knowledge about their medication (Burge *et al.*, 2005). Supplementing verbal education with written educational material

improves the patient's understanding and knowledge (Sandler, 1989; Kitching, 1990; Kessels, 2003; Thickett, 2006).

The importance of the patient's agreement (Lewis *et al.*, 2003) and the significance of the patient's role within the doctor-patient relationship have been emphasized, which has led to replacing the term compliance with more patient-centered synonyms such as adherence and concordance (Lewis *et al.*, 2003; Mullen, 1997; RPSGB, 1997).

Quality of life is referred as the patient's appraisals of and satisfaction with their current level of functioning compared with what they perceive to be possible or ideal (Cella, 1992). The perception of a person's quality of life varies between individuals. This means that people with different expectations will report a different quality of life, even when they have the same objective health status. Therefore, insight into a patient's quality of life can only be obtained by asking a patient's perspective. Quality of life encompasses several life domains, usually physical, psychological and social well-being (Ferrell *et al.*, 1995).

The treatment of a symptomless condition such as hyperlipidemia signifies a particular challenge to both doctor and patient. It has been difficult to identify the scope of the problem, as adherence rates from hyperlipidemia trials shown considerable variation, ranging from 37 to 80%, depending on factors such as study population, background morbidity, classes of drugs, duration of follow up and adherence measuring methods (Tsuyuki *et al.*, 2001). For long-term treatments, no simple intervention and only some complex ones led to some improvement in health outcomes (Haynes *et al.*, 2008).

The consequences of non-adherence have been studied and shown to be significantly associated with factors such as lack of disease control and hospital admissions or readmissions (Cramer *et al.*, 2008). There are few studies evaluating pharmacist intervention plays a significant role in management of chronic diseases such as coagulation disorder (Garabedian-Ruffalo *et al.*, 1985), dyslipidemia (Bogden *et al.*, 1997), oncology (Wong Swe *et al.*, 1999), smoking cessation (Lancaster *et al.*, 2000), hypertension (Borenstein *et al.*, 2003), and diabetes mellitus (Leal *et al.*, 2004). As

Clinical Pharmacy profession is developing in India in health care arena, opportunities are arising where pharmaceutical care concept can be more involved in patient-focused activities in hospital setting.

Thus there is a need to study in detail about medication adherence to lipid lowering drugs used in hyperlipidemia patients. In the present study parameters studied are assessment of medication adherence, quality of life and evaluation of patient medication education programme to improve medication adherence by pharmacist managed patient counselling center. Hence, the present study was undertaken to compare medication adherence in hyperlipidemia patient's attending referral center and paid clinic, factors affecting medication adherence, clinical outcome, adverse effects encountered with hypolipidemic agents, patient satisfaction with the medical services provided, and effect of patient education programme by pharmacist at patient counselling center with respect to efficacy in control of surrogate end points. Outcome of this study may be useful to the practicing physicians in designing the appropriate therapeutic regimen.