CHAPTER – I
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CHAPTER I
INTRODUCTION

1.1 Introduction

Epilepsy is the most common serious brain disorder in every country in the world (The Lancet Editorial, 1997). There are around five million people with epilepsy in India (Thomas, 2004). Age-standardized rates from a meta-analysis revealed an overall prevalence of 5.59 per 1000 in India. The prevalence in men (6.05/1000) was higher than in women (5.18/1000). Urban men and women had a higher prevalence of epilepsy compared with rural ones (Rajshekhar et al., 2006; Sridharan & Murthy, 1999). The crude point prevalence ratio of epilepsy among the people of the state of Kerala, which is distinguished from the rest of India by a high level of literacy, is estimated to be 4.9 cases per 1,000 people. The age-adjusted prevalence ratio was 4.7 cases per 1,000 population. Sex-specific prevalence rates did not significantly differ (Radhakrishnan et al., 2000). It is estimated that there are over 2.5 million women with epilepsy (WWE) in India, and 52% of them are in the reproductive age group (Thomas, 2006). Though it affects both men and women somewhat equally, gender differences bring forth special issues in women with epilepsy especially during the childbearing years (Roste & Tauboll, 2007). Women have higher incidence of epilepsy at certain periods of their life. During the reproductive years women may show change in seizure frequency during certain phases of menstrual cycle, pregnancy and post partum period (Thomas, 2003).

In the United States of America, there are over 800,000 women with epilepsy who are in their childbearing years and probably one-third continue to have seizures despite efforts to achieve control with the older antiepileptic drugs (Morrell, 2003a) and more than 24,000 infants are born each year to these women with epilepsy (Pennell, 2004).

Although epilepsy affects men and women equally, there are many women’s health issues in epilepsy, especially for women of childbearing age. These include menstrual cycle influence on seizure activity, pharmacokinetic changes during pregnancy, teratogenicity of antiepileptic drugs, safety of breast feeding, contraceptive-AED interaction, and impact of AEDs on bone health and sexual function. These health issues challenge both the women with epilepsy and the healthcare providers involved in their care. In recent years there is a substantial growth in the literature on women’s issues in epilepsy. Many groups have developed clinical practice guidelines. Neurologists and obstetricians are increasingly faced with WWE during pregnancy, but apparently are not adequately informed about their optimal management (Krauss et al., 1996; Long & Montouris, 2005; Morrell et al., 2000; Russell et al., 1996). It also appears that there is an inadequate knowledge on important health issues that challenge WWE among women themselves (Bell et al., 2002; Crawford, 2003; Long et al., 2005).

Despite clinical guidelines, the care of women with epilepsy remains sub optimal even in developed countries. It is suggested that further measures are required to improve the effectiveness of information provision in relation to women of childbearing age with epilepsy (Bell et al., 2002). A recent survey of British WWE indicated that one third of women of child bearing age were not considering having children because of their epilepsy (Crawford, 2003). WWE need regular review and should receive appropriate information about the impact of their treatment. Nevertheless, the ‘Ideal World’ survey (Crawford, 2003) of Epilepsy Action found that women were not
receiving important information about their condition and possible adverse effects of
treatment, which could have profound implications for their health and the health of
their unborn child. Among the 202 attendees of the American college of physicians
2003 annual meeting, fewer than half (47%) of the participants only knew that women
taking AEDs could breast feed safely. This sample of health care providers was not
adequately informed about the unique issues affecting WWE. An aggressive educational
effort is necessary to close the gaps in knowledge (Long et al., 2005). It is suggested
that we must continue to educate not only our patients but also our colleagues so that
women with epilepsy will cease to face discriminatory behaviour.

1.2. Background of the study

1.2.1. Epilepsy and its Classification

The word epilepsy comes from a Greek word meaning “to be seized by forces from
without”. Epilepsy is a group of neurologic conditions, the common and fundamental
characteristic of which is recurrent, usually unprovoked epileptic seizures. Epileptic
seizures, in turn, represent the clinical manifestations (symptoms and signs) that result
from excessive, synchronous abnormal firing patterns of neurons that are located
predominantly in the cerebral cortex. Such abnormal paroxysmal activity is usually
intermittent and self-limited. No definition of epilepsy however is definitive or all­
inclusive (Engel & Pedley, 1997). John Hughlings Jackson (1825 – 1911) the father
of the modern concepts of epilepsy proposed that seizures were caused by sudden
excessive rapid and local discharges of gray mater and defined epilepsy in 1873 as “a
sudden, excessive, and rapid discharge” of electricity by brain cells. A seizure is a
finite event in time with a distinct beginning and end, and epilepsy is a chronic disorder
with recurrent symptoms or seizures (DeLorenzo, 1991). A single episode is called a
seizure. The International League Against Epilepsy (ILAE) classification of epileptic
seizures is shown in Table 1.1 (Dreifuss, 1981).
Table 1.1
The International League Against Epilepsy (ILAE)
classification of epileptic seizures

<table>
<thead>
<tr>
<th>No.</th>
<th>Seizure Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Partial (focal, local) Seizures</td>
</tr>
<tr>
<td></td>
<td>A. Simple Partial Seizures (Consciousness not impaired)</td>
</tr>
<tr>
<td></td>
<td>1. with motor signs.</td>
</tr>
<tr>
<td></td>
<td>2. with somatosensory or special sensory symptoms.</td>
</tr>
<tr>
<td></td>
<td>3. with autonomic symptoms or signs.</td>
</tr>
<tr>
<td></td>
<td>4. with psychic symptoms.</td>
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<tr>
<td></td>
<td>B. Complex Partial Seizures (with impairment of consciousness)</td>
</tr>
<tr>
<td></td>
<td>1. Simple partial onset followed by impairment of consciousness</td>
</tr>
<tr>
<td></td>
<td>a. with simple partial features (A1 to A4) followed by impaired consciousness</td>
</tr>
<tr>
<td></td>
<td>b. with automatisms</td>
</tr>
<tr>
<td></td>
<td>2. with impairment of consciousness at onset.</td>
</tr>
<tr>
<td></td>
<td>a. with impairment of consciousness only</td>
</tr>
<tr>
<td></td>
<td>b. with automatisms</td>
</tr>
<tr>
<td></td>
<td>C. Partial Seizures, evolving to secondarily generalised seizures</td>
</tr>
<tr>
<td></td>
<td>1. Simple partial seizures evolving to generalised seizures</td>
</tr>
<tr>
<td></td>
<td>2. Complex partial seizures evolving to generalised seizures</td>
</tr>
<tr>
<td></td>
<td>3. Simple partial seizures evolving to complex partial seizures evolving to generalised seizures</td>
</tr>
<tr>
<td>II.</td>
<td>Generalised Seizures (convulsive and nonconvulsive)</td>
</tr>
<tr>
<td></td>
<td>A. Absence seizures</td>
</tr>
<tr>
<td></td>
<td>1. Absence seizures with impairment of consciousness only, mild clonic components, atonic components, tonic components, automatisms, autonomic components</td>
</tr>
<tr>
<td></td>
<td>2. Atypical absence seizures</td>
</tr>
<tr>
<td></td>
<td>B. Myoclonic seizures</td>
</tr>
<tr>
<td></td>
<td>C. Clonic seizures</td>
</tr>
<tr>
<td></td>
<td>D. Tonic seizures</td>
</tr>
<tr>
<td></td>
<td>E. Tonic-clonic seizures</td>
</tr>
<tr>
<td></td>
<td>F. Atonic seizures</td>
</tr>
<tr>
<td></td>
<td>(Combinations may occur, such as B and F or B and D)</td>
</tr>
<tr>
<td>III.</td>
<td>Unclassified epileptic seizures</td>
</tr>
</tbody>
</table>

Many types of epilepsy are combinations of different kinds of seizures. Epilepsy is classified as either symptomatic or idiopathic according to whether the cause is known or unknown. Both of these types may be further subdivided into partial and generalized.
types depending on whether the seizures are due to a localized limited brain lesion or to widespread brain lesion, respectively. The International League Against Epilepsy (ILAE) defines Epilepsy under the following headings:

a) Epileptic Disorder: A chronic neurological condition characterised by recurrent epileptic seizures.

b) Epilepsies: Those conditions involving chronic recurrent epileptic seizures that can be considered epileptic disorders.

c) Epileptic Seizure: Manifestation(s) of epileptic (excessive and/or hypersynchronous), usually self-limited activity of neurons in the brain.

d) Epilepsy syndrome: An epileptic disorder characterized by a cluster of signs and symptoms customarily occurring together.

The International League Against Epilepsy (ILAE) Classification of Epilepsies and Epilepsy Syndromes (Commission on Classification and Terminology of the International League Against Epilepsy 1989) is given in Table 1.2.
Table 1.2
The International League Against Epilepsy (ILAE) Classification of Epilepsies and Epilepsy Syndromes

<table>
<thead>
<tr>
<th>No.</th>
<th>Epilepsies and Epilepsy Syndromes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Localization-related (focal, local, partial) epilepsies and syndromes</td>
</tr>
<tr>
<td>1.1</td>
<td>Idiopathic (with age-related onset)</td>
</tr>
<tr>
<td></td>
<td>• Benign childhood epilepsy with centrotemporal spikes</td>
</tr>
<tr>
<td></td>
<td>• Childhood epilepsy with occipital paroxysms</td>
</tr>
<tr>
<td></td>
<td>• Primary reading epilepsy</td>
</tr>
<tr>
<td>1.2</td>
<td>Symptomatic</td>
</tr>
<tr>
<td></td>
<td>• Chronic Progressive epilepsia partialis continua of childhood (Kojewnikow’s syndrome).</td>
</tr>
<tr>
<td></td>
<td>• Syndromes characterised by seizures with specific modes of precipitation</td>
</tr>
<tr>
<td></td>
<td>• Temporal lobe epilepsies</td>
</tr>
<tr>
<td></td>
<td>• Frontal lobe epilepsies</td>
</tr>
<tr>
<td></td>
<td>• Parietal lobe epilepsies</td>
</tr>
<tr>
<td></td>
<td>• Occipital lobe epilepsies</td>
</tr>
<tr>
<td>1.3</td>
<td>Cryptogenic</td>
</tr>
<tr>
<td></td>
<td>Cryptogenic epilepsies are presumed to be symptomatic and the etiology is unknown. This category thus differs from the previous one by the lack of etiologic evidence.</td>
</tr>
<tr>
<td>2.</td>
<td>Generalised epilepsies and syndromes</td>
</tr>
<tr>
<td>2.1</td>
<td>Idiopathic (with age-related onset - listed in order of age)</td>
</tr>
<tr>
<td></td>
<td>• Benign neonatal familial convulsions</td>
</tr>
<tr>
<td></td>
<td>• Benign neonatal convulsions</td>
</tr>
<tr>
<td></td>
<td>• Benign myoclonic epilepsy in infancy</td>
</tr>
<tr>
<td></td>
<td>• Childhood absence epilepsy (pyknolepsy)</td>
</tr>
<tr>
<td></td>
<td>• Juvenile absence epilepsy</td>
</tr>
<tr>
<td></td>
<td>• Juvenile myoclonic epilepsy (impulsive petitmal)</td>
</tr>
<tr>
<td></td>
<td>• Epilepsy with grandmal (GTCS) seizures on awakening</td>
</tr>
<tr>
<td></td>
<td>• Other generalised idiopathic epilepsies not defined above</td>
</tr>
<tr>
<td></td>
<td>• Epilepsies with seizures precipitated by specific modes of activation</td>
</tr>
</tbody>
</table>
2.2 Cryptogenic or symptomatic (in order of age)
   - West syndrome (infantile spasms, Blitz-Nick-Salaam Krämpfe)
   - Lennox-Gastaut syndrome
   - Epilepsy with myoclonic-astatic seizures
   - Epilepsy with myoclonic absences

2.3 Symptomatic
2.3.1 Non-specific etiology
   - Early myoclonic encephalopathy
   - Early infantile epileptic encephalopathy with suppression burst
   - Other symptomatic generalised epilepsies not defined above

2.3.2 Specific syndromes
   - Epileptic seizures may complicate many disease states. Under this heading are included diseases in which seizures are a presenting or predominant feature

3. Epilepsies and syndromes undetermined whether focal or generalised
3.1 With both generalised and focal seizures
   - Neonatal seizures
   - Severe myoclonic epilepsy in infancy
   - Epilepsy with continuous spike-waves during slow wave sleep
   - Acquired epileptic aphasia (Landau-Kleffner syndrome
   - Other undetermined epilepsies not defined above

3.2 Without unequivocal generalised or focal features. All cases with generalised tonic clonic seizures in which clinical and EEG findings do not permit classification as clearly generalised or localization related, such as in many cases of sleep-grandmal (GTCS) are considered not to have unequivocal generalised or focal features

4. Special syndromes
4.1 Situation-related seizures (Gelegenheitsanfälle)
   - Febrile convulsions
   - Isolated seizures or isolated status epilepticus
   - Seizures occurring only when there is an acute metabolic or toxic event due to factors such as alcohol, drugs, eclampsia, nonketotic hyperglycemia.
1.2.2. Antiepileptic Drugs and Epilepsy Care

The established or “first-generation” AEDs include phenobarbital, phenytoin, primidone, carbamazepine, ethosuximide and valproic acid and the “second-generation” AEDs include felbamate, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, tiagabine, topiramate, vigabatrin and zonisamide (McAuley & Anderson, 2002).

The survey results from 160 countries conducted by the International League Against Epilepsy (ILAE)/ World Health Organization (WHO), and the International Bureau for Epilepsy (IBE) ‘Global Campaign Against Epilepsy’ indicated that epilepsy care is grossly inadequate compared with the needs in most countries (Dua et al., 2006). The services for epilepsy are urban-based and there is under utilization of services, general practitioners and specialists. Newer AEDs (although expensive) are gradually emerging in Indian market. Facilities for epilepsy surgery, therapeutic drug monitoring and services of clinical psychologist or medical social workers are limited (Thomas et al., 2001).

Findings thus far suggest that epilepsy care in developing countries is inadequate and lagging behind than in the developed countries.

1.2.3. Women With Epilepsy (WWE) and Quality of Life

Many factors influence the quality of life of people with epilepsy, including seizure severity, stigma, fear, and the presence of cognitive or psychiatric problems. Compared with normal women of similar age, women with epilepsy tended to present lower scores for each health-related quality of life (HRQOL) domains, mostly Role Physical, General Health, Social Functioning, and Role Emotional. This reflects the physical, social, and emotional implications of the disease (Beghi et al., 2004).

1.2.3.1. Health related Quality of Life (HRQOL)

In WWE it can be defined as the functional effect of epilepsy and anti epileptic drug (AED) therapy on these women as perceived by them (Cramer, 2003). The major domains used to describe HRQOL are physical health domain, psychosocial domain, and biological domain including pregnancy and child rearing.
1.2.3.2. Physical health issues

Severe seizures cause injury from falling. Even mild seizures can lead to danger during periods of altered consciousness. Burns related to household activities can occur among WWE (Thomas, 2004). In addition, treatment with AED often brings unwanted side effects like obesity (Valproic acid, Carbamazepine) (Morrell, 2003b; Ness-Abramof & Apovian, 2005), and cosmetic side effects like coarseness of facial features and hirsuitism (Phenytoin). It is found that sometimes cognition and memory also were affected.

1.2.3.3. Psychosocial problems

Women with epilepsy experience several gender related physical and social problems (Thomas, 2006). These may result directly from the epilepsy or its treatment or indirectly from the consequences of living with a seizure disorder (Shafer, 2002). Psychosocial issues that patients and family members may encounter are categorized into four broad areas of epilepsy self-management: access to care, identification of healthcare needs specific to epilepsy, personal care and safety, and social relationships and community living. The health care issues for women with epilepsy are shown in Table 1.3.

Anxiety (fear of exposure of diagnosis), lack of control (recurrence of seizures) and dependency are commonly seen psychological reactions. Personality problems and mood disorders are more common among WWE. Women with epilepsy of childbearing age are at high risk of depression. Factors associated with depression include lack of occupation, the presence of an underlying disabling condition (with treatment), and the severity of epilepsy. The effects of AEDs and seizures may impinge on psychological well-being leading to social withdrawal. Turner et al. (2006) found that the rate of post partum depression (PPD) was higher among women with epilepsy than among women without epilepsy.
Table 1.3

Health Care issues for women with epilepsy (Shafer, 2002)

<table>
<thead>
<tr>
<th>No.</th>
<th>Health Care issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.</td>
<td>Coping with the diagnosis</td>
</tr>
<tr>
<td>02.</td>
<td>Observing and recording seizures</td>
</tr>
<tr>
<td>03.</td>
<td>Identifying potential triggers and high-risk times</td>
</tr>
<tr>
<td>04.</td>
<td>Maintaining personal safety</td>
</tr>
<tr>
<td>05.</td>
<td>Handling seizure emergencies</td>
</tr>
<tr>
<td>06.</td>
<td>Managing adverse drug effects</td>
</tr>
<tr>
<td>07.</td>
<td>Understanding the nonmedical options for seizure management</td>
</tr>
<tr>
<td>08.</td>
<td>Managing concomitant illness</td>
</tr>
<tr>
<td>09.</td>
<td>Understanding the relationship between seizures and hormonal states</td>
</tr>
<tr>
<td>10.</td>
<td>Practising family planning</td>
</tr>
<tr>
<td>11.</td>
<td>Managing pregnancy and menopause</td>
</tr>
<tr>
<td>12.</td>
<td>Maintaining bone health</td>
</tr>
</tbody>
</table>

Social function is impaired because of the stigma associated with epilepsy. Epilepsy in women is often concealed, due to associated stigma (Bharucha, 2000). Low social acceptance, poor self-esteem and stigma related to epilepsy are major problems in epilepsy, but they have greater impact on women than men (Thomas, 2004). Relationship within the family may change with less responsibility given to WWE. Relationships with friends and co-workers are affected limiting the social contacts. There may be strains on the marital relationship. Abandonment or deserting by husband or avoidance by husband’s family is also seen. Women are more vulnerable and tend to be neglected than men. Fewer women receive specialised medical or surgical treatment although epilepsy occurs equally among men and women (Thomas, 2004). It appears that women with epilepsy are more vulnerable and tend to be neglected than men (Agarwal et al., 2006).
1.2.3.4. **Biological Problems**

Women who take Antiepileptic drugs (AEDs) may notice a reduction in sexual desire or a change in their menstrual cycle. Nearly a third of women with epilepsy have specific predisposition to seizures during certain phases of menstrual cycle, which is classified as catamenial epilepsy (Thomas, 2004). They constitute high obstetric risk because of reduced fertility (Kaplan, 2004), risk of seizures during pregnancy and complications of pregnancy (Thomas, 2006). Enzyme inducing antiepileptic drugs (phenytoin, Carbamazepine, tiagabine, topiramate, and phenobarbitone) can increase the failure rate of hormonal contraception thus increasing the chance for unplanned pregnancies. Although pregnancy in these women is now considered generally safe with proper seizure control, there is still an increased risk of congenital malformations. It also appears that there is an increased risk of impaired cognitive functioning in children born to WWE (Harden et al., 2005; Kaplan, 2004). Postmenopausal women are prone to osteoporosis specially those who are on enzyme inducing AEDs.

1.2.4. **Women with Epilepsy, Marriage and law**

Marriage, family and reproduction are important aspects of a woman’s normal life. Women with epilepsy however have been denied this privilege in many parts of the world due to the social stigma of epilepsy. As a heavily stigmatized disorder, Epilepsy is surrounded by a number of common misconceptions. Women with epilepsy face special challenges especially in the area of reproductive health because of biological and social role differences. In the past many women with epilepsy were wrongly advised against marriage and reproduction. As early as 1982, there were even laws in some states of USA, restricting the ability of people with epilepsy to marry and have children (Morrell, 2003a; Yerby, 2005). The reasons for this varied from inability to care for the baby to exacerbation of seizures for the mother as well as birth defects, subnormal intellect and seizures for the baby (Callanan, 2003). There were occasions where
physicians performed ineffective therapies like removal of uterus and ovaries in an attempt to decrease seizures in women.

Epilepsy has significant impact on marriage, reproduction and pregnancy. People with epilepsy are less likely to marry (especially women) and have children than rest of the population. They have higher rates of sexual dysfunction and higher rates of birth defects among offspring. Epilepsy was interpreted by the court as temporary insanity and was legally considered a reason for divorce if either spouse suffered from epilepsy. This law was used against women more often than men and marriage and childbirth were not an option for several women with epilepsy in India. After 25 years of appeals/court cases the Government of India finally agreed to remove epilepsy as a cause for annulment of marriage in the year 1999 (Arjundas & Arjundas, 2000).

Despite progress in medical and surgical therapy, better social acceptance, and favourable legal stand, WWE are less often married (59%), when compared with others in the community (65%) (Thomas et al., 1999). In a recent study done in Kanpur, India, it was seen that people with epilepsy had lower marriage prevalence rate, delayed marriage (especially females), withheld marriage and higher divorce rate compared to general population. Females compared to males had higher divorce rate and withheld marriage. Marriage rate was lower in people with age at onset of epilepsy less than 20 years and in whom seizures were not in remission. Majority of people with epilepsy (95.54%) did not disclose epilepsy before marriage (Agarwal et al., 2006). This study suggests that even after many years of passing a promising law for people with epilepsy, the attitudes as well as practices of many Indians haven’t changed.

1.2.5. Pregnancy Registries for WWE

As public attitudes became more receptive, and medical management more effective, women with epilepsy (WWE), are choosing parenthood in increasingly larger numbers.
Yet many health care providers are not informed about the unique issues facing women with epilepsy (Morrell, 2003a). Epilepsy Foundation of America's survey results demonstrated deficiencies in knowledge of women's issues among professionals involved in the care of WWE. Even in developed countries like the United States, health care professionals who are unfamiliar with the issues faced by these women, treat many women with epilepsy. Accurate information and proper guidance from Epilepsy specialists are the right of every woman with epilepsy. Epilepsy Foundations in developed countries have realized this and special Registries have come up for the care of women with epilepsy. The Epilepsy Foundation’s Women and Epilepsy Initiative in the United States, started in 1997, is a campaign to bring hope and help to women with epilepsy. In a developing country like India also such initiatives have come up. It is no wonder that Kerala, which is well known for its maximum reproductive health indices, could be the birthplace of such a Registry for women with epilepsy.

The Kerala Registry of Epilepsy and pregnancy (KREP) was started in 1998 in the R.Madhavan Nayar Centre for Comprehensive Epilepsy Care, at the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, India. It is estimated that there are about 75,000 women with epilepsy in Kerala of which 30 percent are in the reproductive age group (Thomas et al., 2001). It appears that fewer women with epilepsy (particularly in lower socioeconomic groups) receive tertiary care in this state, in spite of a higher sex ratio (SR) in the community (907 for epilepsy and 1058 for all population). The tertiary treatment gap is wider for women over 30 years (particularly over 50 years), when their longer life expectancy is also taken into consideration (Thomas, 2006). Women with epilepsy face many challenging issues as they reach childbearing age. They constitute high obstetric risk because of reduced fertility, risk of seizures during pregnancy, and complications of pregnancy. Several studies have indicated that hormones may affect seizure control throughout the
reproductive years (Fairgrieve et al., 2000; Morrell, 2003b; Pennell, 2002, 2004; Thomas, 2003; Yerby, 1997). There are concerns regarding the effect of traces of AEDs that pass to the infant during breast-feeding. Recent reports raise the possibility of selective developmental language deficits and neurocognitive deficits with antenatal exposure to AEDs (Thomas, 2006).

In recent years, prospective cohort studies on WWE are underway in pregnancy registries in many countries including India. The Kerala Registry of Epilepsy and Pregnancy (KREP) is a program to monitor the reproductive function in women with epilepsy and offer optimal care. All patients registered in the KREP would be followed up according to a standardized protocol. Appropriate clinical and laboratory investigations are carried out at predetermined intervals. Based on these observations, suitable medical advice on management of epilepsy and pregnancy would be recommended. Babies born to these women would also be followed up into childhood for any developmental problems (Thomas, 2003). The EURAP (Tomson et al., 2004), the North American, Australian and the U.K., AED and pregnancy registries are observational studies that prospectively assess pregnancy outcome after AED exposure using slightly different methods. Each has enlisted 3–5,000 pregnancies in women with epilepsy, and the North American and the U.K. Registries have released preliminary observations (Tomson, 2004). The updates from the UK pregnancy registry showed that almost 96% of live births born to WWE did not have a major congenital malformation (Morrow et al., 2005). The KREP also has released preliminary results (Thomas et al., 2001).

1.2.6. Child Rearing Practices

Child rearing consists of practices that are grounded on cultural patterns and beliefs, which affect the style and quality of care giving (Evans & Robert, 1994). Culture is
embedded in a society in the form of beliefs, ideologies and symbols together with traditional practices based on individual perceptions (Padmadas, 2000). For example, health beliefs during pregnancy, childbirth, and child rearing are endorsed in people’s mind and individuals act according to their knowledge. Child rearing practices include activities which:

- Assure the child’s physical well being – Keeping the child safe and free from harm, providing shelter and clothing, preventing and attending to illness.
- Support the child’s physical development – feeding, bathing, providing safe places to play and explore.
- Promote the child’s mental development – interaction, stimulation and play.
- Promote the child’s psychosocial well being – providing emotional security, socialisation, nurturing and giving affection.
- Facilitate the child’s interaction with others outside the home – within the community.

The child rearing practices comes from the traditions, myths and the religious system that underlie the cultures. The child-rearing patterns of a culture are the child rearing norms. Rearing a child has always been a contentious issue where prevailing social norms have dictated the outcome. It is probably the most challenging responsibilities faced by a parent. The first year of life is the basis of the child’s development and is crucial in laying the foundations of good health. Certain specific biological and psychological needs must be met to ensure the survival and healthy development of an infant into a socially useful productive adult. This is the time for the baby to form attachment with its parents. The trust that builds between the parent and the child is the basis of this close attachment. Trust emerges as the parents specially the mother meet the baby’s basic needs for food, warmth, dryness, protection and stimulation. This is achieved through breast-feeding, constant attention, caring gentle touches, eye contacts and soft voice.
The major child rearing activities during early infancy can be thought of as a blend of exclusive breast-feeding, timely complementary feeding, monitoring growth and development, meeting the cleaning and protecting needs as well as preventing accidents and injuries, and appropriate infant stimulation.

The child’s emotional and behavioural responses are determined by the environment he is brought up in. It depends entirely on the kind of attention he gets from his parents, and the relationships that the parents have when the child is growing up. Parents structure everyday activity for their infants in accordance with cultural values and expectations. The baby’s trust and attachment to someone he or she can depend on early in life lays a foundation for all relationships for the rest of his or her life. The late Dr. Benjamin Spock, who authored ‘The common sense book of baby and childcare’, advocated more cuddling and physical contact between parents and child to give the baby a sense of security and create a stronger parent-child bond. Mothers in India generally keep the child at the breast, demand-feeding it. Physical contact is also appreciable in India where mothers continue to carry their children even when they can walk. Parenting in India is moving from the old-fashioned to the new and from strong family ties to nuclear families.

In most societies the family is the primary unit given the responsibility for child rearing. The level of support the mother receives from others in the family and from society plays an important role in the kind of care she is able to provide during the early infancy stage. The tendency to form nuclear families has perhaps become one of the distinguishing features of the family formation systems in modern Kerala. It is reported that a typical household in Kerala consists of five members (NFHS -1, 1995; NFHS – 2, 2001). There is a common practice of women returning to their parent’s home for delivery of a child particularly the first or second child, and staying there during the post partum period. Even then, in Kerala, modern, educated women are looking for more information, rather than just depending upon the traditional feedback from parents and families. There is not much change in the number of family members in Kerala.
between the survey results of NFHS -1 and NFHS-2 as shown in the table below. The nuclear households were 51.3 percentage and nonnuclear households were 48.7 (NFHS –2, 2001). The percentage of household showing number of usual members in Kerala (NFHS -1, 1995; NFHS -2, 2001) are given in Table 1.4.

<table>
<thead>
<tr>
<th>Number of usual members in the family</th>
<th>Percentage of household NFHS –1</th>
<th>Percentage of household NFHS –2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.4</td>
<td>2.3</td>
</tr>
<tr>
<td>2</td>
<td>6.7</td>
<td>5.9</td>
</tr>
<tr>
<td>3</td>
<td>13.4</td>
<td>13.7</td>
</tr>
<tr>
<td>4</td>
<td>24.2</td>
<td>25.1</td>
</tr>
<tr>
<td>5</td>
<td>20.5</td>
<td>21.9</td>
</tr>
<tr>
<td>&gt;5</td>
<td>32.7</td>
<td>31.1</td>
</tr>
<tr>
<td>Mean household size</td>
<td>5.1</td>
<td>5.1</td>
</tr>
</tbody>
</table>

Regarding child rearing among WWE, Lannon (1994) suggested that after the baby’s arrival, the woman needs to continue to maintain the best possible seizure control and to plan for the safety of herself and her child if seizures occur. This is a family effort. Attention must also be given to the needs of a child growing up in a home where a parent has seizures. Arimoto and Murashima (2007) revealed that mothers with higher child-rearing anxiety had less childcare satisfaction, more depressive symptoms, more worries about the child, less support from the husband, and less social support.

1.3. **Need and Significance of the study**

Gender based physiological difference brings forth issues of unique concern to women with epilepsy. The Epilepsy community - both professionals and patients, has become more aware of these unique issues. The relationship between a woman’s biology and her seizure disorder represents a whole frontier for epilepsy research.
Many KAP studies brought out the knowledge and attitude change related to women with epilepsy across the world. The cross sectional survey of knowledge and attitude in young adult Canadian college students found that the knowledge about epilepsy was patchy and weak, but attitudes were favourable towards person with epilepsy having children (Young et al., 2002). It is of interest that 95 percent of the participants would not object to a person with epilepsy marrying a close relative of them. But more than 90 percent didn’t know that AEDs could cause fetal malformation. Even with an educational brochure, the important concept of AED induced teratogenicity was not improved on.

Choi-Kwon et al. (2004), investigated the perceptions of epilepsy in Seoul, South Korea, a country where social stigma toward epilepsy is still pronounced. A randomly selected 1000 persons living in Seoul were interviewed using telephone regarding public awareness, knowledge, and attitudes toward epilepsy. Among 1000 respondents, the 92 percent who had read or heard about epilepsy became the subjects of the study. Forty-seven percentage believed that epilepsy is inheritable, whereas five percent thought that epilepsy is a mental illness. *Marriage of their children to an epileptic person, childbearing by women with epilepsy, and employing a person with epilepsy were opposed by more than 50 percent of respondents.* The reasons for the negative attitudes were that epilepsy was hereditary and untreatable. This study suggested that there still remain negative attitudes regarding marriage, childbearing, and employment of persons with epilepsy, which might have come from misconceptions about the cause and treatability of epilepsy. Public health education either through media or school health education is urgently needed to improve knowledge about, and attitudes toward epilepsy.
Societal prejudice against epilepsy appears to be a phenomenon associated with the rural upper classes and urban area (Mani & Geetha, 1997). The Rural Epilepsy Control program, Yelandur study, from Karnataka was completed in 1997. A KAP survey of 372 patients or relatives was also conducted which showed that although seventy-six percentage of people surveyed knew about epilepsy, only nine percentage could relate it to the brain. Rejection by family, society or both was reported by only twenty percentage of patients. It appears that the rural lower class people were providing more supportive care to family members/relatives having epilepsy.

The KAP study on Epilepsy done in Kerala was a door-to-door survey covering the entire population of 238,102 people residing in 43,681 households in a semi urban area of central Kerala. It has shown that the prevalence and pattern of epilepsy in central Kerala, South India, did not differ from that of developed countries. Although the awareness of epilepsy among the people of Kerala was comparable to that of developed countries, the attitudes were much more negative. The need for educating the people of Kerala on epilepsy and for incorporating an adequate knowledge of epilepsy in the school curricula cannot be overemphasized (Radhakrishnan et al., 2000).

The data supported the hypothesis that there is a difference in the attitude of public towards people with epilepsy.

Despite all our advances women with epilepsy face obstacles when it comes to pregnancy and childbearing. Many of these obstacles are social, based on incorrect and inappropriate attitudes of the public towards persons with epilepsy. Most women with epilepsy can conceive and bear healthy children (Yerby, 1996). Even then, in a recent survey, it was found that women less than 35 years old were concerned about pregnancy issues. It appears that women with epilepsy who access online health information were not adequately educated by their physicians about the impact of epilepsy and AED therapy (Vazquez et al., 2007).
The issues relating to pregnancy in patients with epilepsy have become increasingly important in the past 30 years (Chary, 2000). Initial interest was related to pregnancy outcome in WWE and the first reports came in the early 1960’s. Later the teratogenic effects of antiepileptic drugs became the focus of attention. Nevertheless, WWE face health issues for which there was no available outcome literature to guide decision-making (Zahn et al., 1998).

Maternal epilepsy is likely to adversely affect the offspring at its various stages of development amounting to increased morbidity and mortality related to uncontrolled seizures and the teratogenic effects of AEDs. Proper planning can optimize the health of these women during pregnancy and reduce the risks to their babies (Crawford, 2005; Morrell, 2003; Thomas, 2003; Yerby, 2003). Presently, most women with epilepsy deliver healthy babies with appropriate management. Preliminary results from the Kerala registry of epilepsy and pregnancy (KREP) are promising. Majority of women with epilepsy had safe pregnancy and childbirth without any aggravation of epilepsy (Thomas et al., 2001). Yet, doubts regarding the ability of the mother to take care of the baby, fear of harming the baby if she breast feeds, as well as fear of inheritance of epilepsy still persist.

Women with epilepsy have various concerns about their reproductive health, ability to conceive, continue pregnancy safely, safe confinement, breastfeeding and other child rearing activities. Child Rearing Practices (CRP) pertains to meeting the developmental needs of the infants which include meeting the feeding needs, monitoring growth and development, meeting the cleaning and protection needs and providing appropriate infant stimulation. The mother is the most important person to meet the various needs especially during infancy. Women with epilepsy may have limitations in achieving these objectives on account of frequent seizures, lethargy and sedative effects of antiepileptic
drugs (AEDs) or lack of motivation. Mothers with epilepsy generally are more apprehensive and they lack self-confidence in bringing up their children. Many a times it is seen that their maternal role is totally taken away by other elder women in the family. Child rearing practices of WWE need to be assessed as to whether they perceive and meet the infants’ needs in an appropriate manner. It has not yet been investigated as to what extent the antiepileptic drugs (AEDs) impair mental abilities, psychological well being, awareness and wakefulness in treated mothers and to what extent this might disturb and alter their interaction with the child. The possible effects of epileptic disorders and/or AEDs on the behaviour of the mother and the child rearing practices need to be addressed.

There is some unwanted scare about breast-feeding. It is also noticed that there is an increased incidence of seizures in postpartum period probably due to sleep deprivation or physiological and hormonal effects. An increased demand of taking care of the child has an adverse effect on epilepsy. There are some reports stating that in the offsprings of epileptic parents a delay of somatic and mental development and maturation occur more often than in the normal population that needs further confirmation. Infants with fetal hydantoin syndrome may have cognitive impairment (Brewer & Patricia, 2003). Studies are urgently needed to investigate potential adverse effects of AED exposure, with special reference to effects on postnatal intellectual development (Perucca, 2005).

Many women with epilepsy experience considerable difficulties in child rearing. The specific problems of WWE related to child rearing have not been studied adequately. Certain observations in developed countries indicate that intervention of a nurse practitioner can facilitate the coping mechanisms in women with epilepsy. Epilepsy nurse specialists are increasingly involved in the management of epilepsy, improving
patient’s quality of life and reducing morbidity and hospital attendance (Hosking & Josemir, 2006). More comprehensive research focusing on the unique health concerns of women with epilepsy will provide information that ultimately improves their family lives. Although there has been a lot of research about pregnancy and epilepsy, little has been written about the challenges for mothers with epilepsy (Crawford, 2005).

The offspring of a woman with epilepsy is an issue currently getting attention because of several implications. A complex interaction between Epilepsy, Pregnancy and its adverse effects on fetus, labor, neonate, congenital malformation, developmental delay and treatment challenges of such cases is increasingly being realized. Time has changed and fortunately today educational materials are available to medical personnel on these issues. However there is still very little literature available for the WWE who also face various epilepsy related issues. There is much anxiety about the possible risks to a child from the mother’s epilepsy, but there is little published evidence. The risk of the child being harmed depends on the type of seizure and its severity and frequency, and this risk is probably small if time is taken to train mothers and caregivers in safety precautions (Crawford, 2005).

Although an increasing number of women with epilepsy are getting married, becoming pregnant and rearing children, scant literature exists on their child rearing practices. In particular, it is unclear whether theses women are rearing rather allowed to rear their children similar to women without epilepsy. Informal observations and a preliminary Case study (Saramma & Thomas, 2007) brought out some lacunae in the child rearing practices of WWE. These WWE lacked information about their children’s growth and development and safety issues. The unpredicted nature of maternal seizures may harm the baby, jeopardising the protection aspect of child rearing. With regard to breast-feeding, a functional letdown reflex is required to provide adequate milk to a
nursing infant which is activated by infant suckling the breast. Many a times post partum seizures or the sedative effect of antiepileptic drugs or even fear and misconceptions causes delay in initiating and sustaining breast-feeding, the most important aspect of child rearing in early infancy. The WWE with low-level education may not provide adequate stimulation to their infants. This understudied area of formal studies kindled the interest of the researcher to undertake a true experimental study to answer the research question 'Is there a true impairment in the child rearing knowledge and practices of WWE in comparison to women without epilepsy and can an educational intervention in the form of a booklet help?

1.4. **Statement of the Problem**


1.5. **Objectives**

The objectives of this study are:

1. To compare the knowledge and practice of child rearing among women with epilepsy (WWE) with that of women without epilepsy (WWoE).
2. To compare the maternal and baby outcome among WWE and WWoE.
3. To determine the effect of Structured Instructional Module on knowledge and practice of child rearing and health related outcome of WWE and their babies.
4. To identify the possible predictors which influence the child rearing practices and baby outcome.

1.6. **Operational Definitions**

**Child Rearing Practices:**

This refers to the self-reported behaviour of the mother in caring her baby during early infancy which includes meeting the feeding needs, monitoring growth and development,
meeting the cleaning and protection needs and providing appropriate infant stimulation, measured with the help of a Child Rearing Practice Scale.

**Women with Epilepsy (WWE):**

Pregnant women in the first trimester, registered in the Kerala Registry of Epilepsy and pregnancy (KREP) who have active epilepsy (had at least one epileptic seizure in the previous five years regardless of antiepileptic drug treatment).

**Women without Epilepsy (WWoE):**

Pregnant women in the first trimester registered in the antenatal registry of Sree Avittom Thirunal Hospital, who do not have any disabling disease and have matching age, education and parity to the enrolled WWE.

**Structured Instructional Module:**

This refers to a Self Instructional Module (SIM) titled ‘You and Your Baby - conception, labor, and infant care- A self Instructional Module for Women with Epilepsy’, developed by the investigator in local language (Malayalam). This printed booklet contains information on care during pregnancy, labor and child rearing and is received by the intervention group of women with epilepsy after the first interview.

**Health Related Problems:**

These refer to self-reported outcome of the women with regard to their personal, family and maternal life, as well as reported/observed baby health, at birth and at three to four months post partum, measured as maternal outcome and baby outcome -1 and Baby outcome-2, using composite scales.

1.7. **Hypotheses**

1. The mean baseline knowledge score of WWE will be significantly lower than the mean baseline knowledge score of WWoE as measured by the Child Rearing Knowledge test.
2. The mean child rearing practice score of WWE will be significantly lower than the mean child rearing practice score of WWoE as measured by the Child Rearing Practice Scale.

3. WWE will report lesser child rearing capability than WWoE as measured by the Visual Analogue Scale - 'Ladder on child rearing capability'.

4. The mean maternal involvement score of WWE will be significantly lower than that of WWoE as measured by Maternal Involvement Scale.

5. The mean outcome score of babies of WWE will be significantly lower than that of the babies of WWoE as measured by Baby Outcome Scale.

6. The mean maternal outcome score of WWE will be significantly lower than that of WWoE as measured by Maternal Outcome Scale.

7. The mean post-test knowledge score of WWE in the intervention group will be significantly higher than the mean post-test knowledge of WWE in the control group.

8. The mean child rearing practice score of WWE in the intervention group will be significantly higher than the mean child rearing practice score of WWE in the control group.

1.8. Conceptual Framework

The conceptual framework for the study is based on Orem’s self care model. Orem’s self care concepts were chosen because of its emphasis on health and person as central to nursing. The core of Orem’s theory is that man has an innate ability to care for himself. This model focuses on each individual’s ability to perform self-care activities. Self-care includes all the activities that individuals initiate and perform on their own behalf in maintaining life, health and wellbeing (Orem, 1985, as cited in Polit, 2004).
According to Orem the goal of nursing is to help people meet their own therapeutic self-care demands. The model explains how nurses facilitate the self care of clients, the phenomenon that is central to nursing. In this model, the ability to care for oneself is referred to as self care agency and the ability to care for others is referred to as dependent care agency. The self-care agency depends on one’s self care capabilities and self care requisites. Self-care capabilities are those abilities essential to perform self-care. Self-care requisites describe the individual’s need for self care. Orem identified three types of nursing systems namely wholly compensatory, partially compensatory, and supportive educative. In the latter the nurse assists the patient in making decisions and acquiring skills and knowledge. The conceptual model for the present study incorporated the supportive educative nursing system of Orem.

In this study, the ability of the WWE to meet the child rearing demands depends mainly on the knowledge and practice about child rearing. The study is based on the assumption that if WWE identify the factors for safe pregnancy, confinement and appropriate child rearing practices they can develop maximum self care ability. This process could be well supported by the provision of a self-instructional module specially prepared for women with epilepsy for their care during pregnancy and for the care of the baby. Certain other factors influence the self-care ability and child rearing capability of WWE as well as the maternal and baby outcome. These include maternal constitutional variables: age, parity, education, and antenatal health; exposure variables: type of family, standard of living, religion, place of residence and mass media exposure. The maternal knowledge and practices on child rearing were related to feeding, growth and development, protection from infection, injury and accidents and infant stimulation. These were incorporated in the tool. Knowledge of self-care during pregnancy influences the maternal and baby outcome. Hence the antenatal care was included in the self-instructional module in addition to infant care.
The self instructional module – You and your baby - a self instructional module for WWE on conception, labor, and infant care- is given to the participants during the first trimester, a time period when a pregnant woman is eager to know about the changes and special care during pregnancy. The module could be taken home, read and assimilated conveniently. The conceptual model assumed that self-care ability would develop if the WWE acquired adequate knowledge on care during pregnancy. It is also believed that the dependent care ability of the WWE would develop by acquiring knowledge about the care of the baby. Thus child rearing knowledge and practice of WWE would improve. Since knowledge results in behaviour modification, it is assumed that ultimately this could strengthen the self-care agency of the WWE. Optimum self care during pregnancy and healthy child rearing practices during the post partum period would enable the WWE to have positive maternal outcome and baby outcome. A well-informed, self-prepared ‘mother to be’ could be a real parent who provides optimum care to the baby. Knowledge on child rearing, child rearing practices, child rearing capability, maternal involvement, maternal and baby outcome, the outcome variables in this study also were selected based on Orem’s self care model. Appropriate tools were constructed for measuring them. The relationships are shown in the diagrammatic representation, Fig 1.1.
Self care requisites to provide optimum self-care & child rearing

Maternal characteristics
- Constitution
  - Age
  - Parity
  - Education
  - Antenatal health
  - Body Mass Index
- Exposure
  - Type of family
  - Standard of living
  - Religion
  - Place of residence
  - Mass media
- Knowledge & Practice on Child rearing
  - feeding
  - growth and development
  - safety and
  - infant stimulation

Measurement Tools
- Structured Interview Schedule
- Child rearing Knowledge Test
  - Feeding, Growth & development, Safety, Infant stimulation
- Child rearing Practice Scale
  - Feeding, Growth & development, Safety, Infant stimulation
- Maternal Involvement Scale
- Visual Analogue Scale
- Maternal Outcome Scale
- Baby Outcome Scale

You and Your Baby - Conception, labor and infant care - A Self Instructional Module for WWE

Fig. 1.1. A conceptual Framework based on Orem's Self Care Model
1.9. **Methodology**

This is a quantitative study using experimental design. This prospective study is done in three phases.

**Phase I** — Developing and testing a self Instructional Module for Women with Epilepsy by the Investigator. Interview schedule and the various scales are content validated and reliability tested. Ethical clearance is obtained.

**Phase II** — Pregnant women with epilepsy who are attending Kerala Registry of Epilepsy and Pregnancy (KREP) and those who fulfil the inclusion criteria are enrolled, and interviewed. Afterwards they are randomly assigned to intervention and control group in a double-blind manner by providing booklets in a sealed cover either the self instructional module prepared by the Investigator or an alternate health education booklet on Epilepsy already available in the Neurology Department of Sree Chitra Tirunal Institute for Medical Sciences and Technology. The module is entitled ‘You and Your baby – conception, labor, and infant care- A self Instructional Module for women with epilepsy’. The KREP is functioning at the R. Madhavan Nayar Centre for Comprehensive Epilepsy care, Department of Neurology at the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala. An age, education and parity-matched pairs of women without epilepsy are selected from a pool of antenatal women in the waiting area of the antenatal clinic, Sree Avittom Thirunal Hospital, the Women and Children Hospital of Medical College, Trivandrum. The investigator establishes good rapport and obtains the informed consent prior to enrolling the pregnant women for the study. Initial data including personal profile, antenatal data, and knowledge assessment regarding child rearing is completed during this preliminary visit. One booklet (randomly numbered, covered and serially arranged) each will be given to the selected WWE, in the order of their appearance thus randomly assigning the WWE into the intervention and control group without the knowledge of
the Investigator. The subjects also would not know whether they belonged to intervention or control group. The women without epilepsy are not given any booklets, but data are collected in the same manner from the age, education and parity matched pairs.

Phase III – Follow up of these women by two more visits, second visit during third trimester to complete antenatal data and the third visit after delivery when the baby is three to four months old. The final interview covered child-rearing practices, outcome status of both mother and baby. The child rearing knowledge test is repeated as post-test.

1.10. Delimitations

The study is delimited to

- Antenatal women attending two Government Institutions only.
- Antenatal WWE attending the Kerala Registry of Epilepsy and pregnancy (KREP) who are in the first trimester of pregnancy and who can read Malayalam.
- Antenatal women coming for registering their pregnancy in the Sree Avittom Tirunal Hospital who are in the first trimester of pregnancy.
- The assessment of child rearing knowledge and practice is mostly limited to verbal responses of the subjects to the interview questions.

1.11. Organisation of the report

The report is divided into six chapters. The first chapter is introduction. In this chapter the background of the study is outlined, the subject - women with epilepsy (WWE), and the outcome variable child rearing practice is briefed, the need and significance of the research problem is stressed, and the problem and objectives are stated. An attempt is made to operationally define the terms so as to clarify the problem. The hypotheses are enlisted, and the conceptual framework is briefly described along with a brief
discussion on methodology adopted for the study. The delimitations are specified.

A summary of related studies pertaining to relevant areas of the present study is reviewed in chapter II. Chapter III deals with the materials and methods of the study and chapter IV analyses and interprets the findings, chapter V presents a brief critique on the present study, discusses its outcome, and mentions its strength and weakness and chapter VI presents a summary of the study including major findings, conclusions, implications, limitations, of the present study together with certain recommendations for further research. The report also includes selected references, and appendices.