
INCIDENCE OF PROLONGED MOTOR AND EEG SEIZURES
IN ELECTROCONVULSIVE THERAPY : A 1 YEAR CROSS-
SECTIONAL HOSPITAL BASED STUDY

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ACRONYMS

APA	American Psychiatric Association
BF	Bi Frontal
BMI	Body Mass Index
BT	Bi Temporal
ECG	Electro Cardio Graphy
ECT	Electro Convulsive Therapy
EEG	Electro Encephalo Graphy
GHPU	General Hospital Psychiatry Unit
ICD-10 DCR	International Classification Of Diseases -10 Diagnostic Criteria For Research
KLES	Karnataka Lingayat Education Society
MECT	Modified Electro Convulsive Therapy
NCSE	Non- Convulsive Status Epilepticus
NIMHANS	National Institute Of Mental Health And Neuro Sciences
NPO	Nil Per Oral
NSAID	Non Steroidal Anti Inflammatory Drugs
OMS	Optical Motion Sensor
RUL	Right Uni Lateral
SE	Status Epilepticus
SSRI	Selective Serotonin Reuptake Inhibitors
UK	United Kingdom

ABSTRACT

Introduction:

Electroconvulsive Therapy has been an effective therapeutic option for psychiatric illnesses. The practice of ECT has evolved over the decades to make it more safer and efficacious by the use of anesthetic agents, muscle relaxants, modifying electric stimulus parameters, electrode placement sites, adjusting concurrent medications etc. Higher rates of adverse effects in ECT are noted with prolonged seizures and status epilepticus. Detecting these by just motor method is unreliable and additional EEG monitoring method has been considered to be a better option.

Aims:

To find the incidence rate of prolonged seizures in patients undergoing ECTs and its associated factors like EEG monitoring and ECT session number.

Materials and methods:

216 sessions in patients undergoing modified ECT for various psychiatric diagnoses were included in this cross-sectional study. Patient characteristics and seizure characteristics were noted after seizure was induced by electric current stimulus from the ECT apparatus with EEG. Seizures were noted as per motor and EEG characteristics defined by Royal College of Psychiatrists ,UK (2005).

Results:

24 were Prolonged seizures, 149 were Adequate seizures. The remaining 33 were missed or inadequate seizures. 9 (37.5%) of these 24 prolonged seizures were

detected exclusively by the use of EEG monitoring. Prolonged seizures were significantly higher in First and second ECT sessions, compared to later sessions.

10 (6.7%) of the 149 adequate seizures were picked up exclusively by EEG monitoring.

There were no significant association of prolonged seizures with gender, BMI, sub-types of psychosis, concurrent use of lithium or clozapine in ECTs.

Conclusion:

EEG monitoring during modified ECT helps in detecting prolonged and adequate seizures which may have otherwise been missed by using only motor criteria. Prolonged seizures were significantly associated with ECT sessions and was higher with the first ECT than second and later ECT sessions.

Keywords:

Electroconvulsive therapy, Electroencephalography in Electroconvulsive therapy, Prolonged seizures, Inadequate seizures

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INTRODUCTION

Electroconvulsive Therapy (ECT) is an important treatment option in psychiatric illness like depression, mania, schizophrenia and occasionally other conditions such as catatonia, the neuroleptic malignant syndrome and parkinsonism.¹⁻⁴

Unmodified Electroconvulsive Therapy was in practice in the earlier days. Current practice is the use of modified Electroconvulsive Therapy (MECT), with the additional use of short acting muscle relaxant and general anaesthesia.^{5,6}

Elicitation of seizure and its adequacy are essential for the therapeutic effects of ECT.^{1,7}

The aim of ECT is to induce a generalised cerebral seizure activity of a type that is associated with a tonic-clonic or grand mal convulsion.^{1,8} To do so an electrical dose that is sufficiently near or above the seizure threshold is necessary to maximise the clinical efficacy of treatment but not so high that it needlessly contributes to the cognitive side effects of treatment.⁹

If adequate or necessary cerebral seizure activity has not been induced, then the objective of the ECT is not achieved. The ECT practitioner must restimulate the patient while he or she is still unconscious – otherwise the treatment session is not beneficial therapeutically.¹⁰

EEG monitoring during ECT is additionally useful to detect both adequacy of cerebral seizure in patients having no or inadequate motor seizures and also to detect prolonged seizures to prevent acute and long term adverse effects.¹¹⁻¹⁵

The minimum electrical dose to induce the necessary generalised cerebral seizure activity is referred to as the “seizure threshold”.¹⁰ The seizure threshold should be routinely measured by an empirical titration method.^{16,17}

Criteria for ECT-Induced Seizure Adequacy:

According to the Revised criteria of Royal College of Psychiatrists, UK (2005)¹⁰, an adequate seizure must have a seizure with either Visual seizure characteristic which is bilateral tonic-clonic seizure of no specified length, or EEG seizure Characteristics which is the presence of typical seizure features: Polyspike activity, Spike and wave complexes & Postictal suppression or both.¹⁰

The seizure onset is indicated by occurrence of spikes and poly spikes which are above 8-10 Hz in frequency. These are gradually replaced by more rhythmic spike and slow-wave discharges. The frequency of this slow-wave phase initially is about 4 Hz and reaches 2½ -3 Hz. Typically, the seizure ends with a fit-switch which is characterized by abrupt cessation of EEG discharges. Sometimes, the termination does not occur with such a fit-switch. The high amplitude spike and wave activity is replaced by low voltage slow waves. Its amplitude is smaller than that seen in the EEG before the stimulus application.⁸

Prolonged seizures occur during ECT which do not add any therapeutic benefit but instead cause higher rates of adverse effects like confusion, memory disturbances.

According to Revised Royal College of Psychiatrists criteria (2005), a prolonged seizure is any seizure of duration more than 2 minutes.¹⁰ Whereas American Psychiatrists Association (2001), defines it as any seizure more than 3 minutes or 180 seconds duration.¹⁵ The general consensus is that any seizure lasting more than 2-3 minutes is prolonged and must be terminated as soon as they are detected.¹⁰

A study conducted by Benbow in Manchester, UK in 2003 showed Prolonged seizures occurred in 19% of ECT courses studied. EEG seizure length was significantly longer than the observed motor seizure length.¹¹

Mayur(1999) conducted a study in India at NIMHANS, Bangalore in which EEG seizure was prolonged in 38 (16%) out of 232 that were in the study. The motor seizure was shorter than 90 seconds in 15 of the 38 (39%) prolonged seizure patients.¹⁸

These 39% of the overall prolonged seizures during ECT would have gone undetected if it wasn't monitored by electroencephalogram (EEG). Results are applicable to the first ECT session only.

The number of Indian studies in this regard are few and mainly from the central institutes and very few studies from General Hospital Psychiatry Units (GHPU) which caters to significant number of psychiatric patients, most of the GHPU do not have EEG monitoring of ECTs. Hence, this study is done to assess the incidence of prolonged seizures and the factors affecting it during ECT by EEG monitoring.

OBJECTIVES

1. To find the incidence of prolonged seizures in patients undergoing modified electroconvulsive therapy by motor and EEG criteria.
2. To find the incidence of adequate seizure by EEG criteria but inadequate by motor criteria in patients undergoing modified electroconvulsive therapy.
3. To find the correlation of incidence of prolonged seizures in patients undergoing modified electroconvulsive therapy with session number and other factors like gender, BMI, sub-types of psychosis, concurrent medications like lithium and clozapine.

REVIEW OF LITERATURE

HISTORY OF ELECTROCONVULSIVE THERAPY:

1)EVOLUTION OF CONCEPT OF CONVULSIVE THERAPY

Manfred Sakel in 1933, a psychiatrist from Vienna(Austria) had invented Insulin induced Coma as a therapy for the psychiatric patients. Initially he was treating morphine withdrawal patients using this technique and then after its success he used it in Schizophrenia patients.This method later came to be called as the "Insulin-shock treatment".¹⁹ It typically involved using daily injections of high doses of insulin which caused the patients to produce intense sweat, go into somnolence and produce coma, which he termed as “wet shocks” or in some patients it would produce epileptic tonic-clonic fits and other seizure effects which he termed as “dry shocks”.²⁰ He also described that this technique had lethal consequences like hypoglycemic coma in the hands of untrained personnel and it would be made safer with timely intervention using glucose infusion. This required the procedure to be done by trained personnel. Sakel had got the idea for this technique around the time of a major medical breakthrough by Wagner-Jauregg’s theory of biological basis of disease for which he received the Nobel Prize in Medicine in the year 1927.^{21,22} This principle further lead to various successful treatment modalities that is based on the physiological processes of disease for therapeutic purposes such as convulsive therapy.

A few years later,a Hungarian psychiatrist called Ladislas Von Meduna from Budapest in the month of January 1934 introduced Convulsive therapy by using chemicals which had seizures/convulsions producing ability. Initially, he was injecting an oilbased camphor preparation intramuscularly in patients of

Schizophrenia. Later on, he started using Metrazol (also Cardiazol) as camphor injections were unreliable for inducing convulsions effectively. He reported observations in 26 cases of Schizophrenia.^{21,23} He had hypothesized a theory of biological antagonism between Schizophrenia and epilepsy for which valuable data was available during the time based on observations of Schizophrenia patients who also had epilepsy and his own professional experience. Nyíröet al. in January 1931 noted that the rate of schizophrenia were significantly lower among those with epilepsy than that of the general population. the general population.²² Meduna had also found interesting a report by Muller in 1930 about two schizophrenia patients whose symptoms remitted following a few epileptic seizures.²¹

He concluded in his own observation that epileptic seizures had influence on the behavior of patients of Schizophrenia.²⁴

Ugo Cerletti who had been studying in University of Genoa (Italy), observed while working with Battelli who in 1903 had started using domestic electric current available from the city of Genoa on animals to produce seizures.²⁵ This procedure involved placing one electrode in the animal's mouth and another one in the back of the animal's neck . Upon passing electric current it would induce an epileptic seizure. Battelli was considering that as a safe procedure and having observed it from close quarters Cerletti was influenced by the same.²⁶

Cerletti had developed a working idea based on his observations of Meduna's Convulsive therapy for Schizophrenia as well as Battelli's method of inducing epileptic seizures in animals by using electric current. He thought of combining the two ideas and perhaps to try and use electric current to induce seizures in patients of psychiatric illness as it was being used effectively in animals to induce seizures. But

he had to be sure of the safety of using electric current and contrive an effective and harmless method to administer it safely in humans. He had started collecting data from his animal experiments and analyzing it to ensure that it was a safer way to induce seizures than chemicals like Metrazol or Insulin which were being used then.²⁵

He initially begun experimenting this technique on street dogs which were caught and brought in vans every week during a period between 1936-1937. Cerletti's assistant Lucio Bini used electric current while Cerletti's other assistant Accornero used insulin method and studied the histopathological changes in Ammon's area in the dog's brains.²⁷ It was necessary to differentiate the post-mortem changes with that of the effects of the induced seizure by electricity and other methods.²⁶

However, he was still worried about the safety of using electric current in humans and it took him many years of applying it on experimental animals before being confident of using ECT for humans.

Lucio Bini helped in eliminating the fatal aspects of Electroconvulsive therapy in experiments with animals as he noticed that placing one electrode on the head and another on the anus of animals caused the death of the animals as they would cause Cardiac Arrest. He suggested that both the electrodes maybe placed on the head after testing various circuits in which no animals died further in the experiments.²²

After the initial success of safely using electricity induced seizures in animals, one of the vital moments in electroconvulsive therapy happened at the first international meeting on "New therapies for Schizophrenia" organized by the Swiss Psychiatric Association in Munsingen, Switzerland headed by Dr. Max Müller in 1937.²⁸ Bini who was representing Cerletti and the team, presented their first report of electric current induced epileptic seizure in dogs as well as another report on insulin

coma therapy. This is the first ever public discussion on Electro Convulsive Therapy.²²

2) INVENTION OF ELECTRO-CONVULSIVE THERAPY

Cerletti despite the success of his method of using electric current safely to induce seizures was still worried that people may criticize and compare his method with that of electric chair used for murderers in prison, especially that the procedure will be seen as a crude, inhuman procedure.^{29,30} After Bini returned from the Conference in Switzerland, he observed in his experiments on animals like pigs being electrocuted in the slaughterhouses with electrodes to their heads did not prove fatal, and they had a quick recovery post electricshocks. The pigs were not being killed by electric shocks instead they were being anesthetized before they were being slaughtered.^{22,29,31}

Cerletti and Bini then started Electro Convulsive Therapy in treating humans in April 1938. It was first administered in their Clinic. The first patient was a man who was found aimlessly traveling in the train station without a ticket and diagnosed to have Schizophrenia. He was given a course of 13 ECTs over a period of 2 months and had complete remission but he was lost to follow up for the next 2 years but remained recovered in that period.^{29,32,33}

Cerletti gave the first public presentation of ElectroConvulsive Therapy in a conference in Rome in the month of May 1938 and it soon became an accepted procedure for not just Schizophrenia but a variety of psychiatric disorders like Depression, Mania, Bipolar Disorder, Catatonia, Psychosis etc and even non-psychiatric disorders like Parkinsonism.^{33,34}

Thus, the procedure of electrocution of pigs by applying an electric shock to their heads in slaughterhouses in Europe before they were slaughtered which caused seizures was replicated and introduced by Cerletti and team on humans for therapeutic purpose. The patients had shown remarkable improvement in psychiatric symptoms especially that of catatonia. The main drawback of this procedure were the violent seizures which caused severe injuries in the form of fractures, abrasions, lacerations and also dislocations, including spinal fractures in many of them.^{29,35}

INTRODUCTION OF MODIFIED ELECTROCONVULSIVE THERAPY

1) USE OF SKELETAL MUSCLE RELAXANTS IN ECT

After the initial wave of success with ECT across the world in the late 1940s, especially in the US and European World. There were concerns regarding adverse effects such as joint dislocations, bone fractures including spinal fractures, risk of additional injuries due to the violent nature of seizures associated with the procedure.^{36,37}

By then skeletal muscle relaxants based on plant product curare which were used to cause paralysis in hunted animals by tribals was isolated by Harold King.^{38,39} A chemical called d-tubocurarine was synthesized from a sample of curare and was subsequently used in practice by anesthetists in surgeries requiring immobilisation of the patient.³⁸

Initially curare compounds found indication in the treatment of tetanus, epilepsy and hydrophobia initially.^{38,39} The most widespread usage for curare containing products began due to use in ECT more than other procedures at the time. An American neuropsychiatrist Abram E. Bennett from Nebraska had an idea of using

curare in ECT to block neurotransmission and preventing the occurrence of severe fractures and dislocations associated with the procedure as he was unhappy with the high incidence of spinal fractures in his practice.^{33,40}

Later, after the introduction of Succinylcholine which is a non-depolarizing ultra-short acting muscle relaxant, the procedure became more easy and convenient to conduct. With these there were significant reduction in the fractures, dislocations and violent injuries. But patients were also completely paralyzed including diaphragm which is the active muscle for respiration.^{38,39,41}

Using curare or succinylcholine in ECT had another significant drawback. It was that the patients were not just paralysed completely but they would also be aware of the seizures while in a paralysed state during ECTs leading to “awareness syndrome”.⁴²

It is due to the inability to breathe during the paralysis of the respiratory muscles like diaphragm causing a great amount of distress to the patients. This awareness of not being able to move or voluntarily breathe while having a generalized convulsion was particularly distressing and a significant problem.^{42,43}

2) USE OF GENERAL ANAESTHETIC DRUGS IN ECT

By the late 1950s, the invention of Anaesthetic medications had already been in routine usage in various surgeries requiring complete loss of awareness and sensory sensations. The usage of these anaesthetic drugs in Electroconvulsive Therapy were started in the same era. Abolishing the distress caused by an “aware” state of muscle paralysis during use of muscle relaxant during ECT by the use of anaesthetic drugs was a big step towards providing the patient a huge relief.^{44,45}

The use of this general anaesthetics caused the patient to enter a plane of anaesthesia with complete loss of awareness, sensation and suppression of reflexes which are needed only for a short duration of time. This was taken care of by using short acting Barbiturates like Methohexitone, Pentothal(thiopentone sodium) having these desirable properties.^{46,47}

The faster induction, shorter action and quicker recovery at a mild-moderate dosage range of these drugs along with their anticonvulsant property in case of need for termination of a prolonged seizure made them the anaesthetic agents of choice for this new “modified electro-convulsive therapy”.^{6,48}

It was after the invention of the anaesthetic drugs and skeletal muscle relaxants by the late 1950's that the ECT procedure became more acceptable in terms of the absence of fractures, dislocations and anxiety symptoms.

The use of muscle relaxants like succinylcholine, can have effects of strain on the cardiovascular system but the dose of these drugs used in MECT is significantly lesser than the dose associated with adverse effects. However, the occurrence of such adverse cardiovascular effects have been very minimal in its severity or frequency.⁴⁹

The muscular convulsions during ECT produces a markedly increased cardiac load which the heart may not be able to handle. Blood-pressure and pulse rate are also significantly altered during the tonic phase of the convulsion due to the vagal tone of the heart.⁵⁰ The muscle convulsions are reduced by an ultra-short acting skeletal muscle relaxant with a safer adequate dose and vagal block by using drugs like Atropine or Glycopyrrolate. They also reduce salivation and thus reduce the risk of aspiration.^{50,51} Intravenous use of these drugs, preferably glycopyrrolate over atropine has greater advantage than subcutaneous administration.^{51,52}

3) USE OF PRE-OXYGENATION DURING MODIFIED ECT

Oxygenation is used prior to giving ECT stimuli as well as during post ECT period till the patient regains respiration.

If oxygenation is inadequate like in situations where pre-oxygenation is not done or inadequate before administering the electric stimulus, then there is an increased risk of hypoxia. This in turn may lead to low seizure duration and inadequate seizure.^{53,54} Repeated electric stimulation is needed to get an adequate seizure. Hypoxia can cause cerebral dysfunction during prolonged seizures, which can lead to prolonged confusional states, agitation and cognitive impairments or even non-convulsive status epilepticus.^{11,54} Animal studies have shown an increased risk of structural brain damage, cardiopulmonary, and cardiovascular complications in prolonged seizures regardless of efforts to maintain oxygenation.^{11,54}

The ECT procedure became very sophisticated and requires the additional service of a qualified anesthetist to administer electro-convulsive therapy.¹⁰ This administration of general anaesthetic and skeletal muscle relaxant during ECT is termed as modified Electroconvulsive therapy (MECT).⁴⁰

The procedure has now become more safe with the near elimination of risk of fractures, cardiac arrest and anxiety with these measures. By the 1960s, adverse effects like cognitive disturbances like brief confusion, memory loss, agitation, headache started getting more attention to maximise the treatment benefits. Most of the ECT related research in the last 4 decades is done in this regard.⁵⁵

Factors like electrode placement sites, interval between successive ECTs , the treatment course of ECTs , concomitant medications being used that can affect seizure threshold, anaesthetic drugs used etc also have been shown to affect the seizure duration and/or its adverse effects.^{16,17,56,57}

4) USE OF NEWER ELECTRODE PLACEMENT TECHNIQUES

An important factor affecting safety and the efficacy of ECT studied is the site of electrode placement. Various sites have been successfully tried, common among these are bitemporal, bifrontal, right unilateral and left anterior right temporal placements.

1. Bitemporal(BT) - the center of the electrodes are placed 4cm above and perpendicular to the midpoint of the line joining lateral angle of the orbit and external auditory meatus on either side of the head.¹⁰

2. Bifrontal (BF) site– the center of the electrodes are placed 5cm above the bridge of the nose about 2 cm apart on either side.¹⁰ Initially introduced by Richard Abrams and Max Fink in 1972, it was not successful in their trials. It gained attention from studies in the 1990s with various reports of varying efficacy and adverse effects. But in a large randomized trial conducted, it did not show as much as efficacy as bitemporal.⁵⁸

3. Right Unilateral(RUL) – also called as non-dominant hemisphere ECT. D’Elia established the standard RUL ECT position. The center of one electrode is placed on the side of the head just above the midpoint of a line running from the lateral angle of the orbit to the external auditory meatus. The other one which is the vertex electrode, is placed just to the right of a line down the midline of the skull at its intersection with a perpendicular line across the skull connecting the 2 external auditory canals.¹⁰

The severity of impairment of memory is more in Bilateral ECT than Unilateral ECT at lower electric doses. Among bilateral ECTs bitemporal ECT is noted to have more cognitive impairment than bifrontal.^{59,60} However, bitemporal ECT is still reported in majority of the studies on electrode positioning to be better than the others in terms of efficacy. Also unilateral ECT when administered at doses 6 times more than the

seizure threshold, the efficacy and adverse effects are noted to be similar to bitemporal ECT.⁶¹

5) ALTERING THE ELECTRIC CURRENT STIMULUS PARAMETERS

The ECT stimulation technique also contributes to the type of adverse effects, both cognitive and non-cognitive. Electric stimulus parameters like wave-form, pulse-width, duration of stimulus, frequency, amplitude have been studied with various results.⁶²

Over the last few decades lot of thought and research has been done in this aspect.

Electric current wave-form in ECT

1. Sine-wave ECT – This is the first wave-form of electric current used by Cerletti and Bini. It delivers an electric current of amplitude which varies continuously with the total duration of the stimulus.⁴⁰ Sine-wave current requires more energy to produce seizure and may contribute to the increased rate of adverse effects.³³

2. Brief-pulse wave ECT- It was noted that the sine wave has long duration along with gradual rise and fall of wave amplitude is physiologically inefficient and causes adverse effects. The electric pulses were made shorter by substituting brief pulses in place of peaks of sine-waves.⁶²

Brief-pulse ECT was introduced by American Psychiatrist Dr. Blatchley in the year 1976. It delivers electric current in pulses instead of the traditional continuous sine-wave form of electric current and has definite advantage over cognitive adverse effects.³³

The pulse width for brief pulse is between 0.5 – 2ms duration. Rectangular brief pulse is the commonest pulse technique used for this purpose.⁵⁶ But it was not until the 1980s that conclusive evidence emerged that brief rectangular pulse ECT could match

the efficacy of sine-wave ECT while dramatically reducing the cognitive adverse effects.⁶³

APA (2001) recommends that the brief-pulse waveform be the standard in ECT treatment and use of sine-waveform ECT cannot be justified any further.^{6,54}

3.Ultra-Brief pulse – ECT delivered with electric current of pulse-width less than 0.5ms.⁵⁶ Evidence to compare the efficacy of ultra-brief pulse ECT with that of brief-pulse ECT and sine-wave ECT is not sufficient. Studies have mentioned that ultra-brief pulse ECTs had been switched to brief-pulse ECT when responses were poor.⁶⁴

Classification of ECT induced seizures

ECT produces seizures but not all seizures are satisfactory. These seizures to be effective have to be adequate but not prolonged. Inadequate seizures are not efficacious while prolonged seizures and status epilepticus cause excessive adverse effects.⁶⁵

Just observation of motor manifestations may be misleading and an ECT seizure may be wrongly deemed to be inadequate or adequate and prolonged seizure activity or status epilepticus may be missed.¹⁵ Hence, it has become an accepted rule to monitor ECT seizure activity with EEG monitoring so that adequacy and prolonged activity are not missed. Hence, it is essential to classify seizures as adequate, inadequate, prolonged and status epilepticus which are defined as per their motor and EEG characteristics.

1) Adequate seizure:

The clinical efficacy depends on elicitation of a typical or adequate seizure. Older Royal College of Psychiatrists guidelines (1995) suggested that ECT induced seizures must have more than 15 seconds of tonic-clonic convulsions or 25 seconds

of EEG seizure characteristics to be adequate.^{15,66} These were later revised in the year 2005 and the criteria are described below.

Criteria for typical ECT-Induced Seizure or adequate seizure:

According to the Revised criteria of Royal College of Psychiatrists, UK (2005).

Any seizure with a bilateral tonic-clonic seizure activity regardless of its duration observed visually or the presence of characteristic EEG features - Polyspike activity, Spike and wave complexes & Postictal suppression.^{8,10}

A typical seizure has phases of “polyspike activity” having high frequency spike waves, continuing into slow and spike wave complexes and followed by either a relative or complete suppression of electrical activity “post-ictal suppression”.^{8,10}

2) Inadequate seizure

A well-modified seizure will manifest with either tonic-clonic convulsions or a typical seizure pattern on an EEG. The absence of both is considered as a missed or inadequate seizure.¹⁰

The seizures when inadequate or missed during ECT is not therapeutically advantageous and another adequate or typical seizure has to be produced by restimulation.¹⁰

3) Prolonged seizure:

The APA (American Psychiatric Association) guidelines (2001), define any seizure which is more than 180 seconds as prolonged seizure.⁵⁴

Revised guidelines of Royal College of Psychiatrists, UK (2005), defines prolonged seizures as any seizure duration of more than 120 seconds.¹⁰

4) Status Epilepticus:

Status epilepticus can be of two convulsive and non-convulsive types. Generalised convulsive and non-convulsive status epilepticus (SE) are neurological and medical emergencies defined as 5 or more minutes of either continuous seizure activity or repetitive seizures with no intervening recovery of consciousness.⁶⁷

Prolonged seizures and **Status Epilepticus** are important adverse effects that especially occur in those receiving medications/drugs that lower seizure threshold. Routinely used psychiatric medications like SSRIs, Clozapine and drugs like theophylline or pre-existing medical conditions like electrolyte imbalance can lower seizure threshold. They are a major concern during ECT sessions and have to be managed by skipping or stopping the drug.⁶⁸

IMPORTANCE OF DETECTING PROLONGED SEIZURES AND STATUS EPILEPTICUS

Non-convulsive Status Epilepticus (**NCSE**) is particularly difficult to diagnose as there are no easily observable visual seizure characteristics. In such cases, EEG monitoring helps in detecting cerebral seizure characteristics and is a better tool to assess the end of any seizure. Those receiving modified ECT and having prolonged confusional state and agitation may probably be in a state of NCSE as the motor convulsions have stopped. This is considered a neurological emergency and hence has to be terminated as soon as it is detected.¹⁰

As a result of prolonged seizures and Status Epilepticus, higher rates of cognitive and non-cognitive adverse effects can occur.¹²

However, the ability of non-memory cognitive functions is not usually impaired like planning, intelligence, abstraction etc. It is even noted that memory impairment in severe depression has improved post ECT sessions in test scores done before the initiation and when compared with the after completion of ECT scores.¹⁰

ADVERSE EFFECTS IN ELECTRO-CONVULSIVE THERAPY

Patients may experience physical side effects after ECT like headache, nausea and muscle pain due to soreness particularly during the initial part of the treatment. These may due to the effects of the seizure, anaesthesia or some combination of the two and are not usually medically serious.⁶³ These can be managed by NSAIDs, anti-emetic medications. In case of persistent soreness of muscle , curare or newer non-depolarizing muscle relaxants can be used.⁶⁹

Prolonged seizures are a major concern while performing ECT session as they increase the risk of adverse effects.¹⁰

The confusional states in the post-ECT period can be managed by using moderate doses of benzodiazapenes like diazepam, lorazepam, midazolam or a higher dose of inducing agents like barbiturates.^{10,70}

This is a major concern since the initial days of unmodified ECT administration and continues to have negative perception in the general public, news media, cinema etc. Certain events like the death of American author Ernest Hemingway who committed suicide after ECT course as well as several writers and other famous personalities complained of memory disturbance in various television interviews in the 1960s-80s.^{71,72}

These adverse effects were also the main points undertaken by the Anti- ECT movement or the Anti-psychiatry movement in general by prominent personalities which included Psychiatrists like Thomas Szasz , Peter Breggin , Sociologist Erving Goffman to promulgate their agenda.⁷³ This had put pressure on the ECT practitioners to regulate and invent techniques to minimize adverse effects as much as possible and maximize the therapeutic benefit of ECT.⁷²

There were also concerns regarding the ethical issues pertaining to ECT as the practice in the initial period violated principles of patients' autonomy and beneficence. It was also inappropriately used without adequate consent from the patient or their attendants.^{4,71} American Psychiatric Association (APA) in 1978 formed the first task force on ECT and in the year 1990 issued guidelines, recommendations , treatment protocol including the consent aspect of it and is periodically updated by its sitting members.⁹ These guidelines along with the guidelines by Royal College of Psychiatrists, United Kingdom have influenced most of ECT related recommendations by other groups around the world.

ELECTROENCEPHALOGRAPHY MONITORING IN ELECTROCONVULSIVE THERAPY

Electroencephalogram (EEG) is a neurophysiological method to assess electrical activity in the brain. Cerebral seizures may continue long after motor convulsions have stopped during any seizure including those induced in ECT. In some cases, cerebral seizures may occur without an accompanying motor convulsion. An EEG record is the best tool to detect and assess the seizure activity.^{7,10}

A typical seizure has polyspikes, slow spike-wave complexes and suppression of electrical activity which is seen in an EEG.^{8,13}

The older Royal College of Psychiatrists guidelines (1995) suggested that an ECT induced seizure should be of at least 15 seconds of tonic-clonic seizures or 25 seconds EEG seizure duration to be considered as adequate.¹⁰ However, the length of either motor or EEG seizure duration was not related to ECT's efficacy which might be a result of a partial or focal seizure.⁸

Hence, the revised guidelines especially considers EEG criteria of typical seizure characteristics as a recommendation for adequate seizure.¹⁰ A tonic-clonic convulsion can be considered in case of non-availability of EEG. Such is the importance of EEG that it has been recommended although not mandatory to be routinely used in ECT clinics by the Royal College of Psychiatrists, UK.¹⁰

Also detection of prolonged seizures and non-convulsive status epilepticus in the absence of motor convulsions can be detected by the use of simultaneous EEG monitoring during ECT.¹²

STUDIES ABOUT PROLONGED SEIZURES

In a study by Greenberg (1985) in New York, about 126 people received a total of 1233 seizures and about 54(4.25%) of the total number of seizures were prolonged which 43 were detected by EEG criteria and 11 by motor criteria using cuff method. 79.6% of them were detected with the use of EEG monitoring. This was one of the first studies to report in this regard and raised the issue of high rates of undetected prolonged seizures by using cuff method only.¹⁴

In a study in Manchester city by Benbow (2003) 18 out of 67 patients in a total of 95 ECT sessions had prolonged seizure as per EEG criteria of 120 seconds which makes up an incidence of 19% of the total ECTs. There were also 19 of the total 95 ECTs which had inadequate motor seizure while they all satisfied EEG seizure criteria including 1 prolonged seizure of more than 120 seconds.¹¹

In a study by Mayur (1999) a total of 232 participants undergoing their first ECT sessions, 38(16%) of them had prolonged seizures. Prolonged EEG seizures occurred in all whereas only 23 of them had prolonged motor seizure raising the concern that 15 of them would have gone unnoticed without EEG monitoring leading to further repeated electrical stimulation at higher doses. 1 of these 15 even had inadequate motor seizures, as EEG seizure was prolonged and all of them wouldn't have been treated for prolonged seizure causing no extra therapeutic benefit but rather increase the adverse effects and recovery of the patient both immediately and short term.¹⁸

The study also compared and tried to find a correlation between motor and EEG seizure duration, it was favorable in those with adequate seizure duration only with a Pearson's correlation coefficient 'r' value of 0.8 which had a good correlation, while with prolonged seizures the correlation was poor with a 'r' value of 0.1.¹⁸

In a study by Jayaprakash (1998), 158 patients undergoing first ECT were monitored by Hamilton's cuff method as well as EEG. Totally prolonged seizures were found in 32 patients (20.3%) of them undergoing first ECT. Of which, 18 of them were having adequate seizure by motor criteria but detected to be prolonged by EEG criteria, about 56.2% of them with prolonged seizures would have gone undetected without EEG criteria which can only be detected by proper EEG monitoring.¹⁵

Also, inadequate seizures by motor criteria were found in 12(8%) of the patients, out of which 11 of them were all detected to have adequate seizure by EEG criteria and 1 of whom even had prolonged seizure without an adequate motor seizure. This would have caused unnecessary restimulation of seizure with a higher dose of electric current and increase in subsequent doses of electric current henceforth. This

was prevented by the use of EEG monitoring device during ECT session. This study concluded that seizure monitoring by motor seizure criteria alone may lead to missing of a significant number of prolonged and inadequate seizures.¹⁵

In the study by Girish (2002)in ,which aimed at studying the merits of EEG monitoring, there was an important finding of prolonged seizure incidence of 18.8%.In a total of 485 patients, 91 of them had a prolonged seizure ,and only 59(64.83%) of them would have been identified by the “cuff method” of observing motor seizures of duration more than 90 seconds. The remaining 32(35.17%) of them were picked up only by EEG monitoring of these ECT sessions which is about 35% of all prolonged seizures in this study, including 2 of them who had no motor seizure at all but had only prolongation of EEG seizures more than 120 seconds. In these patients, based on their motor criteria alone they would not have been able to identify prolonged cerebral seizures to abort them without which it could have lead to various adverse effects and no therapeutic advantage.¹²

But in about 15(16.4%) of them, motor seizures were prolonged and EEG seizures adequate, leading to unnecessary anticonvulsant medication to terminate those seizures which would have otherwise resolved itself. This merits the use of both motor and EEG seizure monitoring in ECTs.

In about 29(6%) patients, there were inadequate motor seizures but detected to have adequate seizures by EEG criteria, who otherwise with just motor seizure criteria alone and without EEG monitoring would have otherwise been subject to unnecessary restimulation with a higher dose of electric current to treat.¹²

The study also had showed a higher risk of prolonged seizures in young aged individuals. Seizure threshold was lower in those with prolonged seizures and seizure duration lower in those receiving high dose of electric current.Some medications like

lithium increased the risk of prolonged seizures, 45% of the patients receiving lithium had prolonged seizures but antipsychotics and benzodiazapenes did not have significant extra effect on prolonged seizures.

Overall, the study concluded that although certain risk factors like young age, concurrent lithium administration had higher risk of prolonged seizures during ECT, it was largely difficult to predict who may have prolonged seizure and who may not. It advocated the use of routine EEG monitoring in ECT clinics.¹²

This study however had studied only the first ECT sessions and did not have data on subsequent ECTs and correlation of prolonged seizure with the ECT session number or whether one can predict that a subsequent ECT can also have high rate of prolonged seizure.

All these previous studies have failed to predict prolonged seizure duration based on just motor seizure criteria alone and the error was very significant in calculating and the correlation was poorer as the seizure duration increased and the need for identifying the correct termination of motor and/or cerebral seizure by EEG criteria is necessary and warrants the use of both. Earlier data supports this conclusion and most data exists with respect to first ECT session alone and none on subsequent ECTs and their correlation with prolonged seizures or inadequate/missed seizures.

METHODOLOGY

Patients who were admitted under the Department of Psychiatry, K.L.E.S Prabhakar Kore Hospital and undergoing modified electro-convulsive therapy after being diagnosed with a psychiatric or mental illness by applying the criteria from the 10th revision of the International Classification of Diseases and Related Health Problems, Diagnostic Criteria for Research Fifth chapter containing the classification of Mental and Behavioral disorders (ICD-10 DCR chapter -V) were taken for the study.⁷⁴

Type and period of Study:

A 1 year cross-sectional study conducted between 1st January 2018 till 31st December 2018

Study population:

Patients admitted in the department of Psychiatry in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi with diagnoses of psychiatric illnesses. These patients who have been advised modified electroconvulsive therapy procedure by the treating psychiatrist who fulfilled the following criteria were taken for the study.

Inclusion criteria :

- 1) All patients who have been indicated for modified ECT.
- 2) Age more than 18 years.

Exclusion criteria:

- 1) Known history of seizure disorder.
- 2) Contraindication for modified ECT.

SAMPLE SIZE:

n = Number of ECTs to be assessed,

calculated using the formula

$$n = \frac{4pq}{d^2}$$

where $p=16$, $q=100-p = 100-16= 84$ $d=5$

based on a related study by Mayur (1999) which had 16% incidence of prolonged seizures¹⁸

$$n = \frac{4 \cdot 16 \cdot 84}{25} = \frac{5376}{25} = 215.04$$

$$n = 216$$

Therefore 216 ECT sessions with their motor and EEG seizure recordings will be assessed for this study.

Study design:

Definitions:

Seizures will be classified based on the following characteristics by the observation of motor & EEG criteria recommended by Royal College of Psychiatrists, UK (2005).¹⁰

Missed or Inadequate seizures – Seizures with the absence of either tonic-clonic convulsions or typical seizure pattern on EEG is termed as missed or inadequate seizures.¹⁰

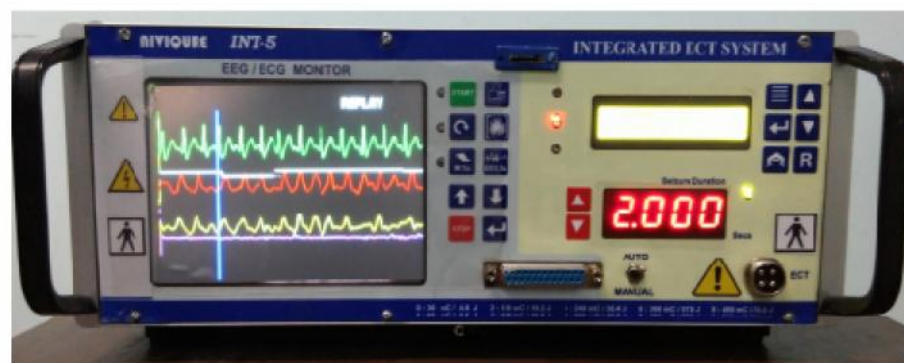
Adequate or typical seizure – Any seizure with a bilateral tonic-clonic seizure activity observed visually or the presence of characteristic EEG features which are polyspike waves activity, spike & wave complexes of 3Hz and postictal suppression.¹⁰

Prolonged seizure – Any seizure with duration more than 120 seconds. It can be measured as the duration of either visual generalised tonic-clonic convulsions or typical seizure characteristics on EEG.¹⁰

Status Epilepticus – 5 minutes or longer duration of any continuous seizure or repetitive seizures with no intervening recovery of consciousness.⁶⁷

Protocol followed for modified ECT in the study

1. Detailed histories of the patients were taken including past history of psychiatric illness, current & past psychiatric treatments and co-morbid medical illnesses.
2. Detailed Physical examination like height, weight, body-mass index, vital parameters and also cardiovascular, respiratory, abdomen and central nervous systems are assessed. Fundoscopy was also done to rule out papilledema.
3. Blood investigations – complete blood count, liver and renal function tests, electrocardiography in all the patients and when indicated brain imaging were done. Additional investigations were done as required to assess for fitness for the procedure.
4. Medical fitness were taken from Consultant Physicians, if deemed fit they were considered for modified ECT.
5. Patients and their attendants were informed about the indication for the procedure, its risks, adverse effects and complications of the procedure and informed consents were taken from them.



ECT machine and electric stimulus parameters:

ECT was given using a machine manufactured by NiviqureMeditechPvt. Ltd.®, Model INT-5, Serial number: I-01-17 which has an attached EEG monitor with 4-channel capabilities (2-EEG channels on either side, ECG and an Optical Motion sensor channel)

The EEG leads are attached just above the midline of the eyebrow on each side and on the skin over the mastoid process behind both ears. It is referred to as “pre-frontal-mastoid positioning”. It gives two channels of EEG, one from each side of the head.

One ECG channel is placed using the standard limb-leads placed in left arm, right arm and left leg.

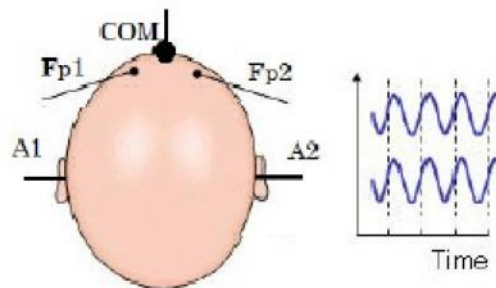
An optical motion sensor attached to one finger/toe in the isolated limb forms the fourth channel. It picks up the tonic-clonic movements of the finger during seizure which is visualized in the EEG monitor.

All the patients were given modified ECT with the following electric current parameters:

- 1. Electrode placement-** Bitemporal position (4cm above and perpendicular to the midpoint of a line joining the lateral angle of orbit and external auditory meatus).
- 2.Pulse-width-** Brief-pulse ECT with a pulse width of 1.5ms (microseconds) duration.
- 3.Amplitude-** 800mA (milliAmperes)
- 4. Frequency-** 125pps (pulses per second)
- 5. Stimulus duration-** stimulus duration varied directly in proportion to the electric charge administered. For every 60mC increase in electric charge, the stimulus duration increases by 0.4 seconds.

6. Electric charge- the charge was delivered from the ECT machine in multiples of 60mC based on known seizure threshold or titration to establish seizure threshold. There is an upper limit of 540 mC. (No patients in the study received current at a dose more than 360 mC)

EEG Electrode placement:



Fp1: Frontal Polar (left)
Fp2: Frontal Polar (right)
A1 : Auricular (left)
A2 : Auricular (right)

Pre- ECT preparation and modified ECT protocol

1. Patients were asked to remain nil per oral (NPO) overnight and maintain the same for atleast 6 hours for solid foods and 2 hours for clear liquids. Any concurrent medications such as benzodiazepines, antiepileptic medications/mood stabilizers which can interfere with the seizure threshold in the procedure were withheld for the night dose. Rest of the medications including psychiatric medications like antipsychotics, antidepressants were given on the previous night.
2. Precautionary measures such as checking for loose teeth and artificial dentures were done in the morning on the day of ECT. Orientation and memory were assessed. General medications like antihypertensives, antacids, anti-emetics tablets were given with sips of water atleast more than 2 hours before the procedure. Glucose monitoring were done for patients with diabetes or impaired glucose levels. These patients were

taken early for the procedure and their morning dose withheld until recovery of the patient.

3. Routine physical examination was done, Vital parameters like temperature, Blood Pressure, Pulse rate, Respiratory rate and Oxygen Saturation were recorded. ECG limb leads were attached and then the EEG leads are attached just above the midline of the eyebrow and on the skin over the mastoid process on each side called as pre-frontal-mastoid positioning forming two channels of EEG from each side of the head.

4. Anaesthetist injects 0.2-0.6mg of glycopyrrolate bromide and 4-8mg of ondansetron dose intravenously.

5. Anaesthetist injects thiopentone sodium intravenously from an inserted cannula with a dose of 2-5mg/kg body weight.¹⁰

6. A sphygmomanometer cuff is tied to one of the limbs between shoulder and elbow in the upper limbs or between knee and ankle in the lower limbs and is kept above the measured systolic blood pressure (Adderley and Hamilton's limb isolation method).⁷⁵

The Optical Motion sensor (OMS) from the ECT machine was also attached to one of the fingers/toes from the isolated limb.

7. Anaesthetist injects succinylcholine bromide intravenously at a dose of 0.5-1 mg/kg body weight after the eye lash reflex and laryngeal reflexes are diminished indicating stage 3 of anaesthesia.^{10,76}

8. Patients are then oxygenated mechanically using airway circuits from Boyle's apparatus for at least 20 respiratory cycles which takes approximately 1 minute. Muscle fasciculations caused due to succinylcholine bromide injection are observed which recede quickly except in the isolated limb which doesn't show fasciculations.

9. The centre of the electrodes from the ECT apparatus are placed on the bitemporal site on each side of the head (4cm above and perpendicular to the midpoint of a line joining the lateral angle of orbit and external auditory meatus).¹⁰

10. Electric current starting at the lowest dose (60mC) from the ECT apparatus is given to induce seizures in the patient.

(a). If the patients develop tonic-clonic convulsions and/oradequate seizure characteristics on the EEG monitor in the ECT machine.They are not further re-stimulated with any electrical dose.

(b). If seizure is not stimulated or is inadequate by motor and EEG characteristics, they are considered as “inadequate or missed seizures”. If the patient is still under the anaesthesia and muscle relaxant effects, re-stimulation is done after a period of atleast 45 seconds with the next higher dose in increments of 60mC during each attempt until an adequate seizure in the patient is induced. The electrical dose at which an adequate seizure is achieved is called as the “seizure threshold”.

11. The Blood pressure cuff in the isolated limb is released. The ECT practitioner and a trained independent observer measure the seizure duration by visual method until the last clonic movement observable and by EEG method in the monitor until post-ictal suppression and the baseline activity resumes.

12. (a) If the seizure is an adequate seizure then the patient is oxygenated again from the boyle’s apparatus until he regains spontaneous respiration.

(b) If the seizure is a prolonged seizure then the patient is given intravenous diazepam 10mg or thiopentone sodium at a dose of 100-200 mg to terminate the seizure and oxygenation is resumed until the patient regains spontaneous respiration. The prolonged seizure duration is noted.

13. Once the patient regains spontaneous respiration, he is observed until he regains consciousness and is hemodynamically stable.

14. All the necessary details of the doses of pre-anaesthetic drugs, motor and EEG seizure duration in the procedure were noted and tabulated for analysis.

DATA ANALYSIS:

Data analyses were done using Microsoft® Excel for Office 365 MSO (16.0.11929.20298) 32-bit.

Comparison of nominal/ordinal data were done by applying Fisher's exact test and Chi-square tests for testing the significance of association of variables.

A probability value (p-value) of less than or equal to 0.05 at 95% confidence interval was considered as 'critical value' for statistical significance.

ETHICAL CLEARANCE:

Ethical clearance was obtained prior to the commencement of the study from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi (ANNEXUREII)

INFORMED CONSENT:

The patients or their guardians who fulfilled the selection criteria were explained about the nature of the study and a written informed consent was obtained before enrolment in the study (ANNEXUREI)

RESULTS

TABLE 1: Sociodemographic details of the study sample

Characteristics		Frequency (n=110)	Percentage (%)
Mean Age		30.6 ± 6.88	
Age distribution	Young adult (18-35 years)	85	77.27
	Middle aged adult (36-55 years)	25	22.73
	Older adult (56 and above)	0	0
Gender	Male	60	54.54
	Female	50	45.46
Locality	Rural	59	53.64
	Urban	51	46.36
Socio-economic status	Upper class	2	1.82
	Upper middle class	7	6.36
	Middle class	93	84.55
	Lower middle class	8	7.27
	Lower	0	0
Religion	Hindu	99	90.0
	Muslim	9	8.18
	Christian	0	0
	Other	2	1.82

Table 1 shows the demographic details of the entire study sample. There were a total of 110 individuals whose 216 ECT sessions were recorded. The mean age of the study sample was 30.6 ± 6.88 .

About 85 (77.27%) of them were young adults between 18 and 35 years of age, the remaining 25 (22.73%) from middle age group between 35 and 55 years. There were no older adults (56 and above) in the study.

Males were 60 (54.54%) of them forming the majority and females were the remaining 50 (45.46%).

Religion wise about 99 (90.0%) of the 110 people were hindus, followed by muslims who were about 9 (8.18%) people and the remaining 2 (1.82%) belonged to other religions.

Majority of them were located in rural areas 59 (53.64%), remaining 51 (46.36%) were from an urban background.

As per modified BG Prasad Socio-economic classification (Jan 2019), 93 (84.55%) of them belonged to Middle Class, 8 (7.27%) to lower middle class, 7 (6.36%) of them to upper middle class and 2 (1.82%) to upper class.⁷⁷

TABLE 2: Incidence of prolonged, adequate and missed seizures in the patients undergoing ECT

ECT seizure characteristic	Frequency	Percentage (%)
Prolonged seizures	24	11.11
Adequate seizures	159	73.61
Missed/inadequate seizures	33	15.28
Total	216	100.00

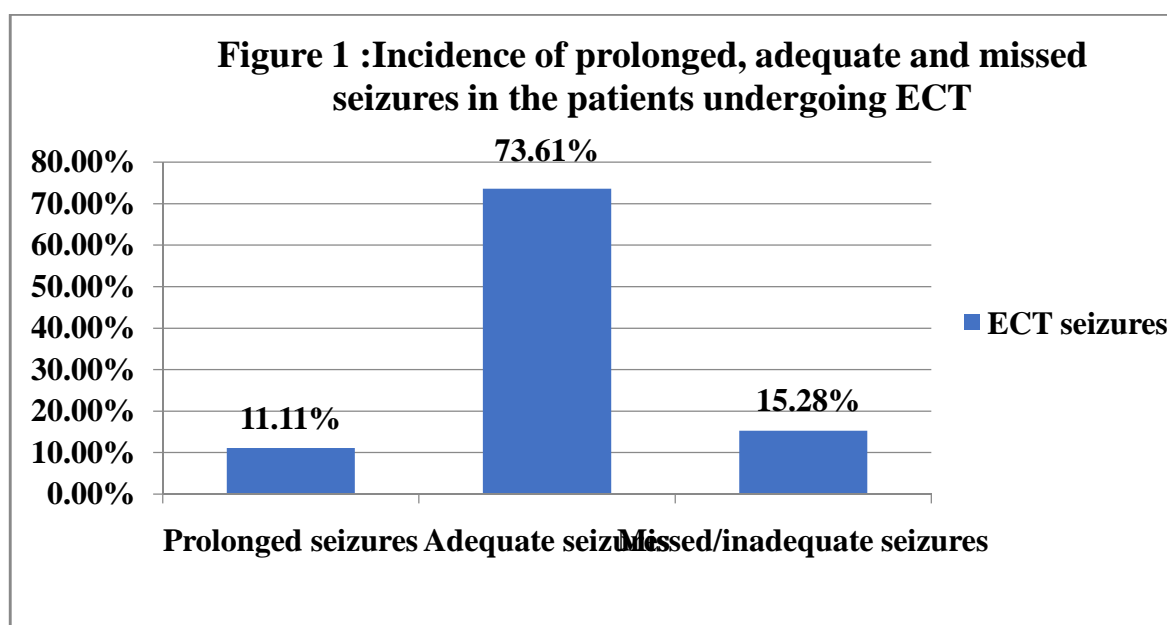
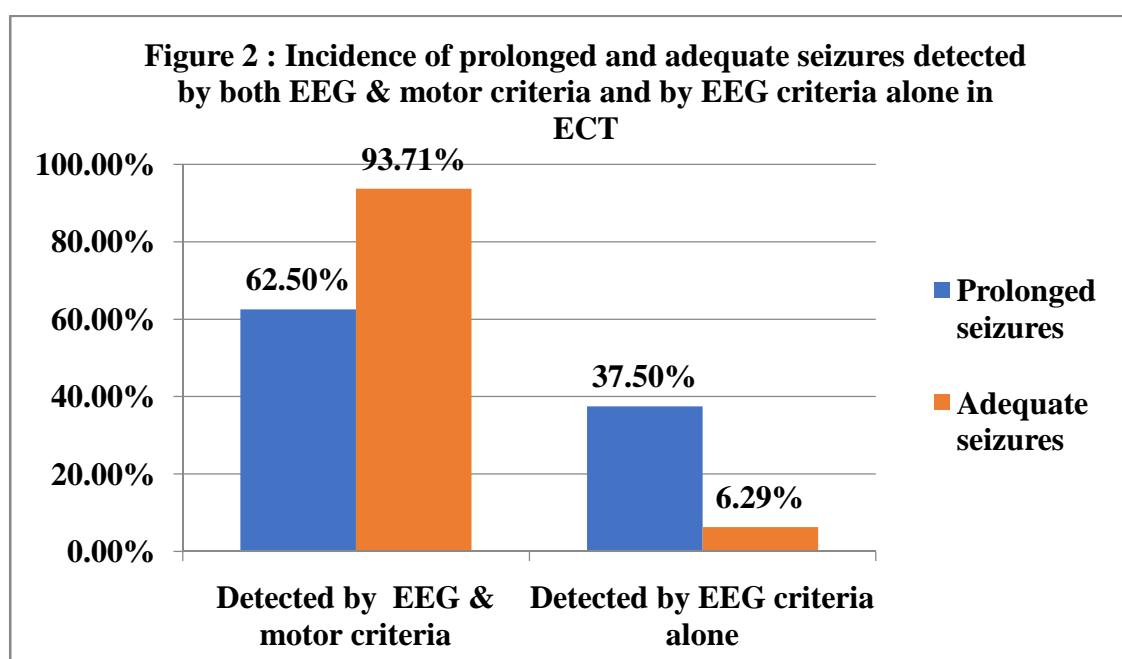


Table 2 and figure 1 depicts the incidence of prolonged seizures, missed/inadequate and adequate seizures in the study of 216 ECT seizures. The majority of them had adequate seizures which was about 159 (73.61%). While 24 of them had prolonged seizures and 33 of them had missed/inadequate seizures which amounts to 11.11% and 15.28% respectively.

Table 3. Incidence of prolonged and adequate seizures detected by both EEG & motor criteria and by EEG criteria alone in ECT

	Prolonged seizures		Adequate seizures	
	Frequency	Percentage (%)	Frequency	Percentage (%)
Detected by motor & EEG criteria	15	62.5	149	93.71
Detected by EEG criteria alone	9	37.5	10	6.29
Total	24	100.00	159	100.00
Fisher's exact test, p-value <0.0001				



Incidence of prolonged and adequate seizures detected by both EEG criteria & motor criteria and by EEG criteria alone in ECT is shown in Table 3 and figure 2. Out of the 24 prolonged seizures in ECT, about 15 (62.5%) prolonged seizures were detected by both EEG & motor criteria and 9 (37.5%) prolonged seizures were detected by EEG criteria alone. Among adequate seizures, 149 (93.71%) were detected by both EEG & motor criteria and 10 (6.29%) were detected by EEG criteria alone. Fisher's exact test gives a p-value <0.0001 which is significant ($p < 0.05$).

Table 4: Incidence of prolonged ECT seizures in different ECT sessions

ECT session	ECT Frequency		Percentage of prolonged seizures(%)
	Total	Prolonged seizures	
First ECT	41	9	21.95
Second ECT	45	5	11.11
Third and subsequent ECT	130	10	7.69
Total	216	24	11.11
Chi-Square test = 6.417, p-value = 0.04			

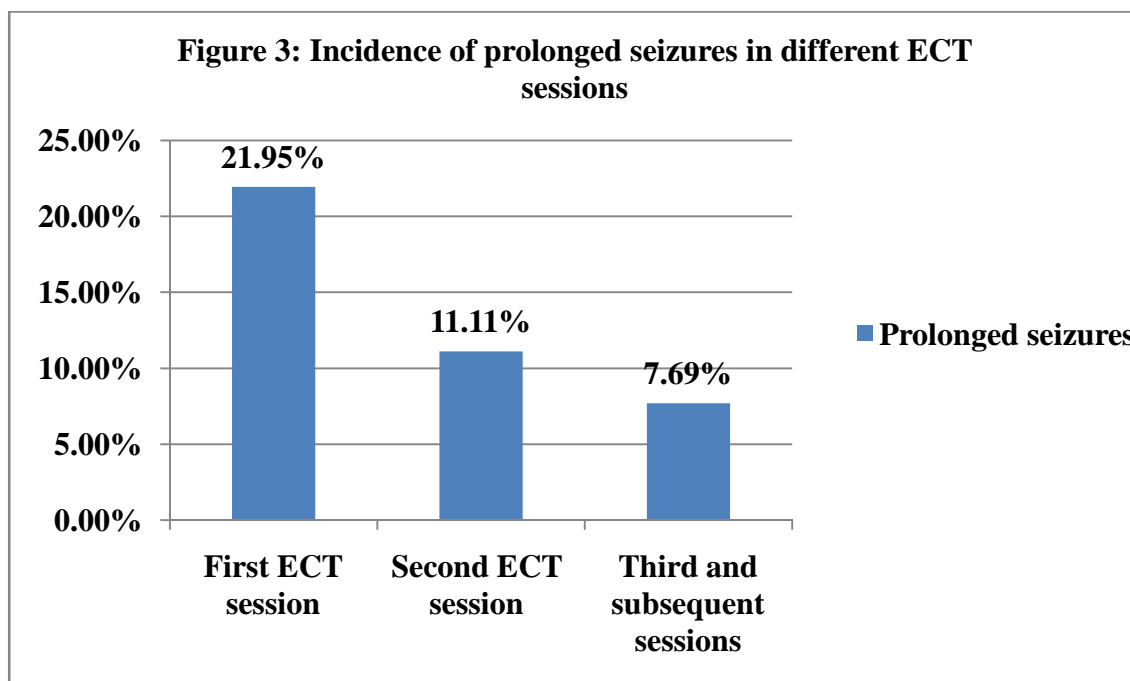


Table 4 and figure 3 show the incidence of prolonged ECT seizures which were observed in relation to the number of ECT sessions. A total of 41 first ECT sessions were observed, 45 second ECT sessions and 130 third and subsequent ECT sessions. Among the first ECT sessions, the incidence of prolonged seizures was 9 (21.95%), in the second ECT sessions it was 5 (11.11%) and 10 (7.69%) in the third and subsequent ECT sessions.

Chi-Square test for independence of variables = 6.417 with a p-value = 0.04 which is significant ($p < 0.05$).

Table 5: Incidence of prolonged seizures in patients undergoing ECT among different psychiatric diagnoses

Diagnosis	ECT Frequency		Percentage of prolonged seizures (%)
	Total	Prolonged	
Psychosis	112	11	9.82
Mania	68	10	14.70
Depression	36	3	8.57
Total	216	24	11.11
Chi- square test value =1.360 , p value = 0.507			

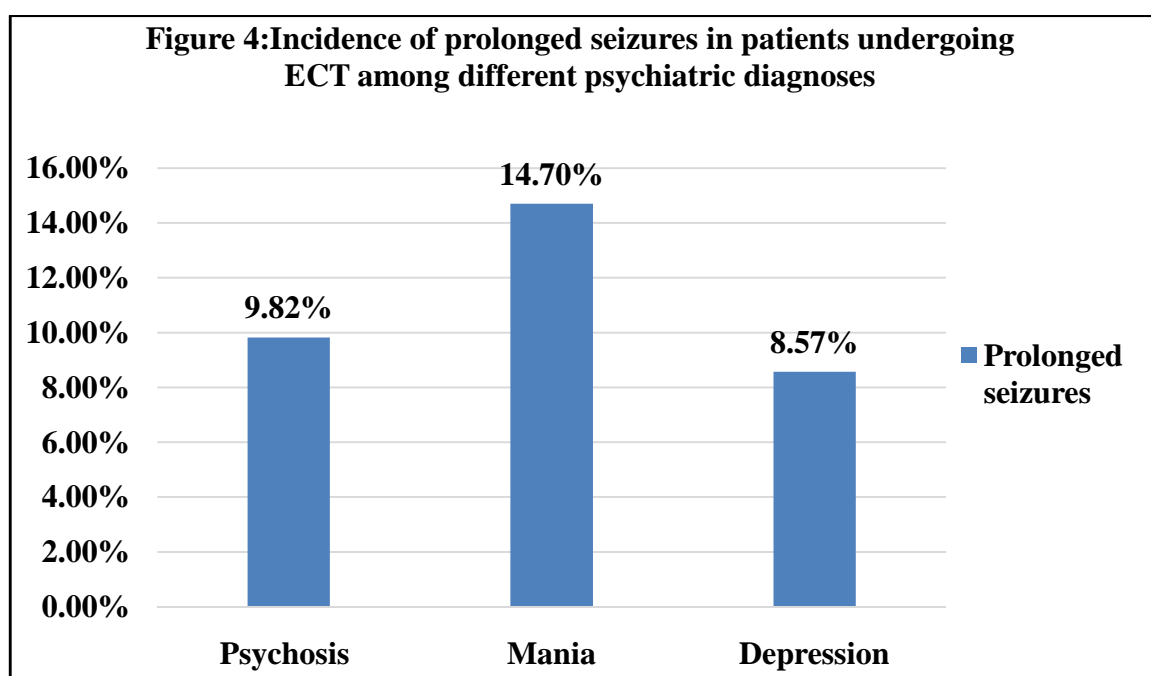


Table 5 and figure 4 show the incidence and percentage of prolonged ECT seizures according to the various psychiatric diagnosis classified. Psychosis had 11 prolonged seizures out of 112 amounting to 9.82%, mania had about 10 prolonged seizures out of 68 amounting to 14.70% and depression had 3 prolonged seizures out of 36 amounting to 8.57%.

Chi- square test value = 1.360 with a p-value = 0.507 which is not statistically significant ($p > 0.05$).

Table 6: Comparison of gender in prolonged seizures in ECT

Gender	ECT frequency		Percentage of prolonged seizures (%)
	Total	Prolonged seizures	
Male	124	14	11.29
Female	92	10	10.86
Total	216	24	11.11

Fisher's exact test, p value = 1.0

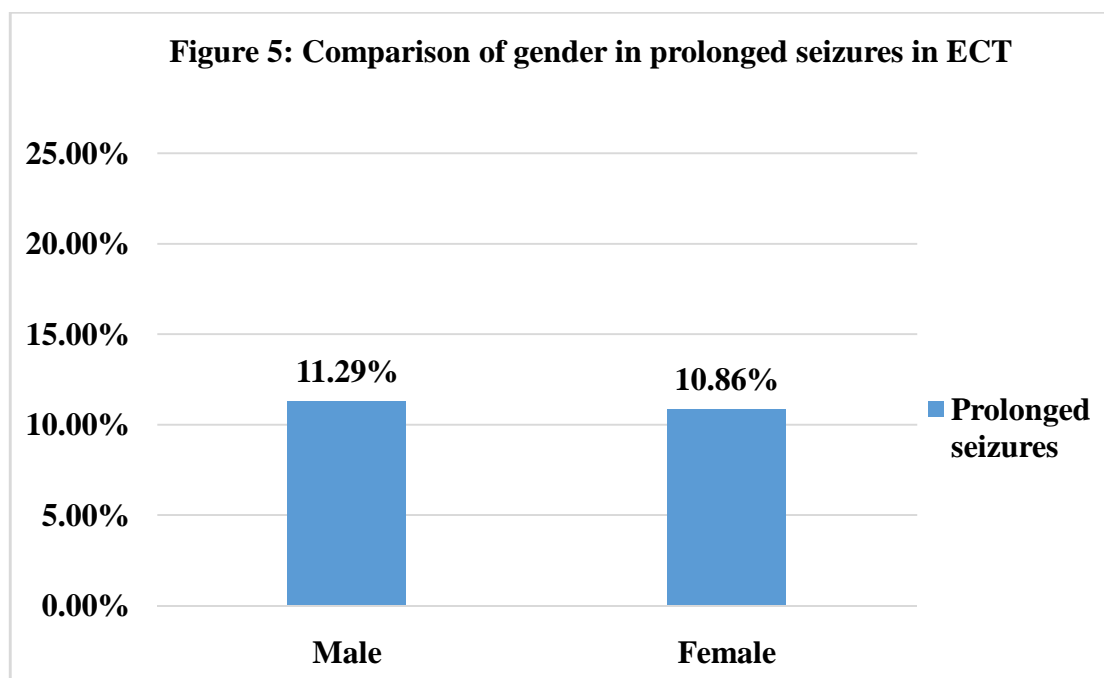


Table 6 and figure 5 show gender wise statistics for Adequate and prolonged seizures. Prolonged seizures were noted in 14 out of 124 ECTs in males (11.29%) and 10 out of 92 ECTs in females (10.86%). Fisher's exact test p-value =1.0 which is not statistically significant ($p>0.05$).

TABLE 7 : Comparison of BMI in prolonged seizures in ECT

BMI (Body-Mass Index)	ECT Frequency		Percentage of prolonged seizures (%)
	Total	Prolonged seizures	
Normal	135	14	10.44
Overweight	61	10	16.39
Others	20	0	0.00
Total	216	24	11.11
Chi-square test = 4.298, p-value = 0.117			

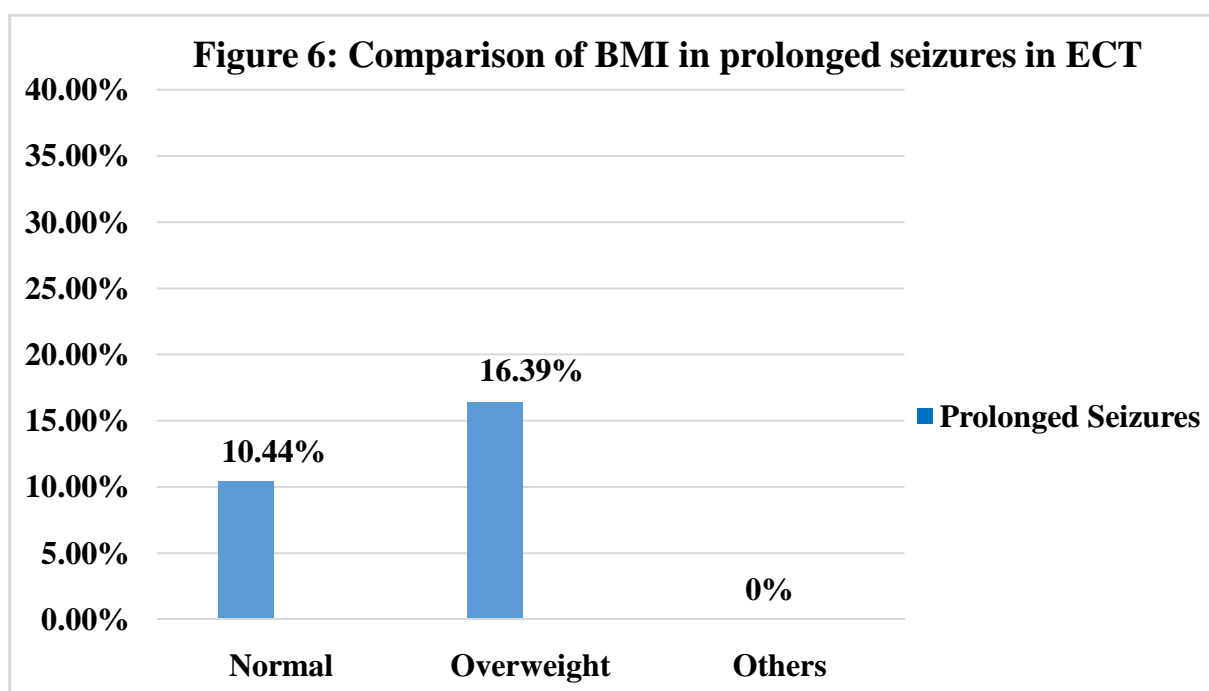


Table 7 and figure 6 show the comparison of BMI in prolonged seizures in ECT. There were a total of 133 ECTs in normal, 62 ECTs in overweight and 20 ECTs in others categorized by BMI out of 216 ECTs in the study. Prolonged seizures were noted among 14 of the normal and 10 of the overweight individuals amounting to 10.52% and 16.12% for their respective groups. There were no prolonged seizures in the others category. Chi-square test value = 4.298, p-value = 0.117 which is not significant ($p > 0.05$).

Table 8: Comparison of prolonged seizures in ECT in patients receiving lithium carbonate and patients not receiving lithium carbonate

	ECT Frequency		Percentage of prolonged seizures (%)
	Total seizures	Prolonged seizures	
Patients on lithium carbonate	46	6	11.59
Patients not on lithium carbonate	170	18	13.04
Total	216	24	11.11
Fisher's exact test p-value = 0.604			

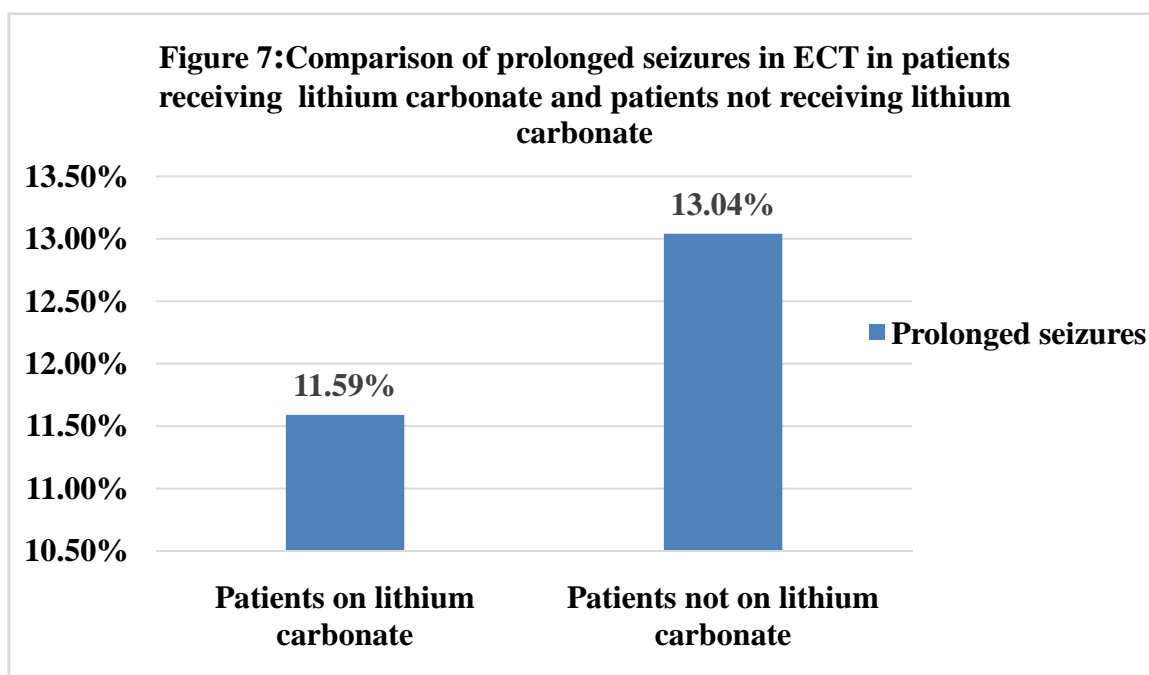


Table 8 and figure 7 show the comparison of prolonged seizures in ECT in patients receiving lithium and not receiving lithium. The study had about 46 ECTs in patients receiving lithium and 170 ECTs in patients not receiving lithium out of 216 ECTs. Out of the lithium receiving group, 6 (13.04%) ECTs had prolonged seizures, and among the non-lithium receiving group about 18 (11.59%) ECTs had prolonged seizures. Fisher's exact test p-value = 0.604 which is not statistically significant ($p > 0.05$).

Table 9 : Comparison of prolonged seizures in ECT in patients receiving clozapine and patients not receiving clozapine

	ECT Frequency		Percentage of prolonged seizures (%)
	Total seizures	Prolonged seizures	
Patients receiving clozapine	12	3	25
Patients not receiving clozapine	204	21	10.29
Total	216	24	
Fisher's exact test p-value=0.135			

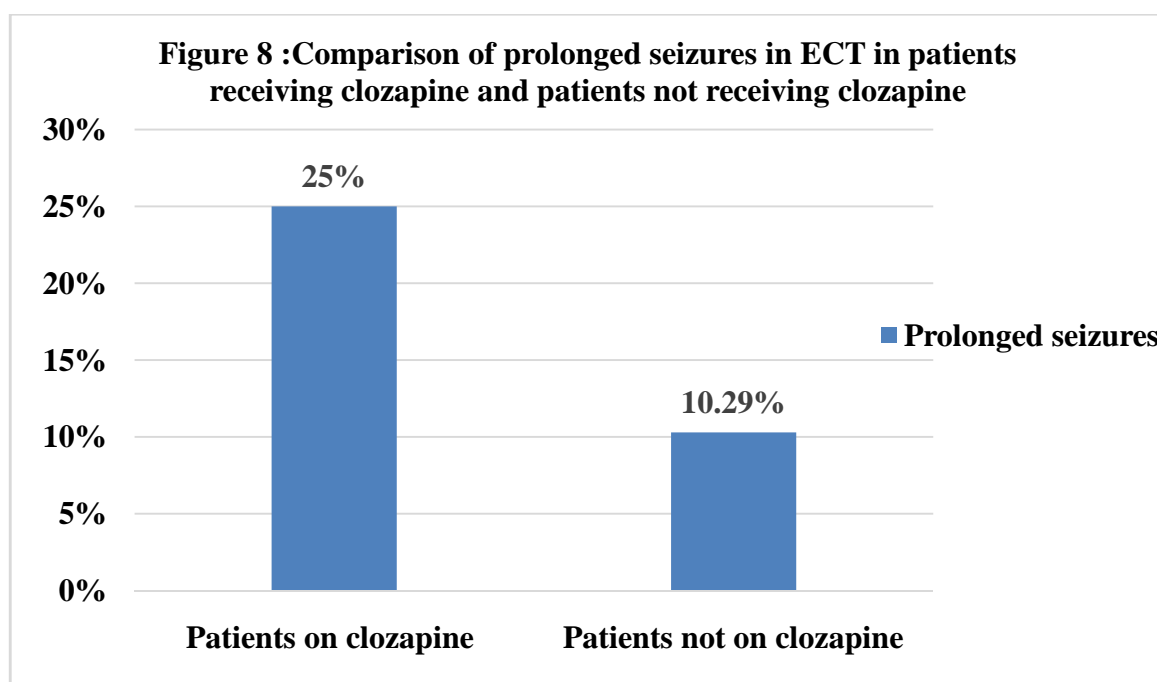


Table 9 and figure 8 show the comparison of prolonged seizures in ECT in patients receiving clozapine and patients not receiving clozapine. The study had a total of about 12 ECTs in patients receiving clozapine and 204 ECTs in patients not receiving clozapine. About 3 (25%)ECTs had prolonged seizures among the patients receiving clozapine and 21(10.29%) ECTs had prolonged seizures among the patients not receiving clozapine. Fisher's exact test p-value = 0.135 which is not statistically significant ($p > 0.05$).

Table 10: Incidence of prolonged seizures in ECT in sub-types of Psychosis (total number of patients with psychosis =112)

	Frequency		Percentage of prolonged seizures (%)
	Total seizures	Prolonged seizures	
Paranoid schizophrenia	59	5	9.43 %
Non-paranoid schizophrenia	28	4	14.28 %
Other psychosis	25	2	8 %
Total	112	11	
Chi-square test value = 0.845, p-value = 0.655			

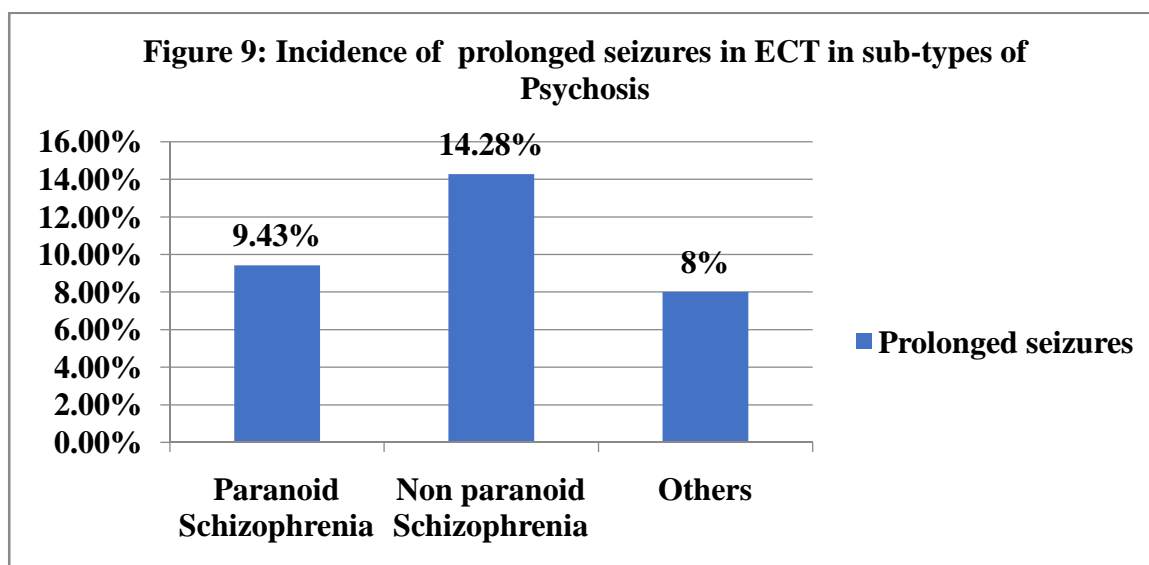


Table 10 and figure 9 shows the Incidence of prolonged seizures in ECT in psychosis sub-types. Out of the 112 ECTs in psychosis group, 59 were given in paranoid schizophrenia, 28 in non-paranoid schizophrenia and 25 in the others sub-types. Prolonged seizures were noted in about 5 (9.43%) ECTs of the paranoid schizophrenia patients followed by 4 (14.28%) ECTs in non-paranoid Schizophrenia and 2 (8%) among the others sub-types of psychosis. Chi-Square test gives a value = 0.845 with a p-value = 0.655 which is not statistically significant ($p > 0.05$).

DISCUSSION

Electro-Convulsive Therapy is one of the most important and extensively used therapeutic interventions in psychiatric treatment. Its benefits, safety and adverse effects have been well studied in all the years since the treatment has started. The addition of General Anaesthetics and Skeletal muscle relaxants have resulted in the improvement of the more serious adverse effects and the overall safety of the procedure, which is termed as “Modified Electro Convulsive Therapy (MECT)”.⁶

The study was a cross-sectional observational study in patients receiving Modified Electro Convulsive Therapy in the department of Psychiatry, K.L.E.S Dr. Prabhakar Kore Hospital & MRC, Belagavi which is a tertiary care centre catering to urban and rural areas around. The patients who were diagnosed with psychiatric illness according to the Tenth revision of the International Classification of Diseases and Related Health Problems Diagnostic Criteria for Research (ICD-10 DCR) under the Chapter V: Mental and behavioural disorders (F00-F99) who were advised Modified Electro Convulsive Therapy and included/excluded as per the criteria formed the sample participants of the study.

Patients who had a history of seizure disorder were excluded as seizure threshold and duration of ECT induced seizures may get confounded in such cases.

All modified ECTs were administered using bitemporal, brief-pulse technique using a standard ECT machine with additional EEG monitoring capability. EEG monitoring was done using prefrontal-mastoid channels on both sides of the head and visualized on the monitor included in the ECT machine.

Visual motor convulsions were measured by Adderley & Hamilton's limb isolation method by tying a sphygmomanometer cuff to one of the limbs. The cuff was inflated above the systolic blood pressure to a level sufficient enough to interrupt

the blood supply and observe for unmodified seizures on the isolated limb without muscle relaxant effect.

Interpretation of the seizures were done by the ECT practitioner and an independent observer who record the EEG and motor durations respectively.

Modified ECT was administered to patients using thiopentone sodium(2-5 mg/kg), succinylcholine bromide (1-2mg/kg) and glycopyrrolate bromide (0.2-0.6mg) while maintaining airway ventilation for pre-oxygenation as well as maintenance of ventilation during the stage of respiratory paralysis during the procedure. The electric current was applied using ECT machine with a fixed amplitude of 800mA,pulse width of 1.5ms and frequency of 125 pps (Pulses per second).

The stimulus dose for first session of this Modified ECT was started with 60mC and observed visually in the isolated limb for motor seizures as well as EEG characteristics on the monitor and analyzed for seizure adequacy.

The absence of either tonic-clonic convulsions or a typical seizure pattern on an EEG was considered as a “missed/inadequate seizure”. The patients were re-stimulated after a period of 45 seconds with next higher dose of electric current in increments of 60mc until adequate seizures were noted and the electric dose was considered as “seizure threshold” of the patient. Subsequent ECT sessions were given based on seizure threshold from previous sessions. Once the seizure stimulation is adequate, the seizureis monitored by Hamilton’s cuff method for motor characteristics and EEG characteristics to observe for cessation of the seizure.

If the seizureshad a duration less than 120 seconds with tonic-clonic convulsions or typical seizure characteristics on EEG, they wereconsidered as “adequate seizures”.¹⁰

If the seizures continued beyond 120 seconds by either the motor or EEG criteria, they were considered as “prolonged seizures”.¹⁰ An additional dose of intravenous diazepam 10-20mg or thiopentone sodium (100-200mg) were administered to terminate the seizures as soon as they were detected.

Once the seizures were terminated, oxygen ventilation was resumed until the patients recovered spontaneous breathing and shifted to recovery room later once recovered from the anaesthesia effects and regained consciousness.

The patients were observed in the recovery room for a period of at least 1 hour and if they developed agitation or confusion (post ECT adverse effects) during any of these periods, it was managed with administration of diazepam 10-20mg intramuscularly or intravenously.¹⁰

This study aims at assessing the incidence rates of prolonged seizures and adequate seizures detected by EEG monitored simultaneously during ECT. Also the factors affecting prolonged seizures like ECT session number, BMI, gender, psychiatric diagnoses and concurrent psychiatric medications detected by EEG monitoring in these patients who are undergoing Modified Electro Convulsive Therapy were assessed.

Comparison of sociodemographic profile across the study population:

Table 1 describes the sociodemographic details of the sample of those included in the study as per the criteria of those receiving modified ECTs.

Age distribution:

The mean age of the sample was 30.6 ± 6.88 years which is not much varied when compared to Girish (2002) which had a mean age of 29.9 ± 7 years, Mayur (1999) which had a mean age of 29.8 ± 10.8 years and Jayaprakash (1998) which had 29.3 ± 10.5 years.^{12,15,18} Whereas it was much higher in western studies such as Benbow

(2003) which had a mean age of 64.3 ± 19.3 years and Greenberg (1985) had a median age of 43.5 years with a range of 17 to 83 years.^{11,14}

The majority of them belonged to young adult age group who formed about 78.60% of the total 110 individuals, followed by middle aged adults who formed the remaining 21.39%. There were no older adults or elderly individuals in this study.

Gender distribution:

Males were the majority among the genders with 60 out of 110 amounting to 54.54% and the remaining 50 (45.46%) to females in this study. Another study by Girish (2002) had 204 males (51.77%) and 190 females (48.23%), the study by Jayaprakash (1998) had 85 males (53.79%) and 73 females (46.21%) and the study by Mayur (1999) had 116 males and females each (50%).^{12,15,18} These were closely within the gender distribution rate in our study.

While Benbow (2003) had 37% males and 63% females among the 67 individuals who received 95 ECTs.

Geographical and social distribution:

Out of the 110 patients in this study, Rural patients were 59 (53.64%) and urban patients were 51 (46.36%). It represents the majority rural population which the hospital provides services to.

Socio-economic status of the 110 patients in this study were assessed using Modified B.G.Prasad Classification, January 2019 update and 93 (84.55%) of them forming the majority belonged to middle class, 8 (7.27%) of them belonging to lower middle class, 7 (6.36%) of them belonging to upper middle class and 2 (1.82%) of them to upper class.⁷⁷

Most of them were Hindu by Religion - 99 (90.0%), followed by Muslims -9 (8.18%) and 2 from the other religions. It corresponds to the Indian population demographically.

Other studies have not mentioned any data regarding the geographical and social distribution of their study population.

Incidence of prolonged seizures among patients undergoing ECT

There were 24 ECTs with prolonged seizures out of the 216 ECTs as depicted in table 2 and figure 1. The incidence rate for prolonged seizures was 11.11% in this study.

The study by Benbow (2003) in Manchester reported prolonged seizure incidence to be reported 19% for the ECT sessions.¹¹

A study in Bangalore by Jayaprakash (1998), had a total of 32 prolonged seizures out of a total of 158 ECT sessions forming about 20.3% incidence of prolonged seizures among first ECTs.¹⁵

Mayur (1999) had about 38 patients with prolonged seizures out of 232 patients undergoing first ECT session amounting to 16% incidence.¹⁸

Another study by Girish (Bangalore,2002) had about 91 prolonged seizures out of 485 patients undergoing first ECT session with an incidence of 18.8%.

An earlier study by Greenberg (1985) in New York which was one of the first studies assessing the incidence of prolonged seizures was 54 out of 1233 ECTs amounting to 4.25% incidence. However the study did not have specifically first ECT sessions as the other studies mentioned above. The lower incidence rate of prolonged seizures could be due to the effect of reduced seizure duration with increased seizure threshold in subsequent ECTs after first session and also a higher median age in Greenberg's study (1985).¹⁴

The incidence of prolonged ECT seizures in our study for first ECT sessions also corresponds well with the incidence rates of the studies by Jayaprakash (1998), Girish (1999), Mayur (2002) at 21.95%.^{12,15,18} However as our study also looked at the general incidence of patients undergoing ECT on any session regardless of the number, the overall incidence came to 11.11%. This is reflective of more incidence of prolonged seizures among first ECT sessions when compared to the incidence rate in all sessions combined.

Incidence of prolonged and adequate seizures detected by EEG criteria but not by motor criteria:

Adequate seizures can be considered as adequate by the presence of either motor/EEG criteria or both.¹⁰ Table 3 and figure 2 show incidence of adequate seizures in ECT which were detected by EEG criteria but not by motor criteria. About 149 (93.71%) out of a total 159 adequate seizures were detected visually by motor and EEG criteria. But the remaining 10 (6.29%) of them were detected by observing EEG criteria exclusively.

This 6.29% is the incidence rate of adequate seizures detected by EEG criteria that is missed by motor criteria.

Mayur (1999) reported adequate EEG seizures with inadequate motor seizure criteria in 14 out of the 188 adequate seizures amounting to an incidence rate of 7.44%.¹⁸

Similarly Jayaprakash(1998) reported 11 ECTs with adequate EEG seizures with inadequate motor seizure criteria out of 126 adequate seizures amounting to an incidence rate of 8.73%.¹⁵

Girish(2002) reported that 29 of the adequate EEG seizures had inadequate motor criteria out of a total of 391 with an incidence rate of 7.41%.¹²

These studies had used the older Royal College of Psychiatrists criteria (1995) for defining missed/inadequate seizure which were 15 seconds for tonic-clonic convulsions and 25 seconds for EEG seizures.

However, our study uses the revised criteria of Royal College of Psychiatrists and these rates are still closely corresponding to the incidence rate in our study for ECTs with adequate EEG seizures missed by motor criteria (6.29%). These were picked up by EEG criteria due to additional EEG monitoring only.

Prolonged seizures were noted in about 24 of the 216 ECTs in the study. Among these 15 (62.5%) of them were detected by both motor and EEG criteria while the remaining 9 (37.5%) were detected exclusively by the use of EEG criteria.

Jayaprakash (1998) reported that about 18 of the 32 prolonged seizures in a total of 158 ECTs were detected exclusively by the use of EEG criteria (56.25%).¹⁵

Mayur (1999) reported that about 15 of the 38 prolonged seizures of the total 232 ECTs were detected by the use of EEG criteria exclusively (39.47%).¹²

Girish (2002) reported that among the 91 prolonged seizures in the study of 485 ECTs, about 32 were detected by EEG criteria exclusively (35.16%).¹⁸

These findings are closely corresponding to the rate of prolonged seizures detected by EEG criteria exclusively in our study which is 37.5%.

Statistical analysis of ECT seizure type (prolonged & adequate) inferred that there was a significant relationship between ECT seizure type and those seizures detected by EEG monitoring which were missed by motor criteria (p-value <0.0001).

American Psychiatric Association(2001) and Royal College of Psychiatrists, UK (2005) in their guidelines strongly recommended EEG monitoring during ECT practice but have not suggested it as a mandatory practice.^{10,54}

The results of the study reflect the importance of this additional EEG monitoring during ECTs.

Incidence of prolonged ECT seizures among different psychiatric diagnoses

Table 5 and figure 4 show the incidence of prolonged ECT seizures among different psychiatric diagnoses. The highest percentage of prolonged seizures occurred in patients of mania with 10 (14.70%) out of a total of 68 ECTs, followed by 11 (9.82%) out of 112 ECTs in psychosis and 3 (8.57%) out of 36 ECTs of depression (Table 5 and Figure 4). Although higher rate was noted among patients of mania subtype for prolonged seizures, statistically it was not a significant difference (p-value= 0.507) with other psychiatric diagnoses.

Earlier data from Girish (2002) suggests that patients with mania had more rates of prolonged seizures compared to other subtypes of psychiatric illnesses which was statistically significant.¹²

The finding in our study despite not having statistical significance is still reporting higher rate of prolonged seizures among patients of mania. This could be explained by earlier literature which suggest that there is an inverse relationship between seizure duration reduces and seizure threshold.⁷⁸ Manic patients were noted to have low seizure threshold in the study by Coffey et al.,⁷⁸ this explains the observation of higher rate of prolonged seizures among patients with mania who have lower seizure threshold.⁷⁸⁻⁸⁰

Comparison of gender in prolonged seizures in ECT

Table 6 and figure 5 show the comparison of gender in prolonged seizures in ECT. Out of 216 ECTs, males received 124 ECTs and females received the remaining 92 ECTs. Among which 14 ECTs in males and 10 ECTs in females had prolonged seizures which amount to 11.29% and 10.86% respectively.

Fisher's exact test p-value is equal to 1.0, which suggests that there is no significant association between gender and prolonged seizures ($p > 0.05$). A Study by Girish (2002) showed 57 prolonged seizures in 204 ECTs in males and 34 prolonged seizures in 190 ECTs in females with a p-value of 0.08 implying no significant difference in the prolonged seizure rates among the male and female genders.^{12,15}

Coffey (1995) and Benbow (2003) reported seizure threshold to be higher in males, but there were no significant difference in their seizure durations.^{11,78}

Incidence of prolonged seizures and Body-mass Index (BMI)

Out of the 216 ECTs in the study, 9 were underweight, 133 were normal, 62 were overweight and 11 were obese individuals. Among these, prolonged seizures were noted in 14 of the normal and 10 of the overweight individuals amounting to 10.52% and 16.12% respectively. There were no prolonged seizures among the others (underweight and obese). There was no statistically association between BMI and prolonged seizures (p-value 0.117). Also there were no prior studies which reported any positive or negative correlation finding based on BMI.

Incidence of prolonged seizures and concurrent lithium carbonate administration in ECT

Table 8 and figure 7 show the comparison of incidence of prolonged seizures in patients receiving lithium carbonate and patients not receiving lithium carbonate.

The study had a total of 46 ECTs in patients receiving on lithium carbonate and 170 ECTs without lithium carbonate.

Out of the lithium receiving group, about 6 of them had prolonged seizures and 40 of them had adequate seizures with an incidence value of 13.04% which is almost as much as the incidence of the study overall which was 11.11%.

Statistically as well, lithium carbonate and seizure duration variables weren't significantly associated (p-value = 0.604).

Girish (2002) reports trend level significant association between prolonged seizures and lithium administration (p-value = 0.056).¹²

Royal College of Psychiatrists (2005) recommends that lithium is not a contraindication for ECT and introduction of lithium reduces the likelihood of the risk of early relapse after ECT but may cause prolonged seizures and recommends to maintain and monitor lithium at a lower serum concentration during ECT. Lithium is also reported to cause lowering of seizure threshold.¹⁰ APA (2001) also cautions that the combination of lithium and ECT should be avoided unless necessary.^{54,81}

Earlier concerns about lithium and ECT were that it could cause prolongation of the action of neuromuscular blocking agents. However, a study of case reports by Dolenc and Rasmussen (2005) revealed no significant association between seizure length duration between lithium and the mean seizure lengths were similar in those with and without concurrent lithium administration. This study also suggests the combination of lithium and ECT is safe based on their and other previous studies and case reports.⁸¹

Our study suggests that the lithium receiving patients did not have any significantly higher rate of prolonged seizures compared with those who did not receive lithium. However, further studies with larger sample size of those receiving lithium and not receiving lithium may be done to study the outcome.

Incidence of prolonged seizures and concurrent Clozapine administration in ECT

Table 9 and figure 8 show the incidence of prolonged seizures in ECTs inpatients receiving clozapine and the patients not receiving clozapine. There were a total of 12 ECTs with concurrent Clozapine use and the rest 204 without it.

Among the clozapine receiving patients about 9 of them had adequate seizure duration and the remaining 3 had prolonged seizures with an incidence rate of 25%.

However, this high incidence rate was not statistically significant in the incidence of prolonged seizures due to the low number of ECTs with concurrent clozapine in the study (p-value= 0.135).

There were no previous studies on prolonged seizures in ECTs for patients who were on concurrent Clozapine administration. A few of the treatment resistant Schizophrenia patients undergo maintenance ECTs along with clozapine use due to poor response to medications alone. Since the number of patients in this study who had been receiving clozapine were low, the study finding is not generalizable despite the high rate (25%) of prolonged seizures reported.

Clozapine is known to reduce seizure threshold and may cause prolonged seizures.¹⁰ Although Royal College of Psychiatrists (2005) suggest that can be safely given in ECT, it warrants further studies to assess the risk of prolonged seizures in ECT in patients with concurrent clozapine administration.¹⁰

Incidence of prolonged seizures and different sub-types of Psychosis

Table 10 and figure 9 show the incidence of prolonged seizures and different sub-types of psychosis, there were a total of 112 ECTs given to patients of psychosis in the study, out of which paranoid schizophrenia were about 59 patients, non-paranoid schizophrenia 28 patients and 25 belonged to other types of psychosis.

Prolonged seizures were found in about 5(9.43%) of the paranoid schizophrenia, 4(14.28%) of the non-paranoid schizophrenia and 2(8%) out of the other psychosis sub-types.

Although there was about 1.5 times the rate of prolonged seizures among non-paranoid schizophrenia group compared to the other 2 groups, it was not statistically significant (p-value = 0.655).

Earlier studies had not studied subtypes of psychosis and prolonged seizures for comparison with this study. However, a larger study size of psychosis patients with various sub-types can be done to further study whether there is any significant association between prolonged seizures and specific psychosis sub-types.

Strengths of the Study:

1. The study has used standard guidelines of Modified Electro-Convulsive Therapy procedure.
2. Additional data were studied apart from the primary objectives such as BMI, psychosis subtypes and their relation to prolonged ECT seizures.
3. Only one site of electrode application was studied i.e. Bitemporal placement. This makes the study statistics more generalisable without too many dependent variables involved in analysis.

Limitations:

1. There were concurrent medications such as clozapine used, which needed larger sample of ECTs in those receiving the drug in order to study its effects on prolonged seizures in ECT.
2. Effects of different Anaesthetic agents such as propofol could have been studied

CONCLUSION

Electro Convulsive Therapy is a widely used therapeutic intervention with history of 80 years and counting period of good rates of successful outcomes in psychiatric illnesses and other conditions. Innovative techniques to improve the acceptability, safety, efficacy and to reduce adverse effects and complications associated with the procedure are being done.

Since a few years of introduction of the procedure, the use of Skeletal Muscle relaxants, General anaesthetic drugs, Unilateral electrode placement, change in wave-form of electrical stimulus and other stimulus parameters, spacing the sessions etc. have all been or being evaluated with greater impact on favourable outcomes.

Studies have shown that inadequate seizures are not effective and prolonged seizures during ECT are associated with significant adverse effects. Many times both adequate seizure and prolonged seizures are missed without EEG monitoring during ECT. Our study brings out the finding that 11.11% of seizures in ECT are prolonged and about 6.29% of the adequate seizures are detected by EEG monitoring only and motor observation alone will not suffice.

The study also reports that prolonged seizures were noted to be significantly higher in the first ECT sessions than 2nd or later sessions.

There were no significant association of prolonged seizures with psychiatric diagnosis, gender, BMI, sub-types of psychosis or concurrent use of lithium or clozapine in ECTs.

Overall, this study has shown a significant benefit of using EEG monitoring along with observation of motor convulsions to detect adequate seizures missed by motor criteria and also detect the undesirable prolonged seizures for better outcome of the procedure.

SUMMARY

- The study was an attempt to assess the overall incidence of prolonged seizures during modified ECT by EEG monitoring
- The sample size was 216 ECTs among 110 individuals, mean age of the study was 30.6 ± 6.88 years. Majority of them were males 60 (54.54%).
- Majority of the patients were young adults with 85 (77.27%) of them, rural people with 59 (53.64%) of them, middle class were 93 (84.55%) of them and hindus were 99 (90%) of them.
- Prolonged seizures were noted in 24 out of 216 ECTs with an incidence rate of 11.11%, out of which 9 were picked up by EEG criteria exclusively. This amounts to about 37.5% of prolonged seizures would have been missed if EEG monitoring hadn't been done.
- The rate of adequate seizures by EEG monitored criteria but inadequate by motor criteria was about 6.82% which were about 10 cases out of the total 216 samples studied.
- The rate of prolonged seizures were noted to be significantly higher in the first ECT sessions than 2nd sessions and subsequent sessions.
- There were no significant association of prolonged seizures with psychiatric diagnosis, gender, BMI, concurrent use of Lithium or Clozapine in ECTs.
- There were no significant association of prolonged seizures with sub-types of psychosis.

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ANNEXURE I
INFORMED CONSENT

Title: “INCIDENCE OF PROLONGED MOTOR AND EEG SEIZURES IN ELECTROCONVULSIVE THERAPY: A 1 YEAR CROSS-SECTIONAL HOSPITAL BASED STUDY”

Principal Investigator (PI):

Objective/Purpose of the study: You/your relative are/is being requested to be a subject in a cross-sectional study, the purpose of which is to know incidence of prolonged seizures in patients receiving ECT by studying them through an EEG monitored ECT machine in K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010 conducted between 1st January 2018 and 31st December 2018, by Dr _____, a post graduate student in the Department of Psychiatry at Jawaharlal Nehru Medical College, KLE University, Belagavi, Karnataka.

You/your relative have/has been requested to participate in this study as you/your relative is/are diagnosed with a psychiatric illness which needs intervention called the ELECTROCONVULSIVE THERAPY, which will be studied so that effective treatment can be given to not just you/your relative but also other patients in the future based on the study interpretation once it is done if helpful.

Procedure involved: If you/your relative agree to be a part of the study, the patient who is undergoing Electroconvulsive Therapy will be considered for study. The patient undergoing the procedure will be stimulated with an electric current using a standard 4-channel EEG monitored ECT machine and the seizure characteristics of motor and cerebral seizures are observed and monitored using the same 4-channel

EEG monitored ECT machine and restimulation at a higher electrical dose is done if the seizure characteristics are not therapeutically adequate and the process is repeated if the criteria is not satisfied for seizure adequacy. The seizure is noted by its characteristics and deemed adequate and if motor seizures occur for 90 seconds or more or, if EEG seizures occur for 120 seconds or more they are immediately terminated by medications. Seizures which are adequate and below 90 seconds duration of motor seizure and 120 seconds duration of EEG seizure do not need any special management and standard protocol for recovery after the procedure is followed.

Risks and benefits involved: There are no risks involved. During the period of study which involves undergoing the Electroconvulsive therapy, the existence or development of any significant findings or complication will be treated by the treating doctors and information will be given to and consent taken from you/your relative will be taken for the appropriate action needed if any arise(s).

Alternatives: Your/your relative's participation in this study is a completely voluntary decision. If you/your relative do/does not want to be a part of the study, you/your relative may refuse for the same or if you/your relative are/is already a part of the study and if you/your relative want/wants to withdraw from the study for any reason, you/your relative may do so without any hesitation. Discontinuation from the study for any reason will not affect your/your relative's current or future relationship with K.L.E.S Dr. Prabhakar Kore Hospital, Belagavi.

Privacy and confidentiality: The information provided by you/your relative will be known to the treating doctors and the members of the research team. This information

will remain confidential and will be disclosed to others only with your/your relative's written permission or if required by the law.

Financial incentives for participation: You/your relative will not be paid/offered any gifts for participation in the research. There will not be any remuneration for participating in the research and you/your relative will not be reimbursed for any expenses, such as bus/train travelling /companion/assistant etc.

Authorization to publish results: When the results of the research are to be published or discussed in conferences by the PI, no information will be disclosed that will reveal your/your relative's identity.

If you/your relative have/has any questions about this study, you/your relative may contact

Dr. _____, Postgraduate student, Department of Psychiatry, J.N.M.C, Belagavi;

Dr. _____, Professor and Head, Department of Psychiatry, J.N.M.C, Belagavi;

Dr. Roopa Bellad, Chairman, Institutional Ethical Committee for Human Subjects Research, Jawaharlal Nehru Medical College, Belgaum, Ph. 0831 2471350. You/your relative will be given a copy of this consent form for your/your relative's information and records.

STATEMENT OF CONSENT

I/my relative have/has read and have/has completely understood the entire information given in the consent form, which explains all the details of the study, i.e, the purpose, procedure involved, risks & benefits, privacy & confidentiality, incentives and the authorization to publish the results of the study. My/my relative's signature in the space provided for signature below indicates that I/my relative have/has voluntarily agreed to participate in the study. I/my relative may withdraw my/my relative's participation for any reason or may be withdrawn by the investigator from the study for any reason at any time. I/my relative am/is not giving up any of my/my relative's legal rights by signing this consent form. I/my relative will be given a copy of this consent form.

Signature of the participant with date: _____

Name of the participant: _____

Signature of the authorized relative with date: _____

Name of the authorized relative: _____

His/her relationship to the participant: _____

Signature of the witness with date: _____

Name of the witness: _____

Signature of the Investigator with date: _____

ಒಪ್ಪಿಗಪತ್ರ

ಶೀರ್ಷಿಕೆ: " ಇನ್ನಡನ್ಸೆ ಆಫ್ ಲಾಂಗ್ವೋಟಾ ಅಂಡ್ ಇ. ಇ. ಜನೀಯುಸ್ ಇನ್ ಎಲೆಕ್ಟ್ರಾನಿಕ್ಸ್ ಕನ್ಸಲ್ಟಿಂಗ್ :
ಅ 1 ಇಯುಕ್ಯಾಸ್ -ಸಕ್ಷನಲ್ ಸ್ಟಾಟಿಸ್ಟಿಕ್ಸ್ ಡೆ"

ಮುಖ್ಯಸಂಶೋಧಕರು:

ಅಧ್ಯಯನದ ಉದ್ದೇಶ: ನೀವು / ನಿಮ್ಮ ಸಂಬಂಧಿ ಒಂದು ಅಧ್ಯಯನದ ಲ್ಲಿ ಭಾಗವಹಿಸಲು ವಿನಂತಿಸಲ್ಪಡುತ್ತದೆ.
ಇ.ಸಿ.ಟಿ ಪಡೆಯುವ ರೋಗಿಗಳ ಲ್ಲಿ ಸುದೀರ್ಘವಾದ ಸೀಯುಸ್ ಗಳ ಸಂಭವವನ್ನು ತಿಳಿಯುವುದು ಈ ಅಧ್ಯಯನದ
ಉದ್ದೇಶವಾಗಿದೆ. ಇ.ಇ.ಜಿ.ಮಾನಿಟರ್ ಇ.ಸಿ.ಟಿ ಯು ಮೂಲಕ ಇದನ್ನು ಮಾಡುವ ಸ್ಥಳ ಕೆ.ಎಲ್.ಇ.ಎಸ್.ಡಾ.ಪ್ರ
ಭಾಕರ್ ಕೋರ ಆಸ್ಪತ್ರೆ ಮತ್ತು ವೈದ್ಯಕೀಯ ಸಂಶೋಧನಾ ಕೇಂದ್ರ, ನಹರು ನಗರ, ಬೆಳಗಾವಿ-
590010. ಜನವರಿ 1, 2018 ಮತ್ತು 31 ನೇ ಡಿಸೆಂಬರ್ 2018 ರ ನಡುವೆ ಈ ಅಧ್ಯಯನ ನಡೆಯುತ್ತದೆ,
ಇದನ್ನು ನಡೆಸುವವರು ಡಾ. , ಕೆ.ಎಲ್.ಇ.ವಿಶ್ವವಿದ್ಯಾಲಯ, ಬೆಳಗಾವಿ,
ಜಿವಾಹರ ಲಾಲ್ ಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನ ಲ್ಲಿ ಸೈಕಿಯಾಟ್ರಿ ಇಲಾಖೆಯ ಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ವಿದ್ಯಾರ್ಥಿ.

ನೀವು / ನಿಮ್ಮ ಸಂಬಂಧಿ /

ಮನೋವೈದ್ಯಕೀಯ ಅನಾರೋಗ್ಯದ ಮೂಲಕ ರೋಗಿಗಳಿಗೆ ನಷ್ಟವನ್ನು ತಡೆಗಟ್ಟುವ ಎಲೆಕ್ಟ್ರಾನಿಕ್ಸ್ ಕನ್ಸಲ್ಟಿಂಗ್ ಸಂಘ
ದ ಕಾರ್ಯವಿಧಾನವನ್ನು ವಿವರಿಸಿ ಅಗತ್ಯವಿರುತ್ತದೆ,

ಇದನ್ನು ಪರಿಣಾಮಕಾರಿ ಚಿಕಿತ್ಸೆಗಾಗಿ ಅಧ್ಯಯನ ಮಾಡಲಾಗುವುದು.

ಇದರಂತೆ ಸಹಿ ತರರೋಗಿಗಳಿಗೆ ಭವಿಷ್ಯದ ಲ್ಲಿ ಸಹಾಯಕವಾಗಿ ಬಹುದು.

ಅಧ್ಯಯನದ ವಿಧಾನ ಪ್ರಕ್ರಿಯೆ: ನೀವು / ನಿಮ್ಮ ಸಂಬಂಧಿ ಅಧ್ಯಯನದ ಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡರೆ,
ಎಲೆಕ್ಟ್ರಾನಿಕ್ಸ್ ಕನ್ಸಲ್ಟಿಂಗ್ ಸಂಘದ ಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ.

ಕಾರ್ಯವಿಧಾನವನ್ನು ಒಳಗೊಳ್ಳುವುದು ಒಂದು ವಿದ್ಯುತ್ ಪ್ರವಾಹದಿಂದ ಪ್ರೇರಿತವಾದ 4-

ಚಾನೆಲ್ ಇ.ಇ.ಜಿ.ಮಾನಿಟರ್ ಇ.ಸಿ.ಟಿ ಯಂತ್ರವನ್ನು ಬಳಸಿಕೊಂಡು ಪ್ರಚೋದಿಸಲ್ಪಡುತ್ತದೆ ಮತ್ತು ಮೋಟಾ
ರು ಮತ್ತು ಮಿದುಳಿನ ಸೀಯುಸ್ ಗಳು ಉಣ್ಣೆಗಳನ್ನು ಗಮನಿಸಲಾಗುವುದು ಮತ್ತು ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲಾಗು
ತ್ತದೆ.

ಸೀಯುಸ್ ಗಳು ಉಣ್ಣೆಗಳು ಚಿಕಿತ್ಸೆ ಕವಾಗಿ ಸಮರ್ಪಕವಾಗಿ ಲ್ಲಿ ದೃಢೀಕರಣವನ್ನು ವಿದ್ಯುತ್ ಮಾಣದ ಲ್ಲಿ ವಿಶ್ರಾಂತಿ
ಗದು ಮತ್ತು ಮೈಕೂಡಲಾಗುತ್ತದೆ.

90 ಸಕಂಡುಗಳು ಅಥವಾ ಅದಕ್ಕೂ ಹೆಚ್ಚಿನ ಕಾಲ ಮೋಟಾರ್ಸ್ ಜರ್ನಲ್ ಸಂಭವಿಸಿದ ಲ್ಲಿ ಅಥವಾ,
ಇಇಜಿ ಸೀಯುಸ್ ಗಳು 120

ಸಕಂಡುಗಳು ಅಥವಾ ಹೆಚ್ಚಿನ ಕಾಲ ಸಂಭವಿಸಿದ ರ ಪ್ರತ್ಯೇಕವಾಗಿ ಬೆಳಕುಗಳಿಂದ ಲ್ಲಿ ಸಲಾಗುವುದು.

ಸೀಯುಸ್ಸುಗುಣಲಕ್ಷಣಗಳಿಂದಗುರುತಿಸಲ್ಪಡುತ್ತದಮತ್ತುಸಾಕಷ್ಟುಪ್ರಮಾಣವೆಂದುಪರಿಗಣಿಸಲಾಗದ.

ಅಪಾಯಗಳುಮತ್ತುಅನುಕೂಲಗಳು:

ಒಳಗೊಂಡಿರುವಲಭ್ಯವಿರುವನದಲಿಯಾವುದೇಅಪಾಯಗಳಲ್ಲ.ಚಿಕ್ಕಕ್ಕವ್ಯದ್ಯಯಾವುದೇತೂಡಕುಗಳನ್ನು ಕಂಡರಪರಿಗಣಿಸುತ್ತಾರಮತ್ತುನಿಮಗಮಾಹಿತನಿಮಗನೀಡಲಾಗುವುದು.

ನಿಮ್ಮಒಪ್ಪಿಗತಗದುಕೂಳ್ಳಲಾಗುವುದುಮತ್ತುಸಂಯಾದಕ್ರಮಕ್ಕೂಳ್ಳಲಾಗುವುದು.

ಪರ್ಯಾಯಗಳು: ಈಲಭ್ಯವಿರುವನದಲಿನಿಮ್ಮ /
 ನಿಮ್ಮಸಂಬಂಧಭಾಗವಹಿಸುವಿಕೆಯುಸಂಪೂರ್ಣವಾಗಿಸ್ವಯಂಪ್ರೇರಿತವಾಗುತ್ತದೆ. ನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಲಭ್ಯವಿರುವನದಲಿನಿಮ್ಮಭಾಗವಾಗರಬೇಕೆಂದುಬಯಸದಿದ್ದರೆ, ನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಿಯುಒಂದೇರೀತಿನಿರಾಕರಿಸಬಹುದುಅಥವಾನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಿಈಗಾಗಲೇಲಭ್ಯವಿರುವನದಭಾಗವಾಗಿದ್ದರಮತ್ತುನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಿಯುಸದರಿಯಾವುದೇಕಾರಣಕ್ಕಾಗಲಿಲಭ್ಯವಿರುವನದಿಂದಹಿಂದೆಗದುಕೂಳ್ಳಬಯಸದರೆ, ನೀವು / ನಿಮ್ಮಸಂಬಂಧಿಯಾವುದೇಹಂಜಿರಿಯಿಲ್ಲದಹಾಗಮಾಡಬಹುದು.
 ಯಾವುದೇಕಾರಣಕ್ಕಾಗಲಿಲಭ್ಯವಿರುವನದಮುಂದುವರಿಸಿ ನಿಮ್ಮ /
 ನಿಮ್ಮಸಂಬಂಧಿಪ್ರಸ್ತುತಅಥವಾಭವಿಷ್ಯದಸಂಬಂಧವನ್ನುಕ.ಎಲ್.ಇ.ಎಸ್ .ಡಾ.ಪ್ರಭಾಕರ್ಕೋರಿಸ್ವತ್ತ, ಬಳಗಾವಜೂತಪರಿಣಾಮಬೀರುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆ :ನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಿಒದಗಿಸಿದಮಾಹಿತಿಯುಮುಖ್ಯಸಂಶೋಧಕರುಮತ್ತುಸಂಶೋಧನಾತಂಡದಸದಸ್ಯರಿಗತಿಳಿದಿರುತ್ತದೆ. ಈಮಾಹಿತಿಯುಗೌಪ್ಯವಾಗಿರಬೇಕೆಂದುನಿಮ್ಮ /
 ನಿಮ್ಮಸಂಬಂಧಿರಲಿಖಿತಅನುಮತಿಯೊಂದಿಗಲಿಖಿತವಾಕಾನೂನಿನಲಿಗತ್ಯವಿದ್ದರಮಾತ್ರಇತರರಿಗಬಹಿರಂಗಗೊಳ್ಳುತ್ತದೆ.

ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯಹಣಕಾಸಿನಪ್ರೋತ್ಸಾಹ: ನೀವು / ನಿಮ್ಮಸಂಬಂಧಿಪಾವತಿಸುವುದಿಲ್ಲ /
 ಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಯಾವುದೇಉಡುಗೂರಗಳನ್ನುನೀಡಲಾಗುವುದಿಲ್ಲ.
 ಸಂಶೋಧನೆಯಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುಯಾವುದೇಸಂಭಾವನೆಯಿಲ್ಲಮತ್ತುನೀವು / ಬಸ್ / ರೈಲುಪ್ರಯಾಣ /
 ಸಹಯೋಗ / ಸಹಾಯಕಮುಂತಾದಯಾವುದೇಖರ್ಚುಗಳಿಗೆನೀವು /
 ನಿಮ್ಮಸಂಬಂಧಿಗಳನ್ನುಮರುಪಾವತಿಸಲಾಗುವುದಿಲ್ಲ.

ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಲು ದೃಢೀಕರಣ:

ಸಂಶೋಧನೆಯ ಫಲಿತಾಂಶಗಳು ಮುಖ್ಯ ಸಂಶೋಧಕರಂದ ಸಮಾವೇಶಗಳಲ್ಲಿ ಪ್ರಕಟವಾಗಬೇಕಾದರೂ

ವಾಚರ್ಷಿಕೆ ಸಬೇಕಾದರೆ, ನಿಮ್ಮ ಮಾಹಿತಿಯನ್ನು ನಿಮ್ಮ /

ನಿಮ್ಮ ಸಂಬಂಧಿಯು ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ.

ನೀವು / ನಿಮ್ಮ ಸಂಬಂಧ / ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಹೊಂದಿದ್ದರೆ, ನೀವು /

ನಿಮ್ಮ ಸಂಬಂಧಿಯು ಸಂಪರ್ಕಿಸಬಹುದು.

ಡಾ. , ದೂರವಾಣಿ ಸಂಖ್ಯೆ. , ಕೆ.ಎಲ್.ಎಲ್.ಶಿವದ್ವೈಲಯ,
ಬೆಳಗಾವಿ,

ಜವಾಹರಲಾಲ್ ಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜಿನಲ್ಲಿ ಸೈಕಿಯಾಟ್ರಿ ಇಲಾಖೆಯಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರವಿದ್ಯಾರ್ಥಿ.

ಡಾ. , ದೂರವಾಣಿ ಸಂಖ್ಯೆ. ,

ಪ್ರೊಫೆಸರ್ ಮತ್ತು ಇಲಾಖೆಯ ಮುಖ್ಯಸ್ಥ, ಡಿಪಾರ್ಟ್‌ಮೆಂಟ್ ಆಫ್ ಸೈಕಿಯಾಟ್ರಿ, ಜಿ.ಎನ್.ಎಂ.ಸಿ, ಬೆಳಗಾವಿ,

ಡಾ. ರೂಪಾಬಲ್ಲದ್, ಛೇರ್ಮನ್, ಮಾನವ ವಿಷಯಗಳ ಸಂಶೋಧನಾ ಸಂಸ್ಥೆ, ತಿರಸಮಿತಿ,

ಜವಾಹರಲಾಲ್ ಹರು ಮೆಡಿಕಲ್ ಕಾಲೇಜ್, ಬೆಳಗಾವಿ, ದೂರವಾಣಿ ಸಂಖ್ಯೆ. 0831 2471350

ಅನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು .

ನಿಮ್ಮ / ನಿಮ್ಮ ಸಂಬಂಧಕರ ಮಾಹಿತಿ ಮತ್ತು ದಾಖಲೆಗಳಿಗಾಗಿ ನೀವು /

ನಿಮ್ಮ ಸಂಬಂಧಿಗಳ ಸಮ್ಮತಿಯ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗುವುದು.

ಸಮ್ಮತಿಯಪತ್ರ

ನಾನು / ನನ್ನಸಂಬಂಧಿಬಿಟ್ಟಿರುವವನು ಒದಲದರಸಂಪೂರ್ಣಮಾಹಿತಿಯನ್ನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ,
 ಇದು ಅಧ್ಯಯನದ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ವಿವರಿಸುತ್ತದೆ, ಅಂದರೆ, ಒಳಗೊಂಡಿರುವ ಉದ್ದೇಶ,
 ಅಧ್ಯಯನದ ವಿಧಾನದ ಪ್ರಕ್ರಿಯೆ, ಅಪಾಯಗಳು ಮತ್ತು ಅನುಕೂಲಗಳು, ಗೌಪ್ಯತೆ
 , ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯ ಹಣಕಾಸಿನ ಪ್ರೋತ್ಸಾಹ ಮತ್ತು ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸಲು ದೃಢೀಕರಣ.
 ಕಳಗಿರುವ ಸಹಿಗಾಗಿ ಒದಗಿಸಲಾದ ಜಾಗದಲ್ಲಿ ನನ್ನ / ನನ್ನ ಸಂಬಂಧಿಯ ಸಹಿ ನಾನು / ನನ್ನ ಸಂಬಂಧಿ /
 ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಬಿಟ್ಟಿರುವೆ ಎಂದು ಸೂಚಿಸುತ್ತದೆ. ನಾನು /
 ನನ್ನ ಸಂಬಂಧಿಯಾದುದೇ ಕಾರಣಕ್ಕಾಗಿ ನನ್ನ /
 ನನ್ನ ಸಂಬಂಧಿ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು ಅಥವಾ ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ಅಧ್ಯಯನ
 ದ ಸಂಶೋಧಕರು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನಾನು / ನನ್ನ ಸಂಬಂಧಿ ಆಮ್ /
 ನನ್ನ ಸಮ್ಮತಿಯ ರೂಪದಲ್ಲಿ ಸಹಿ ಮಾಡುವ ಮೂಲಕ ನನ್ನ /
 ನನ್ನ ಸಂಬಂಧಿ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ಬಿಟ್ಟುಕೊಡುವುದಿಲ್ಲ. ನಾನು /
 ನನ್ನ ಸಂಬಂಧಿ ಈ ಸಮ್ಮತಿಯ ರೂಪದಲ್ಲಿ ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗುವುದು.

ದಿನಾಂಕದೊಂದಿಗೆ ಪಾಲ್ಗೊಳ್ಳುವವರ ಸಹಿ: _____

ಪಾಲ್ಗೊಳ್ಳುವವರ ಹೆಸರು: _____

ಅಧಿಕೃತ ಸಂಬಂಧಿ : _____

ದಿನಾಂಕದೊಂದಿಗೆ

ಅಧಿಕೃತ ಸಂಬಂಧಿ ಹೆಸರು: _____

ಪಾಲ್ಗೊಳ್ಳುವವರೊಂದಿಗೆ ಅವರ ಸಂಬಂಧಿ: _____

ದಿನಾಂಕದೊಂದಿಗೆ ಸಾಕ್ಷಿಯ ಸಹಿ: _____

चैनल डेड जीमॉनिटर डेसीटोमशीन द्वारा संचालित होती है जो एकांवेद्युत प्रवाह द्वारा संचालित होती है और मोटर और मास्तिष्क सीज़र की विशेषताओं को मॉनिटर किया जाता है। | यादेंदौरेकेलक्षणांचोके त्सीयकांलेएपयोप्तनहोहैं,

तोउन्हेबहालाकियाजासकताहैऔरउच्चवतेमानमेआपांतेकोजासकतीहै।

यादेंमोटरसीज़से 90 सेकडयाउससेआंधिककांलेएहोतेहैं, यायादेंडै.ई.जीसीज़से 120 सेकडयाउससेआंधिकहो, दवासेबंदकरेगा।

सीज़सेकोविशेषताओकाअध्ययनकियाजाताहैऔरइसेपयोप्तरूपसेमात्रात्मकमानाजाताहै।

जोखिमऔरलाभ:

इसमेंशांमेलअध्ययनमेंकोडेंजोखिमनहोहैं।|चोकेत्सीयांचोकेत्सकाकेसीभीजांटेलाओपरांवेचारकरेगेंऔरआपकोजानकारीदोजाएगी।|चोकेत्सीयांचोकेत्सकाकेसीभीजांटेलाओपरांवेचारकरेगेंऔरआपकोजानकारीदोजाएगी।आपकोसहमांतेलोजाएगीऔरउंचेतकारेवाडेंकोजाएगी।

विकल्प: इसअध्ययनमेंआपको / आपकोसापेक्षभागीदारोपूरोतरहसेस्वोच्छकहैं।यादेंआपअपने

/ अपनेसापेक्षअध्ययनकाहेस्सानहोबननाचाहतेहैं, आप /

आपकेरिश्तेदारकोइनकारकरसकतेहैंयायादेंआप /

आपकेरिश्तेदारपहलेसेहोअध्ययनकाहेस्साहैंऔरयादेंआप /

आपकेरिश्तेदारकेसीभीकारणसेअध्ययनसेपीछेहटनाचाहतेहैं, आप /

आपकेरिश्तेदारबेनाकेसींझेझककेऐसाकरसकतेहैं।|केसीभीकारणसेअध्ययनकोनरतरताआ

पके / अपनेरिश्तेदारवतेमानयाभाविष्यकेसबधकेसाथहैंहैं।के.एल.

ई.एसडॉप्रभाकरकोरेहोस्पिटलनेबेलगामकोप्रभावेतनहोहोगा।

एकांत: आपके /

आपकेरिश्तेदारद्वारादोगडेंसूचनाउपचारांचोकेत्सकोऔरअनुसंधानदलकेसदस्योकोजानीजाए

गी। यह जानकारी गोपनीय रहेगी और केवल आपके /
आपको रिश्तेदार को लिखित अनुमति के साथ ही दूसरो को बताया जाएगा या देकानून द्वारा जरूरी है।

भागीदारी के लिए वित्तीय प्रोत्साहन: अनुसंधान में भाग लेने के लिए आप /
आपके रिश्तेदार को कोड़े उपहार नहीं दिया जाएगा /
पेशकश नहीं किया जाएगा। अनुसंधान में भाग लेने के लिए कोड़े पारिश्रामिक नहीं होगा और आप /
आपके रिश्तेदार को किसी भी खर्च के लिए प्रातिपूतन ही होगी, जैसे कि बस / ट्रेन यात्रा / साथी /
सहायक आदि।

परिणाम प्रकाशित करने के लिए प्राधिकरण: जब शोध के परिणाम द्वारा सम्मेलन में प्रकाशित या चर्चा
किए जाएंगे, कोड़े जानकारी नहीं दी जाएगी जो आपको / आपको रिश्तेदार को पहचान प्रकट करेगी।
यादि आप / आपके रिश्तेदार / इस अध्ययन के बारे में कोड़े प्रश्न हैं, तो आप /
आपके रिश्तेदार से संपर्क कर सकते हैं।

डॉ। एम. स्नातकोत्तर छ, मनोचिकित्सा विभाग, जे.एन.एम.सी, बेलागवी,
फोन नंबर-

डॉ. , प्रोफेसर और प्रमुख, मनोचिकित्सा विभाग, जे.एन.एम.सी, बेलागवी; फोन नंबर-

डॉ। रूपा बेलाड, अध्यक्ष, मानवाविषय अनुसंधान के लिए सस्थागत नैतिक समीति,
जवाहरलाल नेहरू मेडिकल कॉलेज, बेलागवी, फोन नंबर- 0831 2471350 ।

आप / आपके रिश्तेदार को आपके /

आपको रिश्तेदार को जानकारी और रिकॉर्ड के लिए इस सहमति फॉर्म को एक प्रातिपूतन दिया जाएगा।

सहमतिकवक्तव

में / मेरेरिश्तेदारने / सहर्मातेपत्रमेदोपूरोजानकारोकोपढालेयाहैंऔरपूरोतरहसेसमझालेयाहैं, जोअध्ययनकेसभीवेवरणबतातेहैंयानी, उद्देश्य, प्रक्रियाशामेल, जोखेमऔरलाभ, गोपनीयता, भागीदारीकेलेएवेत्तीयप्रोत्साहनऔरपारेणामप्रकाशितकरनेकेलेएप्राधिकरण।नीचेदेएगएह स्ताक्षरकेलेएउपलब्धकराएगएस्थानमेमेरे / मेरेरिश्तेदारकेहस्ताक्षरङ्गितकरताहैंकेमें / मेरेरिश्तेदारनेस्वेच्छासेअध्ययनमेभागलेनेकेलेएसहर्मातेव्यक्तकोहैं।केसीभीकारणसेमें / मेरारिश्तेदारकोभागीदारीकोवापसलेसकताहैयाकेसीभीसमयाकेसीभीकारणसेअन्वेषकभीसेअध्ययनसेवापसकरसकताहै।इससहर्मातेफॉर्मेपरहस्ताक्षरकरकेमें / मेरारिश्तेदारमेरा/मेरारिश्तेदारकाकेसीभीकानूनीआधिकारोकोनहीदेरहाहू।में / मेरेरिश्तेदारकोइससहर्मातेफॉर्मेकोएकप्रांतेदोजाएगी।

तिथिकेसाथप्रांतेभागीकेहस्ताक्षर: _____

प्रांतेभागीकानाम: _____

आधिकृतारिश्तेदारकेहस्ताक्षर: _____

तिथिकेसाथ: आधिकृतारिश्तेदारकानाम: _____

प्रांतेभागीकोउसका / उसकेरिश्ते: _____

तिथिकेसाथगवाहकेहस्ताक्षर: _____

गवाहकानाम: _____

तिथिकेसाथअन्वेषककेहस्ताक्षर: _____

ANNEXURE II
ETHICAL CLEARANCE LETTER



K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: <http://www.jnmc.edu>
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 53

Date: 22/11/2017

To,
D
PG student in Psychiatry,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "INCIDENCE OF PROLONGED MOTOR AND EEG SEIZURES IN ELECTROCONVULSIVE THERAPY: A 1 YEAR CROSS SECTIONAL HOSPITAL BASED STUDY", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE III

STUDY PROFORMA

**“ INCIDENCE OF PROLONGED MOTOR AND EEG SEIZURES IN
ELECTROCONVULSIVE THERAPY : A 1 YEAR CROSS-SECTIONAL
HOSPITAL BASED STUDY”**

Date:

Time:

IP/OP No:

Serial No:

Name:

Age:

Sex: M/F

Religion: Hindu/Muslim/Christian/Others

Marital Status: SINGLE/MARRIED/DIVORCED/WIDOWED

Address/Place:

Socio-economic status:

Informant:

Diagnosis:

Duration of illness:

Past treatment history:

Present treatment history:

General Physical Examination:

BP: PULSE: RR:

TEMPERATURE:

Height: Weight: BMI:

Systemic Examination:

CNS:

CVS:

RS:

P/A:

Mental Status Examination:

CONSCIOUSNESS:

ORIENTATION:

MEMORY:

SPEECH:

THOUGHT:

MOOD:

PERCEPTION:

JUDGEMENT:

INSIGHT:

ELECTROCONVULSIVE THERAPY(ECT)

ECT NO:

ANESTHETIC DRUGS WITH DOSE:

ECT electrical dose -	Motor seizure duration	EEG seizure duration

S.NO	DIAGNOSIS	AGE	Age group	RELIGION	GENDER	RURAL/URBAN	SOCIO-ECONOMIC STATUS	HT (in cm)	WT (in Kg)	BMI (in kg/m ²)	clozapine	benzodiazepenes	Lithium	BMI STATUS	ECT NUMBER	ECT DOSE (in mc)	MOTOR SEIZURE DURATION (in seconds)	motor result	EEG seizure duration (in seconds)	EEG result	Prolonged either seizure	THIOPENTONE dose (in mg)	SCOLINE (dose in mg)
1	F10.2+F12.2+F31.2	27	Young adult	HINDU	MALE	URBAN	3	160	58	22.65625	no	yes	yes	Normal	1	60	94	normal	130	prolongedeeg seizure	Prolonged either seizure	125	50
2	F10.2+F20.0	34	Young adult	HINDU	MALE	RURAL	3	167	68	24.38237298	no	yes	no	Normal	2	120	141	prolonged motor	157	prolongedeeg seizure	Prolonged either seizure	125	50
3	F20.0	27	Young adult	HINDU	MALE	RURAL	4	160	62	24.21875	no	yes	no	Normal	1	60	54	normal	124	prolongedeeg seizure	Prolonged either seizure	125	50
4	F20.0	28	Young adult	HINDU	MALE	URBAN	3	165	68	24.97704316	yes	yes	no	Overweight	35	60	122	prolonged motor	155	prolonged eeg seizure	Prolonged either seizure	125	50
5	F20.0	29	Young adult	HINDU	MALE	RURAL	3	167	60	21.51385851	no	yes	no	Normal	4	60	126	prolonged motor	142	prolongedeeg seizure	Prolonged either seizure	200	50
6	F20.0	41	middle aged adult	HINDU	FEMALE	RURAL	3	158	74	29.64268547	no	yes	no	Overweight	1	120	134	prolonged motor	144	prolongedeeg seizure	prolonged either seizure	150	50
7	F20.0	27	Young adult	HINDU	MALE	URBAN	3	170	68	23.52941176	no	yes	no	Normal	1	60	78	normal	130	prolongedeeg seizure	prolonged either seizure	125	50
8	F20.3	28	Young adult	HINDU	MALE	URBAN	3	165	68	24.97704316	yes	yes	no	Overweight	34	180	85	normal	126	prolongedeeg seizure	prolonged either seizure	125	50
9	f20.3	28	Young adult	HINDU	MALE	URBAN	3	163	70	26.34649403	yes	yes	no	Overweight	36	120	133	prolonged motor	150	prolongedeeg seizure	prolonged either seizure	175	50
10	F20.3	33	Young adult	HINDU	MALE	RURAL	3	171	72	24.62296091	no	yes	no	Normal	1	120	138	prolonged motor	155	prolongedeeg seizure	prolonged either seizure	150	50
11	F20.3	33	Young adult	HINDU	MALE	RURAL	3	171	72	24.62296091	no	yes	no	Normal	4	120	129	prolonged motor	136	prolongedeeg seizure	prolonged either seizure	125	50
12	F25.0	24	Young adult	HINDU	MALE	RURAL	3	152	48	20.77562327	no	yes	no	Normal	1	60	142	prolonged motor	160	prolongedeeg seizure	prolonged either seizure	125	50
13	F30.2	45	middle aged adult	HINDU	MALE	RURAL	3	159	73	28.87544005	no	yes	no	Overweight	1	60	135	prolonged motor	146	prolongedeeg seizure	prolonged either seizure	150	50
14	F31.1	28	Young adult	HINDU	FEMALE	URBAN	3	150	48	21.33333333	no	yes	yes	Normal	8	120	92	normal	132	prolongedeeg seizure	prolonged either seizure	100	50
15	F31.1	19	Young adult	HINDU	MALE	RURAL	3	173	65	21.71806609	no	yes	yes	Normal	4	120	138	prolonged motor	150	prolongedeeg seizure	prolonged either seizure	125	50
16	F31.1	46	middle aged adult	HINDU	MALE	URBAN	3	166	70	25.40281608	no	yes	yes	Overweight	1	60	95	normal	133	prolongedeeg seizure	prolonged either seizure	125	50

17	F31.1	46	middle aged adult	HINDU	MALE	URBAN	3	166	70	25.40281608	no	yes	yes	Overweight	3	120	138	prolonged motor	154	prolongedeeg seizure	prolonged either seizure	125	50
18	F31.1	45	middle aged adult	HINDU	MALE	RURAL	3	159	73	28.87544005	no	yes	no	Overweight	2	60	85	normal	133	prolongedeeg seizure	prolonged either seizure	125	50
19	F31.1	45	middle aged adult	HINDU	MALE	RURAL	3	159	73	28.87544005	no	yes	no	Overweight	3	60	146	prolonged motor	162	prolongedeeg seizure	prolonged either seizure	125	50
20	F31.2	24	Young adult	HINDU	FEMALE	URBAN	3	159	68	26.89767019	no	yes	no	Overweight	3	120	74	normal	128	prolongedeeg seizure	prolonged either seizure	125	50
21	F32.2	35	Young adult	HINDU	MALE	RURAL	3	168	64	22.67573696	no	no	no	Normal	2	60	145	prolonged motor	148	prolonged eeg seizure	prolonged either seizure	125	40
22	F34.1+F32.3	38	middle aged adult	HINDU	FEMALE	URBAN	3	163	62	23.33546614	no	yes	no	Normal	1	60	124	prolonged motor	130	prolonged eeg seizure	Prolonged either seizure	100	50
23	F34.1+F32.3	38	middle aged adult	HINDU	FEMALE	URBAN	3	163	62	23.33546614	no	yes	no	Normal	2	60	132	prolonged motor	134	prolonged eeg seizure	Prolonged either seizure	125	50
24	F31.1	21	Young adult	HINDU	MALE	URBAN	3	168	62	21.96712018	no	yes	yes	Normal	2	180	82	normal	128	prolonged eeg seizure	prolonged either seizure	100	30
25	F10.2+F12.2+F31.2	27	Young adult	HINDU	MALE	URBAN	3	160	58	22.65625	no	yes	yes	Normal	2	120	0	normal	74	normal	normal	125	50
26	F10.2+F12.2+F31.2	27	Young adult	HINDU	MALE	URBAN	3	160	58	22.65625	no	yes	yes	Normal	3	120	57	normal	68	normal	normal	125	50
27	F10.2+F12.2+F31.2	27	Young adult	HINDU	MALE	URBAN	3	160	58	22.65625	no	yes	yes	Normal	4	120	45	normal	58	normal	normal	100	30
28	F10.2+F12.2+F31.2	27	Young adult	HINDU	MALE	URBAN	3	160	58	22.65625	no	yes	yes	Normal	6	120	63	normal	82	normal	normal	100	30
29	F10.2+F20.0	33	Young adult	HINDU	MALE	RURAL	2	165	69	25.34435262	no	yes	no	Overweight	7	180	57	normal	60	normal	normal	100	30
30	F10.2+F20.0	29	Young adult	HINDU	MALE	RURAL	2	168	76	26.92743764	no	yes	no	Overweight	2	120	0	normal	34	normal	normal	125	50
31	F10.2+F20.0	29	Young adult	HINDU	MALE	RURAL	2	168	76	26.92743764	no	yes	no	Overweight	3	120	39	normal	39	normal	normal	125	50
32	F10.2+F20.0	29	Young adult	HINDU	MALE	RURAL	2	168	76	26.92743764	no	yes	no	Overweight	4	120	44	normal	48	normal	normal	125	50
33	F10.2+F20.0	29	Young adult	HINDU	MALE	RURAL	2	168	76	26.92743764	no	yes	no	Overweight	5	120	36	normal	42	normal	normal	125	50
34	F10.2+F20.0	34	Young adult	HINDU	MALE	RURAL	3	167	68	24.38237298	no	yes	no	Normal	1	120	45	normal	56	normal	normal	125	50
35	F10.2+F20.0	34	Young adult	HINDU	MALE	RURAL	3	167	68	24.38237298	no	yes	no	Normal	3	120	42	normal	47	normal	normal	125	50
36	F10.2+F20.0	34	Young adult	HINDU	MALE	RURAL	3	167	68	24.38237298	no	yes	no	Normal	4	180	35	normal	41	normal	normal	125	50
37	F10.2+F31.1	37	middle aged adult	HINDU	MALE	URBAN	3	169	80	28.01022373	no	yes	no	Overweight	2	60	34	normal	39	normal	normal	150	50
38	F20.0	31	Young adult	HINDU	MALE	RURAL	4	164	54	20.07733492	no	yes	no	Normal	3	120	50	normal	50	normal	normal	125	50
39	F20.0	31	Young adult	HINDU	MALE	RURAL	4	164	54	20.07733492	no	yes	no	Normal	4	120	54	normal	62	normal	normal	125	50
40	F20.0	22	Young adult	HINDU	FEMALE	RURAL	3	155	50	20.81165453	no	yes	no	Normal	6	120	63	normal	67	normal	normal	100	50
41	F20.0	38	middle aged adult	HINDU	FEMALE	RURAL	3	168	84	29.76190476	no	yes	no	Overweight	3	240	46	normal	59	normal	normal	125	50
42	F20.0	22	Young adult	HINDU	FEMALE	URBAN	3	162	82	31.24523701	no	yes	no	Obesity	6	360	42	normal	44	normal	normal	150	50
43	F20.0	39	middle aged adult	HINDU	MALE	URBAN	3	173	66	22.05219018	no	yes	no	Normal	2	60	73	normal	102	normal	normal	125	50
44	F20.0	22	Young adult	HINDU	FEMALE	URBAN	3	144	69	33.27546296	no	yes	no	Obesity	5	120	36	normal	43	normal	normal	150	75
45	F20.0	28	Young adult	HINDU	FEMALE	RURAL	3	152	48	20.77562327	no	yes	no	Normal	1	120	49	normal	78	normal	normal	100	50
46	F20.0	28	Young adult	HINDU	FEMALE	RURAL	3	152	48	20.77562327	no	yes	no	Normal	2	120	42	normal	50	normal	normal	100	30
47	F20.0	28	Young adult	HINDU	FEMALE	RURAL	3	152	48	20.77562327	no	yes	no	Normal	3	120	40	normal	49	normal	normal	100	30
48	F20.0	32	Young adult	HINDU	MALE	RURAL	3	172	68	22.98539751	no	yes	no	Normal	1	120	53	normal	56	normal	normal	175	50
49	F20.0	32	Young adult	HINDU	MALE	RURAL	3	172	68	22.98539751	no	yes	no	Normal	2	120	60	normal	75	normal	normal	125	50
50	F20.0	29	Young adult	HINDU	MALE	RURAL	3	167	60	21.51385851	no	yes	no	Normal	1	60	38	normal	46	normal	normal	125	50

51	F20.0	31	Young adult	HINDU	FEMALE	RURAL	3	150	59	26.22222222	no	yes	no	Overweight	2	120	44	normal	56	normal	normal	125	50
52	F20.0	35	Young adult	HINDU	FEMALE	RURAL	3	162	59	22.48132907	no	yes	no	Normal	3	180	58	normal	72	normal	normal	100	25
53	F20.0	29	Young adult	HINDU	MALE	RURAL	3	167	60	21.51385851	no	yes	no	Normal	2	60	48	normal	62	normal	normal	100	50
54	F20.0	32	Young adult	HINDU	FEMALE	URBAN	3	155	55	22.89281998	no	yes	no	Normal	6	120	47	normal	60	normal	normal	100	50
55	F20.0	30	Young adult	HINDU	FEMALE	URBAN	3	159	58	22.94213045	no	yes	no	Normal	1	120	50	normal	62	normal	normal	100	50
56	F20.0	30	Young adult	HINDU	FEMALE	URBAN	3	159	58	22.94213045	no	yes	no	Normal	2	180	40	normal	58	normal	normal	125	50
57	F20.0	43	middle aged adult	HINDU	FEMALE	RURAL	3	145	56	26.63495838	no	yes	no	Overweight	6	120	47	normal	50	normal	normal	75	50
58	F20.0	29	Young adult	HINDU	MALE	RURAL	3	167	60	21.51385851	no	yes	no	Normal	5	120	47	normal	64	normal	normal	150	50
59	F20.0	22	Young adult	HINDU	FEMALE	RURAL	3	144	69	33.27546296	yes	yes	no	Obesity	11	180	33	normal	45	normal	normal	125	50
60	F20.0	24	Young adult	HINDU	MALE	URBAN	3	171	65	22.22906193	no	yes	no	Normal	1	60	50	normal	54	normal	normal	150	50
61	F20.0	31	Young adult	HINDU	FEMALE	RURAL	3	150	59	26.22222222	no	yes	no	Overweight	7	120	52	normal	65	normal	normal	125	50
62	F20.0	32	Young adult	HINDU	FEMALE	RURAL	3	164	66	24.5389649	no	yes	no	Normal	2	180	61	normal	80	normal	normal	125	75
63	F20.0	32	Young adult	HINDU	MALE	RURAL	3	181	78	23.80879705	no	yes	no	Normal	7	180	24	normal	26	normal	normal	175	50
64	F20.0	22	Young adult	HINDU	FEMALE	URBAN	3	144	69	33.27546296	no	yes	no	Obesity	15	120	58	normal	74	normal	normal	150	50
65	F20.0	32	Young adult	HINDU	FEMALE	URBAN	3	164	66	24.5389649	no	yes	no	Normal	4	180	69	normal	103	normal	normal	150	50
66	F20.0	34	Young adult	HINDU	FEMALE	RURAL	3	162	59	22.48132907	no	yes	no	Normal	2	120	46	normal	67	normal	normal	125	50
67	F20.0	34	Young adult	HINDU	FEMALE	URBAN	3	162	59	22.48132907	no	yes	no	Normal	3	120	44	normal	58	normal	normal	125	50
68	F20.0	34	Young adult	HINDU	FEMALE	RURAL	3	162	59	22.48132907	no	yes	no	Normal	4	120	55	normal	60	normal	normal	100	30
69	F20.0	26	Young adult	HINDU	FEMALE	RURAL	3	165	57	20.93663912	no	yes	no	Normal	2	120	34	normal	37	normal	normal	100	30
70	F20.0	31	Young adult	HINDU	MALE	RURAL	3	168	78	27.63605442	yes	yes	no	Overweight	26	129	34	normal	34	normal	normal	125	50
71	F20.0	26	Young adult	HINDU	FEMALE	RURAL	3	165	57	20.93663912	no	yes	no	Normal	3	120	45	normal	51	normal	normal	125	50
72	F20.0	26	Young adult	HINDU	FEMALE	RURAL	3	165	57	20.93663912	no	yes	no	Normal	4	120	42	normal	42	normal	normal	125	50
73	F20.0	35	Young adult	HINDU	MALE	RURAL	3	167	82	29.4022733	no	yes	no	Overweight	1	60	45	normal	62	normal	normal	150	50
74	F20.0	26	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	no	Normal	1	60	37	normal	40	normal	normal	125	50
75	F20.0	35	Young adult	HINDU	MALE	RURAL	3	167	82	29.4022733	no	yes	no	Overweight	2	60	48	normal	55	normal	normal	125	50
76	F20.0	26	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	no	Normal	2	60	42	normal	44	normal	normal	125	50
77	F20.0	35	Young adult	HINDU	MALE	RURAL	3	167	82	29.4022733	no	yes	no	Overweight	3	60	44	normal	52	normal	normal	125	50
78	F20.0	26	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	no	Normal	3	120	35	normal	44	normal	normal	125	50
79	F20.0	26	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	no	Normal	4	120	39	normal	39	normal	normal	125	50
80	F20.0	35	Young adult	HINDU	MALE	RURAL	3	167	82	29.4022733	no	yes	no	Overweight	4	120	45	normal	53	normal	normal	150	50
81	F20.0	38	middle aged adult	HINDU	MALE	RURAL	3	166	64	23.22543185	no	yes	no	Normal	1	120	56	normal	62	normal	normal	125	50
82	F20.0	38	middle aged adult	HINDU	MALE	RURAL	3	166	64	23.22543185	no	yes	no	Normal	2	120	53	normal	56	normal	normal	125	50
83	F20.0	43	middle aged adult	HINDU	MALE	RURAL	3	165	73	26.81359045	yes	yes	no	Overweight	26	180	34	normal	41	normal	normal	125	50
84	F20.0	38	middle aged adult	HINDU	MALE	RURAL	3	166	64	23.22543185	no	yes	no	Normal	2	120	48	normal	52	normal	normal	125	50
85	F20.0	38	Young adult	HINDU	MALE	RURAL	3	166	64	23.22543185	no	yes	no	Normal	4	120	37	normal	42	normal	normal	125	50
86	F20.0	38	middle aged adult	HINDU	MALE	RURAL	3	166	64	23.22543185	no	yes	no	Normal	5	120	38	normal	38	normal	normal	125	50
87	F20.0	25	Young adult	HINDU	MALE	URBAN	3	168	71	25.15589569	no	yes	no	Overweight	1	120	52	normal	58	normal	normal	125	50
88	F20.3	24	Young adult	HINDU	MALE	RURAL	3	174	55	18.16620425	no	yes	no	Underweight	2	120	57	normal	69	normal	normal	125	50
89	F20.3	24	Young adult	HINDU	MALE	RURAL	3	174	55	18.16620425	no	yes	no	Underweight	3	120	29	normal	38	normal	normal	125	75

90	F20.3	48	middle aged adult	HINDU	FEMALE	URBAN	3	162	70	26.6727633	no	yes	no	Overweight	9	120	0	normal	57	normal	normal	100	30
91	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	152	74	32.02908587	yes	yes	no	Obesity	10	120	0	normal	22	normal	normal	125	50
92	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	152	74	32.02908587	yes	yes	no	Obesity	11	120	19	normal	21	normal	normal	125	50
93	F20.3	31	Young adult	HINDU	MALE	RURAL	2	168	68	24.09297052	no	yes	no	Normal	4	120	30	normal	43	normal	normal	150	50
94	F20.3	29	Young adult	HINDU	MALE	URBAN	3	180	103	31.79012346	no	yes	no	Obesity	6	120	50	normal	66	normal	normal	150	50
95	F20.3	35	Young adult	HINDU	FEMALE	RURAL	3	162	59	22.48132907	no	yes	no	Normal	4	180	49	normal	55	normal	normal	125	50
96	F20.3	23	Young adult	HINDU	MALE	RURAL	2	170	57	19.72318339	no	yes	no	Normal	6	240	36	normal	44	normal	normal	150	50
97	F20.3	29	Young adult	HINDU	MALE	URBAN	3	180	103	31.79012346	no	yes	no	Obesity	7	120	58	normal	72	normal	normal	200	75
98	F20.3	36	middle aged adult	HINDU	MALE	URBAN	3	167	73	26.17519452	yes	yes	no	Overweight	1	120	56	normal	68	normal	normal	125	50
99	F20.3	36	middle aged adult	HINDU	MALE	URBAN	3	167	73	26.17519452	yes	yes	no	Overweight	2	120	48	normal	65	normal	normal	125	50
100	F20.3	36	middle aged adult	HINDU	MALE	URBAN	3	167	73	26.17519452	yes	yes	no	Overweight	3	120	46	normal	51	normal	normal	100	30
101	F20.3	36	middle aged adult	HINDU	MALE	URBAN	3	167	73	26.17519452	yes	yes	no	Overweight	4	120	44	normal	44	normal	normal	125	50
102	F20.3	38	middle aged adult	HINDU	FEMALE	RURAL	3	156	54	22.18934911	no	yes	no	Normal	3	120	33	normal	33	normal	normal	125	50
103	F20.3	38	middle aged adult	HINDU	FEMALE	RURAL	3	156	54	22.18934911	no	yes	no	Normal	4	120	35	normal	39	normal	normal	125	50
104	F20.3	38	middle aged adult	HINDU	FEMALE	RURAL	3	156	54	22.18934911	no	yes	no	Normal	5	120	33	normal	35	normal	normal	125	50
105	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	161	59	22.76146754	no	yes	no	Normal	1	60	0	normal	33	normal	normal	125	50
106	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	161	59	22.76146754	no	yes	no	Normal	2	120	35	normal	46	normal	normal	125	50
107	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	161	59	22.76146754	no	yes	no	Normal	3	120	31	normal	31	normal	normal	125	50
108	F20.3	33	Young adult	HINDU	FEMALE	RURAL	3	161	59	22.76146754	no	yes	no	Normal	4	120	36	normal	40	normal	normal	125	50
109	F20.3	33	Young adult	HINDU	MALE	RURAL	3	171	72	24.62296091	no	yes	no	Normal	3	120	56	normal	98	normal	normal	125	50
110	F20.3	32	Young adult	HINDU	FEMALE	URBAN	3	162	68	25.91068435	no	yes	no	Overweight	1	120	42	normal	47	normal	normal	125	50
111	F20.3	32	Young adult	HINDU	FEMALE	URBAN	3	162	68	25.91068435	no	yes	no	Overweight	2	120	37	normal	41	normal	normal	125	50
112	F22.0	33	Young adult	HINDU	MALE	URBAN	1	170	66	22.83737024	no	no	no	Normal	3	120	46	normal	57	normal	normal	125	50
113	F25.0	24	Young adult	HINDU	MALE	URBAN	3	152	48	20.77562327	no	yes	no	Normal	3	120	45	normal	56	normal	normal	175	50
114	F28	31	Young adult	HINDU	MALE	RURAL	4	157	45	18.25631871	no	yes	no	Underweight	3	60	21	normal	22	normal	normal	100	30
115	F28	31	Young adult	HINDU	MALE	RURAL	3	165	66	24.24242424	no	no	no	Normal	1	120	67	normal	70	normal	normal	125	50
116	F28	31	Young adult	HINDU	MALE	RURAL	3	165	66	24.24242424	no	no	no	Normal	2	120	24	normal	39	normal	normal	125	50
117	F28	31	Young adult	HINDU	MALE	RURAL	3	165	66	24.24242424	no	no	no	Normal	3	120	49	normal	53	normal	normal	125	50
118	F30.1	31	Young adult	HINDU	FEMALE	RURAL	4	167	52	18.64534404	no	yes	yes	Normal	1	60	25	normal	25	normal	normal	100	50
119	F30.1	31	Young adult	HINDU	FEMALE	RURAL	4	167	52	18.64534404	no	yes	yes	Normal	2	120	23	normal	28	normal	normal	100	50
120	F30.1	31	Young adult	HINDU	FEMALE	RURAL	4	167	52	18.64534404	no	yes	no	Normal	3	120	0	normal	24	normal	normal	100	50
121	F30.2	19	Young adult	HINDU	MALE	URBAN	3	169	84	29.41073492	no	yes	no	Overweight	6	360	23	normal	27	normal	normal	250	50
122	F30.2	31	Young adult	HINDU	FEMALE	RURAL	4	167	52	18.64534404	no	yes	no	Normal	4	120	26	normal	30	normal	normal	100	50
123	F31.1	29	Young adult	HINDU	FEMALE	URBAN	2	157	63	25.5588462	no	yes	yes	Overweight	1	60	34	normal	43	normal	normal	125	50
124	F31.1	24	Young adult	HINDU	MALE	URBAN	2	169	70	24.50894577	no	yes	no	Normal	6	60	42	normal	52	normal	normal	125	50
125	F31.1	24	Young adult	HINDU	MALE	URBAN	2	169	70	24.50894577	no	yes	no	Normal	7	60	52	normal	55	normal	normal	125	50
126	F31.1	24	Young adult	HINDU	MALE	URBAN	2	169	70	24.50894577	no	yes	no	Normal	8	120	48	normal	60	normal	normal	125	50
127	F31.1	42	middle aged adult	HINDU	MALE	URBAN	3	163	48	18.06616734	no	yes	yes	Underweight	12	120	45	normal	67	normal	normal	125	50

128	F31.1	30	Young adult	HINDU	MALE	RURAL	3	173	65	21.71806609	no	yes	yes	Normal	2	120	38	normal	50	normal	normal	150	50
129	F31.1	19	Young adult	HINDU	MALE	RURAL	3	173	65	21.71806609	no	yes	yes	Normal	3	120	40	normal	46	normal	normal	125	50
130	F31.1	19	Young adult	HINDU	MALE	RURAL	3	173	65	21.71806609	no	yes	yes	Normal	5	120	70	normal	98	normal	normal	100	50
131	F31.1	20	Young adult	HINDU	MALE	RURAL	4	162	63	24.00548697	no	yes	no	Normal	5	180	0	normal	23	normal	normal	125	30
132	F31.1	31	Young adult	HINDU	FEMALE	RURAL	3	161	58	22.37567995	no	yes	yes	Normal	2	120	65	normal	78	normal	normal	125	50
133	f31.1	35	Young adult	HINDU	FEMALE	URBAN	3	163	65	24.4646016	no	yes	yes	Normal	2	120	29	normal	39	normal	normal	125	50
134	F31.1	35	Young adult	HINDU	FEMALE	URBAN	3	163	65	24.4646016	no	yes	yes	Normal	3	180	39	normal	52	normal	normal	125	50
135	F31.1	21	Young adult	HINDU	MALE	RURAL	3	159	62	24.52434635	no	yes	no	Normal	1	60	66	normal	92	normal	normal	125	50
136	F31.1	46	middle aged adult	HINDU	MALE	URBAN	3	166	70	25.40281608	no	yes	yes	Overweight	2	60	77	normal	92	normal	normal	125	50
137	F31.1	46	middle aged adult	HINDU	MALE	URBAN	3	166	70	25.40281608	no	yes	yes	Overweight	4	120	52	normal	64	normal	normal	100	30
138	F31.1	32	Young adult	HINDU	MALE	RURAL	3	172	67	22.64737696	no	yes	yes	Normal	1	60	45	normal	57	normal	normal	125	50
139	F31.1	32	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	yes	Normal	2	60	62	normal	78	normal	normal	125	50
140	F31.1	32	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	yes	Normal	3	120	53	normal	53	normal	normal	125	50
141	F31.1	32	Young adult	HINDU	MALE	URBAN	3	172	67	22.64737696	no	yes	yes	Normal	4	120	46	normal	55	normal	normal	125	50
142	F31.1	32	Young adult	HINDU	MALE	RURAL	3	169	73	25.55932916	no	yes	no	Overweight	1	60	36	normal	40	normal	normal	125	50
143	F31.1	32	Young adult	HINDU	MALE	RURAL	3	169	73	25.55932916	no	yes	no	Overweight	2	60	42	normal	56	normal	normal	125	50
144	F31.1	32	Young adult	HINDU	MALE	RURAL	3	169	73	25.55932916	no	yes	no	Overweight	3	120	34	normal	37	normal	normal	125	50
145	F31.1	32	Young adult	HINDU	MALE	RURAL	3	169	73	25.55932916	no	yes	no	Overweight	4	120	39	normal	41	normal	normal	125	50
146	F31.2	25	Young adult	HINDU	FEMALE	URBAN	1	177	63	20.10916403	no	yes	yes	Normal	6	120	43	normal	58	normal	normal	125	50
147	F31.2	24	Young adult	HINDU	MALE	RURAL	3	145	50	23.78121284	no	yes	no	Normal	4	180	20	normal	42	normal	normal	125	50
148	F31.2	25	Young adult	HINDU	MALE	URBAN	3	167	63	22.58955144	no	yes	no	Normal	3	180	26	normal	32	normal	normal	125	50
149	F31.2	34	Young adult	HINDU	MALE	RURAL	3	159	61	24.12879237	no	yes	no	Normal	6	240	33	normal	36	normal	normal	175	50
150	F31.2	25	Young adult	HINDU	MALE	URBAN	3	167	63	22.58955144	no	yes	yes	Normal	4	240	24	normal	32	normal	normal	150	50
151	F31.2	26	Young adult	HINDU	MALE	RURAL	3	165	53	19.46740129	no	yes	yes	Normal	1	120	40	normal	47	normal	normal	175	50
152	F31.2	27	Young adult	HINDU	MALE	URBAN	3	174	54	17.83590963	no	yes	yes	Underweight	3	120	48	normal	50	normal	normal	175	50
153	F31.2	29	Young adult	HINDU	MALE	RURAL	3	168	72	25.51020408	no	yes	yes	Overweight	1	60	0	normal	78	normal	normal	100	30
154	F31.2	29	Young adult	HINDU	MALE	RURAL	3	168	72	25.51020408	no	yes	yes	Overweight	2	60	56	normal	56	normal	normal	100	30
155	F31.2	29	Young adult	HINDU	MALE	RURAL	3	168	72	25.51020408	no	yes	yes	Overweight	3	120	45	normal	47	normal	normal	125	50
156	F31.2	22	Young adult	HINDU	FEMALE	RURAL	3	159	54	21.35991456	no	yes	yes	Normal	1	60	45	normal	45	normal	normal	100	50
157	F31.2	22	Young adult	HINDU	FEMALE	RURAL	3	159	54	21.35991456	no	yes	yes	Normal	2	60	48	normal	55	normal	normal	100	50
158	F31.2	22	Young adult	HINDU	FEMALE	RURAL	3	159	54	21.35991456	no	yes	yes	Normal	3	60	47	normal	50	normal	normal	100	50
159	F31.2	22	Young adult	HINDU	FEMALE	RURAL	3	159	54	21.35991456	no	yes	yes	Normal	4	60	39	normal	44	normal	normal	125	50
160	F31.2	27	Young adult	HINDU	FEMALE	URBAN	3	164	72	26.76977989	no	yes	no	Overweight	3	120	41	normal	45	normal	normal	125	50
161	F31.2	23	Young adult	HINDU	MALE	URBAN	3	169	68	23.80869017	no	yes	yes	Normal	4	120	43	normal	50	normal	normal	125	50
162	F31.4	26	Young adult	HINDU	FEMALE	RURAL	3	149	35	15.76505563	no	yes	no	Underweight	1	60	39	normal	51	normal	normal	100	50
163	F31.5	27	Young adult	HINDU	FEMALE	URBAN	3	164	72	26.76977989	no	yes	no	Overweight	1	60	45	normal	45	normal	normal	125	50
164	F31.5	27	Young adult	HINDU	FEMALE	URBAN	3	164	72	26.76977989	no	yes	no	Overweight	2	60	49	normal	51	normal	normal	125	50
165	F31.5	27	Young adult	HINDU	FEMALE	URBAN	3	164	72	26.76977989	no	yes	no	Overweight	4	120	35	normal	41	normal	normal	125	50
166	F32.2	38	middle aged adult	HINDU	FEMALE	URBAN	3	167	64	22.94811574	no	yes	no	Normal	10	60	47	normal	62	normal	normal	175	50
167	F32.2	34	Young adult	HINDU	FEMALE	URBAN	3	152	45	19.47714681	no	yes	no	Normal	2	60	34	normal	34	normal	normal	100	50
168	F32.2	48	middle aged	HINDU	FEMALE	URBAN	3	163	68	25.59373706	no	yes	no	Overweight	1	60	53	normal	72	normal	normal	125	50

			adult																				
206	F31.1	40	middle aged adult	MUSLIM	FEMALE	RURAL	4	146	42	19.7035091	no	yes	yes	Normal	4	180	34	normal	36	normal	normal	100	50
207	F31.1	40	middle aged adult	MUSLIM	FEMALE	RURAL	4	146	42	19.7035091	no	yes	yes	Normal	5	180	0	normal	16	normal	normal	100	40
208	F31.1	19	Young adult	MUSLIM	MALE	URBAN	3	173	63	21.0498179	no	yes	yes	Normal	6	120	66	normal	92	normal	normal	125	40
209	F31.2	22	Young adult	MUSLIM	MALE	URBAN	3	173	63	21.0498179	no	yes	yes	Normal	3	60	61	normal	61	normal	normal	175	30
210	F31.2	24	Young adult	MUSLIM	FEMALE	RURAL	3	153	65	27.76709812	no	yes	yes	Overweight	9	240	0	normal	22	normal	normal	150	50
211	f31.2	19	Young adult	MUSLIM	MALE	URBAN	3	173	63	21.0498179	no	yes	yes	Normal	9	180	76	normal	92	normal	normal	150	50
212	F31.4	38	middle aged adult	MUSLIM	MALE	URBAN	3	165	75	27.54820937	no	yes	no	Overweight	6	60	38	normal	43	normal	normal	125	50
213	F20.0	45	middle aged adult	OTHER	FEMALE	RURAL	3	157	64	25.96454217	no	yes	no	Overweight	2	180	36	normal	45	normal	normal	200	75
214	F20.0	45	middle aged adult	OTHER	FEMALE	RURAL	3	157	64	25.96454217	no	yes	no	Overweight	3	120	39	normal	43	normal	normal	175	50
215	F20.0	45	middle aged adult	OTHER	FEMALE	RURAL	3	157	64	25.96454217	no	yes	no	Overweight	6	120	43	normal	52	normal	normal	175	50
216	F32.2	44	middle aged adult	OTHER	FEMALE	URBAN	2	165	60	22.03856749	no	no	no	Normal	4	120	49	normal	51	normal	normal	175	50