"COMPARATIVE STUDY OF CLINICAL EFFICACY AND SAFETY OF GABAPENTIN VS TRIHEXYPHENIDYL IN TREATING DYSTONIA IN CHILDREN WITH DYSKINETIC AND MIXED CEREBRAL PALSY: AN OPEN LABEL RANDOMIZED CONTROLLED TRIAL AT A TERTIARY HEALTH CARE CENTRE."

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This is to certify that the dissertation entitled **"Comparative Study Of Clinical Efficacy And Safety Of Gabapentin Vs Trihexyphenidyl In Treating Dystonia In Children With Dyskinetic And Mixed Cerebral Palsy: An Open Label Randomized Controlled Trial At A Tertiary Health Care Centre"** is a bonafide research work done by **(REG No. BM0119009)** in partial fulfillment of the requirement for the degree of M.D. Pediatrics.

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LIST OF ABBREVIATIONS USED

CP	Cerebral palsy
WHO	World Health Organisation
GABA	Gamma Amino Butyric Acid
CNS	Central Nervous System
GMFCS E and R	Gross Motor Function Classification System ,Expanded and Revised
MACS	Manual Ability Classification System
CFCS	Communicating Function Classification System
MACS	Manual Ability Classification System
MRI	Magnetic Resonance Sonography
EEG	Electroencephalogram
GMFM	Gross Motor Function Measures
QUEST	Quality of Upper Extremity Skill Test
BADS	Barry Albright Dystonia Scale?,m
LAQ-CP	Lifestyle assessment questionnaire Cerebral palsy
IAP	Indian Academy of Paediatrics
QOL	Quality Of Life
CFCS	Communicating function classification system
PedsQL	Paediatric Quality of Life Inventory
EDACS	Eating and Drinking Ability Classification System
PT and OT	Physiotherapy and Occupational Therapy
CIMT	Constraint Induced Movement Therapy
SDR	Selective Dorsal Rhizotomy

AFO	Ankle Foot Orthoses
CDC	Child Developmental Clinic
NICU	Neonatal Intensive Care Unit
PROM	Premature Rupture of Membrane
HAT	Hypertonia Assessment Tool
DQ/IQ	Developmental Quotient/ Intelligent Quotient
SCPE	Surveillance for Cerebral Palsy in Europe
LBW	Low Birth Weight
SGA	Small for Gestational Age
VFCS	Visual function classification system
ICF	International Classification of Functioning Disability and Health
CMV	Cytomegalovirus
GERD	Gastroesophageal Reflux disease
CT	Computed Tomography
MR	Mental Retardation
PEDI	Pediatric Evaluation of Disability Inventory.
GPi	Globus Pallidus Interna
MSNs	Median Spiny Neurons
FTT	Failure to thrive
ANC	Antenatal Care
NNH	Neonatal Hyperbilirubinemia
DSAP	Dystonia Severity Assessment Plan
LSCS	Lower Segment Cesarian Section

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INTRODUCTION:-

Disabled children are of great concern to a family, society as well as to the nation. When disability is discussed, particularly in children, about one fourth of chronic childhood problems are neurological in origin. Cerebral palsy (CP) is the leading cause of chronic disability in children[1] .

Overall prevalence of CP globally stands at 1-4 per thousand live births i.e 1 in every 323 children. According to meta analysis by Chauhan A, et al, done in the year 2019 the pooled prevalence of cerebral palsy in India which included data from rural, urban and mixed rural urban is 2.95 per 1000 children. This study screened prospective/ retrospective, cross sectional, and cohort studies of children with cerebral palsy.[2]

Initially cerebral palsy was attributed to birth asphyxia but there are wide varieties of causative factors for cerebral palsy, ranging from intrauterine life till age group of 3-5 years for example intrauterine TORCH infections, birth injuries, severe neonatal jaundice, inflammation of brain meninges and parenchyma I.e meningitis and encephalitis respectively during early childhood.[3] Insult to the cerebral cortex, cerebellum, and other key areas of the brain is the primary causal factor. These insults affect the developing brain and occur during the antenatal, perinatal, or postnatal periods up to 3-5 years of age, resulting in movement and posture disorders, as well as sensory disturbances, depth perception, and other vision-related issues, speech problems, and intellectual disability.[4]

Dyskinetic cerebral palsy, either alone or in combination with spasticity, is the most prevalent physiological kind of cerebral palsy in India. It is caused by birth asphyxia, hyperbilirubinemia, hypoglycemia, and infections, and its care differs from that of other

types of cerebral palsy.[5] In developed countries, however, spastic cerebral palsy is the most frequent kind that is caused mostly by factors such as prematurity. Data on spasticity management is abundantly available whereas the data on treatment of dyskinetic CP is very limited.

Oral medications are often used to address dystonia in children with CP as a first-line medical treatment.[4] Many drugs like baclofen, Trihexyphenidyl, carbidopa-Levodopa, benzodiazepines have been used to treat dystonia in children. Botulinum toxin injections into the muscles are a well known therapy for focal dystonia, torticollis, single limb dystonia and blepharospasm. However it is not an option in generalized dystonia like dystonia cerebral palsy. However most of these drugs are not very effective and are associated with many side effects in the form of sedation, drooling, constipation, vomiting etc which leads to discontinuation of treatment. Hence, there is need for newer treatment options for management of dystonic cerebral palsy.

Amongst the drugs available for management of Dystonic cerebral palsy Trihexyphenidyl has been commonly used. Trihexyphenidyl is an anticholinergic agent which acts as competitive inhibitor of acetylcholine action by blocking acetylchoiline muscarinic receptors and has been in use for the treatment of extrapyramidal disorders in children since very long. Poor tolerance and side effects are common such as agitation, constipation, dry mouth and poor sleep, confusion, dizziness, urinary retention and constipation. So we need other effective and potent drugs which are used more commonly.[6]

Gabapentin has been recently found to be of use in the management of dyskinetic cerebral palsy. It can provide significant relief of childhood dystonic by relieving pain due to dystonia, disturbed or poor sleep, distress and lack of contentedness. It also helps the children with severe dystonia who don't show any improvement with the help of conventional management by improving their activity and participation.[7] However, there are no well conducted prospective comparative trials on Gabapentin.

Hence, we conducted a study to determine the clinical efficacy and safety profile of gabapentin in treatment of dyskinetic cerebral palsy and compare it with one of the most commonly used drug I.e trihexyphenidyl in an open label randomized control trial at our centre.

OBJECTIVES

PRIMARY OBJECTIVE:

-To study and compare the clinical efficacy of trihexyphenidyl and gabapentin in the treatment of dyskinetic CP.

SECONDARY OBJECTIVE:

-To study the safety profile and cost effectiveness of trihexyphenidyl and gabapentin in the treatment of dyskinetic CP.

REVIEW OF LITERATURE

HISTORY:-

Cerebral means "of, or pertaining to, the cerebrum or the brain" and palsy means "paralysis generally partial, where by a local body area is incapable of voluntary movement"

The ancient Indian physician Susrutha, in his compendium wrote about ''*ritu* (time of conception), *kshetra* (uterus), *ambu* (amniotic fluid) and *beeja (* sperm and ovum) as the causes leading to Cerebral palsy.''[3] Another ancient text (Indian), Charakas Samhita, mentions about ''*Garbho paghata karabhava* which means factors associated with fetal development, *Garbhini Paricharya,* the do's and dont's of pregnancy, as some of the causes for deformities in an infant, there by shedding light on the understanding of these diseases by our fore fathers''.

William John Little (1810-1894), the inventor of orthopaedics surgery in England, was the first person to devote his life to cerebral palsy.

He conducted multiple lectures on neurologic "Deformity of the Human Frame" in children between 1843 and 1844, which were published in the Lancet.

"...in many cases, the spasmodic affection is formed at the time of birth or within a few hours or days following that event," he said in this lecture series.

He invented the phrase "Little's disease" to describe spastic diplegia, which he linked to prematurity and birth asphyxia.

A German orthopaedics physician, Jacob von Heine (1799-1879), suggested that symmetrical paralysis of the lower extremities was caused by brain disease rather than spinal disease in the second edition of his "Spinale Kinderlahmung".

"The Cerebral Palsies of Children," by William Osler (1849-1919), was published as a book monograph . He was the second person to contribute to CP after Little, and he drew attention to the link between difficulties during birth, hypoxia, extended resuscitation, and seizures.

Segmund Freud authored a number of works named "Cerebral Palsy" between 1891 and 1897. He was the third significant figure in recent memory to make a historical contribution to CP.

He also gave his contribution in describing the various syndromes of movement disorders in children.

Winthrop Phelps was the first doctor to treat patients with cerebral palsy and establish a therapy regimen that was largely concerned with the peripheral muscular skeletal system in his study titled "the management of cerebral palsy." According to his classification method, the five basic kinds of CP are spasticity, athetosis, rigidity, tremor, and incoordination.[9]

In 1947, Strauss and Lehtinen observed behavioral and emotional issues in cerebral palsy children.[10]

In 1953, Virginia Apgar devised a scoring system that required obstetricians to assess the condition of newborns at delivery and determine whether therapy was required; this score was the first to codify the "language of asphyxia."

Andreas Peto, a physician and neuropsychologist who lived from 1893 to 1967, is known as the "Father of Conductive Education." Rather than being a therapeutic strategy, this is an educational system based on cortical conscious guided movement, language, and function.[11]

DEFINITION:-

Cerebral Palsy has been defined by various working groups and eminent minds in order to understand it in a better way and for better outreach.

CP is a ‘’collective term used to describe the disorder affecting the posture, movement and balance’’.

Mac Keith and Polani of Little Club in 1959 defined cerebral palsy as "A persistent but not irreversible irregularity of movement and posture that occurs in the early years of life and is caused by a non-progressive malfunction of the brain as a result of interference during its development."[12]

Bax and his colleagues provided a widely accepted definition of CP in 1964, describing it as "a disorder of movement and posture connected to a defect or lesion of the adolescent brain."[13]

In the initial half of 1990, after knowing the concepts of the pathology in early brain damage and complexities of disorders under CP, Mutch and colleagues laid the emphasis on motor involvement and non progressive nature of disorder as annotated previously by modifying the definition as "an umbrella name for a set of non-progressive, but frequently fluctuating, motor dysfunction syndromes caused by brain injuries or anomalies in the early stages of development"[14]

An global Workshop was held in year 2004 for the purpose of definition and classification system of cerebral palsy and for understanding newer concepts of developmental neurobiology, functional status of these children, participation and the realisation of association of other development and behavioral disorders with cerebral palsy.

In a 2006 paper, they released the following definition: " "Cerebral palsy is a term that refers to a series of permanent movement and postural issues that limit one's activities and are caused by non-progressive abnormalities in the developing foetal or baby brain. Sensory, perceptual, cognition, communication, and behaviour difficulties are common in cerebral palsy, as are epilepsy and secondary musculoskeletal disorders."

This definition helped in enlightening the idea of a comprehensive multi disciplinary approach to treat Cerebral palsy.[15]

EPIDEMIOLOGY:-

According to an estimate by WHO, the worldwide prevalence of disability stands at 15% with those individuals suffering from some or the other form of disability.[16]

In India the population suffering from disabilities is 3.8%.[17] And amongst these cerebral palsy is the commonest disabling illness of the childhood. The prevalence of CP is 2-3 for every 1000 live births worldwide.[16] The frequentness of cerebral palsy on the whole has not changed over the years despite the advancement in the perinatal medicine and this is due to rising abidance of preterm babies.[18] The prevalence in developed countries is 2.11 per 1000 live births, and 2 to 2.8 in middle and low income countries.[19,20] The incidence and prevalence of cerebral palsy varies across countries on the basis on the basis of prenatal, intranatal and postnatal medical facilities available and the total estimated individuals affected worldwide stands at 17 million.[21]

Though well conditioned data is lacking from India , however the prevalence is calculated at somewhere near 3 per 1000 live births and there are roughly about 24 lakh individuals living with CP as per the recent data.[22]

RISK FACTORS:

Birth asphyxia has always been perceived as a most important reason of cerebral palsy. But against this common belief, studies have found out perinatal asphyxia to be causative factor for only 10% of CP cases.[23] Various post natal events such as stroke, infections, hypoglycemia and trauma, which were recently thought to be the etiology of cerebral palsy, accounted for 10% of the cases.[18] The majority I.e, in around 80% of the causes of cerebral palsy are believed to be due to intrauterine events, such as prematurity, chorioamnionitis, genetic factor etc.

The causative/ Risk factors for CP.[24-29]

1. Prenatal causes(80%)- premature birth, low birth weight, intrauterine growth retardation, multiple gestation, intracranial hemorrhage, white matter injury, periventricular leucomalacia, genetic defects like L1S1 mutation, GPR56 gene(polymicrogyria), COL4A1 genetic mutations.
2. Perinatal causes(10%)- perinatal asphyxia, maternal infections, stroke, neonatal hyperbilirubinemia, hypoglycemia, Dys-electrolytemia and septicemia.
3. Postnatal causes(10%)- meningitis, stroke, head trauma, Hypoxic events.

Disturbance in the developing foetal brain before 20 weeks period of gestation, due to factors such as infections in mother or recently identified genetic defects which lead to

brain malformations by abnormalities of neuronal migration , lead to severe phenotype of CP causing spasticity and dystonia.[24,29]

Disturbance in the developing foetal brain between 24-32 weeks periods of gestation, lead to injury of periventricular white matter due to its vulnerable blood supply. This leads to characteristic spastic diplegic presentation owing to the representation of legs on the homunculus on periventricular cortex. Prematurity and LBW have been attributed as one of major causes of cerebral palsy, where the prevalence is as high as 40 to 100 for every 1000 live births and the risk is 70 times higher if the weight at time of birth is less than 1.5kgs.[30,31,16]

Intra partum insult to the brain commonly affects the highly metabolic active areas such as basal ganglia due to the vigorous vascular development which usually leads to dyskinetic type of CP. But if the damage is extensive , can also present as spastic and dyskinetic variant.[16]

Stroke usually present with unilateral involvement of the body as middle cerebral artery territory is usually involved and arms being affected more than legs.[32]

CLASSIFICATION OF CEREBRAL PALSY:-

I. QUALITY OF MOTOR IMPAIRMENT: The classification method outlined in the reference and training handbook for Cerebral Palsy Surveillance in Europe has incorporated this (SCPE).[33]

1. Pyramidal- Spastic cerebral palsy (most common).
2. Extra pyramidal- Dyskinetic or mixed cerebral palsy.

Dyskinetic cerebral palsy can either be choreoathetoid or dystonic cerebral palsy. **Hypertonia assesement tool (HAT)** is used to distinguish between different types of

hypertonia and can differentiate pure dystonia, spasticity or mixed type of cerebral palsies. Validated for children ages four to nineteen, this is a seven-item clinical assessment test. In this set, there are two spasticity items, two rigidity items, and three dystonia items. Each of the seven items is given a score indicating whether it is present or not. If one of the sub-items is marked as present, hypertonia is present. If the child scores present on two or more sub-items from distinct categories, the youngster exhibits mixed hypertonia. Overall, this tool was found to be more effective at detecting spasticity and dystonia than it was at detecting their absence. As a result, it can be used to evaluate the presence or absence of dystonia, spasticity, and rigidity in both clinical and research contexts.

II. TOPOGRAPHICAL CLASSIFICATION:

1. **Spastic hemiplegia**(20-30%)-Spasticity predominantly involving hemi body, including arm and a leg.
2. **Spastic diplegia**(30-40%)-Spasticity predominantly involving bilateral lower limbs than upper limbs and sometimes only lower limb is involved.
3. **Spastic quadriplegia**(10-15%)- all four limbs and trunk are involved and this is due to more severe peri-ventricular leukomalacia and thus larger area of white matter is affected.
4. **Dyskinetic cerebral palsy**- presence of extrapyramidal signs in form of abnormal movements(athetoid, choreoathetoid and dystonic), hyper tonicity is usually present.
5. **Monoplegia**- Rare , involvement in only 1 limb and here the other causes of monoplegia should be ruled out other than cerebral palsy.
6. **Double hemiplegia**-upper limbs are predominantly involved than lower limbs.

III. FUNCTIONAL CLASSIFICATION:[23,34,35]

1. GMFCS- Its the most common classification system for overall function. The GMFCS levels tells about the CP child's daily activities and amount of social participation. GMFCS levels at a specific period can predict the child's future functional alterations. It aids in decision-making and parental counselling on whether children with CP can maintain their current level of competence or need to be reclassified at different times.[23,35] It investigates actions such as sitting, walking, and using mobility aids. It's useful because it gives you: a) a clear picture of the child's current motor function; and b) an idea of what equipment or mobility aids the youngster might need in the future, such as crutches, walking frames, or wheelchairs.

2.MACS /manual ability classification system- In 2006, Eliasson et al. created the Manual Ability Classification System, a scale for assessing upper extremity function. For children aged four to eighteen, this is a five-point ordinal classification system.[23,35]

3.CFCS (communicating function classification system)- According to WHO's International Classification of Functioning Disability and Health (ICF), the gross motor function classification system and the manual ability classification system are used to classify mobility and handling items, respectively. However, 31-88 percent of CP patients have communication challenges, and a Norwegian research found that 19 percent of CP patients had no speech. Addressing this at the treatment level is critical, which is why the CFCS was created to evaluate overall communication progress. It is divided into five tiers based on communication effectiveness.[23,35]

4.EDACS(eating and drinking ability classification system)- The EDACS assesses eating and drinking safety (aspiration and choking) as well as efficiency (amount of food lost and time taken to eat). The EDACS also adds an additional three point ordinal scale that addresses the amount of assistance a person needs:independent; requires assistance; or dependent for eating and drinking.

5.VFCS(visual function classification system)- This is a valid and reliable system. It classifies visual abilities of children with cerebral palsy in clinical and research settings. It is 5 level classification system that describes usually daily performance of a child with cerebral palsy rather than his or her best capacity.

CLINICAL FEATURES: Each child must be assessed individually, with treatment and management strategies devised. Certain properties of various types of CP, on the other hand, should be kept in mind. These will aid in determining therapy goals, prognosis, and priorities.[36]

Clinical features of CP change throughout life, and the exact CP syndrome may not be recognized until the age of 3-5 years, however suggestive signs and symptoms may appear sooner. Early recognition of symptoms of cerebral palsy is necessary to intervene at the earliest with intervention, thereby improving the child's activity and participation. Early predictors of CP in an infant usually include:[25]

-Delayed motor milestones: probably the most important symptoms of CP. Children usually present with delayed motor milestones.

-Tone and posture: can present with either of Hypotonia, hypertonia or normal tone. Lack of head control, floppiness, hand fisting, oro motor pattern. Abnormalities like tongue

thrusting and grimacing, early hand preference(before 15 months), commando crawl, apparent early head control in some cases due to increased axial muscle tone.

- Abnormal reflexes: exaggerated neonatal reflexes or delay in their disappearance.
- Abnormal neurobehavioral signs: such as irritability, lethargy , difficulty in handling, excessive or reduced sleep.

There are 3 predominant types of CP syndromes-Spastic cerebral palsy/Dyskinetic cerebral palsy/Ataxic cerebral palsy.

Dyskinetic cerebral palsy as mentioned earlier can be sub classified into **Choreo-athetoid** and **Dystonic cerebral palsies** and they present mainly with hypotonia at rest, with variable tone while movements or emotion, reduced spontaneous movements, head persistently turned to one side, drooling, involuntary grimace, characteristic involuntary movements, dysarthria, intellectual disability, dystonia and striatal toe.

COMORBIDITIES:-[36,37]

1. **Seizur**es: Seizures affect over 30% of people with cerebral palsy, and they are a substantial cause of morbidity. Seizures are most commonly seen in spastic quadriplegics and hemiplegics.

2. Cognition/Learning disabilities: Seen in almost half of individuals with CP.The likelihood of accompanying cognitive or learning issues varies depending on the kind of CP; nevertheless, quadriplegic CP patients have the highest risk, whereas hemiplegic CP patients have the lowest.

3. Speech: In dyskinetic CP, aphasia, dysarthria, and dyslalia are more prevalent.

4. Vision: present in 30% of patients with CP. Commonly in combination with prematurity. Retinopathy of prematurity, Amblyopia, Refractive errors, strabismus and Myopia are common causes. Congenital CMV, toxoplasmosis, or rubella may have caused a cataract, colobomas, or retinal lesions, including pigmentary retinopathy, as a result of the CP.

5. **Hearing:** Seen in 30-40% of instances, and can range from fluctuating loss associated with secretory otitis media to sensorineural loss or a combination of both. Hearing loss is more likely in preterm babies who have had an intrauterine CMV infection or have been on an extracorporeal membrane oxygenator.

6. Gastrointestinal: 90% of children with CP are affected with GI problems. Feeding problems, GERD, constipation(80% cases), incontinence and bulbar palsy causes swallowing problem. Its mostly seen in children with severe physical disability and it ultimately leads to malnutrition and growth failure.

7. Spasticity and dystonia are two examples of **abnormal tone.**

8. **Nutrition and growth:** Compared to peers, you're more likely to be underweight and short. Some people may be obese.

9. **Urinary problems:** Voiding problems, such as enuresis, increased frequency, dribbling urine, urinary tract infections and so on, can affect up to 60% of children with CP.

10. Sleep disturbance: Its a Common problem seen in children with CP.

DIAGNOSIS:[38,39]

Since William Little's first description of cases of CP in the 1800s, there has been a lot of debate over getting a diagnosis as soon as possible in order to "encourage beneficial treatment of the illnesses when detected in the early stages." Following this many developments have taken place in order to get early diagnosis and early intervention.

Diagnostic assessment of cerebral palsy:

1. **Neuroimaging:** It is not a must for diagnosis of cerebral palsy. But in many cases it suggests aetiology of cerebral palsy and helps to rule out cerebral palsy mimics in cases where the aetiology is not very clear.

-Computed tomography: According to research, the likelihood of discovering an abnormal CT scan in a kid with CP is considerable and is connected to the kind of CP. In many youngsters, scan anomalies may reveal an aetiology, but there was insufficient evidence to investigate further. Scan abnormalities may occasionally uncover curable illnesses and may indicate a greater risk of related conditions including mental retardation and epilepsy.

-**Magnetic Resonance Imaging(MRI):** According to research, the yield of discovering an abnormal MRI scan in a child with CP is quite high (approximately 89 %) and higher than the yield recorded utilizing CT scans (77 percent). In cases of CP associated with preterm, In comparison to infants delivered at term, MRI is more likely to be abnormal, revealing abnormalities such as periventricular leukomalacia.

2. **Mental retardation**, **Ophthalmic impairments, Speech and language disorder, Hearing impairment:** Children with CP are more likely to have related conditions such as mental retardation (52%), ocular defects (38%), hearing defect (12%), speech and language dysfunction (38%), and other oral-motor deficiencies. Children with CP should be tested for MR, ophthalmic and hearing abnormalities, and speech and language difficulties due to the high prevalence of related conditions. Swallowing dysfunction should be monitored in terms of nutrition, growth, and other factors.

MANAGEMENT OF CEREBRAL PALSY:

CP has long been perceived as an untreatable disease. Though not curable, the symptoms and co-morbidities can be mitigated there by improving the quality of life of these children. Managing a case of cerebral palsy is a huge task to a pediatrician as it involves not only treating the child, but also alleviates the undue stress borne by the families and caregivers. Also, the wide spectrum of symptoms and co-morbidities associated with CP, mandate a multi-disciplinary approach in its management.[40]

The goal of any intervention should be to modify the course of disease. Novak et al, in their exhaustive review , opined that among 64 intervention techniques, 24% were effective, 70% were still uncertain regarding the outcomes and 6% were ineffective. Physical therapy , occupational therapy and medicines were the most effective of the interventions. Psychology, speech therapy, social work and education etc had a low quality of evidence for effectiveness. Though most these interventions focused at the level of body functions and activity but not participation of the above mentioned WHO classification of functioning, disability and health , lack of evidence in this context doesn't mean they offer no benefit. But it should also be borne in mind that it is ultimately both activity and participation that impact the quality of life of these patients.[41]

To summarize, the interventions used should affect the following: to correct tone and posture, improve mobility, focus on mitigating co-morbidities, to improve care given to the patients, improve life's quality, provide comfort to the patient and caregivers, make the patient as self-sufficient as possible.

The factors to be considered before initiating the treatment are: Patients' and families' goals and expectations, not simply clinicians, the age of the patients, financial status, willingness for regular followup and compliance.

A multidisciplinary team is needed to handle a CP child's medical, psychological, educational, and therapeutic goals. The goal of management should be to promote the child's development and achieve maximal independence in daily activities.[25]

Functional evaluation: The treatment plan is determined by the patient's functional limitations.

i)Gross motor function classification system(GMFCS)-The most extensively used functional classification system is the Gross Motor Function Categorization System (GMFCS). This method is used to classify a patient's motor function based on his age and performance in various situations. The title for each level is the method of mobility that is most characteristic of performance after 6 years of age. The scale is ordinal.

ii)The Manual Ability Classification System (MACS) is the upper extremity analogue of the GMFCS and its a simple, five point ordinal classification system and designed for use in children aged 4-18 years. Mini MACS is designed for 1-4 years of age. This system classify a child's typical use of both hands and upper limbs; and its not meant to reflect best use or individual hand function. Here we offer age appropriate objects such as eating, dressing, playing, drawing or writing.

iii)Communication Function Classification System (CFCS)- This is a 5 point classification system, and designed to be analogous and complementary to the GMFCS and MACS. It assesses both how information is expressed and how it is received. It allows all methods of communication(eg. Vocalizations, manual signs, eye gaze, pictures, communication boards, speech generating devices).

iv)Eating and drinking ability classification system(EDACS)- It assesses eating and drinking safety (aspiration and choking) as well as efficiency (amount of food lost and time taken to eat). it also adds an additional three point ordinal scale that addresses the amount of assistance a person needs: independent; requires assistance; or dependent for eating and drinking.

Tone evaluation: Tone testing is crucial for determining the strength of specific muscle groups before and after a treatment with botulinum toxin or baclofen. Two of the most commonly used scales are the Modified Ashworth Scale (which assesses resistance to passive range of motion) and the Modified Tardieu Scale (which assesses resistance to active range of motion) (defines the spasticity angle, and quality of movement at multiple velocities).

I.Management of Motor Impairment:

-Physiotherapy:[42] It has been shown to improve muscle strength, local muscular endurance, and joint range of motion in children with CP[43,44]. Physiotherapy exercises, such as passive moderate range of motion exercises and stretches across main joints, can help prevent or minimize joint contractures. Muscular strength is increased with regular, increasingly increasing resistance exercises involving all major muscle groups. Muscle endurance is improved through low-resistance, high-repetition exercises of key muscle

groups. Balance, postural control, gait, mobility, and transfers are all improved with specific physiotherapy exercises.[43,44,45,46,47]

The following are some of the **Physiotherapy** based techniques that have been recommended in the literature:[25]

-Bimanual training, Constraint induced movement therapy, context-oriented treatment, Goal directed functional training, Treadmill training[43,45,48-53,] Occupational therapy,[53] Orthotics, adaptive equipment and assistive technology[54-60]

II.Other interventions: In the treatment of CP, a variety of various specialized therapies or intervention techniques have been tried.Some of these procedures or methods include acupuncture, neuro developmental training, sensory integration, electrical stimulation, suit treatment, hippo-therapy, music therapy, video game therapy, and stem cell therapy. [61-76]

1. Feeding and nutrition:[25]Feeding issues and oro-motor dysfunction are common in children with CP due to dyskinesia, bulbar palsy, and/or pseudobulbar palsy. Longer feeding times, choking, and frequent vomiting are all symptoms of these children's sucking/chewing and swallowing difficulties42. As a result, these children should have their feeding abilities and nutritional status assessed every three to four months. For infants with growth failure and/or persistent aspiration, other feeding options (including gastrostomy feeding) should be examined. Dietary modification, change in food consistency, antacids etc may help in gastro esophageal reflux disease. Fundoplication for severe GERD may be done. However no specific evidence is available with regard to CP children.[82]

2.Drooling: Oromotor dysfunction in children with CP frequently results in drooling, which is a major social barrier.[78] Pharmacotherapy, behaviour treatment, and surgery are

among options for treating drooling. For youngsters who can grasp commands and participate with training, a trial of behavioral treatment is appropriate. Positive reinforcement is utilized to promote lip and jaw closure, tongue movements, and swallowing via oral awareness and oral motor skills training. Anticholinergic medications (trihexyphenidyl or glycopyrrolate; reduces saliva flow) and Botox-A injections into the salivary gland are used to treat drooling.Repositioning of the sub mandibular gland duct, single side occlusion of the parotid duct, and possibly removal of the sublingual gland are all surgical options.[89] **The Drooling Scale of the Teacher**: This is a simple grading system for drooling at the bedside. It is graded on a scale of one to five, with the intensity of drooling increasing as we proceed up the scale. Drooling is divided into five categories: no drooling, rarely drooling, occasional drooling, frequent drooling, and persistent drooling.

3.Social support: Social and psychological support are essential for every family with a kid who has a persistent medical ailment. All of the parent's questions, such as "How did this happen?" and "Why did this happen to my child?" should be answered by the doctor. Parents of children with CP may endure chronic grief, as well as shame, frustration, denial, animosity, and embarrassment.[80]

4.Epilepsy management: Being the most common co-morbidity of CP children, epilepsy management should be prioritized. Many times seizure are under recognized due to their partial/focal nature.[81]

5.Pain management: pain is almost always associated with vast majority of CP patients. Pain affects motor abilities and reduces sleep time there by affecting the quality of life of CP children. It’s always important to communicate with the children who have good cognition or the parents regarding pain as it can be mitigated[82-84]

6.Speech and language difficulties: Many children with CP have been development delay. So speech and language delay are common in them. They are one of the contributors for poor Quality of Life.[85]

7.Bowel and bladder dysfunction: Constipation is an issue caused by aberrant primary tone, poor food habits, and immobility. Adequate tone management , excessive water and fibre diet are used to treat. Laxatives and suppositories may be given.

Bladder dysfunction leading to incontinence may be treated with bio feedback mechanism, drugs and occasional surgery.[86,87]

8.Quality of life in cerebral palsy: any intervention in cerebral palsy should be assessed by assessing quality of life as quality of life in particular is one of the most important methods of quantification of the impact of these interventions as ultimately it is the improvement in quality of life is what both the patients and care givers strive for.[88] There are various scales to measure the quality of life in cerebral palsy such as-Pediatric Evaluation of Disability Inventory(PEDI)[89], Pediatric Quality of life inventory (PedsQL)[90], TNO-AZL Children's Health-Related Quality of Life(TACQOL) scale[91], The care giver priorities and child health index of life with disabilities[92] , the life style assessment Questionnaire-CP(LAQCP)[93]. Among the various questionnaire's available for QoL assessment the LAQ-CP was validated for Indian population in Delhi.[104,105]

DYSTONIC CEREBRAL PALSY MANAGEMENT: Dystonia, according to the Dystonia Foundation, is defined as "A movement disease characterized by involuntary persistent or intermittent muscle contractions that result in twisting and repetitive movements, aberrant postures, or both".[4] Dystonia affects up to 15% of patients with CP, according to published studies. However, in the recent study by Kamate et al, either as predominant form or in mixed form dyskinetic CP is seen in almost 2/3rds of cases of

cerebral palsy. The three basic treatments for dystonia are pharmacological therapy, botulinum toxin injections, and surgical approaches.

Pathophysiology of Dystonia:-

-Injuries or anomalies to the basal ganglia and cortical relay system.

-Disruption of basal ganglia circuits and the globus pallidus interna causes abnormal activity in the primary and supplemental motor cortex (GPi).

Medical management:-[96] Neurotransmitter systems are crucial for dystonia medical treatment: Cholinergic,GABAergic, and dopaminergic systems are the three main neurotransmitter systems involved.

Anticholinergics, baclofen, benzodiazepines, and dopamine-related medicines are the most regularly prescribed pharmaceuticals.

A. **Cholinergic system:** Giant spiny inter neurons or The medium spiny neurons in the striatum receive acetylcholine from A.cholinergic inter neurons, which are an intrinsic source, whereas the pedunculopontine nucleus neurons are an extrinsic one. Because of their unique attribute of independent firing without synaptic activity, they are also known as tonically active neurons.[97] The improvement of dystonia with anticholinergics could be explained by hyperactivity of the cholinergic inter neurons.[98] In the treatment of dystonia, anticholinergics such as trihexyphenidyl, benztropine, ethopropazine, procyclidine, and biperiden have been utilized.[107-111]The most widely used medicine is trihexyphenidyl. High dosage trihexyphenidyl for dystonia was introduced by Fahn (1983)[97]. Treating patients within the first 5 years of disease onset was statistically significantly more successful than delaying treatment in both children and adults regardless of severity(Greene et al.,1988)[97]. Thus, starting treatment early is important. This therapy is

generally well tolerated when the dose is increased slowly.[97] Anticholinergics, in general, work as antagonists at the postsynaptic level. These show lot of side effects/adverse effects in the form of dry mouth, blurring of vision, urinary retention, reduced gut motility, cognitive and behaviour changes etc.

B. GABAergic system: In the brain and spinal cord, GABA is an inhibitory neurotransmitter. GABA is widely distributed in neurons that serve the basal ganglia circuitry, in addition to (medium spiny neurons) MSNs. The relevance of GABA in the pathogenesis of dystonia is unknown. In primary dystonia, aberrant GABAA receptor binding was found in motor cortices, likely resulting to sensorimotor dis inhibition, according to one report. In another study, there was no difference in focal dystonia. The GABAergic system is predominantly affected by benzodiazepines. After binding to GABAA receptors, they enhance the frequency of chloride channel opening, which promotes inhibitory signals.

-Dopaminergic system: Pre synaptic dopamine depletors like tetrabenazine and post synaptic dopamine blocking medicines like clozapine, quetiapine, and typical neuroleptics are examples of medications that influence the dopaminergic system**.** Possible side effects observed are sedation, Parkinsonism and tardive dyskinesia.

-Gabapentin: It's a GABA analogue that's neither an agonist nor an antagonist of GABA. By preventing thrombospondin's binding to voltage-gated calcium channels, it prevents the formation of glutaminergic excitatory synapses. Gabapentin can help children with dystonia by reducing discomfort, poor sleep, sadness, and a lack of contentment. It can also help children with severe dystonia who aren't responding to traditional treatment increase their activity and participation. When compared to pain alone, a higher but safe dosage is necessary for dystonia. There are not many studies on the use of gabapentin for

managing dystonia in individual with cerebral palsy. A recent retrospective observational study analysed the use of gabapentin for severe dystonia as measured by the Dystonia Severity Assessment Plan in 69 children out of whom 25 had cerebral palsy.[7] There was significant decrease in the severity of dystonia and significant improvement were seen in sleep quality, sleep amount, mood and agreeableness, pain, general muscle tone, involuntary muscle contractions and seating tolerance(*$p<0.01$ in all areas).* however since less than 50% of participants had cerebral palsy the study was not significant enough.[100]

Another study by Lumsden De, Crowe B Basu A, et al. epub ahead of print: 2018-316309. the most commonly used medications for dystonia in cerebral palsy were baclofen(39.3%), trihexyphenidyl(20.4%), and gabapentin(18.5%). However according to this study trihexyphenidyl, gabapentin and clonidine were infrequently used when dystonia was not present.[101]

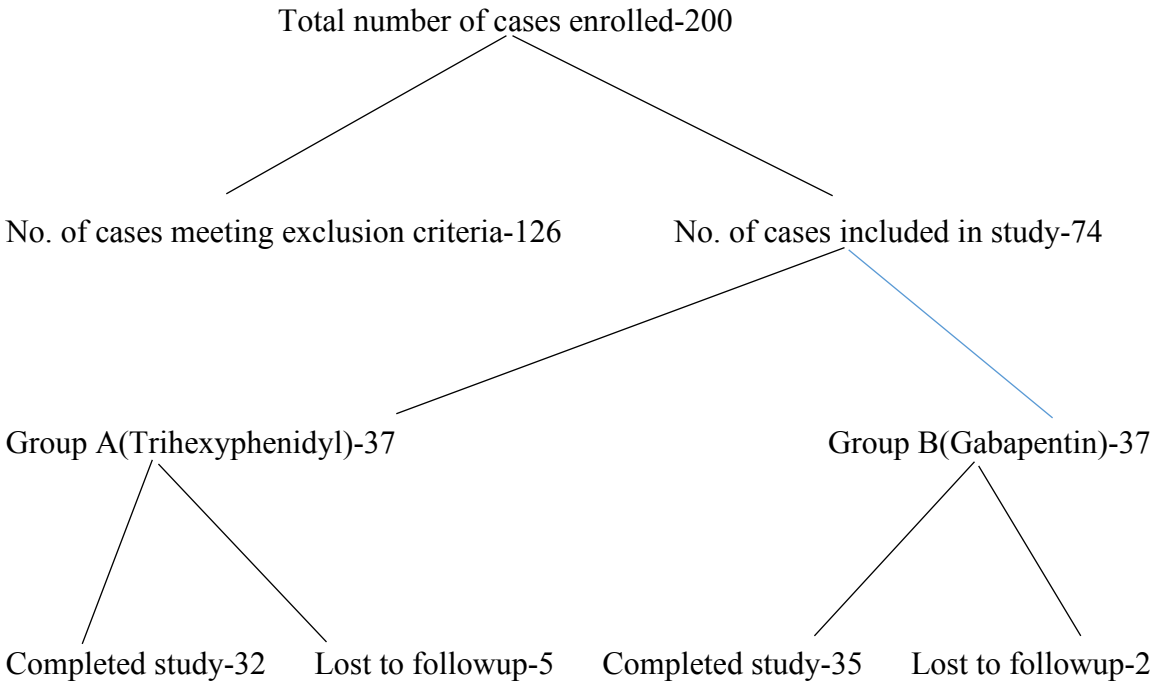
In a prospective study of the management of dystonia in 57 children and young patients with CP at a tertiary care centre in Australia, baclofen and gabapentin were the most commonly used oral drugs.[102]

Gabapentin is a widely used medication for the management of neuropathic pain. However it remains to be determined to what extent its use in children and young patients is focused primarily on reduction of tone.

Side effects of gabapentin-somnolence(21% in drug vs 5% in placebo), emotional liability(6% in drugs vs 1.3% in placebo).[100] other side effects-drowsiness, gastrointestinal issues, fatigue, weakness, irritability.[103]

To know the effect of gabapentin on dystonia in children palsy, we conduced this prospective open labeled randomised trail to compare the efficacy of gabapentin with trihexyphenidyl in treatment of dyskinetic CP.

FLOW CHART



METHODOLOGY

This study was conducted from June 2020 to November 2021 in the Child Development clinic of KLES Dr Prabhakar Kore Hospital and Medical Research centre(MRC), Belagavi, a 2400 bedded hospital including super-specialties.

Study Design:

Hospital Based Randomized control study – open label

Study duration and study period:

One and half year duration from June 2020 to November 2021. Study was extended by 6 months in view of less recruitment/drop outs of patients due to covid pandemic.

Place:

The study was conducted in the child developmental clinic at KLES Dr Prabhakar Kore Hospital and Medical Research Centre in Belagavi, a teaching hospital affiliated with Jawaharlal Nehru Medical College.

Source of Data:

At the first visit, children with dyskinetic or mixed cerebral palsy who attended the CDC of KLE Dr Prabhakar Kore Hospital were included in the study.

INCLUSION CRITERIA: Children aged 1 to 18 years old with a new or untreated clinical diagnosis of cerebral palsy (dyskinetic/mixed-spastic with dyskinetic CP).

EXCLUSION CRITERIA:

1. Children who have received Botox injection in last 6 months period.
2. If already on treatment with any other drugs for dystonia.
3. If has undergone any surgery for dystonia.
4. Children with uncontrolled epilepsy.

Sample size :

A sampling of 74 children with cerebral palsy attending Child development clinic between June 2020 to September 2021 fulfilling the criteria.

Sample size will be estimated by the formula-

The minimum sample size formula based on two proportions is

$$n = \frac{(z_\alpha + z_\beta)^2 \bar{p}(1-\bar{p})}{d^2}$$

where p_1 and p_2 are the proportions of the two groups.

$$p = \frac{p_1 + p_2}{2} \text{ and } d = p_1 - p_2$$

z_α is linked with the level of significance and z_β is linked with the power of the test.
For 5% level of the significance $z_\alpha = 1.96$ and $z_\beta = 0.84$ for 80% power of the test.
Ref:
By taking proportion of success of the treatment, p_1 = 42/69 (60.87%) and
p_2 = 9/31 (29.03%) the sample size obtained is 37.
There would be two groups with size of 37.

Ethical clearance:

The institutional ethical committee of Jawaharlal Nehru Medical College, Belagavi, approved the study prior to its start (Annexure IX)

Informed Consent: The study's nature was explained to the parents of children with cerebral palsy who met the eligibility criteria. A written informed consent was also collected prior to enrolment in a language that they were familiar with (Annexure I).

METHODOLOGY:

Once the child was registered in the CDC outpatient clinic, he/she was examined after taking a thorough history and classified into the respective type of cerebral palsy. The child was classified into respective type of CP– Anatomical/Topographic/Dyskinetic/ Ataxic/Mixed classifications using HAT

If the child fulfilled the eligibility criteria he/she was enrolled into the study and were randomized in to 2 groups according to random number table. Children with any other cause of dystonia or already on medication or who had undergone any surgical interventions were excluded from study.

After taking the consent, relevant data was obtained from the parents and recorded in a structured proforma along with the details of examination (Annexure II).

The demographic details, presenting complaints, antenatal, perinatal and postnatal history, infancy history, relevant family history, details of thorough CNS examination and other systemic examination, relevant investigation reports like MRI were obtained if required.

At the baseline meeting I.e. at 0 week the child was assessed with help of various tools such as :-

-Gross motor function measurement was assessed in five areas: lying, rolling, sitting, crawling, and kneeling, as well as standing, walking, running, and leaping, using the GMFM (Annexure III).

- the Lifestyle assessment Questionnaire-CP (LAQ-CP) (*vide infra*) and the score was calculated after ensuring that the parent/care-taker understood it in detail (Annexure IV). HAT score (Annexure VI) and DSAP score sheet (Annexure VII) were also used. Translators were used whenever necessary. The questionnaire was filled by the investigators based on the answers given by the care-givers. The parents/care-takers were subjected to a questionnaire .

-Barry Albright Dystonia Scale (BAD): This scale serves to quantify the severity of dystonia-related posturing and involuntary movement (Annexure V).

-Degrees of the Teacher Drooling Scale (Annexure VIII).

This was done with with the help of pediatric physiotherapists.

After the final diagnosis and assessment of the dystonia, he or she was subjected to interventions according to the group they were included: .

The dosage for trihexyphenidyl is as follows:

Week 1: 0.2 mg/kg/d in three separate doses

Week 2: 0.5 mg/kg/d, divided into three doses

Week 3: 1.0 mg/kg/d, divided into three doses

Week 4: 2.0 mg/kg/d, divided into three doses

Week 5: 2.0 mg/kg/d, divided into three doses

Week 6: 2.0 mg/kg/d, divided into three doses

Weeks 7 to 12 2.0 mg/kg/d divided into three doses

Patients who developed any side effects at any particular dose were not subjected to further escalation of dose and were continued with same dose.

Gabapentin dosage:

Week 1: 10 mg/kg/d in three divided doses

Week 2: 20 mg/kg/d, divided into three doses

Week 3: 30 mg/kg/d, divided into three doses

Week 4: 40 mg/kg/d, divided into three doses

Week 5: 40 mg/kg/d, divided into three doses

Week 6: 40 mg/kg/d, divided into three doses

Weeks 7-12: 40mg/kg/d, split into three doses

All the 74 subjects were given standard physiotherapy and were also advised to continue the same at home.

Follow up period: Patients were followed up at 3rdmonth. A telephonic interview was done at 1 month to know the compliance with medication and regarding any adverse events related to medication. Clinical evaluation for clinical improvement in dystonia was done at the end of 3 months using Gross motor function measures (GMFM66), Barry Albright Dystonia Scale, Dystonia Severity Action Plan, Degrees of the Teacher Drooling Scale and LAQCP was assessed with help of set of questionnaire to the caregiver.

Outcome variables:

1.GMFM-66:-The Gross Motor Function Measure (GMFM) is a technique for evaluating gross motor function improvements in five areas: lying, rolling, sitting, crawling, kneeling, standing, walking, running, and leaping. The GMFM-88, the real version of the GMFM, has 88 components.The GMFM-66 is a 66-item subset of the GMFM-88 that was found to best characterize the gross motor function of children with cerebral palsy by Rasch analysis. Each item is graded on a point 4 ordinal scale ranging from 0 to 3, with 0 indicating that the child does not initiate the task, 1 indicating that the child initiates the task (complete 10% of activity), 2 indicating that the child partially completes the task (10-99% of activity), 3 indicating that the child completes the task (100 percent), and NT indicating that the child was not tested.

After three trials, each dimension's score is expressed as a percentage of the maximum score for that dimension. GMFM-66 is employed in our research.

2.BAD(Barry Albright dystonia scale):-This scale was developed to assess the degree of posturing and involuntary movements caused by dystonia. The quantification of motions

allows a physician to track changes in movement that may make caring for a patient easier or more comfortable, but not changes in function. The BAD scale is a five-point ordinal scale used to assess secondary dystonia in the eyes, mouth, neck, trunk, and four extremities. The scores for each region vary from 0 (no dystonia) to 4 (dystonia) (severe dystonia).The maximum scale is 32, which is the sum of all the measured regions. Overall, the BAD scale is a reliable clinical instrument when utilised by experienced users.

SCORING CRITERIA	**SCORE(POINTS)**
0-> Absent 1->Slight(<10% of time, does not interfere with function); 2->mild(<50% of time, does not interfere with function) 3->moderate(interferes with function) 4-> severe(prevents function of body part)	**Score: each body part** **Total BADS (32 points)**

3.LAQ-CP (LIFESTYLE ASSESSMENT QUESTIONNAIRE):-It's used to assess the impact of impairment on cerebral palsy (CP) children and their families. Clinical burden, physical freedom, mobility, schooling, economic load, and social integration are the six dimensions of basic questions. The clinical load, physical independence, and mobility of a child are all linked to their neurological health. Based on the scores in each dimension, dimensional scores were calculated, and a final standard score was determined. They are graded on a scale of one to ten.

The following is an analysis of the score:

-30 percent good-score

-Score between 30 and 50 percent if you're mildly influenced.

-Moderately afflicted-scores ranging from 51 to 70%

-Scores >70% for -severely affected-

4.DSAP:- Dystonia Severity Action Plan, which uses a simple grading system to determine the medical severity of status dystonicus and life-threatening dystonia. Children and teenagers with dystonia may experience an abrupt deterioration in their dyskinesia, which is defined as a "generalized, severe, and potentially deadly aggravation of muscle contractions."

Because early discovery can aid intervention and prevent development, the scoring technique should be swift and accurate, as well as understandable to parents and other health-care practitioners. As a result, this system provides simple objective clinical criteria against which the severity of a child's dystonia can be assessed and appropriate action taken, assisting in treatment planning and determining where care should be given, such as on the ward, in high dependence, or in critical care.

5.The Drooling Scale of the Teacher: This is a simple grading system for drooling at the bedside. It is graded on a scale of one to five, with the intensity of drooling increasing as we proceed up the scale. Drooling is divided into five categories: no drooling, rarely drooling, occasional drooling, frequent drooling, and persistent drooling.

6.Adverse effects of Trihexyphenidyl and Gabapentin.

7.Cost analysis of these two drugs.

Data analysis:

The data was coded and entered into Microsoft Excel workbooks, and SPSS version 20 was used to analyse it.

The mean and standard deviation of continuous variables were calculated. Before and after interventions, the BAD, HAT, GMFM, and LAQ-CP scores were calculated and compared using mean and standard deviations, as well as the Wilcoxon signed-rank test. A non parametric test (Wilcoxon signed-rank test) was used because the study result values did not have a normal distribution. The alpha level was set at 5%, which implies that any p value less than 0.05 was considered significant. For categorical data, frequencies were calculated and expressed as percentages.

RESULTS

RESULTS FOR CLINICAL EFFICACY OF TRIHEXYPHENIDYL VS GABAPENTIN IN TREATING DYSTONIA IN CHILDREN WITH CEREBRAL PALSY

A total of 74 samples were collected, out of which 7 were lost for follow up, 5 in trihexyphenidyl and 2 in gabapentin group reason being 2 children dropped due to excessive vomiting and sedation, 4 due to pandemic situation, 1 child expired and hence, were excluded from the study. So study was conducted with sample size of 74 who were divided in to 2 groups of trihexyphenidyl and gabapentin according to random number table and were followed up by telephone call at the end of 1 month to know the child's condition and compliance with the medication and again at 3 month at CDC for clinical assessment.

DEMOGRAPHIC DATA.

1. AGE DISTRIBUTION-

Children in the age group between 1-18 years were enrolled in the study. The age group distribution in Trihexyphenidyl and Gabapentin group is depicted in table no 1.

Table 1. Distribution of study population as per age.

Age in Years	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
<5	29	78.4%	27	73.0%
5--10	4	10.8%	9	24.3%
>10	4	10.8%	1	2.7%
Total	37	100.0%	37	100.0%
P=0.15				

In our study, the age distribution was from 1-18 years out of which, majority of the children I.e 75.6% were in the age group of 1-5 years and only 6.7% patients were above 10 years.

Mean age as a whole was 3.87 years however, mean age was 4.06 years in Trihexyphenidyl group and 3.65 years in Gabapentin group.

2. GENDER DISTRIBUTION-

Out of 74 children who completed the study, 44 (59.45%) were male and 30 (40.54%) were females.

The gender distribution of subjects in Trihexyphenidyl and Gabapentin group has been shown in table no 2.

Table 2. Distribution of study population as per gender.

Gender	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
Male	21	56.8%	23	62.2%
Female	16	43.2%	14	37.8%
Total	37	100.0%	37	100.0%
P=0.81				

In the present study, Male to Female ratio was 1.46:1. While in Trihexyphenidyl group it was 1.3:1 and in Gabapentin group it was 1.6:1. This difference was not statistically significant.

3. DEVELOPMENTAL QUOTIENT(DQ)/INTELLECTUAL DISABILITY-

The DQ was assessed below 5 years of age based upon developmental history and developmental assessment while for children >5 years IQ was assessed.

Distribution of subjects based upon motor, language and social milestones in Trihexyphenidyl and Gabapentin group is depicted below.

Table 3. Distribution of DQ/IQ among the study population.

Complaints - DQ	Trihexyphenidyl		Gabapentin		P-value
	Number	%	Number	%	
Gross Motor Delay	37	100.0%	37	100.0%	-
Social Delay	36	97.3%	33	89.2%	0.17
Language Delay	36	97.3%	34	91.9%	0.3

Along with gross motor delay more than 90% of subjects had associated social and language delay. There was no significant difference in both the groups.

4. NEUROLOGICAL CO-MORBIDITIES-

The children in the study were screened for neurological co-morbidities like Global developmental delay, mental retardation, seizures, hearing, visual impairments and speech delay.

The distribution of neurological co-morbidities in both the age groups is shown in below table.

Table 4. Distribution of neurological co-morbidities among the study population.

Neurological Complaints	Trihexyphenidyl		Gabapentin		*P-value
	Number	%	Number	%	
Seizure	17	45.9%	17	45.9%	1
Global Developmental Delay	36	97.2%	34	91.9%	0.62
Mental Retardation	6	16.2%	7	18.9%	1
Hearing Impairment	10	27.0%	4	10.8%	0.14
Speech Delay	36	97.3%	34	91.9%	0.62
Vision Problem	7	18.9%	6	16.7%	0.8

*Chi-square test.

The most common neurological co-morbidity was Global developmental delay seen in 97.2% of patients in Trihexyphenidyl group and 91.9% of patients in gabapentin group. Following this speech delay was seen in 97.3% in Trihexyphenidyl group and 91.9% in gabapentin group.

The least common was vision problem which was seen in 18.9% of patients in trihexyphenidyl group and 16.7% of patients in gabapentin group in the form of refractive error and squint.

The neurological co-morbidities were comparable between the two groups.

5. NON -NEUROLOGICAL CO-MORBIDITIES:

The children in our study were screened for non neurological co-morbidities like caries tooth, constipation, GERD, contracture, callosities, scabies, asthma, FTT, obesity.

The trends of various non neurological co-morbidities in both the groups are shown in below table.

Table 5. Distribution of non-neurological co-morbidities among the study population.

Non-Neurological Complaints	Trihexyphenidyl		Gabapentin		*P-value
	Number	%	Number	%	
Caries Tooth	14	37.8%	13	35.1%	1
Constipation	24	64.9%	25	67.6%	0.81
GERD	9	24.3%	7	18.9%	0.78
Contracture	5	13.5%	5	13.5%	1
Callosities	11	29.7%	9	24.3%	0.79
Scabies	3	8.1%	1	2.7%	0.62
Failure To Thrive	15	40.5%	12	32.4%	0.63

GERD- gastro-esophageal reflux disease

*Fisher Exact test.

In this study, all participants were screened for non neurological co-morbidities and most common co morbidity was constipation which was seen in 64.9% of cases of cases in trihexyphenidyl group and 67.6% of cases from gabapentin group. The least common non neurological co-morbidity was scabies which was seen only in 8.1% of study population in trihexyphenidyl group and 2.7% in gabapentin group.

The distribution of co-morbidities among the two groups were comparable.

6. FAMILY HISTORY.

Family history in view of Degree of consanguanity among the two groups were sought for and results obtained are shown in table below.

Table 6.Distribution of study population according to consanguanity.

Family History	Trihexyphenidyl		Gabapentin		*P-value
	Number	%	Number	%	
Consanguanity	14	37.8%	14	37.8%	1

*Fisher Exact test

In the present study, it was found that 37.8% cases enrolled in trihexyphenidyl group were born out of consanguineous marriage and 37.8% cases from gabapentin group were born out of consanguineous marriage. Results from both the groups were similar and comparable.

7. BIRTH HISTORY-

Birth records of all the children were carefully looked in for ANC visits, gestational period, place of delivery, type of delivery, presence of PROM, multiple delivery, cry at birth, birth weight , NICU admission, NNH(neonatal hyperbilirubinemia) and hypoglycemia.

Table 7.Distribution of study population as per birth events.

Variable	Category	Trihexyphenidyl		Gabapentin		*P-value
		Number	%	Number	%	
Birth order	1	26	70.3%	28	75.7%	0.79
	2	9	24.3%	8	21.6%	
	3	2	5.4%	1	2.7%	
ANC visits	Present	33	89.2%	37	100.0%	0.12
	Absent	4	10.8%	0	0%	
Gestation	Term	33	89.2%	27	73.0%	0.14
	Preterm	4	10.8%	10	27.0%	
Place of delivery	Hospital	34	91.9%	37	100.0%	0.24
	Home	3	8.1%	0	0%	
Mode of delivery	NVD	30	81.1%	28	75.7%	0.78
	LSCS	7	18.9%	9	24.3%	
PROM	Present	2	5.4%	4	10.8%	0.67
	Absent	35	94.6%	33	89.2%	
Multiple delivery	Absent	35	94.6%	34	91.9%	1
	Present	2	5.4%	3	8.1%	
Cry at birth	Present	17	45.9%	16	43.2%	1
	Absent	20	54.1%	21	56.8%	
Birth weight	AGA	22	59.5%	19	51.4%	0.64
	LBW	15	40.5%	18	48.6%	
NNH	Present	8	21.6%	7	18.9%	1
	Absent	29	78.4%	30	81.1%	
Hypoglycemia	Present	0	0%	1	2.7%	1
	Absent	37	100.0%	36	97.3%	

*Fisher Exact test

ANC- antenatal care

PROM- premature rupture of membrane
NNH- neonatal hyperbilirubinemia
LSCS- lower segment cesarian section
AGA- appropriate for gestational age
NVD- normal vaginal delivery
LBW- low birth weight

In our study, we found that out of total 74 patients enrolled 89.2% of mother's of babies in trihexyphenidyl group had regular ANC visits whereas, 100% from gabapentin group had regular ANC visits.

Regarding preterm deliveries 10.8% of cases from trihexyphenidyl group were born as preterm and 27% from gabapentin group were born before 37 weeks of gestation.

With respect to deliveries conducted at home only 8.1% from trihexyphenidyl group were delivered at home and 100% of deliveries from gabapentin group were conducted at hospital.

Delayed cry(referred to as babies who required assistance in the form of bag and mask ventilation immediately after birth) was present in 54.1% of cases from trihexyphenidyl group and 56.8% from gabapentin group. This was comparable between two groups.

NNH(neonatal hyperbilirubinemia) which is one of the important cause of Dystonic CP was seen in 21.6% of cases enrolled in trihexyphenidyl group and 18.9 % of cases in gabapentin group.

8. NICU STAY-

Table 8. Distribution of study population as per NICU admission after birth.

NICU Stay	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
Present	29	78.4%	31	83.8%
Absent	8	21.6%	6	16.2%
Total	37	100.0%	37	100.0%
*P=0.77				

NICU- neonatal intensive care unit

*Chi-square test

In our study, NICU admission as a whole was seen in 60 (81.08%) of subjects I.e 29 (78.4%)subjects from trihexyphenidyl group and 31 (83.8%) of subjects from gabapentin group had NICU admission post delivery.

TYPES OF CEREBRAL PALSY-

9. TOPOGRAPHICAL CLASSIFICATION-

Based on the limbs affected CP was classified into quadriplegic(involving all 4 limbs), diplegic (predominantly involving lower limbs), hemiplegic (predominantly involving one side of body) and monoplegic (predominantly involving one single limb).

Distribution of subjects based on topographical classification in both the groups is shown below in table no 9.

Table 9. Distribution of study population according to the Topographical diagnosis.

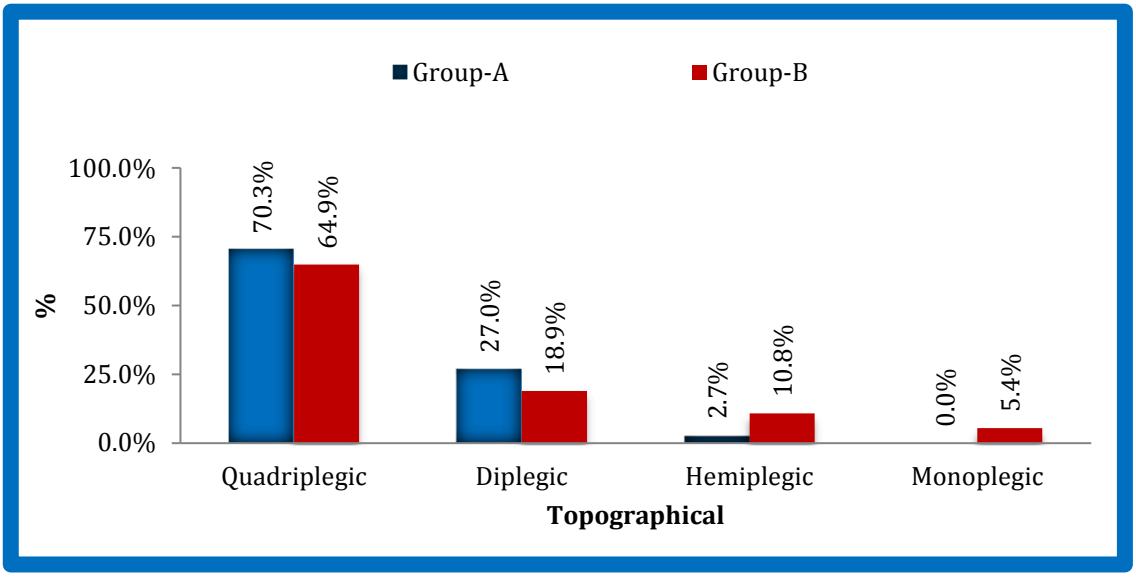
Topographical Classification	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
Quadriplegic	26	70.3%	24	64.9%
Diplegic	10	27.0%	7	18.9%
Hemiplegic	1	2.7%	4	10.8%
Monoplegic	0		2	5.4%
Total	37	100.0%	37	100.0%
*P=0.22				

*Chi-square test.

This study showed, Quadriplegic CP as most common type of topographical CP with total of 50 (67.56%) cases from both the groups and followed by diplegic CP with 17 (22.9%) patients out of total 74 patients enrolled.

The distribution of different types of topographical types of CP among the two groups as shown in above table is comparable with p value of 0.22 which is statistically not significant.

Figure 1.Topographical Diagnosis.



Group A- Trihexyphenidyl
Group B- Gabapentin

10. PHYSIOLOGICAL CLASSIFICATION-

HAT(Hypertonia Assessment Tool) was used to assess the tone of the subjects and based upon the HAT score subjects were divided into spastic CP, mixed CP and dyskinetic CP. Only dystonic and mixed CP children were included in study.

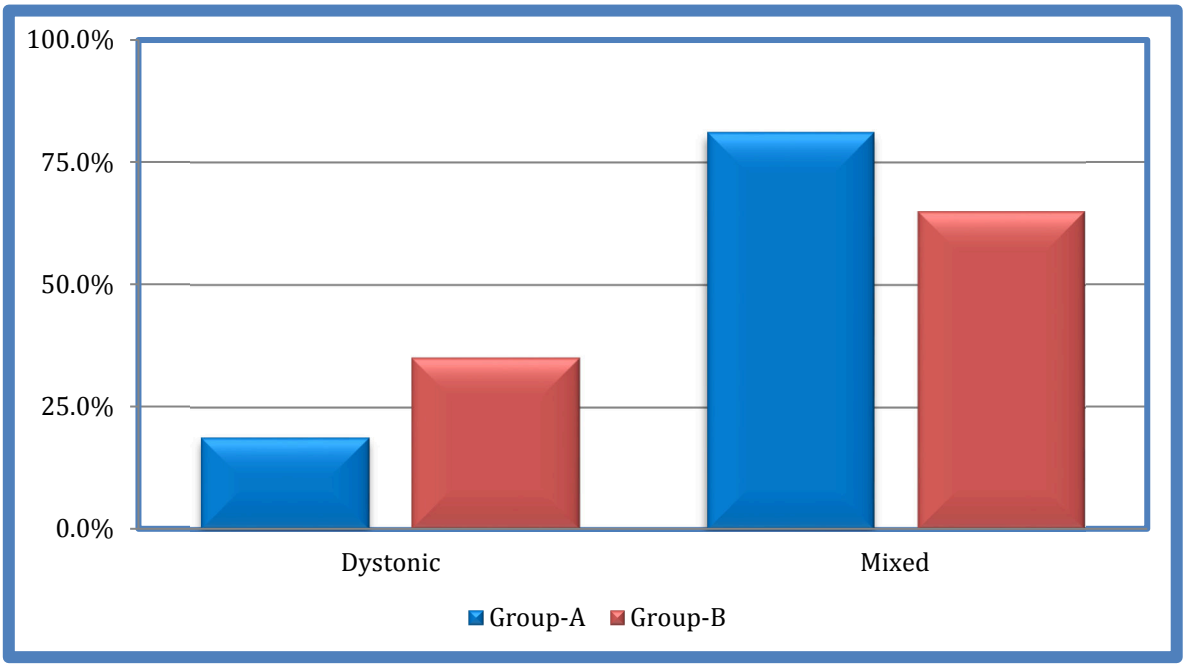
Distribution of subjects based on the tone in both the groups is shown in table below-

Table 10.Distribution of children as per physiological type of CP.

Physiological Classification	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
Dystonic	7	18.9%	13	35.1%
Mixed	30	81.1%	24	64.9%
Total	37	100.0%	37	100.0%
*P=0.19				

*Chi-square test.

Figure 2. Distribution of study population as per physiological type of CP.



Group A- Trihexyphenidyl

Group B- Gabapentin

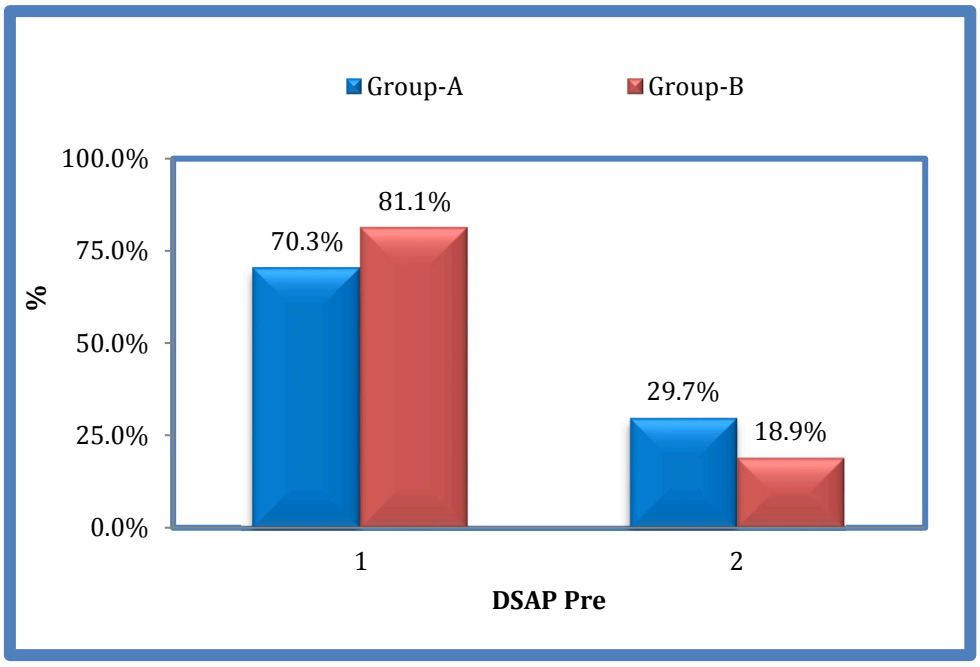
Out of total 74 cases in our study, the most common type of physiological type of CP was mixed CP which was seen in 54 (72.9%) patients and dystonic CP in 20 (27.02%) patients. Distribution of different types of CP in both the groups was comparable with p value of 0.19 which was not statistically significant.

11.DSAP(DYSTONIA SEVERITY ASSESSMENT PLAN)-

It uses a simple grading system to determine the medical severity of status dystonicus and life-threatening dystonia. This system provides simple objective clinical criteria against which the severity of a child's dystonia can be assessed and appropriate action taken, assisting in treatment planning and determining where care should be given, such as in the ward, in high dependence, or in critical care.

In our study, we found that pre-intervention out of total 74 subjects enrolled 56 (75.6%) were in category 1 and remaining 18 (24.32%) were in category 2 of dystonia severity plan with p value of 0.41 which was statistically insignificant. Hence, both the groups are comparable.

Figure 3. Distribution of subjects in DSAP category pre-intervention.



DSAP- dystonia severity assessment plan

Group A- Trihexyphenidyl
Group B- Gabapentin

Table 11 .Table showing DSAP scores post intervention in both the study groups.

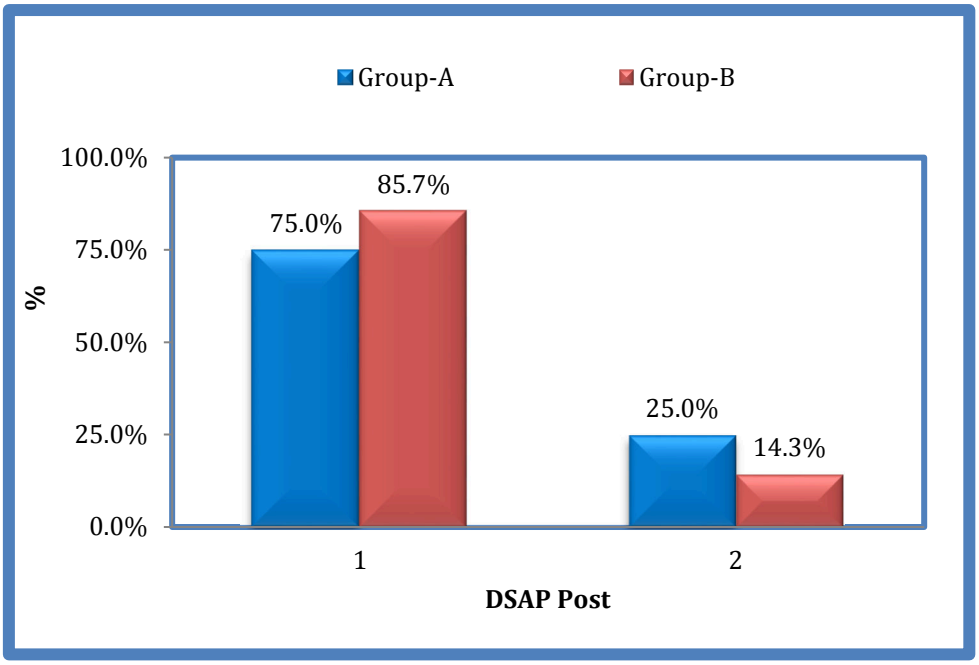
DSAP Post	Trihexyphenidyl		Gabapentin	
	Number	%	Number	%
Category 1	24	75.0%	30	85.7%
Category 2	8	25.0%	5	14.3%
Total	32	100.0%	35	100.0%
*P=0.36				

DSAP- dystonia severity assessment plan

*Fisher Exact test

Post intervention it was found that 54 (80.5%) of subjects belonged to category 1 and 13 (19.4%) belonged to category 2. Here 7 patients were either lost to followup or expired.

Figure 4. Distribution of patients in DSAP category post intervention.



DSAP- dystonia severity assessment plan

Group A- Trihexyphenidyl
Group B- Gabapentin

So here we can see that the overall percentage of cases from both the groups, post intervention increased in category 1 with increase of 4.7% in trihexyphenidyl group and 4.6% of increase in gabapentin group. Hence, both are comparable.

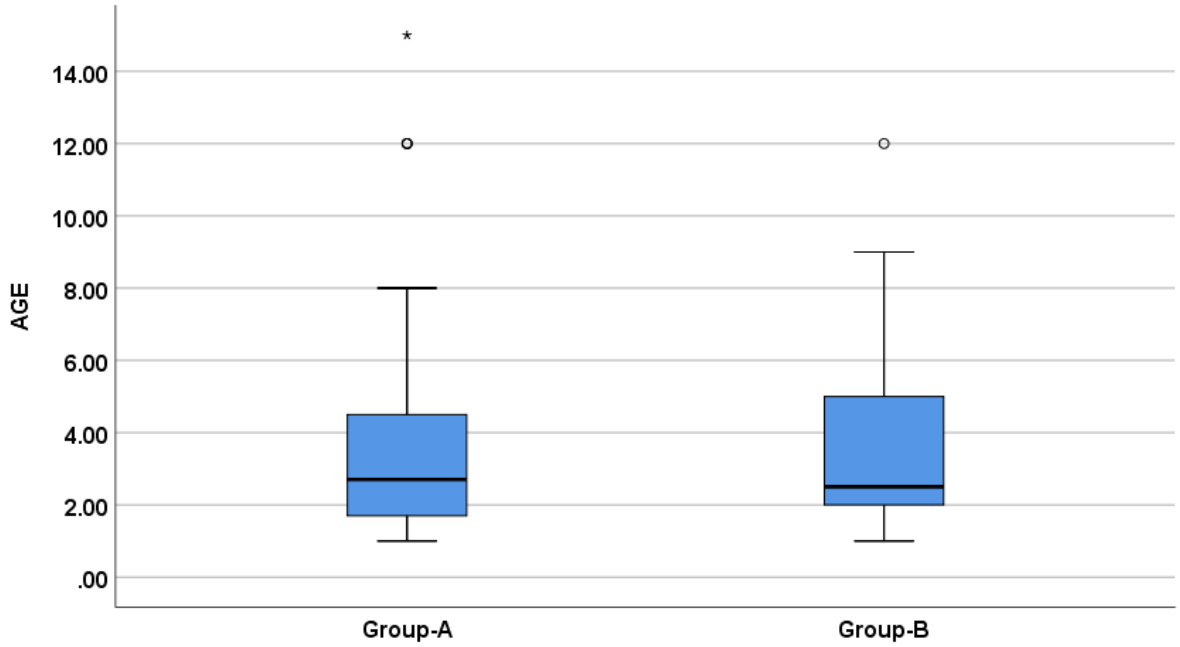
Table showing DSAP score in both the study groups (post intervention). Post DSAP scores were compared using Mann Whitney test due to non normal distribution of data with p value of 0.95 which is statistically not significant. But both the groups are comparable.

Table 12. showing DSAP scores in both study groups post-intervention.

Variable	Trihexyphenidyl						Gabapentin						*P-value
	Min.	Max.	Mean	SD	Median	IQR	Min.	Max.	Mean	SD	Median	IQR	
Age	1.00	15.00	4.06	3.51	2.70	2.95	1.00	12.00	3.69	2.69	2.50	3.05	0.95

*Mann-whitney test

Figure 5.Box and Whisker plot showing DSAP scores in both study groups post-intervention.



Group A- Trihexyphenidyl
Group B- Gabapentin

12.GMFM(GROSS MOTOR FUNCTION MEASURES)

It is an assessment tool designed to measure the 5 domains of motor function- ''lying, and rolling, sitting, crawling and kneeling, standing, walking, running and jumping.''

Table 13. Showing GMFM scores in both the study groups (pre and post intervention

Variable	Trihexyphenidyl						Gabapentin						*P-value (A vs B)
	Min.	Max.	Mean	SD	Median	IQR	Min.	Max.	Mean	SD	Median	IQR	
GMFM Pre	0.39	95.83	34.22	26.54	30.78	44.96	1.18	95.44	34.95	26.18	28.09	38.30	0.84
GMFM Post	5.14	92.74	41.49	27.69	38.34	48.22	4.52	97.78	42.85	27.90	35.57	38.95	0.73
#P-value (Pre vs Post)	**<0.001**						**<0.001**						

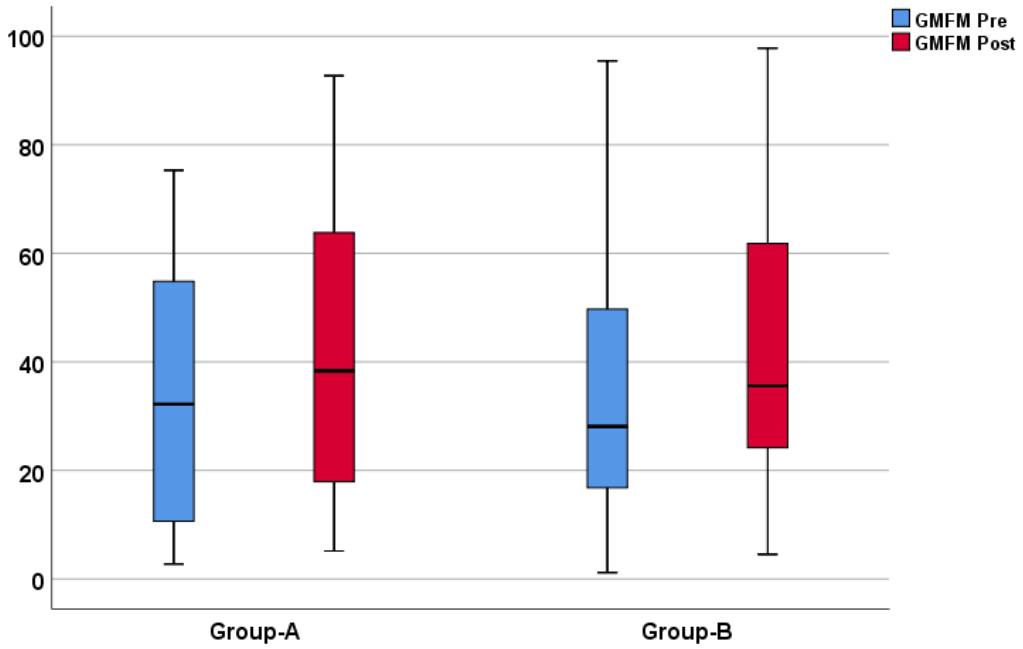
GMFM- gross motor function measure

*Mann-Whitney U test (A vs B).
#Wilcoxon test (Pre vs Post)

Pre and post intervention GMFM scores were compared using Wilcoxon test. Where as GMFM scores between Trihexyphenidyl and Gabapentin groups were compared using Mann-Whitney U test with p value <0.05 which was taken as statistically significant. It shows significant improvement in GMFM score in both the groups over 3 months suggesting that there is significant improvement of dystonia in both the groups.

However, when the post interventional scores of the two groups were compared with each other there was no significant difference between the two groups suggesting that both the drugs are equally effective. The post interventional p value between the two groups was 0.73.

Figure 6. Box and Whisker plot showing GMFM scores in both the study groups (pre and post intervention)



Group A- Trihexyphenidyl
Group B- Gabapentin

13.LAQCP (LIFE STYLE ASSESSMENT QUESTIONNAIRE-CP)

It is assessed by interviewing the patients. It tells at given point the impact of disabilities on the lives of children with cerebral palsy and their family, as perceived by the child's parents or carer.

Questions are asked to assess the child in components like physical independence, mobility, clinical burden, schooling, economic burden and social integration.

Distribution of LAQCP scores pre and post interventions in both groups are depicted below.

Table 14. Table showing LAQ-CP scores in both the study groups (pre and post interventions).

Variable	Trihexyphenidyl						Gabapentin						*P-value
	Min.	Max.	Mean	SD	Median	IQR	Min.	Max.	Mean	SD	Median	IQR	
LAQCP Pre	21.15	67.88	42.94	16.05	43.04	25.02	17.18	74.27	54.44	19.66	63.12	27.10	0.16
LAQCP Post	21.30	67.88	43.61	16.89	47.26	25.87	16.41	74.98	51.22	22.83	62.18	42.23	0.34
#P-value	**0.008**						0.31						

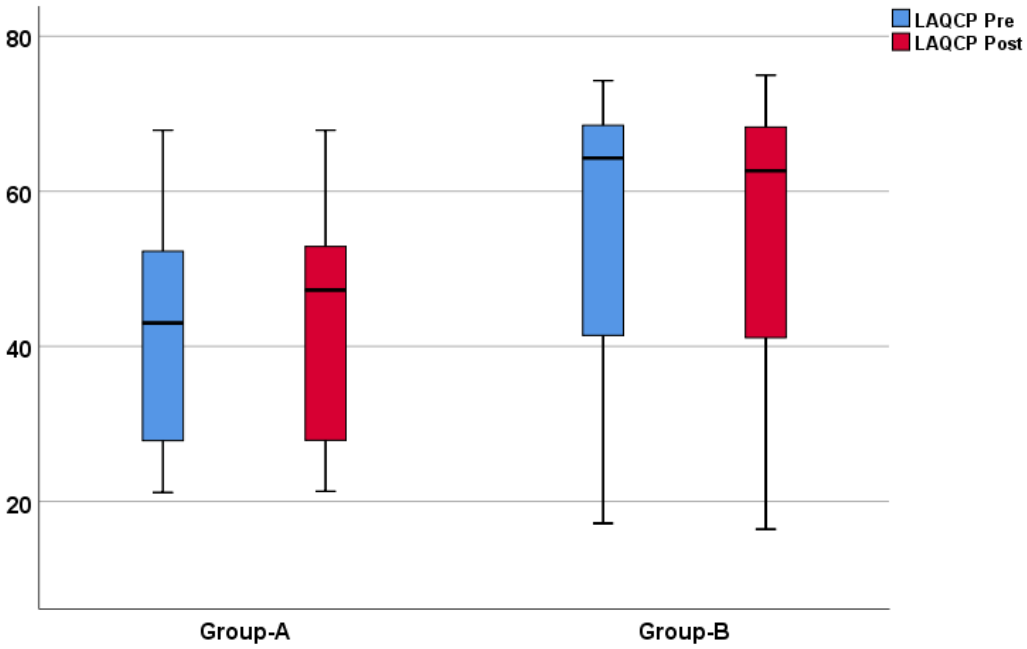
LAQCP- life style assessment questionnaire cerebral palsy
*Wilcoxon test (A vs B).
#Mann-Whitney U test(Pre vs Post)

Pre and post LAQ-CP scores were compared using Mann-Whitney U test due to non normal distribution of data. Where as the LAQ-CP scores in trihexyphenidyl and gabapentin groups were compared using Wilcoxon test.

The p value of LAQ-CP score in trihexyphenidyl group between pre and post intervention over a period of 3 months was 0.008 which was statistically significant however, the p value for pre vs post intervention in gabapentin group was not statistically significant.

The LAQ-CP scores post intervention between the two groups were comparable with each other with p value of 0.73 and its statistically not significant. Hence, both the drugs are equally effective and comparable.

Figure 7. Box and Whisker plot showing LAQ-CP scores in both the study groups (pre and post interventions).



LAQCP- life style assessment questionnaire cerebral palsy

Group A- Trihexyphenidyl
Group B- Gabapentin

14.DROOLING

A simple grading system for drooling was used., which graded on a scale of one to five, with the intensity of drooling increasing as we proceed up the scale. Drooling is divided into five categories: no drooling, rarely drooling, occasional drooling, frequent drooling, and persistent drooling.

This study showed the drooling score in trihexyphenidyl group to be 2.14+-1.34 pre intervention and post intervention it was 1.72+-0.99 with p value of 0.046 which was statistically significant. However, in gabapentin the pre intervention score was 2.08+-1.34 and post intervention score was 1.71+-2.08 with p value of 0.17 which was statistically insignificant and hence it shows that trihexyphenidyl has better action in controlling drooling which is attributed to its anticholinergic action. But when the post interventional scores of the two groups were compared it showed the p value of 0.85 which is statistically insignificant.

Table 15. showing gradings of drooling between two groups.

Variable	Trihexyphenidyl						Gabapentin						*P-value
	Min.	Max.	Mean	SD	Median	IQR	Min.	Max.	Mean	SD	Median	IQR	
Drooling Pre	1.00	5.00	2.14	1.34	2.00	2.00	1.00	5.00	2.08	1.34	1.00	2.00	0.83
Drooling Post	1.00	5.00	1.72	0.99	1.00	1.00	1.00	5.00	1.71	1.05	1.00	1.00	0.85
#P-value	0.046						0.17						

*Mann-whitney test (trihexyphenidyl vs gabapentin)
#Wilcoxon test (pre vs post)

15.BAD (BARRY ALBRIGHT DYSTONIA SCALE)

The BAD scale is a five-point ordinal scale used to assess secondary dystonia in the eyes, mouth, neck, trunk, and four extremities. The scores for each region vary from 0 (no dystonia) to 4 (dystonia) (severe dystonia).The maximum scale is 32, which is the sum of all the measured regions.

Present study showed BAD score in trihexyphenidyl group was 11.11+-6.85(pre intervention) and 8.44+-6.65 (post intervention) with improvement in BAD score of 2.66 and pre vs post p value of <0.001 which was statistically significant. In gabapentin group BAD score pre intervention was 9.49+-6.74 and post intervention was 6.69+-6.13 with overall improvement in score of 2.8 and pre vs post p value of <0.001.

However, the p value between the trihexyphenidyl and gabapentin group post intervention was 0.26 which was statistically insignificant and hence both the drugs are equally effective in improving dystonia.

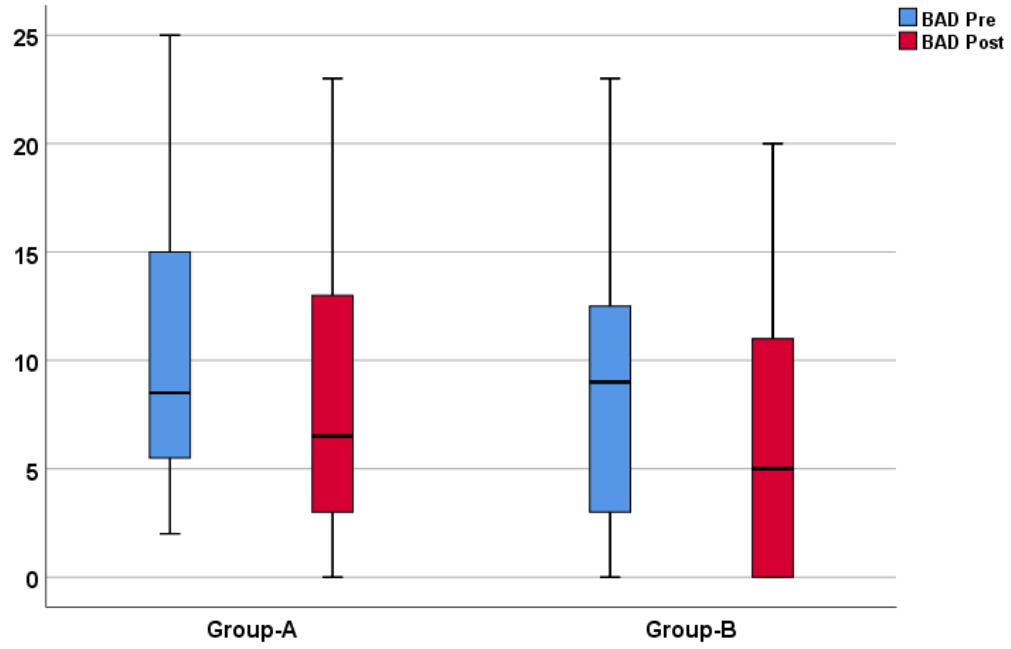
Table 16. showing distribution of BAD score between the two study population, pre and post intervention.

Variable	Trihexyphenidyl						Gabapentin						*P-value
	Min.	Max.	Mean	SD	Median	IQR	Min.	Max.	Mean	SD	Median	IQR	
BAD Pre	2.00	25.00	11.11	6.85	9.00	9.50	0.00	25.00	9.49	6.74	9.00	11.50	0.29
BAD Post	0.00	23.00	8.44	6.65	6.50	10.00	0.00	20.00	6.69	6.13	5.00	11.00	0.26
#P-value	**<0.001**						**<0.001**						

BAD- Barry Albright Dystonia Scale

*Mann-whitney test (trihexyphenidyl vs gabapentin)
#Wilcoxon test (pre vs post)

Figure 8. Box and Whisker plot showing distribution of BAD score between the two study population, pre and post intervention.



Group A- Trihexyphenidyl
Group B- Gabapentin

16.ADVERSE EFFECT

Table 17. Showing adverse effects of trihexyphenidyl and gabapentin.

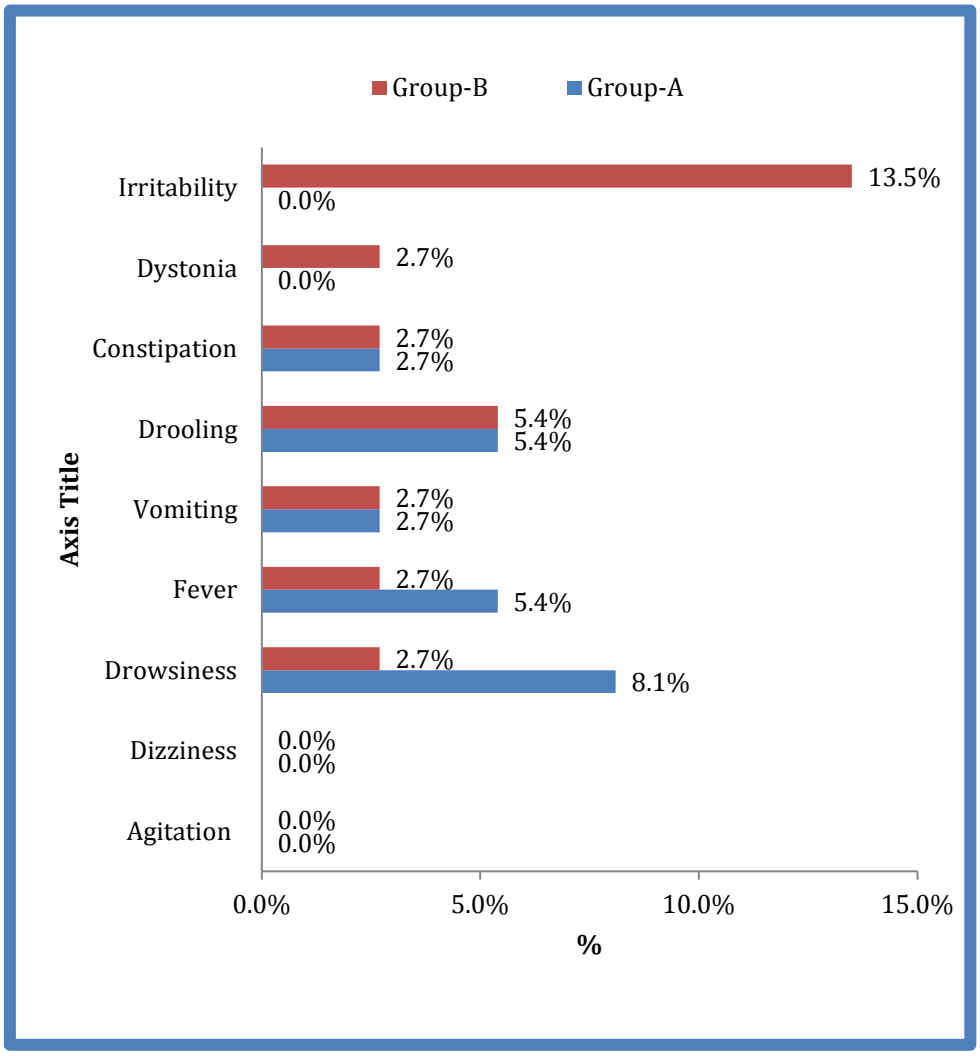
	Trihexyphenidyl		Gabapentin		P-value
	Count	%	Count	%	
Drowsiness	3	8.1%	1	2.7%	0.62
Fever	2	5.4%	1	2.7%	1
Vomiting	1	2.7%	1	2.7%	1
Drooling	2	5.4%	2	5.4%	1
Constipation	1	2.7%	0	0%	-
Dystonia	0	0%	1	2.7%	-
Irritability	0	0%	5	13.5%	-

Fisher exact test

Almost 9 (24.32%) patients experienced adverse effects in trihexyphenidyl group in various different forms in comparison to gabapentin where 12 (32.43%) of them had various adverse effects. Irritability was the most common adverse effect seen in 5 (13.5%) of total patients and was exclusively seen in gabapentin group (5 or 13.5%). Following this drooling and drowsiness stands together accounting for 5.4% each of over all sample size. Drooling accounted for 2 (5.4%) in trihexyphenidyl and 2 (5.4%) in gabapentin group. Drowsiness was more common in trihexyphenidyl reported in 3 (8.1%) patients. Fever was seen in 2 (54%) patients in trihexyphenidyl group and 1 (2.7%) of patients in gabapentin. 1 patient in gabapentin group even showed aggravation of dystonia.

Overall we can see trihexyphenidyl is marginally better tolerated when compared with gabapentin, however this margin is very narrow.

Figure 9.Figure showing adverse effects.



Group A- Trihexyphenidyl
Group B- Gabapentin

17.AVERAGE COST OF THE DRUGS FOR 1 MONTH IN A 10 KG CHILD:

When looked into the cost analysis for 1 month medication in a child with 10kg weight, we found that trihexyphenidyl costed around Rs 372 (tablet) and gabapentin costed around Rs 900. Trihexyphenidyl was found to be of almost half of the cost of gabapentin.

DISCUSSION

Cerebral palsy is a neuro-developmental condition that affects muscle tone, movement and motor skills. This is not a single disease but rather a heterogeneous clinical syndrome resulting from injury to the developing brain. Although the disorder itself is non-progressive, the clinical expression changes over time as the brain matures. The current definition of CP, as adopted by the International consensus in 2005 is " a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occured in the developing fetal or infant brain".

Dystonia can have devastating effects on function, including impairment of communication and swallowing, and it can create difficulties in completing self care tasks and being comfortably seated in a wheelchair. Children also get into cycles of dystonia causing musculoskeletal pain, which in turn exacerbates their dystonia crisis, which can require muscle paralysis/sedation[106] .These difficulties can negatively affect the quality of life of the individual and their caregivers[104,105].

Oral medications are often used to address dystonia in children with CP as a first-line medical treatment[4]. Many drugs like baclofen, Trihexyphenidyl, carbidopa-Levodopa, benzodiazepines have been used to treat dystonia in children. Trihexyphenidyl is an anticholinergic agent which acts as competitive inhibitor of acetylcholine action by blocking acetylchoiline muscarinic receptors. Poor tolerance and side effects are common such as agitation, constipation, dry mouth and poor sleep, confusion, dizziness, urinary retention and constipation. So we need other effective and potent drugs which are used more commonly[6]. Gabapentin has been recently found to be of use in the management of dyskinetic cerebral palsy. It can provide significant relief of childhood dystonic by relieving pain due to dystonia, disturbed or poor sleep, distress and lack of contentedness. Hence, we decided to conduct a study to determine the clinical efficacy and safety profile of gabapentin in treatment of dyskinetic cerebral palsy and compare it with one of the most commonly used drug i.e. trihexyphenidyl in an open label randomized control trial at our centre.

This study was conducted in KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belgavi from June 2020 to November 2021. 74 treatment naive children with dyskinetic and mixed cerebral palsy between the age group 1-18 years attending the child development clinic were enrolled for the study after meeting inclusion criteria.

They were randomized to two groups according to random number table and were subjected to physical examination like Hypertonia Assessment Tool (HAT) to assess the type of hypertonia, followed by Gross motor function measure (GMFM) and Barry Albright Dystonia Scale(BADS) to assess the degree of dystonia, followed by Dystonia Severity assessment Plan (DSAP) to assess the severity of dystonia and followed by Degree of the Teacher Drooling Scale to assess the degree of drooling and at last parents were subjected for set questionnaire for knowing the quality of life (LAQ-CP). According to the group randomized, the study subjects were started on either Trihexyphenidyl or Gabapentin. They were followed up at the end of 3 months and the same assessment scores were used to study the clinical improvement in the child.

In our study, we included children aged 1-18 years. Children below 1 years were excluded as the diagnosis of cerebral palsy is difficult to ascertain below one year of age. In our study majority of the children I.e. n=56 (75.67%) were in the age group of 1-5 years and only 5 patients were above 10 years. This is similar to the study by Najar et al., which reported maximum cases between age group between 2-5 years with 78.94% and also to the study by Vyas A.G. et al., who showed 87.5% were below 4 years of age group[107, 3].

Mean age was 4.06 years in Trihexyphenidyl group and 3.65 years in Gabapentin group. Our study included more children <5 years as most of the older children were already on treatment hence were excluded. In our study n=44 (59.45%) were male and n=30 (40.50%) were female ,with male to female ratio of 1.46:1. In trihexyphenidyl group it was 1.3:1 and in Gabapentin it was 1.6:1. These findings are similar with the Dobhal et al., study from Delhi where 64% were male and 36% females[95]. Ebru Yilmaz et al., study conducted in Turkey showed 58.8% were males and 41.2% were females, with a male to female ratio of 1.4:1[108]. Possible reason for such a ratio could be gender bias that is commonly seen in our part of world where males are provided with better care than the girls.
The children in our study were also screened for other neurological co-morbidities apart from developmental delay/intellectual disability and it was found that the most common

neurological morbidity was speech delay seen in n=36 (97.3%) in Trihexyphenidyl group and n=34 (91.9%) in Gabapentin group. Following this seizure was the second most common seen in n=17 (45.9%) in trihexyphenidyl group and n=17 (45.9%) in gabapentin group. Hearing impairment was seen in n=10 (27%) in trihexyphenidyl group compared to n=4 (10.8%) in gabapentin group. Visual impairment in the form of refractory error and squint was seen in n=7 (18.9%) in trihexyphenidyl group and n=6 (16.7%) in gabapentin group. The groups were similar in terms of comorbidities.

An Indian study done by Gowda et al., showed 46% seizures, 11% cases of hearing defect and 26% of visual defect in cerebral palsy children[109]. A study by Subramanium N.D. et al., showed behavioral abnormality as most common co-morbidity with 45% followed by seizures in 31% [110].

Among non-neurological co-morbidities, our study showed, constipation to be most common seen in n=49 (66.21%) followed by caries tooth and failure to thrive (FTT) seen in n= 27 (36.48%) each followed by callosities seen in n=20 (27%) children. GERD was seen in 16 (21.62%) of children. This is important as drugs used to treat dystonia like THP can themselves cause constipation. A study by Hollung J. et al., had 23% with dental caries and 39.1% with GI disturbance like constipation and vomiting[111].

Since most of our study population were from low socioeconomic strata residing in rural areas with absence of physiotherapy centers and poor referral system, they had high prevalence of deformities. These children also lacked in appropriate dental and oral hygiene care so showed high prevalence of dental caries.

Total of 28 (37.83%) children were born out of consanguineous marriage which is in accordance with study done by Subramaniam N.D. et al., from southern India reporting incidence of consanguinity around 23.33% [110].

In our study 71 (95.94%) children were born at hospital indicating availability of good health care facilities and health care seeking behaviour amongst people. Similar results were shown by the study done by Vyas A.G. et al., in Gujarat showing 93.7% deliveries taking place in hospitals[3]. However it differed from the results obtained by the study which

was done by Subramaniam N.D., in the year 2019 showing 40% of deliveries were conducted at home[110].

In our study 70 (94.59%) of mother had regular ANC visits which again reflects availability of good health care facilities and awareness amongst mothers. In this study, 14 (18.9%) children were born prematurily and only 16 (21.62%) children were delivered via LSCS. Out of 74 children 41 (55.40%) children had significant history of perinatal asphyxia/delayed cry at birth. Study done by Vyas A.G. et al reports prevalence of delayed cry at birth 68.75% and Dobhal et al reported it at 40%[3,95]. So the results obtained from our study are similar to these studies. PROM (premature rupture of membrane) is defined as rupture of membranes before the onset of labor. This study showed 6 (8.1%) i.e. 2 in trihexyphenidyl group and 4 in gabapentin with PROM. Mynarek M. et al a national registry based cohort study showed 11.6% of PROM[112]. Neonatal hyperbilirubinemia was reported in 15 (20.27%) children and received phototherapy for the same. This is almost similar to results obtained by the study which was done by Foley J., where 57 (26.02%) out of 219 cases of the dyskinetic and dystonic forms of cerebral palsy which were seen in the course of three decades at a single clinic had kernicterus. NICU admission was seen in 60 (81.08%) children, with n=29 (78.4%) in trihexyphenidyl group and n=31 (83.8%) children in gabapentin group[114]. A study conducted by Jain V., on perinatal risk factors showed , out of total 217, 70.7% children had a history of admission to NICU at the time of birth[113].

Our study showed that, in the terms of topographical classification of cerebral palsy, quadriplegic cerebral palsy is the most common type of cerebral palsy with total of 50 (67.56%) patients (26 in trihexyphenidyl group and 24 in gabapentin group), followed by diplegic type accounting for 17 (22.9%) of total patients and this was followed by hemiplegic cerebral palsy 5 (6.75%). Least common was monoplegic cerebral palsy constituting just 2 (2.7%) of total patients.

Our results were in accordance to results obtained by the study done by Subramaniam N.D. et al, which had 72% quadriplegic cerebral palsy, 25% diplegic cerebral palsy, and 3% of hemiplegic cerebral palsy[110]. Minocha P., et al study of India showed 56.6% cases of quadriplegic cerebral palsy as most common followed by diplegic cerebral palsy which is 16.11% and hemiplegic cerebral palsy of 10%[113]. Thus our study correlates with the fact that majority of the cases of cerebral palsies with significant perinatal asphyxia later

presents in the form of quadriplegic CP, as in our study quadriplegic CP (67.56%) was most common type and we also had 41 (55.40%) of patients with history of birth asphyxia.

In our study majority of the cases 54 (72.97%) were mixed type of physiological CP followed by 20 (27.02%) of pure dystonic CP. However two of the Indian studies conducted by Subramaniam N.D. et al and Minocha P. et al., shows spastic CP to be most common physiological CP I.e 81% and 84.4% respectively[110,113].
Since inclusion criteria of our study were only dyskinetic and mixed CP cases I.e why our study results are differing with the above two mentioned Indian studies.

EFFECT OF DRUG INTERVENTION

BAD (Barry- Albright Dystonia Score)

The BAD scale is a five-point ordinal scale used to assess secondary dystonia in the eyes, mouth, neck, trunk, and four extremities. The scores for each region vary from 0 (no dystonia) to 4 (dystonia) (severe dystonia).The maximum scale is 32, which is the sum of all the measured regions.

Present study showed BAD score in trihexyphenidyl group was 11.11+-6.85(pre intervention) and 8.44+-6.65 (post intervention) with improvement in BAD score of 2.66 and pre vs post p value of <0.001 which was statistically significant. In gabapentin group BAD score pre intervention was 9.49+-6.74 and post intervention was 6.69+-6.13 with overall improvement in score of 2.8 and pre vs post p value of <0.001.
However, the p value between the trihexyphenidyl and gabapentin group post intervention was 0.26 which was statistically insignificant and were comparable.

A study by Rice J. et al., where oral trihexyphenidyl was used as intervention reported the baseline Barry Albright Dystonia score to be 18.4 and at the end of trihexyphenidyl phase, the mean score was 18.3[6]. There was no significant treatment effects as measured by change in outcome scores. However, a key limitation of this study's methodology was the absence of a repeat baseline measurement at the end of the first washout period which may have significantly limit the validity of measurement obtained in the second phase of the

study. Similarly a study by Harvey A. et al., where oral gabapentin was used as intervention found no change in severity of dystonia(BADS), conducted over 12 weeks of time103.

GMFM(Gross Motor Function Measure)

It is a technique for evaluating gross motor function improvements in five areas: lying, rolling, sitting, crawling, kneeling, standing, walking, running, and leaping. Each item is graded on a point 4 ordinal scale ranging from 0 to 3, with 0 indicating that the child does not initiate the task, 1 indicating that the child initiates the task (complete 10% of activity), 2 indicating that the child partially completes the task (10-99% of activity), 3 indicating that the child completes the task (100 percent), and NT indicating that the child was not tested. Scores for each dimension are expressed as percentage of maximum score for that dimension and the total score is obtained by averaging the percentage score across the five dimensions.

Present study showed GMFM total scores in Trihexyphenidyl, pre intervention values to be 34.22+-26.54 and post intervention 41.49+-27.69 with p value of 0.001. In Gabapentin group it is 34.95+-26.18(pre intervention) and 42.85+-27.90 (post intervention) with p value of 0.001. The pre intervention scores were almost same in both group with p value of 0.84 suggesting that pre intervention severity of disability was comparable in both group. Post intervention there was improvement in GMFM score in both group with 7.27 point in trihexyphenidyl group and 7.9 point in gabapentin group., however this difference is not statistically significant as the post intervention the p value between the two groups was 0.73 and hence both the drugs were comparable.

So both trihexyphenidyl and gabapentin are effective in reducing dystonia which improves mobility and gives better GMFM scores. Concurrently physiotherapy was advised which would have resulted in improvement of scores.

DSAP(Dystonia Severity Assessment Plan)

It uses a simple grading system to determine the medical severity of status dystonicus and life-threatening dystonia.

This system provides simple objective clinical criteria against which the severity of a child's dystonia can be assessed and appropriate action taken, assisting in treatment planning and determining where care should be given, such as on the ward, in high dependence, or in critical care.

This study showed DSAP score in trihexyphenidyl group, post intervention to be 4.06+-3.51 and in gabapentin group to be 3.69+-2.50 post intervention with p value of 0.95 and was statistically insignificant.

So both the drugs are equally effective in managing the dystonia severity and hence are comparable.

According to a study conducted by Liow NY-K et al., where gabapentin was used as intervention ,the DSAP grade fell significantly from grade 3 before to grade 1 after the maximal optimal dose of gabapentin in mg/kg/dose three times a day was reached. However in this study out of 69 participants only 25 had dystonia due to CP rest all had dystonia of varying aetiologies[7].

LAQ-CP (Life Style Assessment Questionnaire For Cerebral Palsy)

The Questionnaire has been categorized into six domains and takes into account very minute details of the child's condition-clinical burden, economic burden, physical independency, mobility, schooling and social integration. The score measures at any given point, the impact of disabilities on the lives of children with CP, as perceived by the parents/care-givers.

In our study we found that most of the study population i.e. 47.82% had moderate disability LAQ-CP scores, followed by Good scores in 26.08% and Mild in 13.04% and no severe cases. The scores obtained in our study were similar to the ones noted by Dobhal et al., where majority of the children were in moderate (37%) groups[95].

The present study showed LAQ-CP values in Trihexyphenidyl group was 42.94+-16.05 (pre intervention) and 43.61+-16.89(post intervention) with p value of 0.16 and in gabapentin group it is 54.44+-19.66 (pre intervention) and 51.22+-21.83 (post intervention) with p value of 0.34. Present study did not show much improvement in the LAQ-CP values.

The study duration of just 3 months could be one reason that no notable changes in LAQ-CP scores were noted. A longer duration of study may reflect changes in the quality of life.

The Drooling Scale of the Teacher

This is a simple grading system for drooling at the bedside. It is graded on a scale of one to five, with the intensity of drooling increasing as we proceed up the scale. Drooling is divided into five categories: no drooling, rarely drooling, occasional drooling, frequent drooling, and persistent drooling.

This study showed the drooling score in trihexyphenidyl group to be 2.14+-1.34 pre intervention and post intervention it was 1.72+-0.99 with p value of 0.046 which was statistically significant. However, in gabapentin the pre intervention score was 2.08+-1.34 and post intervention score was 1.71+-2.08 with p value of 0.17 which was statistically insignificant and hence it shows that trihexyphenidyl has better action in controlling drooling. But when the post interventional scores of the two groups were compared it showed the p value of 0.85 which is statistically insignificant and hence both are comparable.

A study done by Carranza-del Rio J et al., showed that out of 101 patients enrolled for treatment for dystonia or sialorrhea, 61 (60.4%) reported improvement in sialorrhea with trihexyphenidyl[115].

Hence, trihexyphenidyl being an anticholinergic drug it reduces secretion of saliva and hence decreases drooling and so can be a good drug when excessive drooling is present as co-morbidity.

ADVERSE EFFECTS

Our study showed that n=21 (28.3%) of the children experienced adverse effects in various forms. 9 (24.32%) of the cases from trihexyphenidyl group had adverse effects when compared with 12 (32.43%) of cases of gabapentin group. Irritability was the most common adverse effect seen in 5 (13.5%) of total patients and was exclusively seen in gabapentin group (n=5,13.5%). Following this drooling and drowsiness stood together accounting for 5.4% each from over all sample size. Drooling accounted for 2 (5.4%) in trihexyphenidyl and 2 (5.4%) in gabapentin group. Drowsiness was more common in trihexyphenidyl reported in 3 (8.1%) patients. Fever was seen in 2 (54%) patients in trihexyphenidyl group and 1 (2.7%) of patients in gabapentin. 1 patient in gabapentin

group even showed aggravation of dystonia. This was in accordance to a study done by Pina M.A.[116] .

Overall we can see trihexyphenidyl is marginally better tolerated when compared with gabapentin. The side effects of drugs can also be utilized to treat the common problems of CP. For example cases of CP with excessive drooling trihexyphenidyl can be used and in those with associated seizures gabapentin can be used as it has anti seizure property.

COST ANALYSIS:

When looked into cost analysis, we found that trihexyphenidyl costed around Rs 372 (tablet) for total 1 month in a child with 10kg, whereas it was Rs 900 for gabapentin.

So in our country where most of the patients belong to lower socioeconomic class , the cost of the therapy plays an important role in deciding the treatment.

Trihexyphenidyl appears to be almost half of the cost of gabapentin, that would be the major advantage of trihexyphenidyl.

STRENGTHS.

- The present study was a prospective Randomized Controlled Trial on Dyskinetic Cerebral Palsy.
- The current study used objective method for Physiological classification of cerebral palsy and assessment.

- Physiotherapist were blinded to the intervention and did the assessment.

LIMITATIONS OF STUDY

- Our study was an open labelled Randomized Controlled Trial.
- Present study had non normal distribution of data. So a larger sample with normal distribution would have allowed us to use robust parametric test for the statistical analysis.
- We included mixed cerebral palsy cases where drugs like Baclofen which can affect dystonia were used.
- Physiotherapy which was done at home was not supervised/quantified.

RECOMMENDATIONS FOR FUTURE STUDIES

- Conducting a multi-centre study.
- Larger sample size.
- Compare pure dyskinetic CP and Mixed CP cases.
- Need to conduct closed label and Randomized Controlled Trial.

CONCLUSIONS

- In children with Dyskinetic CP (either predominantly dyskinetic or in mixed dystonic CP) drug intervention in the form of Trihexyphenidyl or Gabapentin shows clinical improvement in dystonia.
- The efficacy of Trihexyphenidyl in treating dystonia was comparable with the efficacy of gabapentin.
- Trihexyphenidyl costs 50% less and is also better tolerated than that of gabapentin.

SUMMARY

This study was conducted in KLES Dr Prabhakar Kore Hospital and Medical Research Centre, Belagavi from June 2020 to November 2021. 74 children with cerebral palsy between the age group 1-18 years attending the child developmental clinic were enrolled for the study after meeting inclusion criteria. They were randomized to two groups according to random number table and were subjected to Hypertonia Assessment Tool (HAT) for physiological classification of CP and then were subjected to Gross Motor Function Measure (GMFM), Barry Albright Dystonia Scale(BAD), Dystonia Severity Assessment Plan (DSAP) for assessing the severity of dystonia and finally Teachers Bedside Drooling Scale to know the grade of drooling . Parents were subjected to set of questionnaire for knowing the quality of life (LAQ-CP). According to the group randomized the study subjects were started on either Trihexyphenidyl or Gabapentin drug.

They were followed up at the end of 3 months and same assessment scores were used to study the clinical improvement in the child. The study results are summarized below:
The age distribution was from 1-18 years out of which, majority of the children i.e. n=56 (75.6%) were in the age group of 1-5 years and only 4 patients were above 10 years.
Mean age was 4.06 years in trihexyphenidyl group and 3.65 years in gabapentin group.

Male to female ratio was 1.46:1. While in trihexyphenidyl group it was 1.3:1 and in gabapentin group it was 1.6:1.

The most common neurological morbidity was Global developmental delay seen in n=36 (97.2%) in trihexyphenidyl group and n=34 (91.9%) in gabapentin group. Following this speech delay was the second most common neurological morbidity which was seen in 36(97.3%) patients in trihexyphenidyl group and 34 (91.9%) of the patients in gabapentin group. The third most common neurological problem observed was seizure accounting for 45.9% (17) in the trihexyphenidyl group and 45.9% (17) in gabapentin group. Hearing defect was present in 10 patients from trihexyphenidyl and 4 from gabapentin group. And lastly vision problems in the form of refractory errors and squint was seen in 7 (18.9%) in trihexyphenidyl and 6 (16.7%) of gabapentin group.

In our study most common non neurological comorbidity was constipation seen 24 (64.9%) participants from trihexyphenidyl group and 25 (67.6%) from gabapentin group. The second most common was caries tooth found in 14 (37.8%) patients fro trihexyphenidyl group and in 13 (35.1%) from gabapentin group. FTT was also encountered in 15 (40.5%) patients from trihexyphenidyl and in 12 (32.4%) patients from gabapentin group.
The distribution of co-morbidities among 2 groups is similar and is comparable.

This study showed, a total of 14 (18.91%) children had preterm gestation and 60 (81.08%) had term gestation. There were no post-datism babies. 16 (21.62%) out of 74 had LSCS as mode of delivery. PROM (premature rupture of membrane) is defined as rupture of membranes more than one hour before the onset of labour was seen in 6 (8.1%) cases, 2 (2.70%) in trihexyphenidyl and 4 (5.4%) in gabapentin group.

Delayed cry (referred to as babies who required assistance in terms of bag and ventilation immediately after birth) was seen in 41(55.4%) children with 20(54.05%) patients in trihexyphenidyl group and 21(56.8%) cases in gabapentin group and were comparable.

NICU admission was seen in 60(81.08%) subjects, with 29(78.4%) patients in trihexyphenidyl group and 31(83.8%) in gabapentin group.

Among topographical classification, Quadriplegic CP as most common type with total of 50 (67.56%) patients followed by Diplegic CP with 17 (22.9%) patients. Hemiplegic CP constituted for 5 (6.7%) cases. The distribution of different types of CP among the 2 groups as shown in above table is comparable with p value of 0.22 which is not statistically significant.

Current study showed dystonic CP in 20(27.02%) patients and mixed CP in 54 (72.9%) patients. Distribution of different types of CP in both groups was comparable with p value of 0.19(not statistically significant). For this physiological classification we used objective method I.e HAT(hypertonia assessment tool).
74 enrolled study subjects were randomised in to two groups with 37 patients in each group. Group 1 received Trihexyphenidyl and Group 2 received Gabapentin drugs according to the body weight.

Patients in each group were followed up after 3 months to know the clinical improvement based on BAD, DSAP, GMFM, TEACHERS BEDSIDE DROOLING SCALE and LAQ-CP.

-On comparison of DSAP values pre-intervention we found that 56 (75.6%) of subject were in category 1 and remaining 18 (24.32%) were in category 2 of dystonia severity plan with p value of 0.41 which was statistically insignificant. Hence, both the groups are comparable.
Post intervention it was found that 54 (80.5%) of subjects belonged to category 1 and 13 (19.4%) belonged to category 2. Here 7 patients were either lost to followup or expired. So here we can see that the overall percentage of cases from both the groups, post intervention increased in category 1 with increase of 4.7% in trihexyphenidyl group and 4.6% of increase in gabapentin group. Hence, both are comparable.

-Present study showed BAD score in trihexyphenidyl group was 11.11+-6.85 (pre intervention) and 8.44+-6.65 (post intervention) with improvement in BAD score of 2.66 and pre vs post p value of <0.001 which was statistically significant. In gabapentin group BAD score pre intervention was 9.49+-6.74 and post intervention was 6.69+-6.13 with overall improvement in score of 2.8 and pre vs post p value of <0.001.
However, the p value between the trihexyphenidyl and gabapentin group post intervention was 0.26 which was statistically insignificant and hence both the drugs were comparable.

-The pre intervention GMFM scores were almost same in both group with p value of 0.84 suggesting that pre intervention severity of disability was comparable in both group. Post intervention there was improvement in GMFM score in both group with 7.27 point in trihexyphenidyl group and 7.9 point in gabapentin group., however this difference is not statistically significant as the post intervention the p value between the two groups was 0.73 and hence both the drugs were comparable.

-In our study we found that most of the study population I.e 47.82% had moderate disability LAQ-CP scores, followed by Good scores in 26.08% and Mild in 13.04% and no severe cases. The present study showed LAQ-CP values in Trihexyphenidyl group was 42.94+-16.05 (pre intervention) and 43.61+-16.89(post intervention) with p value of 0.16 and in gabapentin group it is 54.44+-19.66 (pre intervention) and 51.22+-21.83 (post

intervention) with p value of 0.34. Present study did not show much improvement in the LAQ-CP values.

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-Our study ,showed that total 21 (28.3%) of the children experienced adverse effects in various forms. 9 (24.32%) of the cases from trihexyphenidyl group had adverse effects when compared with 12 (32.43%) of the cases from gabapentin group. Irritability was the most common adverse effect seen in 5 (13.5%) of total patients and was exclusively seen in gabapentin group (n=5,13.5%). Following this drooling and drowsiness stood together accounting for 5.4% each from over all sample size. Drooling accounted for 2 (5.4%) in trihexyphenidyl and 2 (5.4%) in gabapentin group. Drowsiness was more common in trihexyphenidyl reported in 3 (8.1%) patients. Fever was seen in 2 (54%) patients in trihexyphenidyl group and 1 (2.7%) of patients in gabapentin. 1 patient in gabapentin group even showed aggravation of dystonia.

-Average cost of the drug, for a 10kg child trihexyphenidyl costs around Rs 372. Gabapentin’s cost for a 10kg child in one month was around Rs 900 and hence, trihexyphenidyl was found to be a less expensive drug.

BIBLIOGRAPHY:

1. Shoals MG. Cerebral palsy: Diagnosis, Risk factors, Early intervention and Management of the spastic child. In: Datta AK, Sachdeva A, ed. Advances in pediatrics. New Delhi: Jaypee Publishers;2007.p.623.
2. Chauhan A, Singh M, Jaiswal N, Agarwal A, Zsahu JK. Prevalence of cerebral palsy in Indian Children: A systematic review and meta-analysis. Indian J pediatr. 2019 Dec;86(12): 1124-1130. Epub 2019 13.
3. Vyas AG, Kori VK, Rajagopala S, et al. Etiopathological study on cerebral palsy and its management by Shashtika Shali Pinda Sweda and Samvardhana Ghrita. Ayu. 2013 ;34:56-62.
4. Imms C.. Children with Cerebral palsy participate: A review of the literature. Disability and Rehabil, 2008;30:1867-1884.
5. Kamate M, Detroja M, Which is the most common physiological type of cerebral palsy? Neurology India (In press).
6. Rice j, Waugh MC. Pilot study on trihexyphenidyl in the treatment of dystonia in children with cerebral palsy. J Child Neurol. 2009 ;24:176-82.
7. Liow NY-K, Gimeno H, Lumsden DE, Marianczak J, Kaminska M, Tomlin S, Lin JP. Gabapentin can significantly improve dystonia severity and quality of life in children. Eur J Paediatr Neurol. 2016 ;20:100-7.
8. Raju TN. Historical perspectives on the etiology of cerebral palsy. Clin Perinatol. 2006 ;33:233-50.
9. Phelps W. The management of the cerebral palsy. J Am Med Assoc 1941;117:1621-5
10. Mayer-Gross, W.(1948) Psychopathology and Education of brain-injured child. By A.A. Strauss and L.E. Lehtinen New York: Grune and Stratton, 1947. Pp.206.46 illustrations. Journal of mental science,94(397), 852-853.
11. Darrah J, Walkins B, Chen L, Bonin C; AACPDM. Conductive education intervention for children with cerebral palsy: an AACPDM evidence report. Dev Med Child Neurol 2004;46:187-203.
12. Keith RC, Mackenzie IC, Polani PE. The Little Club: Memorandum on Terminology and Classification of “Cerebral Palsy”. Developmental Medicine & Child Neurology. 1959;1:27-35.
13. Bax MC. Terminology and classification of cerebral palsy. Dev Med Child Neurol. 1964;6:295-7.

14. Mutch L, Alberman E, Hagberg B, Kodama K, Perat MV. Cerebral palsy epidemiology: where are we now and where are we going?. Dev Med Child Neurol. 1992;34:547-51
15. Richards CL, Malouin F. Cerebral palsy: definition, assessment and rehabilitation. Handb clin neurol 2013; 111:183-95.
16. Bhati P, Sharma S, Jain R, Rath B, Beri S, Gupta VK, et al. Cerebral Palsy in North Indian Children: Clinico-etiological Profile and Comorbidities. J Pediatr Neurosci. 2019;14:30-35.
17. Paneth N, Hong T, Korzeniewski S. The descriptive epidemiology of cerebral palsy. Clin Perinatol. 2006 ;33:251-67.
18. Prevalence and characteristics of children with cerebral palsy in Europe. Dev Med Child Neurol. 2002;44:633-40.
19. Oskoui M, Coutinho F, Dykeman J, Jette N, Pringsheim T. An update on the prevalence of cerebral palsy: a systematic review and meta-analysis. Dev Med Child Neurol. 2013;55:509-19.
20. Gladstone M. A review of the incidence and prevalence, types and aetiology of childhood cerebral palsy in resource-poor settings. Ann Trop Paediatr. 2010;30:181-96.
21. Kathy J. Incidence of Cerebral Palsy Remains Constant in India on Indian Health News.[Internet].[Updated on 2010 Oct 04; Accessed on 2013 Jan 22].
22. World Health Organization. Disability prevention and rehabilitation: report of the WHO Expert Committee on Disability Prevention and Rehabilitation [meeting held in Geneva from 17 to 23 February 1981].
23. American Academy of Pediatrics. Neonatal Encephalopathy and Neurologic Outcome, Second Edition Report of the American College of Obstetricians and Gynecologists' Task Force on Neonatal Encephalopathy. Pediatrics. 2014;133:e1482-8.
24. Monokwane B, Johnson A, Gambrah-Sampaney C, Khurana E, Baier J, Baranov E, et, al. Risk factors for cerebral palsy in children in Botswana. Pediatr neurol. 2017;77:73-77.
25. Gulati S, Sondhi V. Cerebral palsy: an overview. Indian J Pediatr. 2018;85:1006-1016.

26. Vohr BR, Wright LL, Poole WK, McDonald SA. Neurodevelopmental outcomes of extremely low birth weight infants< 32 weeks' gestation between 1993 and 1998. Pediatrics. 2005;116:635-43.
27. Escobar GJ, Littenberg B, Petitti DB. Outcome among surviving very low birthweight infants: a meta-analysis. Arch Dis Child. 1991;66:204-11.
28. Krägeloh-Mann I, Cans C. Cerebral palsy update. Brain and development. 2009;31:537-44.
29. Wu YW, Croen LA, Shah SJ, Newman TB, Najjar DV. Cerebral palsy in a term population: risk factors and neuroimaging findings. Pediatrics. 2006;118:690-7.
30. Sewell MD, Eastwood DM, Wimalasundera N. Managing common symptoms of cerebral palsy in children. BMJ. 2014;349:g5474.
31. Jarvis S, Glinianaia SV, Arnaud C, Fauconnier J, Johnson A, McManus V, et al,SCPE collaboration of European CP Registers. Case gender and severity in cerebral palsy varies with intrauterine growth. Arch Dis Chil. 2005;90:474-9.
32. Kirton A, deVeber G. Paediatric stroke: pressing issues and promising directions. Lancet Neurol. 2015;14:92-102.
33. Surveillance of cerebral palsy in Europe: a collaboration of cerebral palsy surveys and registers. Dev Med Child Neurol.2000;42:816-24.
34. Compagnone E, Maniglio J., Camposeo S, Vespino T, Losito L, De Rinaldis M, et al, Functional classification for cerebral palsy: Correlations between the gross motor function classification system (GMFCS), the manual ability classification system (MACS) and the communication function classification system (CFCS). Res Dev Disabil. 2014; 35: 2651-2657.
35. Susan A. R, Deirdre D. R, Robert M. K. Classification systems in cerebral palsy. Orthop Clin N Am 41 (2010) 457-467.
36. Vykuntaraju KN. Cerebral palsy and early stimulation. 1/e.New Delhi Jaypee;2014.
37. Novak I, Hines M, Goldsmith S, Barclay R. Clinical prognostic messages from a systematic review on cerebral palsy. Pediatrics. 2012;130:e1285-312.
38. Jones MW, Morgan E, Shelton JE, Thorogood C.. Cerebral palsy: introduction and diagnosis (part I). J Pediatr Health Care. 2007;21:146-52.
39. Harb A, Kishner S. Modified Ashworth Scale. 2021 May 9. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021.

40. Kancherla V, Amendah DD, Grosse SD, Yeargin-Allsop M, Van Naarden Braun K. Medical expenditures attributable to cerebral palsy and intellectual disability among Medicaid-enrolled children. Res dev disabil. 2012 ;33:832-40.
41. Rosenbaum P, King S, Law M, King G, Evans J. Family-centred service: A conceptual framework and research review. Physical & Occupational Therapy in Pediatrics. 1998 ;18:1-20.
42. Patel DR, Neelakantam M, Pandher K, Merrick J. Cerebral Palsy in children: a clinical overview. Transl Pediatr. 2020 Feb;9:S125-S135.
43. Dod K, Imms C, Taylor NF. Editors. Physiotherapy and occupational therapy for people with cerebral palsy: A Problem based Approach to Assessment and Management. London:Mac Keith Press, 2010:73-281.
44. Das SP, Ganesh GS. Evidence -based approach to physical therapy in cerebral palsy. Indian J Orthop 2019;53:20-34.
45. Patel DR. Therapeutic interventions in cerebral palsy. Indian J Pediatr. 2005;72:979-83..
46. Dewar R, Love S, Johnston LM. Exercise interventions improve postural control in children with cerebral palsy: a systemic review. Dev Med Child Neurol 2015;57:504-20.
47. Kaya Kara O, Livanelioglu A, Yardrmci BN, Soylu AR. The effects of functional progressive strength and power training in children with unilateral cerebral palsy. Pediatr Phys Ther 2019;31:286-295.
48. Mall V. Treadmill therapy in cerebral palsy. Eur J Pediatr Neurol 2019;23:543.
49. Valentin-Gudiol M, Mattern-Baxter K, Girabent-Farres M, Bagur-Calafat C,Hadders-Algra M, Angulo-Barroso RM. Treadmill Interventions in children under six years of age at risk of neuromotor delay.Cochrane Database syst Rev2017;7:CD009242.
50. Chrysagis N, Skordilis EK, Stavrou N, Grammatopoulou E, Koutsouki D. The effect of treadmill training on gross motor function and walking speed in ambulatory adolescent with cerebral palsy: a randomized controlled trial. Am J Phys Med Rehabil 2012;91:747-60.
51. Valentin -Gudiol M, Mattern-BaxterK, Girabent-Farres M, Bagur-Calafat C, Hadders-Algra M, Angulo-Barroso RM. Treadmill intervention with partial body weight support in children under six years of age at risk of neuromotor delay. Cochrane Database Syst Rev 2011;(12):CD009242.

52. Novak I, McIntyre S, Morgan C, Campbell L, Dark L, Morton N, et al. A systemic review of intervention for children with cerebral palsy: state of the evidence. Dev Med Child Neurol 2013;55:885-910.
53. Carvalho I, Pinto SM, Chagas DDV, Praxedes Dos Santos JL, de Sousa Oliveira T, Batista LA. Robotic gait training for individuals with cerebral palsy: a syst review and meta analysis. Arch Phys Med rehabl 2017; 98:2332-44.
54. Johnson TL, Chin EM, Hoon AH. Cerebral palsy. In: Batshaw Ml, Roizen NJ, Pellegrino L editors. Children with disability and youth with with cerebral palsy. 8th edition. Baltimore : Paul Brooks, 2019; 423-56.
55. Liptak GS, Murphy NA, Council on children with Disabilities. Providing a primary care medical home for children and youth with cerebral palsy. Pediatric 2011;128:e1321-9.
56. Blumetti FC, Wu JCN , Barzi F, Axt MW, Waugh MC, Selber P. Orthopedic surgery in dystonic cerebral palsy. J pediatr Orthop 2019;39:209-16.
57. Bovid KM, Patel DR. Orthopedic considerations. In: Rubin IL, Merrick J, Greydanus DE. Editors. Healthcare for people with intellectual and developmental disabilities across the lifespan. Cham: springer international publishing, 2016:1107-22.
58. Individuals with disabilities act. Statue and regulations. Available online: https://sites.ed.gov/idea/statuteregulations/
59. Desch LW. The spectrum of assistive and augmentive technology for individuals with developmental disabilities. In: Accardo PJ. Editor. Capture and Accardo's neurodevelopmental disabilities in infancy and childhood. 3rd edition. Baltimore: Paul H. Brookes, 2008:691-720.
60. Cusack SR. Assistive technology. In: Rubin IL, Crocker AC. Editors. Medical care for children and adults with developmental disabilities. 2nd ed. Baltimore : Paul H. Brookes, 2008:548-56.
61. Salazar AP, Pagnussat AS, Pereira GA, Scopel G, Lukrafka JL. Neuromuscular electrical stimulation to improve gross motor function in children with cerebral palsy: a meta-analysis. Braz J Phys Ther .2019;23:378-386.
62. Sanchez-Kuhn A, Perez-Fernandez C, Canovas R, Flores P, Sanchez-Santed F. Transcranial direct current stimulation as a motor neurorehabilitation tool: an empirical review. Biomed eng online 2017;16(Suppl 1):76.

63. Bosques G, Martin R, McGee L Sadowsky C. Does therapeutic electrical stimulation improve function in children with disabilities? A comprehensive literature review. J Pediatr Rehabil Med 2016;9:83-99.
64. Karadag-sayg E, Giray E. The clinical aspect and effectiveness of suit therapies for cerebral palsy: a systematic review. Turk J Phys Med Rehabl 2019;65:93-110.
65. Sahin S, Kose B, Aran OT, Bahadir Agce Z, Kayihan H. The effects of virtual reality on motor function and daily life activities in unilateral spastic cerebral palsy: a single-blind randomised controlled trial. Games Health J 2020;9:45-52.
66. Tekin F, Kavlak E, Cavlak U, Altug F. Effectiveness of neuro-developmental treatment on postural control and balance in cerebral palsied children. J Back Musculoskeletal Rehabl 2018;31:397-403.
67. Martin valero R, Vega-Ballon J, Perez-Cabezas V. Benefits of hippo therapy in children with cerebral palsy: a narrative review. Euro J Pediatr Neurol 2018;22:1150-60.
68. Pavao SL, Rocha NACF. Sensory processing disorders in children with cerebral palsy. Infant Behav Dev 2017;46:1-6.
69. Jing G. Summary of curative effects of scalp acupuncture exercise therapy on spastic cerebral palsy. Ann Phys rehabl Med 2018;61:e322.
70. Li LX, Zhang MM, Zhang Y , He J. Acupuncture for cerebral palsy: a metaanalysis of randomised controlled trials. Neural Regen Res 2018;13:1107-17.
71. Kulak-Bejda A, Kulak P, Bejda G, Krajewska-Kulak, E, Kulak W. Stem cells therapy in cerebral palsy: a systematic review. Brain dev 2016;38:699-705.
72. Boruckzkowski D, Pujal JM, Zdolinska-Malinowska I. Autologous cord blood in children with cerebral palsy: a review. Int J Mol Sci 2019.;20:2433.
73. Novak I, Walker K, Hunt RW, Wallace EM, Fahey M, Badawi N. Concise review: stem cell interventions for people with cerebral palsy:systematic review with meta analysis. Stem cells transl med 2016;5:1014-25.
74. Sections on Complementary and Integrative Medicine; Council on Children with Disabilities; American Academy of pediatrics, Zimmer M, Desch L. Sensory integration therapies for children with developmental and behavioral disorders. Pediatrics 2012;129:1186-9.
75. Alves-pinto A, Turova V, Blumenstein T, Lampe R. The case for musical instrument training in cerebral palsy for neurorehabilitation. Neural Plast 2016;2016:1072301.

76. Tarakci D, Ozdincler AR, Taracki E, Tutuncuoglu F, Ozmen M. Wii-based balance therapy to improve balance function of children with cerebral palsy: a pilot study . J Phys Ther Sci 2013;25:1123-7.
77. Vernon-Roberts A, Sullivan PB. Fundoplication versus postoperative medication or gastro-oesophageal reflux in children with neurological impairment undergoing gastrostomy. Cochrane Database Syst Rev.2013(8):CD006151.
78. Lespargot A, Langevin MF, Muller S, Guillemont S. Swallowing disturbances associated with drooling in cerebral-palsied children. Dev Med Child Neurol. 1993;35:298-304.
79. Greensmith AL, Jhonstone BR, Reid SM, Hazard CJ, Jhonson HM, Reddihough DS. Prospective analysis of the outcome of surgical management of drooling in the pedaitric population: a 10-year experience. Plastic and reconstructive surgery. 2005;116:1233-42.
80. Taylor DC. Counselling the parents of handicapped chiildren. Br Med J(Clin Res Ed). 1982;284:1027-8
81. Zafeiriou DI, Kontopoulos EE, Tsikoulas I. Characteristics and prognosis of epilepsy in children with cerebral palsy. Journal of Child Neurology. 1999;14:289-94.
82. Parkinson KN, Gibson L, Dickinson HO, Colver AF. Pain in children with cerebral palsy: a cross-sectional multicentre European study. Acta Paediatr. 2010;99:446-51..
83. Parkinson KN, Dickinson HO, Arnaud C, Lyons A, Colver A; SPARCLE group. Pain in young people aged 13 to 17 years with cerebral palsy: cross-sectional, multicentre European study. Arch Dis Child. 2013;98:434-40.
84. Castle K, Imms C, Howie L. Being in pain: a phenomenological study of young people with cerebral palsy. Developmental medicine & child neurology. 2007 ;49:445-9.
85. Pennington L, Goldbart J, Marshall J. Speech and language therapy to improve the communication skills of children with cerebral palsy. Cochrane Database of Systematic Reviews. 2004(2).
86. Dursun E, Dursun N, Alican D. Effects of biofeedback treatment on gait in children with cerebral palsy. Disability and rehabilitation. 2004 ;26:116-20.
87. Bloom R, Przekop A, Sanger TD. Prolonged electromyogram biofeedback improves upper extremity function in children with cerebral palsy. Journal of child neurology. 2010 ;25:1480-4.

88. The WHOQOL Group. Development of the WHOQOL rationale and current status. International Journal of Mental Health. 1994;23:24-56

89. Stewart, K. Measuring Well being and Exclusion in Europe's Regions. 2002. Case Paper 53, London: centre for Analysis of social Exclusion, London School of Economics.

90. Varni, J. W., Seid, M. S. & Kurtin, P.S. PedsQL^{TM} 4.0: reliability and validity of the pedaitric quality of life inventory^{TM} version 4.0 generic core scales in healthy and patients populations. Medical Care. 2001;39:800-812.

91. Vogels, T., Verrips, G.H. W., Verloove-Vanhorick, S. P., Fekkes, M., Kamphius, R. P., Koopman, H. M.,et al. Measuring health-related quality of life in children: the development of the TACQOL parent form. Quality of life research. 1998;457-465.

92. Narayanan U. G., Fehling D. L, Campbell K, Weire S, Knights S, Kiran S. Initial development and validation of the caregiver priorities and child health index of life with disabilities(CPCHILD). Dev Med Child Neurol. 2006;48:804-12.

93. Mackie P.C, Jessen E.C, Jarvis S N. The lifestyle Assessment Questionnaire: An instrument to measure the impact of disability on the lives of children with cerebral palsy and their families. Child: care, health & development. 1998;24:473-486.

94. Tsoi WS, Zhang LA, Wang WY, Tsang KL, Lo SK. Improving quality of life of children with cerebral palsy: a systematic review of clinical trials. Child Care Health Dev. 2012;38:21-31.

95. Dobhal M, Juneja M, Jain R, Sairam S, Thiagarjan D. Health-related quality of life in children with cerebral palsy and their families. Indian pediatr. 2014;51:385-7.

96. Termsarasab P, Thammongkolchai T, Frucht SJ. Medical treatment of dystonia. J Clin Mov Disord. 2016;3:19.

97. Benarroch EE. Effect of acetylcholine in the striatum. Recent insights and therpaeutic implications. Neurology. 2012;79:274-81.

98. Pisani A, Bernardi g, Ding J, Surmeier DJ. Re emergence of striatal cholinergic interneurons in movement disorder. Trends Neurosci. 2007;30:545-53.

99. Jankovic J, Hallett M, Fahn S. In: Principles and practices of movement disorders; Elsevier Health Sciences.2011.p.293-310.

100. FehlingD, Brown L, Harvey A, Himmelmann K, Lin JP, Macintosch A, et al. Pharmacological and neurosurgical interventions for managing dystonia in cerebral palsy: a systematic review. Dev Med Child Neurol. 2018 ;60:356-366.

101. Lumsden DE, Crowe B, Basu A, Amin S, Devlin A, DeAlwis Y. Pharmacolgical management of abnormal tone and movement in cerebral palsy. Arch Dis Child. 2019;104;775-780.

102. Lubarr N, Bressman S. Treatment of generalized dystonia. Curr Treat options Neurol 2011;13:274-89.

103. Harvey A, Waugh MC, Rice J, Antolovich G, Copeland L, Orsini F. A pilot feasibility study of gabapentin for managing pain in children with dystonic cerebral palsy. BMC Pediatr. 2021; 21:36.

104. Harvey AR, Baker LB, Reddihough DS, Scheinberg A, Williams K. Trihexyphenidyl for dystonia in cerebral palsy. Cochrane Database of systematic review 2018. Issue 5. Art No.:CD12430.

105. Sanger TD,Delgado MR, Gaebler-Spira D, Hallett M, Mink JW. Task Force on Childhood Motor Disorders. Classification and definition of disorders causing hypertonia in childhood. Pediatrics 2003;111:e89-97.

106. Allen NM, Lin J-P, Lynch T, king MD. Status dystonicus:a practise guide. Developmental medicine and child neurology 2014;56:105-12.

107. Najar BA, Kachroo A, Gattoo IA, Hussain SQ. Cerebral palsy: Risk factors, co morbidities and associated MRI findings, a hospital based observational study. International journal of contemporary pediatrics. 2015;2:90.

108. Yilmaz Yalcinkya E, Huner B, Dincer U, Diracoglu D. Demographic and clinical findings in cerebral palsy patients in Istanbul: a multi centre study. Turkish journal of physical medicine and rehabilitation. 2014;60(2).

109. Gowda VK, Kumar A, Shivappa SK, Srikanteswara PK, shivananda, Mahadeviah MS, et al. Clinical profile, predisposing factors , and associated co morbidities of children with cerebral palsy in south india. J pedaitr neurosci. 2015;10:108-13.

110. Subramaniam ND, Jenifer A, Devi U, Suresh P. Etiology, outcome and co-morbidities among cerebral palsy children attending tertiary care hospital, India : a prospective study. Inter J contemp pedaitr,2019;6:1023.

111. Hollung SJ, Bakken IJ, Vik T, Lydersen S, Wilk R, Aaberg Km, et al. Comorbidities in cerebral palsy: a patient registry study. Dev Med Child Neurol. 2020;62:97-103.

112. Mynarek M, Bjellmo S, Lydersen S, Strand Km, Afset JE, Andersen GL, et al. prelabor rupture of membranes and the association with cerebral palsy in term born children; a national registry-based cohort study. BMC pregnancy childbirth. 2020;20:67.

113. Minocha P, Sitaraman S, sachdeva P. Clinical spectrum, co morbidities, and risk factors profile of cerebral palsy children: A prospective study. J pediatr Neurosci. 2017;12:15-18.
114. Foley J. Dyskinetic and dystonic cerebral palsy and birth. Acta paediatr. 1992;81:57-60; discussion 93-4.
115. Carranza-del Rio J, Clegg NJ, Moore A, Delagdo MR. Use of trihexyphenidyl in children with cerebral palsy. Pediatr Neurol. 2011;44:202-6.
116. Pina MA, Modrego PJ. Dystonia induced by gabapentin. Ann Pharcmacother. 2005;39:380-2.

ANNEXURE I- CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH

Principal Investigator :

Co – investigator :

You have been asked to involve your child in the above said research to be conducted at KLE university's JN medical college hospital, Belgaum by, PG student in the Department of Paediatrics at Jawaharlal Nehru Medical College, Belgavi.

Introduction

PURPOSE OF THE STUDY: Participation of your child will help us know the clinical efficacy between the 2 drugs I.e trihexyphenidyl vs gabapentin in the treatment of dystonia in children with dyskinetic and mixed CP. You are free to discontinue the participation in the study at any time for any reason and you will not be paid any reimbursement for participation the research. Hence involving your child in the study is your voluntary decision.

Voluntary participation

Your child's participation in this study is your voluntary decision, whether or not to participate will not affect your current or future relationship with KLES Dr. Prabhakar Kore
Hospital & MRC, Belgavi.

Risk and benefits

There are no risks involved.
Reduction in morbidity and mortality .

Privacy and Confidentiality

The only people who will know that you are a research participant are member of the research team. No information about you or provided by you, during research will be

disclosed to others without your written consent. When the results of the research are published or discussed in the conferences, no information will be disclosed that would reveal your identity. Any information obtained in connections with this study and that can be identified with you remain confidential and will be disclosed only with your permission.

Queries

If you have any queries you may contact
Post Graduate Student
Department of Pediatrics
JNMC ,Belagavi-590010
Phone No. 8867165220

PROFESSOR DEPARTMENT OF PAEDIATRICS,
JNMC ,Belagavi-590010
Phone No._____ Ext no.

If you have any questions about your rights or research participation you may contact Chairman ethical committee:

PROFESSOR
DEPARTMENT OF PAEDIATRICS,
K.L.E UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAVI-590010

You will be given a copy of this form for your information and to keep for your records.

STATEMENT OF CONSENT

I hereby voluntarily agree for my participation in this study. I understand that even if I have the liberty to withdraw at any time. My signature below indicates that I have read or have been told in the language I understand , about this entire consent form including the risks and benefits and have had all my questions answered. I will be given a copy of this consent form.

Signature of the authorized representative/ parent: _____

Date: _____

Name: _____

Relation to the Subject: _____

Signature of the witness: _____

Date: _____

Name: _____

Signature of investigator: _____

Date: _____

Name: _____

ANNEXURE II- Proforma

NAME:

AGE/SEX:

HOSPITAL NO.:

DATE OF EVALUATION:

MOTHER AGE:

PHONE NO. :

ADDRESS:

PRESENTING COMPLAINTS:

1. Developmental delay	A. Motor	B. Language	C. Social or fine
2. Abnormal posture/ movement	A. Absent	B. Present	C. Myoclonic

3. Current reason for coming to OPD:

COMORBIDITIES:

1. Neurological:

A. Epilepsy	
B. Global developmental delay	
C. Mental retardation	
D. Hyperactivity	
E. Hearing problem	
F. Speech delay	
G. Vision problem	
H.	

2. Medical:

A. Gastrointestinal system:

i.Caries tooth	
ii.Constipation	
iii.Bleeding PR	
iv.Gastro esophagial reflux	

B. Respiratory system:

i. Acute respiratory tract infection	
ii. Asthama	
iii.	

C. Musculo skeletal system:

i. Contracture	
ii. Fractures	
iii. Kyphoscoliosis	
iv. Subluxation of hip joint	

D. Dermatology:

i. Callosities	
ii. Ulcers	
iii. Pyoderma	
iv. Scabies	

E. Nutrition :

i. FTT	
ii. Obesity	

CAUSES:

1. Prenatal:

A. Structural malformation of CNS	
B. Congenital or intrauterine infections	
C. Maternal or obstetric complications	
D. Teratogens	

2. Perinatal:

A. Birth asphyxia	
B. Prematurity	
C. LBW/VLBW	
D. Birth trauma	
E. ICH/IVH	
F. Hyperbilirubinemia	
G. Hypoglycemia	
H.CNS infections	

3. Post natal:

A. CNS infection	
B. Hypoxia	
C. Trauma	
D. ICH	
E. Hypoglycemia	
F. Hyperpyrexic damage	
G. Toxins	

BIRTH WEIGHT:

DEVELOPMENTAL MILESTONES:

1. GROSS MOTOR	Age	2. FINE MOTOR	Age
A. Neck holding		A. Bidextrous reach	
B. Rolling over		B.Immature pincer grasp	
C. Sits with support		C.Pincer grasp	
D. Sits without support		D.Tower of 2	
E. stands		F. Tower of 6	
G. Walks		H. Tower of 9	
INFERENCE:		**INFERENCE:**	

3.SOCIAL	Age	4.LANGUAGE	Age
A. Social smile		A. Alert to sound	
B. Recognizes mother		B.Coos	
C. Stranger anxiety		C.Monosyllable	
D. Waves bye bye		D. Bisyllable	
E. Copies parents in task		E.1-2 words	
F. Goes to toilet alone		F.2-3 words	
INFERENCE:		**INFERENCE:**	

Examination:

1. Vitals signs :

A. HR: B. RR: C. Hydration:

2. Anthropometry:

	Measured	Comments
A. Height		I.N, ii.<3rd , iii>3rd
B. Head circumference		
C. Weight		

3. CENTRAL NERVOUS SYSTEM:

A. Behavioral problem:

i. Hyperactive	
ii.Irritable	
iii. Apathy	

B. HAT:

i. Dystonic	
ii. Mixed	

C. BAD:

D.DSAP:

DRUGS DOSAGE:
Dosage of trihexyphenidyl is:
Week 1 0.2 mg/kg/d in 3 divided doses
Week 2 0.5 mg/kg/d in 3 divided doses
Week 3 1.0 mg/kg/d in 3 divided doses
Week 4 2.0 mg/kg/d in 3 divided doses
Week 5 2.0 mg/kg/d in 3 divided doses
Week 6 2.0 mg/kg/d in 3 divided doses
Week 7-12 2.0 mg/kg/d in 3 divided doses

-dosage of gabapentin:
Week 1 10 mg/kg/d in 3 divided doses
Week 2 20 mg/kg/d in 3 divided doses
Week 3 30 mg/kg/d in 3 divided doses
Week 4 40 mg/kg/d in 3 divided doses
Week 5 40 mg/kg/d in 3 divided doses
Week 6 40 mg/kg/d in 3 divided doses
Week 7-12 40mg/kg/d in 3 divided doses

FOLLOW-UP:
1. 0 month (0 weeks):
A. Scores:
i. GMFM:
ii. LAQCP:
iii. BAD:
iv. HAT:
v. DSAP**:**

2. 1st month (4 weeks):
A. Compliance:
B. Side effects:

3. 3rd month (12 weeks):

A. Scores:

i. GMFM:
ii. LAQCP:
iii.BAD:
iv.HAT:
v.DSAP**:**

B. Compliance:

C. Side effects:

DIAGNOSIS:

1. Topographical:

A. Quadriplegic	
B. Hemiplegic	
C. Monoplegic	
D. Diplegic	

2. Physiological:

A. Spastic:

i. Quadriplegic	
ii. Hemiplegic	
iii.Diplegic	

B. Dyskinetic:

i. Dystonic	
ii. Choreoathetoid	

C. Ataxic

D. Mixed

ASSESEMENT TOOLS:

0 WEEK **4 WEEKS**

12 WEEKS

SCORES	BASELINESCORE	PRE POST ASSESS ASSESS		PRE POST ASSESS ASSESS	
1. BAD					
2.DSAP					
3.HAT					
4.GMFM					
5.LAQCP					

SIDE EFFECTS: A. TRIHEXYPHENYDIL.

SIDE EFFECTS	**4WEEK**	**12WEEKS**
1.AGITATION		
2.DRY MOUTH		
3.CONSTIPATION		
4.CONFUSION		
5.DIZZINESS		
6.URINARY RETENTION		
7.POOR SLEEP		
8.OTHERS		

SIDE EFFECTS: B. GABAPENTIN:

SIDE EFFECTS	**4 WEEEK**	**12 WEEKS**
1. DIZZINESS		
2.DROWSINESS		
3.SEDATION		
4.FEVER		
5. FATIGUE		
6. VIRAL INFECTION		
7. ATAXIA		
8. NYSTAGMUS		

ANNEXURE III- GMFM Score Sheet

GROSS MOTOR FUNCTION MEASURE (GMFM)
SCORE SHEET (GMFM-88 and GMFM-66 scoring)

Child's Name: _____ ID#: _____

Assessment Date: _____ year / month / day

GMFCS Level[1]: ☐ I ☐ II ☐ III ☐ IV ☐ V

Date of Birth: _____ year / month / day

Chronological Age: _____ year / month / day

Evaluator's Name: _____

Testing Condition (e.g., room, clothing, time, others present):

_____

The GMFM is a standardized observational instrument designed and validated to measure change in gross motor function over time in children with cerebral palsy. The scoring key is meant to be a general guideline. However, most of the items have specific descriptors for each score. It is imperative that the guidelines contained in the manual be used for scoring each item.

SCORING KEY

0 = does not initiate
1 = initiates
2 = partially completes
3 = completes
9 (or leave blank) = not tested (NT) [used for the GMAE-2 scoring*]

It is important to differentiate a true score of "0" (child does not initiate) from an item which is Not Tested (NT) if you are interested in using the GMFM-66 Ability Estimator (GMAE) Software.

*The GMAE-2 software is available for downloading from www.canchild.ca for those who have purchased the GMFM manual. The GMFM-66 is only valid for use with children who have cerebral palsy.

Contact for Research Group:
CanChild Centre for Childhood Disability Research,
Institute for Applied Health Sciences, McMaster University,
1400 Main St. W., Room 408,
Hamilton, ON Canada L8S 1C7
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CanChild Centre for Childhood Disability Research

[1]GMFCS level is a rating of severity of motor function. Definitions for the GMFCS-E&R (expanded & revised) are found in Palisano et al. (2008). Developmental Medicine & Child Neurology. 50:744-750 and in the GMAE-2 scoring software. http://motorgrowth.canchild.ca/en/GMFCS/resources/GMFCS-ER.pdf

Check (3) the appropriate score: if an item is not tested (NT), circle the item number on the right column

	Item	A: LYING & ROLLING	SCORE				NT
	1.	SUP, HEAD IN MIDLINE: TURNS HEAD WITH EXTREMITIES SYMMETRICAL	0☐	1☐	2☐	3☐	1.
*	2.	SUP: BRINGS HANDS TO MIDLINE, FINGERS ONE WITH THE OTHER	0☐	1☐	2☐	3☐	2.
	3.	SUP: LIFTS HEAD 45°	0☐	1☐	2☐	3☐	3.
	4.	SUP: FLEXES R HIP & KNEE THROUGH FULL RANGE	0☐	1☐	2☐	3☐	4.
	5.	SUP: FLEXES L HIP & KNEE THROUGH FULL RANGE	0☐	1☐	2☐	3☐	5.
*	6.	SUP: REACHES OUT WITH R ARM, HAND CROSSES MIDLINE TOWARD TOY	0☐	1☐	2☐	3☐	6.
*	7.	SUP: REACHES OUT WITH L ARM, HAND CROSSES MIDLINE TOWARD TOY	0☐	1☐	2☐	3☐	7.
	8.	SUP: ROLLS TO PR OVER R SIDE	0☐	1☐	2☐	3☐	8.
	9.	SUP: ROLLS TO PR OVER L SIDE	0☐	1☐	2☐	3☐	9.
*	10.	PR: LIFTS HEAD UPRIGHT	0☐	1☐	2☐	3☐	10.
	11.	PR ON FOREARMS: LIFTS HEAD UPRIGHT, ELBOWS EXT., CHEST RAISED	0☐	1☐	2☐	3☐	11.
	12.	PR ON FOREARMS: WEIGHT ON R FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD	0☐	1☐	2☐	3☐	12.
	13.	PR ON FOREARMS: WEIGHT ON L FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD	0☐	1☐	2☐	3☐	13.
	14.	PR: ROLLS TO SUP OVER R SIDE	0☐	1☐	2☐	3☐	14.
	15.	PR: ROLLS TO SUP OVER L SIDE	0☐	1☐	2☐	3☐	15.
	16.	PR: PIVOTS TO R 90° USING EXTREMITIES	0☐	1☐	2☐	3☐	16.
	17.	PR: PIVOTS TO L 90° USING EXTREMITIES	0☐	1☐	2☐	3☐	17.
		TOTAL DIMENSION A					

	Item	B: SITTING	SCORE				NT
*	18.	SUP, HANDS GRASPED BY EXAMINER: PULLS SELF TO SITTING WITH HEAD CONTROL	0☐	1☐	2☐	3☐	18.
	19.	SUP: ROLLS TO R SIDE, ATTAINS SITTING	0☐	1☐	2☐	3☐	19.
	20.	SUP: ROLLS TO L SIDE, ATTAINS SITTING	0☐	1☐	2☐	3☐	20.
*	21.	SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD UPRIGHT, MAINTAINS 3 SECONDS	0☐	1☐	2☐	3☐	21.
*	22.	SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD MIDLINE, MAINTAINS 10 SECONDS	0☐	1☐	2☐	3☐	22.
*	23.	SIT ON MAT, ARM(S) PROPPING: MAINTAINS, 5 SECONDS	0☐	1☐	2☐	3☐	23.
*	24.	SIT ON MAT: MAINTAIN, ARMS FREE, 3 SECONDS	0☐	1☐	2☐	3☐	24.
*	25.	SIT ON MAT WITH SMALL TOY IN FRONT: LEANS FORWARD, TOUCHESTOY, RE-ERECTS WITHOUT ARM PROPPING	0☐	1☐	2☐	3☐	25.
*	26.	SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S R SIDE, RETURNS TO START	0☐	1☐	2☐	3☐	26.
*	27.	SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S L SIDE, RETURNS TO START	0☐	1☐	2☐	3☐	27.
	28.	R SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0☐	1☐	2☐	3☐	28.
	29.	L SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0☐	1☐	2☐	3☐	29.
*	30.	SIT ON MAT: LOWERS TO PR WITH CONTROL	0☐	1☐	2☐	3☐	30.
*	31.	SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER R SIDE	0☐	1☐	2☐	3☐	31.
*	32.	SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER L SIDE	0☐	1☐	2☐	3☐	32.
	33.	SIT ON MAT: PIVOTS 90°, WITHOUT ARMS ASSISTING	0☐	1☐	2☐	3☐	33.
*	34.	SIT ON BENCH: MAINTAINS, ARMS AND FEET FREE, 10 SECONDS	0☐	1☐	2☐	3☐	34.
*	35.	STD: ATTAINS SIT ON SMALL BENCH	0☐	1☐	2☐	3☐	35.
*	36.	ON THE FLOOR: ATTAINS SIT ON SMALL BENCH	0☐	1☐	2☐	3☐	36.
*	37.	ON THE FLOOR: ATTAINS SIT ON LARGE BENCH	0☐	1☐	2☐	3☐	37.
		TOTAL DIMENSION B					

Item		C: CRAWLING & KNEELING	SCORE				NT
	38.	PR: CREEPS FORWARD 1.8m (6')	0☐	1☐	2☐	3☐	38.
*	39.	4 POINT: MAINTAINS, WEIGHT ON HANDS AND KNEES, 10 SECONDS	0☐	1☐	2☐	3☐	39.
*	40.	4 POINT: ATTAINS SIT ARMS FREE	0☐	1☐	2☐	3☐	40.
*	41.	PR: ATTAINS 4 POINT, WEIGHT ON HANDS AND KNEES	0☐	1☐	2☐	3☐	41.
*	42.	4 POINT: REACHES FORWARD WITH R ARM, HAND ABOVE SHOULDER LEVEL	0☐	1☐	2☐	3☐	42.
*	43.	4 POINT: REACHES FORWARD WITH L ARM, HAND ABOVE SHOULDER LEVEL	0☐	1☐	2☐	3☐	43.
*	44.	4 POINT: CRAWLS OR HITCHES FORWARD 1.8m(6')	0☐	1☐	2☐	3☐	44.
*	45.	4 POINT: CRAWLS RECIPROCALLY FORWARD1.8m (6')	0☐	1☐	2☐	3☐	45.
*	46.	4 POINT: CRAWLS UP 4 STEPS ON HANDS AND KNEES/FEET	0☐	1☐	2☐	3☐	46.
	47.	4 POINT: CRAWLS BACKWARDS DOWN 4 STEPS ON HANDS AND KNEES/FEET	0☐	1☐	2☐	3☐	47.
*	48.	SIT ON MAT: ATTAINS HIGH KN USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0☐	1☐	2☐	3☐	48.
	49.	HIGH KN: ATTAINS HALF KN ON R KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0☐	1☐	2☐	3☐	49.
	50.	HIGH KN: ATTAINS HALF KN ON L KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0☐	1☐	2☐	3☐	50.
*	51.	HIGH KN: KN WALKS FORWARD 10 STEPS, ARMS FREE	0☐	1☐	2☐	3☐	51.

TOTAL DIMENSION C ☐

Item		D: STANDING	SCORE				NT
*	52.	ON THE FLOOR: PULLS TO STD AT LARGE BENCH	0☐	1☐	2☐	3☐	52.
*	53.	STD: MAINTAINS, ARMS FREE, 3 SECONDS	0☐	1☐	2☐	3☐	53.
*	54.	STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS R FOOT, 3 SECONDS	0☐	1☐	2☐	3☐	54.
*	55.	STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS L FOOT, 3 SECONDS	0☐	1☐	2☐	3☐	55.
*	56.	STD: MAINTAINS, ARMS FREE, 20 SECONDS	0☐	1☐	2☐	3☐	56.
*	57.	STD: LIFTS L FOOT, ARMS FREE, 10 SECONDS	0☐	1☐	2☐	3☐	57.
*	58.	STD: LIFTS R FOOT, ARMS FREE, 10 SECONDS	0☐	1☐	2☐	3☐	58.
*	59.	SIT ON SMALL BENCH: ATTAINS STD WITHOUT USING ARMS	0☐	1☐	2☐	3☐	59.
*	60.	HIGH KN: ATTAINS STD THROUGH HALF KN ON R KNEE, WITHOUT USING ARMS	0☐	1☐	2☐	3☐	60.
*	61.	HIGH KN: ATTAINS STD THROUGH HALF KN ON L KNEE, WITHOUT USING ARMS	0☐	1☐	2☐	3☐	61.
*	62.	STD: LOWERS TO SIT ON FLOOR WITH CONTROL, ARMS FREE	0☐	1☐	2☐	3☐	62.
*	63.	STD: ATTAINS SQUAT, ARMS FREE	0☐	1☐	2☐	3☐	63.
*	64.	STD: PICKS UP OBJECT FROM FLOOR, ARMS FREE, RETURNS TO STAND	0☐	1☐	2☐	3☐	64.

TOTAL DIMENSION D ☐

Item		E: WALKING, RUNNING & JUMPING	SCORE				NT
*	65.	STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO R	0☐	1☐	2☐	3☐	65.
*	66.	STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO L	0☐	1☐	2☐	3☐	66.
*	67.	STD, 2 HANDS HELD: WALKS FORWARD 10 STEPS	0☐	1☐	2☐	3☐	67.
*	68.	STD, 1 HAND HELD: WALKS FORWARD 10 STEPS	0☐	1☐	2☐	3☐	68.
*	69.	STD: WALKS FORWARD 10 STEPS	0☐	1☐	2☐	3☐	69.
*	70.	STD: WALKS FORWARD 10 STEPS, STOPS, TURNS 180°, RETURNS	0☐	1☐	2☐	3☐	70.
*	71.	STD: WALKS BACKWARD 10 STEPS	0☐	1☐	2☐	3☐	71.
*	72.	STD: WALKS FORWARD 10 STEPS, CARRYING A LARGE OBJECT WITH 2 HANDS	0☐	1☐	2☐	3☐	72.
*	73.	STD: WALKS FORWARD 10 CONSECUTIVE STEPS BETWEEN PARALLEL LINES 20cm (8")APART	0☐	1☐	2☐	3☐	73.
*	74.	STD: WALKS FORWARD 10 CONSECUTIVE STEPS ON A STRAIGHT LINE 2cm (3/4") WIDE	0☐	1☐	2☐	3☐	74.
*	75.	STD: STEPS OVER STICK AT KNEE LEVEL, R FOOT LEADING	0☐	1☐	2☐	3☐	75.
*	76.	STD: STEPS OVER STICK AT KNEE LEVEL, L FOOT LEADING	0☐	1☐	2☐	3☐	76.
*	77.	STD: RUNS 4.5m (15'), STOPS & RETURNS	0☐	1☐	2☐	3☐	77.
*	78.	STD: KICKS BALL WITH R FOOT	0☐	1☐	2☐	3☐	78.
*	79.	STD: KICKS BALL WITH L FOOT	0☐	1☐	2☐	3☐	79.
*	80.	STD: JUMPS 30cm (12") HIGH, BOTH FEET SIMULTANEOUSLY	0☐	1☐	2☐	3☐	80.
*	81.	STD: JUMPS FORWARD 30 cm (12"), BOTH FEET SIMULTANEOUSLY	0☐	1☐	2☐	3☐	81.
*	82.	STD ON R FOOT: HOPS ON R FOOT 10 TIMES WITHIN A 60cm (24") CIRCLE	0☐	1☐	2☐	3☐	82.
*	83.	STD ON L FOOT: HOPS ON L FOOT 10 TIMES WITHIN A 60cm (24") CIRCLE	0☐	1☐	2☐	3☐	83.
*	84.	STD, HOLDING 1 RAIL: WALKS UP 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET	0☐	1☐	2☐	3☐	84.
*	85.	STD, HOLDING 1 RAIL: WALKS DOWN 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET	0☐	1☐	2☐	3☐	85.
*	86.	STD: WALKS UP 4 STEPS, ALTERNATING FEET	0☐	1☐	2☐	3☐	86.
*	87.	STD: WALKS DOWN 4 STEPS, ALTERNATING FEET	0☐	1☐	2☐	3☐	87.
*	88.	STD ON 15cm (6") STEP: JUMPS OFF, BOTH FEET SIMULTANEOUSLY	0☐	1☐	2☐	3☐	88.

TOTAL DIMENSION E ☐

Was this assessment indicative of this child's "regular" performance? YES ☐ NO ☐
COMMENTS:

GMFM-88 SUMMARY SCORE

DIMENSION	CALCULATION OF DIMENSION % SCORES	GOAL AREA (indicated with ✓ check)
A. Lying & Rolling	$\frac{\text{Total Dimension A}}{51} = \frac{\quad}{51} \times 100 = \quad\%$	A. ☐
B. Sitting	$\frac{\text{Total Dimension B}}{60} = \frac{\quad}{60} \times 100 = \quad\%$	B. ☐
C. Crawling & Kneeling	$\frac{\text{Total Dimension C}}{42} = \frac{\quad}{42} \times 100 = \quad\%$	C. ☐
D. Standing	$\frac{\text{Total Dimension D}}{39} = \frac{\quad}{39} \times 100 = \quad\%$	D. ☐
E. Walking, Running & Jumping	$\frac{\text{Total Dimension E}}{72} = \frac{\quad}{72} \times 100 = \quad\%$	E. ☐

TOTAL SCORE = $\frac{\%A + \%B + \%C + \%D + \%E}{\text{Total \# of Dimensions}}$

$= \frac{\quad}{5} = \quad = \quad\%$

GOAL TOTAL SCORE = $\frac{\text{Sum of \%scores for each dimension identified as a goal area}}{\text{\# of Goal areas}}$

$= \quad = \quad\%$

GMFM-66 Gross Motor Ability Estimator Score [1]

GMFM-66 Score = _____ _____ to _____ 95% Confidence Intervals

previous GMFM-66 Score = _____ _____ to _____ 95% Confidence Intervals

change in GMFM-66 = _____

[1] from the Gross Motor Ability Estimator (GMAE-2) Software

ANNEXURE IV-LAQ-CP Score sheet

The scoring key has been included in the questionnaire here, although usually it is held separately. We have also omitted the introductory front sheet.

Parents generally complete the questionnaire very thoroughly. However, occasionally a question is left blank, and a score of 0 is then assigned. If more than 5 questions have been left blank, the LAQ-CP becomes invalid.

1. How many times has your child been seen **over the last year** by a doctor other than the school doctor or your family doctor? (Please circle one of the following)

	0	1	2-5	6-12	13+
Score	*0*	*1*	*2*	*3*	*4*

2. Has your child had to stay in hospital for any length of time **over the last year?** Please indicate in **weeks** the total amount of time spent in hospital. (Please circle one of the following)

	0	<1	1-3	4-26	27+
Score	*0*	*1*	*2*	*3*	*4*

3. How many operations have been carried out on your child **over the last year**? (Please circle one of the following)

	0	1	2	3	4+
Score	*0*	*1*	*2*	*3*	*4*

4. Has your child had a leg, arm or other part of his/her body in plaster **over the last year?** Please indicate in **weeks** the total time your child has spent in plaster. (Please circle one of the following)

	0	≤6	7-11	12-17	18+
Score	*0*	*1*	*2*	*3*	*4*

5. Has your child had to wear some form of body or leg support **over the last year?** Please indicate in **weeks** the total time the support was worn. (Please circle one of the following)

	0	1-16	17-32	33-51	52
Score	*0*	*1*	*2*	*3*	*4*

6. How many tablets, pills or doses of medicines did your child take **yesterday**? (Please circle one of the following)

	0	1-4	5-8	9-12	13+
Score	*0*	*1*	*2*	*3*	*4*

7. Is your child currently receiving a special diet for any reason? (Please circle one of the following)

	YES	**NO**
Score	*4*	*0*

8. How many times has your child suffered from any fits or blackouts **over the last year?** (Please circle one of the following)

	Score
No Fits at all	*0*
Occasional fit during day averaging one per month	*1*
Some fits most weeks day or night	*2*
Many fits on most days and nights	*3*
Constant fits in frequent succession	*4*

9. Has your child been seen by a specialist about difficulties with his/her behaviour **over the last year?** (Please circle one of the following)

	YES	NO
Score	*4*	*0*

10. How often has your child been seen by any sort of therapist **over the last year?** (Please circle one of the following)

	0	1	2-12	13-52	53+
Score	*0*	*1*	*2*	*3*	*4*

11. Which of the following services/allowances is your child currently receiving?
(Please circle all of those currently received)

Visits from Health Visitor	Visits from Home Help	Visits from Social worker
Visits from Community Nurse	**Voluntary Services**	

Number of services provided	*0*	*1-2*	*3+*
Score	*0*	*2*	*4*

12. How many items of special equipment are there in the home which are currently, or have been, essential for your child?
(Please circle one of the following)

	0	1-3	4-7	8-10	11+
Score	*0*	*1*	*2*	*3*	*4*

13. What has been the financial cost to the family for your child **over the last year** in purchasing and maintaining such special equipment? (Please circle one of the following)

	£0	£1-100	£101-200	£201-300	£301+
Score	*0*	*1*	*2*	*3*	*4*

14. What has been the extra financial cost to the family **over the last year** other than in purchasing special equipment, which was not covered fully by grants and allowances? (Please circle one of the following)

	£0	£1-100	£101-200	£201-300	£301+
Score	*0*	*1*	*2*	*3*	*4*

15. Has your child's present home been adapted in any way **over the last year** because of your child?
(Please circle one of the following)

YES	**NO**
	0

If yes how many adaptations have been made? (Please circle one of the following)

	1-3	4-7	8-10	11+
Score	*1*	*2*	*3*	*4*

16. Please indicate how many (further) adaptations are planed or are considered necessary?
(Please circle one of the following)

	0	1-3	4-7	8-10	11+
Score	*0*	*1*	*2*	*3*	*4*

17. For each of the following activities, please tick **one** of the spaces to indicate how much help you would normally give to your child to complete that activity.

	No Help given	Some help/ supervision given	Has to be done for him/her
Washing hands	.....	.....	.....
Eating a bowl of cereal	.....	.....	.....
Putting on a vest/T-shirt	.....	.....	.....
Doing up buttons or buckles	.....	.....	.....
Getting out of bed	.....	.....	.....
Getting out of the bath	.....	.....	.....
Going to the toilet	.....	.....	.....
Climbing stairs	.....	.....	.....
Getting in and out of a car	.....	.....	.....
Opening doors	.....	.....	.....
Picking up an object from the floor	.....	.....	.....
Carrying a drink the length of a room	.....	.....	.....

Score

		No Help	*Some Help*	*Has to be done for them*
(i)	*Washing hands*	*0*	*2*	*4*
(ii)	*Eating cereal*	*0*	*2*	*4*
(iii)	*T-shirt*	*0*	*2*	*4*
(iv)	*Buttons Buckles*	*0*	*2*	*4*
(v)	*Getting out of bed*	*0*	*2*	*4*
(vi)	*Getting out of bath*	*0*	*2*	*4*
(vii)	*Toilet*	*0*	*2*	*4*
(viii)	*Climbing stairs*	*0*	*2*	*4*
(ix)	*In/out of car*	*0*	*2*	*4*

17 (i – ix) renders nine separate scores

17 (x – xii) renders one score as follows:

Opening doors	*0*	*2*	*4*
Picking up objects	*0*	*2*	*4*
Carry drinks	*0*	*2*	*4*

Add the values for 17 (x – xii) and assign final score as follows:

Added Value	*0*	*2*	*4-6*	*8-10*	*12*
Score	*0*	*1*	*2*	*3*	*4*

18. How many times did you **need** to lift your child on the last occasion you spent a **full day** with him/her?

Multiply the number of lifts from this question by the appropriate weight on the front sheet.

If weight given in stones and pounds, convert to stones and round up or down to one decimal point. Score the product as follows:

	< 0.5	=	*0*
	0.5 - 9.4	=	*1*
	9.5 – 22.4	=	*2*
	22.5 – 43.9	=	*3*
	44 +	=	*4*

If weight given in kilograms and grams, convert to kilograms and round up or down to one decimal point. Score the product as follows:

	<3.2	=	*0*
	3.2 – 60.4	=	*1*
	60.5 – 143	=	*2*
	143.1 – 279.9	=	*3*
	280 +	=	*4*

19. How often has your child required assistance during the night **over the last week**? (Please circle one of the following)

	0	1-3	4-7	8-10	11+
Score	*0*	*1*	*2*	*3*	*4*

20. Please list any other areas where your child requires assistance in the course of a normal day?

Score	*No areas noted*	=	*0*
	1 area noted	=	*1*
	2 areas noted	=	*2*
	3+ areas noted	=	*3*
	Constant supervision	=	*4*

21. (a) How many rooms (excluding halls and passages) are there in your child's usual place of residence ?
(b) Over the **past week**, how many of these did your child go into?
(c) How many of these did your child enter unassisted?

Score Two scores are calculated for this question ACCESS 1 and ACCESS 3

Calculate ACCESS 1 by using the values given for 21a and 21b as follows.
Multiple 21b by 100 and divide the product by 21a.

Score as follows.	*100*	=	*0*
	75 – 99	=	*1*
	50 – 74	=	*2*
	25 – 49	=	*3*
	0 – 24	=	*4*

Calculate ACCESS 3 by using the values given for 21b and 21c as follows:
If 21c = 0, then score 4.
If 21c = 1 or more, then multiple 21c by 100 and divide the product by 21b.

Score as follows	*100*	=	*0*
	66.6 – 99.9	=	*1*
	33.4 – 66.5	=	*2*
	1 – 33.3	=	*3*

22. Does you child normally need help in getting in and out of the house? (Please circle one of the following)

	YES	**NO**
Score	*4*	*0*

23. What is the furthest distance your child has gone outside without assistance **over the past week?**
(Please circle one of the following)

	0	1-100 yards	101-440 yards	1/4 - 1/2 mile	1/2 + miles
Score	*4*	*3*	*2*	*1*	*0*

24 How often has your child been out of the house by himself/herself **over the past week**?
(Please circle one of the following)

	0	1-7	8-13	14-20	21+
Score	*4*	*3*	*2*	*1*	*0*

25 Excluding trips to and from nursery/school, how many times has your child been on a longer outing **over the past week**, which required some form of transport? (Please circle one of the following)

	0	1-3	4-7	8-10	11+
Score	*4*	*3*	*2*	*1*	*0*

26. What type of nursery/school, is your child currently attending? (Please circle one of the following)

None
Pre-school (e.g. Nursery, Playgroup etc.)
Special Pre-school
Infant/Primary without Special Support Unit attached
Infant/Primary with Special Support Unit attached
Special School: Physical disability
Special School: Learning difficulties
Home teaching (Including Portage)
Other (please specify) .....

27 How often does your child attend school? (Please circle one of the following)

Part-time
Daily
Weekly boarding
Full boarding

Assign one score for questions 26 & 27, and take into account child's age as follows.

	Not school age, not at school	
Part time or daily	*Not school age, Pre-school (e.g. nursery, playground)*	*0*
	School age, Infant/primary without special unit	
	School age, Infant primary with special unit	
	Not school age, Special pre-school	*1*
	School age, Special school - physical disability	
	School age, Special school - learning difficulties	*2*
	School age, Home teaching: not at school	*3*
Boarding		*4*

28 Approximately how long does it take for your child to travel from home to school?
(Please circle one of the following)

	0-15mins	16-30 mins	31-45mins	46-1hr	1hr +
Score	*0*	*1*	*2*	*3*	*4*

29 How many friends has your child seen outside of school hours **over the past week**?
(Please circle one of the following)

	0	1-3	4-7	8-10	11+
Score	*4*	*3*	*2*	*1*	*0*

30. Do you have any family or friends locally to whom you can turn for help if necessary?
(Please circle one of the following)

	YES	**NO**
Score	*0*	*4*

31 Do you think that the people in your local area are generally supportive and understanding where your child is concerned? (Please circle one of the following)

	YES	**NO**	**SOMETIMES**
Score	*0*	*4*	*2*

32 Do you think that your child restricts your social life in any way? (Please circle one of the following)

	YES	**NO**	**SOMETIMES**
Score	*4*	*0*	*2*

33 Do you have any difficulties in organising family holidays because of your child? (Please circle one of the following)

	YES	**NO**
Score	*4*	*0*

34. How many other members of your child's family are living at the same residence as your child? Please state their relationship to your child.

If this question is left blank, assume the child is living with both natural parents.

Assign Score	*If the child is living with both natural parents*	=	*0*
	If the child is living with only one natural parent	=	*2*
	If child living with neither natural parent or in an institution	=	*4*

35. Please describe if any member of the family has had to change their employment situation to make caring for your child easier.

If this question is left blank, assume no changes have been made to family employment.

Assign Score	*No changes to family employment*	=	*0*
	Temporary/occasional interruption or difficulty to either parent	=	*2*
	Permanent change in employment situation for either parent	=	*4*

36. Do you think that your child has placed any extra stress on you as parents/carers? (Please circle one of the following)

	NONE	SLIGHT	SEVERE
Score	*0*	*2*	*4*

37. Do you think that your child has placed any stress on any other children within the family? (Please circle one of the following)

	NO OTHER CHILDREN	NONE	SLIGHT	SEVERE
Score	*0*	*0*	*2*	*4*

SCORING PROCEDURE

Use the scored questionnaire with the Scoring Form to complete this procedure.

Create a **raw score** by summating the scores for the questions pertaining to each dimension as follows:

Physical independence	Questions	17(i),17(ii),17(iii),17(iv), 17(v),17(vi),17(vii), 17(viii),17(ix),18,19,20
Clinical burden	Questions	1,2,3,4,5,6,8,9,10,11,12
Mobility	Questions	17(x - xii), 21ACCESS 1, 21ACCESS 3,22,23,24,25
Economic burden	Questions	7,13,14,15,16,35
Social integration	Questions	29,30,31,32,33,34,36,37
Schooling	Questions	26&27,28

Convert this into a **dimensional score** out of 100, which is comparable between dimensions, by multiplying the raw score for each dimension by the appropriate dimension constant:

Physical independence	2.0834
Mobility	3.5714
Clinical burden	2.2728
Schooling	12.500
Economic burden	4.1667
Social integration	3.1250

Create the overall Lifestyle Assessment Score (LAS) by using the weighted additive model:

$$J = \beta_1 n_1 + \beta_2 n_2 + \beta_3 n_3 + \beta_4 n_4 + \beta_5 n_5 + \beta_6 n_6 + C,$$

where:
J = LAS
β = weighting applied to each dimensional score
n = dimensional score
C = constant term = 4.05

by using the following weightings with each dimensional score:

Physical independence	0.357
Mobility	0.270
Clinical burden	0.033
Schooling	0.016
Economic burden	0.082
Social integration	0.224

Multiply each dimensional score by its weighting, to create a **weighted score**. Summate the weighted scores and the constant term C to arrive at the LAS.

SCORING FORM

Use this form in conjunction with each completed and scored questionnaire, and refer to the Scoring Procedure as described under Appendix 3 of the LAQ-CP Manual.

CHILD'S NAME: .....

Physical Independence
Raw Score = ... x 2.0834 = ... *(Dimensional Score)* x 0.357 = ... *(Weighted Score)*

Mobility
Raw Score = ... x 3.5714= ..... *(Dimensional Score)* x 0.270 = ... *(Weighted Score)*

Clinical Burden
Raw Score = ... x 2.2728 = ... *(Dimensional Score)* x 0.033 = ... *(Weighted Score)*

Schooling
Raw Score = ... x 12.500 = ... *(Dimensional Score)* x 0.016 = ... *(Weighted Score)*

Economic Burden
Raw Score = ... x 4.1667 = ... *(Dimensional Score)* x 0.082 = ... *(Weighted Score)*

Social Integration
Raw Score = ... x 3.1250 = ... *(Dimensional Score)* x 0.224 = ... *(Weighted Score)*

Sum of Weighted Scores = ... + 4.05

= **LAS** ☐

Standardised descriptive profile of Dimensional Scores:

Physical	0	10	20	30	40	50	60	70	80	90	100
Mobility	0	10	20	30	40	50	60	70	80	90	100
Clinical	0	10	20	30	40	50	60	70	80	90	100
Schooling	0	10	20	30	40	50	60	70	80	90	100
Economic	0	10	20	30	40	50	60	70	80	90	100
Social Int.	0	10	20	30	40	50	60	70	80	90	100

ANNEXURE V- BADS Score sheet

Barry–Albright Dystonia Scale
Patient's Name: _____ Date: _____

Directions: Assess the patient for dystonia in each of the following regions: eyes, mouth, neck, trunk, each upper and lower extremity (8 body regions). Write the scores on the lines provided. Rate severity based only on dystonia as evidenced by abnormal movements or postures. When assessing functional limitations, do not score dystonia based on other factors, such as weakness, lack of motor control, cognitive deficits, primitive reflexes, and/or other movement disorders as defined below.

Dystonia:	Sustained muscle contractions causing twisting and repetitive movements or abnormal postures
Spasticity:	Velocity-dependent resistance to passive stretch
Athetosis:	Distal writhing or contorting movements
Chorea:	Brief, rapid, unsustained, irregular movements
Ataxia:	Incoordination of movement characterized by wide-based unsteady gait, flailing movements.

Eyes: signs of dystonia of the eyes include: prolonged eyelid spasms, and/or forced eye deviations

0 – Absence of eye dystonia
1 – Slight. Dystonia less then 10% of the time and does not interfere with tracking
2 – Mild. Frequent blinking without prolonged spasms of eye closure, and/or eye movements less than 50% of the time.
3 – Moderate. Prolonged spasms of eyelid closure, but eyes open most of the time, and/or eye movements more than 50% of the time that interfere with tracking, but able to resume tracking
4 – Severe. Prolonged spasms of eyelid closure, with eyes closed at least 30% of the time, and/or eye movements more than 50% of the time that prevent tracking
* – Unable to assess eye movements

Eyes: ____

Mouth: signs of dystonia of the mouth include: grimacing, clenched or deviated jaw, forced open mouth, and/or forceful tongue thrusting

0 – Absence of mouth dystonia

1 – Slight. Dystonia less than 10% of the time and does not interfere with speech and/or feeding

2 – Mild. Dystonia less than 50% of the time and does not interfere with speech and/or feeding

3 – Moderate. Dystonia more than 50% of the time, and/or dystonia that interferes with speech and/or feeding

4 – Severe. Dystonia more than 50% of the time, and/or dystonia that prevents speech and/or feeding

* – Unable to assess mouth movements

Mouth: _____

Neck: signs of dystonia of the neck include: pulling of the neck into any plane of motion: extension, flexion, lateral flexion or rotation

0 – Absence of neck dystonia

1 – Slight. Pulling less than 10% of time and does not interfere with lying, sitting, standing and/or walking

2 – Mild. Pulling less than 50% of the time and does not interfere with lying, sitting, standing and/or walking

3 – Moderate. Pulling more than 50% of the time and/or dystonia that interferes with lying, sitting, standing and/or walking

4 – Severe. Pulling more than 50% of the time and/or dystonia that prevents sitting in standard wheelchair, standing and/or walking

(e.g. requires more than standard head rest for seating)

* – Unable to assess neck movements

Neck: _____

Trunk: signs of dystonia of the trunk include: pulling of the trunk into any plane of motion: extension, flexion, lateral flexion or rotation

0 – Absence of trunk dystonia

1 – Slight. Pulling less than 10% of the time and does not interfere with lying, sitting, standing and/or walking

2 – Mild. Pulling less than 50% of the time and does not interfere with lying, sitting, standing and/or walking

3 – Moderate. Pulling more than 50% of the time, and/or dystonia that interferes with lying, sitting, standing and/or walking

4 – Severe. Pulling more than 50% of the time, and/or dystonia that prevents positioning in standard wheelchair, standing and/or walking (e.g. requires adapted seating system to control posturing, such as ASIS bar)

* – Unable to assess trunk movements

Trunk: _____

Upper extremities: signs of dystonia of the upper extremities include: sustained muscle contractions causing abnormal posturing of the upper extremities

0 – Absence of upper extremity dystonia

1 – Slight. Dystonia less than 10% of the time and does not interfere with normal positioning and/or functional activities

2 – Mild. Dystonia less than 50% of the time and does not interfere with normal positioning and/or functional activities

3 – Moderate. Dystonia more than 50% of the time and/or dystonia that interferes with normal positioning and/or upper extremity function

4 – Severe. Dystonia more than 50% of the time and/or dystonia that prevents normal positioning and/or upper extremity function (e.g. arms restrained in wheelchair to prevent injury)

* – Unable to assess upper extremity movements

Left upper extremity: _____

Right upper extremity: _____

Lower extremities: signs of dystonia of the lower extremities include: sustained muscle contractions causing abnormal posturing of the lower extremities

0 – Absence of lower extremity dystonia

1 – Slight. Dystonia less than 10% of the time and does not interfere with normal positioning and/or functional activities

2 – Mild. Dystonia less than 50% of the time and does not interfere with normal positioning and/or functional activities

3 – Moderate dystonia more than 50% of the time and/or dystonia that interferes with normal positioning and/or lower extremity weight bearing or function

4 – Severe dystonia more than 50% of the time and/or dystonia that prevents normal positioning and/or lower extremity weight bear ing and/or function (e.g. cannot maintain standing due to severe dystonia at ankles)

* – Unable to assess lower extremity movements

Left lower extremity: _____

Right lower extremity: _____

Total score: _____ Rater's initials: _____

ANNEXURE VI- HAT Score sheet

Holland Bloorview
Kids Rehabilitation Hospital

Bloorview
RESEARCH INSTITUTE

HYPERTONIA ASSESSMENT TOOL (HAT) - SCORING CHART

Name:_____ Chart/File #:_____

Clinical Diagnosis:_____ Date of Birth: _____

Limb Assessed: Gender: ☐ Male ☐ Female

☐ Arm ☐ Left ☐ Right HAT Assessor:_____

☐ Leg ☐ Left ☐ Right Date of Assessment: _____

HYPERTONIA ASSESSMENT TOOL (HAT)

HAT ITEM	SCORING GUIDELINES (0=negative or 1=positive)	SCORE 0=negative 1=positive (circle score)	TYPE OF HYPERTONIA
1. Increased involuntary movements/postures of the designated limb with tactile stimulus of another body part	0= No involuntary movements or postures observed	0	DYSTONIA
	1= Involuntary movements or postures observed	1	
2. Increased involuntary movements/postures with purposeful movements of another body part	0= No involuntary movements or postures observed	0	DYSTONIA
	1= Involuntary movements or postures observed	1	
3. Velocity dependent resistance to stretch	0= No increased resistance noticed during fast stretch compared to slow stretch	0	SPASTICITY
	1= Increased resistance noticed during fast stretch compared to slow stretch	1	
4. Presence of a spastic catch	0= No spastic catch noted	0	SPASTICITY
	1= Spastic catch noted	1	
5. Equal resistance to passive stretch during bi-directional movement of a joint	0= Equal resistance not noted with bi-directional movement	0	RIGIDITY
	1= Equal resistance noted with bi-directional movement	1	
6. Increased tone with movement of another body part	0= No increased tone noted with purposeful movement	0	DYSTONIA
	1= Greater tone noted with purposeful movement	1	
7. Maintenance of limb position after passive movement	0= Limb returns (partially or fully) to original position	0	RIGIDITY
	1= Limb remains in final position of stretch	1	

SUMMARY SCORE – HAT DIAGNOSIS

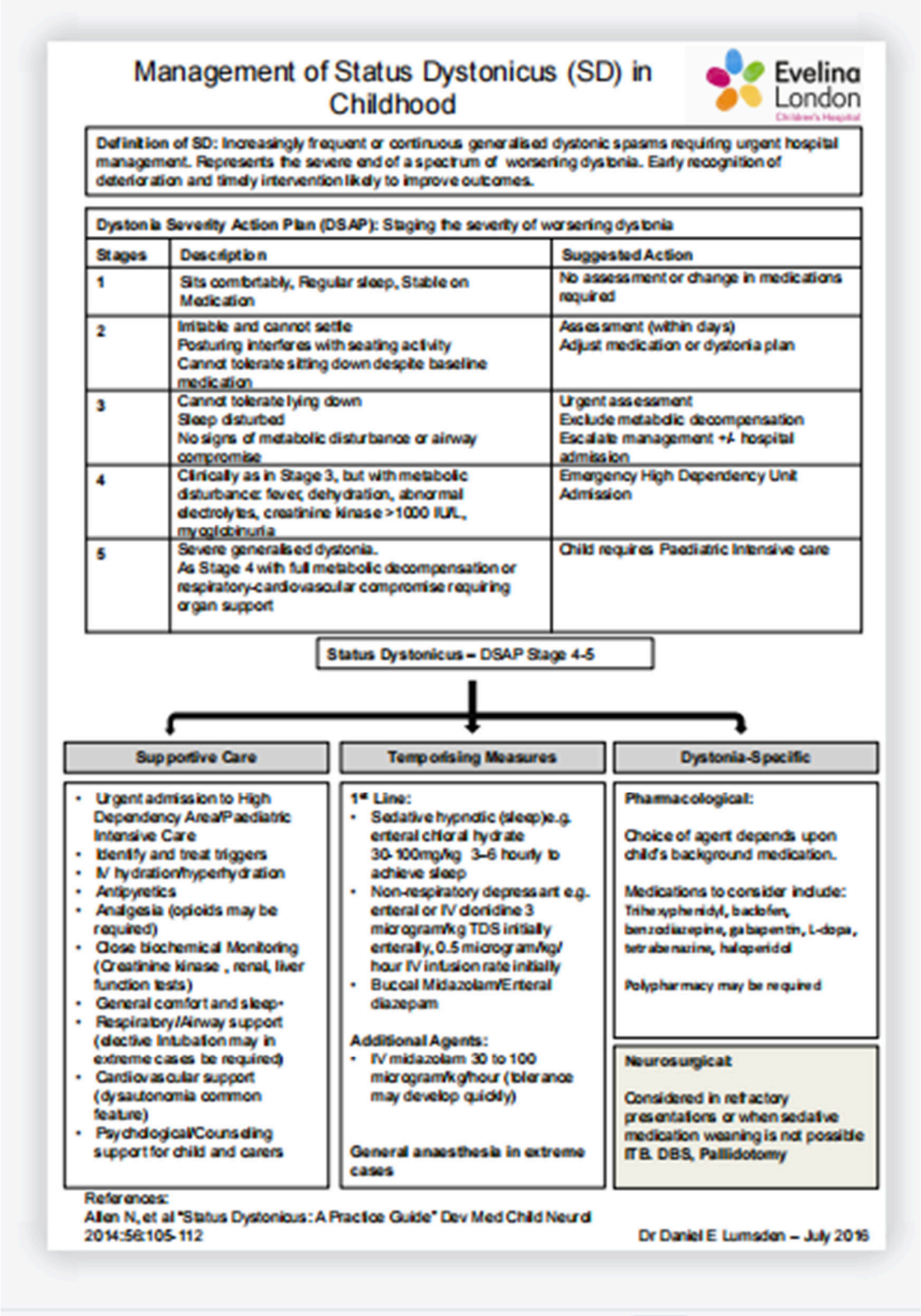
		Check box:
DYSTONIA →	Positive score (1) on at least one of the items #1, 2, or 6	☐ Yes ☐ No
SPASTICITY →	Positive score (1) on either one or both of the items #3 or 4	☐ Yes ☐ No
RIGIDITY →	Positive score (1) on either one or both of the items #5 or 7	☐ Yes ☐ No
MIXED TONE →	Presence of 1 or more subgroups (e.g. dystonia, spasticity, rigidity)	☐ Yes ☐ No

HAT DIAGNOSIS:
(Fill in all that apply) _____

HAT Manual can be accessed at: http://www.hollandbloorview.ca/hat

© (2010) Fehlings D, Switzer L, Jethwa A, Mink J, Macarthur C, Knights S, & Fehlings T
Development of the Hypertonia Assessment Tool (HAT): *Dev Med & Child Neurol* 2010; 52(5):e83-e87.

ANNEXURE VII- DSAP Score sheet



Management of Status Dystonicus (SD) in Childhood

Evelina London Children's Hospital

Definition of SD: Increasingly frequent or continuous generalised dystonic spasms requiring urgent hospital management. Represents the severe end of a spectrum of worsening dystonia. Early recognition of deterioration and timely intervention likely to improve outcomes.

Dystonia Severity Action Plan (DSAP): Staging the severity of worsening dystonia

Stages	Description	Suggested Action
1	Sits comfortably, Regular sleep, Stable on Medication	No assessment or change in medications required
2	Irritable and cannot settle Posturing interferes with seating activity Cannot tolerate sitting down despite baseline medication	Assessment (within days) Adjust medication or dystonia plan
3	Cannot tolerate lying down Sleep disturbed No signs of metabolic disturbance or airway compromise	Urgent assessment Exclude metabolic decompensation Escalate management +/- hospital admission
4	Clinically as in Stage 3, but with metabolic disturbance: fever, dehydration, abnormal electrolytes, creatinine kinase >1000 IU/L, myoglobinuria	Emergency High Dependency Unit Admission
5	Severe generalised dystonia. As Stage 4 with full metabolic decompensation or respiratory-cardiovascular compromise requiring organ support	Child requires Paediatric Intensive care

Status Dystonicus – DSAP Stage 4-5

Supportive Care

- Urgent admission to High Dependency Area/Paediatric Intensive Care
- Identify and treat triggers
- IV hydration/hyperhydration
- Antipyretics
- Analgesia (opioids may be required)
- Close biochemical Monitoring (Creatinine kinase , renal, liver function tests)
- General comfort and sleep
- Respiratory/Airway support (elective Intubation may in extreme cases be required)
- Cardiovascular support (dysautonomia common feature)
- Psychological/Counselling support for child and carers

Temporising Measures

1st Line:

- Sedative hypnotic (sleep)e.g. enteral chloral hydrate 30-100mg/kg 3-6 hourly to achieve sleep
- Non-respiratory depressant e.g. enteral or IV clonidine 3 microgram/kg TDS initially enterally, 0.5 microgram/kg/hour IV infusion rate initially
- Buccal Midazolam/Enteral diazepam

Additional Agents:

- IV midazolam 30 to 100 microgram/kg/hour (tolerance may develop quickly)

General anaesthesia in extreme cases

Dystonia-Specific

Pharmacological:

Choice of agent depends upon child's background medication.

Medications to consider include: Trihexyphenidyl, baclofen, benzodiazepine, gabapentin, L-dopa, tetrabenazine, haloperidol

Polypharmacy may be required

Neurosurgical:

Considered in refractory presentations or when sedative medication weaning is not possible ITB, DBS, Pallidotomy

References:

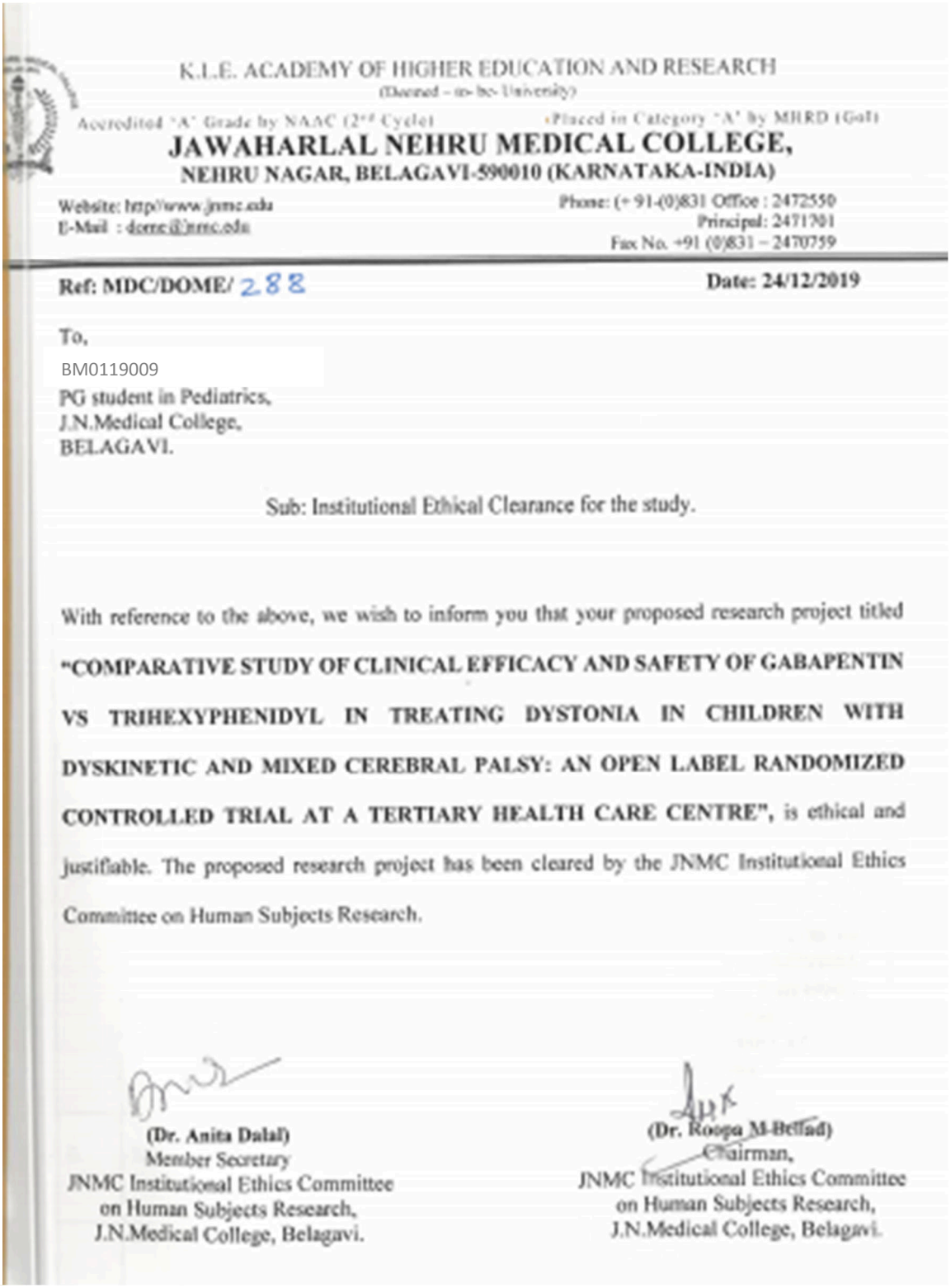
Allen N, et al "Status Dystonicus: A Practice Guide" Dev Med Child Neurol 2014:56:105-112

Dr Daniel E Lumsden – July 2015

ANNEXURE VIII- Teachers Drooling Scale

Degree	Description
1	No drooling
2	Infrequent drooling, small amount
3	Occasional drooling, intermittent all day
4	Frequent drooling, but not profuse
5	Constant drooling, always wet

ANNEXURE IX- Ethical Clearance Letter



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 288 **Date: 24/12/2019**

To,

BM0119009

PG student in Pediatrics,
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 **"COMPARATIVE STUDY OF CLINICAL EFFICACY AND SAFETY OF GABAPENTIN VS TRIHEXYPHENIDYL IN TREATING DYSTONIA IN CHILDREN WITH DYSKINETIC AND MIXED CEREBRAL PALSY: AN OPEN LABEL RANDOMIZED CONTROLLED TRIAL AT A TERTIARY HEALTH CARE CENTRE"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

ANNEXURE X- Key to master chart

GENDER	**MALE-1**
	FEMALE-2
GROSS MOTOR DELAY	**PRESENT-1**
	ABSENT-2
SOCIAL DELAY	**PRESENT-1**
	ABSENT-2
LANGUAGE DELAY	**PRESENT-1**
	ABSENT-2
COMORBIDITIES	**PRESENT-1**
	ABSENT-2
GROSS DEVELOPMENTAL DELAY	**PRESENT-1**
	ABSENT-2
CONSANGUANITY	**PRESENT-1**
	ABSENT-2
ANC	**PRESENT-1**
	ABSENT-2
GESTATION	**TERM-1**
	PRETERM-2
PLACE OF DELIVERY	**HOSPITAL-1**
	HOME-2

MODE OF DELIVERY	**NVD-1**
	LSCS
PROM	**YES-1**
	NO-2
MULTIPLE PREGNENCY	**NO-1**
	YES-2
CRY AT BIRTH	**NORMAL-1**
	DELAYED-2
BIRTH WEIGHT	**AGA-1**
	SGA-2
NNH	**PRESENT-1**
	ABSENT-2
NICU STAY	**PRESENT-1**
	ABSENT-2
TOPOGRAPHICAL CLASSIFICATION	**QUADRIPLEGIC-1**
	DIPLEGIC-2
	HEMIPLEGIC-3
	MONOPLEGIC-4
PHYSIOLOGICAL CLASSIFICATION	**DYSTONIC-1**
	MIXED-2
	SPASTIC-3
HAT	**DYSTONIA-1**
	MIXED-2
	NORMAL-3
	SPASTICITY-4

BAD	**0 - 32**
GMFM	**0 - 100%**
LAQ-CP	**0 - 100%**
TEACHERS DROOLING SCALE	**1 - 5**
DSAP	**1 - 5**
ADVERSE EFFECT	**YES-1, NO-2**

SLNO	NAME	DRUG	AGE	GENDER	GROSS MOTOR	SOCIAL	LANGUAGE	SEIZURE	GDD	MR	HEARING IMPAIRMENT	SPEECH DELAY	VISION PROBLEM	CARIES TOOTH	CONSTIPATION	GERD	CONTRACRURE	CALLOSITIES	SCABIES	ASTHAMA	FTT	OBESITY	CONSANGUANITY	V?	BIRTH ORDER	ANC	GESTATION	PLACE OF DELIVERY	MODE OF DELIVEREY	PROM	MULTIPLE DELIVERY	CRY AT BIRTH	BIRTH WEIGHT	NNH	HYPOGLYCEMIA	NICU STAY	TOPOGRAPHICAL
1	SWAROOP	A	12.0	1	1	1	1	1	1	1	2	1	2	1	2	2	2	1	2	2	2	2	2		1	1	1	1	1	2	1	1	1	1	2	1	1
2	RAJVEER	A	4.0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2		1	1	1	1	2	1	1	1	2	1	2	1	1
3	AFIA ARIF	A	2.0	2	1	1	1	2	1	2	2	1	2	2	2	2	1	2	2	2	1	2	1	2ND	2	2	1	2	1	2	1	2	2	2	2	2	1
4	B/O KEERTI	A	1.3	1	1	1	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	1	2ND	2	1	2	1	1	2	1	2	2	2	2	1	2
5	ANIRUDH	A	2.4	1	1	1	1	2	1	2	2	1	2	1	2	2	2	2	1	2	1	2	1	2ND	2	1	1	1	1	2	1	1	1	2	2	2	2
6	MD MUFIZ	A	4.0	1	1	1	1	2	1	2	2	1	2	2	2	2	2	2	2	2	1	2	2		1	1	1	1	1	2	1	2	1	2	2	1	2
7	YALGURESH	A	4.0	1	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	1	2	2		1	1	1	1	1	1	1	2	1	2	2	1	2
8	ARAINA	A	3.9	2	1	1	1	1	1	2	2	1	2	2	2	1	2	1	2	2	1	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
9	SANIKA	A	1.2	2	1	1	1	2	1	2	1	1	2	1	1	2	2	2	2	2	2	2	1	2ND	1	1	1	1	1	2	1	1	1	2	2	2	2
10	SHREYASH	A	2.7	1	1	1	1	2	1	2	2	1	1	1	1	2	2	2	2	2	1	2	1		2	1	1	1	2	2	2	1	2	1	2	1	2
11	VIKRANT	A	1.1	1	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	1	2	2	2	2	1
12	NUTAN	A	2.3	2	1	1	1	2	1	2	2	1	1	2	1	1	2	2	2	2	2	2	2		1	1	1	1	1	2	1	1	1	2	2	2	1
13	KAVITA	A	15.0	2	1	1	1	2	1	1	1	1	2	1	2	1	1	1	2	2	1	2	1	3RD	1	1	1	1	1	2	1	1	1	2	2	2	1
14	ALLAUDIN	A	4.6	1	1	1	1	1	1	2	2	1	2	1	2	1	1	1	2	2	1	2	1	2ND	2	1	1	1	1	2	1	2	1	2	2	1	1
15	SAMARTH	A	3.3	1	1	1	1	1	1	2	2	1	2	1	1	2	1	2	2	2	1	2	1	2ND	1	1	1	1	1	2	1	2	1	2	2	1	2
16	GOUSIYA	A	8.0	2	1	1	1	2	1	1	1	1	2	1	1	2	2	1	1	2	2	2	2		1	2	1	1	1	2	1	2	1	2	2	1	1
17	ARFA	A	1.5	2	1	1	1	2	1	2	2	1	2	2	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	1	1	2	2	2	2
18	ANJANEYA	A	2.3	1	1	1	1	2	1	2	2	1	2	1	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	2	2	2	1	1
19	GIRIJAMMA	A	7.0	2	1	1	1	2	1	1	1	1	1	1	1	1	2	1	2	2	1	2	2		1	2	1	2	1	2	1	2	1	2	2	1	1
20	TANUSHREE	A	2.0	2	1	1	1	1	1	2	1	1	2	2	1	2	2	2	2	2	2	2	2		2	1	1	1	1	2	1	2	2	1	2	1	1
21	ALADIN	A	1.7	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
22	AFAN	A	1.0	1	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	2	1	2ND	1	1	2	1	1	2	1	2	2	2	2	1	1
23	MANVITA	A	1.5	2	1	1	1	2	1	2	2	1	2	2	1	1	2	2	2	2	2	2	2		1	1	1	1	1	2	1	1	1	2	2	1	1
24	HOSNAIN	A	4.2	1	1	1	1	1	1	2	1	1	2	2	2	2	2	1	1	2	1	2	2		2	1	1	1	2	2	2	1	2	2	2	1	1
25	NANDEESH	A	12.0	1	1	1	1	2	1	2	1	1	2	1	1	2	1	1	2	2	1	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
26	AADYA	A	2.0	2	1	2	1	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2		2	1	1	1	1	2	1	2	2	1	2	1	1
27	DHANUSH	A	6.0	1	1	1	1	1	1	2	2	1	2	2	2	2	2	1	2	2	1		2		1	1	1	1	1	2	1	2	1	2	2	1	1
28	SATHWIK	A	5.5	1	1	1	1	2	1	2	2	1	2	1	1	2	2	1	2	2	1	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
29	SAMARTH II	A	2.3	1	1	1	1	1	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2		1	1	1	1	2	2	1	1	1	2	2	1	2
30	BHIMASI	A	1.2	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	2	2	2	1	2ND	2	1	1	1	1	2	1	1	2	2	2	1	1
31	ADITYA	A	3.0	1	1	1	1	2	1	2	2	1	2	2	1	1	2	2	2	2	2	2	1	3RD	1	1	2	1	2	2	1	1	2	1	2	1	3
32	SWARA	A	1.5	2	1	1	1	1	1	2	1	1	1	2	1	1	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
33	ADITYA PADNEKAR	A	4.5	1	1	1	1	2	1	2	2	1	2	2	2	2	2	2	2	2	2	2	1	2ND	1	1	2	1	2	2	1	1	2	2	2	1	1
34	SHRAVANI	A	1.4	2	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	2	1	3RD	1	1	1	1	2	2	1	2	2	2	2	1	1
35	TANVI	A	3.3	2	1	1	1	1	1	2	2	1	2	1	1	2	2	2	2	2	2	2	2		3	1	1	1	1	2	1	1	1	2	2	2	2
36	IRAMMA	A	12.0	2	1	1	1	2	1	1	1	1	2	1	1	2	2	1	2	2	1	2	1	2ND	3	2	1	2	1	2	1	1	1	1	2	1	1
37	SHIVANI N	A	2.7	2	1	1	1	2	1	2	2	1	2	2	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	2	2	2	1	1
38	KHUSHI	B	2.0	2	1	2	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	2	1	3RD	1	1	1	1	1	2	1	1	2	2	2	1	3
39	RAKSHITA	B	1.2	2	1	1	1	1	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
40	VIHAN	B	1.2	1	1	1	1	2	1	2	2	1	2	2	1	2	1	2	2	2	2	2	1	2ND	1	1	2	1	1	2	1	1	2	1	2	1	2
41	VEDANT	B	1.5	1	1	1	1	1	1	2	2	1	2	2	1	1	2	2	2	2	2	2	1	2ND	1	1	1	1	1	2	1	2	2	2	2	1	2
42	LUBABA	B	5.0	2	1	1	1	2	1	1	1	1	2	1	1	1	1	1	2	2	1	2	2		1	1	2	1	2	1	1	1	1	1	2	1	1
43	ABHILASH	B	12.0	1	1	1	1	2	1	1	2	1	1	2	1	2	2	1	2	2	1	2	2		1	1	1	1	1	2	1	1	1	2	2	1	1
44	DHANANJAY	B	2.5	1	1	1	1	2	1	2	1	1	2	1	1	1	2	2	2	2	2	2	1	3RD	1	1	2	1	1	1	1	2	2	2	2	1	1
45	KHUSHI	B	5.5	2	1	1	1	1	1	1	2	1	2	2	2	2	2	2	2	2	1	2	2		1	1	2	1	2	2	1	2	2	1	2	1	1
46	SOHAIL	B	2.0	1	1	1	1	1	1	2	2	1	2	1	1	1	2	2	2	2	1	2	2		1	1	1	1	2	2	1	2	1	2	1	1	1
47	ANIL	B	5.0	1	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	1	2	2		2	1	1	1	1	2	1	2	1	2	2	1	1
48	TANVEERJI	B	2.8	1	1	1	1	2	1	1	2	1	2	2	2	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
49	YADNESH	B	4.0	1	1	1	1	2	1	2	1	1	2	1	2	2	2	2	2	2	2	2	2		2	1	1	1	2	2	1	1	1	1	2	1	1
50	SAMRUDDHI	B	2.0	2	1	1	1	2	1	2	2	1	2	2	1	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	2
51	HARSHIT	B	1.5	1	1	1	1	2	1	2	2	1	2	2	1	2	2	2	2	2	2	2	2		2	1	1	1	1	2	1	1	1	2	2	2	3
52	TANUSHREE	B	4.0	2	1	2	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	2ND	1	1	1	1	2	2	1	1	1	2	2	2	3
53	NIRMAY	B	1.5	1	1	1	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	2	1	3RD	1	1	1	1	1	2	1	2	1	2	2	1	4
54	HARSHIT	B	1.0	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		1	1	1	1	1	2	1	1	1	2	2	2	4
55	UMESHA	B	9.0	1	1	2	2	1	2	2	2	2	2	2	1	2	2	1	2	2	2	2	2		1	1	2	1	1	2	2	1	2	2	2	1	1
56	HARIZ	B	2.7	1	1	1	1	1	1	2	2	1	2	1	2	2	1	1	2	2	2	2	2		3	1	1	1	1	2	1	1	1	2	2	2	1
57	AISHWARYA	B	2.5	2	1	1	1	1	1	2	2	1	2	1	1	1	2	2	2	2	2	2	1	2ND	1	1	2	1	1	2	1	1	2	1	2	1	2
58	VIRAAT	B	3.5	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	2	2	2	1	2ND	2	1	1	1	2	2	1	1	1	2	2	1	1
59	MD AAQIUB	B	2.3	1	1	1	1	2	1	2	2	1	2	2	2	2	2	2	2	2	2	2	1	2ND	2	1	2	1	1	1	2	1	2	2	2	1	1
60	KHATIJA	B	8.0	2	1	1	1	1	1	1	2	1	2	2	2	1	2	2	2	2	1	2	2		1	1	1	1	1	2	1	2	2	2	2	1	1
61	TANUSHREE	B	4.0	2	1	1	1	2	1	2	2	1	2	2	2	2	2	2	2	2	1	2	2		1	1	1	1	1	2	1	2	2	2	2	1	2
62	SHIVANAND PUNDALIK	B	6.0	1	1	1	1	1	1	2	2	1	2	1	1	2	1	1	2	2	1	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
63	SHIVANAND PUJERI	B	2.0	1	1	1	1	2	1	2	2	1	1	2	1	2	2	2	2	2	2	2	1	3RD	2	1	1	1	1	2	1	2	2	2	2	1	1
64	ASHWINI	B	5.0	2	1	1	1	1	1	2	2	1	2	1	1	2	2	2	2	2	1	2	1	2ND	1	1	1	1	1	2	1	2	1	2	2	1	2
65	SIDDHARTH	B	2.3	1	1	1	1	2	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
66	ARADHYA	B	4.5	2	1	1	1	2	1	2	2	1	2	2	1	2	2	1	2	2	2	2	2		1	1	1	1	1	2	1	1	1	2	2	2	3
67	SIDDHARTH PISE	B	9.0	1	1	1	1	2	1	1	2	1	2	1	1	2	2	2	2	2	1	2	2		1	1	2	1	2	2	1	2	2	1	2	1	1
68	KRISH	B	1.9	1	1	1	1	2	1	2	1	1	1	1	2	1	2	2	2	2	2	2	1	2ND	1	1	1	1	1	2	1	2	2	2	2	1	1
69	MALIK	B	9.0	1	1	1	1	1	1	1	2	1	2	1	1	2	1	1	2	2	2	2	2		1	1	1	1	2	2	1	2	2	1	2	1	1
70	SHAHIN	B	2.5	2	1	1	1	1	1	2	2	1	1	1	1	2	2	1	2	2	1	2	1	2ND	2	1	1	1	1	2	1	2	2	2	2	1	1
71	ADITYA	B	1.0	1	1	1	1	2	1	2	2	1	1	2	1	2	2	2	2	2	2	2	1	3RD	2	1	2	1	2	2	2	1	2	2	2	1	1
72	NEHA	B	2.0	2	1	1	1	2	1	2	2	1	2	2	2	2	2	2	2	2	1	2	2		1	1	1	1	1	2	1	2	2	2	2	1	1
73	ARFAAN	B	1.7	1	1	1	1	1	1	2	2	1	2	1	1	2	2	2	1	2	2	2	2		1	1	1	1	1	2	1	2	1	2	2	1	1
74	SHRADDHA NADAGEKAR	B	2.8	2	1	1	1	2	1	2	2	1	2	2	1	2	2	1	2	2	2	2	2		1	1	2	1	1	1	1	2	2	2	2	1	2

PHYSIOLOGICAL	GMFM Pre	BAD Pre	HAT Pre	LAQCP Pre	DROOLING Pre	DSAP Pre	Post	GMFM Post	BAD Post	HAT Post	LAQCP Post	DROOLING Post	DSAP Post	AGITATION	DIZZINESS	DROWSINESS	FEVER	VOMITING	DROOLING	CONSTIPATION	DYSTONIA	IRRITABILTY
2	70.11	5	2		3	1		73.6	7	2		2	1	2		2	2	2	2	2		
2	33.67	12	2	66.99	1	1		40.004	7	2	67.07	1	1	2		2	2	2	2	2		
2	21.43	5	2		2	1		36.68	5	2		2	1	2		1	2	2	2	2		
2	19.56	6	2		1	1		23.02	4	2		1	1	2		1	2	1	2	2		
2	45.8	5	2		1	1		51.39	5	2		1	1	2		2	2	2	2	2		
2	52.9	2	2	50.79	1	1		57.38	0	4	51.35	1	1	2		2	2	2	2	2		
2	69.7	7	2	40.711	1	1		82.65	9	2	41.35	2	1	2		2	2	2	1	2		
2	60.55	15	2	27.15	1	2		70.65	15	2	27.23	1	2	2		1	1	2	2	2		
1	13.31	10	1		1	1		18.78	3	1		1	1	2		2	2	2	2	2		
2	52.48	6	2		1	1		54.94	4	2		1	1	2		2	2	2	2	2		
1	3.73	25	1		2	2		7.98	22	1		2	2	2		2	2	2	2	2		
2	40.32	9	2		1	1		47.54	3	2		1	1	2		2	2	2	2	1		
2	26.42	20	2		1	2		29.78	15	2		1	2	2		2	2	2	2	2		
2	4.01	21	2	67.88	2	2		9.72	16	2	67.88	1	2	2		2	2	2	2	2		
1	61.75	8	1	52.76	4	1		67.60	3	1	53.1	2	1	2		2	1	2	2	2		
2	54.27	8	2	21.15	2	1		60.01	5	2	21.3	2	1	2		2	2	2	2	2		
2	10.23	4	2		1	1		16.32	2	2		1	1	2		2	2	2	2	2		
2	14.2	12	2		4	1		22.74	6	2		2	1	2		2	2	2	2	2		
2	55.38	7	2	43.01	4	1		50.41	5	2	47.26	1	1	2		2	2	2	2	2		
2	17.2	11	1		3	1		21.67	8	2		2	1	2		2	2	2	2	2		
1	11.07	19	1		3	2		17.05	13	1		3	2	2		2	2	2	2	2		
2	2.74	15	2		2	2		7.99	9	2		2	1	2		2	2	2	2	2		
2	4.31	23	2		1	2		9	21	2		1	2	2		2	2	2	2	2		
2	48.72	6	2	51.78	1	1		88.9	3	2	52.68	1	1	2		2	2	2	2	2		
1	21.08	21	1		3	2	EXPIRED							2		2	2	2	2	2		
1	72.77	15	1		1	1		74.9	13	1		1	1	2		2	2	2	2	2		
2	75.30	9	2	21.47	1	1		81.9	2	2	21.92	1	1	2		2	2	2	2	2		
2	34.24	8	2	43.07	5	1	DROPPED							2		2	2	2	2	2		
1	95.83	2	1		1	1	LOST							2		2	2	2	2	2		
2	5.82	15	2		1	1	LOST							2		2	2	2	2	2		
2	53.64	2	2		5	1		56.67	3	2		2	1	2		2	2	2	2	2		
2	0.39	15	2		3	2	LOST							2		2	2	2	2	2		
2	66.38	5	2	28.55	5	1		92.738	0	3	28.55	5	1	2		2	2	2	1	2		
2	2.74	5	2		3	1		5.136	8	2		3	1	2		2	2	2	2	2		
2	9.5	7	2		1	1		20	10	2		1	1	2		2	2	2	2	2		
2	30.78	24	2		3	2		25.42	23	2		4	2	2		2	2	2	2	2		
2	3.8	22	2		3	2		5.26	21	1		3	2	2		2	2	2	2	2		
2	51.07	5	2		4	1		82.92	0	3		2	1		2	2	2	2	2		2	2
2	1.48	5	2		1	2		4.52	5	2		1	2		2	2	2	2	2		2	2
1	20.22	3	1		1	1		25	0	1		1	1		2	2	2	2	2		2	2
1	5.76	2	1		2	1		6.76	0	3		2	1		2	2	2	2	2		2	2
2	6.882	25	2	62.34	4	2	DROPPED								2	2	1	2	2		1	1
1	64.37	16	1		1	1		69.13	13	1		1	1		2	2	2	2	2		2	2
2	29.59	11	2		2	1		33.8	3	2		2	1		2	2	2	2	2		2	2
2	19.63	7	2	71.09	2	1		23.39	5	2	70.43	4	1		2	1	2	2	1		2	2
2	38.74	13	2		4	2		43.66	11	2		5	1		2	2	2	2	1		2	1
2	46.8	8	1	65.71	1	1		61.32	8	1	64.7	1	1		2	2	2	2	2		2	2
2	52.72	6	2		2	1	DROPPED								2	2	2	1	2		2	2
1	10.98	18	1	74.27	1	2		17.79	15	1	74.98	1	1		2	2	2	2	2		2	2
1	60.28	1	1		1	1		62.336	0	3		1	1		2	2	2	2	2		2	2
2	71.78	2	2		1	1		87.97	0	4		1	1		2	2	2	2	2		2	2
2	95.44	0	1		1	1		97.776	0	4		1	1		2	2	2	2	2		2	2
2	28.09	3	2		3	1		39.66	1	2		3	1		2	2	2	2	2		2	2
1	18.62	3	1		1	1		34.98	2	1		1	1		2	2	2	2	2		2	2
2	25.59	18	2	48.73	1	1		37.32	15	1	58.48	1	1		2	2	2	2	2		2	2
2	11.56	12	2		3	1		16.55	10	2		3	1		2	2	2	2	2		2	2
1	26.75	5	1		3	1		28.91	4	1		2	1		2	2	2	2	2		2	2
2	5.92	23	2	65.92	3	2		11.28	20	2	62.18	2	2		2	2	2	2	2		2	2
2	26.54	9	2		2	1		30.76	5	2		2	1		2	2	2	2	2		2	1
2	15.64	11	2	71.43	5	1		14.92	7	2	70.09	1	1		2	2	2	2	2		2	2
1	81.52	2	1	18.26	3	1		85.64	0	3	16.41	3	1		2	2	2	2	2		2	2
2	79.946	7	1	34.08	1	1		90.14	7	1	33.1	1	1		2	2	2	2	2		2	2
1	17.95	19	1		1	1		26.76	15	2		1	2		2	2	2	2	2		2	1
1	48.35	4	2	63.12	5	1		59.51	0	3	63.12	2	1		2	2	2	2	2		2	2
1	19.47	9	1		1	1		28.42	9	1		1	1		2	2	2	2	2		2	2
2	79.52	2	2	17.18	1	1		86.44	0	4	17.82	1	1		2	2	2	2	2		2	2
2	43.68	11	2	50.18	1	1		51.37	11	2	49.14	1	1		2	2	2	2	2		2	2
2	8.58	17	2		5	2		30.322	4	1	19	1	1		2	2	2	2	2		2	1
2	34.76	12	2	65.43	1	1		36	13	2	66.47	1	1		2	2	2	2	2		2	2
1	36.85	11	1		1	1		35.57	12	1		1	1		2	2	2	2	2		2	2
2	29.64	17	1		1	1		38.83	9	1		2	1		2	2	2	2	2		2	2
2	1.176	20	2		3	2		5.63	20	2		4	2		2	2	2	2	2		2	2
1	3.744	11	1		3	1		9.72	10	1		2	2		2	2	2	2	2		2	2
2	73.67	3	2		1	1		84.77	0	3		1	1		2	2	2	2	2		2	2