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Department of Pharmacy Practice
Seven Hills College of Pharmacy
(Autonomous)
Tirupati, Andhra Pradesh.
In association with
Sri Padmavathi Medical College for Women,
Alipiri Road, Tirupati (Dist.,),
Andhra Pradesh, India.
Contact Us:
pharmacypractice@shcptirupati.edu.in
Phone: 7730084513, 7702484513

VISION

To emerge as one of the premier pharmacy colleges in the country and produce pharmacy professional of global Standards.

MISSION

- To deliver quality academic programs in Pharmacy and empower the students to meet industrial standards.
- To build student community with high ethical standards to undertake R&D in thrust areas of national and international standards.
- To extend viable outreach programs for the health care need of the society.
- To develop industry institute interaction and foster entrepreneurial spirit among the gradutes

CASE REPORT ON DEMYELINATING DISORDER

K. SWATHI , B. SOWMYA
Pharm D III rd year

INTRODUCTION :

Multiple sclerosis(MS) is a chronic autoantibodies cause the destruction of the myelin sheath covering the nerves of the central nervous system. It is highly varied entity and course of the disease is unpredictable. The etiological factor that causes MS is environmental and genetic factors and viral infections. Individuals with low levels of vitamin -D have reported high incidence of MS. Genetic mutation in a particular susceptibility gene known as HLA-DR2 is responsible for the development of MS. MS is a type 4 hypersensitivity reaction. The Antigen (Ag) of unknown nature when entering the body, is phagocytosed by Antigen presenting cells(APC) ,mostly macrophages . Later they present Ag to T – Helper cells, which identify the Ag as a mimic of myelin protein. The symptoms of MS are usually manifested as charcots neurological triad. This is characterised as dysarthria , Nystagmus and intention tremors , compromise the movements of muscles like oropharyngeal muscles including speech , mastication and swallowing .

Patient might complain of complete loss of vision, blurred vision , double vision. Cerebrospinal fluid analysis and MRI are the main factors for the diagnosis of MS . MRI of the brain and spinal cord with or without contrast is considered as first line of diagnosis. The visual evoked potential(VEP) test is considered as the second line of the diagnostic approach.

CASE DISCUSSION:

SUBJECTIVE EVIDENCE :
A 67 years old Male patient admitted in Neurology department
CHIEF COMPLAINTS: blurred vision in both eyes since 1month and diplopia present, shortness of breath since 2days and weakness of limbs
PAST MEDICAL HISTORY: K/C/O Hypertension and H/O Seizures and H/O insomnia H/O pulmonary Koch for 1year
SOCIAL HISTORY: Ex- smoker , Ex-alcoholic and tobacco chewing

OBJECTIVE EVIDENCE
Bilateral dropping of eyelids
Paraphonia present
Aprexia present
Sensory swagging to right side
REFLEXES :B . J. S. . K. T.. P.
RIGHT 2+ 2+.2+. 2+ +. +
LEFT. 2+ 2+. 2+.2+ +. +

LABORATORY INVESTIGATIONS

TLC	20,000cells/cum
ESR	12mm/1st Hr
RBC	5.07 mill/cum
S. Sodium	133mmol/L
S potassium	2.3 mmol/L
Alkaline Phosphate	69 IU/L
T. Cholesterol	304mg/dL
HDL	45mg/dL
LDL	123 mg/dL

TREATMENT CHART

DRUGS	DOSE	ROA	FREQ	DAYS
T. Thiamine	200mg	P/O	TID	10days
T. Rejunex	1tab	P/O	OD	10days
T. Levetiracetam	500mg	P/O	BD	3days
T. Montleukast - fexofenadine	1tab	P/O	OD	7 days
INJ. Pantop	40mg	IV	OD	7 days
T. Wysolone	40mg	P/O	OD	4 days

CONCLUSION :

From the above case, we can conclude that patient had past medical history of hypertension and pulmonary Koch, which is one of the risk factor for Demyelinating disorder.
There is no specific cure that physical therapy can provide , so we make it a goal to use the technique , exercises and knowledge that we have in order to best improve the quality of life of the patient .

REFERENCE :

Celius E.G., Thompson H., Pontaga M., Langdon D., Laroni A., Potra S., Bharadia T., Yeandle D., Shanahan J., van Galen P., et al. Disease Progression in Multiple Sclerosis: A Literature Review Exploring Patient Perspectives. Patient Prefer. Adherence. 2021;15:15–27.
doi: 10.2147/PPA.S268829. - DOI – PMC.

UNDESIRABLE EFFECTS OF ISOTRETINOIN A NATURAL DERIVATIVE OF VITAMIN "A"

SRIJA.S – Pharm.D Internt

Isotretinoin capsule is a medicine that contains isotretinoin. It is a naturally occurring derivative of vitamin A. This medicine is used for the treatment of a severe form of acne called nodular acne characterized by large, inflamed, painful acne lesions deep under the skin. It acts on skin glands to reduce the production of a substance called sebum that can cause acne or pimples. It also has an anti-inflammatory action which decreases the redness and swelling associated with acne.

ACTION:

Isotretinoin is a retinoid, when administered in pharmacologic dosages of 0.5 to 1.0 mg/kg/day inhibits sebaceous gland function and keratinization.

PHARMACODYNAMIC PROPERTIES:

Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secretion. The decrease in sebum secretion is temporary related to the dose and duration of treatment with ISOTROIN, and reflects a reduction in sebaceous gland size and an inhibition of sebaceous gland differentiation.

PHARMACOKINETIC PROPERTIES:

ABSORPTION :

Due to its high lipophilicity, oral absorption of isotretinoin is enhanced when given with a high-fat meal. The time to peak concentration (Tmax) was also increased with food and may be related to a longer absorption phase.Therefore ISOTROIN should always be taken with food. Clinical studies have shown that there is no difference in the pharmacokinetics of isotretinoin between patients with nodular acne and healthy subjects with normal skin.

DISTRIBUTION :

Isotretinoin is more than 99.9% bound to plasma proteins, primarily albumin.

METABOLISM :

After oral administration of isotretinoin, three metabolites have been identified in hurnan plasma 4-oxo-isotretinoin, retinoic acid and 4-oxo-retinoic acid (4-oxo-tretinoin). These three metabolites are further metabolized to conjugates, which are then excreted in urine and faeces.

ELIMINATION :

Isotretinoin and its metabolites are ultimately excreted in the feces and urine in relatively equal amounts (total of 65% to 80%)

UNDESIRABLE EFFECTS :

The adverse reactions listed below reflect experience from investigational studies of isotretinoin and post marketing experiences

S.No	SYSTEM	Disorder
1.	BODY AS WHOLE	Allergic reactions, including vasculitis, anaphylactic reactions, systemic hypersensitivity, oedema, fatigue, weight loss
2.	INFECTIONS	Gram positive (mucocutaneous) bacterial infection
3.	CARDIOVASCULAR	Palpitation, tachycardia, vascular thrombotic disease, stroke.
4.	ENDOCRINE/ METABOLIC DISORDERS	Decreased appetite, weight fluctuation, hyperlipidemia. Hypertriglyceridemia.
5.	GASTROINTESTINAL	Nausea, constipation, diarrhoea, abdominal pain, vomiting Inflammatory bowel disease, hepatitis, pancreatitis,bleeding of the gums, colitis, dry throat, gastrointestinal hemorrhage, hemorrhagic diarrhoea, oesophagitis.
6.	HAEMATOLOGIC	Allergic reactions, anaemia, thrombocytopenia, neutropenia, red blood cell sedimentation rate increased, thrombocytes, rare agranulocytosis
7.	INFECTIONS	Nasopharyngitis, upper respiratory tract infection
8.	MUSCULOSKELETAL AND CONNECTIVE TISSUE	Skeletal hyperostosis, calcification of tendons and ligaments, premature epiphyseal closure, decreases in bonemineral density, musculoskeletal symptoms (sometimes severe), including back pain (particularly in children and adolescent patients), myalgia and arthralgia transient pain in the chest, arthritis, tendonitis, other types of bone abnormalities, musculoskeletal pain, neck pain, pain in extremity, musculoskeletal stiffness
9.	NEUROLICAL	Pseudotumorcerebri, dizziness, drowsiness, headache, lethargy, malaise, nervousness, paraesthesia's, seizures convulsions, stroke. weakness, benign intracranial hypertension
10.	SKIN AND APPENDAGES	Acne fulminans, acne aggravated (acne flare), erythema (facial), exanthema, alopecia (which in some cases persists bruising dry lips,dry mouth, dry nose, dry skin, dermatitis, localized exfoliation, epistaxis, eruptive xanthomas, erythema multiforme Rushing, fragility of skin hair hirsutism hyperpigmentation and hypopigmentation, infections (including disseminated herpes simplex), nail dystrophy.
11	PSYCHITARY	Suicidal ideation, insomnia, suicide attempts, suicide, depression, instability, panic attack, anger, euphoria, depression, aggression, violent behaviours, anxiety, mood alterations, abnormal behaviour, emotional instability.
12.	SPECIAL SENCES	Hearing impairment, tinnitus, Eye pruritis, increased lacrimation.

PATIENT COUNSELLING INFORMATION:

What are ISOTROIN?

• ISOTROIN contains isotretinoin and are prescribed to treat severe form of pimples, which in medical terminology is called as severe refractory nodulocystic acne

What facts do I need to know about ISOTROIN?

- ISOTROIN are indicated in severe pimples in both males and females and is to be taken under a doctor's supervision only.
- ISOTROIN are strictly a prescription-based drug. Under no circumstances should you suggest it to anyone else even if his or her condition resembles yours.
- You might have difficulty in using contact lenses.
- Vitamin A supplements should be avoided while on therapy.
- Patients with a family or personal history of diabetes, liver disease, heart disease or depression should inform their doctor before the start of the therapy.
- If your acne returns, do not take ISOTROIN of your own on your old prescription. Consult your doctor again.

What precautions do I need to take when I am on ISOTROIN therapy?

- Do not donate blood during the course of therapy and 1 month after discontinuation of therapy.
- Avoid prolonged exposure to sunlight. Use a sunscreen.
- Avoid night driving.
- Avoid removal of body hair by using wax due to the increased chances of scarring and for at least 6 months thereafter.

What special precautions to be taken by female patients of childbearing potential?

- ISOTROIN may cause severe birth defects; you must not take this medicine if you are pregnant or may likely become pregnant during treatment.
- You should also avoid pregnancy for 6 months after stopping the treatment.
- Patients should use effective contraceptive methods 1 month prior to starting the therapy, during the therapy, and 6 months after stopping the therapy.
- Avoid breastfeeding during the therapy and one month after stopping the therapy.
- You must sign a consent form before undertaking the treatment of isotretinoin

TRANEXAMIC ACID

Tranexamic acid is a medication used to treat or prevent excessive blood loss from major trauma, postpartum bleeding, surgery, tooth removal, nosebleeds, and heavy menstruation. It is also used for hereditary angioedema. It is taken either orally or by injection into a vein

Composition: Tranexamic acid will be available in Film coated tablet contains Tranexamic Acid IP 500mg

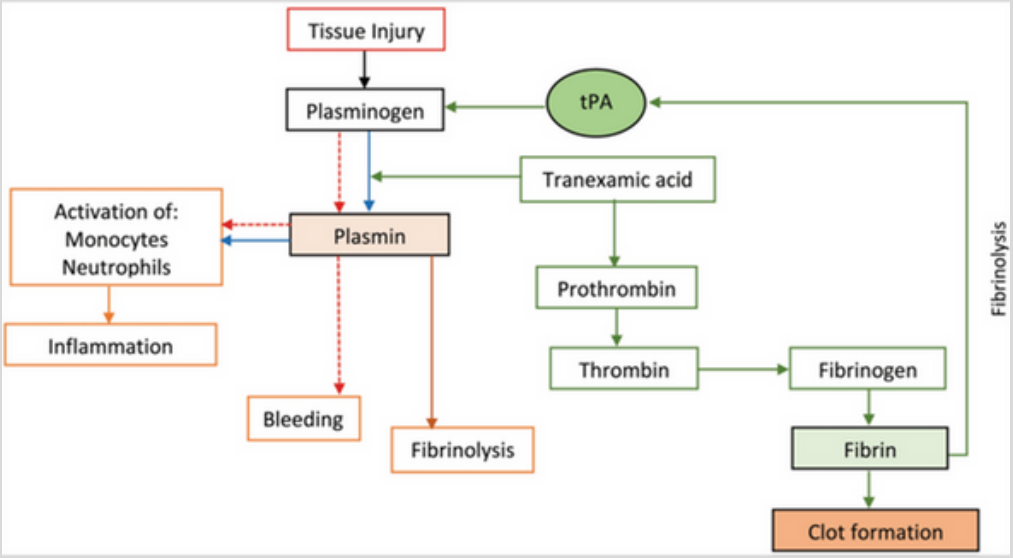
Pharmacological Classification: Antifibrinolytic agent

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The inhibitory effect of Tranexamic acid in plasminogen activation by urokinase has been reported to be 6-100 times and by streptokinase 6-40 times greater than that of aminocaproic acid. The antifibrinolytic activity of Tranexamic acid is approximately ten times greater than that of aminocaproic acid.

Mechanism of Action:



Pharmacokinetics:

Absorption:

- Peak plasma Tranexamic acid concentration is obtained immediately after intravenous administration (500mg). Then concentration decreases until the 6th hour Elimination half-life is about 3 hours.

Distribution:

- Tranexamic acid administered parenterally is distributed in a two compartment model. Tranexamic acid is delivered in the cell compartment and the cerebrospinal fluid with delay. The distribution volume is about 33% of the body mass Tranexamic acid crosses the placenta, and may reach one hundredth of the serum peak concentration in milk of lactating women.

Elimination:

- Tranexamic acid is excreted in urine as unchanged compound 90% of the administered dose is excreted by the kidney in the first hours after administration (glomerular excretion without tubular reabsorption)
- Plasma concentrations are increased in patients with renal insufficiency

Indications and Usage:

- Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditatoryangioneuroticoedema.
- Abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, haemorrhage, epistaxis, renal bleeding abnormal bleeding during or after prostate surgery).

Contraindications:

- Severe renal impairment (risk of accumulation)
- History of convulsions
- History of venous or arterial thrombosis

Adverse Reaction:

- Immune system disorders
- Hypersensitivity reactions including anaphylaxis
- Eye disorders
- Colour vision disturbances, retinal vein artery occlusion Vascular disorders
- Thromboembolic events Very rare Arterial or venous thrombosis at any sites
- Gastro-intestinal disorders
- Very rare Digestive effects such as nausea, vomiting and diarrhea may occur but disappear when the dosage is reduced
- Skin and subcutaneous issue disorders Rare Allergic skin reactions
- Nervous System Disorders

Drug Interactions:

- Tranexamic acid will counteract the thrombolytic effect of fibrinolytic preparations.

Overdosage:

- Symptoms may be nausea, vomiting, orthostatic symptoms and/or hypotension. Initiate vomiting, then stomach lavage, and charcoal therapy maintain a high fluid intake to promote renal excretion. There is a risk of thrombosis in predisposed individuals Anticoagulant treatment should be considered.

Storage:

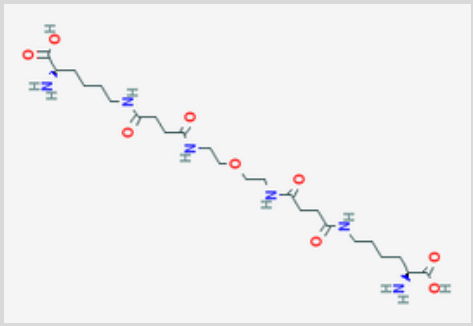
- Store in cool and dry place Protect from light.

DRUG MONOGRAPH - ELFABRIO

G.V.Tejaswini,R.Pavan kumar
Pharm D III rd year

Drug name : ELFABRIO
Approved by FDA in may 10th ,2023
Brand name: Elfabrio
Generic name : Pegunigalsidasealfa
Drug class : Lysosomal enzymes
Mechanism of action: Fabry disease is caused by a deficiency in alpha-galactosidase A, an enzyme that is supplied by ELFABRIO, which is internalized and transported into lysosomes to reduce Gb3 accumulation.

Chemical structure:



Pharmacokinetic properties:

Absorption: In adult patients with Fabry disease, the pharmacokinetic profile of pegunigalsidasealfa at 0.2, 1, and 2 mg/kg given IV every two weeks was assessed. During the first day of the study and at these dose levels, pegunigalsidasealfa's AUC0-∞ increased as the dose was raised. Additionally, the dose-normalized AUC0-2wk mean values were found for all dosages, indicating a dose-proportional pharmacokinetic profile for pegunigalsidase alfa.5.

When patients with Fabry disease who had not received any previous enzyme replacement therapy were given an intravenous infusion of pegunigalsidasealfa at a dose of 1 mg/kg every two weeks, their Cmax increased from 11.1 µg/mL on day 1 to 17.3 µg/mL on week 52, and their AUCinf increased from 391 µg•h/mL on day 1 to 1428 µg•h/mL on week 52. In Fabry disease individuals receiving enzyme replacement therapy

Distribution: The volume of distribution in Fabry disease patients who had not received any prior enzyme replacement therapy and were administered an intravenous infusion of pegunigalsidasealfa at a dose of 1 mg/kg every two weeks was 321 mL/kg on day 1, 271 mL/kg on week 13, 226 mL/kg on week 26, and 186 mL/kg on week 52.7.

Metabolism: Pegunigalsidasealfa is a recombinant protein, hence peptide hydrolysis is anticipated to be its mode of metabolism. Consequently,

it is unlikely that reduced liver function will have a clinically meaningful impact on pegunigalsidasealfa's pharmacokinetics. Pegunigalsidasealfa is not anticipated to be a target of cytochrome P450 enzymes based on its metabolism.

Elimination : The molecular weight of pegunigalsidasealfa is roughly 116 kDa, which is double the glomerular filtration cut-off value. Filtration and/or proteolytic breakdown in the kidneys are therefore improbable.

Pegunigalsidasealfa given in two-week intervals has a plasma half-life that ranges from 53 to 134 hours across dose groups and visit day.

Pharmacodynamics :

The amounts of plasma globotriaosylsphingosine (lyso-Gb3, a metabolite of Gb3) are higher in Fabry disease patients. In Fabry disease individuals who were [refer to Clinical Studies (14)]

ELFABRIO treatment led to significant reductions in median plasma lyso-Gb3 concentrations compared to baseline of approximately ○ -43% (Week 4), -57% (Week 26), -68% (Week 52), and -84% (Week 104) in male patients, and -3% (Week 4), -19% (Week 26), -32% (Week 52), and -75% (Week 104) in female patients who were either ERT-naïve or had not received ERT treatment for at least 26 weeks and had a negative test for anti-pegunigalsidasealfa-iwxj antibodies (Trial 1).

After starting ELFABRIO medication after receiving ERT for at least 104 weeks,median plasma lyso-Gb3 concentrations increased relative to baseline by about 11%

Therapeutic uses : Used to treat adults confirmed with Fabry disease

Adverse reactions :

Hypersensitivity reactions including with anaphylaxis :Anaphylaxis and other hypersensitivity reactions have been documented in patients receiving ELFABRIO. Twenty percent of patients treated with ELFABRIO in clinical trials developed hypersensitivity reactions. Of these, four patients (three percent; one ERT naïve and three ERT-experienced) developed anaphylaxis during the first infusion and tested positive for anti-pegunigalsidasealfa-iwxjIgE antibodies, also known as IgE ADA. In some patients, the risk of hypersensitivity connected to pegunigalsidasealfa-iwxj may be elevated due to pre-existing ADA from previous ERT.

Anaphylaxis manifested as a headache, nausea, vomiting, tightness in the throat, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema, and it happened between five and forty minutes after the first infusion started. Patients were treated with antihistamines and, epinephrine

Infusion associated reactions :

IRRs were reported in 32 patients (22%) in total: 26 patients (23%) treated with 1 mg/kg every two weeks, and 6 patients (20%) treated with 2 mg/kg every four weeks. The most frequently reported symptoms associated with IRRs for the 1 mg/kg dosage were chills, dizziness, rash, and itching, while pain was the most commonly reported symptom for the 2 mg/kg dose. IRRs

were mostly mild or moderate in intensity and resolved with continuous treatment; however, 5 patients (all male, 1 mg/kg dose) experienced 5 severe IRRs. These 5 IRRs were also serious, and 4 of these events were confirmed type I hypersensitivity reactions, three of which resulted in the study's discontinuation. Another patient was later withdrawn

Membrane proliferative glomerulonephritis:

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials, leading to a decline in renal function that improved upon discontinuation of ELFABRIO but did not return to baseline by the end of the trial.

Most common adverse reactions (≥15%) are: infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Doses: Injection-20 mg/10 mL (2 mg/mL) of pegunigalsidasealfa-iwxj in a clear and colorless solution in a single-dose vial

Dosage forms and ROA: Injection, solute and concentrate.

- The recommended dosage of ELFABRIO, based on actual bodyweight, is 1 mg/kg administered by intravenous infusion every 2 weeks.
- The initial recommended ELFABRIO infusion rates for ERT-experienced or ERT-naïve patients are based on actual body weight .
- If one or more doses are missed, restart ELFABRIO treatment as soon as possible, maintaining the 2 week interval between infusions thereafter. Do not double a dose to compensate for a missed dose.

Storage conditions :

- Should the diluted ELFABRIO solution not be utilized right away, store it in the refrigerator for a maximum of 24 hours, keeping it between 2°C and 8°C (36°F and 46°F). After being taken out of the refrigerator, the solution needs to be infused within 8 hours, including the entire infusion period, or it will be thrown out.
- For up to eight hours, keep the diluted solution at room temperature, between 20°C and 25°C (68°F and 77°F). The solution needs to be used up within eight hours (including the infusion period) or thrown away.
- Avoid shaking or freezing.

Reference :

- **https://www.google.com/urlsa=t&source=web&rct=j&opi=89978449&url=https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761161s000lbl.pdf&ved=2ahUKEwiR0qKmwpmDAxUy8jgGHWN-DNQQFnoECBQQAQ&usg=AOvVaw3PLiwknDHmVBAsmfMJ_giR**
2. **https://go.drugbank.com/drugs/DB14992**

DEPARTMENTAL ACTIVITIES IN JULY- 2023

PERFECT CLICKS

FRESHERS DAY CELEBRATIONS

WORLD ZOONOSES DAY

DENTAL CAMP BY CKS CHARITY TRUST

SHCP STUDENTS RECEIVED THE PRIZE IN YUVA UTSAV COMPETITIONS AT SPMVV, TIRUPATI

DOCTORS DAY CELEBRATIONS

INTERNATIONAL WORKSHOP CONDUCTED BY SHCP (AUTONOMOUS), TIRUPATI IN ASSOCIATION WITH SV UNIVERSITY, TIRUPATI