

## **PHARMANEXUS**

### THE ERODE COLLEGE OF PHARMACY



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### **MYOSITIS**



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### **Introduction:**

Dermatomyositis (DM), polymyositis (PM), necrotizing myopathy (NM), and inclusion body myositis (IBM) are examples of idiopathic inflammatory myopathies, or simply myositis. Every one of them exhibits muscle weakness. Clinical examination (distribution of paresis) and test results, such as autoantibodies and creatine kinase (CK), electromyography (EMG), and skeletal muscle histology, are used to make the diagnosis. In addition to identifying a suitable muscle for biopsy, skeletal muscle magnetic resonance imaging (MRI) can show the pattern of damaged muscles beyond clinical presentation, which aids in ruling out conditions such muscular dystrophies.[1]

### **Understanding Myositis:**

Myositis, which means "muscle inflammation" in Greek, is a term used to describe a group of inflammatory muscle diseases. This group comprises several specific types of myositis, each with distinct characteristics. The most common types of myositis include:

PHARMANEXUS - 2 -

**1.Polymyositis (PM):** PM primarily affects skeletal muscles and causes muscle weakness and inflammation. It can also affect other organs, such as the heart and lungs.

- **2. Dermatomyositis (DM):** DM is characterized by muscle inflammation and a distinctive skin rash. It often impacts the skin, muscles, and sometimes internal organs.
- **3. Inclusion Body Myositis (IBM):** IBM typically occurs in older adults and is characterized by muscle weakness, particularly in the wrists and fingers. It is the most common type of myositis in individuals over the age of 50.
- **4. Juvenile Myositis (JM):** JM is a rare form of myositis that affects children and adolescents. It includes subtypes like juvenile dermatomyositis and juvenile polymyositis.

### Causes and Risk factors:

The exact causes of myositis remain poorly understood, but it is generally considered an autoimmune disease. In autoimmune diseases, the body's immune system mistakenly attacks its own tissues. Genetic factors, environmental triggers, and infections may play a role in the development of myositis.

### **Symptoms of Myositis:**

Myositis presents with a range of symptoms that can vary in severity.

Common symptoms include:

- 1. Muscle weakness
- 2. Muscle pain or tenderness
- 3. Fatigue

- 4. Difficulty swallowing
- 5. Skin rashes (in the case of dermatomyositis)
- 6. Joint pain and inflammation
- 7. Fever
- 8. Difficulty breathing (In severe cases)

### **Diagnosis:**

To properly diagnose myositis, a thorough medical history and examination are necessary. In contrast to a proximal weakness, which is similar in DM, PM, and NM, the paresis distribution might show a pattern typical for IBM. An elevated CK is typically seen in laboratory testing, and occasionally other enzymes like LDH, AST, or ALT, as well as autoantibodies specific to myositis, may be found.[2]

### **Treatment Options:**

The treatment of myositis generally involves a multidisciplinary approach, often including rheumatologists, neurologists, and physical therapists. Treatment options may include:

- **1.** Corticosteroids: High-dose corticosteroids are commonly used to reduce inflammation in the muscles. They can provide relief, but long-term use can have side effects.
- **2. Immunosuppressive drugs:** These medications help suppress the immune system to prevent it from attacking the muscles.
- **3. Physical therapy:** Rehabilitation and exercise programs are essential to maintain muscle strength and mobility.

PHARMANEXUS - 3 -

**4. Supportive care:** Depending on the specific subtype of myositis, treatment may also involve managing skin rashes or addressing organ involvement.

### **Conclusion:**

Myositis is a complex group of diseases that impact muscle health and overall well-being. It requires a comprehensive and multidisciplinary approach to diagnosis and management. While there is currently no cure for myositis, ongoing research and advancements in treatment options offer hope for improved outcomes and a better quality of life for those affected by these conditions. If you or a loved one experience symptoms of myositis, it is crucial to seek medical attention and consult with healthcare professionals who specialise in autoimmune diseases.

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EMERGING ROLE OF ARTIFICIAL
INTELLIGENCE WITH ROBOTICS IN THE
SYSTEM

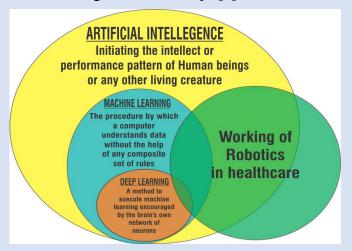


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AI works with an amalgamation of enormous amounts of data using fast and complex algorithms. This permits the software to quickly adapt the pattern of the data characteristics. It has the possibility to collide with most of the facets of the health system which may range from discovery to prediction and deterrence.

The use of AI with robotics in the healthcare sector has shown a remarkable rising trend in the past few years. Functions like

- 1. Assistance with surgery,
- 2. Streamlining hospital logistics,
- 3. Conducting routine checkups.[1]



Working of Robotics in Healthcare. Image credit: Niyati Deo. doi:10.7759/cureus.39416

# ADVANTAGES OF USING ROBOTICS IN HEALTHCARE:

### **Exclusive Patient Care**

Socially Assistive Robots (SARS) are the result of the development of AI along with physically assisted technologies. Sars are emotionally intelligent machines that lead to exclusive patient care, as these are capable of communicating with patients through a communicative range that makes them respond emotionally. PHARMANEXUS - 4 -

The different types of response include interaction, communication, companionship, and emotional attachment.[2]

### AI in Nanotechnology Research

Recent advances have been made in the field of medicine using nanotechnology. AI tools can be successfully merged with nanotechnology to understand the various events happening in the nanosystems. This can help in designing and developing drugs by developing the nano-systems.[3]

### Prediction of an Epidemic Outbreak:

One of the most amazing tasks of AI in healthcare is that it is capable of forecasting the outbreak of an epidemic. Although it cannot control or mitigate the outbreak, it can warn us beforehand to make preparations in time. The calculation is done by generating an algorithm by collecting all the data from the news bulletins in all languages, airline ticketing, and reports related to plant and animal diseases.[4]

### AI in Diagnosis

About 80,000 people die every year due to wrong diagnoses of illnesses. Loads of excessive cases with partial details have led to severe mistakes in the past. As AI is resistant to these errors, it is capable of predicting and diagnosing diseases at a faster pace.[5]

### **Boost in Clinical Trials:**

Details of patients saved in the computer can be analysed and the lessons learned can be used for future trials, thus saving time and cost It also works efficiently to observe the patients consistently and share the data across different computers. The self-learning capacity of AI enhances the accuracy of the trial and foresees the chances of dropouts.

### References:

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   BLDE Univ J Health Sci. 2019, 4:1-6.
- 2. Bora GS, Narain TA, Sharma AP, Mavuduru RS, Devana SK, Singh SK, Mandal AK: Robot-assisted surgery in India: a SWOT analysis. Indian J Urol. 2020, 36:1-3.
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PHARMANEXUS - 5 -

### STATUS OF β-THALASSEMIA AT PRESENT



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The  $\beta$ -thalassemia are a class of hereditary hemoglobin (Hb) synthesis disorders characterized by chronic anemia of varying degrees of severity.

The severity of anemia and the requirement for routine transfusion therapy depend on a number of genetic and environmental factors. Depending on whether a person has -thalassemia minor, intermedia, or severe, their symptoms can differ greatly.

Although thalassemia has historically been a rare disease in the United States, it is quite common in the Mediterranean, Middle East, Africa, South Asia, and India.

They classify patients as having Transfusiondependent thalassemia (TDT) or Non-transfusiondependent thalassemia.

Routine transfusion therapy is a standard procedure to categorize patients as having either Transfusion-dependent (TDT) or Non-transfusion-dependent (NTDT) -thalassemia.

Patients with TDT (major and severe types of HbE/-thalassemia) typically present in early childhood with severe anemia and need transfusion therapy for the rest of their lives to survive.

Although the introduction of transfusions increased longevity in TDT patients, it was not without its own adverse effects, including systemic iron excess that caused end-organ damage and an increase in death from heart or liver illness.

Improvements in iron chelation therapy and the use of MRI to identify organ-specific iron excess have resulted in better patient outcomes and management. TDT still imposes a significant burden on patients, doctors, and the entire healthcare system because of persistent morbidity, high healthcare utilization, limited access to the best care, expensive treatment, and a number of unmet needs in terms of effectiveness, safety, and adherence to conventional therapies, particularly in countries with limited resources.

Only a small percentage of patients with appropriate donors can get allogeneic hematopoietic stem-cell transplantation (HSCT), which has been utilized successfully for the past several decades to provide curative therapy for TDT patients.

### **Treatment:**

Red blood cell transfusions at regular intervals, often every 2 to 4 weeks, and chelation therapy using a medication like deferoxamine (Desferal; Novartis) or deferasirox to remove extra iron from the bloodstream are the main management methods for thalassemia.

Patients with beta-thalassemia may endure symptoms like persistent fatigue, liver and heart problems, and discomfort without transfusions and chelation therapy. PHARMANEXUS - 6 -

A stem cell transplant is the only effective treatment for -thalassemia major.

Luspatercept-aamt (Reblozyl; Bristol Myers Squibb), which was licensed for use in late 2019, is the first medication to treat anemia in adult thalassemia patients who require frequent red blood cell transfusions.

The beleive trial (NCT02604433), a phase 3 multicenter, randomized, double-blind, placebocontrolled trial enrolling 336 adult patients with thalassemia needing regular red blood cell transfusions, supported the approval of luspaterceptaamt. Luspatercept-aamt 1 mg/kg subcutaneous injections every three weeks, with dose increments of 1.25 mg/kg as allowed, or placebo subcutaneous injections every three weeks were given to trial participants in a 2:1 randomization. All patients were allowed to continue receiving the greatest supportive treatment, including dietary assistance, antibiotics, chelating agents, transfusions, and antiviral and antifungal medications.

Headache, bone pain, arthralgia, weariness, cough, abdominal pain, diarrhoea, nausea, problems breathing, and dizziness are among the most frequent side events (AEs) connected with luspatercept-aamt.

Hypertension and thromboembolic events have also been linked to luspatercept-aamt therapy.

According to the Thalassaemia International Federation's 2021 guidelines for the management of transfusion-dependent -thalassemia, luspatercept-aamt may be the best option for treating patients who live in areas with limited access to blood transfusions as well as those who were previously transfusion independent but now need transfusions

# FDA Approves First Gene Therapy for Beta-thalassemia: Aug 17, 2022

The FDA approved Betibeglogene autotemcel (Zynteglo), the first cell-based gene therapy for the treatment of adult and pediatric patients with betathalassemia who require regular red blood cell transfusions.

For adults, adolescents, and children with all genotypes ( $\beta$  0  $\beta$ 0 and non-  $\beta$ 0  $\beta$ 0) of transfusion-dependent -thalassemia, betibeglogene autotemcel (Zynteglo; bluebird bio) is a one-time ex vivo gene therapy. With betibeglogene autotemcel, the patient's stem cells are removed, functional copies of a modified globin gene ( $\beta$  A[T87Q]-globin gene) are inserted into the stem cells using a BB305 lentiviral vector, and the changed cells are then infused back into the patient. The patient should then be able to create their own functional adult hemoglobin produced from gene therapy and no longer require red blood cell transfusions once they have a functional  $\beta$  A(T87Q) globin gene.

For patients with transfusion-dependent -thalassemia 12 years of age and older who are qualified for stem cell transplantation but do not have a donor available, betibeglogene autotemcel is now approved in the European Union, United Kingdom, Iceland, Liechtenstein, and Norway. Additionally, Bluebird Bio has provided the FDA with a biologics licensing application (BLA) that is backed by information from phase 1/2 and phase 3 trials.

PHARMANEXUS - 7 -

Twenty-three adult and pediatric patients with non-0/0 genotypes received betibeglogene autotemcel treatment in the phase 3 NorthStar-2 trial (NCT02906202). 22 patients were eligible for examination, and 20 of them, including 6 of 7 patients under the age of 12, were transfusion independent. The FDA also granted the BLA submission priority review; the anticipated action date is now August 19, 2022, delaying the date from the original May 20, 2022, to provide the FDA time to analyze additional clinical data.

Codeveloped by CRISPR Therapeutics and partner Vertex, CTX001 is a gene treatment that is now undergoing phase 3 clinical studies.

It is a one-time ex vivo treatment, similar to betibeglogene autotemcel, except it increases the production of fetal hemoglobin by using CRISPR/Cas9 to modify the BCL11A gene in the patient's cells.17 In the VX21-CTX001-141 experiment (NCT05356195), preliminary data from 10 adult and pediatric patients with various genotypes showed that CTX001 treatment boosted hemoglobin and fetal hemoglobin. Within two months of starting medication, all 10 patients in the trial were able to discontinue receiving transfusions.18 In late 2022, CRISPR Therapeutics and Vertex intend to submit a BLA to the FDA.

# Potential Drawbacks of -Thalassemia Gene Therapy:

There are some risks and safety issues with gene therapy. Although the myeloid malignancies have not been explicitly linked to the gene therapy used to treat sickle cell disease, reports of them occurring after treatment have been made. Despite the fact that people with sickle cell disease and transfusion-dependent -thalassemia have a higher chance of developing myeloid malignancies, this is still a cause for concern. The duration of the effect is similarly unknowable.

Cost may prevent patients with -thalassemia from receiving gene therapy in addition to safety issues. In Europe, the cost of Betibeglogene autotemcel is equivalent to \$1.8 million, and bluebird bio withdrew its clearance in Germany as a result of a disagreement about pricing.

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- 3. Luebird bio submits biologics license application (BLA) to FDA for betibeglogene autotemcel (beticel) gene therapy for patients with  $\beta$  thalassemia who require regular red blood cell transfusions.
- 4. New Treatment Options Are on the Horizon for  $\beta$ -Thalassemia Aug 25, 2022 Adrienne Brennan, Pharm.D, CSP.
- 5. Non-Transfusion-Dependent Thalassemia: A Panoramic Review Hwazen Shash.

PHARMANEXUS - 8 -

## **DEPARTMENTAL ACTIVITIES**

We (The Erode College of Pharmacy, Erode) have signed (14.04.2023-Friday) a new MoU with The Erode Cancer Centre to bring the best collaborative work and the wellness and development of our Institution



Pharm.D (27 Nos.) Students & Faculty (1 No.) of The Erode College of Pharmacy, Erode participated in the Workshop "In Clincial Pharmacist Interventions and Awareness of Career Opportunities" on 17.04.2023 (Monday) at PPG College of Pharmacy, Coimbatore. Dr. Karthik Rakam, Pharm.D, CEO of Avenida Innovations gave a "Practical Insight of the Scope of Pharm.D". Dr. Gowtham Sampathkumar, enlightened



The Management, Principal and Faculty members of The Erode College of Pharmacy, Erode, Celebrated "International Day Against Drug Abuse and Illicit Trafficking" was held on 26.06.2023 (Monday) at College Seminar Hall. B.Pharm and Pharm.D Students were participated in the function (100 Nos.). Presentation on Drug Abuse was presented by Avinash, IV-Pharm.D student and Illicit Trafficking of Drug was presented by Vizaag, III-Pharm.D. The program was organized by Dept. of Pharmacy Practice



Pharm.D (07 Nos.) Students & Faculty (1 No.) of The Erode College of Pharmacy, Erode participated in the 7th National Seminar on Clinical Pharma Practice Indian & Global Scenario CPP-IGS 2023 was held on 23 and 24th June 2023 at Swamy Vivekananda College of Pharmacy, Tiruchengode. A pre conference workshop on Antimicrobial Stewardship Programme was conducted by Dr. Grace Mary John, Chief Clinical Pharmacist, Believers Church Medical College Hospital, Kerala. Dr. Sameer Gokhale, Lead - Health Economics, Novartis, Mumbai, Dr. Grace Mary John, Dr. Lokeh Prasad, Scientific Officer & Govt. Analyst Head Hi-tech Laboaratroy, DTL, Bengaluru, Dr. Juliya Susan Reji (Alumni of SVCP) Community Pharmacist, UK, enlightened the Seminar with their informative talk.

