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Review Article

Stem Cell Transplantation For Leukemia Treatment: An Overview, Clinical Trials, and Stem Cell Donation

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Abstract - *Leukemia is a heterogeneous cluster of hematological malignancies associated with the uncontrolled proliferation of abnormal blood-forming cells, resulting in systemic complications. Although there have been a lot of advances regarding the biological understanding of leukemia, treatment of the disease has been complicated by the heterogeneity of the disease and relapse. The existing treatment modalities have increased rates of remission and survival, as per research. Nevertheless, these treatment approaches frequently suffer drawbacks with drug resistance, toxicity, failure to eliminate all leukemic stem cells, and high relapse rates, especially in high-risk and refractory situations.*

Stem Cell Transplantation (SCT) is a novel therapeutic approach that has the ability to surmount some of the drawbacks of traditional therapies. The great benefit of SCT is that it results in the recovery of normal hematopoiesis after intense conditioning therapy. Autologous and allogeneic SCT are both useful in the treatment of leukemia and vary according to type, stage, and specifics of the patient.

This review outlines the use of various sources of stem cells in the treatment of leukemia. Overall, SCT represents a critical and evolving component of leukemia treatment, supported by robust clinical evidence and ongoing research aimed at improving safety, accessibility, and outcomes.

Keywords *- Biology, Cancer Biology, Leukemia, Stem Cells, Clinical Trials.*

1. Introduction

Leukemia[1] is a heterogeneous cluster of hematologic malignancies, whereby the clonal growth of malignant white blood cells, which start in the bone marrow, involves the proliferation of malignant white blood cells. It is one of the most common cancers in the pediatric population and also leads to a great proportion of cancer-related morbidity and mortality in adults globally. Genetic and epigenetic mutations in hematopoietic stem or progenitor cells result in disregarded cell differentiation, apoptotic dysfunction, and unregulated proliferation, which are the causes of the disease. Malignant leukocyte build-up also impairs normal hematopoiesis, leading to anemia, thrombocytopenia, immunodeficiency, and predisposition to infections and bleeding disorders.

Leukemia can broadly be categorized into four major sub-types [2], depending on the cell lineage and the progression of the disease, which are Acute Lymphoblastic Leukemia (ALL), Acute Myeloid Leukemia (AML), Chronic Lymphocytic Leukemia (CLL), and Chronic Myeloid Leukemia (CML). Acute leukemias are typified by the rapid progression of the disease and need immediate management, and the chronic leukemias are usually typified by lengthy clinical progression. Despite the fact that the exact pathogenesis of leukemia is not entirely known, various risk factors have been reported, such as ionizing radiation, environmental and occupational toxins, chemotherapeutic agents, hereditary genetic syndromes, and family history.

Recent developments in molecular biology have further brought into the limelight the importance of abnormalities in chromosome functions and oncogenic mutations in the development and prognosis of disease.

The traditional methods of treating leukemia have traditionally been chemotherapy [3] and radiation therapy, which seek to eliminate tumorous cells and achieve remission. Over the past few decades, there have been increased treatment approaches that encompassed targeted therapies, immunotherapies, and donor lymphocyte infusions, which have greatly enhanced the survival of some leukemia subtypes. In spite of these developments, relapse and resistance to treatment have been among the greatest challenges that are especially experienced in high-risk and refractory cases.

Stem cell therapy has become a potential remedy for various diseases such as Neurodegenerative Diseases, Cardiovascular Diseases, Autoimmune Diseases, and Blood-Related Disorders. These therapies are intended to cure or fix damaged tissues and normalize physiological activity by exploiting the special quality of stem cells to self-renew and develop into specialized types of cells. Stem cell transplantation [4] has been shown to have great therapeutic potential in hematological diseases like leukemia. It allows the substitution of malignant or damaged bone marrow with healthy Hematopoietic Stem Cells (HSC), which restores normal blood cell production and improves immune function, providing a potential ultimate cure to a significant number of patients.

This is a review article that seeks to present a critical review of stem cell transplantation as a form of treatment for leukemia. It will look into the biological foundation and clinical application of Haematopoietic Stem Cell Transplantation (HSCT), outline major results obtained during clinical trials, and comment on the current state of the roots of donating and transplanting stem cells, such as the issue of donor match and ethical issues. This review aims to identify the clinical potential of stem cell transplantation, as well as identify the current limitations in the use of this treatment in leukemia management, by incorporating clinical evidence with the currently developing research.

2. Leukemia

Leukemia is a Hematologic Cancer Disorder originating in the marrow, and is an uncontrolled growth of Abnormal White Blood Cells. The current name leukemia combines the Greek words Leukos (white) and Haima (blood), because of the historical increase in the level of white blood cells in the bodies of patients. In leukemia, genetically altered hematopoietic cells proliferate rapidly and accumulate within the bone marrow and bloodstream, thereby suppressing normal hematopoiesis [5]. This congestion denies healthy Red Blood Cells (RBC), White Blood Cells (WBC), and Platelets their normal physiological functions, and eventually interferes with normal body functioning. There are four major subtypes of leukemia: Acute Lymphoblastic Leukemia (ALL), Acute Myeloid Leukemia (AML), Chronic Lymphocytic Leukemia (CLL), and Chronic Myeloid Leukemia (CML). Acute leukemias are the ones that result in the rapid division of immature precursor cells, resulting in rapid development of illness, and chronic leukemias are the ones that result in the more gradual amassing of more mature, partially functional cells [6]. The pathogenesis of these malignancies can be explained by genetic mutations deforming the DNA structure and regulatory systems that regulate cell growth and differentiation.

Myeloid leukemias are caused by mutations in Myeloid Stem Cells, which, in a normal situation, develop into Red Blood Cells, platelets, and some White Blood Cells. Accordingly, such leukemias affect the oxygen supply and weaken the immune system of the body. Lymphocytic Leukemias, on the other hand, impact the lymphoid precursors which develop to B Lymphocytes and T Lymphocytes, which are key elements of the adaptive immune response [7]. Antibody production and immunological memory are also done by B cells, whereas T cells are central in the destruction of infected or malignant cells. In leukemia, these abnormal lymphocytes are functionally incompetent and numerically excessive, thus additional impairment of immune competency occurs. In contrast to a solid tumor, leukemic cells do not develop as localized masses but disrupt the production of circulating blood cells, making leukemia a cancer of the blood. Though most patients with leukemia are children, it can affect persons of all ages and acute leukemias take up a significant percentage of children with the disease[8]

3. Etiology, Predisposing Factors, and Treatments for Leukemia

The exact etiology of leukemia is not fully comprehended yet, but a variety of risk factors associated with the environment, genes, and treatment are established. One of the most established risk factors is exposure to ionizing radiation, which may cause breaks in the DNA strands by breaking the Phosphodiester bonds of the DNA backbone [9]. Malignant development of Hematopoietic Cells can be caused by such Genomic Damage. Incidence of leukemia has been reported to be more prevalent in atomic bomb victims, early radiation workers and patients undergoing radiation therapy of other malignant conditions. Leukemogenesis has also been attributed to environmental toxins, especially benzene and some pesticides. In adults, the cumulative genetic damage of long exposure over time to carcinogens leads to an increase in malignancy, but in children, short exposure periods may still lead to malignancy because of the increased sensitivity in cells. Moreover, some chemotherapeutic agents, like the alkylating agents and the Topoisomerase II inhibitors, are linked to the occurrence of secondary leukemias due to therapy.

There is also a genetic vulnerability to leukemia. Others get mutations that predispose them to malignancy, whereas others get the mutations spontaneously. The increased risk of leukemia is linked with chromosomal disorders[10], including Down syndrome and syndromes of inherited bone marrow failure. Molecular mechanisms of cancer development include the changes in three major categories of genes: proto-oncogenes, tumor suppressor genes, and DNA repair genes[11]. Proto-oncogenes can be mutated into oncogenes, which enhance unrestrained cell division, and tumor suppressor and DNA repair genes malfunction, which only intensifies the genomic instability. Although the mechanisms of leukemia have been studied, the general pathogenesis of leukemia is multifactorial. Table 1 summarises different types of leukemia and current treatment options.

Table 1. Types of Leukemia and Current Treatment Options

Serial Number	Leukemia type	Treatments
1	Acute Lymphoblastic Leukemia (ALL)[12]	1. Chemotherapy: Paediatric Chemotherapy is divided into induction, consolidation, intensification, and remission maintenance therapy 2. Radiotherapy 3. Targeted Therapies 4. Immunotherapy for Pediatric
2	Acute Myeloid Leukemia (AML)[13]	1. Chemotherapy (includes remission induction therapy and consolidation therapy) 2. Radiation Therapy 3. Chemotherapy with Cell Transplant 4. Targeted therapy
3	Chronic Myeloid Leukemia (CML)[14]	1. Targeted Therapy 2. Chemotherapy 3. Immunotherapy 4. High-Dose Chemotherapy with Stem Cell Transplant 5. Donor Lymphocyte Infusion
4	Chronic Lymphocytic Leukemia (CLL)[15]	1. Watchful waiting (wait to see symptoms and treat Asymptomatic, Symptomatic, and Progressive CLL) 2. Immunotherapy 3. Targeted therapy 4. Chemotherapy

4. Applications of Stem Cell Transplantation in Leukemia Treatment

Hematopoietic Stem Cell Transplantation (HSCT)[16] is a life-saving form of treatment of leukemia and other serious blood diseases. The Chemotherapy and radiation treatment, typical of eradicating the malignant cells, are usually done in high doses; hence, greatly suppressing the Bone Marrow. This is called Myelosuppression and causes Neutropenia, Anemia, and Thrombocytopenia, and thus exposes the patient to the risk of infection, fatigue, and bleeding. In others, the bone marrow cannot be remedied suitably, or it can continue producing cancerous cells and thus necessitates stem cell transplantation.

The blood cells that can differentiate into all the blood cell lineages are Hematopoietic Stem Cells (HSC), which are multipotent cells. The donors can be Syngeneic (Identical Twins), Allogeneic (Genetically Different People of the Same Species), or Xenogeneic (Cross-Species, Mostly Experimental). The most widespread method is Allogeneic Transplantation, where in most cases the donors are siblings, parents, or other family members. In case of unavailability of appropriate Donor(s) within the family, registries of unrelated donors are applied. The best transplant is one that is associated with minimal risk of Graft-Versus-Leukemia (GVHD)[17] and a high level of Graft-Versus-Leukemia (GVL), which is an effector response to the remaining leukemic cells, by the donor immune cells.

Hematopoietic Stem Cell Transplantation (HSCT) and stem cell-based therapies are still the focus of curative programs of most leukemias[18].

4.1. The Hematopoietic Stem Cells (HSCs)

4.1.1. Sources

- Bone Marrow (BM)

This is the original source and the most traditional source of HSCs. Aspiration is done on the iliac crest of the donors. HSCs of BM are demonstrating strong engraftment and are commonly applied in pediatric and adult HSCT for leukemia.[18]

Peripheral Blood Stem Cells (PBSCs)

Stimulated into circulation by such agents as G-CSF and captured by Apheresis. The transplants are also prone to Graft-Versus-Host Disease (GVHD)[14,] and transplants made with PBSC tend to engraft more quickly than BM.

- Umbilical Cord Blood (UCB)[18]

Neonatal HSCs possess high proliferation ability and a low incidence of GVHD. Nonetheless, the small number of cells per unit could limit its application in adults.

- Embryonic Stem Cells (ESCs) & Induced Pluripotency Stem Cells (IPSCS).

Initiatives to produce transplantable HSCs in vitro were driven by experimental sources, and issues associated with the safety of these cells (e.g., Teratoma Risk) and effective Hematopoietic Differentiation. [18]

4.1.2. Mechanisms of the Antileukemic Effect.[18]

In place of the diseased Hematopoietic System of the patient, the normal production of Blood and Immune Cells is restored by using HSCT to replace it with healthy donor

HSC. The positive Graft-Versus-Leukemia (GVL) effect is present in allogeneic HSCT; the donor immune cells can recognize remaining leukemic cells and destroy them, reducing the chances of relapse.

4.2. Mesenchymal Stem Cells (MSCs)[19]

4.2.1. Sources

MSCs are Multifocal Stromal Cells derived from multiple sources, including Bone Marrow, Adipose Tissue, Umbilical Cord, Placental Tissues

4.2.2. Applications in Leukemia

MSCs are not directly involved in the direct conversion into Hematopoietic Leukemia curing Cells, but have supportive functions like optimizing HSCs engraftment after the transplant, reduction of GVHD by immune modulation and secrecy of trophic factors which affect the bone marrow niche and recovery of hematopoiesis.[19]

4.2.3. Mechanisms of Action

MSCs regulate immune functions as well as the Microenvironment of the Bone Marrow. They can produce Anti-Inflammatory Cytokines, Alloimmune Reactions-Suppress, and help Hematopoietic Recovery[20.]

4.3. HSCs Gene-Edited and Future Directions.

The current research is aimed at editing HSCs with genes (e.g., CRISPR/Cas9 modification) to increase antileukemic effect or disease-resistance mutations. These are mainly preclinical, although promising in long-term tumor clearance and immune restoration.[21]

5. Stem Cell-Based Clinical Trials for Leukemia Treatment

Stem cell therapies have revolutionized the therapy of leukemia, especially in the area of hematopoietic stem cell transplantation and new cell-based therapies.

The clinical trials of stem cells in leukemia are meant to enhance remission, reduce relapses, and minimize treatment toxicity through optimization of the sources of stem cells, conditioning, and immune-mediated antileukemic activities. Table 2 summarises different clinical trials.

Table 2. Clinical Trials for Leukemia using Stem Cell Transplantation (https://clinicaltrials.gov/)

Serial No.	Clinical Trial n Ame	Clinical Trial Code	Stem Cell Type	Status of Clinical Trial
1.	Stem Cell Transplant for Juvenile Myelomonocytic Leukemia (JMML)	NCT00167219	Hematopoietic Cell Transplantation	Completed
2.	Trial of Haploidentical Stem Cell Transplantation for Hematological Cancers	NCT01597219	Haploidentical Stem Cell	Completed
3.	A Study Comparing Allogeneic Hematopoietic Cell Transplantation Versus Best Available Standard of Care Therapy in Elderly Patients With Acute Myeloid Leukemia	NCT04822766	Allogenic Hematopoietic Cell	Active, Not Recruiting
4.	Bone Marrow Transplantation in Treating Patients With Chronic Lymphocytic Leukemia	NCT00002844	Allogenic and Autologous Bone Marrow Transplantation	Completed
5.	Allogeneic Stem Cell Transplantation (SCT) With Treosulfan, VP-16, and Cyclophosphamide for Patients With Acute Lymphoblastic Leukemia	NCT00682305	Allogenic Stem Cell Transplantation	Completed
6.	Study Evaluating AMD3100 for Transplantation of Sibling Donor Stem Cells in Patients With Hematological Malignancies	NCT00241358	Hematopoietic Cell Transplantation	Completed
7.	Umbilical Cord Blood Stem Cell Transplantation in Adults With Advanced Blood Disorders or	NCT00312429	Allogenic Umbilical Cord Blood Stem	Completed

	Cancer			
8.	Donor Stem Cell Transplant in Treating Patients With Previously Treated Lymphoma, Multiple Myeloma, or Chronic Lymphocytic Leukemia	NCT00612716	Allogenic Hematopoietic Stem Cell Transplantation	Completed
9.	Peripheral Blood Stem Cell Transplant vs Bone Marrow Transplant in Individuals With Hematologic Cancers	NCT00075816	Hematopoietic Stem Cells	Completed
10.	Donor Stem Cell Transplant in Treating Patients With Hematologic Cancer or Other Diseases	NCT00453206	Hematopoietic stem cells	Completed
11.	Chemotherapy Plus Peripheral Stem Cell Transplantation in Treating Patients With Acute Myeloid Leukemia in Second Remission	NCT00002768	Peripheral Stem Transplantation of Hematopoietic Stem Cells	Completed
12.	Bone Marrow or Peripheral Stem Cell Transplantation in Treating Patients With Chronic Myeloid Leukemia	NCT00002789	Hematopoietic Stem Cells	Completed
13.	Alemtuzumab Plus Peripheral Stem Cell Transplantation in Treating Patients With Chronic Lymphocytic Leukemia	NCT00006390	Hematopoietic Stem Cells	Completed
14.	Blood Stem Cell Transplantation for the Treatment of Older Patients With Acute Myelogenous Leukemia	NCT00623935	Hematopoietic Stem Cells	Completed
15.	Donor Stem Cell Transplant or Bone Marrow Transplant in Treating Patients With Acute Myeloid Leukemia in Remission	NCT01020734	Hematopoietic Stem Cells	Completed
16.	Chemotherapy With or Without Imatinib and/or Peripheral Stem Cell Transplant in Acute Lymphoblastic Leukemia	NCT00458848	Hematopoietic Stem Cell	Completed
17.	Autologous Stem Cell Transplantation in Chronic Lymphocytic Leukemia	NCT00931645	Autologous Stem Cell Transplantation of Hematopoietic Cells	Completed
18.	Chemotherapy Followed by Peripheral Stem Cell Transplantation And Biological Therapy in Treating Patients With Chronic Myelogenous Leukemia	NCT00005948	Hematopoietic Stem Cell	Completed

19.	Combination Chemotherapy Followed by Peripheral Stem Cell Transplantation in Treating Patients With Chronic Myelogenous Leukemia or Myelodysplastic Syndrome	NCT00027924	Hematopoietic Stem Cells	Completed
20.	Donor Peripheral Stem Cell Transplant in Treating Patients With Relapsed Acute Myeloid Leukemia	NCT00274846	Peripheral Stem Transplant Using NK Cells	Completed

6. Stem Cells Donation

Stem Cell Donation is a crucial domain of Stem Cell Transplantation (SCT) and the most crucial part in the effective treatment of leukemia. Adequacy of donors, as well as the quality of Hematopoietic Stem Cells donated, is relevant in the success of allogenic SCT. There are three main sources of donor stem cells: Bone Marrow, Peripheral Blood, and Umbilical Cord Blood, and each has certain clinical pros and cons[22].

Historically, hematopoietic stem cells were obtained by means of bone marrow donation[23] and have traditionally been a source of such cells purposely harvested under general anesthesia and usually at the iliac crest. It is linked with reduced chronic Graft-Versus-Host Disease (GVHD), thus being a choice for some pediatric and non-malignant indications. The most commonly used source is peripheral blood stem cell donation, which is collected using leukapheresis following the mobilization of the Donor with Granulocyte Colony-Stimulating Factor, because of quicker engraftment and subsequently easier collection. It could, however, have an increased risk of chronic GVHD among recipients.

Another source of stem cells is the Umbilical Cord Blood[24], which is especially beneficial with patients who do not have Human Leukocyte Antigen (HLA)-compatible related or unrelated donors. The cord blood units are less stringent in terms of match to the HLA and are linked to lower rates of severe GVHD, though delayed engraftment is an issue. There are improvements in the cord blood expansion and transplantation of two units, which have enhanced clinical outcome.

The availability of donors and access to different populations has greatly increased due to global registries of donors and public cord blood banks. Ethics, safety of the Donor, informed consent, and fair access to donation programs are still critical issues of stem cell donations. Further awareness of the masses, technological development, and global cooperation would be essential in enhancing the stem cell donation system and global treatment success stories in leukemia.

7. Conclusion

The use of Stem Cell Transplantation (SCT) has proven to be an essential and potentially curative option of therapy in treating leukemia, especially in patients having high-risk, relapsed, or treatment-refractory disease. Improvement in the knowledge of the biology of leukemia, coupled with the improvement of treatment of transplantation and conditioning of the transplantation, and post-transplant care, has greatly improved the survival rates and decreased the complications that come with the transplantation. The results of many clinical trials have enhanced patient selection, optimal timing of transplantation, and use of targeted therapies and immunotherapeutic methods to enhance disease control prior to and following SCT.

The availability of donor sources such as Bone Marrow, Peripheral Blood Stem Cells, and Umbilical Cord Blood has made transplant available to a wider range of patients. Advances made in Haploidentical Transplantation and the Presence of Global Donor Registries have further solved problems of donor availability and matching. However, SCT is still associated with significant drawbacks, including the risk of Graft-Versus-Host Disease, Risk of Infection, and Long-Term Toxicities, which makes it essential to conduct further research.

Altogether, transplantation of stem cells remains to be developed as a foundation of Leukemia Treatment. The continual clinical trials, novel developments in stem cell donations, and quality of supportive care will likely only make safety improvements, broaden eligibility requirements, and increase long-term results, which will further strengthen SCT as the core of Leukemia Treatment in the future.

Future Perspectives

Scientific innovation and translational research in Stem Cell Transplantation (SCT) treatment of leukemia are destined to continue in the future. Future and continued clinical trials should further improve patient stratification, conditioning regimens, and reduce transplant-related toxicity with no loss of Antileukemic Efficacy. Through a combination of new targeted therapies, immune checkpoint Antibodies, and Cellular Immunotherapies, including CAR-T

cells with SCT, the Eradication of Diseases and the Reduction of Relapse Rates Can Improve. The development of graft engineering, such as T-cell modification and Gene-Edited Stem Cells (GE-SCs), will provide an opportunity to reduce the rate and severity of Graft-Versus-Human Disease. Moreover, recent advances in the Haploidentical Transplantation and Cord Blood Expansion procedures will probably increase the number of donors and enhance the engraftment rates. Enhancement of the global donor registries and the ethical systems of donating stem cells will also improve the availability of transplantation. All these advances will lead to a safer, more accessible, and successful stem cell transplantation in the long term, solidifying the use of stem cells in the majority of Leukemia Treatments.

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