Multidimensional Evolution in Transfusion Medicine

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ABSTRACT

Transfusion Medicine is a rapidly developing clinical entity. Since no artificial substitute is available for major elements in blood, a safe transfusion chain is quite essential. Efficient blood donor recruitment is most important in transfusion services. Blood component separation and technologies like apheresis have helped in utilizing available resources to their maximum potential. Transfusion Transmitted Disease testing and immunohematological investigations have evolved continually to maintain the highest quality. The methodology for testing for TTDs has shifted to better versions of Enzyme-Linked Immunosorbent Assay (ELISA) to Chemiluminescence immunoassay (CLIA), and additionally Nucleic Acid Amplification Testing (NAT). Automation and more sensitive platforms for immunohematological testing have helped in attaining precision and decreasing workload. Nowadays, clinical transfusion practice is having well-established policies, guidelines, audits, training etc. This has helped in maintaining the quality of services from vein to vein. Therapeutic apheresis is the mainstay of treatment for many diseases. Research is ongoing for the development of RBC and platelet substitutes. Regenerative medicine is rapidly evolving to its best potential. Hematopoietic stem cell transplantation (HSCT) is the most frequently used cell therapy and is used to treat a variety of blood cancers and hematologic conditions. Apart from bone marrow and peripheral blood, the umbilical cord has been recognized as an alternate source of stem cells. Slowly, tissue banking is gaining its importance. Intrauterine transfusion is a novel modality that saves the fetus from anaemia or thrombocytopenia and its complications. Platelet-rich plasma (PRP) injections are gaining popularity for a variety of conditions, from sports injuries to hair loss. Likewise, Autologous platelet gel has many applications in sports medicine, dermatology, surgery etc. These rapid advances along with good governance promise better transfusion practice and patient care in upcoming years.

Keywords: Blood, Transfusion Transmitted Disease, Immunohematology, Platelets, Transfusion, Transplantation

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Transfusion Medicine is a rapidly evolving branch of medical science. It started its journey long back in the 17th century. However, the science of Immunohematology got well established by the beginning of the 20th century after the discovery of the ABO blood group system by Karl Landsteiner. The 20th century later witnessed the development of anticoagulants for the storage of blood, the establishment of blood banks, the screening of Transfusion Transmitted Diseases (TTDs), the separation of blood into components etc. By the 21st century, Transfusion Medicine took its turn to better clinical practices, newer modalities like apheresis, stem cell and tissue banking, sophisticated immunohematological and infectious disease screening methods etc.[1] Currently, this promising specialty has become well-established all over India with post-graduate courses and fellowship in its subspecialties.

DONOR RECRUITMENT

Unless an artificial substitute for blood gets discovered, the source of blood is human beings themselves. The blood donor program started on a serious note in 2009 when the World Health Organization (WHO) identified the importance of Voluntary Blood Donation. After the consortium of 40 countries in Melbourne, the WHO has directed all countries to have a Voluntary Blood Donation policy and establish a specific program.[2] Currently, India has a strong Voluntary Blood Donation program and a flawless system for recruitment of blood donors. The development in information technology is being utilized increasingly for the recruitment of blood donors.[3] Many mobile applications, software, and platforms like e-raktkosh (initiative by government of India) are being used for conduct-

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ing blood donation camps and mobilization of donors. Nowadays, trends in blood donor management are directed towards a categorical approach. Goal-directed programs, especially for youth and women are very active across the country. In Kerala, various programs like VIVA and activities of NSS, club-25, Red Ribbon Club etc. are integrated with Voluntary Blood Donor recruitment.

BLOOD COMPONENTS

From the practice of Whole Blood transfusion in yesteryears, the current scenario has shifted completely to blood component therapy. The blood collected in plastic bags which contain anticoagulants (usually CPDA) and additive solutions helps in maximally extending the storage of blood to better shelf lives.[4] Many advances in blood collection systems like diversion pouches, modified needle mechanisms, standardized bag manufacturing processes etc. ensure safety and quality. Nowadays each unit of Whole Blood is separated into Packed Red Blood Cells (PRBCs), Platelets and Plasma. The frozen plasma can be used for producing Cryo precipitate, a component which can be used for the treatment of Hemophilia-A, Von-Willebrand disease, factor-XIII deficiency, Disseminated Intravascular Coagulation etc. Component separation helps in utilizing a single unit of blood for multiple patients, thereby adjusting the dose, and avoiding unnecessary transfusion or wastage.[5]

Various component modification processes are in place. Many methods including filtration can perform leukoreduction, and it ensures the removal of leukocytes from the blood unit. This modification helps in reducing Human Leukocyte Antigen (HLA) allo-immunization, incidence of Febrile Non-Hemolytic Transfusion Reaction, Cytomegalovirus (CMV) transmission etc.[5] Irradiation of blood products can inactivate T-Lymphocytes, which helps in preventing Transfusion Associated Graft Versus Host Disease (TA-GVHD). Irradiated products are usually used for transfusion in patients having malignancies, in immunocompromised states, neonates etc. Methods are available to freeze and store PRBCs for many years, which can later be used, especially for rare blood groups and in emergencies like wars, requiring huge volumes of blood.[5]

PREVENTION OF TRANSFUSION-ASSOCIATED INFECTIONS

The spread of microbial infections through transfusion of blood products is a serious threat in clinical practice. Modification processes for the inactivation of pathogens like treating them with psoralen or riboflavin or methylene blue are currently available. This pathogen inactivation procedure helps prevent spread of transfusion-associated infection due to known or unknown or emerging or residual microbes.[6] Practice of aliquoting blood units and separating it into multiple units in a sterile manner has helped in controlling the wastage of blood and adjusting volume according to the needs of patient.[5] The plasma collected from blood donors can be sent for fractionation and be separated into various fractions like albumin, globulins, coagulation factors etc.

APHERESIS - PRINCIPLE AND APPLICATIONS

Apheresis is a process in which blood is removed from a subject and continuously separated into parts, allowing a desired component (s) to be retained while the remainder is returned to the subject. The principle of apheresis machines includes intermittent or continuous flow centrifugation. The procedure can be employed in a blood donor for the collection of various products like Platelets (Single Donor Platelets), plasma, RBCs, Granulocytes, Neocytes, Hematopoietic Stem Cells etc. Likewise, the procedure can be used to remove unwanted components like antibodies or toxins from a patient, which is termed therapeutic apheresis. The procedures include therapeutic plasmapheresis, Erythrocytapheresis, Leukapheresis, Thrombopheresis etc.[7]

Indications for therapeutic plasmapheresis include Myasthenia Gravis, Polyneuropathy (CIDP), Hyper viscosity syndrome, Goodpasture's syndrome, Guillain Barre syndrome, Cryoglobulinemia etc. and the most followed guideline is formulated by American Society for Apheresis (ASFA).

In a modification of apheresis named extracorporeal photopheresis, patients' White Blood Cells (WBCs) are treated with Methoxsalen and exposed to UVA irradiation resulting in immunomodulation and T cells mount an immune response to pathogenic T cells. This method is employed for cutaneous T-cell lymphoma, GVHD, organ rejection, autoimmune diseases etc. There are many recent advances in apheresis which include Immunoadsorption apheresis, LDL apheresis, double red cell collection, multi-component collection, Rheopheresis etc.[8]

RBC SUBSTITUTES

Red blood cell (RBC) substitutes can be a promising alternative to allogeneic RBC transfusions. The toxicity

and non-physiologic performance of early-generation RBC substitutes have resulted in the development of strategies to produce safe and effective materials.

Current development of RBC substitutes focuses on two classes of materials: hemoglobin (Hb)-based oxygen carriers (HBOCs) capable of binding oxygen and emulsified perfluorocarbon (PFC) solutions capable of dissolving oxygen. To improve the overall performance of HBOCs, researchers have employed strategies like chemical cross-linking, surface conjugation, encapsulation, genetic engineering etc. Work has also been done to increase the solubility of oxygen in emulsified PFC solutions to match the oxygen-delivering capacity of RBCs.[9] Similarly, trials are going on to manufacture Universal RBCs (Group O) by enzymatically converting other groups (ECO) and masking of antigens by pegylation (Stealth cells).

PLATELET SUBSTITUTES

Similarly, many experimental approaches have been explored to produce hemostatically active novel human platelet products and substitutes capable of long-term storage. Platelet substitutes can be divided into red cell derivatives, liposomal derivatives, and nanoparticles. Unfortunately, to date, none of these technologies have advanced far enough to be commercially viable. Instead, the development of thrombopoietic agents and drugs to facilitate platelet function remains the mainstay of treatment for thrombocytopenic patients.[10]

IMMUNOHEMATOLOGY

Immunohematology is the central pillar of transfusion medicine. Right from the basic test tube technique, several newer technologies like column agglutination (gel cards, beads), microplate, solid phase assay etc. have been established.[11] Reference laboratories of Immunohematology have evolved to molecular methods of testing using gene chips which help in fetal genotyping, zygosity testing etc. The use of blood group genotyping and DNA sequencing have given exceptional insights into blood group antigens and have become remarkable tools for the resolution of challenging immunohematological problems. Molecular testing using DNA arrays helps in mass screening of donors to increase inventories of antigen-negative RBC components, and precisely matching the antigen profile of a transfusion recipient to that of a donor.[12]

In red cell immunology, apart from basic technologies for ABO blood grouping, Rh-D typing, cross-matching and Anti Human Globulin (Coombs) testing, many other developments are currently in place. It includes screening and detection of alloantibodies, extended typing of minor blood group antigens, working up of Autoimmune Hemolytic Anemia etc. Automation in immunohematology and strategies like electronic cross-matching has helped in attaining precision and decreasing the workload of labs.[13]

HLA molecules are present on the surface of blood cells and facilitate interactions between immune cells that lead to adaptive immune responses. Thus, HLA typing and matching is a mandatory requirement for both stem cell and organ transplantation. Methods of HLA typing include serological and molecular methods.[14] Likewise platelet antigen typing, and crossmatch are quite useful in clinical scenarios like platelet refractoriness, Immune Thrombocytopenic Purpura, Neonatal Alloimmune Thrombocytopenia etc.[15]

TRANSFUSION TRANSMITTED DISEASES

Transfusion Transmitted Diseases (TTDs) are one of the biggest threats related to blood product transfusion and safety is the cornerstone of any transfusion practice. In India, screening for TTDs was started in the 1980s. The test methodology for testing for TTDs has shifted to better versions of Enzyme Linked Immunosorbent Assay (ELISA) to Chemiluminescence immunoassay (CLIA), and additionally Nucleic Acid Amplification Testing (NAT).[16] The newer technologies have added an additional layer of safety, increased the sensitivity and specificity of tests, and decreased the window period of disease.[17]

The methodologies of NAT include Polymerase Chain Reaction (PCR), transcription-mediated amplification (TMA) Nucleic Acid Sequence Based Amplification (NASBA) etc.[18] Even though NAT testing of blood units is not mandatory in India, ELISA or CLIA done in stringent test conditions and application of statistical tools to it has made transfusion practice safe to a Six Sigma level. Apart from TTD testing, steps like meticulous screening of donors and recruitment of Voluntary Blood Donation have gained importance in terms of TTD transmission.

CLINICAL TRANSFUSION PRACTICE

For decades, clinical transfusion practice was the least noticed horizon in Transfusion Medicine. However, since transfusion of blood products is related to adverse events, over the years, it gained its importance. Many studies were conducted to compare liberal and restrictive transfusion strategies. Most of the studies

proved that restrictive transfusion is better in terms of adverse events, rate of infection, hospital stay etc.[19] Thus many scientific institutions like the British Society of Hematology, Association for the Advancement of Blood & Biotherapies etc. released guidelines for each transfusion setup. All medical conditions like anemias in general and those specifically associated with hemoglobinopathies, hemolytic conditions etc. thrombocytopenia, malignancies, transplantation, coagulation abnormalities like Hemophilia etc. are dealt with in detail in such guidelines. Each category of patients like obstetric patients, neonates, surgical patients etc. too mandate specific guidance for different clinical conditions.[20]

For transfusion related to surgeries, mechanisms like Maximum Surgical Blood Order Schedule (MSBOS) were established to avoid unnecessary transfusions. Likewise, Patient Blood Management (PBM) is considered most important during surgeries. PBM is based on 3 pillars: the first is the optimization of the patient's endogenous red cell mass, the second is the minimization of bleeding and blood loss and the third involves harnessing and optimizing the patient-specific physiological tolerance of anaemia, including adopting more restrictive transfusion thresholds. PBM primarily identifies patients at risk of transfusion and provides a management plan aimed at reducing or eliminating the need for allogeneic transfusion, thus reducing the inherent risks, inventory pressures and escalating costs associated with transfusion.

Autologous transfusion is actively being tried in surgical setups. It includes three main techniques: pre-deposit autologous donation (PAD), acute normovolaemic haemodilution (ANH), and perioperative cell salvage (PCS).[21] Massive transfusion in surgical emergencies too needs a collaborative approach which resulted in the formulation of definite protocols. Point-of-care tests like Thromboelastography, Rotational Thromboelastometry etc have helped in decreasing the usage of blood products in surgical and critical care scenarios.

The basic motto of transfusion practice remains 'right blood to the right person at the right time and place".

The State of Kerala released a Transfusion Policy and Clinical guide in 2018. It widely covered all areas of transfusion along with policy points dealing with strengthening of operations, inventory management, uniform supply of blood products across the state, support to special transfusion needs, patient blood management, disaster management, addressing of adverse events related to transfusion etc. Guidelines for routine transfusion in medical, surgical, trauma, critically ill, obstetrics, gynaecology, neonatal and pediatric patients and management of their special situations in transfusion were detailed in it.

Blood inventory management and administration mandates an unerring mechanism for preventing any adverse event resulting from transfusion. Newer technologies like Radio Frequency Identification (RFID), barcoding, blood locks, ISBT labeling systems etc. help in avoiding clerical errors.[22] Strong policies and specific guidelines have been established in clinical transfusion setup. Rigorous training in areas like basics of transfusion practice, indications for transfusion, blood product handling, management of transfusion reaction etc. is being rendered to all categories of staff involved in the transfusion chain.

REGENERATIVE MEDICINE

Regenerative medicine is defined as the process of replacing or "regenerating" human cells, tissues, or organs to restore or establish normal function. With new technologies and products, different types of cells are used for the treatment of diseases. It includes hematopoietic, skeletal muscle and mesenchymal stem cells, lymphocytes, dendritic cells, pancreatic islet cells etc.

Hematopoietic stem cell transplantation (HSCT) is the most frequently used cell therapy and is used to treat a variety of blood cancers and hematologic conditions. Potential applications of cell therapies include treating cancers, autoimmune diseases, urinary problems, and infectious diseases, rebuilding damaged cartilage in joints, repairing spinal cord injuries, improving a weakened immune system, and helping patients with neurological disorders.[23]

HSCT has become the standard of care for many patients with defined congenital or acquired disorders of the hematopoietic system or with chemo sensitive, radiosensitive, or immuno-sensitive malignancies. Bone marrow, peripheral blood or cord blood can act as a source for stem cells.[24] More than 14 million typed volunteer donors or cord blood units from many registries worldwide provide stem cells for patients. India has undergone a rapid expansion in technology and use of HSCs. According to ICMR statistics, our country has more than 95 transplant centers, conducting around 19000 transplants. Despite HSCT being a well-established clinical practice, a gap is still there in providing services in terms of region, economy, and facilities.

Rather than being regarded as a wasteful tissue after birth, the umbilical cord has been recognized as an alternate source of stem cells. Cord blood banking is a process of collecting stem cells from the umbilical cord and storing them for future use. Umbilical cord-derived cells are immature, so they can assume the form of any other cell easily. Umbilical cord stem cell transplants have been performed in children and adults for inborn errors of metabolism, hematopoietic malignancies, genetic disorders of the blood and immune system etc.[25]

INTRAUTERINE TRANSFUSION

Intrauterine transfusion is one of the newer modalities of transfusion in which red blood cells from a donor are injected into the fetus. Intrauterine PRBC transfusion is recommended when a fetus has anemia due to the destruction of fetal red cells by maternal antibodies, Parvovirus B19 infection, foeto maternal hemorrhage, twin-twin transfusion syndrome, placental/fetal tumors etc. O negative, irradiated, leukocyte-depleted, double-packed blood with a hematocrit of nearly 80, is transfused through routes like infraumbilical (umbilical vein), intrahepatic part of the portal vein, or intraperitoneal one.[26] Likewise, intrauterine transfusion of platelets may be indicated in severe life-threatening thrombocytopenia in the fetus.

PLATELET-RICH PLASMA (PRP) – HEALING ACROSS AILMENTS

Platelet-rich plasma (PRP) injections are gaining popularity for a variety of conditions, from sports injuries to hair loss. The treatment uses a patient's own blood cells to accelerate healing in a specific area. Indications include tendon, ligament, muscle and joint Injuries, post-surgical Healing, osteoarthritis, hair loss, skin rejuvenation etc. After creating platelet-rich plasma from a patient's blood sample, that solution is injected into the target area. The mechanism behind PRP injections is not completely understood. Studies show that the increased concentration of growth factors in platelet-rich plasma may stimulate or speed up the healing process, shortening healing time for injuries, decreasing pain, and even encouraging hair growth.[27]

Autologous platelet-gel (APG) is the process of harvesting one's own platelets, concentrating them through centrifugation, exposing them to an agonist which induces activation and releases intrinsic substances, and finally applying them to a target area to accelerate wound healing. APG concentrates many biologically active substances, which are primarily proteins that participate in a series of mechanisms involved in inflammation and wound healing. It has been used in numerous applications including sports medicine, dermatology, and surgery.[27]

Fibrin glue, a topical biological adhesive, consists of concentrated human fibrinogen activated by adding bovine thrombin and calcium chloride. The resultant clot helps in haemostasis and tissue sealing and is absorbed during wound healing.

The hemostatic and adhesive properties of fibrin glue can be employed in any surgery. The usefulness of the glue is well documented in cardiovascular, ENT and neurosurgery.[28]

TISSUE BANKING

Challenges in availability have forced the scientists to find out techniques for preservation of living tissue. Harvesting, processing, storage, and transportation of human tissues for clinical use is the major activity of tissue banks. Practically any human tissue can be harvested and banked for clinical use and research. Newer applications of autologous banked tissues include blood vessels, testicular tissue, ovarian tissue, nipple areola complex, sperm, penile skin etc. Tissue banking is a very complex system and needs high technical expertise. Strict tissue transplant acts and stringent regulations helps to streamline the whole process of tissue banking.[29]

BLOOD POLICY

Good governance is an important factor deciding the success of the transfusion program in any country. In India, the blood centers are under licensure control of Central Drugs Standard Control Organization (CDSCO) along with regulatory and administrative coordination by National Blood Transfusion Council (NBTC), National AIDS Control Organizations (NACO) and Ministry of Health and Family Welfare. There is a National Blood Policy for the country. The adverse events related to blood donation and transfusion is overviewed by a Hemovigilance program. These regulations help in ensuring quality and safety of each unit being transfused. Additional systems for ensuring quality like accreditation with National Accreditation Board for Hospitals & Healthcare Providers (NABH) and external quality assessment programs are in place. Quality assurance programs, audits, monitoring indicators, application of statistical tools etc. is making blood banking safer.[30]

After a statewide study by WHO, the state of Kerala has established a nodal system and hemotherapy cell for dissemination of transfusion services. This includes an administrative network system to coordinate each stakeholder in the transfusion chain. A State Nodal Officer and District Nodal Officers were identified. State Nodal Officers act as a nodal point for connecting blood banks (through district nodal officers) to various other government, regulatory and related agencies. The District Nodal Officer establishes a connection between blood centers and other stakeholders of the VBD network and state authorities. Likewise, the hemotherapy cell is functioning to regulate climate transfusion practice in an excellent manner.

To conclude, the numerous rapid advancements hold great promise for the future of transfusion practice and patient care. Nevertheless, in India, a significant gap persists between the patient needs and the delivery of transfusion services in health care. An active collaboration of different stakeholders involved in transfusion practice is needed to ensure the best outcomes soon.

END NOTE

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