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Mini Review Article

Introduction Of Monoclonal Antibodies and Its Usage in Human as Medicine

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ABSTRACT

Monoclonal antibodies are highly specific antibodies produced by identical plasma cells derived from a single clone, allowing for their indefinite growth and B cells that produce these antibodies can function normally. They can also become cancerous, known as myeloma. Monoclonal antibodies are mostly utilized in diagnostics and research purposes. However, their integration into human therapies has been more gradual. In certain therapeutic applications, the antibodies can directly trigger the body's immune response and they bind to their specific target. In other words, they are attached to additional molecules such as fluorescent dyes for imaging purposes or radioactive isotopes like iodine-131 for targeted cell destruction. Monoclonal Antibodies in Medicine are:- Immune Suppression: Muromonab-CD3 (OKT3): This antibody is employed to suppress the immune system, particularly in transplant patients. Infliximab (Remicade®):This drug targets tumor necrosis factor-alpha (TNF-α) and shows effectiveness against inflammatory diseases, including rheumatoid arthritis. However, it may reactivate latent tuberculosis and promote the formation of autoantibodies. Targeting Cancer Cells: Rituximab (Rituxan®): This monoclonal antibody targets the CD20 molecule present on most B-cells, making it useful for treating B-cell lymphomas. Vitaxin: This antibody binds to a vascular integrin (αv/β3) found on the blood vessels of tumors but not on those of healthy tissues. Early Phase II clinical trials suggest it may effectively shrink solid tumors without significant side effects.

INTRODUCTION

Monoclonal antibodies (mAbs) are antibodies that are made by identical immune cells, all of which are clones of a single parent cell. This characteristics makes them highly specific to a particular antigen . since their discovery in 1975 by Georges kohler and Cesar Milstein, Monoclonal antibodies have been developed for use in a wide range of therapeutic applications.

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Their ability to specifically target and bind to antigens has made them a powerfull tool in diagnostics, treatment , and disease prevention. Monoclonal antibodies have had a profound impact on human medicine, particularly in oncology, immunology , and infectious disease. By harnessing the natural immune response , mAbs have been engineered to target cancer cells, block viral infections , modulate immune responses, and more. This paper will provide a comprehensive review of the development , production, and clinical application of monoclonal antibodies in human medicine , with particular focus on their therapeutic impact and the challenges associated with their use.

2. The Discovery and Development of Monoclonal Antibodies

2.1 Historical Background

The concept of monoclonal antibodies was first introduced in 1970s when scientists successfully developed a method for producing large quantities of identical antibodies. The process they pioneered , known as Hybridoma technology, invoves fusing a single antibody producing B cell with a myeloma (Cancer) cell , or hybridomas , which can be cultured and produce large amounts of a single type of antibody , hence the term " Monoclonal"

Hybridoma Technology

Hybridoma technology , which remains the cornerstone of monoclonal antibody production , was revolutionary because it allowed the mass production of a specific antibody that could be used as a drug or diagnostic tool. The process involves isolating a single B cell from an immunized animal , fusing it with a myeloma cell , selecting for hybridomas that produce the desired antibody. Once selected , the hybridoma can be cloned , leading to the production of large amount of monoclonal antibody.

2.2 Evaluation of mAb Production

Since the advent of hybridoma technology , advancement in biotechnology have significantly improved the production of monoclonal antibodies. Techniques such as recombinant engineering , and phages display have further enchanced the specificity , affinity , and productionefficiency of mAbs. Additionally, improvements in cell culture systems , like the use of Chinese hamster ovary (CHO) cells , have facilitated the production of humanizedand fully human monoclonal antibodies , which are more suitable for clinical applications.

2.3 Progression from Murine to Humanized and Fully Human mAbs

The early mAbs were murine (derived from mouse sources) , which led to immune reactions when used in human due to their non-human origins. To address this , chimeric antibodies (Combining mouse and human components) were developed, followed by humanized antibodies, which are predominantly human , except for a small portion of the antibody that binds to the target antigen. The final step in this evaluation is the development of fully human antibodies , which are derived entirely from human sources , significantly reducing immunogenicity.

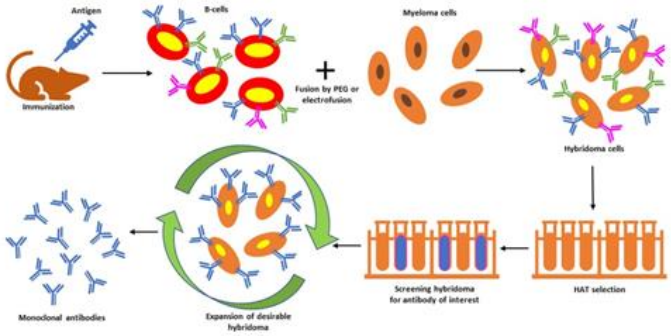

Fig : - 1 Monoclonal antibody production using the hybridoma technique

3. Mechanism of Action of mAbs

Monoclonal antibodies exert their therapeutic effects through several mechanisms of action , depending on the target antigen and the disease being treated . These mechanisms include:

3.1 Direct Neutralization: mAbs can bind directly to pathogens , such as viruses or bacteria , neutralizing their ability to infect host cells (for Example , in the case of COVID-19).

Targeting Cancer Cells: In cancer therapy , mAbs can bind to specific proteins on the surface of tumor cells , either blocking growth signals or tagging the cancer cells for desctruction by the immune system.

Immunomodulation: Some mAbs work by modulating immune responses, such as enhancing the immune system's ability to recognize and attack tumor cells or reducing inflammation in autoimmune diseases.

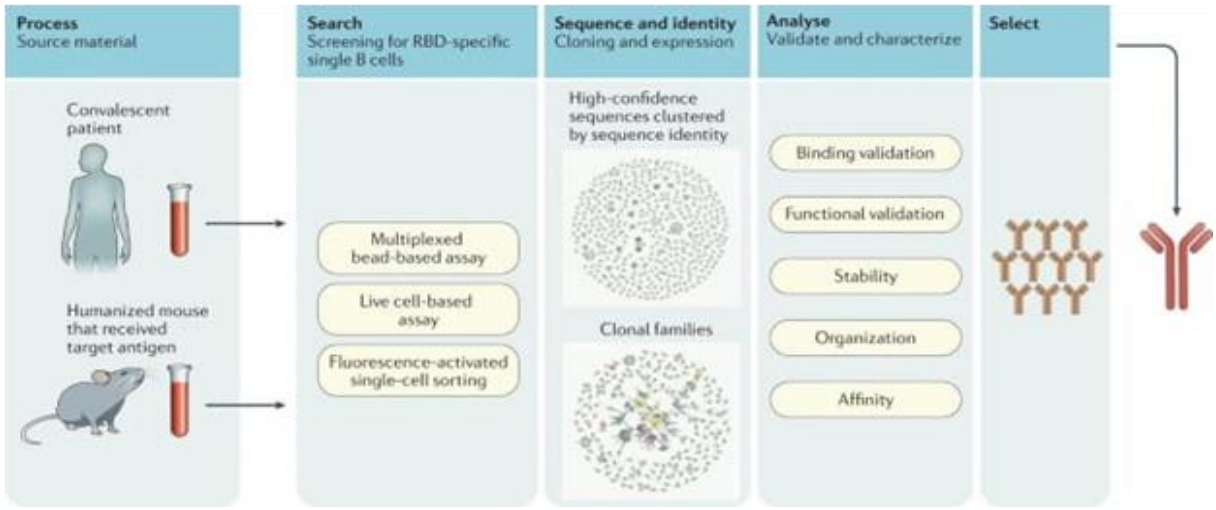

Fig:2 The Neutralizing monoclonal antibodies (mAbs) given emergency use authorization for treatment of COVID-19 were derived from either convalescent patients or humanized mice exposed to severe acute respiratory syndrome coronavirus2 (SARS-CoV-2) antigens. The pathway of mAb generation depictedhere converge in the process of selection and production.

4. Clinical Application of Monoclonal Antibodies

4.1 Cancer Therapy

One of the most significant applications of mAbs is in the treatment of cancer. mAbs can be designed to target tumor associated antigens, facilitating the immune system's recognition and destruction of cancer cells. For example, Rituximab , a mAb targeting CD20 on B cell , has been used successfully in treating non-Hodgkin lymphoma and chronic lymphocytic leukemia.

Another notable example is Trastuzumab (Herceptin) , which target the HER2/neu receptor in breast cancer , improving patient survival rates and reducing recurrence. Bevacizumab , which inhibit vascular endothelial growth factor (VEGF) , is used to prevent the growth of new blood vessels in tumors , limiting their nutrient supply.

In addition to direct tumor targeting , monoclonal antibodies can also be used in combination with other therapies , such as chemotherapy or radiation therapy , to enhance the overall effectiveness of treatment.

4.2 Immunology

Monoclonal antibodies have revolutionized the treatment of autoimmune diseases such as rheumatoid arthritis , Crohn's disease , and multiple sclerosis. By specifically targeting and neutralizing inflammatory cytokines or immune cell receptors , mAbs can help reduce the pathological effects of these diseases. For example: Adalimumab (Humira) , target tumor necrosis factor alpha , a key cytokine involved in inflammation.

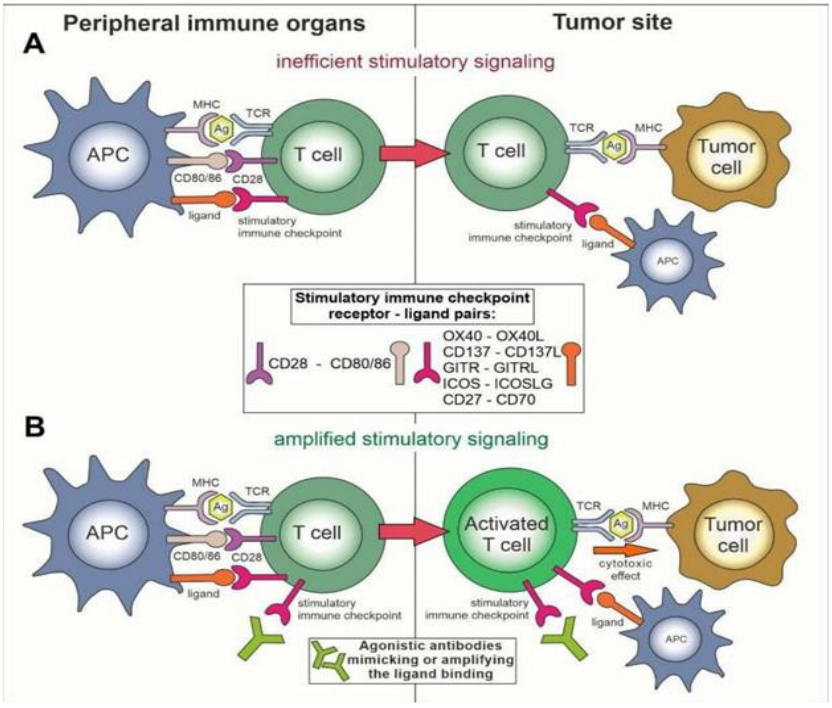

Fig : 3. Targeting the positive immune checkpoints with monoclonal antibodies. (A) The mechanism of stimulation of a T cell effector function via positive immune checkpoints. The interaction of CD28 with its ligands, CD80 or CD86, follows TCR signaling and co-stimulates immune cell activation. Some of the

other stimulatory immune checkpoints may also provide a co-stimulatory signal, but most of them start being expressed on already activated immune cells. In advanced cancer, this positive signaling is, however, often insufficient for eliminating the malignant cells. (B) Application of agonistic antibodies mimicking or amplifying binding of the ligands for stimulatory immune checkpoints increases effector activity of T cells towards tumor cells with prospective elimination of cancer cells.

4.3 Infectious Diseases

Monoclonal antibodies have also been developed to treat a range of viral infections. Recent studies suggest that monoclonal antibodies (mAbs) could offer a promising strategy for preventing the colonizationof Streptococcus mutans , a major contributor to dental caries. By identifying novel peptide subunits (epitopes) of S. mutans, mAbs could be employed to target and effectively manage this bacterial infection. The mucosal defense mechanism , particularly through secretory immunoglobulin A (IgA) in saliva , plays a crucial role in preventing the colonization of pathogens such as S. mutans and Lactobacillus spp , which are major components of the oral microbiome. Immunization with purified S. mutans antigens can stimulate the production of IgA antibodies , which are then secreted into the saliva by B-cells activated at the induction sites. This immune response helps to neutralize bacterial pathogens at the mucosal surface.

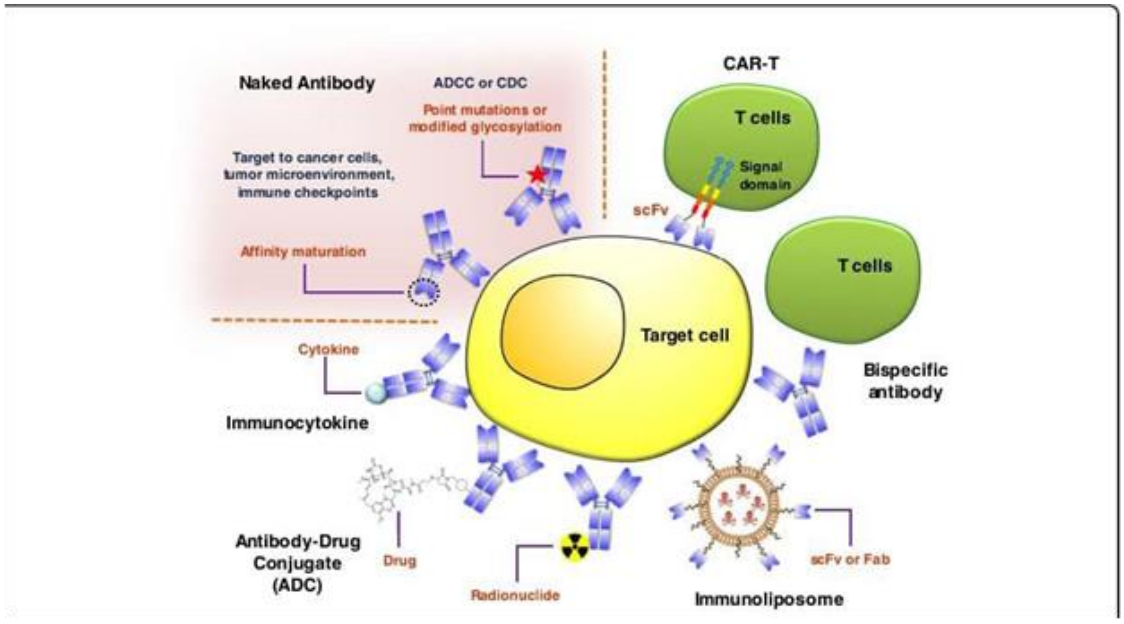

Fig : 4 Schematic overview showing the development of antibody-based therapeutics for the treatment of cancer. Therapeutic antibocies can be oughly separated into two broad categories The first category involves the direct use of the naked antibody for disease therapy. Antibocies in his category are used ior cancer treatment and elicit cel death by differens mechanisms, incucing ADCC/CDC, direct targeting of cancer cells to ndure anoptosis, targeting the tumor microenvironment, or targeting immane checkpoints. For antibodies in the second category, additional engineering is performed to enhance ther therapeute efficacy some general approaches for the use of these antibodies include immunocytokine, antibody-drug conjugate (ALX), antibody-adiorudide conjugate (ARC), bispecific antihocy, immunolposome, and CAR

4.4 Other Application

Monoclonal antibodies have also been used in the treatment of conditions like asthma , transplant rejection , and even rare diseases like paroxysmal nocturnal hemoglobinuria (PNH). Their ability to specifically target disease pathway with minimal off target effects make them an attractive option for a variety of medical conditions.

5. Challenges of Monoclonal Antibody Therapy

Monoclonal antibody therapies , like all therapeutic agents , can cause unintended side effects , which may vary severity depending on the mAb class and the route of administration. Common mild reactions , such as skin rashes , may occur with the first dose , while more systemic side effects like fatigue , headaches, fever , nausea, diarrhea , and hypotension are also frequently observed. For instance , Bevacizumab , a mAb targeting tumor associated blood vessels , has been associated with severe adverse effects, including renal failure ,bleeding complications , impaired wound healing , and elevated blood pressure. Similarly , Raxibazumab , an FDA approved mAb for inhalational anthrax , has been linked to severe skin reactions , intense pain , and drowsiness. Despite their efficacy , these side effects underscore the need for careful monitoring during mAb treatments. Another key challenge facing mAb therapies is their high cost. Although several mAbs have been approved by regulatory agencies like the FDA , the price of these therapies remains a significant barrier for many patients , especially since most of these drugs are still without competition from generics. While the market for first generations mAbs is strong , with some products (such as Bevacizumab) becoming more affordable due to increased competition , the overall financial burden on healthcare systems and patients remains high. However , the emergence of biosimilars (near identical copies of biologic drugs) and alternative production methods is gradually reducing costs , making mAb theraspies more accessible.

6. Future Prospects of Monoclonal Antibody Therapies

The future of monoclonal antibodies lies in their continuous evolution and refinement. Strategies like bispecific antibodies , which can simultaneously bind to two different antigens , are being explored to enchance efficacy , especially in cancer therapies. Antibody drug conjugates (ADCs) , which combine the targeting specificity of mAbs with cytotoxic agents , represents another promising areafor target cancer treatment. Nanobodies , which are smaller than traditional mAbs and are derived from camelids (e.g llamas and camels) , have gained attention for their potential to overcome some limitations of traditional mAbs , such as reduced immunogenicity and ease of production. The development of biosimilar (generic versions of biologic drugs) is expected to make mAb therapies more affordable and accessible , further expanding their use.

6. CONCLUSION

Monoclonal antibodies have transformed the landscape of medical treatment , offering highly targeted and effective therapies for a range of diseases. Although challenges remain in terms of immunogenicity , side effects , and cost ongoing innovations in antibody engineering and biosimilar development hold promise for enchancing the safety , efficacy , and accessibility of mAb based therapies in the future. With advancements in technology and production methods , mAbs will likely continue to play a crucial role in personalized medicine and improve patients outcomes across various therapeutic areas.

REFERENCES

1. Köhler, G., & Milstein, C. (1975). Continuous cultures of fused cells secreting antibody of predefined specificity. Nature, 256(5517), 495–497.
2. Jain, R. K. (2005). Vascular and interstitial barriers to delivery of therapeutic agents in tumors. Cancer and Metastasis Reviews, 24(3), 257–264
3. Liu, J., & Wang, Y. (2021). Monoclonal antibodies: An overview. Molecular Therapy - Methods & Clinical Development, 20, 453-474.
4. Rituximab (Rituxan®) for Cancer Treatment. (2014). National Cancer Institute. https://www.cancer.gov/about-cancer/treatment/drugs/rituximab
5. Jung, G. (2017). The humanization of monoclonal antibodies. In Therapeutic Monoclonal Antibodies
6. Reichert, J. M. (2019). Monoclonal Antibodies: The Top Selling Drugs in 2018. Nature Biotechnology, 37(10), 1071-1074.
7. Goldenberg, D. M., & Shadduck, R. K. (1992). Monoclonal antibodies in cancer therapy. Nature, 355(6358), 209-218.
8. Adams, R. D., & Cunningham, D. (2011). Monoclonal Antibodies in Cancer Therapy. Cancer Treatment Reviews, 37(5), 289-298.
9. Segal, B. H., & Lutz, R. (2010). The use of monoclonal antibodies in the treatment of cancer. Clinical Cancer Research, 16(7), 1903-1910.
10. Kim, C. K., et al. (2013). Engineering the next generation of monoclonal antibodies. Nature Reviews Drug Discovery, 12(2), 99-112.
11. Dupont, B., & Lemieux, R. (2005). Monoclonal Antibodies in Autoimmunity. Current Opinion in Immunology, 17(6), 617-624.
12. Mendelsohn, J. (2001). Epidermal growth factor receptor-targeted therapy in oncology. Endocrine-Related Cancer, 8(2), 101-113.
13. Amgen (2020). Understanding Biologics: Monoclonal Antibodies. Amgen Inc.
14. Hollingshead, L. M., et al. (2001). Human monoclonal antibody therapeutics. Nature Reviews Drug Discovery, 1(2), 96-108.
15. Sliwkowski, M. X., & Mellman, I. (2013). Antibody therapeutics in cancer. Science, 341(6151), 1191-1198.
16. Stieger, B., & Weidmann, M. (2011). Antibody-based therapies in oncology: Current status and future trends. Journal of Clinical Oncology, 29(12), 148-158.
17. Finkelman, F. D. (2012). Mechanisms of action of monoclonal antibodies: Focus on immunogenicity. Journal of Immunotherapy, 35(8), 461-474.
18. Baeuerle, P. A., & Reinhardt, C. (2009). Bispecific T-cell engaging antibodies for cancer therapy. Cancer Research, 69(3), 3136-3143.
19. Bhattacharya, S. (2015). Monoclonal antibodies and their development in the treatment of infectious diseases. Journal of Clinical Microbiology, 53(6), 2026-2033.
20. This paper offers an in-depth exploration of monoclonal antibodies and their integration into human medicine, examining their history, mechanisms, applications, challenges, and future potential.

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