

Regenerative Medicine and the Promise of Novel Therapies for the Future

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Probably for the first time in the history of medicine, through the applications of Regenerative Medicine we can talk about actually "curing" a chronic condition rather than manage these conditions for life or even provide robust solutions for life-threatening diseases, including deadly hematological cancers, diabetes or progressive neurological conditions like ALS. Although this field is becoming a frontier only in recent times, there is documented evidence of this science in older times, including during the Greek times. Prometheus was supposed to possess an immortal liver which was feasted by the eagle of Zeus; although this has mythological significance, it continues to be of significance today, where we know the liver is one of the organs that have a high regenerative capacity [1]. This exciting field continues to evolve with a new armamentarium of therapies available to treat or potentially cure chronic degenerative conditions that were not known to have a potential cure previously.

Most of the Regenerative Medicine Therapies (RMT) is in pre-clinical and early phase 1 and 2 trials. This is a field of medicine that falls under close FDA scrutiny as numerous small-scale healthcare institutions claim therapies that have not been approved for the conditions they claim to cure. Certain criteria need to be met for any new treatment protocol to fall under Regenerative Medicine

Advanced Therapy (RMAT), namely, the investigational drug must address the unmet need for clinical therapies, it has to fall under Section 361 of Public Health Service Act and part 1271 of title 21, Code of Federal Regulations or the drug or therapy has shown the potential to address life-threatening conditions [2]. It's of utmost importance that the public is aware of this potential hoax

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claims and is advised to consult the regulatory website or consult established institutions or experts in this field before embarking on this treatment journey. Although stem cell therapies have been established to be safe and well tolerated, there has been documented evidence of adverse events, including a few that have been life-threatening, including precipitating the development of tumors, which could be attributed to the multipotent proliferation capacity of these cells if left unchecked [3]. Hence, it's of utmost importance that consumers undergo therapies that are effective, yet safe and FDA approved.

Various neurological trials have focused on the role of regenerative therapies, namely bone marrow MSCs in progressive, and possibly life-threatening conditions like ALS, and Parkinson's disease. A systematic review has shown that MSC could help arrest the progression of the decline in respiratory function in a few clinical trials, but others have not shown many benefits. So, there is conflicting evidence on the same and larger scale robust RCTs are needed to understand the potential benefits better [4]. A certain number of pre-clinical/phase 1 and 2 studies have shown that intra-thecal injections of bone marrow MSC (BM-MS) have shown promise in aiding faster neurological recovery in those suffering from spinal cord injury (SCI). But the potential limitation of these studies is that most of them are involving a small number of patients, which could render the results equivocal [5].

The role of immunotherapy in treating deadly hematological malignancies has been very promising, especially the advances in CAR-T therapy for leukemia. With the advent of

Adoptive Cell Transfer therapy (ACT), the revolutionary therapy has given promise in patients suffering from B cell malignancies, where we can selectively expand a healthy lineage of immune cells from the patient itself to attack the malignant cells and wipe them out [6]. However, challenges still exist in using these therapies for solid tissue tumors, since the local microenvironment of tumor is not supportive of the entry of these cells into the tissue. These therapies further to address these challenges too.

Acute cardio-metabolic conditions continue to pose a major challenge currently. Acute coronary events constitute the major cause of mortality globally. Although we have a huge number of treatment modalities available as pharmaceutical agents to support cardiac health post-MI or a major cardiovascular event, therapies that aid repair of cardiac tissue are limited; rather the currently available drugs are aimed at supporting the functioning of the damaged myocardium, which would not be the best strategy, hence regenerative solutions that provide a different approach would be of huge potential benefit for ailing patients.

Interestingly, the use of MSC has shown to be of promise in Covid-19 patients, especially those presenting with severe inflammatory states. MSC possess strong immunomodulatory effects through its potentiation of CXCL9,10,11 and CCL5 chemokines [7]. This could possibly be a potential therapeutic window for providing solutions for the ever-evolving problem of mutations in the virus, where currently only vaccination seems to provide a solution, which has its own limitations and challenges.

The advent of stem cell therapies posed its own challenges, especially the use of embryonic stem cells was an ethical challenge; the use of hematopoietic and BM- MSC circumvents this problem. Now, with the discovery of induced pluripotent stem cells (iPSC) by Shinya Yamanaka [8], it promises to be potentially revolutionary since one could still harness the pluripotency of stem cells without the ethical concerns as such. Now with the evolution of Platelet Rich Therapies (PRP), prolotherapy etc. it's not just MSC therapy, but also more sustainable options that are less invasive are available for patients with chronic degenerative conditions like osteoarthritis [9]. Platelets are rich sources of growth factors, named platelet-derived growth factors (PDGF) that when extracted carefully could aid in regenerating worn and torn cartilage. Prolotherapy works on the principle that injecting a local irritant, like hypertonic dextrose, can cause the local tissue to gear up repair mechanisms and aid in the healing of the condition through local cell proliferation.

It's clear that this branch of medicine has a wide variety of applications in various conditions and may serve as a boon to address them and provide long-lasting solutions. At the same time, we must remember that the core of regenerative medicine is still focused primarily on bench research, which forms the foundations for any frontiers of medicine in the nascent stages, but the utility of the science only comes with the application of the same onto the bedside. Most of the bench research is focused on differentiating MSC to adult cells using differentiation techniques. There is a lot of work that needs to be done in translating this science for patient therapies through well-established clinical protocols. Yet, it is concluded that in a current stage wherein one could to a certain degree confidently state that regenerative medicine could be the medicine of the future hailing as a boon to ailing mankind from various debilitating and life-threatening conditions.

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