




Review Article

Mesenchymal Stem Cell Treatment Does Not Result in Tumor Formation: A Systematic Review

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Abstract

Mesenchymal stem cells (MSCs) have emerged as a promising therapeutic avenue for various conditions due to their regenerative properties and immunomodulatory effects. Embryonic stem cells divide more freely than MSCs, and embryonic stem cells can cause teratomas. Perhaps for this reason, and although mesenchymal stem cells have not been generally associated with tumors, there has been concern about potential tumorigenicity of MSCs. This paper presents a comprehensive review aimed at investigating the potential tumorigenicity of MSC therapy. A systematic search of PubMed-indexed literature was conducted, focusing on clinical trials involving intravenous, intra-articular, intramuscular, and intra-theatal delivery routes of MSCs. Additionally, studies examining the occurrence of tumor formation post-MSC treatment in humans were reviewed. Among 217 identified studies, no tumors arising from injected MSCs, and no difference in the incidence of tumorigenesis from host tissues was found. While acknowledging that the duration of some studies may be shorter than the latency period of tumor formation, this review provides robust evidence supporting the safety of MSC therapy with regard to tumorigenicity. It is concluded that properly conducted MSC treatment is not tumorigenic.

Keywords: Mesenchymal Stem Cells; Safety; Oncogenesis; Tumor; Tumorigenesis

Introduction

Mesenchymal stem cells (MSCs) are multipotent cells used for the treatment of various conditions due to their immunomodulatory, healing, and anti-inflammatory properties [1-4]. Numerous clinical

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trials using both allogeneic and autologous mesenchymal stem cells have shown efficacy for the treatment of various conditions including osteoarthritis, inflammatory arthritis, back pain, inflammatory bowel disease, polycystic ovary syndrome, asthma multiple sclerosis, rheumatoid arthritis, and autism [5-14].

All stem cells fall into a specific category of potency, which defines the types of cells into which they can differentiate and how freely they divide. MSCs are considered multipotent, limiting their differentiation to remain within a single germ layer while embryonic stem cells are characterized by their pluripotency [15]. Pluripotency is also demonstrated by the ability to form teratomas, also known as teratogenicity, in which a tumor consisting of all 3 germ layers is formed [16]. While embryonic cells are no longer widely used clinically or in research studies, this has led to some confusion as to whether the more differentiated MSCs also have tumorigenic properties [17]. However, a comprehensive 2024 systematic review of embryonic stem cells found no incidence of serious adverse events including tumorigenicity related to the use of embryonic stem cells or their derivatives for age-related macular degeneration, spinal cord injury, Stargardt's macular dystrophy, Type 1 Diabetes, as well as heart failure [18]. Notably, one study from September 2021 in which seven patients had transplantation of human embryonic stem cell-derived retinal pigment epithelium found no tumorigenesis or abnormal cell proliferation during the 5 year follow-up period [19]. The lack of tumorigenicity in the more freely dividing embryonic stem cells supported our hypothesis about MSCs. Specifically, we hypothesized that MSCs are not tumorigenic and conducted a formal systematic literature review to test this hypothesis.

Methods

To determine if MSCs are tumorigenic we conducted "PubMed" indexed literature searches as follows:

1. Search by site of delivery: We searched the literature for clinical trials that used intravenous, intra-articular, intramuscular, and intra-theatal routes of MSC delivery.
2. MSC tumorigenicity: Using the PubMed search engine, we reviewed the scientific literature to evaluate the incidence of tumor formation after MSC treatment in humans. Using the clinical trial filter, the term "Mesenchymal stem cell" was cross-referenced with the following terms: "malignancy", "tumor", "cancer", or "neoplasm". Patients with pre-cancerous lesions or conditions or a current diagnosis of cancer were excluded. Articles that tested combination treatments as part of the trial and articles not available in English were removed from the selection of literature.

Following the collection of data, a two-sided paired t-test was performed to determine the statistical significance of the differences between control group malignancies and MSC treatment malignancies.

Results

The process of literature selection and the application of exclusionary criteria is portrayed in Figure 1. The site-specific search

resulted in 300 clinical trials performing intravenous, intra-articular, intrathecal, or intramuscular administration of MSCs. Through the MSC and tumorigenicity cross-referenced search a total of 187 clinical trials were found. Across both criteria, a total of 487 articles were collected. Using EndNote as a citation manager, 41 duplicate articles were removed.

The exclusion criteria were then applied to the 487 articles. Subsequently, a total of 229 articles were removed. Studies were excluded if patients received a combined therapy of MSCs and any additional treatment. Additional exclusionary criteria included studies in which patients were previously diagnosed with cancer or precancerous conditions/lesions. A total of 217 articles remained and were analyzed for this review [20-236].

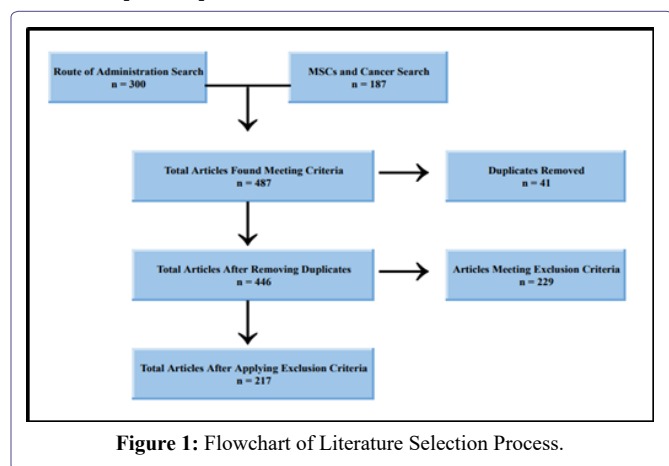


Figure 1: Flowchart of Literature Selection Process.

In Table 1, an analysis of the studies reviewed showed no difference in tumorigenicity between treatment and control groups. Of 4796 patients who received MSC treatment across controlled and non-controlled studies, only 12 malignancies were reported. Of the 2359 participants in control groups, 6 of them were reported to have developed a malignancy within the follow-up period. Performing a 2-sided paired T-test for the controlled clinical trials, a p-value of 0.82 was calculated, demonstrating no statistically significant difference between control groups and MSC groups for tumor formation.

Study Design	Controlled Studies	Non-Controlled Studies	Totals
	n = 110 Articles n = 5223 Patients	n = 107 Articles n = 1932 patients	n = 217 Articles n = 7155 Patients
# of MSC Treatment Malignancies n = 4796 Patients	6 (0.21%) p = 0.819744	6 (0.31%) p = 0.057	12 (0.25%) p = 0.697
# of Control Treatment Malignancies n = 2359 Patients	6 (0.25%)	N/A	6 (0.25%)
Total # of Malignancies	12 (0.23%)	6 (0.31%)	18 (0.25%)

Table 1: Malignancy Incidence in Controlled and Non-Controlled Studies of Mesenchymal Stem Cell Treatment.

The follow-up periods of the individual clinical trials vary from 0 months to 120 months, with longer follow-up periods providing better data for the tumorigenic potential of MSC treatment. In Table 2 a summary of the follow-up periods is shown, with 76.96% of studies

providing follow-up data for at least 6 months. These articles account for 79.39% of all patients within this review. The mean duration of patient follow-up was found to be 13.92 months.

Follow-up Period	Less than 6 months	6+ Months
Number of Studies n = 217	48	167
Percentage of Studies	22.12%	76.96%
Number of Patients n = 7155	1526	5680
Percentage of Patients	21.33%	79.39%

Table 2: Follow-up Periods for all Patients.

Discussion

Despite questions raised due to the pluripotent characteristics of embryonic cells, we looked for any incidence of tumorigenesis following the use of pluripotent-derived stem cells and found none. We further conducted a formal literature review based on MSCs specifically, which are a part of the mesoderm germ layer. There was no evidence of an increase in tumor incidence due to MSC treatment, suggesting that MSCs did not undergo malignant transformation or promote any malignant transformation of tissue.

A strength of our study is the comprehensive nature of our literature search, encompassing over 4,500 patients receiving the treatment across 217 studies. The selected studies also included MSCs derived from various tissues, both autologous and allogeneic, including the umbilical cord, bone marrow, and adipose tissue, demonstrating the consistency of safety across many sources of MSCs. Further, we compared the tumor formation within MSC treatment groups to that of control groups where patients with similar characteristics did not receive the treatment. This provided an accurate representation of the tumorigenicity solely due to MSCs by demonstrating the incidence of malignancy from the control group for direct comparison to that of the treatment group. A notable constraint in this review pertains to the latency period of tumorigenesis. In 48 of the 217 studies, the duration of follow-up was less than 6 months. While the majority of patients within this review were followed up with for at least 6 months, it is conceivable that the manifestation of tumorous growth occurred subsequent to the cessation of data collection.

Conclusion

Properly performed MSC injections in humans do not appear to lead to an increased incidence of tumor formation. Across all studies in this review, we saw no significant difference between the control groups and MSC groups with malignancies. The results of this review reinforce the safety of MSC treatments for their wide variety of uses.

Statements and Declarations

Competing Interests and Funding

The funding for this publication was provided by the Foundation for Orthopaedics and Regenerative Medicine. No third-party funding was provided. The authors have no relevant financial or non-financial interests to disclose.

Declarations

Ethics approval and Consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of supporting data

All data is available upon request from the authors.

Conflicts of interest

The authors have no relevant financial or non-financial interests to disclose.

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Author's contribution

LP and KN performed data acquisition, data analysis, literature search, and literature analysis, and created the prose for this paper. CP conceptualized the study, conducted the study design, and created the prose for this paper.

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