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# Efficacy of mesenchymal stem cell therapy in patients with liver cirrhosis: A systematic review

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## Abstract

Liver cirrhosis is a chronic liver disease characterized by histological structural changes in the form of fibrotic tissue accumulation as a response to ongoing liver injury. The World Health Organization (WHO) reports that the global prevalence of liver cirrhosis reaches approximately 170 million people. One emerging therapeutic approach is cell-based therapy, particularly Mesenchymal Stem Cells (MSCs), which have immunomodulatory, reparative, and regenerative properties. This study aims to determine the effectiveness of MSC therapy in improving liver function in patients with liver cirrhosis, using indicators such as albumin and bilirubin levels, while accounting for the dose, frequency, and route of MSC administration. This research is a systematic review using search methods through PubMed, ScienceDirect, SpringerLink, and Cochrane databases, as well as citation searching. The article selection process follows the PRISMA diagram, and risk of bias assessment is conducted using the risk-of-bias tool (RoB2) with the help of RevMan 5.4 software. Of the 305 identified articles, 4 meet the inclusion criteria. The results show that MSC therapy significantly increases albumin levels and decreases bilirubin levels at certain doses and frequencies, whereas a single high dose does not show a significant effect. The intravenous and hepatic artery routes of administration do not differ in effectiveness. MSC therapy with the appropriate dose and frequency is effective in improving liver function in patients with liver cirrhosis.

**Keywords:** Liver cirrhosis; MSC therapy; Albumin Level; Bilirubin level

## 1. Introduction

Liver cirrhosis is a disease characterized by histological changes in the liver structure in the form of regenerative nodules surrounded by fibrotic connective tissue as a response to chronic liver injury (1,2). Liver cirrhosis is one of the diseases that poses a problem worldwide, with the most common causes being alcohol and viral infections. The World Health Organization (WHO) in 2006 stated that the global prevalence of liver cirrhosis reached 170 million people, with 3-4 million of them caused by hepatitis viruses. In the United States, the most common cause of liver cirrhosis is hepatitis C, while in Indonesia, hepatitis B accounts for 30-40% of cases, hepatitis C for 20-30%, and 10-20% of cases have unknown causes (3,4). The prevalence of liver cirrhosis in Indonesia, based on government hospital data, is 3.5% among patients treated in the internal medicine department and 47.7% among patients with liver disease.

Liver cirrhosis is divided into 2 stages: compensated and decompensated. In the compensated stage, liver cells can still compensate for impaired liver function because some normal liver cells remain, whereas in the decompensated stage, liver cells cannot compensate for the damage. In laboratory examinations, patients with liver cirrhosis, both

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compensated and decompensated, have low albumin levels that correlate with the severity of liver cirrhosis, while bilirubin levels are normal in the compensated stage and increase in the decompensated stage (5,6).

Effective management of liver cirrhosis currently involves liver transplantation, which is one of the curative treatments for end-stage cirrhosis. However, it has many limitations in its implementation. The limited number of liver donors is the main cause of these limitations, leading to a problem where patients with liver cirrhosis die while waiting for a transplant. The follow-up treatment after a liver transplant is the lifelong use of immunosuppressive drugs, as there is a risk of immune rejection, which can lead to chronic kidney failure and other cardiovascular complications in the long term. Another issue with liver transplantation is the high cost of treatment (1,7).

There is an alternative treatment for liver cirrhosis disease, which is cell-based therapy (8). Many studies have researched stem cell therapy as a treatment for liver cirrhosis. One of them is Mesenchymal Stem Cells (MSCs), which can differentiate into cells resembling hepatocytes. MSCs are multipotent stromal cells that can be easily isolated from various tissues, including adipose tissue, brain, peripheral blood, lungs, skeletal muscle, liver, and dermis. These cells also exhibit low immunogenicity, which is beneficial for liver fibrosis (9).

This MSC-based therapy has many advantages, including immunomodulation, tissue repair, and tissue regeneration. Many studies on MSC therapy in patients with liver cirrhosis are in preclinical and clinical trial stages, focusing on liver function indicators, and show varying results. MSCs can improve fibrosis/cirrhosis in the liver and enhance liver function, as evidenced by significantly increased albumin levels and decreased bilirubin levels to normal values, although some studies show different results. This may be due to different research methods. Therefore, further research is needed to evaluate the effectiveness of MSC therapy in improving liver function in patients with liver cirrhosis using a systematic review approach, considering the potential of MSC-based therapy in treating liver cirrhosis (10).

## 2. Materials and methods

### 2.1. Types and Research Strategies

The research design used in this study is a systematic review, employing a comprehensive search strategy and secondary data from previous articles or studies. The systematic review in this study uses the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) method, which is a literature review based on facts and randomly selected from previously published articles or studies. In this study, the literature used is reviewed using the PICOS method, as shown in Table 1 below.

**Table 1** PICO Analysis

| **Population (P)** | **Intervention (I)** | **Comparison (C)** | **Outcomes (O)** | **Study Design (S)** |
|---|---|---|---|---|
| Patient with hepatitis cirrhosis | Administration of Mesenchymal Stem Cell (MSC) Therapy | Given adjuvant therapy | Liver function improvement as seen from changes in albumin and bilirubin levels | Randomize Clinical Trial (RCT) |

This method can facilitate researchers in identifying relevant journals for the research they are discussing and subsequently evaluating them using the PRISMA flowchart (Figure 1). In the journal search, the researcher uses and arranges keywords, and employs synonyms of those keywords using Medical Subject Headings (MeSH). The keywords used are (“cirrhosis hepatic” OR “liver fibrosis” OR “liver cirrhosis”) AND (“mesenchymal stem cell” OR “stem cell” OR “cell stem” OR “progenitor cells”) AND (“hepatic function” OR “liver function”).

### 2.2. Eligibility Criteria

Researchers determine eligibility criteria to ensure the selected articles address the research questions relevant to the research topic. The inclusion criteria include: 1) Studies discussing the potential use of Mesenchymal Stem Cell (MSC) therapy on albumin and bilirubin levels in patients with decompensated liver cirrhosis; 2) Study design: RCT; 3) Research articles in English; 4) Research articles that are accessible in full-text; 5) Research articles published within the last 10 years (2013-2023). The exclusion criteria are systematic reviews and meta-analyses.

The inclusion criteria used in this systematic review was (a) article published between 2015-2025; (b) research conducted in any country; (c) publications written in English; (d) studies available in full-text and open-access format; (e) indexed in Scopus (Q1-Q4); (f) original research articles; (g) study that investigate soursop leaves (Annona muricata) as a potential anticancer agent against cervical cancer. While the exclusion criteria used in this study were (a) review articles, (b) studies without full-text access, and (c) articles not relevant to the topic of interest.

### 2.3. Bias Risk Assessment

After identifying and selecting relevant research articles, the next step was to assess the risk of bias in the data. To determine the bias quality of articles in Randomized Clinical Trials (RCTs), the risk-of-bias tool (Rob 2) was used, based on recommendations from the Cochrane Handbook for Systematic Reviews, assisted by the reference management application (RevMan 5.4).

## 3. Results and discussion

### 3.1. Article Identification Results

In this systematic review, an initial total of 305 articles were obtained, consisting of 300 from database methods and 5 from citation searching methods. The initial literature search using the database method was filtered through several stages, resulting in 3 final articles. The literature search using citation searching was also filtered through several stages, resulting in 1 final article. Therefore, the total number of final articles included in this systematic review is 4. The article identification results are shown in the PRISMA flowchart (Figure 1).

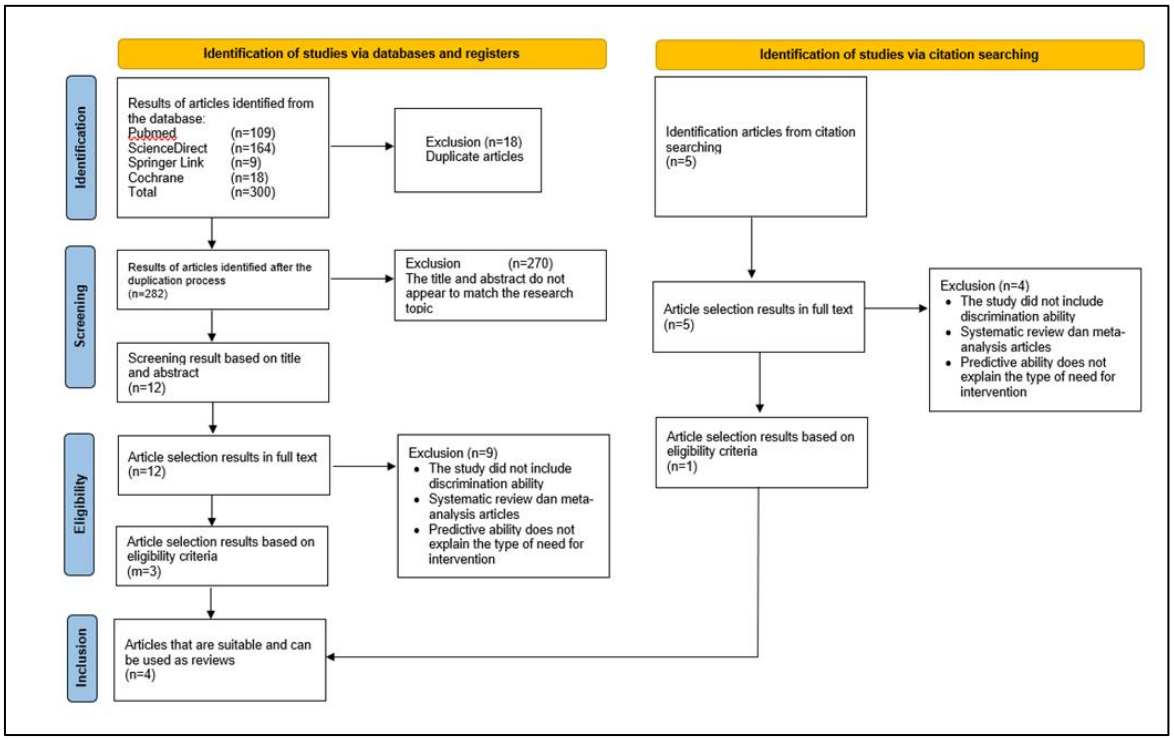


**Figure 1** PRISMA Flowchart

### 3.2. Research Characteristics

In this study, four articles meeting the eligibility criteria were identified: randomized clinical trial (RCT) studies published within the last 10 years (2013-2023). The language used in these four articles is English. The characteristics of these four research articles are shown in Table 2.

**Table 2** Characteristics of research articles

| Author | Title | Year | Country | Study Design |
|---|---|---|---|---|
| Shi et al. | *"Mesenchymal stem cell therapy in decompensated liver cirrhosis: a long-term follow-up analysis of the randomized controlled clinical trial"* | 2021 | China | RCT |
| Suk et al., | "*Transplantation with Autologous Bone Marrow-Derived Mesenchymal Stem Cells for Alcoholic Cirrhosis: Phase 2 Trial"* | 2016 | South Korea | RCT |
| Salama *et al*. | "*Peripheral vein infusion of autologous mesenchymal stem cells in Egyptian HCV positive patients with end-stage liver disease"* | 2014 | Mesir | RCT |
| Mohamadnejad *et al.* | *"Randomized placebo-controlled trial of mesenchymal stem cell transplantation in decompensated cirrhosis"* | 2013 | Iran | RCT |

### 3.3. Bias Risk Assessment

Based on these four systematic review studies, three studies received a low risk of bias assessment, and one study received some concern risk of bias assessment. The risk of bias assessment results are shown in Figure 2.

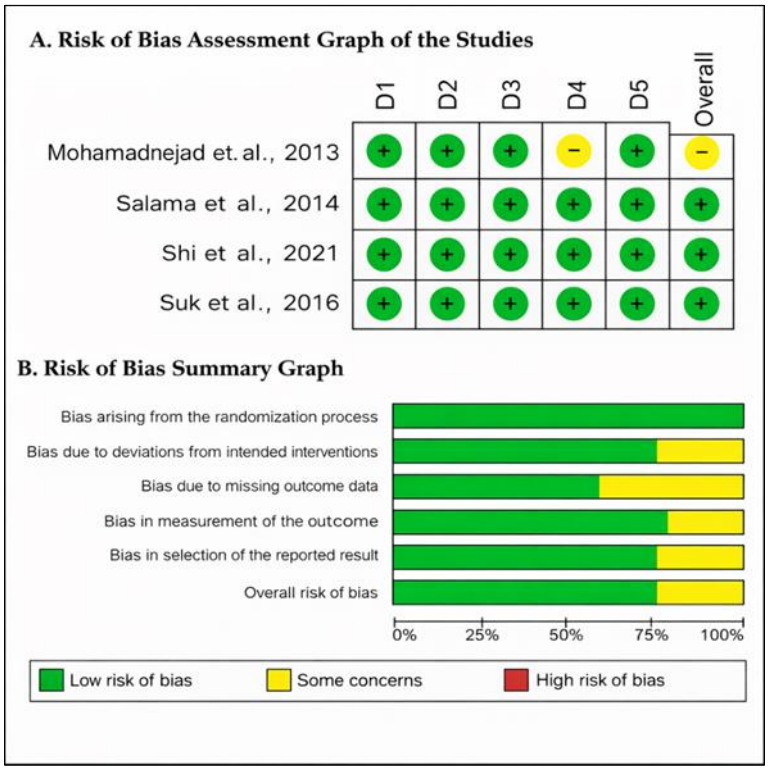


**Figure 2** Bias risk assessment

### 3.4. Data Extraction Results

The four research articles that meet the eligibility criteria were then subjected to data extraction. The data extraction process includes details of the data collection methods and the findings, which are presented in Table 3.

**Table 3** Characteristics of the included study

| No | Author | Diagnosis | Etiology | MSC Source | MSC doses | Route Provision | Frequency of Administration | Observation | Number of Samples | Changes in Serum Levels after MSCs Administration | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | MSC Infusion Group | Control Group | Albumin | Bilirubin |
| 1 | (8) | Decompensated liver cirrhosis | HBV | UC-MSC | 0,5x106/kg | Intravenous injection | 3 | 48 weeks | 108 | 111 | Increase (p-value <0,05) | Constant (p-value >0,05) |
| 2 | (11) | Decompensated liver cirrhosis | Alcohol | BM-MSC | 5x107/kg | Hepatic artery injection | 1<br>2 | 12 months | 18<br>19 | 18 | Increase (p-value <0,05) | Decrease (p-value <0,05) |
| 3 | (12) | Decompensated liver cirrhosis | HCV | BM-MSC | 1x106/kg | Intravenous injection | 1 | 6 months | 20 | 20 | Increase (p-value <0,05) | Decrease (p-value <0,05) |
| 4 | (13) | Decompensated liver cirrhosis | HBV, HCV | BM-MSC | (1.2-2.95)x108/kg | Intravenous injection | 1 | 12 months | 14 | 11 | Constant (p-value >0,05) | Constant (p-value >0,05) |

### 3.5. Albumin Level

The results of this systematic review analysis of albumin levels show that three studies—Shi et al. (2021), Suk et al. (2016), and Salama et al. (2014)—indicate that MSC therapy significantly increases albumin levels with a p-value < 0.05, while one study—Mohamad Nejad et al. (2013)—showed different results, indicating that MSC therapy does not increase albumin levels.

### 3.6. Bilirubin Level

The results of this systematic review's bilirubin level analysis show that two studies, Suk et al. (2016) and Salama et al. (2014), indicate that MSC therapy can significantly reduce bilirubin levels with p-values less than 0.05, while two other studies, Shi et al. (2021) and Mohamad Nejad et al. (2013), show different results, indicating that MSC therapy does not reduce bilirubin levels.

## 4. Discussion

### 4.1. The effect of MSC administration on albumin levels

Albumin is a protein synthesized by the liver and functions to regulate oncotic pressure, as well as transport nutrients, fatty acids, hormones, and waste products. A decrease in albumin levels is caused by disturbances in liver synthesis function (14). In cirrhosis of the liver, there is an accumulation of fibrous connective tissue that damages hepatocytes and can interfere with albumin synthesis.

In this systematic review, the studies by Shi et al. (2021), Suk et al. (2016), and Salama et al. (2014) showed that MSC therapy significantly increased albumin levels, but the study by Mohamadnejad et al. (2013) showed different results, indicating that MSC therapy did not increase albumin levels. These differing results may be due to the study's limited sample size. Other MSC therapy studies on patients with chronic hepatitis and compensated liver cirrhosis by Xu et al. (2014) and Cao et al. (2020) showed an increase in albumin levels.

Based on the three studies above, the administration of MSC therapy has been proven to increase albumin levels in decompensated liver cirrhosis. This is because MSCs can regenerate the liver, thereby improving its albumin synthesis (15). There are five mechanisms by which MSC therapy regenerates the liver: 1) Transdifferentiation into hepatocyte-like cells, supported by several growth factors such as FGF, HGF, OSM, EGF, and BMP, as well as intracellular signaling pathways Wnt/β-catenin and TGF-β; 2) Fusing to become hepatocytes; 3) Modulating immune responses by secreting soluble factors such as NO, PGE2, IDO, IL-6, IL-10, and HLA-G. This process suppresses certain immune cells (B cells, T cells, DCs, and NK cells); 4) Secreting trophic factors through three mechanisms: suppressing hepatic stellate cell activation involving trophic factors like IL-10, HGF, NGF, and TNF-α; increasing hepatocyte proliferation via HGF, EGF, TGF-β, and VEGF; and aiding the differentiation of hepatic progenitor cells with EGF and HGF; 5) Exhibiting antifibrotic effects by inhibiting hepatic stellate cell proliferation through secretion of IL-10, HGF, and TNF-α, inducing apoptosis of hepatic stellate cells via NGF and HGF secretion, and reducing collagen synthesis by secreting IL-10, TNF-α, TGF-β3, and HGF (16).

In this systematic review, the researchers also analyzed the effectiveness of MSC therapy on albumin levels, depending on the source, dose, frequency, and route of MSC administration. Bone Marrow Mesenchymal Stem Cells (BM-MSC) are the primary source of MSC production, while Umbilical Cord Mesenchymal Stem Cells (UC-MSC) are the second most commonly used source in MSC therapy (17,18). The results of this systematic review show that the use of UC-MSC in the study by Shi et al. (2021) and the use of BM-MSC in the studies by Suk et al. (2016) and Salama et al. (2014) indicate that MSC therapy can significantly increase albumin levels. However, the use of BM-MSC in the study by Mohamadnejad et al. (2013) did not increase albumin levels. This may be due to other factors such as the dosage and frequency of MSC administration.

There is variation in the dosage and frequency of MSC administration across the four studies in this systematic review. Shi et al. (2021) used an MSC dose of 0.5×10^6/kg with a frequency of 3 times, Suk et al. (2016) used an MSC dose of 5×10^7/kg with a frequency of once or twice, and Salama et al. (2014) used an MSC dose of 1×10^6/kg with a frequency of once. These three studies showed that MSC therapy can significantly increase albumin levels. However, the study by Mohamadnejad et al. (2013), which used an MSC dose of (1.2-2.95)×10^8/kg with a single administration, showed different results—that MSC therapy did not increase albumin levels. Based on these results, the higher MSC dose used in Mohamadnejad et al. (2013) did not increase albumin levels, indicating that the appropriate dose and frequency are necessary for MSC therapy. Currently, the effective dose and frequency of MSC administration are still unknown (19).

Another factor influencing the effectiveness of MSC therapy in hepatic cirrhosis is the route of administration. Intravenous injections were used in the studies by Shi et al. (2021), Salama et al. (2014), and Mohamadnejad et al. (2013), while hepatic artery injections were used in the study by Suk et al. (2016). The two routes of administration did not differ in albumin levels. Several studies report that intravenous administration is as effective as other routes (20).

### 4.2. The Effect of MSC Administration on Bilirubin Levels

Bilirubin is a compound that is metabolized and excreted by the liver. An increase in bilirubin levels is caused by disturbances in the liver's metabolic and excretory functions. Liver metabolic dysfunction results in bilirubin not being metabolized in the liver, while liver excretory dysfunction causes bilirubin to be unable to be excreted by the liver (21). In cirrhosis of the liver, there is an accumulation of fibrous connective tissue that damages hepatocytes, disrupting the liver's metabolic and excretory processes.

In this systematic review, studies by Suk et al. (2016) and Salama et al. (2014) showed that MSC therapy can significantly reduce bilirubin levels, but studies by Shi et al. (2021) and Mohamadnejad et al. (2013) showed different results, indicating that MSC therapy did not lower bilirubin levels. This is because Shi et al. (2021) showed that the initial bilirubin levels in samples before MSC therapy were higher in the MSC infusion group than in the control group, whereas Mohamadnejad et al. (2013) were limited by a small sample size. Another MSC therapy study on patients with chronic hepatitis by Gazdi et al. (2017) showed a reduction in bilirubin levels.

Based on the two studies above, MSC therapy can reduce bilirubin levels in patients with hepatic cirrhosis. This is because MSCs can differentiate into various cell types, including hepatocytes. MSCs also have the capacity to secrete several bioactive molecules, including growth factors and cytokines such as FGF, HGF, OSM, EGF, and BMP, which can increase endogenous cell proliferation and promote liver regeneration. Additionally, MSCs can modulate the immune response to liver cell damage by inducing the selective emigration of leukocytes from damaged liver cells (22).

In this systematic review, the researchers also analyzed the effectiveness of MSC therapy on bilirubin levels, based on cell source, dosage, frequency, and route of administration. BM-MSCs are the primary source of MSCs for MSC therapy, while UC-MSCs are the second most commonly used source. (17). The results of this systematic review, the use of BM-MSC in the studies by Suk et al. (2016) and Salama et al. (2014), showed that MSC therapy significantly reduced bilirubin levels. However, the use of UC-MSC in the study by Shi et al. (2021) and BM-MSC in the study by Mohamadnejad et al. (2013) indicated that MSC therapy was unable to lower bilirubin levels. This may be due to other factors such as the dosage and frequency of MSC administration.

There is variation in the dosage and frequency of MSC administration across the four systematic review studies. Suk et al. (2016) used an MSC dose of 5×10^7/kg at once or twice, and Salama et al. (2014) used an MSC dose of 1×10^6/kg with a single administration, both showing that MSC therapy significantly reduced bilirubin levels. However, Shi et al. (2021) used an MSC dose of 0.5x10^6/kg with three administrations, Salama et al. (2014) used a dose of 1x10^6/kg once, and Mohamadnejad et al. (2013) used a dose of (1.2-2.95)x10^8/kg once, and these studies indicated that MSC therapy did not lower bilirubin levels. This is because Shi et al. (2021) showed that initial bilirubin levels before MSC therapy were higher in the MSC infusion group than in the control group, which could influence results when using doses similar to those in Suk et al. (2016) and Salama et al. (2014). Meanwhile, Mohamadnejad et al. (2013) used a higher MSC dose than the other three studies. MSC therapy must be administered with the correct dose because exceeding the optimal dose can lead to tumor formation in tissues. However, the effective dose and frequency of MSC administration are still unknown at this time (19).

Another factor influencing the effectiveness of MSC therapy in hepatic cirrhosis is the route of administration. Four studies in this systematic review used two routes of MSC administration: intravenous injection in the studies by Shi et al. (2021), Salama et al. (2014), and Mohamadnejad et al. (2013), and hepatic artery injection in the study by Suk et al. (2016). The two routes did not differ in bilirubin levels, suggesting that the intravenous injection route can either decrease or not decrease bilirubin levels. Both intravenous and hepatic artery injection routes are commonly used in MSC therapy. Some studies suggest that intravenous administration may be as effective as other routes. There is also research indicating that after intravenous injection, the number of MSCs available to migrate to the target organ may decrease due to cell clearance in the lungs (20,23).

## 5. Conclusion

Based on the results of the study conducted in this systematic review, it is concluded that the administration of Mesenchymal Stem Cell (MSC) therapy effectively increases albumin levels and decreases bilirubin levels in hepatic cirrhosis.

## Compliance with ethical standards

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*Disclosure of conflict of interest*

The authors declare no conflicts of interest.

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