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A Study on The Efficacy of Epidermal Cell Suspension in The Treatment of Stable Vitiligo in Tertiary Healthcare Centre in Uttar Pradesh

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Abstract

Introduction: Vitiligo is a chronic skin disorder characterized by the loss of melanocytes, leading to noticeable white patches on the skin. This condition significantly impacts patients' psychological and social well-being. Current treatments show variable efficacy and often have adverse effects. Epidermal cell suspension, a novel cellular therapy, offers a promising treatment option by transferring autologous epidermal cells to depigmented areas to restore pigmentation.

Objectives: This study aims to assess the efficacy of epidermal cell suspension in treating stable vitiligo at a tertiary healthcare centre in Uttar Pradesh, evaluating clinical progress and potential adverse reactions.

Method: This prospective interventional study was conducted over two years at the Dermatology Department of SIMS, Hapur. Sixty patients with stable vitiligo were enrolled, underwent pre-procedure assessments, and received epidermal cell suspension treatment. Follow-up evaluations were conducted at 1 week, 1 month, 3 months, and 6 months post-procedure, with digital photography and subjective assessments.

Results: The study found progressive repigmentation in most participants, with mean repigmentation increasing from 17.95% at 1 week to 71.93% at 6 months.

Conclusion: Epidermal cell suspension is an effective and safe treatment for stable vitiligo, showing significant repigmentation and improved quality of life for patients. Further research is warranted to optimize the procedure and address complications.

Keywords: Vitiligo; Melanocytes; Epidermal cell suspension; Repigmentation; Autologous transplantation.

Introduction

Vitiligo is a chronic skin disorder marked by the loss of melanocytes, presenting a considerable challenge in dermatology and significantly impacting the well-being of those affected. Beyond its visible effects, which can be emotionally taxing due to the prominent white patches on the skin, vitiligo often brings about significant psychological distress, societal stigma, and a decline in self-confidence. Despite its relatively common occurrence, affecting around 1-2% of the global population, treatment options for vitiligo remain limited and not universally agreed upon. The condition's intricate and multifaceted development stems from a combination of genetic, autoimmune, and environmental factors, contributing to its complex etiology.[1]

Cellular therapies have risen as a hopeful frontier in the pursuit of better vitiligo treatment options. Among these, epidermal cell suspension stands out as a noteworthy method. This novel approach entails harvesting and transferring autologous epidermal cells from the patient's healthy skin to the areas affected by depigmentation. The goal is to reestablish pigmentation and halt the advancement of vitiligo. The underlying principle rests on leveraging the regenerative capabilities of epidermal cells, which are vital for preserving skin health and pigmentation.[2]

Conventional therapies like topical corticosteroids, calcineurin inhibitors, and phototherapy have demonstrated mixed effectiveness and may come with adverse effects such as skin thinning and increased sensitivity to light. Moreover, these treatments typically demand long-term application, and their success hinges on patient adherence. Surgical procedures like autologous melanocyte transplantation offer potential benefits but are not universally feasible due to factors like donor site availability and inconsistent results.[3]

The potential advantages of epidermal cell suspension in the treatment of stable vitiligo are multifaceted. Autologous transplantation minimizes the risk of immune rejection, and the use of the patient's own cells ensures compatibility and safety. Furthermore, the procedure can be performed as an outpatient treatment, potentially reducing the burden on healthcare resources compared to more invasive surgical options. As they delve into Paul et al. study, their objective is to comprehensively evaluate the efficacy and safety of epidermal cell suspension as a treatment modality for stable vitiligo, shedding light on its potential as a therapeutic breakthrough.[4]

Vitiligo, a persistent skin disorder with multiple underlying factors, is characterized by the gradual disappearance of melanocytes, the cells responsible for skin, hair, and eye coloration. This condition presents as distinct pale patches against the normal skin, affecting individuals across various ethnicities and genders. Its prevalence globally is estimated at 1-2% of the population. Although the exact cause of vitiligo remains uncertain, it is widely understood to be an autoimmune condition, where the body's immune system mistakenly

attacks and eliminates melanocytes, resulting in skin depigmentation. Genetic influences also play a role, with a higher occurrence observed among individuals with family histories of vitiligo.[5]

The clinical manifestations of vitiligo are variable, with lesions appearing on any part of the body, often symmetrically. These depigmented patches may initially be small and well-defined but can enlarge and merge over time, affecting extensive areas of the skin. The progression of vitiligo is unpredictable, with periods of stability interspersed with episodes of worsening, triggered by factors such as stress, trauma, or infections. The most commonly affected sites include the face, hands, feet, elbows, and genitalia. Additionally, involvement of mucosal surfaces, such as the lips and oral cavity, may occur, further contributing to the heterogeneity of vitiligo's clinical presentation.[6]

Beyond the physical manifestations, the impact of vitiligo extends to psychological and social domains. Individuals with vitiligo often grapple with feelings of self-consciousness, embarrassment, and diminished self-esteem due to the conspicuous nature of the depigmented patches. The psychosocial burden is particularly pronounced in societies where a significant emphasis is placed on physical appearance. Social stigmatization, misconceptions about the condition, and the lack of a definitive cure contribute to the challenges faced by those living with vitiligo.[7]

This investigation becomes particularly pertinent considering the profound impact of vitiligo on patients' psychosocial well-being and the limitations of existing therapeutic options. The exploration of epidermal cell suspension as a treatment strategy is not only a scientific endeavor but also a response to the pressing need for more effective and patient-friendly interventions.

Through this research, we aspire to bridge the gap in knowledge, paving the way for improved outcomes and a better quality of life for individuals grappling with the challenges of stable vitiligo. Understanding its clinical manifestations is crucial not only for accurate diagnosis and management but also for addressing the holistic impact on the lives of affected individuals.

Aim:

To study the efficacy of epidermal cell suspension in the treatment of stable vitiligo in tertiary healthcare centre in Uttar Pradesh.

Objective:

- To Assess the effectiveness and longevity of EPIDERMAL cell suspension in treating stable vitiligo at a tertiary healthcare center in Uttar Pradesh through objective evaluation, including clinical progress and photographic evidence.

Methodology

Site of the Study: The study was conducted in Hapur, Uttar Pradesh, at the tertiary healthcare facility known as the Saraswathi Institute of Medical Sciences and Hospital.

Study Period: July 2022 – June 2024 (2 years)

Study Design: Prospective, interventional study

Study population: study was focus on individuals seeking treatment at the vitiligo clinic within the dermatology outpatient department.

Study sample – 60 patients that visited to our vitiligo clinic were taken for the study.

Inclusion Criteria:

1. Age: Individuals aged 18 years and older were deemed eligible for participation in the study.
2. Clinical Diagnosis: Patients diagnosed with stable vitiligo based on clinical assessment were considered eligible for inclusion.

3. Treatment History: Patients who had not undergone treatment for vitiligo within the previous month were included in the study.
4. Willingness for Procedure and Follow-up: Participants who demonstrated a willingness to undergo the procedure and comply with scheduled follow-up visits were included in the study cohort.

Exclusion Criteria

1. Bleeding Disorders: Patients with a documented history of bleeding disorders were ineligible for participation.
2. Keloidal Tendency: Individuals displaying a propensity for keloid formation were not enrolled in the study.
3. Anticoagulant Medications: Patients currently prescribed anticoagulant medications such as aspirin, warfarin, or heparin were excluded from the study.
4. Active Infection: Individuals with ongoing infections at the treatment site were deemed ineligible for participation.
5. History of Psoriasis or Lichen Planus: Patients with a medical history of psoriasis or lichen planus were excluded due to the potential risk of Koebner phenomenon.
6. HIV and HBsAg Positivity: Patients testing positive for HIV or HBsAg were excluded from study participation.
7. Major Medical Illness: Individuals diagnosed with significant medical conditions such as hepatic or renal disease, epilepsy, or other major illnesses were not included in the study.
8. Pregnancy: Pregnant individuals were excluded from participating in the study.

Results of the Study

The study on epidermal cell suspension for stable vitiligo at a tertiary health care centre .Initially, 88.30% achieved 0-25% repigmentation; over six months, 61.70% achieved 51-75%, and 33.30% achieved 76-90%. Mean repigmentation increased from 17.95% at one week to 71.93% at six months, with significant reductions in pigmentation ($p < 0.001$) as seen in figure 1.

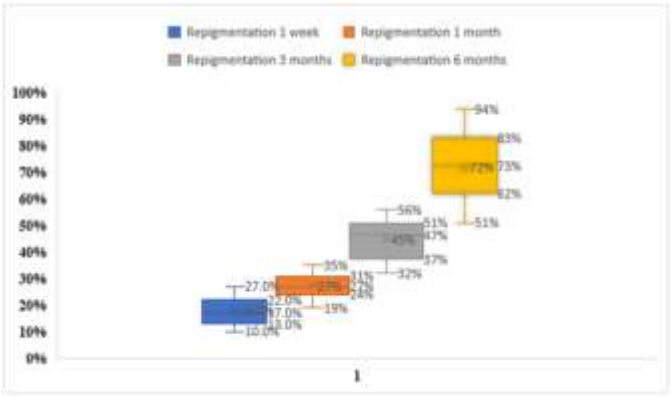

Figure 1: Comparison of Repigmentation at different follow-ups.

Table 1: Difference in pigmentation at different follow-ups from 1 week pigmentation

Difference in pigmentation	Mean ± SD	P value	95% CI(Lower-Upper)
Repigmentation follow up at 1 week%- 1 Month%	-9.38 ± 1.39	<0.001*	-9.74 to -9.02
Repigmentation follow up at 1 week%- 3 Month%	-25.47 ± 8.1	<0.001*	-27.5 to -23.3
Repigmentation follow up at 1 week%- 6Month%	-48.68 ± 20.2	<0.001*	-53.9 to -43.5

Initially, 88.30% achieved 0-25% repigmentation; over six months, 61.70% achieved 51-75%, and 33.30% achieved 76-90%. Mean repigmentation increased from 17.95% at one week to 71.93% at six months, with significant reductions in pigmentation ($p < 0.001$) as seen in table one.

Discussion

From the current study, majority of participants, 88.30%, experienced 0-25% repigmentation within the first week, while 11.70% showed 26-50% repigmentation, indicating varied responses to the treatment early on. Over the subsequent three-month period, 68.30% achieved 26-50% repigmentation, with 31.70% showing 0-25% repigmentation, demonstrating continued but varied progress. At the six-month mark, 70.69% achieved 26-50% repigmentation, and 29.31% attained 51-75% repigmentation, showcasing significant improvement. Finally, after six months, 65.45% experienced 51-75% repigmentation, 29.09% achieved 76-90% repigmentation, and 5.45% reported extensive repigmentation (91% or more), indicating substantial and exceptional responses to treatment over time. Overall, the data illustrate significant and varied improvements in skin pigmentation post-treatment, highlighting the need for continued monitoring to assess long-term effectiveness.

At one week post-procedure, participants showed an average repigmentation of 17.95% ± 5.209%, ranging from 10.0% to 27.0%, indicating an early treatment response. By one month, repigmentation increased significantly to a mean of 27.33% ± 4.425%, with individual ranges from 19.0% to 35.0%, demonstrating continued improvement. At three months, there was a notable enhancement in repigmentation, averaging 44.91% ± 7.5%, ranging from 32.0% to 56.0%, indicating substantial progress. Finally, at the six-month mark, participants exhibited considerable repigmentation, with a mean of 72.69% ± 12.1%, ranging from 51.0% to 94.0%, reflecting significant improvement in skin pigmentation over the treatment period.

According to findings from a study by Tyagi S et al., after a 12-week follow-up period, the results indicated that 60% of the lesions demonstrated excellent repigmentation, defined as exceeding 75% improvement. Additionally, 35% of the lesions achieved good repigmentation, falling within the range of 51% to 75% improvement, while 5% exhibited fair repigmentation, corresponding to a range of 26% to 50% improvement. [8]

After applying the basal cell layer epidermal cell suspension, which was abundant in melanocytes, Olsson and Juhlin reported an 85% success rate. This success rate aligns with the findings of Tyagi S., where the treated area ranged from two to ten times the donor area. [9]

Conclusion

The study on the efficacy of epidermal cell suspension for treating stable vitiligo at a tertiary healthcare centre yielded valuable insights into various aspects of the condition and treatment outcomes.

Repigmentation Outcomes: Participants demonstrated progressive repigmentation over the treatment period, with significant improvements observed at each follow-up interval. These findings indicate the effectiveness of epidermal cell suspension in promoting repigmentation and restoring skin pigmentation in individuals with stable vitiligo. In conclusion, the study provides valuable insights into the demographics, characteristics, treatment outcomes, and quality of life implications of epidermal cell suspension therapy for stable vitiligo. The findings support the efficacy and safety of this treatment modality and emphasize the importance of individualized, comprehensive care approaches in managing vitiligo to achieve optimal outcomes and enhance patients' quality of life.

Limitation

The study may have had a relatively small sample size, which could limit the generalizability of the findings to a broader population. Conducting the study at a single tertiary healthcare center may limit the diversity of the patient population and may not represent the broader demographic characteristics of patients with stable vitiligo. Some participants had been lost to follow-up at various time points during the study, which could introduce bias and affect the reliability of the results, especially in longitudinal assessments.

The use of subjective outcome measures such as patient-reported quality of life assessments may introduce bias due to individual interpretation and perception of their condition and treatment outcomes.

The absence of a control group or comparison with alternative treatment modalities may limit the ability to attribute observed outcomes solely to the epidermal cell suspension treatment.

The relatively short follow-up duration of six months may not capture long-term outcomes and potential complications associated with the treatment, limiting the assessment of treatment sustainability and safety over time.

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