European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 09, Issue 07, 2022

**ORIGINAL RESEARCH**

# A Comparative Study of Clobetasol Propionate (0.05%) Cream and Tacrolimus (0.1%) Ointment in the Management of Localised Vitiligo

**M. Naga Sayana Rao[1], S. Jareena Begum[2]**

[1]MD, Associate Professor of DVL, ACSR, Government General Hospital, Nellore, Andhra Pradesh, India

[2]MD, Assistant Professo of DVL, ACSR, Government General Hospital, Nellore, Andhra Pradesh, India

## ABSTRACT

**Background: To study and compare tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) in the management of localised vitiligo. To know the common types of vitiligo, age and sex distribution and to know the percentage of regimentation and adverse effects encountered with tacrolimus ointments (0.1%) and clobetasol propionate cream (0.05%).**

**Material and Methods:The present prospective study includes 50 cases of clinically diagnosed vitiligo attending the outpatient department of DVL, ACSR, Government General Hospital, Nellore from 01/06/2021 to 30/05/2022 over a period of 12 months. In this study patient with focal, local, segmental, lip-tip, mucosal and acrofacial vitiligo were included. Generalized and universal vitiligo (vitiligo vulgaris) were excluded in this study.**

**Results: In the present study 50 cases of vitiligo divided into two equal group treated with either tacrolimus ointment (0.1%) or clobetasol propionate cream (0.05%) were included. In this study the peak incidence of vitiligo is the age group of 21-30 years, with slight female preponderance (58%). Focal form of vitiligo in common (36%), response to clobetasol propionate cream (0.05%) 36 % whereas with tacrolimus ointment (0.1 %) it is 64 %. Adverse effects in clobetasol propionate cream (0.05%) were seen in 7 patients (28 %) and with tacrolimus in one patient (4 %).**

**Conclusion: In the present study clinical efficacy of tacrolimus ointment (0.1%) was almost equal to clobetasol propionate cream (0.05%) and tacrolimus ointment (0.1%) had fewer side effects than clobetasol propionate cream (0.05%) but the compliance was found to be better with clobetasol propionate cream (0.05%) due to its cost effectiveness.**

**Keywords: Vitiligo, clobetasol propionate cream (0.05%), tacrolimus ointment (0.1%).**

**Corresponding Author:** Dr. M. Naga Sayana Rao, Associate Professor of DVL, ACSR, Government General Hospital, Nellore, Andhra Pradesh, India

## INTRODUCTION

Vitiligo is a specific type of pigmentary disorder manifested by depigmentation, occasionally hypopigmentation of the epidermis. Clinically it is characterized by circumscribed chalky white marks or patches, few or more in number, which tend to enlarge centrifugally over time.[1,2,3] All races and ethnic groups are equally affected with female preponderance. Vitiligo is neither contagious nor does it contribute to the loss of general health. There is immense social stigma associated with this condition. The resultant effect of psyche of the patient is dramatic, often with a distortive body image, fear and anxiety. Vitiligo cannot be

considered as a single entity but at the end, result of interplay of numerous factors.[3,4] Vitiligo involves 0.5 % to 4 % of the world population and causes alteration in the physiology of the epidermis as well as cosmetic and psychological problems.[4,5] A variety of therapeutic agents are used for the treatment of vitiligo, but none is clearly a definitive cure. Therapy for vitiligo must emphasize not only the medical and surgical aspects but also take into account of the psychological aspects. The present study is a comparative study of tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) in the management of vitiligo.

## MATERIALS & METHODS

The present prospective study includes 50 cases of clinically diagnosed vitiligo attending the outpatient department of DVL, ACSR, Government General Hospital, Nellore from 01/06/2021 to 30/05/2022 over a period of 12 months. In this study patient with focal, local, segmental, lip-tip, mucosal and acrofacial vitiligo were included. Generalized and universal vitiligo (vitiligo vulgaris) were excluded in this study. A detailed history including the age, sex, occupation and socioeconomic status, duration of diseases, diabetic status and personnel history were taken. Routine investigations like urine examinations and blood investigations were done. The patients were divided in two groups. One group was treated with tacrolimus ointment (0.1%) and the other group treated with clobetasol propionate cream (0.05%) for a period of 3 months. They were devoid of any other topical or systemic therapy for 2 months prior to inclusion. Patients were evaluated every month for a period of 3 months; repigmentation and adverse effects were recorded.

## RESULTS

In the present study 50 cases of clinically diagnosed vitiligo were divided into two groups. One group was treated with tacrolimus ointment and the other group was treated with clobetasol propionate cream for a period of 3 months. In the present study peak incidence of vitiligo seen in the age the group of 21-30 years, accounting for 40 % of cases and sex distribution shows slight preponderance of females. Male to female ratio being 1:1.38. In the present study focal vitiligo was more common than other clinical form of vitiligo with 36 %, segmental form (24 %), mucosal form (18%), lip tip form (14 %) and acrofacial vitiligo (8%). In this study percentage of response with tacrolimus ointment (0.1%) in the first month was 37.5 %, second month 50 %, third month 12.5 % respectively and with clobetasol propionate cream (0.05 %) was 47.36 % in the first month, 42.10 in the second month, 10.52 % in the third month [Table 1].

**Table 1: Monthly percentage response of tacrolimus ointment (0.1%) and Clobetasol propionate cream (0.05%)**

| Month | First month | Second month | Third Month |
|---|---|---|---|
| **Tacrolimus ointment (0.1%)** | 37.5% | 50% | 12.5% |
| **Clobetasol propionate cream (0.05%)** | 47.36% | 42.10% | 10.52% |

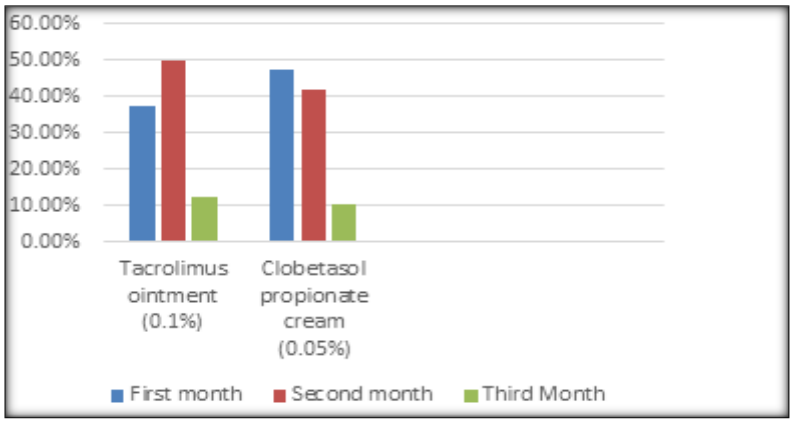



**Figure 1: Graphical Representation of % Monthly Response of Tacrolimus Ointment and Clobetasol Propionate Cream**

In total percentage of patients responding to tacrolimus ointment (0.1 %) was 64 % and clobetasol propionate cream (0.05 %) was 76 %.

In the present study of tacrolimus ointment (0.1%) showed 1-25 % of repigmentation in 9 patients, 26-50 % in 4 patients, 51-75 % in 2 patients and only one patient showed > 75% of repigmentation, 4 patients did not show any repigmentation and 5 patients were lost for follow up. Likewise with clobetasol propionate cream (0.05%) 8 patients had 1-25 %, 6 patients had 26-50%, 3 patients had 51-75 % and only 2 patient showed >75 % of repigmentation. No response was seen in 4 patients and 2 patients were lost for follow up. Thus, it may be concluded that the repigmentation grades were almost the same for both the drugs [Table 2].

**Table 2: Comparative study of tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) on repigmentation**

| | **No. of patients** | **Repigmentation in %** |
|---|---|---|
| **Tacrolimus ointment (0.1%)** | 9 | 1-25% |
| | 4 | 26-50% |
| | 1 | >75% |
| | 4 | No repigmentation |
| | 5 | Lost for Follow up |
| **Clobetasol propionate cream (0.05%)** | 8 | 1-25% |
| | 6 | 26-50% |
| | 3 | 51-75% |
| | 2 | >75% |
| | 4 | No response |
| | 2 | Lost for Follow up |
| **Total** | 50 | |

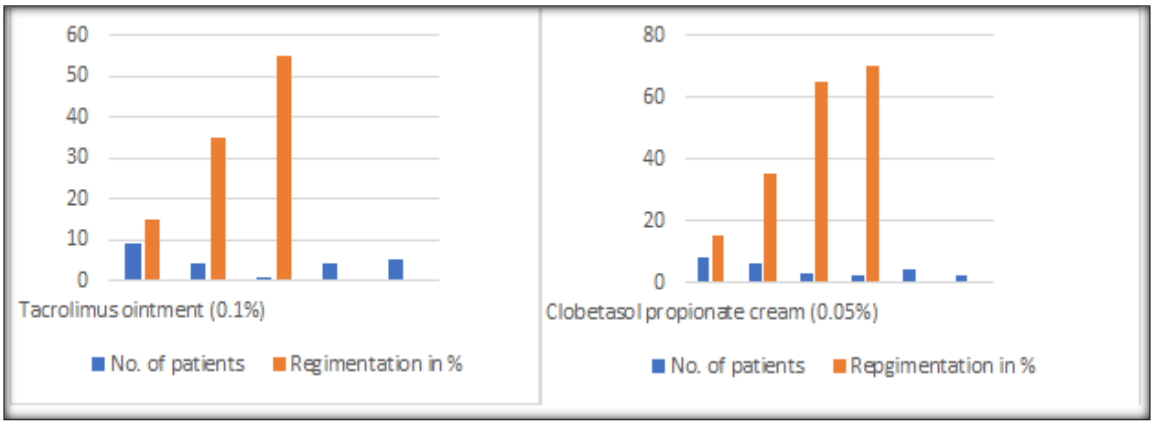
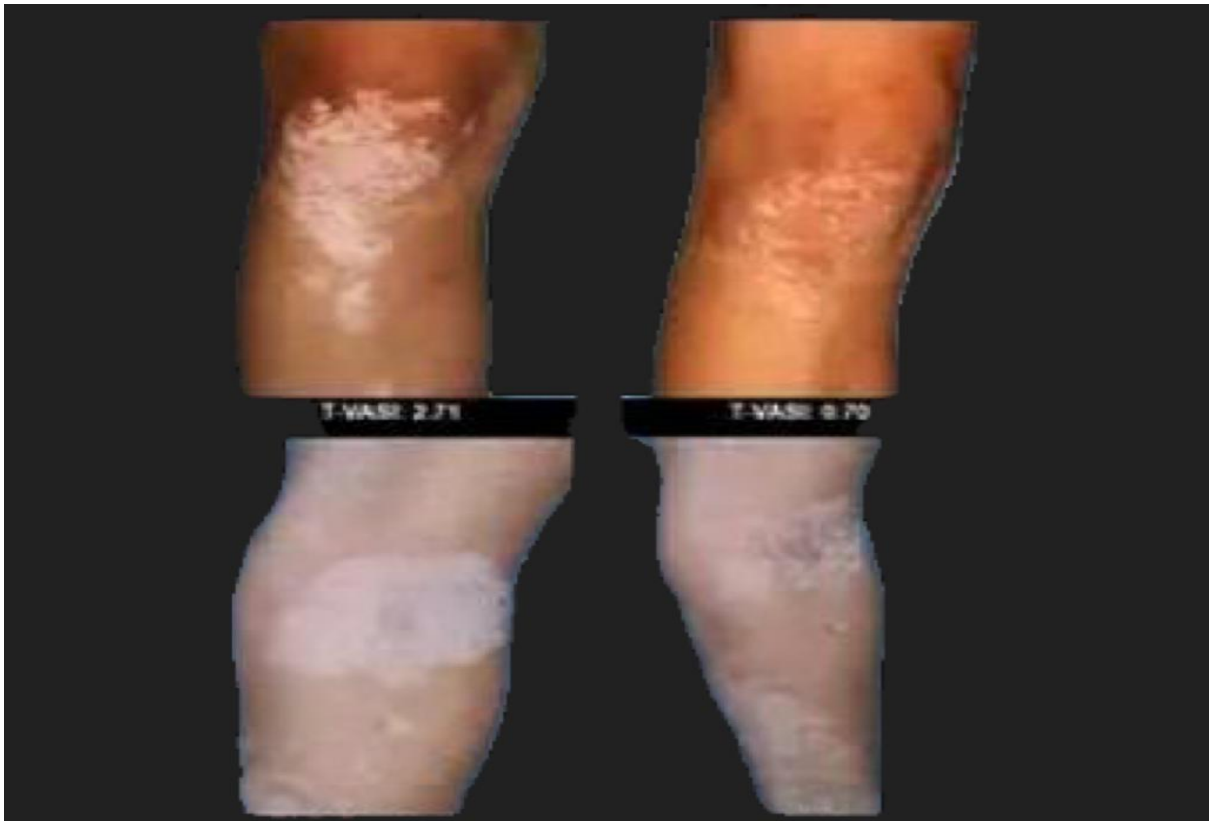



**Figure 2: Graphical representation of tacrolimus ointment (0.1%) and clobetasol propionate cream (0.05%) on repigpimentation.**

In the present study side effects were encountered in 7 patients with clobetasol propionate cream (0.05%) and one patient with tacrolimus ointment (0.1%), thus tacrolimus has a wider safety than clobetasol propionate.

In the present study tacrolimus ointment (0.1%) proved to be costlier for patients in contrast to clobetasol propionate cream (0.05%) which was cheaper. For this reason, the compliance was better with clobetasol propionate cream (0.05%) than tacrolimus ointment (0.1%)



Clinical Response with Clobetasol Propionate (0.05%) Cream and Tacrolimus (0.1%) Respectively

## DISCUSSION

Vitiligo has been mentioned in the literature of various ancient civilisations.Earlier reports on patchy diseases were found in Ebers Papyrus dating back to as far as 1500 B.C. The social effects of skin diseases may cause more hardship than physical limitations. The psychosocial aspects of vitiligo were evaluated in various studies by porter et al.[6,7]

In the present study 50 clinically diagnosed cases of vitiligo attending the outpatient department of DVL, ACSR, Government General Hospital, Nellore were studied for comparing the efficacy of tacrolimus ointment (0.1 %) and clobetasol propionate cream (0.05%) in the treatment of vitiligo. The patients were divided into two groups of 25 each to study the effect of tacrolimus ointment (0.1 %) and clobetasol propionate cream (0.05%). Clinical response was observed once in a month during the study period of 3 months.

The observations showed that the peak incidence of vitiligo was in the age group of 21-30 years (40%) with a slight female preponderance in the ratio of 1:1.38. in the study conducted by R.V. Korame et al., patients below age of 30 years constituted 85 % of the study group.[7] In another study by N. R. Mehta et al., males and females were similarly affected, the age of specific incidence was found to be maximum in the age group of 6-15 years with 33 % of cases falling in this age group.

The most common clinical form of vitiligo was focal vitiligo (36 %) and the least common was acrofacial vitiligo (8%). The other clinical form of vitiligo with descending order were segmental (24 %); mucosal (18 %) and lip tip (14 %). Generalized and universal vitiligo were excluded from this study because of the risk of systematic absorption of the medication and the financial inputs associated with the treatment. In this study, percentage of response with tacrolimus ointment (0.1%) in the first month was 37.5 %, second month 50%, third month 12.5 %, respectively and with clobetasol propionate cream (0.05%) was 47.36 % in the first month, 42.10 % in the second month, 10.52 % in the third month respectively.

The clinical response in a period of 3 month was almost equal for both tacrolimus ointment (64 %) and clobetasol propionate cream (76 %).

In the present study tacrolimus ointment (0.1 %) showed 1-25 % of repigmentation in 9 patients, 26.50 %, in 4 patients, 51-75 % in 2 patients and only one patient showed >75 % of repigmentation, 4 patients did not show any repigmentation and 5 patients were lost for follow up. Likewise, with clobetasol propionate cream (0.05%), 8 patients had 1-25 % of repigmentation, 6 patients had 26-50 %, 3 patients had 51.75 % and only 2 patients showed >75 % of repigmentation. No response was seen in 4 patients and 2 patients were lost for follow up. Thus, it may be concluded that the repigmentation grades were almost the same for both the drugs.[7,8]

In a randomized trial by Lepe V, et al., 18 (90 %) of 20 patients experienced some pigmentation. The percentage of repigmentation was (49.3%) for clobetasol propionate cream (0.05 %) and 41.3 % for tacrolimus ointment (0.1 %) Lesions in 3 patients using clobetasol propionate cream (0.05 %) presented with atrophy, and 2 lesions were incurred telangiectasia.[7-9]

Tacrolimus ointment (0.1%) caused burning sensation in 2 lesions.[8,9] In another study Sanjay singrodia et al., the safety and efficacy of topical tacrolimus (0.1%) showed moderate response in 5 %, poor response in 30 %. Neither topical tacrolimus nor topical clobetasol showed excellent response. It was concluded from their study that neither of the drugs alone was effective for the treatment of segmental vitiligo and topical tacrolimus (0.1%) caused lesser side effects than clobetasol propionate cream (0.05 %).[10-12] According to a 2009 study, roughly 83.3% of vitiligo patients who received tacrolimus ointment for four months experienced some repigmentation. Another 2008 study evaluated the effects of topical

immunomodulators with topical corticosteroids and found that patients treated with topical immunomodulators experienced repigmentation earlier. Another 2003 study compared topical tacrolimus ointment with clobetasol propionate cream. About 90% of the patients had some degree of repigmentation, and there was little difference between the two groups. According to the study's findings of Mumtaz H et al., topical tacrolimus may be chosen since it has less side effects because repigmentation rates with both medications were similar, but corticosteroids were associated with greater negative side effects. In individuals with vitiligo, study of Mumtaz H et al., contrasted topical 0.05% clobetasol propionate cream and 0.1% tacrolimus ointment. Repigmentation was assessed by keeping an eye on the lesions' size, colour, and whether or not they had undergone follicular repigmentation. Tacrolimus treatment resulted in partial repigmentation in 51.9% of patients, whereas clobetasol propionate cream treatment resulted in partial repigmentation in 58% of patients. The statistical differences between the effectiveness of these two drugs were not particularly noteworthy.[12,13]

In study of Ezgi Özkur MD et al., Tacrolimus 0.1% ointment and clobetasol propionate 0.05% ointment both considerably improved from baseline in a head-to-head analysis with 32 patients, although tacrolimus was noticeably superior to clobetasol (p 0.001).

Tacrolimus has a satisfactory safety profile and had undergone an excessive number of studies. Simon et al. found that 10 atopic dermatitis patients receiving topical tacrolimus therapy had lower lymphocyte counts in peripheral blood. In the trial, neither group's mean peripheral blood lymphocyte count decreased following treatment.[15,16] The majority of TCI side effects that have been documented in the literature are itching or burning sensations. There was no statistically significant difference between the groups, despite the fact that more patients in the tacrolimus group experienced erythema and pruritus. It's interesting to note that more patients in the clobetasol group complained of burning and pain. However, only the clobetasol group reported striae, telangiectasia, and local infections. Small sample size, retrospective design, non-homogeneous distribution of particular LP types to treatment arms, and non-use of life quality indicators were limitations of Ezgi Özkur MD et al. study.[16,17]

In our present study the clinical efficacy was almost similar with tacrolimus ointment (0.1%) clobetasol propionate cream (0.05%). Side effects like atrophy were observed in 7 patients treated with clobetasol propionate cream (0.05%), and burning sensation was observed in one patient treated with tacrolimus ointment (0.1%). Thus, tacrolimus is a safer drug with fewer side effects than clobetasol propionate cream (0.05%) and can be used safely for prolonged periods even in the sensitive areas of skin.

Tacrolimus ointment (0.1%) is costlier than clobetasol propionate cream (0.05%). Since tacrolimus is costly the dropouts with tacrolimus were 20% (5 cases) and dropouts with clobetasol propionate cream were only 8% (2 cases).

## CONCLUSION

In the present study, clinical efficacy of tacrolimus ointment (0.1%) was almost equal to clobetasol propionate cream (0.05%) and tacrolimus ointment 0.1% had a fewer side effects than clobetasol propionate cream (0.05%) but the compliance was found to be better with clobetasol propionate cream (0.05%) due to its cost effectiveness.

## REFERENCES

1. Hann, S. K., & Nordlund, J. J. (2000). Vitiligo: A monograph on the basic and clinical science. In Vitiligo: A monograph on the basic and clinical science (pp. xiv-306).
2. Nair, B. K. Vitiligo- A retrospect. International Journal of Dermatology, 1978,17, 755-7.Halder, R. M., Grimes, P. E., Cowan, C. A., Enterline, J. A., Chakrabarti, S. G., &

Kenney Jr, J. A. (1987). Childhood vitiligo. Journal of the American Academy of Dermatology, 16(5), 948-954.

3. Cassileth, B. R., Lusk, E. J., & Tenaglia, A. N. (1982). A psychological comparison of patients with malignant melanoma and other dermatologic disorders. Journal of the American Academy of Dermatology, 7(6), 742-746.
4. Koranne R V, Sachdeva K G (1988) vitiligo, Int. J. Dermatol 27: 676-681.
5. Mehta, N. R., Shah, K. C., Theodore, C., Vyas, V. P., & Patel, A. B. (1973). Epidemiological study of vitiligo in Surat area, South Gujarat. The Indian journal of medical research, 61(1), 145-154.
6. Lepe, V., Moncada, B., Castanedo-Cazares, J. P., Torres-Alvarez, M. B., Ortiz, C. A., & Torres-Rubalcava, A. B. (2003). A double-blind randomized trial of 0.1% tacrolimus vs 0.05% clobetasol for the treatment of childhood vitiligo. Archives of dermatology, 139(5), 581-585.
7. Xu, A. E., Zhang, D. M., Wei, X. D., Huang, B., & Lu, L. J. (2009). Efficacy and safety of tarcrolimus cream 0.1% in the treatment of vitiligo. International journal of dermatology, 48(1), 86-90.
8. Kwinter, J., Pelletier, J., Khambalia, A., & Pope, E. (2007). High-potency steroid use in children with vitiligo: a retrospective study. Journal of the American Academy of Dermatology, 56(2), 236-241.
9. Al- Mutairi, N., & El- Khalawany, M. (2010). Clinicopathological characteristics of lichen planus pigmentosus and its response to tacrolimus ointment: an open label, non-randomized, prospective study. Journal of the European Academy of Dermatology and Venereology, 24(5), 535-540.
10. Radfar, L., Wild, R. C., & Suresh, L. (2008). A comparative treatment study of topical tacrolimus and clobetasol in oral lichen planus. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology, 105(2), 187-193.
11. Ribero, S., Stieger, M., Quaglino, P., Hongang, T., Bornstein, M. M., Naldi, L., & Borradori, L. (2015). Efficacy of topical tacrolimus for oral lichen planus: real- life experience in a retrospective cohort of patients with a review of the literature. Journal of the European Academy of Dermatology and Venereology, 29(6), 1107-1113.
12. Özkur, E., Aksu, E., Gürel, M., & Savaş, S. (2019). Comparison of topical clobetasol propionate 0.05% and topical tacrolimus 0.1% in the treatment of cutaneous lichen planus. Advances in Dermatology and Allergology/Postępy Dermatologii i Alergologii, 36(6), 722-726.
13. Mumtaz, H., Anis, S., Akhtar, A., Rubab, M., Zafar, A., Niazi, N., ... & Fatima, T. (2020). Efficacy of tacrolimus versus clobetasol in the treatment of vitiligo. Cureus, 12(12).
14. Nissi, R., Eriksen, H., Risteli, J., & Niemimaa, M. (2007). Pimecrolimus cream 1% in the treatment of lichen sclerosus. Gynecologic and obstetric investigation, 63(3), 151-154.
15. Pisani, C., Mallarini, M., & Bilenchi, R. (2018). Genital hypertrophicus lichen planus successfully treated with topical pimecrolimus. Giornale Italiano di Dermatologia e Venereologia: Organo Ufficiale, Societa Italiana di Dermatologia e Sifilografia, 153(2), 296-298.
16. Simon, D., Vassina, E., Yousefi, S., Braathen, L. R., & Simon, H. U. (2005). Inflammatory cell numbers and cytokine expression in atopic dermatitis after topical pimecrolimus treatment. Allergy, 60(7), 944-951.
17. Simon, D., Vassina, E., Yousefi, S., Braathen, L. R., & Simon, H. U. (2005). Inflammatory cell numbers and cytokine expression in atopic dermatitis after topical pimecrolimus treatment. Allergy, 60(7), 944-951.