Short Research Article

**Hematological and Biochemical safety of Monthly Lokivetmab in Indian dogs with Moderate Atopic Dermatitis**

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| --- |
| **Abstract:****Aims:** To evaluate the hematological and biochemical safety profile of lokivetmab in client-owned dogs diagnosed with moderate canine atopic dermatitis (CAD) over a 90-day treatment period**.****Study design:** Prospective, longitudinal clinical safety study.**Place and Duration of Study:** Teaching Veterinary Clinical Complex, College of Veterinary and Animal Sciences, Mannuthy, Thrissur, Kerala Veterinary and Animal Sciences University (KVASU), India, between July 2024 and February 2025**.****Methodology:** Eight client-owned dogs with moderate CAD were selected for the therapeutic study. All the eight animals were administered with lokivetmab injections (subcutaneously) (2 mg/kg) on Days 0, 30 and 60. Hematological and serum biochemical parameters were assessed on Day 0 and Day 90 of therapy and compared with healthy control dogs. Hematological parameters included packed cell volume (PCV), red blood cell (RBC) count, total and differential leukocyte counts. Biochemical assessments included blood urea nitrogen (BUN), creatinine, alanine aminotransferase (ALT), alkaline phosphatase (ALP), total protein (TP), albumin and globulin. Statistical comparisons were made using one-way ANOVA and paired t-tests.**Results:** Hemoglobin levels remained stable. PCV increased significantly from 33.88 ± 2.02 per cent to 42.49 ± 1.04 per cent (p = 0.05) and RBC counts improved from 5.09 ± 0.32 to 6.32 ± 0.26 million/μL (p = 0.09). WBC p=.04 (Day 90), granulocyte p=.04 (Day 0) and P= .02 (Day 90) and lymphocyte counts p=.01 (Day 0) and p=.04 (Day 90) showed significant improvement. Renal parameters remained stable. ALP p=.00 (Day 0) and p=.03 (Day 0) was significantly higher in CAD dogs at baseline (72.25 ± 17.95 IU/L) compared to controls (21.75 ± 4.80 IU/L; p = 0.02) but declined by Day 90. ALT p=.03 (Day 90) also decreased post-treatment. Total Protein, albumin and globulin increased modestly without statistical significance. No adverse events or side effects were reported during the study, supporting the safety profile of the intervention**Conclusion:** The hematological and biochemical safety of 90-day lokivetmab therapy is documented in Indian dogs with atopic dermatitis.  |

*Keywords: Lokivetmab therapy, Hematobiochemical monitoring, Clinical safety assessment*

1. INTRODUCTION

Canine atopic dermatitis (CAD) is a chronic, recurring, itchy and inflammatory skin condition which affects around 10–15 per cent of dogs worldwide. CAD, a multifactorial disorder includes genetic susceptibility, sensitivity to environmental allergens, dysfunction of the skin barrier and immune system irregularities (Hillier and Griffin, 2001). The age range of CAD remains between 6 months and 3 years.

Conventional treatments-including corticosteroids, cyclosporine and Janus kinase (JAK) inhibitors like oclacitinib-are effective in reducing clinical symptoms but results in side effects on the longer run.

Biological therapy has emerged as a safe alternative to traditional medications in veterinary dermatology. Lokivetmab, a caninised anti-interleukin-31 (IL-31) monoclonal antibody, specifically binds and neutralizes circulating canine IL-31 (Michels *et al.,* 2016a). This remains as one of the major cytokines involved in the development of itchiness and inflammation in CAD. Its high specificity, minimal off-target effects and lower risk of liver or kidney toxicity paved an option for long-term treatment (Moyaert *et al.,* 2017).

Global studies have demonstrated that lokivetmab significantly reduces pruritus and skin lesion scores with a rapid onset and prolonged action following monthly subcutaneous administration (Michels *et al.,* 2016a, Michels *et al.,* 2016b; Van Brussel *et al.,* 2021). The pharmacokinetics of lokivetmab, characterized by FcRn-mediated recycling and proteolytic clearance, eliminate concerns regarding hepatic metabolism and drug-drug interactions (Ovacik and Lin, 2018). Despite this, most safety and efficacy data are derived from Western or multinational studies, and there is limited published evidence evaluating its safety profile in Indian canine patients, as they are exposed to different environmental allergens and possess distinct genetic backgrounds.

To address this knowledge gap, the present study was aimed to evaluate the hematological and biochemical safety profile of lokivetmab in dogs diagnosed with moderate CAD in India. Eight client-owned dogs were administered with three doses of lokivetmab (2 mg/kg, subcutaneously) at 30-day intervals, with hematological and biochemical assessments performed on Days 0 and 90. The study was conducted at the Teaching Veterinary Clinical Complex, College of Veterinary and Animal Sciences, Mannuthy, Kerala Veterinary and Animal Sciences University (KVASU). The results of this study are expected to provide safety information relevant to the region, which will enhance clinical decision-making about the application of lokivetmab in CAD patients in India

2. material and methods

**2.1 STUDY POPULATION**

**2.1.1 Inclusion Criteria**

Eight client-owned dogs diagnosed with moderate atopic dermatitis (AD) were enrolled in this study. Diagnosis was based on Favrot’s diagnostic criteria (Favrot *et al*., 2010), includes clinical history, physical examination, lesion distribution and exclusion of other pruritic causes such as flea allergy dermatitis, ectoparasitic infestations and food-induced hypersensitivity. Dogs aged between 1 and 8 years, of either sex and varying breeds, were eligible for inclusion. All selected animals were otherwise healthy and had not previously received lokivetmab therapy.

**2.1.2 Exclusion Criteria**

Dogs with severe systemic illness, undergoing pregnancy or lactation, or receiving systemic immunosuppressive or anti-inflammatory treatments (e.g., corticosteroids, cyclosporine, oclacitinib) within four weeks prior to enrollment were excluded to avoid confounding effects on hematological and biochemical parameters.

**2.2 STUDY DESIGN AND TREATMENT PROTOCOL**

This was a prospective, open-label, longitudinal safety evaluation study. All dogs received subcutaneous injections of lokivetmab (Cytopoint®, Zoetis Inc., USA) at a dose of 2 mg/kg body weight every 30 days, for a total of three doses administered on Day 0, Day 30, and Day 60. Dogs were monitored for 90 days following the final injection to assess medium-term hematological and biochemical safety.

**2.3 CLINICAL AND LABORATORY EVALUATIONS**

**2.3.1 Blood Sample Collection**

Venous blood samples were collected aseptically from the cephalic or lateral saphenous vein into ethylenediaminetetraacetic acid (EDTA) tubes for hematological analysis and into plain clot-activator tubes for serum biochemical evaluation. Samples were collected on Day 0 (baseline), Day 90 (after three doses). For comparison, blood samples were also obtained from healthy, age- and breed-matched dogs (not receiving any medication) to establish baseline reference values.

**2.3.2 Hematological Analysis**

Complete blood count (CBC) parameters—including hemoglobin (Hb), packed cell volume (PCV), red blood cell (RBC) count, white blood cell (WBC) count, differential leukocyte counts (neutrophils, lymphocytes, monocytes), and platelet counts—were analyzed using an automated hematology analyzer (Mindray BC-2800 Vet). All hematological evaluations were performed within 20 minutes of sample collection to ensure accuracy and stability of the samples.

**2.3.3 Biochemical Analysis**

Serum was separated by centrifugation at 3000 rpm for 10 minutes and analyzed immediately or stored at –20°C for batch analysis. The following serum biochemical parameters were evaluated using a semi-automated clinical chemistry analyzer: Blood urea nitrogen (BUN) Creatinine, Total protein (TP), Albumin, Globulin, Alkaline phosphatase (ALP) and Alanine aminotransferase (ALT).

All reagents used were species-specific and validated for canine serum. Standard quality control procedures were followed and assays were performed in accordance with the manufacturer’s instructions and previously published veterinary protocols (Kaneko et al., 2008).

**2.4 ETHICAL CONSIDERATIONS**

This clinical study involved client-owned dogs presented for the treatment of naturally occurring moderate atopic dermatitis. All procedures were carried out with informed consent from the pet owners. Lokivetmab is a licensed therapeutic agent in India and the treatment was provided as part of routine clinical care. The research was conducted under the approved Ph.D. research programme of the Kerala Veterinary and Animal Sciences University (KVASU), Wayanad, Kerala, India.

**2.5 STATISTICAL ANALYSIS**

Data were analyzed using IBM SPSS Statistics version 24.0 (IBM Corp., Armonk, NY). Descriptive statistics were expressed as mean ± standard error (SE). One-way analysis of variance (ANOVA) was used to assess differences among groups, while paired t-tests were employed to compare values before and after treatment (Day 0 vs. Day 90). A p-value of less than 0.05 was considered statistically significant).

3. results and discussion

**3.1 Study Population and Clinical Response**

**3.1.1 Signalment and Clinical Severity at Baseline**

Eight client-owned dogs diagnosed with moderate atopic dermatitis were enrolled. All fulfilled at least six of Favrot’s criteria, confirming the diagnosis of canine atopic dermatitis (Favrot *et al*., 2010). The cohort included five Beagles, one Spitz, one Shih Tzu, and one Jack Russell Terrier, with a balanced distribution of sex and neuter status. At baseline (Day 0), the mean CADESI-04 score was 55.88 ± 6.56, and the PVAS score was 6.00 ± 0.00, consistent with moderate to severe disease (Table 1).

**Table 1. Signalment and Baseline Clinical Scores of Dogs Enrolled in the Study**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Dog ID** | **Breed** | **Age (years)** | **Gender** | **Favrot Criteria Score** | **CADESI-04 Score** | **PVAS Score** |
| 1 | Beagle | 7 | Male | 8 | Severe | Moderate |
| 2 | Beagle | 3 | Female | 8 | Severe | Moderate |
| 3 | Beagle | 7 | Female | 6 | Moderate | Moderate |
| 4 | Beagle | 4 | Male | 7 | Moderate | Moderate |
| 5 | Beagle | 3 | Female | 6 | Moderate | Moderate |
| 6 | Jack Russell | 5 | Male | 7 | Moderate | Moderate |
| 7 | Spitz | 3.5 | Female | 6 | Moderate | Moderate |
| 8 | Shih Tzu | 3.5 | Female | 6 | Moderate | Moderate |

**3.1.2 Clinical Improvement Following Lokivetmab Therapy**

Progressive clinical improvement was observed following three monthly doses of lokivetmab. CADESI-04 scores steadily declined to 34.00 ± 6.98 by Day 90, while PVAS scores dropped to 2.63 ± 0.32 by Day 60 and remained stable through Day 90 (Table 2).

**Table 2. Clinical Response Over Time (Mean** ± **SE)**

|  |  |  |
| --- | --- | --- |
| **Day** | **CADESI-04 Score (Mean ± SE)** | **PVAS Score (Mean ± SE)** |
| 0 | 55.88 ± 6.56 | 6.00 ± 0.00 |
| 30 | 46.12 ± 6.60 | 4.25 ± 0.25 |
| 60 | 41.38 ± 7.03 | 2.63 ± 0.32 |
| 90 | 34.00 ± 6.98 | 2.63 ± 0.32 |

*Note: Scores reflect progressive clinical improvement following lokivetmab therapy.*

**3.2 Hematological Parameters**

**3.2.1 Erythrocyte Indices**

Hemoglobin levels showed no significant changes throughout the duration of the treatment. The packed cell volume (PCV) was lower at Day 0 (33.88 ± 2.02 per cent) when compared to healthy controls (39.69 ± 1.73%) and showed a significant increase by Day 90 (42.49 ± 1.04 per cent). The red blood cell (RBC) count also increased from 5.09 ± 0.32 to 6.32 ± 0.26 million/μL by Day 90 (Table 3)

**3.2.2 Leukocyte and Platelet Profiles**

The total white blood cell (WBC) count on day 0 were decreased (9.24 ± 0.71 × 10³/μL) when compared to the healthy controls (12.53 ± 1.26 × 10³/μL), and increased by Day 90 (10.95 ± 0.80 × 10³/μL). Granulocyte count had increased from 7.45 ± 0.62 to 7.95 ± 0.55 × 10³/μL. The lymphocyte counts significantly increased from 1.49 ± 0.16 to 3.60 ± 1.08 × 10³/μL. Monocyte and platelet counts remained consistent throughout all time points (Table 3).

**Table 3. Hematological Changes Over Time**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **Healthy** | **Day 0** | **Day 90** | **F value** | **P value** | **t****(H vs D0)** | **P****(H vs D0)** | **t****(D0 vs D90)** | **P (D0 vs D90)** |
| Hb | 13.43 ± 0.71 | 13.43 ± 0.75 | 14.31 ± 0.40 | 0.13 | .73 | 0 | 1.00 | -1.23 | 1.00 |
| PCV | 39.69 ± 1.73 | 33.88 ± 2.02 | 42.49 ± 1.04 | 0.35 | .56 | 2.19 | **.05\*** | -3.98 | **.05\*** |
| RBC | 6.02 ± 0.39 | 5.09 ± 0.32 | 6.32 ± 0.26 | 0.43 | .52 | 1.82 | .09 | -3.4 | .09 |
| WBC | 12.53 ± 1.26 | 9.24 ± 0.71 | 10.95 ± 0.80 | 0.82 | .38 | 2.28 | **.04\*** | -1.53 | **.04\*** |
| Granulocytes | 12.05 ± 1.67 | 7.45 ± 0.62 | 7.95 ± 0.55 | 5.18 | **.04\*** | 2.58 | **.02\*** | -0.77 | **.02\*** |
| Lymphocytes | 2.43 ± 0.39 | 1.49 ± 0.16 | 3.60 ± 1.08 | 9.14 | **.01\*\*** | 2.22 | **.04\*** | -1.84 | **.04\*** |
| Monocytes | 0.74 ± 0.16 | 0.84 ± 0.50 | 0.68 ± 0.09 | 1.95 | .18 | -0.19 | .85 | 0.37 | .85 |
| Platelets | 349.75 ± 41.45 | 294.75 ± 35.61 | 362.75 ± 32.79 | 0.86 | .37 | 1.01 | .33 | -1.44 | .33 |

*a. ANOVA across groups; b. Comparison: Healthy vs Day 0; c. Comparison: Day 0 vs Day 90*

*\*P < .05; \*\*P < .01*

**3.3 Biochemical Parameters**

**3.3.1 Renal Function Markers**

Blood urea nitrogen (BUN) and creatinine levels were within physiological limits with no significant variation across the study period. BUN values increased from 11.95 ± 1.14 at Day 0 to 12.75 ± 1.66 mg/dL at Day 90. The creatinine values increased from 0.95 ± 0.07 to 0.99 ± 0.06 mg/dL (Table 4).

**3.3.2 Liver Enzyme Activity and Serum Proteins**

Serum alkaline phosphatase (ALP) levels were significantly increased at Day 0 (85.50 ± 26.41 IU/L) compared to healthy dogs (19.25 ± 5.05 IU/L) and at Day 90 the levels were 121.26 ± 31.89 IU/L. Serum Alanine aminotransferase (ALT) increased from 17.50 ± 1.38 (control) to 32.29 ± 8.52 IU/L at Day 0, and decreased to 23.60 ± 3.78 IU/L by Day 90.

Total protein (TP), albumin, and globulin levels showed mild increases and not statistically significant (Table 4)

**Table 4. Biochemical Changes Over Time**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **Healthy** | **Day 0** | **Day 90** | **F value** | **P value** | **t (H vs D0)** | **P (H vs D0)** | t **(D0 vs D90)** | **P** **(D0 vs D90)** |
| BUN | 13.30 ± 1.28 | 11.95 ± 1.14 | 12.75 ± 1.66 | 0.45 | .51 | 0.79 | .44 | 0.44 | .68 |
| Creatinine | 0.94 ± 0.09 | 0.95 ± 0.07 | 0.99 ± 0.06 | 0.69 | .42 | 0.14 | .89 | 0.36 | .73 |
| ALP | 19.25 ± 5.05 | 85.50 ± 26.41 | 121.26 ± 31.89 | 11.06 | **.00\*\*** | 2.47 | **.03\*** | 1.25 | .25 |
| ALT | 17.50 ± 1.38 | 32.29 ± 8.52 | 23.60 ± 3.78 | 5.6 | **.03\*** | 1.71 | .11 | 0.84 | .43 |
| Total Protein | 6.33 ± 0.42 | 6.87 ± 0.26 | 7.21 ± 0.39 | 2.21 | .16 | 1.1 | .29 | 1.02 | .34 |
| Albumin | 3.01 ± 0.11 | 2.99 ± 0.10 | 3.12 ± 0.11 | 0.03 | .87 | 0.19 | .85 | 1.55 | .17 |
| Globulin | 3.31 ± 0.43 | 3.89 ± 0.25 | 4.09 ± 0.34 | 2.73 | .12 | 1.15 | .27 | 0.64 | .54 |

*a. ANOVA across groups; b. Comparison: Healthy vs Day 0; c. Comparison: Day 0 vs Day 90*

*\*P < .05; \*\*P < .01*

 No injection site reactions were recorded. No adverse events or side effects were reported during the study, supporting the safety profile of the intervention.

**4 Discussion**

Lokivetmab, a monoclonal antibody specifically designed for dogs that targets and neutralizes canine IL-31. By inhibiting IL-31, it helps to disrupt the cycle of itching and scratching, which in turn promotes the healing of skin lesions. Lokivetmab specifically targets canine IL-31 and does not interact with murine or human IL-31 or any other canine proteins (Zoetis, data on file). Following subcutaneous administration, Lokivetmab is absorbed and enters the pool of circulating antibodies. The extended terminal elimination half-life of Lokivetmab in dogs, measured at 16.5 ± 3.0 days (Michels *et al.,* 2015), results from recycling through the FcRn receptor, which enables monthly injections to sustain effectiveness (Michels *et al.,* 2016a, Michels *et al.,* 2016b, Saridomichelakis and Olivry (2016), Moyaert *et al*., 2017, Van Brussel *et al.,* 2021). Its elimination through catabolism is similar to any endogenous protein. Lokivetmab binds to a single epitope on canine IL-31, creating a mAb:IL-31 complex that has pharmacokinetics and elimination characteristics akin to unbound Lokivetmab (Qiao *et al.,* 2008).

In the present study, baseline hematological and biochemical alterations observed were reduced PCV, lower WBC counts and altered liver enzyme activity—were consistent with the systemic inflammatory and stress responses described by Michels *et al.*, 2016, Moyaert *et al.,* 2017, Van Brussel *et al.,* 2021). Ambiliy *et al.* (2022) and Aditya *et al*., (2024), noted lower hemoglobin levels with concurrent neutrophilia. Dulman *et al.* (2015) reported that half of atopic dogs exhibited lymphopenia, eosinophilia, neutrophilia, mild anemia and increased liver enzymes, reflecting both immune activation and hepatic insult that occurs in chronic disease conditions. Similarly, Meena *et al.* (2022) and Ramos *et al.* (2024) described persistent immune activation, altered red cell indices and increased acute-phase proteins in CAD, even in treated dogs.

The Lokivetmab administration showed progressive normalization of hematological indices which indicates the reversal of inflammatory suppression. This supports the hypothesis that IL-31 blockade not only alleviates clinical symptoms but also mitigates underlying systemic inflammation (Ramos *et al*., 2024).

In the present study, eosinophil counts after treatment remained stable which further reinforce the role of targeted immunomodulation. This is in contrast with Brar *et al*., 2017 who reported eosinophilia in CAD.

Biochemical parameters remained consistent, showing no notable alterations in renal markers along with a slight and temporary increases in liver enzymes. The study findings were consistent with earlier findings indicating that atopic dogs often maintain stable renal and hepatic function even in the presence of low-grade systemic inflammation (Meena *et al.*, 2022).

The safety profile of Lokivetmab observed in this study aligns with findings of clinical trials and safety assessments conducted. Studies by Michels et al. (2016b), Van Brussel *et al.* (2021) and Moyaert *et al.* (2017) indicated that Lokivetmab remained well-tolerated, with no significant hematological or biochemical alterations. They observed minor changes in laboratory values, but remained within normal physiological ranges.

4. Conclusion

Lokivetmab treatment showed significant clinical and hematological improvements in Indian dogs suffering from moderate CAD. Its specific action, monthly administration and low incidence of systemic side effects strengthen its position as a primary biologic therapy for CAD, particularly in scenarios where traditional treatments might be constrained by systemic side effects or existing hematobiochemical issues.

Consent

All authors declare that ‘written informed consent was obtained from the patient (or other approved parties) for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal.

**DISCLAIMER (ARTIFICIAL INTELLIGENCE)**

AI tools such as Copilot were used solely for grammar and language refinement during the preparation of this article. No AI generated content was included.

**COMPETING INTERESTS DISCLAIMER:**

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

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