# Study of efficacy and safety of reconstituted, recombinant human interferon alpha 2b eyedrops without refrigeration as a therapy for immunoreduction and/or treatment of ocular surface squamous neoplasia

Dear Editor,

Ocular surface squamous neoplasia (OSSN) is common ocular surface malignancy ranging from dysplasia to invasive carcinoma. Interferon alpha 2b (INF alpha 2b) is a cytokine commonly used in treatment of OSSN.[1,2] We are using it in our institute since 2016.

While treating OSSN with Interferon alpha 2b what we noted that cold storage during its usage at home can be major limiting factor due to unavailability of refrigerator.

We realized that many of our patients had no refrigeration facility at home that is why were asked to store it in a neighborhood refrigerator, but on follow-up some of them revealed the use of interferon without refrigeration and still clinical response was noted.

We found 31 such patients during interrogation on follow-up during March 2017–May 2020 and reporting the same.

Treatment protocol included Interferon alpha 2b in a topical formulation of 1 million IU/mL 4 times a day, prepared by reconstitution of 1 mL of Intalfa eye drop (interferon alfa-2b 3 millionIU/mL) [Intas Pharamaceutical] with 2 mL of Lacrimos eye drop (carboxy methylcellulose 0.5% eyedrop) [Lupin Pharmaceutical] until at least 1 month beyond complete clinical resolution of the tumor. Three monthly follow-up afterwards, 26 (83.9%) tumors completely resolved [Figs. 1 and 2], which was comparable with Shields *et al*. study,[3] while four (12.9%) tumors showed only partial resolution and one (3.2%) tumor showed no response to treatment which were later managed by surgical excision. Median time to complete tumor resolution was 12 weeks. Recurrence was noted in one case (3.8%) after 6 weeks of complete resolution.

We compared results of our study with results of other similar studies in which refrigerated interferon alpha 2b is in terms of percentage of complete resolution, median time of resolution, and recurrence after treatment and adverse effects. We did not observe any significant difference between our study and other studies.[3,4]

Plausible reason for this observation is can be either stability of interferon at room temperature similar to body temperature or oxychlorocomplex of tear substitute used for reconstitution giving thermal stability.

Our study has the following limitations: (1) small sample size, (2) lack of comparison group, (3) and lack of long-term follow-up.

In conclusion, the use of recombinant human interferon alpha 2b eyedrops without refrigeration is efficacious and safe as a therapy for immunoreduction and/or treatment of OSSN.

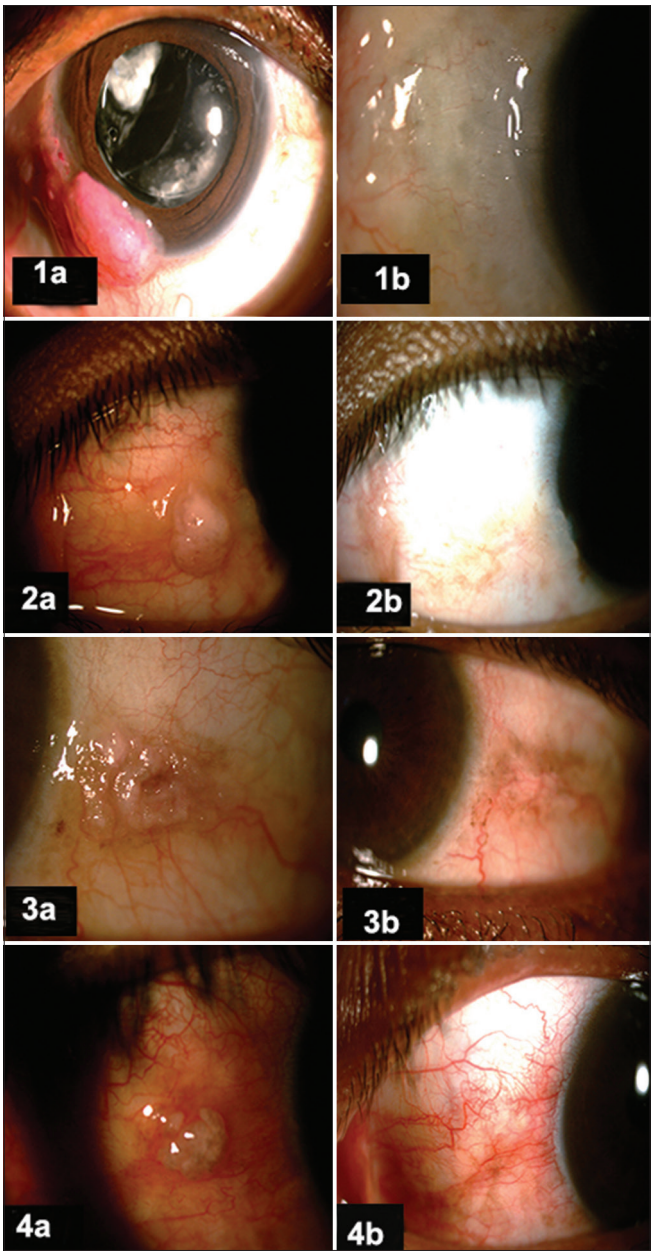


**Figure 1:** Slit-lamp photography images of patients 1–4. (a) before commencing treatment and (b) after complete resolution

In future, if stability of interferons in wide temperature range substantiated and confirmed by further studies, it can reduce the cost of the therapy by abating need for cold chain maintenance during transportation and storage and widen the spectra of use being independent of refrigeration need.

However, larger controlled trials for efficacy of nonrefrigerated interferon and studies on physical and chemical stability are required to support our findings. We believe that our findings should incite such studies in future.

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Nil.

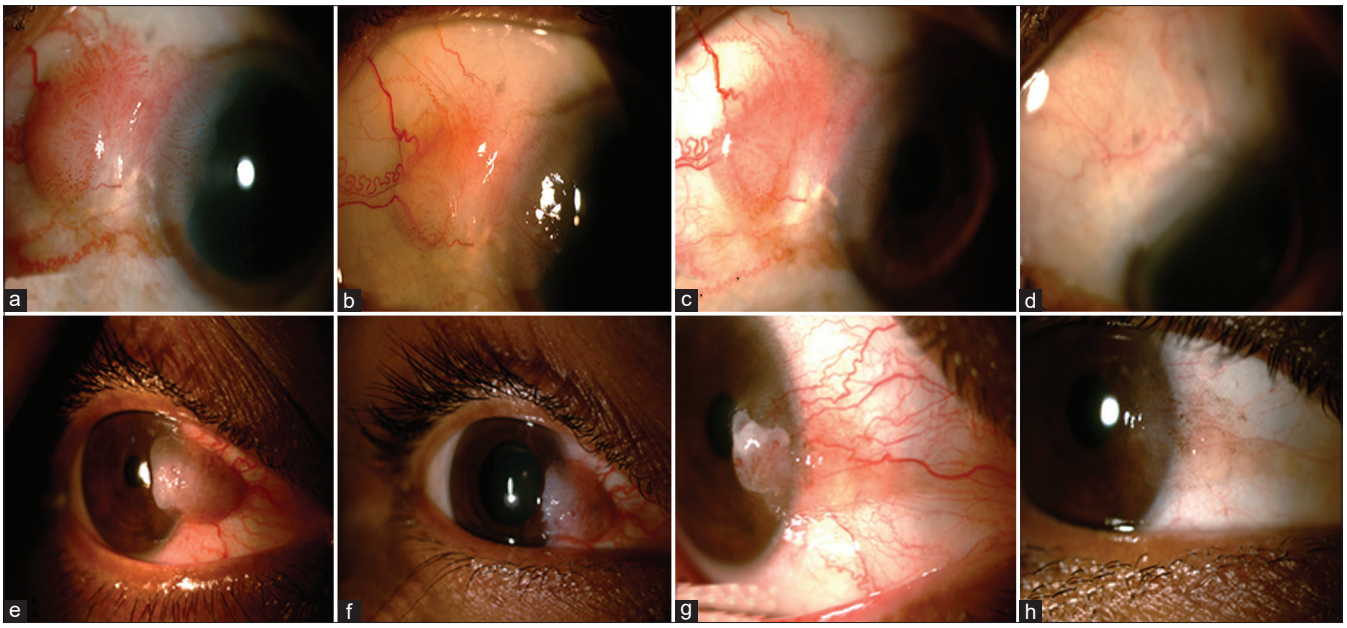


**Figure 2:** Serial slit-lamp images of two patients with OSSN on treatment showing resolution. (a) and (e) At presentation, (b) and (f) at 1 monthly follow-up, (c) and (g) at 2 monthly follow-up, and (d) and (h) after complete resolution

## Conflicts of interest

There are no conflicts of interest.

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