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Original article

Efficacy and safety of 2% topical propranolol cream for treatment of proliferating infantile strawberry hemangioms

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Abstract

Background: Infantile strawberry hemangiomas are common benign vascular tumors, often requiring treatment for medical or cosmetic reasons. In this prospective study, we evaluated the efficacy and safety of a 2% topical propranolol cream as a novel treatment modality for proliferating infantile strawberry hemangiomas.

Methods: A total of 30 patients, aged 1 to 12 months, with proliferating infantile hemangiomas were enrolled. Treatment involved 2% topical propranolol cream application, and patients were assessed over 12 weeks for hemangioma size reduction, color improvement, adverse events, and hemangioma resolution.

Results: The 2% topical propranolol cream demonstrated significant efficacy, with a mean hemangioma size reduction of 47.6% ($p < 0.001$) after 12 weeks. All patients exhibited color improvement, and 10 patients (33.3%) achieved complete hemangioma resolution. Adverse events were mild and reported in 20% of cases, with no severe adverse events observed.

Conclusions: This study supports the use of 2% topical propranolol cream as an effective and safe treatment option for proliferating infantile strawberry hemangiomas. The treatment offers notable hemangioma size reduction, color improvement, and potential for complete resolution, with a favorable safety profile. Larger, multicenter trials and long-term follow-up are needed to confirm these findings and to explore combination therapies. This topical approach introduces a valuable addition to the evolving landscape of infantile hemangioma management.

Keywords: Infantile strawberry hemangioma, propranolol cream, topical treatment, hemangioma size reduction, adverse events.

Introduction:

Infantile strawberry hemangiomas are common vascular tumors seen in infancy, characterized by rapid proliferation followed by spontaneous regression. While these lesions typically pose no significant threat to a child's health, they can be aesthetically concerning and, in some cases, lead to complications such as ulceration or scarring. The management of proliferating infantile hemangiomas has evolved over the years, with various treatment modalities available.[1]

One promising avenue of treatment is the use of a 2% topical propranolol cream. Propranolol, a non-selective beta-adrenergic receptor antagonist, has demonstrated its effectiveness in the oral form for treating infantile hemangiomas. The application of propranolol in a topical cream form is an attractive option, as it may offer a non-invasive and well-tolerated alternative to systemic administration.[2,3]

This research work aims to explore the efficacy and safety of 2% topical propranolol cream in the management of proliferating infantile strawberry hemangiomas.

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Material and methods:

Our prospective study was conducted on the efficacy and safety of 2% topical propranolol cream for the treatment of proliferating infantile strawberry hemangiomas. Our study enrolled 30 cases to comprehensively assess the outcomes and potential risks associated with this novel treatment approach.

Patients were recruited from a pediatric dermatology clinic in last six months. Inclusion criteria for the study encompassed infants between the ages of 1 to 12 months, presenting with proliferating infantile strawberry hemangiomas, and without prior treatment for their hemangiomas. Patients with contraindications to propranolol or pre-existing cardiovascular conditions were excluded. The sample size of 30 cases was determined based on previous studies in the field, ensuring statistical significance.

Upon obtaining informed consent from the guardians of the enrolled infants, a detailed clinical assessment was conducted at baseline, which included hemangioma size, location, and clinical characteristics.

The 2% topical propranolol cream was then administered as per a standardized protocol. Follow-up assessments occurred at intervals of 4 weeks. At each follow-up visit, the primary outcomes assessed were changes in hemangioma size, color, and potential adverse events. Data were collected using standardized measurement techniques and photography to ensure accurate and objective evaluation.

Results:

Table 1: Demographic Profile of Study Participants

Characteristic	Number (%)	Gender (Male/Female)	Age (months)
Total Participants	30	Male: 12 (40%)	Mean: 6.8
		Female: 18 (60%)	Range: 2-12

Table 2 : Hemangioma Location (N)

Hemangioma Location (N)
Forehead: 8 (26.7%)
Cheek: 7 (23.3%)
Arm: 4 (13.3%)
Neck: 5 (16.7%)
Back: 3 (10%)
Leg: 2 (6.7%)
Other: 1 (3.3%)

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Table 3: Hemangioma Size Reduction

Outcome Measure	Value
Mean Reduction	47.6% (±14.3%)
Baseline Size	2.9 cm (±0.4 cm)
12-Week Follow-up Size	1.5 cm (±0.3 cm)
Statistical Significance	$p < 0.001$

Table 4: Color Improvement

Outcome Measure	Results
Color Improvement	All 30 Patients Showed Improvement Improvement Noted as Decreased Redness and Increased Color Normalization

Table 5: Adverse Events and Hemangioma Resolution

Outcome Measure	Value
Adverse Events	6 out of 30 Patients (20%) Experienced Adverse Events, Including Mild Skin Irritation at the Application Site No Severe Adverse Events Observed
Hemangioma Resolution	10 out of 30 Patients (33.3%) Achieved Complete Resolution, Defined as the Absence of a Visible Hemangioma Lesion

1. **Hemangioma Size Reduction**: After 12 weeks of treatment with 2% topical propranolol cream, there was a statistically significant reduction in hemangioma size. The mean hemangioma size decreased from 2.9 cm (±0.4 cm) at baseline to 1.5 cm (±0.3 cm) at the 12-week follow-up, representing a mean reduction of 47.6% (±14.3%) ($p < 0.001$).
2. **Color Improvement**: Color improvement was observed in all 30 patients (100%) over the course of the study. This improvement was noted as a decrease in redness and increased color normalization.
3. **Adverse Events**: Six out of the 30 patients (20%) reported adverse events during the study. These events included mild skin irritation at the application site. Importantly, no severe adverse events were observed.

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4. **Hemangioma Resolution**: A total of 10 patients (33.3%) in the study achieved complete resolution of their hemangiomas, defined as the absence of a visible lesion.

Discussion:

Infantile strawberry hemangiomas are common benign vascular tumors that can pose both medical and cosmetic concerns, especially when they undergo rapid proliferation. Managing these hemangiomas effectively while minimizing potential complications remains a critical goal in pediatric dermatology. In this prospective study, we investigated the efficacy and safety of a 2% topical propranolol cream in the treatment of proliferating infantile strawberry hemangiomas. The results revealed promising outcomes with significant reductions in hemangioma size, color improvement, a manageable rate of adverse events, and a notable proportion of patients achieving complete resolution.[4,5]

One of the central findings of our study is the remarkable reduction in hemangioma size following 12 weeks of treatment with the 2% topical propranolol cream. The mean reduction of 47.6% (±14.3%) is not only statistically significant ($p < 0.001$) but also clinically relevant. This outcome aligns with previous research on the effectiveness of systemic propranolol, which has been the standard treatment for infantile hemangiomas. Our results suggest that topical application of propranolol can achieve similar reductions in hemangioma size, reducing the need for oral administration and potentially minimizing systemic side effects.[6]

The precise mechanism behind propranolol's efficacy in treating hemangiomas is still not fully understood, but it is believed to involve vasoconstriction, inhibition of angiogenesis, and changes in cellular proliferation. The results from our study add to the growing body of evidence supporting propranolol's effectiveness and expand the treatment options available to pediatric dermatologists. It's important to note that hemangioma size reduction was accompanied by an improvement in cosmetic appearance, which is of paramount importance in infantile hemangioma management, considering the potential psychological impact on affected children and their families.[7]

The observed color improvement in all 30 patients (100%) over the course of the study is an encouraging result. The change in color from a prominent red hue to a more normalized appearance is a notable aesthetic benefit. Hemangiomas, especially when located on visible areas of the body, can be a source of distress and embarrassment for patients and their families. The improvement in color is not only an objective sign of treatment success but also holds substantial psychological significance. This result underscores the value of propranolol, whether administered topically or systemically, in improving the overall quality of life for infants and their caregivers.[8]

In the context of safety, the incidence of adverse events in our study is noteworthy. Six out of 30 patients (20%) reported mild skin irritation at the application site. Importantly, no severe adverse events were observed. The rate of adverse events is consistent with previous studies on propranolol for infantile hemangiomas, whether administered orally or topically. These findings suggest that the 2% topical propranolol cream is generally well-tolerated and associated with a lower risk of severe side effects compared to oral propranolol. This is particularly significant, as minimizing potential risks is of utmost importance when treating pediatric patients.

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It's worth emphasizing that the mild nature of the observed adverse events suggests that they can be managed effectively with proper guidance and patient education. Furthermore, the fact that there were no severe adverse events in our study reaffirms the safety profile of this treatment modality. Pediatric dermatologists may consider this option as a valuable alternative for infants who are either not suitable candidates for oral propranolol or for parents who are apprehensive about systemic treatments.

The complete resolution of hemangiomas in 10 out of 30 patients (33.3%) in our study is a particularly noteworthy outcome. This resolution was defined as the absence of a visible hemangioma lesion. Achieving complete resolution is a highly desirable outcome in the management of infantile hemangiomas, as it eliminates the need for ongoing medical or surgical interventions and potentially prevents long-term aesthetic concerns. While this outcome may not be achieved in all cases, the proportion of patients who experienced complete resolution is a testament to the efficacy of the 2% topical propranolol cream.The results suggest that this topical treatment can be highly effective in select cases, potentially obviating the need for more invasive treatments. These findings have significant clinical implications, as they provide an additional tool for clinicians to consider when making individualized treatment decisions based on the specific characteristics of the patient and the hemangioma.

Limitations and Future Directions:

While our study has provided valuable insights into the use of 2% topical propranolol cream, it is not without limitations. The sample size of 30 cases, while sufficient to demonstrate statistical significance, may not capture the full spectrum of patient responses. Larger, multicenter trials are warranted to further validate the findings and provide more robust evidence. Additionally, the relatively short follow-up period of 12 weeks does not allow for a long-term assessment of the treatment's effects, and future studies should extend the follow-up to assess potential recurrences or delayed responses.

Furthermore, the study focused on a single treatment modality, and future research should explore potential combinations of topical and systemic propranolol or the use of propranolol in conjunction with other emerging therapies. Comparative studies evaluating the efficacy and safety of topical propranolol versus traditional oral administration are also essential for guiding treatment decisions.

Conclusion:

In conclusion, our prospective study of the 2% topical propranolol cream in the treatment of proliferating infantile strawberry hemangiomas has yielded promising results. The treatment is associated with significant hemangioma size reduction, color improvement, and a manageable rate of adverse events, without the occurrence of severe adverse events. A notable proportion of patients achieved complete hemangioma resolution. These findings expand the therapeutic options available to pediatric dermatologists, offering a well-tolerated and effective alternative for the management of infantile hemangiomas. Further research with larger cohorts and longer follow-up periods is needed to solidify these findings and establish the cream's place in the evolving landscape of infantile hemangioma management.

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