International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

Original Research Article.

Comparative Evaluation of Efficacy of Oral Prednisolone with or without Propranolol in Treating Infantile Hemangioma Cases: A Clinical Institutional Based Study

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ABSTRACT

Background: Infantile hemangiomas (IH) are the most common tumors of childhood. Systemic corticosteroids (prednisolone) have been the mainstay of treatment for IH, for several decades. Hence; we planned the present study to assess and compare the efficacy of oral prednisolone and propranolol in regression of infantile hemangioma (IH).

Materials & Methods: The present study included assessment and comparison the efficacy of oral prednisolone and propranolol in regression of IH. A total of 30 patients were included in the present study. All the patients were randomly divided into three study groups as follows: Group 1: Patients who received oral prednisolone 5 mg/kg/day, Group 2: Patients who received oral propranolol 3 mg/kg/day, and Group 3: Patients who received oral prednisolone 5 mg/kg/day and propranolol 3 mg/kg/day simultaneously. We categorized cases as partial response in which there occurred a change in color and consistency. All the results were analyzed by SPSS software.

Results: We observed significant results while comparing the response rates of the subjects of the group 1. However; we didn't observe any significant result, while comparing the treatment response in subjects of group 2 and 3.

Conclusion: In managing patients with IH, oral prednisolone is a viable and time tested therapeutic option. However; when used either alone or in combination, prednisolone offers no other added benefits.

Key words: Infantile Hemangioma, Prednisolone, Propranolol.

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Article History:

Received: 26-01-2019, **Revised:** 23-02-2019, **Accepted:** 18-03-2019

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2019.5.2.059	

INTRODUCTION

Infantile hemangiomas (IH) are the most common tumors of childhood. IH are benign but possess potential for local tissue damage, ulceration, infection, bleeding, functional impact, and pain. The most common locations of IH are the head, neck, and trunk, but they can occur almost anywhere throughout the body, including the extremities, the spine, and visceral organs.[1-3]

Unlike other tumors, they have the unique ability to involute after proliferation, often leading primary care providers to assume they will resolve without intervention or consequence. Unfortunately, a subset of IHs rapidly develops complications, resulting in pain, functional impairment, or permanent disfigurement. As a result, the primary clinician has the task of determining which lesions require early consultation with a specialist.[4,5]

Systemic corticosteroids (prednisolone) have been the mainstay of treatment for IH, for several decades. The mechanism of action of steroids is not entirely clear, though it is postulated to have an inhibitory effect on the production of vascular endothelial growth factor A (VEGF-A) by stem cells in haemangiomas.[6,7]

Under the light of above mentioned data, we planned the present study to assess and compare the efficacy of oral prednisolone and propranolol in regression of infantile hemangioma (IH).

MATERIALS & METHODS

The present study was planned in the department of paediatric medicine of the medical institute and it included assessment and comparison the efficacy of oral prednisolone and propranolol in regression of IH.

Ethical approval was obtained from institutional ethical committee and written consent was obtained after explaining in detail the entire research protocol. In the present study, we included those cases in which HI was located in high risk location with measurement of more than five cm.

Exclusion Criteria

- Patients who didn't gave consent for the present study,
- Patients who didn't completed the follow-up of four months,

- Patients who have underwent any form of previous treatment for the same,
- Patients with underlying any form of metabolic disorder

A total of 30 patients were included in the present study. All the patients were randomly divided into three study groups as follows:

- **Group 1:** Patients who received oral prednisolone 5 mg/kg/day,
- **Group 2:** Patients who received oral propranolol 3 mg/kg/day, and
- **Group 3:** Patients who received oral prednisolone 5 mg/kg/day and propranolol 3 mg/kg/day simultaneously.

We obtained complete clinical and demographic records of all the patients. Standard photographs were used for making record file during follow-up time in all the patients. Evaluation of the patients was done at one month and four month time. We obtained response as the regression observed at the fourth month visit. In cases, in which, less than 50 percent regressions was observed, those cases were categorized as negative response. We categorized cases as partial response in which there occurred a change in color and consistency. All the results were analyzed by SPSS software. Chi- square test and student t test were used for assessment of level of significance.

Table 1: Distribution of subjects according age and pattern of lesion

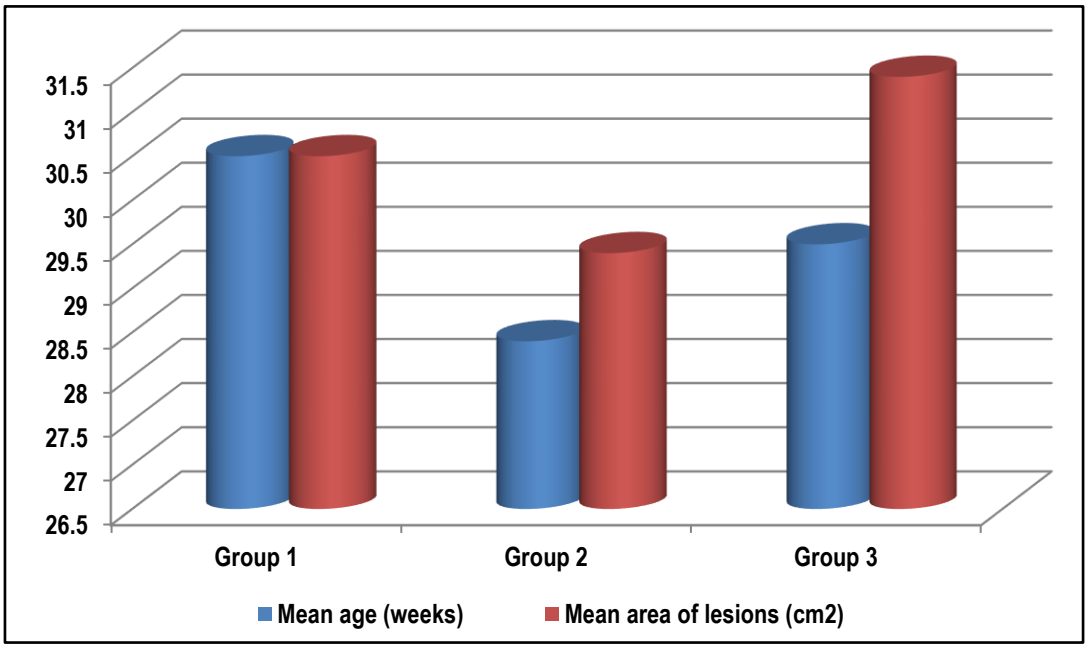
Group	Mean age (weeks)	Mean area of lesions (cm^2)
1	30.5	30.5
2	28.4	29.4
3	29.5	31.4

Table 2: Distribution of subjects according to response rates

Group	No response	Partial response	Good response	P- value
1	2	3	5	0.01*
2	5	3	2	0.08
3	2	5	3	0.10

*: Significant

Graph 1: Distribution of subjects according age and pattern of lesion



RESULTS

In the present study, we analyzed a total of 30 subjects with IH. All the subjects were divided into three study groups- group 1, 2 and 3. Mean age of the subjects of the group 1, group 2 and group 3 were 30.5, 28.5 and 29.5 weeks respectively. Mean area of the lesion of group 1, 2 and 3 were 30.5, 29.4 and 31.4 cm^2. We observed significant results while comparing the response rates of the subjects of the group 1. However; we didn't observe any significant result, while comparing the treatment response in subjects of group 2 and 3.

DISCUSSION

In the present study, we observed significant results while comparing the response rates of the subjects of the group 1. However; we didn't observe any significant result, while comparing the treatment response in subjects of group 2 and 3. Bertrand J et al compared the clinical effectiveness of oral propranolol with that of oral prednisone in the treatment of IH. Patients treated for IH with oral propranolol were retrospectively matched with patients treated with oral prednisone according to type, location, and size of the IH and age at start of treatment. Response to treatment was

evaluated by rating serial medical photographs taken 1, 2, and 6 months after initiation of treatment. Degree of clinical improvement in overall appearance was rated as follows: worse or stable (0), slight (<25%), moderate (25-50%), good (50-75%), or excellent (>75%). A second assessment was done using a 100-mm visual analog scale to rate improvement at 6 months. Pre and post-treatment imaging was available for several patients. Twelve pairs of infants with IH were analyzed. Propranolol appeared superior to oral prednisone in inducing more-rapid and greater clinical improvement in this study.[8]

Anjum MZ et al determined the outcome of combination of low dose oral Prednisolone with oral propranolol for the treatment of infantile hemangioma. All the patients were given oral prednisolone in a dose of 1mg/kg/day and propranolol in a dose of 0.5mg/kg/day twice a day and increased up to 1.5mg/kg/day BID within three days with close monitoring of heart rate, blood pressure and blood glucose as inpatient. Treatment compliance was checked during each visit along with outcome parameters i.e. response which was excellent, good, moderate slight improvement and no effect. Out of total 73 patients, 36.99% (n=27) were one year of age, 32.88% (n=24) were two years of age and 30.13% (n=22) were three years of age, mean± SD: 1.96±0.54 years, 53.42% (n=39) were male and 46.58% (n=34) were females, frequency of response of the treatment was recorded as 56.16% (n=41) had excellent, 23.29% (n=17) had good, 15.07% (n=11) had moderate response, 4.11% (n=3) had slight improvement and 1.37% (n=1) had no effect while frequency of acceptable outcome revealed as acceptable in 79.45% (n=58) while 20.55% (n=15) had not acceptable outcome The frequency of acceptable outcome of combination of low dose oral Prednisolone with oral propranolol for the treatment of infantile hemangioma is higher.[9] Rotter A et al demonstrated the use of serial ultrasonography as an adjunctive tool for assessment of IH treatment with propranolol. A retrospective study of 19 patients with IH treated with propranolol was conducted from January 2009 to March 2014. Data of individual IH volume at the beginning and at least 6 months after the onset of treatment and overall volume reduction by ultrasonographic measurement were obtained. They observed a statistically significant IH volume reduction of approximately 0.51 cm^3. This volume corresponds to an average reduction of 47% in the final volume compared with the initial volume. Ultrasonographic measurements contribute to demonstrate tumor regression and IH response to propranolol. Thus, ultrasonography is an important instrument to guide therapeutic strategies.[10]

Balma-Mena A et al assessed the clinical response to and predictors of propranolol use in the treatment of IH. Two independent assessors evaluated improvement by comparing serial digital photographs using a 100 mm visual analogue scale (VAS), where 5 mm change represented 10% change in the size or appearance of the IH. Propranolol was started at a mean age of 7.8 (SD 8.21) months and was used for 7.3 (SD 4.8) months before weaning. The mean percent improvement compared to baseline (as measured by the VAS) was 78% (SD 23%). Minor adverse events were noted in 32% of patients. The most significant predictor of regrowth after weaning was a IH > 5 cm in size (p = .017). Propranolol is effective in IH, but the side effects and the possibility of regrowth should be considered.[11]

CONCLUSION

From the above results, the authors conclude that in managing patients with IH, oral prednisolone is a viable and time tested therapeutic option. However; when used either alone or in combination, prednisolone offers no other added benefits. Therefore, further studies are recommended.

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Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Pawan Kumar, Virendra Yadav. Comparative Evaluation of Efficacy of Oral Prednisolone with or without Propranolol in Treating Infantile Hemangioma Cases: A Clinical Institutional Based Study. Int J Med Res Prof. 2019 Mar; 5(2): 261-63.
DOI:10.21276/ijmrp.2019.5.2.059