Original Research Paper

Volume - 13 | Issue - 10 | October - 2023 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

ENT

THERAPEUTIC EFFECTS OF INTRALESIONAL BLEOMYCIN SCLEROTHERAPY FOR VASCULAR MALFORMATIONS OF HEAD AND NECK: A SINGLE CENTRE EXPERIENCE FROM NORTH INDIA.

Dr. Durfishan Bashir	MS ENT, Govt. Medical College Srinagar.
Dr. Mohd Umar Shah	Assistant Professor, Govt. Medical College Srinagar.
Dr Irshad Ahmad	MS ENT , Govt. Medical College Srinagar.
Dr. Haris Bashir*	MS ENT , Govt Medical College Srinagar. *Corresponding Author

ABSTRACT **Background:** Percutaneous sclerotherapy has emerged as a minimally invasive treatment option for hemangiomas. The preset study was conducted to evaluate the response of Intralesional Bleomycin sclerotherapy for head and neck hemangiomas at a tertiary care center. **Methods:** The study was conducted at a tertiary care teaching hospital in the Kashmir valley, India, from December 2021 to February 2023. Patients with vascular malformations in the head and neck region were included using convenient sampling and provided with detailed information about the study's purpose. Intralesional bleomycin sclerotherapy was administered and the clinical response was monitored. Serial photography and measurements were used to document the response before, during and after completion of the treatment. **Results:** Our findings revealed significant improvement in the majority of cases, with approximately 45% exhibiting marked improvement in their condition. Complete resolution of the disease was observed in 29.82% of the cases. The adverse effect profile of the treatment was favourable. **Conclusion:** In our study, Intralesional bleomycin sclerotherapy demonstrated a high level of safety, minimal complications, and a substantial rate of lesion improvement. This treatment modality holds promise as an effective option for managing head and neck hemangiomas.

KEYWORDS : Intralesional bleomycin, haemangiomas, percutaneous sclerotherapy, patient-reported outcomes

INTRODUCTION

Vascular anomalies, which are disorders of the endothelium and surrounding cells may appear anywhere in the body; The estimated prevalence is about 4 to 5 %, and the anomalies are usually diagnosed during infancy or childhood about 14–65% of these anomalies occur in the head and neck region. [1,2] The most common problem associated with vascular anomalies on head and neck is psychological distress related to the disfigurement as well as functional defects because of the area involved. Vascular anomalies can lead to many complications like bleeding, infection, obstruction, pain, thrombosis, ulceration, and can affect the anatomical structures .These anomalies can sometimes cause general complications such as congestive heart failure, disseminated intravascular coagulation, pulmonary embolism, thrombocytopenia, and sepsis.[3]Available treatment modalities for vascular malformations are LASER, sclerotherapy, embolization, electrochemical therapy, alcoholic solution of Zein (Ethibloc), surgery or combination of these.[4-6] Surgical excision is the favoured modality of treatment for vascular malformations in head and neck region. But the vicinity of complex neurovascular structure of this region may sometimes be a great challenge for a head and neck surgeon when they envelop the vital structures. Moreover, it may get complicated by wound infection or bad scar. So, percutaneous sclerotherapy was developed as a less invasive modality for the treatment of these lesions using Bleomycin, ethibloc, OK 432, etc. for haemangioma or slow flow vascular malformations.[7-8] We chose percutaneous Bleomycin sclerotherapy because of its low cost, easy availability, effectiveness and safety.

MATERIAL AND METHODS

Study Setting and Design: The study was conducted between December 2021 and February 2023 in the Department of Otorhinolaryngology of a tertiary care teaching hospital in Kashmir valley, India. We employed a prospective study design and participants were followed up for 6 months when the outcome was assessed.

Study Participants: Participant recruitment was designed around clinic flow and patients with vascular malformations in the head and neck region were explained the purpose of the study and their informed consent sought. The participants underwent routine clinical and laboratory workup. The subjects were than explained treatment options available and explained in detail the procedure, success rate and possible complications from Intralesional bleomycin sclerotherapy. A standardized sheet recording patients' details included age, sex, weight, location of lesion, size, clinical history, special Investigations, bleomycin dose, clinical response, adverse effects, and Follow-up. The response was recorded by serial photography and measurement before, during, and after completion of the treatment.

Intralesional Bleomycin Sclerotherapy Administration: The procedure was performed in the operation theatre in a day care basis without anesthesia. The dose of the Bleomycin administered was 0.5mg/kg body weight with adjustment according to the size of lesion. The maximum limit for single dose was 15mg per session and for total dose 5 mg/kg. Single vial of aqueous Bleomycin (15 mg) was diluted in 5 ml of normal saline.

Outcome Assessment: The final outcome assessment was done at 6 months at which time the size, texture and colour of the lesion was recorded and graded using a four point Likert scale individually for all the three above mentioned parameters. The outcome was assessed by a independent health care provider and graded as

- Score 1: No response, that is no change in the size or continued to enlarge.
- Score 2: Mild improvement in case lesions decreased in size, but with less than 50% improvement from baseline
- Score 3: Marked improvement, that is, the lesions decreased in size more than 51%, but less than 100% with remarkable improvement In appearance.
- Score 4: Cured, that is, the lesions disappeared completely without recurrence

Statistical Analysis

Data was entered in Microsoft excel and analysed

RESULTS

A total of 57 patients were recruited for the study out of which 37 patients had haemangiomas and 20 patients had vascular malformations. All patients were given Intralesional bleomycin sclerotherapy. The maximum number of patients were females. majority of the participants were in age groups above 31 years with range from 3 to 46 years and mean age of 22.4 ± 8.4 years (Table 1). The outcome of the treatment with Intralesional bleomycin sclerotherapy showed improvement in majority of cases, with around 45 % showing marked improvement against the diseases. A total of 29.82% showed complete resolution of the disease (Table 2).

Table 1: Demographic Variables Of The Study Population

Variables		Number	%
Age group in years	≤ 20	6	10.53
	21-30	8	14.04
	31-40	12	21.05
	41-50	21	36.84
Gender	Male	23	40.35
	Female	34	59.65
Age (years) (Mean ± SD)	22.4 ± 8.4		

Table 2: Outcome Of The Treatment With Intralesional Bleomycin Sclerotherapy

Outcome	No	%
Complete resolution (Cured)	17	29.82
Marked improvement	26	45.61
Mild improvement	9	15.79
No cure	5	8.77
Total	57	100

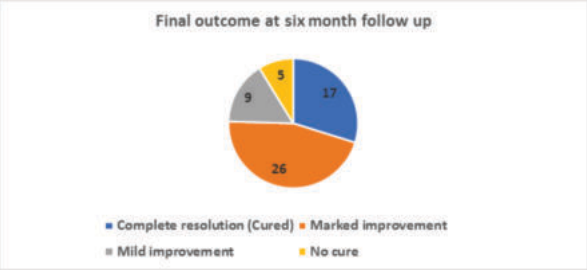

Figure 1: Outcome Among The Patients Treated

DISCUSSION

This Prospective study done between December 2021 and February 2023 was performed on a total of 57 patients who presented with vascular Anomalies, either haemangioma or vascular malformation of head and neck. They were seen in ENT and HNS Department of GMC Srinagar. There were 34 women and 23 men in our study who were treated with percutaneous intralesional bleomycin sclerotherapy. Percutaneous sclerotherapy is an injection of sclerosing agent directly into the lesion for venous or lymphatic malformation. Various such sclerosants have been used in the past for haemangioma and vascular malformation. One of them is Ethanol with the efficacy up to 95%. But it can lead to complications like nerve injury, skin necrosis, thrombophlebitis and cardiovascular collapse when it enters into the circulation. Other agents like OK432 (a low virulence strains if Streptococcus pyogenesis cultured with penicillin-G), alcoholic solution of Zein (Ethibloc) are also used as sclerosing agents. But complications, availability and cost factor limit their use in our settings. We used Injection Bleomycin as a sclerosant in our study which is a low cost and easily available agent. It is a mixture isolated from strains of Streptomyces verticillium and was discovered by Umezawa as antitumor agent in 1966, it acts through inhibition of DNA synthesis. [9,10] Later on, it was found to have sclerosing effect on endothelial cell during its use as in the treatment of malignant pleural effusion. It has shown good results as a sclerosing agent. [7, 13, 14] In our study also the results shown were favorable. The outcome assessment showed improvement in majority of cases, with a total of 29.82% showing complete resolution of the disease. Similar results have been found by other such studies. Conrad Pienaar et al found that there was a 50 to 75 percent reduction in size of the haemangiomas with the bleomycin local injection.[11] In a study done by Neeraj N Mathur et al they found that among 10 paediatric cases of haemangioma of whom 9 had such malformation in the cervical region and one in the parotid region the size of swelling decreased by 50% among 7 of them after percutaneous intralesional administration of bleomycin and there were no major deleterious side effects.[13] Very few minor complications were encountered in this study like fever and hyperpigmentation of skin which is consistent with other researches.[11-14] Since using Injection Bleomycin intralesionaly does not lead it to reach the circulation as opposed to patients treated systemically , the serious complication are extremely rare .

CONCLUSION

The use of Intralesional Bleomycin injection is simple, safe, effective and non-invasive modality of the treatment for head and neck haemangioma. With this modality of treatment the patients in our study suffered minimal complications and majority showed improvement in the lesion.

REFERENCES

1. Redkar RG, Chigicherla S, Joshi S, Bangar A, Tewari S. Efficacy of intralesional bleomycin as an alternative approach in the management of vascular anomalies. Saudi Surg J 2017;5:60-4.
2. Mulliken JB, Glowacki J. Hemangiomas and vascular malformations in infants and children: A classification based on endothelial characteristics. Plast Reconstr Surg 1982;69:412-22.
3. Bracken RB, Johnson DE, Rodriquez L, Samuels ML, Ayala A. Treatment of multiple superficial tumors of bladder with intravesical bleomycin. Urology 1977;9:161-3.
4. Hassan Y, Osman AK, Altyeb A. Noninvasive management of hemangioma and vascular malformation using intralesional bleomycin injection. Annals of plastic surgery. 2013 Jan 1;70(1):70-3.
5. Kullendorff CM. Efficacy of bleomycin treatment for symptomatic hemangiomas in children. Pediatric surgery international. 1997 Jul 1;12(7):526-8.
6. Legiehn GM, Heran MK. Venous malformations: classification, development, diagnosis, and interventional radiologic management. Radiol Clin N Am. 2008;46:545–97.
7. Berenguer B, Burrows PE, Zurakowski D, Mulliken JB. Sclerotherapy of craniofacial venous malformations: complications and results. PlastReconstr Surg.1999;104:1–11.
8. Umezawa H. Recent studies on biochemistry and action of bleomycin. Bleomycin, current status and new developments. NY: Academic. 1978;15-20.
9. Yura J, Hashimoto T, Takahashi L, et al. Bleomycin treatment for cystic hygroma in children. Nihon GekaHokan. 1977;46:607-14.
10. Sarihan H, Mocan H, Yildiz K, Abes M, Akyazici R. A new treatment with bleomycin for complicated cutaneous hemangioma in children. European journal of pediatric surgery. 1997 Jun;7(03):158-62.
11. Pienaar C, Graham R, Geldenhuys S, Hudson DA. Intralesional bleomycin for the treatment of hemangiomas. Plastic and reconstructive surgery. 2006 Jan 1;117(1):221-6.
12. Charabi B, Bretlau P, Bille M, Holmelund M. Cystic hygroma of the head and neck – A long-term follow-up of 44 cases. Acta Otolaryngol Suppl 2000;543:248-50.
13. Mathur NN, Rana I, Bothra R, Dhawan R, Kathuria G, Pradhan Bleomycin sclerotherapy in congenital lymphatic and vascular malformations of head and neck. Int J Pediatr Otorhinolaryngology 2005;69:75-80.
14. Muir T, Kirsten M, Fourie P, Dippenaar N, Ionescu GO. Intralesional bleomycin injection (IBI) treatment for hemangiomas and congenital vascular malformations. Pediatr Surg Int 2004;19:766-73.