African Vision and Eye Health
ISSN: (Online) 2410-1516, (Print) 2413-3183

Clinical and radiological outcomes of intralesional bleomycin for orbital venolymphatic malformations: A retrospective case series

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Dates:
Received: 26 Dec. 2025
Accepted: 09 Aug. 2026
Published: 25 Sept. 2026

How to cite this article:
Mahmoud H, Awny I, Sinjab AAA, Rashdan HT. Clinical and radiological outcomes of intralesional bleomycin for orbital venolymphatic malformations: A retrospective case series. Afr Vision Eye Health. 2026;85(1), a1159. https://doi.org/10.4102/aveh.v85i1.1159

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Background: Intralesional sclerotherapy with bleomycin could be an alternative to surgical excision in the management of orbital venolymphatic malformation (VLM); it could be the sole and primary modality of treatment. Bleomycin represents one of the anti-neoplastic agents that induce significant scarring and fibrosis in the case of local injection into the lesion. It is a sclerosing agent, so it helps in the regression of the lesion.

Aim: The study aims to assess how safe and efficient bleomycin sclerotherapy is when used for treating Orbital and periorbital VLM.

Setting: A retrospective case series with Orbital VLM.

Methods: A retrospective case series of orbital VLM. The cases were assessed ophthalmologically, received intralesional bleomycin and were followed for 3 years. The clinical and radiological responses were evaluated. The number of injections, recurrence and complications were recorded.

Results: This study included 17 cases with a median age of 8 years (interquartile range [IQR] 2.5 years–16.5 years), with a minimum of 9 months and a maximum of 20 years. Of these, eight were females, while nine were males. The lesions were classified as intraconal in three cases, extraconal in seven and in the anterior orbit in seven. Furthermore, two patients received only one injection with complete resolution. Nine patients received two injections with complete resolution. In addition, four patients received three injections with complete resolution, achieving an overall complete resolution rate of 88.2% (95% confidence interval [CI]: 65.7% – 96.7%). No serious side effects were observed.

Conclusion: Bleomycin sclerotherapy showed promising efficacy with acceptable short-term and intermediate-term safety in the management of orbital and periorbital VLM.

Contribution: It contributes to the understanding of bleomycin in the management of orbital and periorbital VLM.

Keywords: bleomycin; venolymphatic; orbital; injection; efficacy.

Introduction

Orbital venolymphatic malformation (VLM) is present in the first decade of life as infiltrative lesions. They are composed of abnormal channels that are liable for haemorrhage and cyst formation. Periorbital haematoma is also common.[1] Periocular and orbital VLM account for 1% – 3% of the orbital masses. They are atypical vascular or lymphatic conduits with a lining of endothelial cells.[2] Their clinical presentation could be just a swelling, or they may present with progressive proptosis, ptosis and/or limited ocular motility. Visual loss could occur in severe cases because of sudden intralesional haemorrhage, which can lead to optic nerve compression.[2,3] The surgical excision, either total or debulking, is highly risky because of the unencapsulated, infiltrative nature of these lesions among vital orbital structures. Indications for surgery include emergency orbital decompression (e.g. severe acute haemorrhage threatening the optic nerve), refractory cases or well-circumscribed superficial lesions.[4] Intralesional sclerotherapy with bleomycin could be an alternative to surgical excision; it could be the sole and primary modality of treatment. Bleomycin represents one of the anti-neoplastic agents that induce significant scarring and fibrosis in the case of local injection into the lesion. It is a sclerosing agent, so it helps in the regression of the lesion.[3] It is indicated for lesions causing proptosis or chronic pain or pressure manifestations or lesions causing significant cosmetic disfigurement. It also can be done in deeply located lesions or intricately wrapped lesions around vital nerves and arteries where open surgery carries an unacceptable risk of

blindness.[4] Possible side effects are abnormal redness, fever, swelling, pain, hyperpigmentation and local gangrene at the injection site. Nevertheless, the efficient and safe intralesional bleomycin injection is under systematic study in relation to orbital and periorbital VLM.[3,5] The present study was conducted in order to assess the clinical and radiological responses. Also, we evaluated the number of injections, recurrence and complications associated with bleomycin sclerotherapy for the treatment of orbital and periorbital VLM.

Research methods and design

This retrospective case series of subjects with orbital and periorbital VLM was conducted at the Sohag Ophthalmology Department, Sohag University, between April 2018 and March 2022. Detailed history was obtained regarding onset, course and duration of the lesion, the main presenting symptoms and any associated local or systemic manifestations. A full ophthalmological examination was done, including best corrected visual acuity (BCVA), spherical equivalent (SE), anterior segment examination, fundus examination and ocular motility test, followed by a detailed examination of the lesion, including its size, colour, depth and relation to surrounding structures. A computerised tomography scan (CT) and magnetic resonance imaging (MRI) of the orbit were conducted to diagnose the lesion and document its extent. Both MRI and CT scans were done before intervention and during follow-up to assess response. All data were collected for analysis.

Inclusion criteria

Patients with orbital and periorbital VLM, both young and adult, were enrolled in the study. No patients were subjected to any surgical intervention related to the tumour before the study. They were followed for at least 3 years after intervention.

Exclusion criteria

Cases that did not follow-up.

Patients with renal impairment, pulmonary function disturbances, pregnant and lactating females and those with hypersensitivity to bleomycin were excluded.

The standard surgical protocol was as follows

Bleomycin is commercially obtained as a dried powder in a vial of 15 international units (IU). Note that 1 IU of bleomycin equals 1 mg. A dose of 0.5 mg of bleomycin for every 1 kg of weight was used but considering that the maximum dose is not more than 15 mg. in order to prepare the solution of bleomycin, normal saline and 2% lignocaine at the ratio of 1:1 were used. The volume used for injection was estimated to equal the lesion volume, noting that it should not go beyond 4 mL per session. A 25-gauge needle size was used to minimise structural trauma to the surrounding orbital structures. Aspiration with the needle was done first before injection to decompress the cyst; following injection, firm digital compression was performed for 3 min–5 min. The injection was done under general anaesthesia in paediatric patients and deep-seated orbital lesions, taking into consideration monitoring oxygen saturation level by the anaesthesiologist (bleomycin risk of pulmonary toxicity and fibrosis with high concentrations of oxygen). Injection under local anaesthesia was done in adult patients. Participants received assessments on the first day after surgery and subsequently after 2 weeks. The patients who needed retreatment would be injected every 4 weeks. Treatment was halted after three injections maximum, and no clinical symptoms of remission were observed. In addition, MRI or CT scan of the orbits was reperformed 3 months following the last injection to verify radiological evidence. Ultimately, the outcome was observed. Direct injection with a syringe was done in most cases, but three cases needed ultrasonography guidance to make sure that there was no connection between the malformation and the cavernous sinus. Omnipaque (Omnipaque 240, GE Healthcare, Oslo) as contrast material was used.

Clinical criteria of resolution of the lesion

Reduction of proptosis, resolution of periocular swelling, restoration of normal ocular motility and maintenance of normal visual acuity and pupillary function. Radiological resolution was defined by comparing pre- and post-procedure scans (typically measuring the largest diameter or volume of the targeted cysts). Complete resolution: More than 90% reduction in size of the lesion, the previous cystic spaces replaced by inactive fibrotic scar. Partial resolution: 25% – 90% reduction in size of the lesion radiologically. Minimum or no response: Less than 25% reduction in size.

Statistical analysis

Data analysis was done using the Statistical Package for Social Sciences (SPSS), Version 26 (IBM Corp., Armonk, NY, US). We used the Shapiro–Wilk test to assess the continuous variables. As we have a small sample size (n = 17), the continuous variables were non-normally distributed and are presented as median and interquartile range (IQR). Categorical variables are presented as frequencies and percentages. As this study has a descriptive and exploratory nature, and we have a limited number of non-responders (n = 2), the formal comparative statistical analysis was not suitable and not performed. Instead, we used univariate comparisons between responders and non-responders using cross-tabulation method, and all comparisons were non-significant. We didn't try multivariate logistic regression because of the limited event count, which would render the analysis weak and misleading.

Ethical considerations

Ethical clearance to conduct this study was obtained from the Sohag University Medical Research Ethics Committee

(No. Soh-Med-25-2PD). The study adopted the principles of the Helsinki Declaration. In addition, informed written consent was provided by all subjects or their legal representatives.

Results

Seventeen participants were included in this study, median 8 IQR (2.5–16.5) years, with a minimum of 9 months to a maximum of 20 years. Eight were females (47.1%, 95% CI: 26.2% – 69.0%), while nine were males (52.9%, 95% CI: 31.0% – 73.8%). They were followed for at least 36 months. The diagnosis was established clinically with the aid of CT and MRI for orbital imaging in all cases. Both BCVA and SE were matched before and after intervention with no significant difference, 0.862 and 0.72, respectively (Table 1).

Characters and site of the lesion

The lesions were classified as intraconal in three cases (17.6%, 95% CI: 6.2% – 41.5%), extraconal in seven cases (41.2%, 95% CI: 21.6% – 64.0%) and anterior orbit in seven cases (41.2%, 95% CI: 21.6% – 64.0%). The involvement was more on the right side in nine cases (52.9%), while eight cases (47.1%) were on the left side. The median duration of the symptoms was 12 months (IQR: 8 months–18 months). The size of the lesions in their largest dimension was 25 mm (IQR: 18 mm – 35 mm). Superficial lesions presented with subcutaneous swelling, purple or deep blue in colour. Deep lesions were associated with normal overlying skin. The median anteroposterior depth was 17 mm (IQR: 10 mm – 25 mm) from the front of the orbit towards the back of the orbit measured radiologically.

Clinical presentation

Eye symptoms and signs were variable. Patients with intraconal lesions presented with ocular motility limitation in two cases in the form of limited adduction and optic nerve affection in one patient. Proptosis was noticed in all intraconal lesions. Additionally, one patient presented with ocular deviation in the form of exotropia.

Radiologically, based on the size of the cysts on MRI or CT scans, 70% of lesions in our study were the mixed type (scans show macrocystic and microcystic features, 95% CI: 46.9% – 86.7%), and 17.6% was of the macrocystic type (cyst size more than 1 cm, 95% CI: 6.2% – 41.0%).

Treatment response

We evaluated the treatment response by both radiological and clinical criteria.

Primary outcome was assessed (radiological response)

Regarding radiological findings, complete response was defined as > 90% reduction in the lesion size, partial response was defined as 25% – 90% reduction and no response was defined as < 25% reduction.

Secondary outcomes

Clinical improvement and number of injections

With regard to clinical findings, the response was evaluated by the resolution of presenting symptoms such as proptosis, visual impairment and pain. Two patients (11.8%, 95% CI: 3.3% – 34.3%) received only a single injection and achieved

TABLE 1: Baseline characteristics of the included 17 patients after injection in the case series.

Parameters	Subclass	Total			
		n	%	Median	IQR
Age	Years	-	-	8	2.5–16.5
Sex	Male	9	52.9	-	-
	Female	8	47.1	-	-
Presentation	Eyelid swelling	12	70.6	-	-
	Proptosis	1	5.9	-	-
	Proptosis and limited ocular motility	3	17.6	-	-
	Proptosis and ocular deviation	1	5.9	-	-
Eye	Left	8	47.1	-	-
	Right	9	52.9	-	-
Site of the lesion	Anterior orbital	7	41.2	-	-
	Extraconal	7	41.2	-	-
	Intraconal	3	17.6	-	-
Cyst size	Years	-	-	2	1.4–2.4
Cyst type	Macrocystis	3	17.6	-	-
	Microcystic	2	11.8	-	-
	Mixed	12	70.6	-	-
Microcystic component	Yes	14	82.4	-	-
	No	3	17.6	-	-
Macrocystis component	Yes	15	88.2	-	-
	No	2	11.8	-	-
Optic nerve involvement	Yes	3	17.6	-	-
	No	14	82.4	-	-

IQR, interquartile range.

TABLE 2: Treatment response and adverse effects of the included 17 patients after injection in the case series.

Parameters	Subclass	*n*	%
Radiological Response	Complete (> 90% reduction)	10	58.8
	Partial (25% – 90% reduction)	5	29.4
	No response (< 25% reduction)	2	11.8
Clinical response	Complete resolution	9	52.9
	Partial improvement	6	35.3
	No improvement	2	11.8
Treatment injection	One	2	11.8
	Two	9	52.9
	Three	6	35.3
Local adverse effects	Itching	4	23.5
	Redness	2	11.8
	Depigmentation	1	5.9
	None	10	58.8
Systemic adverse	None	17	100
Recurrence	None	17	100

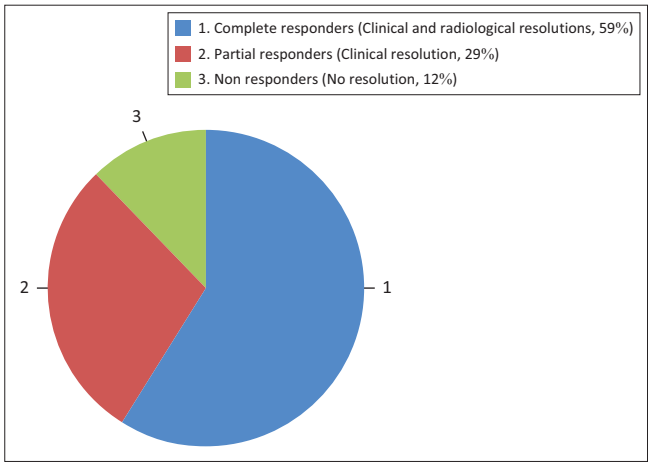

FIGURE 1: Percentage of response after injection and follow-up.

both complete clinical and radiological resolution. Nine patients (52.9%, 95% CI: 31.0% – 73.8%) received two injections; all of them achieved complete clinical resolution, and four of these patients (44.4%, 95% CI: 18.9% – 73.3%) achieved only partial radiological response. Four patients (23.5%, 95% CI: 9.6% – 47.3%) received three injections and achieved both complete clinical and complete radiological resolution. Two patients (11.8%, 95% CI: 3.3% – 34.3%) showed no significant clinical or radiological improvement after three injections and required surgical intervention. Overall, as shown in Figure 1, radiological complete response was observed in 10 patients (58.8%), partial response in five patients (29.4%) and no response in two patients (11.8%) (as shown in Table 2).

Follow-up, complications and recurrence

No serious side effects were observed. Four cases recorded itching at the site of injection (23.5%, 95% CI: 9.6% – 47.3%). Two cases reported redness (11.8%, 95% CI: 3.3% – 34.3%). Moreover, one case reported depigmentation 6 months after the third injection (5.9%, 95% CI: 1.0% – 26.9%), and no case reported recurrence (0.0%, 95% CI: 0.0% – 18.5%) (Figure 2 and Figure 3). The cases were followed by chest and internal medicine specialists for any systemic side effects, with no recorded systemic side effects (0.0%, 95% CI: 0.0% – 18.5%).

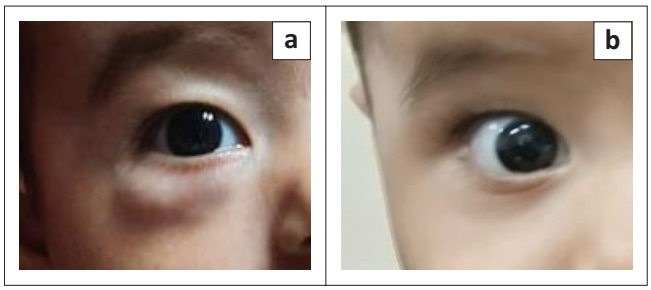

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FIGURE 2: A case (a) with a lower lid anterior orbital lesion that showed (b) complete resolution after two intralesional injections of bleomycin.

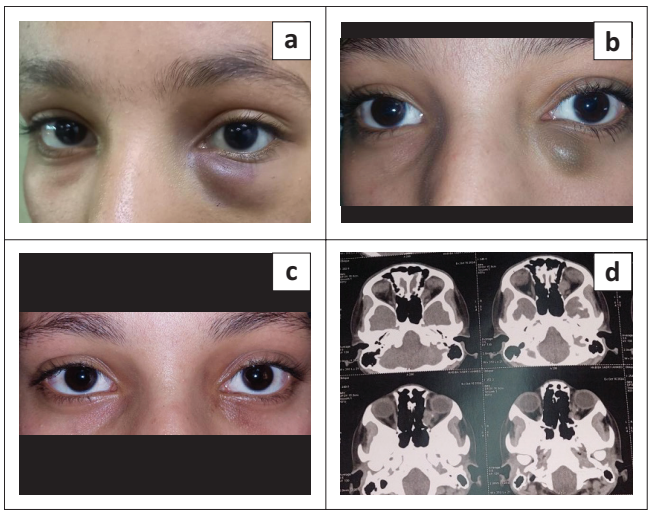

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FIGURE 3: A 15-year-old female patient with (a and b) a lesion with (c) complete resolution after three intralesional injections; (d) computed tomography orbit showed that the lesion is still present but smaller.

Table 3 shows that when comparing the responders and non-responders for all parameters in the study, there are no statistically significant differences found (all $p > 0.05$). The wide confidence intervals 95% is because of the small number of non-responders ($n = 2$); this also limited the precision. All non-responders received three injections, and one case of them had optic nerve involvement. The small sample size, as a case series study, made it difficult to identify the predictors of failure Figure 4 and Figure 5 showed a non-significant negative correlation between cyst size and number of injections and response to treatment when non-response is zero, and complete response is two.

Discussion

Orbital and periorbital VLM are benign lymphatic tumours, featuring the growth of dilated, endothelial-lined lymphatic vessels. They can remain clinically silent or slowly become larger, leading to proptosis and limited ocular motility. Sudden enlargement because of intralesional haemorrhage can cause compressive optic neuropathy. Therefore, treatment is primarily surgical excision; however, their infiltrative nature makes complete excision critical and difficult, with risks of injury to adjacent structures. Furthermore, they are

TABLE 3: Age, sex, site, size, microcystic, macrocytic characterisation, orbit involvement and number of injections in responders and non-responders after injection in the case series (N = 17).

Parameters	Subclass	Complete and partial responders (n = 15)				Non-responders (n = 2)				Total			
		n	%	Median	IQR	*n*	%	Median	IQR	*n*	%	Median	IQR
Age	Years	-	-	8	2–17	-	-	9	4	-	-	8	2.5–16.5
Sex	Male	8	53.3	-	-	1	50	-	-	9	52.9	-	-
	Female	7	46.7	-	-	1	50	-	-	8	47.1	-	-
Presentation	Eyelid swelling	11	73.3	-	-	1	50	-	-	12	70.6	-	-
	Proptosis	1	6.7	-	-	0	0	-	-	1	5.9	-	-
	Proptosis and limited ocular motility	2	13.3	-	-	1	50	-	-	3	17.6	-	-
	Proptosis and ocular deviation	1	6.7	-	-	0	0	-	-	1	5.9	-	-
Eye	Left	7	46.7	-	-	1	50	-	-	8	47.1	-	-
	Right	8	53.3	-	-	1	50	-	-	9	52.9	-	-
Site of the lesion	Anterior orbital	6	40	-	-	1	50	-	-	7	41.2	-	-
	Extraconal	6	40	-	-	1	50	-	-	7	41.2	-	-
	Intraconal	3	20	-	-	0	0	-	-	3	17.6	-	-
Cyst size	Years	-	-	1.9	1.4–2.4	-	-	2.4	2.2	-	-	2	1.4–2.4
Cyst type	Macrocystis	3	20	-	-	0	0	-	-	3	17.6	-	-
	Microcystic	2	13.3	-	-	0	0	-	-	2	11.8	-	-
	Mixed	10	66.7	-	-	2	100	-	-	12	70.6	-	-
Microcystic component	Yes	12	80	-	-	2	100	-	-	14	82.4	-	-
	No	3	20	-	-	0	0	-	-	3	17.6	-	-
Macrocystis component	Yes	13	86.7	-	-	2	100	-	-	15	88.2	-	-
	No	2	13.3	-	-	0	0	-	-	2	11.8	-	-
Optic nerve involvement	Yes	2	13.3	-	-	1	50	-	-	3	17.6	-	-
	No	13	86.7	-	-	1	50	-	-	14	82.4	-	-
Number of injections	1	2	13.3	-	-	0	0	-	-	2	11.8	-	-
	2	9	60	-	-	0	0	-	-	9	52.9	-	-
	3	4	26.7	-	-	2	100	-	-	6	35.3	-	-

IQR, interquartile range.

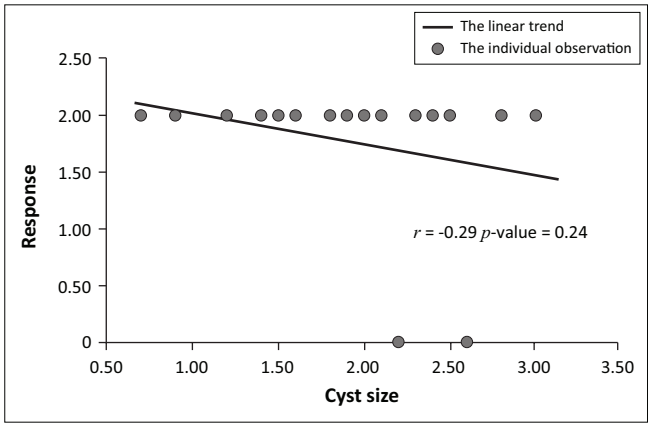

FIGURE 4: Spearman's correlation between cyst size and response to treatment.

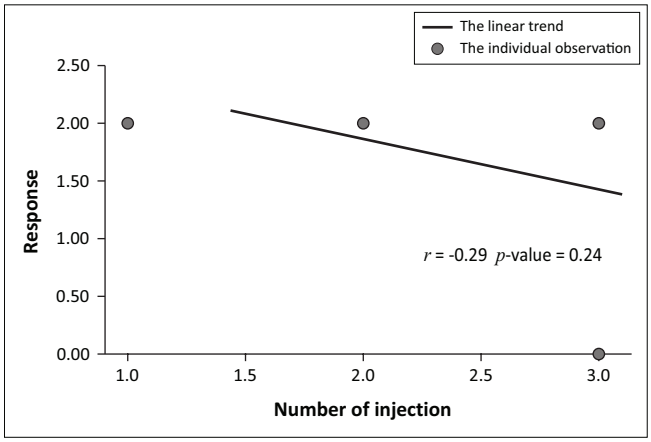

FIGURE 5: Spearman's correlation between the number of injections and the response to treatment.

recurrent if not removed totally.[1,4,6] The injection of sclerotic agents could be a good option in the treatment of these lesions, offering improvement of symptoms and avoiding the complications of surgical intervention.[4,7] Bleomycin is one of the sclerotic agents that was first described by Shen, Gooding and Meyer in the management of orbital and periorbital VLM. The ease of procedure, either through direct injection or ultrasonically guided manoeuvre, supports its use as a primary line of management.[8] This study showed a high success rate of intralesional bleomycin in the management of orbital and periorbital VLM with fewer operative and postoperative complications.[6,9] In the form of postoperative redness, itching and depigmentation. In our study, 15 patients showed improvement with partial or complete resolution of the lesion. Two cases only showed no improvement and required surgical intervention. According to Dave TV et al.,[10] 79% of eyes with orbital VLM showed improved results with transcutaneous and/or transconjunctival non-image-guided bleomycin sclerotherapy. Similarly, Raichura et al.[5,11] revealed a highly significant response rate in 13 cases with no adverse effects or recurrence during follow-up. Lesions with macrocysts and mixed type (macro and microcysts) show better response both radiologically and clinically; the macrocystic spaces (large fluid-filled cavities) act as reservoirs. With fluid aspiration and bleomycin injection, the drug can pool and act directly inside these cavities. This provides prolonged, uniform contact with the inner lining, maximising

TABLE 4: The difference between our study and other published studies regarding the outcome.

Study	Response to bleomycin injection	Reported complications
Our study	Complete radiological response was observed in 58.8%; partial radiological response in 29.4% of cases	No major complications or systemic side effects
Dave et al.[10]	93% clinical response, 58% radiological response	Minor local swelling and pain, no systemic toxicity
Nuruddin et al.[13]	50% achieved complete resolution, 50% achieved more than 70% radiological resolution	No reported major or systemic side effects

Note: Please see the full reference list of this article, Mahmoud H, Awny I, Sinjab AAA, Rashdan HT. Clinical and radiological outcomes of intralesional bleomycin for orbital venolymphatic malformations: A retrospective case series. Afr Vision Eye Health. 2026;85(1), a1159. https://doi.org/10.4102/aveh.v85i1.1159 for more information.

endothelial ablation and causing complete obliteration of the lesion. Possible causes of non-response in two of our cases are the mixed nature of the lesion, as the presence of microcysts limits the distribution of the drug compared to large macrocysts, which show better response, another possible cause is the diffuse nature of the lesion, limiting complete coverage during injection. Inaccurate targeting during injection (extravasation) is an important cause to be considered in non-responding cases, especially in deep-seated lesions with optic nerve involvement or intraconal location; the drug may track into the surrounding healthy orbital fat or connective tissue rather than remaining entirely inside the malformation lumens, causing poor effect and response. In our study, we reported no recurrence. Iskandar et al. reported one case with recurrence in their study. The cause of recurrence in their case was rebleeding inside the chocolate cyst; other possible causes of recurrence may be because of hormonal triggers. Elevated hormone levels can stimulate vascular dilation or endothelial proliferation in residual, under-treated cysts.[12] No serious side effects were observed in our study. Four cases only reported itching at the site of injection, two cases reported redness, one case reported depigmentation 6 months after the third injection and no cases reported recurrence. Khusna et al. reported no serious systemic side effects, such as lung toxicity or fibrosis, in their study, which analysed the safety and efficacy of bleomycin injection for orbital and periorbital VLM.[5] Pulmonary fibrosis is dose dependent, and fatal pulmonary fibrosis occurs when the cumulative dose exceeds 400 mg. This factor is important to be consider for patient safety and to avoid such serious side effects. Concerning safety, bleomycin intralesional injection shows a reasonable degree of safety when used to treat orbital and periorbital VLM, with minor, self-limiting side effects. No major complications were reported.[12]

Table 4 summarises the difference between our study and other published studies.[10,13,14]

The difference between the radiological and clinical response to local bleomycin injection in our study and even previous studies can be attributed to the following causes. This occurs because clinical symptoms in the tight eye socket depend on fluid pressure and compliance, whereas radiological measurements depend strictly on physical volume. Bleomycin induces intense localised fibrosis (scarring). This converts a soft, stretchy, fluid-filled sponge into a hard, rigid, static block of scar tissue. As it can no longer swell or fill with blood or fluid, the clinical symptoms disappear completely, even though the static mass remains clearly visible on a post-procedure scan during radiological evaluation.

Strengths and limitations

The follow-up period (minimum 36 months) is a strong point in this study, with the absence of serious side effects or complications. However, there are several limitations that should be acknowledged. Firstly, the small sample size and the low number of non-responders limited the statistical power of the study. Secondly, it was impossible to do multivariate analysis as a result of the low event count. Thirdly, the orbital VLM is heterogenous, and this limited the subgroup analysis.

Recommendation

This case series study could be a pilot study for further prospective. Larger cohorts and multicentric studies are recommended with standardised imaging using volumetric techniques.

Conclusion

Intralesional bleomycin injection demonstrated favourable clinical and radiologic outcomes in most patients with orbital VLM in this retrospective case series. The procedure appeared relatively safe, with mainly mild local adverse effects observed during follow-up. However, larger prospective studies with standardised outcome measures are required to better establish efficacy, safety and predictors of response.

Acknowledgements

Competing interests

The authors, Hany Mahmoud; Islam Awny; Alaa A.A. Sinjab and Haitham T. Rashdan, declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRediT authorship contribution

Hany Mahmoud: Conceptualisation, Data curation, Formal analysis, Resources, Supervision, Validation. Islam Awny: Investigation, Methodology, Supervision, Writing – review & editing. Alaa A.A. Sinjab: Data curation, Investigation, Visualisation, Writing – review & editing. Haitham T. Rashdan: Data curation, Investigation, Software, Visualisation. All authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication and take responsibility for the integrity of its findings.

Funding information

The authors received no financial support for the research, authorship and/or publication of this article.

Data availability

The data that support the findings of this study are not openly available and are available from the corresponding author, Hany Mahmoud, upon reasonable request.

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