International Journal of Otorhinolaryngology and Head and Neck Surgery
Mishra S et al. Int J Otorhinolaryngol Head Neck Surg. 2021 Nov;7(11):1768-1771
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20214228

Original Research Article

Intralesional 3% sodium tetradecyl sulphate versus hot water in oral cavity hemangioma: a comparative study

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Received: 20 August 2021
Revised: 25 September 2021
Accepted: 04 October 2021

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ABSTRACT

Background: Oral cavity lesions fall among the few most common presentations in the outpatient department of ENT. Hemangioma in oral cavity though do not usually account for any life threatening or serious condition but hampers day to day activities like chewing, speaking and occasionally bleeding from oral cavity. Timely diagnosis and treatment solves the above problem. Though there are various modalities of treatment ranging from cryosurgery to surgical ablation, sclerotherapy is an evolving, effective and easy method for reduction of the size of lesion and preventing recurrence. It can be done as a day care procedure. The aim was to compare between the efficacy of 3% sodium tetradecyl sulphate and hot water in oral cavity hemangiomas.
Methods: A total of 20 patients presenting to the OPD, department of ENT, VIMSAR, Burla, with diagnosis of hemangioma in oral cavity between January 2018 to January 2019 were selected for the study. They were divided into two groups. Group A was administered 3% sodium tetradecyl sulphate whereas group B was administered hot water, both intralesionally, at multiple sites of lesion. Injection were repeated after an interval of 2 weeks for a period of 3-4 months. The results were routinely analysed clinically and statistically and the statistical significance was set at $p<0.05$.
Results: There was a significant improvement ($p<0.05$) in most of the parameters measured, in group A patients as compared to group B patients.
Conclusions: 3% sodium tetradecyl sulphate is a better sclerosing agent than hot water in cases of oral cavity hemangiomas.

Keywords: Hemangioma, Sclerotherapy, 3% sodium tetradecyl sulphate, Hot water

INTRODUCTION

Vascular malformations are characterized by thin non proliferating endothelial wall surrounded by thin smooth muscle layer. They normally do not involute, rather might continue to increase in size.[1]

Hemangiomas are a type of vascular malformations or can be said as benign lesions of blood vessels. They are actively proliferating tumors which demonstrate a characteristic pattern of rapid post-natal growth followed by slow involution. They are common in head and neck regions. Affected regions include lips, tongue, buccal mucosa, gums, palate. There is higher prevalence in females (65%), twins and preterm infants.[2,3]

They are usually asymptomatic with size varying from millimetres to centimetre. Colour varies from red to purple according to the location and depth of tissue

invasion as well as the degree of vascular congestion of the affected area.[2,3]

It can present as a flat or raised lesion with smooth or nodular surface, defined edges, sessile or pedunculated, soft consistency on palpation.[2]

On histopathology study they are seen to exhibit increased blood vessels, thickened subendothelial basement membrane, hyperplastic endothelial cells.[3,4]

Diagnosis is based on history, clinical features, diascopy, aspiration the lesion and imaging studies.

Treatment is planned based on the hemodynamics of the lesion (high flow or low flow) lesion.

Treatment options include surgical excision, laser surgery, cryotherapy, chemotherapy agents, corticosteroids, embolization and sclerotherapy.[4,5]

Sclerotherapy is the substitution of vascular component by a fibrotic tissue in response to an inflammatory process.[6] It is a viable option owing to its safety, ease of administration, acceptable aesthetic and functional outcomes.[7] It counters the proliferative growth, reduces the volume of hemangioma and initializes the process of regression.[5] Some sclerosants include 3% sodium tetradecyl sulphate, 5% phenol, sodium morrhuate, nitrogen mustard, boiling water, sodium psylliate, sodium citrate, invert sugar, absolute alcohol, hypertonic saline hypertonic dextrose.[2]

3% sodium tetradecyl sulphate produces endothelial damage with thrombus formation leading to fibrosis of the lesion which leads to its shrinkage.[7]

Hot water releases heat energy that cause disruption of intima and eventually collapse and blockage of the channels in the anomalous angiomatous tissue.[8]

METHODS

This was a hospital based prospective comparative study carried out in the department of ENT, VIMSAR, Burla from January 2018 to January 2019. Diagnosis of vascular malformation was suspected in cases having painless pinkish to purplish vesicles or bullae with a soft consistency on palpation. In all cases, diascopy showed colour change and intralesional ischemia corroborating with our diagnosis. Doppler ultrasound was performed to rule out high flow lesions.

Inclusion criteria

Cases with FNAC suggestive of hemangioma or vascular malformations were taken into account.

Exclusion criteria

Cases with hypercoagulability, pregnancy, history of venous thrombosis, immunocomprised state, allergy to sclerosants, lesion larger than 10 cm were excluded from the study.

20 cases were selected for our study. Sample size was estimated by purposive sampling technique.

Patients were informed about the risks and benefit of the technique. The subjects were randomly divided into two groups, 10 cases in each group. Randomization was performed by assigning a random number according to a computer generated code created by statistician. Patients were not provided about any information regarding the drugs used in the study.

Group A was treated with intralesional 3% sodium tetradecyl sulphate and group B was treated with intralesional hot water.

The sclerosants were injected using 2 ml syringe and a 24 gauge needle. After introducing the needle the plunger was withdrawn to look for the backflow of blood and to confirm the appropriate entry of the needle to the vascular space. 0.25 to 0.5 ml of the agent was injected and the same procedure was repeated at another site of the same lesion. Thus, the sclerosants were injected into multiple sites of the same lesion and the process continued until the lesion blanched. Compression was applied for at least 2 hours post injection. This method was repeated after a period of two weeks for an interval of 3-4 months. The sclerotherapy injections and post treatment responses were recorded. The responses were graded in terms of no response to complete resolution.

Statistical analysis between the two groups were done by independent t test using SPSS software. A two sided $p<0.05$ was considered to be statistically significant.

RESULTS

It was seen that out of 60% of the patients are male and 40% female. So, no gender predisposition can be concluded from the study.

Only one patient of group B among all 20 patients showed recurrence after 4 months. The p value was found to be 0.627 which proved there was no statistical significance among the two groups in terms of recurrence.

In 2 weeks 8 people of group A showed size reduction whereas 2 people of group B showed size reduction. The observation is noted in Table 2. By the end of 4 months 10 people from group A and 8 people from group B showed size reduction. The response was compared in terms of percentage of size reduction and duration taken for the same. The mean and standard deviation for group

A were found to be 9.25 and 1.088 respectively. The mean and standard deviation for group B was found to be 5 and 2.23 respectively. Using appropriate statistical tests the p value was found to be 0.00001 which showed statistical significance of the study.

Patients under group A had more complications as compared to those under group B. The p value was found to be 0.036 using appropriate statistical tests. This showed there was statistical significance between group A and B in terms of complications.

Table 1: Demographic distribution.

Age (in years)	Male	Female
0-9	3	1
10-19	7	5
20-29	0	1
30-39	1	1
40-49	1	0
50 and above	0	0
Total	12 (60%)	8 (40%)

Table 2: Comparison of response.

Duration	Number of patients showing size reduction	
	Group A	**Group B**
2 weeks	8	2
4 weeks	9	4
2 months	10	6
4 months	10	8

Table 3: Recurrence.

Duration (in months)	Group A	Group B
After 2	Nil	Nil
After 4	Nil	1
After 6	Nil	1

Table 4: Complications.

Complications	Group A (%)	Group B (%)
Pain	70-75	40-50
Edema	60-65	35-40
Ecchymosis	70-80	10-20
Ulceration	35	Nil

DISCUSSION

Vascular malformations are characterized by thin non proliferating endothelial cells surrounded by thin smooth muscle layer. They normally do not involute, rather might continue to increase in size. Hemangiomas are actively proliferating tumors which demonstrate a characteristic pattern of rapid postnatal growth followed by slow involution. Treatment options include minimally invasive interventions such as sclerotherapy, embolization, laser ablation, cryotherapy or more aggressive surgical resection. Management varies according to patient's age, size of lesion, location, type of lesion. Lesions of oral area can be associated with bleeding and discomfort.[2-4]

Sclerotherapy was a viable option due to its safety, ease of administration and acceptable aesthetic and functional outcomes. 3% sodium tetradecyl sulphate had been widely used as sclerosing agent since 1964. Its mechanism of action was to produce maximal endothelial damage with minimal thrombus formation leading to fibrosis of the lesion which led to its shrinkage. Hot water released heat energy that caused disruption of intima and eventually collapsed and blocked the channels in the anomalous angiomatous tissue.[8]

In this case series, 3% sodium tetradecyl sulphate tended to validate as a minimally invasive, safe and effective treatment in oral cavity hemangioma. The responses to therapy were very satisfactory in 80% of the treated patients who showed good to complete response. 20% of the cases showed mild to moderate response. The best response was observed in lesions smaller than 2.5 cm due to the fact that the efficacy of the sclerosis depended on the calibre of the feeder vessels and the blood flow. The lower efficacy of sclerotherapy of larger calibre or faster flow lesions was seen as a result of less sclerosant agent making contact with the endothelial cells of the lesional walls. The optimal formulation was found to be one part sclerosant to four parts air. The concentration depended upon calibre of veins.

Follow up of the patients were scheduled every 2 weeks and repeated injections were scheduled after 4 weeks in those patients with unsatisfactory results. In the present study post injection inflammatory reactions, pain and ecchymosis were observed in most of the patients. But subsequent necrosis and inflammation induced by sclerosis subsides with fibrous tissue formation, culminating in progressive reduction in the lesion size.

Following hot water injection, the inflammatory response was less. Since, water in itself had no sclerosing properties, intralesional injection acts primarily due to transfer of heat and therefore produced much lesser inflammatory reaction but delayed response in terms of reduction of size.

The earlier studies conducted by Alakailly et al showed complete response in 28.57% cases, good response in 35.7%, moderate in 14.28%, mild in 14.28% and no response in 7.14% using setrol as sclerosant.[7] Our study showed response in all cases using 3% sodium tetradecyl sulphate. Almost 80% showed good to complete response by 2 weeks, 20% showed moderate to good response.

Study by Jeyaraj et al in 2017 showed almost complete response using setrol whereas recurrence in 20% cases using boiling water.[2] Similar response was observed in

our study too. There was no recurrence in group A (group with 3% sodium tetradecyl sulphate) but recurrence of 10% in group B (treated with hot water).

Mgbeokwere et al showed moderate to good response using hot saline but lesions further required surgical excision for complete treatment mostly for cases large, deep seated vascular anomalies.[8] In our study surgical intervention was not required as low flow lesions with size from 0-9 centimeters were selected.

Group A had good to complete response in 80% cases, moderate to good response in rest 20% cases and almost no recurrence during 8 months of follow up, though immediate complications could not be ignored.

Group B had moderate to good response in 50% cases, mild to moderate response in rest 50%, recurrence in 5-10% cases during follow up and complications were much less compared to Group A.

Limitation

The study was limited owing to small sample size. Many patients got excluded due to various factors like high flow lesions, severe side effects following previous sclerotherapy, lesion >10 cm, low immunity. A greater sample size could have helped in more extensive analysis and better comparison between the two sclerosants.

CONCLUSION

From the above study it can be concluded that both sodium tetradecyl sulphate and hot water can serve as effective agents for treating oral cavity hemagiomas. Sclerotherapy with direct intralesional injection of 3% sodium tetradecyl sulphate is better than hot water in terms of response, percentage of size reduction and duration taken for size reduction. At the same time it shows more side effects as compared to hot water. Both are simple, safe and effective therapy in managing oral cavity hemangiomas that can be done as office procedure. Though hot water is also effective in resolution of the lesions, 3% sodium tetradecyl sulphate proves to be a better option, owing to its faster action and manageable side effects.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mishra S, Acharya S, Kar A, Mohanta FM, Samal SR. Intralesional 3% sodium tetradecyl sulphate versus hot water in oral cavity hemangioma: a comparative study. Int J Otorhinolaryngol Head Neck Surg 2021;7:1768-71.