Management of Superficial and Deep Vascular Malformations of the Maxillofacial Region

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Abstract: *Introduction:* Haemangiomas and Vascular malformations of the maxillofacial region are formidable lesions causing considerable cosmetic deformity and grave functional debilitation. Technically, their surgical excision is difficult and challenging, fraught with complications like hemorrhage, incomplete excision, facial disfigurement and recurrence. This study has fashioned two techniques directed at permanently treating these lesions.

Aim: Evaluating the safety and long term efficacy of single session sclerotherapy with Polydocanol for superficial cutaneous / mucosal low flow vascular malformations; and of sclerothrombotic therapy with hot water as a neoadjuvant modality followed by surgical excision, for deeper high flow vascular malformations of the maxillofacial region.

Methods: Ten cases of Vascular Malformations of the maxillofacial region were treated. Of them, five were superficial, low flow lesions which were managed using intralesional instillation of Polydocanol alone without any surgical intervention thereafter; and the remaining five were deep, high flow lesions, which were treated first, by intralesional injection of hot water over two sessions, which was then followed by surgical excision of the lesion, which was carried out within the next 72 hours.

Results: Complete resolution of the lesions was achieved in all the cases.

Conclusion: Our results support the fact that single session sclerotherapy with Polydocanol may be considered as the primary modality in the treatment for superficial (cutaneous or mucosal) low flow vascular malformations. However, for deeper, high flow lesions, two sessions of intra lesional injection of hot water followed by surgical excision within 72 hours of the first injection, may be the treatment of choice.

Keywords: Vascular anomalies, Vascular malformations, Haemangioma, Sclerotherapy, Polydocanol, Hot water, Sclerothrombosis.

INTRODUCTION

Vascular lesions or anomalies are a heterogeneous group of blood vessel disorders which, based on their clinical behavior and endothelial cell characteristics, were classified by Mulliken and Glowacki in 1982 into two broad categories, Vascular Tumors, also referred to as Haemangiomas, and Vascular Malformations (VMs) [1, 2]. This comprehensive classification was accepted and adopted by the International Society for the Study of Vascular Anomalies (ISSVA) in 1996. In 2013, the ISSVA Classification was reinforced with an additional review on syndrome-based classification [2].

Haemangiomas are true vascular neoplasms, usually seen in infancy and childhood, comprising of an increased number of normal or abnormal blood vessels lined with thickened subendothelial basement membrane laminas, and hypercellular / hyperplastic endothelial cells. They are characterized clinically by a rapid neonatal growth until the age of 6-8 months

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(proliferative phase) and then a slow regression by the age of 5-10 years (involuting phase), characterized by diminishing cellularity, interstitial fibrosis and fibrofatty replacement [1].

Vascular malformations (VMs) on the other hand, are congenital lesions resulting from developmental anomalies due to errors in vascular and lymphatic morphogenesis, and comprise of abnormally formed channels that are lined by quiescent endothelium (normal endothelial cell turnover). 31% of VMs are found in the Head & Neck region [18]. These lesions are present at birth, though they often go unnoticed, and grow commensurately with the child with a normal rate of endothelial cell turnover. They increase in size during infancy through adolescence proportionally to the overall growth of the patient. Growth may also be triggered by trauma, infection and hormonal fluctuation as in puberty, pregnancy, use of oral contraceptives, etc. Histologically, there is no proliferative or involution phase and endothelial as well as mast cell activity is normal. Vascular channels are lined by mature endothelial cells which are surrounded by a normal reticulum and a single cell layer basement membrane [2]. The mechanism of growth of these lesions is not increased endothelial proliferation, but alteration in the flow dynamics within and around the lesion resulting in the recruitment of collateral vessels and dilatation of the involved vessels.

Lymphatic, capillary, venous, and arteriovenous malformations make up the majority of vascular malformations. They may infiltrate skin, mucosa, muscles, joints, organ systems and sometimes even bones. Symptoms are dependent on the anatomic location of the lesion and can have a great impact on the patient's quality of life. Pain and swelling are common symptoms associated with VMs. With craniofacial lesions, cosmetic disfigurement may be more debilitating than functional limitations [3, 4] often leading to psychological stress and feelings of embarrassment, anxiety, low self-esteem, and antisocial behavior. Moreover, these lesions are often associated with recurrent bleeding episodes. secondary infections and ulcerations. From these perspectives, the treatment of VMs is more than just a cosmetic concern.

Based on flow characteristics which are readily characterized by thrills, bruits and increased warmth; and based on USG findings and CT angiography, Vascular Malformations may be classified as:

(1) Low-flow lesions

- a. Capillary malformation
- b. Venous malformation
- c. Lymphatic malformation
- d. Mixed

(2) High-flow lesions

- a. Arterial malformation
- b. Arteriovenous malformations (AVMs)
- c. Arteriovenous fistulae (AVF)

Conventionally, VMs have been managed surgically with or without embolization. The procedure is often cumbersome, time consuming and associated with technical difficulties and complications, such as inadvertent injury to important head and neck structures, intraoperative bleeding and exsanguinations.

Though newer modalities of treatment of vascular lesions have been added to the options available, such

as Cryosurgery, compression, radiation, flash lamp pulsed laser, intralesional injection of fibrosing agents, interferon alpha-2b electrocoagulation and radiofrequency ablation [5-7], laser therapy [8-10] and so on, the older, time tested techniques *i.e.* percutaneous / permucosal Sclerotherapy and Microembolization [11] are still the mainstay in the treatment of these difficult lesions making them more amenable to easier surgical excision.

Sclerotherapy is a simple, popular, minimally invasive and cost effective procedure, widely used in the management of hemorrhoids, superficial lower extremity telangiectasias and venous abnormalities such as varicose and reticulate veins [12]. It has also found to be effective in craniofacial been haemangiomas [13]. For smaller lesions, Sclerotherapy by itself can lead to a complete cure, while for larger lesions, it may facilitate surgery by reducing lesion size and minimizing intraoperative blood loss [14-16]. It involves the direct injection of a small amount of an irritant solution / sclerosant into the abnormally dilated vessels and applying local compression to maintain the contact of the intravascular solution with the endothelial cells. Over the years, various sclerosants have been employed, such as sodium tetra decylsulphate, 5% phenol, sodium morrhuate, nitrogen mustard, boiling water, sodium psylliate, sodium citrate, invert sugar, absolute alcohol, hypertonic saline or hypertonic dextrose

In our study a total of ten cases of Vascular Malformations (VMs) were managed. Of them, five were superficial, low flow VMs which were treated by a monotherapy technique, using intralesional Polydocanol sclerotherapy alone; and the remaining five were high flow, deep set VMs, which were treated by a bi-therapy technique, using neoadjuvant sclerothrombotic hot water instillation in two cycles, followed by surgical excision of the lesion.

The aim of this study was to assess the efficacy of single session Polydocanol Sclerotherapy in the management of superficial cutaneous and mucosal VMs in maxillofacial region, in terms of reduction in size or complete resolution of the lesion, time taken for resolution and incidence of complications and of recurrence; and to assess the efficacy of hot water scleothrombosis followed by surgical resection in the management of deeper vascular malformations of the maxillofacial region, including incidences of complications and recurrence. The purpose of the study was to thereby, to evaluate the utility of these two

different management protocols for the two different types of VMs.

1. METHODS

This study was carried out at our Centre and included cases treated between 2010 and 2016. The inclusion criteria were Vascular Malformations involving the soft tissues of the maxillofacial region. These included low flow as well as high flow Vascular Malformations involving both superficial as well deeper soft tissues. Patients with other diagnoses *i.e.* intraosseous venous malformations and haemangiomas were excluded from this study. A total of ten patients (two male and eight females) were included in the study. The mean age range was from 28 to 52 years. The patient details are summarized as per Table **1**.

Pre-operative assessment in each of the cases included history and clinical presentation, aided by Magnetic resonance imaging study and Ultrasound color Doppler study of the lesions, which led to a provisional diagnosis of a Venous malformation in all of these cases. FNAC could not be carried out in any patient as even a mild probing gave rise to an immediate and ready ooze of blood. In all the patients, PT, pTTK and INR levels were all within normal limits as was the remaining blood and urine profile. The patients were neither diabetic nor hypertensive. Ultrasound Colour Doppler study was carried out in each case and demonstrated slow (Group A patients) and high flow lesions (Group B patients), consisting of anomalous channels suggestive of vascular malformations. In addition, MRI (T1 & T2 weighted images with Fat Suppression and Fat enhancement, respectively) in each case, showed a space occupying lesion.

There was no randomization of allocation, but rather the Patients were selected and placed into two Groups, depending upon the presentation and characteristics of their VMs, such as the flow pattern, extent and depth of the lesions. Patients with relatively superficial mucosal/cutaneous, easily accessible lesions were placed in Group A, while those with deep set, high flow lesions were placed in Group B.

Group A patients were treated by single session sclerotherapy using intralesional injection of Polydocanol in an Outpatient setting. Informed written consent was obtained from each patient of Group A for intralesional sclerotherapy using Polydocanol.

Whenever possible, the lesion (Figure **1 A**, **B**, **C**, **D**); (Figure **4 A**, **B**) was first isolated using black braided silk sutures to prevent sclerosant spill, reducing its diffusion into adjacent unaffected tissues, and also to prolong its contact with the endothelial cells of the abnormal vascular channels (Figure **1 C**, **D**). Immediately the lesion was found to become engorged and enlarged in size (Figure **1 C**, **D**). 2-3cc of undiluted Polydocanol (2-3mg), depending upon the size of the lesion, was slowly injected into the sides as well as the center of the lesion, using 1 cc syringes, after first infiltrating the area with a local anesthetic. Immediately following the injection, the lesion swelled and became tense (Figure **1 E**, **F**). A mild ooze of blood was noted from the permucosal / percutaneous puncture sites, which soon stopped after application of local pressure



Figure 1: A, B A well demarcated, deep bluish - purple, raised, irregularly shaped, friable and pebbly surfaced patch on the right buccal mucosa, which was continuous with the buccal vestibule and its reflection into the alveolar and gingival mucosa in the right upper posterior quadrant. **C, D** Lesion observed to become engorged and enlarged in size immediately following its isolation using black braided silk sutures, performed to prevent sclerosant spill into the adjacent unaffected mucosa. **E, F** 3cc of undiluted Polydocanol (3mg) was slowly injected into the sides as well as the center of the lesion.

over the area for 3 minutes. The silk sutures were left in situ. The patients were put on anti-inflammatory and analgesic medications for five days and cold compress was advised externally over the region.

All patients were followed up for a period of one to



Figure 2: A, B, C, D Intraoral necrosis and sloughing of mucosal tissue at the site of sclerosant injection, and considerable local edema and swelling of the cheek seen after 5 days of the single session sclerotherpy. E, F, G, H By the third week, the area of whitish grey slough was restricted to the center of the area and the swelling of the cheek and lips had regressed. I, J, K, L Complete elimination and total resolution of the vascular lesion by the fourth week following the single session Sclerotherapy, with practically no evidence of it in the healed buccal as well as alveolar and gingival mucosae. No residual scarring or discoloration was evident.



Figure 3: Ultrasound Colour Doppler of the right cheek performed **A** One month after Sclerotherapy; and **B** Two months after sclerotherapy, showing reduction in size of the hypo-echoic region as well as diminished vascularity within it, indicative of successful resolution of the VM.

five years and there was nil recurrence of the vascular lesions (Figure **3**, **4**, **5**).

Group B patients with more extensive, deeper, high flow lesions, were managed first by sclerothrombosis



Figure 4: A, B Isolation of the VM of the upper lip followed by injection of 1cc of undiluted Polydocanol (1mg) in the center of the lesion. **C, D** One week following sclerotherpy, showing necrosis and sloughing in the region of the lesion and edema and swelling in the surrounding areas. **E, F** Reduction in the swelling, with just a healing crust remaining in the region of the lesion, at the end of two weeks. **G, H** Complete resolution and disappearance of the VM by the end of the third week.



Figure 5: A, B, C VM of the nose in a 45 year old patient. D, E, F 4 weeks following Single session Sclerotherapy with Polydocanol, showing a complete resolution and elimination of the lesion.

with hot water (2 cycles, depending upon the size of the lesion) followed by its surgical excision under General Anesthesia, within 72 hours of the injection **(Figure 6, 7).** Written Informed Consent was obtained from each patient of Group B, for the above treatment protocol employed.

RESULTS

There was complete resolution of the vascular lesions in all patients in Group A as well as Group B. All patients were followed up for a period of one to five years and there was nil recurrence of the lesions, except in one case of Group B.

In all the Group A patients, there was a complete and absolute resolution of the vascular lesion by the fourth week following the single session Sclerotherapy, with practically no evidence of the lesion following treatment (Figure 2 I, J, K, L; Figure 3; Figure 4 G, H). Successful results with this modality of treatment were obtained even with Cutaneous vascular malformations over the face (Figure **5**), with complete resolution of the lesions.

The imaging modalities, such as Magnetic Resonance Imaging and Ultrasound Colour Doppler were of immense value in not only in confirming the diagnosis, but also helped to evaluate the efficacy of the treatment rendered (Figure **3**).

Incidence of Complications: In all cases of Group A, on the fourth or fifth day following sclerosant injection, there was observed considerable local edema and swelling in the region of the lesion (Figure **2 C**, **D**), with necrosis and sloughing of mucosal tissue from it (Figure **2 A**, **B**). Pain was not severe and was effectively managed with analgesics. The patients were also started on a course of antibiotics. By the second week, the swelling, inflammation and sloughing of tissues began to subside and by the third week, the swelling had completely regressed with an area of whitish slough restricted to the center of the area (Figure **2 E**, **F**, **G**, **H**). In some cases, just a healing



Figure 6: A Middle aged female patient presented with a diffuse swelling in the Right Submandibular region. **B, C** CT-Angiogram showing a vascualr lesion involving Facial and Lingual arteries. **D** Post Hot water injection. **E, F, G** Submandibular approach for excision of the lesion and ligation of the feeder vessels. **H, I** Two years Post-op appearance. **J, K, L** Two years Post-op CT Angiogram.

crust remained at the end of two weeks (Figure **4 E, F**). Thereafter, healing took place completely within a period of one to three months, with no residual evidence of the lesion.

In all patients of Group B, clinically satisfactory results were obtained post operatively. All patients were followed up from one to five years post treatment, and all of them remained asymptomatic with no evidence of recurrence, except in one patient in whom there was a recurrence seen in the third postoperative year. There were nil immediate or late post-operative complications.

Histopathological examination of excised specimen revealed numerous irregularly dilated vascular channels lined by a single layer of flattened endothelial cells, dispersed within fibro-collagenous connective tissue stroma, consistent with the diagnosis of Vascular Malformations (Figure **7**).



Figure 7: A Painless, bulbous, soft swelling, 3.0x2x1.5cm in size, present since childhood, showing a recent increase in size over the past six months, following the use of Oral contraceptives. **B** 72 hours following intralesional instillation of Hot water, showing a decrease in size of the swelling. **C, D, E** Excision of the mass. **F** 2yrs postoperative appearance, showing no recurrence of the lesion.



Figure 8: A, B H&E (X 200) Histopathological examination of excised specimen from lower lip. C, D H&E (X 500) Numerous dilated vascular channels lined by flattened endothelial cells, scattered in the fibro-collagenous Connective tissue stroma.

2. DISCUSSION

Management of a VM depends on several factors, such as its flow characteristics, depth, location and anatomical site, extent of involvement and proximity of other structures in the region These [18]. characteristics dictate the choice of the treatment modality to be employed i.e. sclerotherapy, sclerothrombotic therapy, microembolism, surgery etc.

An intralesional Sclerosant on injection, causes marked tissue irritation and necrosis, localized inflammatory reaction with swelling, disruption and destruction of the endothelium of the vessel wall, causing platelets and cellular debris to attach to the lining of the vessels, followed by formation of an intravascular coagulum leading to obliterative thrombosis of the blood vessel [19]. Subsequently, fibrosis of the vascular endothelial spaces takes place, eventually leading to disappearance of the treated vessels by histiocytic digestion, with consequent regression of the lesion and tissue contraction [19]. There are no contraindications to this modality of treatment other than a previous known history of allergic reaction to the sclerosant solution.

Advantages of sclerotherapy are that it is a simple and inexpensive procedure, entailing no loss of blood, and that it can be carried out on an outpatient basis with no need for hospitalization and with a minimal armamentarium. Disadvantages are occasional anaphylactic reactions, post-operative pain and burning sensation, local swelling, inflammation and tissue necrosis, peripheral nerve injury, hemoglobinuria, thromboembolism, infection and delayed muscle fibrosis [20, 21]. Its application should always be carried out in the center and deeper portion of the lesion in order to avoid extensive tissue necrosis of adjacent normal areas [22]. This care was taken during the application of the sclerosing agent in the present case series.

Boiling water sclerothrombosis acts by releasing heat energy that destroys the anomalous vascular tissues. The heat energy adversely affects the vascular endothelial tissues leading to disruption, necrosis and obliteration of the vessel's lumina, which promotes coagulation of blood eventually leading to collapse and blockage of the channels in the anomalous angiomatous tissues with subsequent destruction of these vessels [23]. Since water has no sclerosing properties per se, the injection of the same heated, intralesionally, acts primarily due to the heat injury and therefore produces a much lesser inflammatory response of the surrounding tissues.

In our study, five patients with superficial mucosal/cutaneous low flow vascular malformations, (placed in Group A), were managed using intralesional Polydocanol monotherapy injections. This sclerosant is a mixture of ethers, macrogols, and fatty alcohols that induces endothelial damage through multiple mechanisms. Its clinical efficacy is equivalent to Sodium Tetradecyl Sulfate (STS) but with less severe adverse effects [26]. Furthermore, due to its anesthetic effect, it does not cause much pain [27].

The major issue in the management of a high flow VM is the difficulty in restraining the intralesional sclerosant / thrombotic / embolization agent within the lesion. The high blood flow through the lesion tends to flush out the sclerosant into the surrounding areas [28], thus reducing its efficacy and also risking collateral damage to the adjacent structures e.g. skin, eyes etc. In order to avoid these deleterious effects of agents like Sodium tetradecyl-sulphate and Polydocanol in the management of high flow VMs, hot water proves to be more efficacious in terms of (a) a rapid onset of action, which is heat dependent endothelial damage, thus instant intralesional coagulation; (b) promoting minimum collateral damage as the hot water quickly loses heat on injection into the lesion and the damage due to the outflow from the lesion is minimal [29]. However, due to limited necrosing property of hot water, its use as a standalone therapy in management of such lesions may inefficacious, coupled with the fact that the high flow VMs tend to guickly develop collateral circulation on disruption of flow through the lesion.

In this study, the five patients in whom the VMs were larger and deep-seated, with high flow characteristics demonstrated as by Doppler examinations, (placed in Group B), were managed using hot water injection into the lesion, followed by surgical excision later. Sclerotherapy alone would not have sufficed, as there was a need for a more encompassing technique that would not only collapse and obliterate the abnormal blood vessels to avoid undue hemorrhage, but also extirpate the residual fibrosed tissues. Two hot water injections were given over a period of 24 hours and the lesion was surgically removed within 72 hours of initiation of therapy. All these five cases were those of high flow VMs involving the facial and / or lingual artery. There was complete

Age/ Gender	Site & Extent of Lesion	Clinical Features	Inv	Diag	Treatment Carried Out	Follow up / Recurrence
1. 32/F	Right buccal mucosa & vestibule extending anteriorly upto the angle of the mouth and posteriorly upto the second molar region; reflecting superiorly into the alveolar and gingival mucosa of the right upper posterior quadrant.	Well demarcated and distinct, bluish purple patch, with scattered elevated deep red speckled spots giving the lesion a pebbled appearance. Persisted throughout childhood, adolescence and adulthood, without any rapid increase or decrease in its size. Occasional pain and recurrent episodes of bleeding from the region.	Doppler, TBC, PT, PTTK-MB, INR	Low flow VM	Single session sclerotherapy using 3cc of Polydocanol injected transmucosally into sides and center of lesion.	3 Yrs. No recurrence
2. 45/M	Right side of the nose, extending from the bridge halfway down to the ala, and from nasolabial fold to the midline.	Longstanding, painless, well demarcated raised, deep purplish lesion with a pebbly texture which blanched on pressure. Present since childhood, slowly increasing in size over the years. It bled profusely on occasions.	Doppler, TBC, PT, PTTK-MB, INR	Low flow VM	Single session percutaneous injection of 2cc Polydocanol into the sides as well as center of lesion	2 Yrs. No recurrence
3. 35/F	Vermilion of Upper lip.	A longstanding outgrowth on the upper lip, 0.5X0.5cm in size, which bled repeatedly on minor trauma.	TBC, PT, PTTK-MB, INR	Low flow VM	Single session percutaneous injection of 2cc Polydocanol in center of lesion	1 Yr. No recurrence
4. 42/F	Right submandibular region	Painless, pulsatile, soft swelling, 1.0X2X1.8cm in size, present since childhood and gradually increasing in size. Multiple arterial and venous channels noted within the region on USG.	USG, CT angiography, OPG, TBC, PT, PTTK, INR	High Flow VM involving the facial artery	Sclerothrombosis using hot water x 2 cycles followed by surgical excision via submandibular approach	3 Yrs Diffuse recurrence noted in the 3 rd yr. Slower growth.
5. 28/F	Right Infraorbital region	Longstanding, diffuse, painless, soft pulsatile swelling,	CT angiography, OPG, TBC, PT, PTTK, INR	High Flow VM involving the facial artery	Sclerothrombosis using hot water x 2 cycles followed by surgical excision using submandibular approach	3 Yrs. No recurrence
6. 29/F	Lower labial mucosa, from one corner of the mouth to the other, extending down to the depth of the labial vestibule.	Deep bluish-purple raised patch, with distinct margins. Longstanding, present since childhood, slowly increasing in size, with a recent sudden spurt in growth corresponding with the beginning of use of Oral contraceptives by the patient.	Doppler, TBC, PT, PTTK-MB, INR	Low flow VM	Single session sclerotherapy using 3cc of Polydocanol injected permucosally into sides and center of lesion.	3 Yrs. No recurrence
7. 31/F	Rt preauricular region, 3cm in diameter	Painless, mildly raised, purplish patch with a grainy texture, blanching on pressure. Present since infancy, persisting into adolescence and adulthood, increase in size commensurate with growth of the patient.	Doppler, TBC, PT, PTTK-MB, INR	Low flow VM	Single session percutaneous injection of 2cc Polydocanol into the sides as well as center of lesion	1 yr. No recurrence
8. 45/F	Left submandibular region	Painless, pulsatile, soft swelling, 2.0x2x1.5cm in size, present since childhood and gradually increasing in size. Multiple arterial and venous channels noted within the region on USG.	USG, CT angiography, OPG, TBC, PT, PTTK, INR	High Flow VM involving the facial and lingual arteries	Sclerothrombosis using hot water x 2 cycles followed by surgical excision via visor approach <i>i.e.</i> Risdon's along with submandibular approach	5 yrs. Nil recurrence

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9. 32/F	Lower Lip	Painless, bulbous, warm, soft swelling, 3.0x2x1.5cm in size, present since childhood, showing a recent increase in size over the past six months, following the use of Oral contraceptives.	USG, CT angiography, OPG, TBC, PT, PTTK, INR	High Flow VM involving the Facial and labial arteries.	Sclerothrombosis using hot water x 2 cycles followed by surgical excision.	3 yrs. Nil recurrence
10. 55/M	Upper Lip	Painless, pulsatile, soft swelling, 1.0x2x1.5cm in size, present since childhood, increasing with advancing age.	USG, CT angiography, OPG, TBC, PT, PTTK, INR	High Flow VM involving the labial artery.	Sclerothrombosis using hot water x 2 cycles followed by surgical excision.	3 yrs. Nil recurrence

resolution of all the five lesions, except for one which showed a mild recurrence after two years.

CONCLUSION

Based on our experience we conclude that Sclerotherapy. which is relatively а simple. conservative and inexpensive therapy, can be safely and effectively used in superficial low flow lesions of the maxillofacial region. For patients with larger, deepseated and high flow vascular malformations. intralesional sclerothrombosis using hot water in two cycles followed by surgical excision within 72 hours of the intralesional therapy is recommended as a definitive treatment, having proved to be effective in management of such lesions, without the need of any sophisticated equipment. However, considering the challenging and ominous nature of these lesions, larger studies may be undertaken to corroborate these findings and employ it as an established protocol.

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