Role of Polidocanol as Sclerosant in Treatment of Hemangiomas of Head and Neck Region

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ABSTRACT

Introduction
Haemangiomas are common presentation in head and neck, prevalence being 60% followed by 25% and 15% respectively in trunk and limbs. This report studies the efficacy of Polidocanol as sclerosant in the treatment of hemangiomas in head and neck.

Materials and Methods
The two year prospective study conducted from January 2015 to December 2016 with Polidocanol as sclerosant on 55 patients attending the department of ENT. Intralesional injections of 3 % polidocanol were given at 2 week intervals.

Results
Out of 55 patients 15 cases did not follow up after the first dose, so results were calculated out of 40 patients. 12 patients showed complete regression & 15 showed regression to half the size. Thus 67.5 %patients showed acceptable results. There were no side effects except hyperpigmentation in 2 patients. There were no cases of recurrence during our study period.

Conclusion
Sclerotherapy is a promising method of treatment for haemangiomas of head and neck that may obviate the need for surgical intervention.

Keywords
Sclerotherapy ; Hemangioma ; Polidocanol

Hemangioma is benign developmental abnormality of blood vessels due to proliferation of endothelial lining of blood vessels. Hemangioma is usually not seen at birth. A majority of hemangiomas appear during the first 6 weeks of life. These lesions occur more commonly in females, with a ratio of 3:1 (F:M). This tumor is also more frequent in whites than in blacks. Clinically, hemangioma is characterized by a rapid postnatal growth (the proliferative phase) for the first 8 to 12 months, followed by a slow regression over 5 to 8 years (involutive phase). Hemangioma in its proliferating phase is composed of rapidly dividing endothelial cells forming syncytial masses with or without lumens.

During the involutive phase, endothelial cell activity diminishes and the cellular parenchyma is replaced by fibrofatty tissue. The first sign of a hemangioma is a macular patch that blanches on pressure or a localized area of telangiectasia surrounded by a halo. Rarely, a fully-grown hemangioma is present at birth. Eighty percent of hemangiomas occur as an isolated lesion, whereas 20% are multiple hemangiomas.

The most common site is the head and neck region (60%), followed by the trunk (25%), and then the limbs (15%). Cutaneous hemangiomas are superficial (capillary) in approximately 60% of cases and deep (cavernous) in 15% of cases.

Most hemangiomas in the head-and-neck region grow as small tumors and invariably regress, leaving inconsequential skin changes. Clinical studies confirm that complete resolution of hemangiomas occurs in over 50% of children by age 5 years and in over 70% by the age of 7 years, with continued improvement in
the remaining children until ages 10 to 12. Typically, the skin after involution exhibits mild atrophy, or it may have a wrinkled quality, or a few telangiectatic vessels. The skin may be slightly pale than normal skin. Treatment is indicated for those lesions that do not regress. Besides surgical excision, various approaches like Laser, photocoagulation therapy, cryotherapy, thermocoagulation, corticosteroids, interferon alpha 2a and sclerotherapy have been in use.\textsuperscript{1,2,3}

Intralesional injection of sclerosants is one of treatment modalities for haemangiomas, which causes damage of blood vessels followed by their obliteration. Polidocanol has been used for years in the treatment of haemangiomas and varicose veins (as 3%, 1% or 0.5%)\textsuperscript{3,4,5,6} but the gold standard treatment for small circumscribed lesions or peripheral hemangiomas is surgical excision.\textsuperscript{7} Sclerotherapy is used because of its effectiveness, ease to application, inexpensive nature and ability to conserve the surrounding tissues\textsuperscript{8} with the aesthetic benefit, where surgery could leave unpleasant scarring.\textsuperscript{1,5,9} This prospective clinical study was undertaken to evaluate the efficacy of sclerotherapy with polidocanol (3%) injection in treatment of hemangiomas of head and neck region.

**Materials and Methods**

The study was conducted in the department of ENT. Study period was from January 2015 to December 2016. Total no of cases studied is 55. Fifteen cases were lost in follow up after the first dose, so results were calculated out of 40 patients.

Polidocanol 3% used as the sclerosing agent for treatment. Polidocanol has sclerosant and local anaesthetic effect too, hence the reason for almost painless sclerotherapy. Effect is directed mostly at the vein intima. It effects the intima, which causes fibrosis of the vessel and obliteration. Polidocanol is a safe drug as has been observed in our study. It causes thrombophlebitis of the vessels, thus leading to pain, tenderness and oedema at the site of the lesion. This subsides by the 2nd day. There is a remote possibility of the thrombus being dislodged which may lead to embolisation. So all the patients were hospitalized and kept under observation for 2 days after injection. In our study there was no incidence of embolism.

Diagnosis was done on basis of history, clinical examination and FNA. Ultrasonography was done for hemangiomas in external cheek and neck. Routine blood examination including TLC, DLC, ESR, Hb%, BT & CT was done for all patients.

Procedure: All patients of hemangioma were prepared for injection with 3% Polidocanol in ENT OT. Most of the patients did not require any anaesthesia. 10% lignocaine as surface anaesthesia was administered for lesions in oral cavity. General anaesthesia was required for 2 uncooperative paediatric patients. Intralional injections of 3 % polidocanol were given at 2 week intervals. Patients on follow up were observed for regression of swelling and subsequently called for further doses. They were also observed for any side effects like hyperpigmentation, periphlebitis, necrosis, discoloration of skin etc.

**Results**

Twenty five (45.45%) patients were under the age of 15 years, 19 patients (34.54%) were between 15 to 30 years and 11 patients (20%) were above 30 years of age. Thirty six patients in this series were females (65.5%) and 19 were males (34.5%).

The sites of the haemangiomas are are noted in Table I.

The number patients treated with single dose therapy were 27, whereas 12 patients received 2 doses, 9 patients received 3 doses, 2 patients received 4 doses and 5 patients needed 5 doses.

Out of 40 cases who were followed up, 12 patients (30%) showed complete regression of swelling. (Figs. 1&2) (Table II).

Two patients with past history of surgery came presented with recurrence of swelling. One of them had recurrence of haemangioma of left external auditory canal two months after surgery. He was given 1 dose of sclerosant and swelling completely regressed in size. Another patient had haemangioma of preauricular region on right side for 14 years. She had past history of surgery few years back. She was given two doses of sclerosant at 2 weeks interval. Swelling size reduced to
less than 1 cm and no further increase in size noted at subsequent follow up. (Fig. 3)

15 patients (37.5%) showed regression of swelling to half the original size (Fig. 4) and 11 patients (32.5%) showed <50% reduction in size of the lesion.

There were no side effects except hyperpigmentation in 2 patients. These two patients had haemangioma of right pinna and post auricular region respectively.

Each of them received 1 dose, showed regression of swelling, but with blackish discoloration of skin at the site of pedicle. These two patients were clubbed in the group showing less than 50% regression. There were no cases of recurrence during our study period.

**Discussion**

Most of the cutaneous vascular anomalies are haemangiomas, being more common in females. They are mainly superficial and present mostly on head and neck area followed by trunk.

Histologically, haemangiomas show plump endothelial cells with multilaminated basement membranes and numerous mast cells; immunohistochemistry demonstrates increased vitronectin, perlecan. The use of the immunohistochemical marker GLUT-1 to accurately distinguish haemangiomas (GLUT-1 positive) from vascular malformations has been advocated.

Up to 93% of haemangiomas are easily diagnosed without additional diagnostic tests. An ultrasound in experienced hands is a portable and available tool that can easily confirm a suspected haemangioma without additional testing. Doppler colour flow imaging is notable for its ability to distinguish between high-flow and low-flow lesions.

In our study majority of the lesions were between 5-8 cm and mostly uncomplicated, however ulceration and infections were observed in some cases especially those in oral cavity. The present study was conducted on 55 patients and only 40 patients had completed the

<table>
<thead>
<tr>
<th>#</th>
<th>SITES OF HEMANGIOMAS</th>
<th>NO. OF CASES</th>
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<tbody>
<tr>
<td>1.</td>
<td>Buccal mucosa</td>
<td>10 cases</td>
</tr>
<tr>
<td>2.</td>
<td>Cheek (external surface)</td>
<td>8 cases</td>
</tr>
<tr>
<td>3.</td>
<td>Tongue</td>
<td>17 cases</td>
</tr>
<tr>
<td>4.</td>
<td>Lip</td>
<td>6 cases</td>
</tr>
<tr>
<td>5.</td>
<td>Hard palate</td>
<td>3 cases</td>
</tr>
<tr>
<td>6.</td>
<td>Misc. (neck, post auricular region, pinna, external auditory canal etc)</td>
<td>11 cases</td>
</tr>
</tbody>
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Table 1: Site wise distribution of haemangiomas (N=55)

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Fig. 1. Hemangioma of tongue (left lateral surface) received 5 doses and on follow up after 3 months showed complete regression (A)Before intervention (B) After 3 doses (C) After 5 doses
treatment and turned up for follow up. Out of 40 cases 12 (30%) cases showed complete regression of lesion, in 15 (37.5%) cases size of lesions regressed to half of original size and in 13 (32.5%) cases there was only slight regression in size of lesion. Agarwal in 2012 conducted one study in 20 cases of oral hemangioma and demonstrated high success rate by sclerotherapy with total regression of lesion in 19 cases and partial regression only in one case. Bhadoria et al have reported a case where they injected Polidocanol after diluting it with normal saline and observed regression with no complications. In our study we did not dilute the drug.

The study of Patel et al in 2015 on 10 cases of oral cavity haemangioma, shows satisfactory results with no severe complications, that is comparable to our study. Singh et al in 2012 reported a case of haemangioma tongue who was injected with polidocanol diluted with distilled water in the ratio 1:3. The patient experienced pain which was dealt with by giving oral analgesics. There was regression of swelling with no recurrence.

The surgical treatment has its own risks and advantages, similar to other treatment modalities. Advantage of surgical treatment is that, it allows for a complete surgical excision of the lesion and microscopical diagnosis but with the risks of excessive bleeding, functional impairment of vital functions such as swallowing, speech and airway. Recurrences are fairly common if complete excision is not done and

<table>
<thead>
<tr>
<th>NO. OF PATIENTS</th>
<th>SITE</th>
<th>NO OF DOSES</th>
<th>FOLLOW UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Left external auditory canal(POC)</td>
<td>1</td>
<td>2 months</td>
</tr>
<tr>
<td>1</td>
<td>Lower lip</td>
<td>5</td>
<td>3 months</td>
</tr>
<tr>
<td>2</td>
<td>Cheek</td>
<td>3</td>
<td>2 months</td>
</tr>
<tr>
<td>2</td>
<td>Cheek</td>
<td>4</td>
<td>3 months</td>
</tr>
<tr>
<td>2</td>
<td>Right cheek</td>
<td>5</td>
<td>3 months</td>
</tr>
<tr>
<td>1</td>
<td>Tongue(lateral surface)</td>
<td>5</td>
<td>3 months</td>
</tr>
<tr>
<td>1</td>
<td>Tongue(undersurface)</td>
<td>5</td>
<td>3 months</td>
</tr>
<tr>
<td>1</td>
<td>Neck</td>
<td>1</td>
<td>2 months</td>
</tr>
<tr>
<td>1</td>
<td>Right preauricular region(POC)</td>
<td>2</td>
<td>2 months</td>
</tr>
</tbody>
</table>

Table II: Complete regression of swelling
hence the need for non surgical modalities. Another treatment option for treatment of hemangioma is the laser therapy and Crisan et al (2010) demonstrated laser therapy as a more effective treatment of vascular lesion than sclerotherapy procedure\cite{14} but Witman et al (2006) demonstrated the different complications from laser treatment of hemangiomas, including pain, ulceration, scarring or hyperpigmentation, skin atrophy and even life threatening bleeding.\cite{15}

Sclerotherapy with polidocanol is a minimally invasive modality of treatment with negligible side effects. Patient compliance is high with very little or no morbidity. No anaesthesia is required for most patients and hospital stay is also reduced. Also with sclerotherapy there are no risks of scarring when we compare with surgical management.

In our study, there were variations in number of injections according to the type and size of lesions, single dose therapy was given to 27 cases and maximum five doses given to five cases. Resmije A.A. et al (2016) mentioned two sessions of injections for the treatment of superficial hemangioma.\cite{13}

Winter et al in 2000 published their experience with 132 patients with cavernous hemangiomas treated by

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Fig. 2. Hemangioma of tongue (undersurface) received 5 doses and on follow up after 3 months showed complete regression (A) before intervention (B) after 3 doses (C) after 5 doses

Fig. 3. (A) Recurrent haemangioma of right pre auricular region (B) received 2 doses and showed complete regression on follow up after 2 months

Fig. 4. Hemangioma of lip (A) after receiving 3 doses showed reduction of swelling to half the original size (B)
Polidocanol and demonstrated a satisfactory response and requiring only one to three injections.6 The quantity of the drug and number of applications (doses) during the sclerotherapy treatment depend on the size and location and involvement of adjacent structures and results should be evaluated before the next dose.1,4,5

Conclusion

It is apparent that sclerotherapy is a valuable treatment option in the management of head and neck hemangiomas. As experience grows, its use will become more commonplace. Sclerotherapy with 3% polidocanol is a safe, effective and inexpensive method. It is a valuable and promising treatment of hemangiomas and may obviate the need for any surgical treatment.

References


