



Sclerotherapy with Polidocanol Foam is a Promising Perspective Treatment for Pyogenic Granuloma: A Retrospective Analysis in 52 Cases

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Abstract

Purpose: Sclerotherapy with polidocanol foam has frequently been used for the chronic venous disease, hemangiomas and other vascular malformations, but less report on the evaluation of pyogenic granulomas has been documented. The aim of this study was to evaluate the efficacy and safety of the sclerotherapy with polidocanol foam for pyogenic granulomas.

Patients and Methods: In this study, we summarized our experiences of treating 52 patients with pyogenic granuloma by local injection of 1% polidocanol and evaluated the curative effect and safety. The follow-up period after treatment ranged from 5 months to 18 months and the median duration was 9 months. Descriptive statistics were computed.

Results: 51 of the 52 patients received complete removal of the tumor, without exudation, pigmentation and scarring. Follow-up 5-18 months, 1 of the 51 patients showed lesion recurrence and other 50 patients have reached the standard of cure. No bleeding or infection was found in the wound and no noticeable scar was observed.

Conclusion: Our study indicated that sclerotherapy with polidocanol foam achieved considerable response with low recurrences rate and no complications and is a promising perspective treatment for pyogenic granuloma.

Keywords: Pyogenic granuloma; Sclerotherapy; Polidocanol; Effectiveness

Introduction

Pyogenic Granuloma (PG) is a kind of benign vascular tumor which manifests as a smooth glistening papule in red or purple color. It usually occurs on the gingiva, lips and fingers and can grow rapidly within days or weeks. Many different treatment options for PG have been used, including traumatic approaches, for example, surgical excision, cryosurgery, cautery with electrodesiccation, and laser therapy, which may lead to scar, pain and pigmentation complications; meanwhile, nonsurgical treatments have been attempted, for example, imiquimod, silver nitrate, topical beta-adrenergic receptor antagonists, dictated by the size and location of PGs, for which the high recurrence rate is hard to avoid [1]. Sclerotherapy with Polidocanol (POL) foam has frequently been applied on the chronic venous disease, hemangiomas and other vascular malformations. It causes anesthetic effect by endothelial cell damage and obliteration of vessel Lumina. Moreover, it has no significant risk of damage to the surrounding tissue [2,3]. However, very few reports documented the role of POL foam in the treatment of PGs. To solve this issue, in this study, we summarized our experiences of treating patients with pyogenic granuloma by local injection of 1% polidocanol, which demonstrated a promising perspective for these cases.

Patients and Methods

Study Design

The study was performed at the Department of Oral and Maxillofacial Surgery, Shanghai Ninth People's Hospital, College of Stomatology, Shanghai Jiao Tong University School of Medicine. 52 patients with a clinical diagnosis of pyogenic granuloma were included and they have received

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corresponding treatment between March 2015 and September 2018. This study was carried out in accordance with the recommendations of the Declaration of Helsinki. The protocol was approved by the Institute Review Board of Shanghai Ninth People's Hospital. All subjects gave written informed consent in accordance with the Declaration of Helsinki for the participation in the study, and the publication of identifiable images.

Treatment regimen

All patients were given 1% POL (Aethoxysklerol, Chemische Fabrik Kreussler & Co. GmbH, Wiesbaden, Germany) in the form of foam. The sclerosing foam was provided on-site by the Tessari method [4] using a three-way stopcock. The POL liquid and the air were filled into two syringes separately by a ratio of 1:1. After multiple passages of mixing between the two syringes, the stable sclerosing foam was obtained. The sclerosing foam was then implanted slowly into the lesion's base until blanching was observed. Local anesthesia or compressive dressing was not applied. All the procedure was operated by one specific clinician to keep the homogeneity.

Outcome measurement

Patients were required to return one month after the treatment. Two most experienced clinicians evaluated the outcomes of each patient and classified them as resolution, no improvement, and deterioration. Patients that were not identified as resolution will take the injection of POL foam for the second time. If no further improvement was achieved after the second injection, they will be referred to other treatments. The follow-up period after treatment is ranged from 5 months to 18 months and the median duration was 9 months.

Statistical analysis

We used SPSS software package (version 16.0; SPSS, Chicago, IL) and R program for analysis. The clinical features as well as therapeutic outcomes of all patients were depicted in numbers, percentages, or means ± standard deviations.

Results

Clinical and histological features

A 52 patients including 27 females and 25 males with PG were included in this study. Specifically, the age range of all patients is varied from 11 months to 74 years-old and the mean age at diagnosis was 26. Among the 52 patients of PG, 26 lesions (51.61%) were facial, 12 (22.58%) were on the lip and oral cavity, 6 (9.68%) were on the scalp, 7 (12.90%) were on the extremity and 1 (3.23%) was on the trunk. Furthermore, the diameter of 23 (41.94%) lesions was less than 2 mm, 22 (48.39%) lesions were between 2 mm and 4 mm, and 7 (9.68%) lesions were larger than 4 mm. Among all PGs, 26 (50.00%) patients had bleeding history while 26 (50.00%) had no symptom. Most patients (42 patients, 90.32%) have unknown etiology, except 9 patients (6.45%) had trauma history and 1 patient (3.23%) had irritation history. Detailed clinical characteristics were summarized in Table 1.

Therapeutic outcomes

A 51 of the 52 patients (98.08%) received complete removal of the pyogenic granuloma after one (43 patients) or two (8 patients) times of injection. At the first few days after treatment, the tissue was swollen around the tumor. After about 7 days, the swelling was relieved, and the tumor was in reddish brown before it fully exfoliated within one month. As a result, 1 of the 51 patients showed lesion

Table 1: Clinical characteristic of patients.

Clinical characteristics	N	%
Gender		
Female	27	51.92
Male	25	48.08
Symptom		
Bleeding	26	50.00
Asymptomatic	26	50.00
Size		
<2 mm	23	44.23
2 mm-4 mm	22	42.31
>4 mm	7	13.46
Location		
Face	26	50.00
Lip and oral cavity	12	23.08
Scalp	6	11.54
Extremity	7	13.46
Trunk	1	1.92
Etiology		
Trauma	9	17.31
Irritation	1	1.92
Unknown	42	80.77
Total	52	

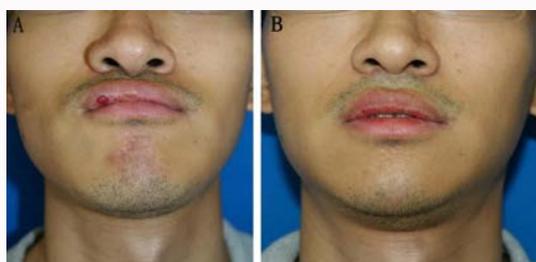


Figure 1: The response to sclerotherapy with POL foam of PG on the upper lip in a 22-year old male patient. (A) Before treatment; (B) 1 month after treatment.



Figure 2: The response to sclerotherapy with POL foam of PG on the cheek region in a 16-year old female patient. (A) Before treatment; (B) 3 month after treatment.

recurrence and the other 50 patients have reached the standard of cure, without exudation, pigmentation and scarring. While for 1 of all the 52 patients, there was residual lesion left and the tumor was removed through surgical excision. The follow-up period after treatment is ranged from 5 months to 18 months and the median duration was 9 months. No bleeding or infection was found in the wound and no noticeable scar was observed. All patients had no

significant discomfort during and after treatment. Typical images with excellent response were shown in Figure 1 and 2.

Discussion

PG is a kind of benign vascular tumor which is often found on lips, gingiva, and fingers. It manifests as a smooth glistening papule in red or purple color and can grow rapidly grow within days or weeks. According to previous research, possible causes of PG are trauma, irritation, as well as changes in hormone levels. In our study, only 9 patients (6.45%) had trauma history and 1 patient (3.23%) had irritation history and there was no case related to pregnancy. PGs have been treated by many different approaches, including destructive approaches such as surgical excision, cautery with electrodesiccation, cryosurgery, and laser therapy. Although these methods can remove the tumor immediately, they would inevitably lead to pain, scar and pigmentation as potential complications. Meanwhile, bleeding is not rare during the surgery and recurrence rate is quite high. Nonsurgical treatments have been reported a lot, for example, imiquimod, silver nitrate, and sclerosants depending on the size and location of PG. Application of topical beta-adrenergic receptor antagonists is also reported recently [5-9]. However, the duration of the treatment is too long to get aesthetic improvement for patients with PGs on their face or other exposed parts of the body, and thus increases the risk of bleeding.

Sclerotherapy has been reported as a useful approach for PG. In 2001 Matsumoto reported the treatment of PGs by local injection of the monoethanolamine oleate solution in nine patients [10]; Hong reported 16 cases of PG who were treated using ethanolamine oleate sclerotherapy [11]. Nevertheless, general anesthesia is required because intravascularly injection causes pain for those sclerosants. Another disadvantage is that the surrounding soft tissue necrosis might happen due to the extravasation. Moreover, some serious complications, e.g. nerve damage, lung embolism, pulmonary vasospasm, and heart arrhythmia have been reported with the use of ethanol. Sclerotherapy with Polidocanol (POL) foam, acting through endothelial cell damage and obliteration of vessel lumina, has frequently been used for chronic venous disease, hemangiomas and other vascular malformations [2,3]. It can cause irreversible damage to the vascular endothelium by disrupting cell membranes and result in sustained vasospasm and the denudation of the venous monolayer [12]. POL is a mixture of ethanol (5%) and hydroxy polyethoxy dodecane (95%) and was first used as a topical and local anesthetic. Since 1960s, it is frequently used as a sclerosing agent due to its ability to sclerose blood vessels without a significant risk of damage to surrounding tissue [13-15]. The recommended concentration range is 0.25% to 3% and has been reported to elicit fewer allergic and inflammatory reactions. Besides, the use of sclerosing foam improved the results of sclerotherapy as well as its safety [16-18]. In 2010 Dr. Carvalho reported the use of POL foam in the treatment of 7 patients of PG and completely removed PGs in 6 patients without recurrence and complications. However, few studies have reported the role of POL foam in the treatment of PG since then. In our study, we successfully cleared the lesion for most of the patients (98.08%), including more extensive lesions, using POL foam without complications. This provides new clues for the valuable alternative for the treatment of patients with PG. As a retrospective study, it was a nontrivial task to study the difference in treatment effects between different POL concentrations. In addition, due to the relatively small number of patients, it is also difficult to explain the relationship clearly

between the recurrence rate and the clinic characteristics. Therefore, prospective studies with adequate quantity of cases are planned in our future study. In conclusion, our study indicated that sclerotherapy with POL foam achieved considerable response with low recurrences rate and no complications and is a promising perspective treatment for PGs.

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References

- Wollina U, Langner D, Franca K, Gianfaldoni S, Lotti T, Tchernev G. Pyogenic Granuloma - A Common Benign Vascular Tumor with Variable Clinical Presentation: New Findings and Treatment Options. *Open Access Maced J Med Sci.* 2017;5(4):423-26.
- Star P, Connor DE, Parsi K. Novel developments in foam sclerotherapy: Focus on Varithena(R) (polidocanol endovenous microfoam) in the management of varicose veins. *Phlebology.* 2018;33(3):150-62.
- de Moraes Silva MA, Ferreira RG, de Jesus-Silva SG, Cardoso RS, Miranda F, Jr. Effect of polidocanol foam administration into rat peripheral veins on pulmonary parenchyma. *Phlebology.* 2018;33(2):122-7.
- Tessari L, Cavezzi A, Frullini A. Preliminary experience with a new sclerosing foam in the treatment of varicose veins. *Dermatol Surg.* 2001;27(1):58-60.
- Oke I, Alkharashi M, Petersen R, Ashenberg A, Shah A. Treatment of Ocular Pyogenic Granuloma With Topical Timolol. *JAMA Ophthalmol.* 2017;135(4):383-5.
- Wollina U, Langner D, Franca K, Gianfaldoni S, Lotti T, Tchernev G. Pyogenic Granuloma - A Common Benign Vascular Tumor with Variable Clinical Presentation: New Findings and Treatment Options. *Open Access Maced J Med Sci.* 2017;5(4):423-6.
- Baek Y, Kwon S, Jeon J. Combination of ligation and timolol before surgical excision of pyogenic granuloma. *J Am Acad Dermatol.* 2018;78(6):e141-2.
- Neri I, Baraldi C, Balestri R, Piraccini B, Patrizi A. Topical 1% propranolol ointment with occlusion in treatment of pyogenic granulomas: An open-label study in 22 children. *Pediatr Dermatol.* 2018;35(1):117-20.
- Piraccini B, Alessandrini A, Dika E, Starace M, Patrizi A, Neri I. Topical propranolol 1% cream for pyogenic granulomas of the nail: open-label study in 10 patients. *J Eur Acad Dermatol Venereol.* 2016;30(5):901-2.
- Matsumoto K, Nakanishi H, Seike T, Koizumi Y, Mihara K, Kubo Y. Treatment of pyogenic granuloma with a sclerosing agent. *Dermatol Surg.* 2001;27(6):521-3.
- Hong SK, Lee HJ, Seo JK, Lee D, Hwang SW, Sung HS. Reactive vascular lesions treated using ethanolamine oleate sclerotherapy. *Dermatol Surg.* 2010;36(7):1148-52.
- Bergan J. Sclerotherapy: a truly minimally invasive technique. *Perspect Vasc Surg Endovasc Ther.* 2008;20(1):70-2.
- Yura J, Hashimoto T, Tsuruga N, Shibata K. Bleomycin treatment for cystic hygroma in children. *Nihon Geka Hokan.* 1977;46(5):607-14.
- Blum RH, Carter SK, Agre K. A clinical review of bleomycin--a new antineoplastic agent. *Cancer.* 1973;31(4):903-14.
- Umezawa H, Maeda K, Takeuchi T, Okami Y. New antibiotics, bleomycin A and B. *J Antibiot (Tokyo).* 1966;19(5):200-9.
- Weitz-Tuoretmaa A, Keski-Nisula L, Rautio R, Laranne J. Quality of life after endovascular sclerotherapy of low-flow venous malformations: the efficacy of polidocanol compared with ethanol. *Acta Radiol.* 2018;59(8):946-952.

17. Sood A, Kotamarti VS, Therattil PJ, Lee ES. Sclerotherapy for the Management of Seromas: A Systematic Review. *Eplasty*. 2017;17:e25.
18. Ali H, Saleh M, Mohammed W. Efficacy and safety of Duplex-guided polidocanol foam sclerotherapy for venous malformations. *Int Angiol*. 2017;36(3):228-36.