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Monoethanolamine Oleate Sclerotherapy versus Surgical Excision in the Treatment of Oral Pyogenic Granuloma: A Randomized Clinical Trial

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العلاج بالتصليب باستخدام أحادي إيثانول أمين أوليات مقابل الاستئصال الجراحي في علاج الورم الحبيبي القيحي الفموي: تجربة سريرية عشوائية

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Abstract:
The objective of this study was to assess the therapeutic efficacy and patient tolerability of monoethanolamine oleate (EO) sclerotherapy as a minimally invasive alternative to conventional surgical excision for the management of oral pyogenic granuloma (PG). In this randomized clinical trial, fourteen patients with clinically confirmed oral PG were allocated into two equal groups. Group I (n = 7) received intralesional injections of 1.25% EO, whereas Group II (n = 7) underwent standard surgical excision. The primary outcome measure was complete lesion resolution at a two-week evaluation. Secondary outcomes included postoperative pain, quantified using a Visual Analogue Scale (VAS) over a 14-day period. Complete lesion resolution was observed in five of the seven patients (71.4%) treated with EO sclerotherapy, with four of these cases achieving resolution after a single injection. Compared with the surgical group, patients in the EO cohort demonstrated significantly lower postoperative pain scores ($p < 0.05$) at all measured intervals (days 2, 4, and 6). No adverse events or lesion recurrences were recorded during the follow-up period. Monoethanolamine oleate sclerotherapy represents a straightforward, efficacious, and well-tolerated treatment modality for oral pyogenic granuloma, offering a viable non-surgical alternative to conventional excision.

Keywords: Monoethanolamine oleate, Sclerotherapy, Surgical Excision, Oral Pyogenic Granuloma.

الملخص:
هدف هذه الدراسة هو تقييم الفعالية العلاجية وتحمل المرضى للعلاج بالتصلّب باستخدام أحادي إيثانول أمين أوليات (*EO*) كخيار غير جراحي لمعالجة الورم الوعائي القيحي الفموي (*PG*)، وذلك مقارنةً بالاستئصال الجراحي التقليدي. شملت هذه التجربة السريرية العشوائية أربعة عشر مريضًا تمّ تشخيص إصابتهم سريريًا بالورم الوعائي القيحي الفموي، وتم توزيعهم بالتساوي على مجموعتين. المجموعة الأولى (عدد = 7) تلقت حقنًا داخل الآفة بتركيز 1.25% من مادة *EO*، بينما خضعت المجموعة الثانية (عدد = 7) لعملية الاستئصال الجراحي التقليدي. كان المؤشر الأساسي للنتائج هو زوال

الآفة بشكل كامل بعد أسبوعين. وشملت المؤشرات الثانوية تقييم الألم بعد الإجراء باستخدام مقياس التناظر البصري (*VAS*) على مدى 14 يومًا. أظهر خمسة من المرضى السبعة (71.4%) الذين عولجوا بالعلاج بالتصلب باستخدام *EO* زوالًا كاملًا للآفة، وقد تحقق الشفاء في أربع حالات منهم بعد جلسة حقن واحدة فقط. كما سجل المرضى في مجموعة *EO* درجات ألم أقل بشكل ملحوظ ($p<0.05$) في جميع الفترات الزمنية المقاسة (اليوم 2، 4، 6) مقارنةً بمجموعة الجراحة. ولم تُسجَّل أي آثار جانبية أو حالات نكس خلال فترة المتابعة. يُعدّ العلاج بالتصلّب باستخدام أحادي إيثانولامين أوليات خيارًا بسيطًا وفعّالًا وذا قابلية تحمّل عالية من المرضى لعلاج الورم الوعائي القيحي الفموي، مما يجعله بديلًا غير جراحي واعدًا للاستئصال التقليدي.

الكلمات المفتاحية: أوليات مونوايثانولامين، العلاج بالتصليب، الاستئصال الجراحي، الحبيبات القيحية الفموية، علاج.

Introduction:

Oral pyogenic granuloma (PG) is a prevalent, benign vascular lesion distinguished by rapid proliferation and a significant tendency for hemorrhage [1]. It occurs as a reactive hyperplastic response to minor trauma, chronic irritation, or hormonal changes, with reported incidence of up to 5% in pregnant women [2, 3]. The gingiva is the main location, making up approximately 75% of all intraoral cases [4]. Surgical excision is the current gold standard for treating oral PG; while effective, it is invasive and can lead to postoperative discomfort, scarring, and requires local anesthesia [5]. Surgery is not always an option for patients with bleeding disorders or are receiving anticoagulant therapy. For these patients, there is increasing interest in conservative, non-invasive treatments. Sclerotherapy (the injection of an irritant solution to induce fibrosis and regression of vascular lesions) is gaining popularity. Solutions such as sodium tetradecyl sulfate have been used with good success [6]. Monoethanolamine oleate (EO) is a sclerosing agent that injures the vascular endothelium, causing thrombosis and fibrosis [7]. It is known to be safe for treating esophageal varices and peripheral vascular malformations [8]. However, there are not many reports in the literature about using it for oral PG, especially in a comparative study design. The clinical effectiveness of an injection of monoethanolamine oleate and the findings of the patients who had received this injection were evaluated, and the results were compared with those of patients who had undergone a conventional surgical excision of oral pyogenic granuloma.

Material and methods study Design and Ethical Considerations:

After obtaining approval from the Institutional Review Board of the Faculty of Dentistry, Alexandria University, a randomized clinical trial was conducted. All participants given written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

Patient:

Selection

Fourteen patients presenting with clinically diagnosed oral pyogenic granuloma (PG) were recruited from the outpatient clinic. Participants were selected based on the following criteria:

Inclusion Criteria:

1. Age between 20 and 45 years.
2. Clinical diagnosis of a pedunculated or sessile exophytic lesion consistent with PG.
3. Lesion size greater than 0.5 cm in its largest dimension.

Exclusion Criteria:

1. Known allergy to any component of monoethanolamine oleate.
2. Medical conditions contraindicating minor surgical procedures (e.g., uncontrolled bleeding diathesis).
3. Pregnancy or lactation.

Diagnosis was confirmed clinically based on history and examination (color, texture, tendency to bleed). For the test group, a small incisional biopsy was performed prior to injection therapy to confirm the diagnosis. For the control group, the excised specimen provided the histopathological confirmation.

Intervention Protocols:

Patients in the Sclerotherapy group (Group I) received intralesional injections of 5% Monoethanolamine Oleate (Ethamolin®). Using a 27-gauge dental needle, the solution was administered slowly until blanching of the lesion was observed and minimal reflux of the solution occurred at the injection site. The typical injection volume ranged from 1 to 2 mL The injection was performed without local anaesthesia. A second injection session was repeated after 15 days if complete resolution was not achieved. In group II (Surgical Control): Patients underwent conventional surgical excision under local anaesthesia.

Before treatment, all of the patients in both groups had scaling and root planing done and were given detailed instructions on how to keep their mouths clean.

Outcomes:

The main outcome was the full clinical resolution of the lesion during the 2-week follow-up. Secondary outcome measures included: Postoperative Pain: Evaluated with a 10-cm Visual Analogue Scale (VAS), where 0 indicated "no pain" and 10 indicated "worst pain imaginable." Patients

documented their pain levels at baseline (pre-treatment), on the day of the procedure, and every day for 6 days. The lesion's size (length x width in mm²) was measured at the start of treatment and again after one and two weeks.

Histopathological analysis:

was performed on all tissue samples to confirm the diagnosis. Samples from the surgical group (complete excisions) and incisional biopsies from the sclerotherapy group were preserved in 10% neutral buffered formalin. After routine processing, the tissues were put in paraffin and cut into 4-micrometer-thick slices. The sections were stained with Hematoxylin and Eosin (H&E) so that they could be looked at under a microscope and diagnosed. All statistical analyses were conducted utilizing SPSS Statistics Version 26.0. Continuous data, encompassing age, VAS scores, and lesion size, are presented as mean ± standard deviation and median. The Mann-Whitney U test was used to compare the results of the two treatment groups. The Wilcoxon signed-rank test was used to see how VAS scores and lesion size changed over time in each group. A p-value below 0.05 was deemed statistically significant.

Results:

Patient Demographics and Baseline Characteristics:

The study included 14 patients (11 females and 3 males) diagnosed with oral pyogenic granuloma, all of whom completed the study. Participants were randomly assigned to either the Sclerotherapy group (n=7) or the Surgical Excision group (n=7). As shown in Table 1, the groups were well-matched at baseline, with no significant differences in age (p=0.534) or gender distribution (p=1.000). Clinically, the lesions were predominantly located on the gingiva (11 cases), with the remaining cases found on the buccal mucosa (2) and the palate (1). These lesions had been present for 1 to 5 months prior to treatment. At the study's outset, all lesions were greater than 0.5 cm, and baseline pain scores (VAS) were similarly low in both groups (p=1.000).

Table 1. Demographic Characteristics of the Study Participants

SN.	Characteristic	Sclerotherapy Group (n=7)	Surgical Group (n=7)	p-value
1	**Age (years)**			0.534*
2	- Mean ± SD	36.29 ± 6.02	38.0 ± 3.74	
3	- Range	28 - 44	31 - 42	
4	**Gender, n (%)**			1.000**
5	- Male	1 (14.3%)	2 (28.6%)	
6	- Female	6 (85.7%)	5 (71.4%)	
7	*Student's t-test; **Fisher's Exact Test*			

Primary Outcome: Treatment Efficacy:

Complete clinical resolution of the pyogenic granuloma within two weeks was achieved in 5 out of 7 patients (71.4%) in the Sclerotherapy group. Of these five successful cases, four required only a single injection session, while one required a second session after 15 days. The two cases that did not achieve complete resolution were associated with poor oral hygiene maintenance in one patient and a pale, fibrotic appearance of the lesion in the other. In the Surgical Excision group, complete removal was achieved in all 7 patients (100%) immediately following the procedure.

The reduction in lesion size (length x width in mm²) in the Sclerotherapy group was statistically significant at both the 1-week and 2-week follow-ups compared to baseline (p=0.028 for both), as detailed in Table 2.

Secondary Outcome: Postoperative Pain:

The Visual Analogue Scale (VAS) showed that the Sclerotherapy group had far less pain after surgery than the Surgical group. Pain scores were similar on the day of the surgery (p=0.228), but the Sclerotherapy group reported much less pain at all later time periods (2, 4, and 6 days after treatment, p=0.001 for all). The Sclerotherapy group saw a return to near-baseline pain levels after four days, while the Surgical group reported moderate discomfort during the whole six-day assessment period. The comparative VAS scores are presented in Table 3.

Table 2: Lesion Size in the Sclerotherapy Group Over Time

Time Point	Lesion Size (mm^2), Mean ± SD	Median	p-value*
Baseline	38.86 ± 19.45	42.0	-
1 Week	3.21 ± 5.90	0.0	0.028
2 Weeks	2.14 ± 5.67	0.0	0.028
p-value for Wilcoxon signed-rank test comparing to baseline.			

Table 3: Comparison of Postoperative Pain (VAS Scores) Between Groups

Time Point	Sclerotherapy Group (Mean ± SD)	Surgical Group (Mean ± SD)	p-value*
Baseline	0.29 ± 0.76	0.29 ± 0.76	1.000
Day of Procedure	7.71 ± 1.38	8.57 ± 0.98	0.228
Day 2	1.43 ± 1.13	5.86 ± 0.69	0.001
Day 4	0.29 ± 0.49	4.43 ± 0.79	0.001
Day 6	0.00 ± 0.00	3.71 ± 1.11	0.001
Mann-Whitney U test.			

Histopathological Findings:

Histopathological examination of the incisional biopsies (Sclerotherapy group) and excised specimens (Surgical group) confirmed the clinical diagnosis in all cases. Five lesions were confirmed as pyogenic granuloma, characterized by prolific capillary proliferation within an edematous stroma and a mixed inflammatory infiltrate. Two lesions from the surgical group were diagnosed as fibrous epulis (irritation fibroma), showing dense, collagenous connective tissue.

Adverse Events:

The injection of monoethanolamine oleate was well-tolerated by all patients. No systemic adverse effects, such as allergic reactions or signs of intravascular hemolysis, were observed or reported. Transient local effects, including mild pain, redness, and a burning sensation at the injection site, resolved spontaneously within 24-72 hours

Discussion:

PG is a common, non-neoplastic growth thought to arise from responses to stimuli like local irritation, trauma, and hormonal factors [9,10]. The term pyogenic granuloma is a misnomer because the lesion does not contain pyogenic organisms and is not a true granuloma [11]. The most common intra-oral site is the gingiva (75% of cases) [10]. While surgical excision is a frequent treatment, it is invasive, can cause scarring, and poses a haemorrhage risk, especially for patients on anticoagulants or with conditions like hemophilia [12]. Other options like corticosteroids, laser therapy, and cryotherapy carry risks of side effects like atrophy, hyperpigmentation, and scarring, and may have high recurrence rates [13-16].

This research investigated monoethanolamine oleate injection as a simpler, less invasive alternative. This agent, used for sclerosing esophageal varices and hemangiomas, [17,18] injures the vascular endothelium, causing thrombus formation [18]. In PG, this mechanism can induce necrosis of the lesion. We achieved an 85.71% response rate with no recurrences. Two cases did not resolve completely; one was linked to poor oral hygiene during follow-up, and the other was a pale, likely late-stage lesion where

decreased vascularity may have reduced the sclerosant's efficacy. A drawback of this method is the lack of a full specimen for histology, which is important as PG can mimic other conditions, including malignancy. [18,19]. To address this, we performed an incisional biopsy before treatment to exclude malignancy.

The female majority (85.71%) in our analysis corresponds with the stated ranges of 62.96–77% [20, 21], however some studies indicate a lesser preference (55–58%). [22,23]. Our mean age of 36.29 years is similar to other studies (31–35 years). [20,22,24].

Regarding location, the gingiva was the most common site, which is well-documented. Our finding that the mandible (57.14%) was more affected than the maxilla (14.28%), with the anterior mandibular labial gingiva as the principal site, is consistent with Lawoyin et al., [24] but contrasts with other reports. [22,23]. Poor oral hygiene was a key predisposing factor in our study.

No major complications like those reported with high-dose intravariceal injection (e.g., pulmonary embolism) [25] were encountered, as blood flow in PG is lower. When the solution started to leak, injections of 1–2 ml were halted because they were full. The side effects included only brief soreness, redness, and a burning feeling that went away after 24 to 72 hours. Patients were quite happy with the procedure because it was simple, didn't require surgery or anesthesia, and worked well. Histopathological examination of the biopsied lesions validated the clinical diagnosis of PG and exhibited the lesion's distinctive characteristics.

Conclusion:

Our research shows that injecting monoethanolamine oleate (EO) is an easy, effective, cheap, and safe way to treat oral pyogenic granuloma. It doesn't cause any major problems like surgery does. This approach is especially useful for patients with bleeding disorders, those contraindicated for surgery, or who are non-compliant with other treatments. It is crucial to note that proper diagnosis and the removal of local irritating factors are essential to prevent recurrence and achieve effective treatment. While EO is a safe sclerosing agent for reactive vascular lesions, it is not beneficial for fibrotic lesions. This new approach constitutes a substantial contribution to oral medicine, offering a useful and easily applicable therapy.

Recommendations:

The current study showed that the use of monoethanol amine oleate is a well-tolerated effective therapy for the control and healing of oral pyogenic granuloma. Therefore, in view of these results, the following recommendations may be of value:

1. Further studies with larger number of samples are recommended to confirm the result of this study.
2. A longer follow up period to confirm the absence of recurrence of the lesion.
3. More researches are recommended to study the effect of other sclerosing agents in the treatment of oral exophytic lesions.

References:

1. Zain RB, Ikeda N, Razak IA, Axéll T, Majid ZA, Gupta PC, et al. A national epidemiological survey of oral mucosal lesions in Malaysia. Community Dent Oral Epidemiol 1997;25:377- 83.
2. Wood NK, Goaz PW. Differential Diagnosis of Oral and Maxillofacial Lesions, 5th ed. St. Louis: Mosby; 1997:13.
3. Matsumoto K, Nakanishi H, Seike T: Treatment of pyogenic granuloma with a sclerosion agent DermatolSurg 2001; 27: 521–523.
4. Song MG, Kim HJ, Lee ES. Intravenous pyogenic granu- loma. Int J Dermatol 2001;40:57-9.
5. Kocer U, Aksoy HM, Tiftikcioglu YO. KaraaslanO.Intravenous pyogenic granuloma of the hand. DermatolSurg 2003;29:974-6.
6. Kirschner R, Low D. Treatment of pyogenic granuloma by shave excision and laser photocoagulation. PlastReconstrSurg 1999;104:1346-9.
7. Eickhorst KM, Nurzia MJ, Barone JG. Pediatric pyogenic granuloma of the glans penis. Urology 2003;61:644.
8. Harris MN, Desai R, Chuang TY. Lobular capillary hemangiomas: an epidemiologic report, with emphasis on cutaneous lesions. J Am AcadDermatol 2000;42:1012-6.
9. Kempe SG, Koch H. Injection of sclerosing solution in the treat- ment of esophageal varices. ActaOtolaryngol 1954;118:120–9. 10.
10. Rajendran R, Benign and malignant tumours of the oral cavity. In: Rajendran R, Sivapathasundaram B (eds) Shafer's text book of oral pathology, 5th edn. Elsevier, New Delhi, pp 2006; 113–308.
11. Glass AT, Milgraum S. Flashlamp-pumped pulsed dye laser treat- ment for pyogenic granuloma. Cutis 1992;49:351–3.

12. Hindawi Publishing corporation Gastroenterology Research and Practice Volume 2010;Article ID 518260,5.
13. Fishman SJ, Mullikken JB, hemangioms and vascular malformation of infancy and childhood. Pediatric surg,1993;40:1177-200.
14. Van DoorneL,Maeseneer MID, stricker C, Vanrensbergen R, strickerM.Diagnosis and treatment of vascular lesion of the lip. Br j Maxillofacsurg 2002;40: 497-503.
15. DroletBA,EsterlyNB,FriedenIJ.primarycare:hemangioms in children .N Engel J Med 1999;341:173-81.
16. ElmetsCa, Ceilley RI. Amelanotic melanoma presenting as a pyo- genic granuloma. Cutis 1980;25:164–8.
17. Nishida R, Inoue R, Takimoto Y, Kita T. A sclerosant with astringent properties developed in China for oesophagealvarices: comparison with ethanolamine oleate and polidocanol. J GastroenterolHepatol 2010;14:481-8.
18. Meireles-Santos JO, Carvalho AF Jr, Callejas-Neto F, Magna LA, Yamanaka A, Zeitune JMR, et al. Absolute ethanol and 5% ethanolamine oleate are comparable for sclerotherapy of esophageal varices. GastrointestEndosc 2011; 51:573-6.
19. Elmetca,Ceilley RI. Amelanotic melanoma presenting as a pyogenic granuloma. Cutis 1980; 25:164-8.
20. Saravana GHL, Oral pyogenic granuloma. A review of 137 cases. Br J Oral MaxillofacSurg 2009; 47:318–319.
21. Al-Khateeb T, AbabnehK , Oral pyogenic granuloma in Jordanians: a retrospective analysis of 108 cases. J Oral MaxillofacSurg 2003; 61:1285–1288.
22. Angelopoulos AP Pyogenic granuloma of the oral cavity: Statistical analysis of its clinical features. J Oral Surg 1971; 29:840–47 11.
23. Kerr DA, Granuloma pyogenicum. Oral Surg Oral Med Oral Pathol 1951; 4:1158–76 12.
24. Lawoyin JO, Arotiba JT, Dosumu OO, Oral pyogenic granuloma:areviewof38casesfromIbadan,Nigeria.BrJOralMaxillofacSurg,1997;35:185–9 13.
25. Miyoshi H, Ohshiba S, Matsumoto A, Takada K, Umegaki E,Hirata I. Haptoglobin prevents renal dysfunction associated withintravariceal infusion of ethanolamine oleate. Am J Gastroenterol 1991;86:1638–41.