Impact of Diode Laser Versus Sclerotherapy in Treatment of Oral Pyogenic Granuloma

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Abstract: Objectives: Recurrence and Bleeding susceptibility represent common complications following excision of pyogenic granuloma utilizing different surgical techniques. This study was conducted to compare clinical outcomes following diode laser excision versus Sclerotherapy in treatment of pyogenic granuloma. **Patients and methods:** Sixteen patients of oral pyogenic granuloma with size ≥2cm in one of its dimensions were divided randomly into two equal groups. The 1st group was treated by diode laser excision. While, 2nd group was treated by 3.75% ethanolamine oleate sclerotherapy on weekly injection visits. Patients of both groups were evaluated intraoperatively for bleeding severity and postoperatively in terms of pain at the 1st and 7th day and swelling at the 2nd and 7th day. Healing time, quality and the overall treatment time were assessed. **Results:** No statistical significant difference was recorded between groups regarding intraoperative bleeding (P=0.457) and postoperative pain either at 1st and 7th days (P=0.708-0.440-0.356-0.143-0.193-0.294-0.544-0.593). While, a statistical significant difference was recorded between postoperative swelling at the 2nd day following the first injection visit in sclerotherapy treated group and postoperative swelling of the laser treated group at the 2nd day (P=0.007). A statistical significant difference was recorded between both groups regarding healing time of the residual ulcer and the overall treatment time (P=0.041-0.033 respectively). **Conclusion:** Although, treatment of pyogenic granuloma using diode laser is reliable and less invasive, it is relatively sensitive technique. On the other hand, ethanolamine oleate sclerotherapy proved to be safer, easier and minimally invasive with less complications especially, when treatment longevity is not a concern.

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1. Introduction

Pyogenic granuloma is a relatively common benign mucocutaneous lesion. The term is a misnomer as the lesion does not contain pus nor it is granulomatous. It was originally described in 1897 by two French surgeons, Poncet and Dor.[1] It is hyper vascular in nature as minor trauma can result in considerable bleeding.[2, 3] Many different treatment modalities have been proposed for pyogenic granuloma, with variable success rates. For some authors, full-thickness surgical excision with primary closure is considered the standard treatment,[4] with reported recurrence rate of 16%.[5] While, conservative techniques such as curettage, shave excision plus electrocauterization, chemical cauterization and cryotherapy became widely used.[4] However, the major drawback of these conservative techniques is the increased recurrence rate. Several studies reported high recurrence rate up to 43.5% by these techniques.[4, 6, 7]

Sclerotherapy is frequently used to treat vascular lesions, and its efficacy has been confirmed. Ethanolamine oleate has been used to treat vascular lesions of the gastrointestinal tract such as esophageal varices.[8] Nowadays, sclerotherapy has been reported to be a suitable simple and effective treatment method for surgically challenging large pyogenic granuloma,[9-11] with no reported recurrences and inconspicuous scars,[12] but has the disadvantage of treatment longevity with multiple treatment sessions.[9, 10]

On the other hand, Innovative technologies, such as diode lasers, have provided considerable benefit to dental patients and dentists. In addition, the role of lasers in dentistry is well established in both the conservative and surgical management of oral diseases. They have the advantages of greater precision, a relatively bloodless surgical and postsurgical course, sterilization of the surgical area, minimal swelling and scarring and less or no postsurgical pain.[13] Based on aforementioned, this study was directed to evaluate the postoperative sequelae, prognosis of healing and the recurrence rate after treatment of oral pyogenic granuloma using diode laser versus sclerotherapy.

2. Patients and Methods

Sixteen patients complaining of oral pyogenic granuloma with size ≥2cm in one of its dimensions were selected from outpatient clinic of Oral and Maxillofacial surgery Department, Faculty of Dentistry, Mansoura University. Immuno-compromise patient, uncontrolled metabolic disorder or any patient

with blood coagulation disorders were excluded from this study. Patients were divided randomly into two equal groups. Eight patients in the 1st group were presented with oral pyogenic granuloma ≥2cm and treated by 810/7, 980/7 diode laser system. While, in the 2nd group, eight patients were presented with oral pyogenic granuloma ≥2cm and treated by injection sclerotherapy using ethanolamine oleate.

Clinical, Radiographic and laboratory assessment

An initial clinical and laboratory examination were performed. The collected data was evaluated and a clinical diagnosis for the type of lesion was established. Preoperative panoramic radiograph was obtained. Incisional biopsies were taken pre-operatively, and the specimens were histologically examined. Patients were informed through written and verbal information on the nature of treatment and the signed informed consent forms were obtained prior to the treatment.

Preoperative phase

All the patients were motivated to maintain proper oral care by scaling preoperatively and frequent mouth rinsing by concentrated 0.2% Chlorhexidine mouth wash (Listerine® mouth wash, McNeil Consumer Healthcare division of Johnson & Johnson) for enhancing gingival condition preoperatively.

Operative procedures

In 1st group (Laser treated group)

The lesion was operated by two steps; cutting off the mass then photo-ablation of the lesion base. The diode laser system (Denlase® 810/7, 980/7, 0.5w-7w, Suzhou Huabang Dental Medical Instrument Co., China) was adjusted with an output power of 5 W, frequency of 100Hz, continuous wave mode, focused 810nm diode laser beam delivered by 2mm (200um) spot size in contact mode.[14] The lesions were excised under regional nerve block anesthesia 2% mepivacaine hydrochloride with 1:20000 levonordephrine (Mepecaine-L®, Alexandria Company for pharmaceutics and chemical industries). Excision started from the periphery of the mass neck toward the center. Then, the mass was completely separated from the surrounding tissues. The specimens were saved in fixative agent 10% Formalin solution for histopathological examination.[14] Immediately after the excision, the device was re-adjusted to an output power of 7 W in non-contact mode then defocused 810 nm diode laser beam was directed to the base of the lesion in sweeping or crisscross motion until total ablation and vaporization of the lesion base with formation of char layer. The size of char layer depended on the nature of the lesion either pedunculated or sessile (Fig. 1).[13, 15]

During the operation smoke evacuator was used to capture the plume. The wound was irrigated with physiological saline solution (SALINE 0.9% NaCl® 500 ml, Egypt Otsuka Pharmacutical Co.) during the surgery in case of need. Local hemostasis was obtained by photocoagulation effect of diode laser combined with subsequent application of sterile surgical gauzes only soaked in physiological solution according to the grade of intraoperative bleeding. Patient was discharged with instructions for post-surgical care consisting of ice compress for 2 hours, abstention of warm food and drinks intake and medications.[14]

In 2nd group (Sclerotherapy treated group)

3.75% EO (Ethanolamine oleate® 5% Amp: EIPICO Company) was applied by diluting 5% EO (2:1.5) (v/v) in normal saline.[8] The volume of EO injected was determined according to the lesion size and the injection amount ranged from 1.5ml to 3ml per injection. The injections was performed using light pressure with 23 gauge needle which inserted interstitially until EO began to leak from the lesion surface or blanching developed. After the injection, the lesions were compressed for at least 5 minutes to enhance the contact time between the vascular endothelial wall and the EO.[7, 8] The lesions were observed once a week after each injection. Repeated sessions of injection may be needed up to 4 sessions on subsequent weeks until the lesion gradually became necrotic and decreased in size till disappear (Fig. 2).

All patients included in both groups received proper antibiotics, Amoxicillin combined with calvulanic acid (Augmentin® 1gm tablet, Medical Union Pharmaceutical) 1gm 2h before treatment, and 1gm/12hrs for 7 days after treatment (only for patients within the 1st group) and non-steroidal anti-infammatory, Diclofenac sodium 50mg tablet (Declophen® 50mg tablet, Pharco Pharmaceutical, Alexandria, Egypt) if needed for pain control.

Clinical evaluation

All patients included in this study within both groups were recalled for close follow up during the treatment period up to 6 months from the end of the treatment, during which the clinical data was collected and analyzed.

Clinical parameters

Bleeding

The bleeding was evaluated intraoperatively into three levels. *Mild bleeding*, subsided under 20 minutes upon applying pressure with a piece of sterile gauze. *Moderate bleeding*, did not subside with such measures and required tranexamic acid irrigation for two minutes and tamponade with tranexamic acid impregnated gauze for 20 minutes. *Severe bleeding,* required further suturing with administration of vitamin K and/or the infusion of fresh frozen plasma.[16]

Pain

Post-operative pain was evaluated at the first and seventh day postoperatively, using numeric rating scale (NRS) for pain which is a segmented numeric version of the visual analogue scale (VAS) in which a respondent selects a number (0–10 integers) that best reflects the intensity of pain. It is a 11-point numeric scale with 0 representing one pain extreme and 10 representing the other pain extreme. *Pain scores are*, score 0 indicates no pain, score 1-2-3 indicates mild pain, score 4-5-6 indicates moderate pain and score 7-8-9-10 indicates sever pain.[17]

Edema and swelling

Edema was evaluated at the second and seventh days postoperatively. It was determined by measuring the distance in millimeters with flexible tape from the corner of the mouth to the tragus of ear (S1) and from the lateral canthus of the eye to the angle of the mandible (S2). The sum of measurement was recorded as the facial size preoperatively and postoperatively at different time intervals of follow up either at 2nd and 7th day.[18]

Healing quality index

Healing index for subsequent formed ulcer was recorded on the basis of tissue color, bleeding on palpation, presence of granulation tissue, suppuration and epithelialization at the 1st, 2nd and 3rd weeks postoperatively after completion of each treatment modality, and healing was recorded as scores from 1 (very poor) to 5 (Excellent) (Table 1).[19]

Degree of lesion regression treated by sclerotherapy

It was done through evaluating the rate of lesion size reduction following subsequent injections compared to its original size.

Healing timing

It was established by evaluating the time required in days after the end of treatment till obtaining the optimal healing quality of the treatment sites (ulcerative wound) on the basis of landry healing index (excellent state or score 5).

Treatment time

It was established by evaluating the overall time recorded in days from the start of treatment maneuver to the end of the healing process.

Tooth preservation and complications

Most of these lesions commonly affect the gingiva which is a dentate area, so one or more teeth usually involved within the lesion with variable periodontal conditions which usually sacrificed in other conventional treatment modalities. For both groups, affected teeth preservations or extractions were recorded. Any complications for example; tissue necrosis, ulceration, bone affection and improper wound healing related to the treatment of both groups were recorded and analyzed.

Recurrence

The process of healing was evaluated through follow-up visits at 3 months and 6 months from the end of the treatment. Any attempt for pathological tissue regrowth was recorded.

3. Results

Sixteen patients were operated, nine males and seven females with ages ranged from 9 to 64 years of mean age 32.62±22.95 years. Preoperative demographic study variables showed no statistical significant differences regarding to sex, age and lesion size (P=1, 0.793, 0.562).

Patients' distribution regarding to intraoperative bleeding severity within both groups was illustrated in (Table 2). Our findings revealed no statistical significant difference between both groups regarding to severity of intraoperative bleeding (P=0.457).

Pain severity among patients included within this study was recorded at the 1st and 7th day postoperatively after laser excision versus the 1st and 7th day following each injection visit in sclerotherapy treated group revealing no statistical significant difference between both groups (P=0.708-0.440-0.356-0.143-0.193-0.294-0.544-0.593).

In 1st group, the average mean of summation of facial swelling was 216.25± 11.97, while in 2nd group it ranged from 235± 11.86 following 1st injection visit compared with 175±0 following 4th injection visit (Table 3). A statistical significant difference was recorded between the postoperative swelling resulted from diode laser treatment in comparison with the swelling resulted following the first injection session of ethanolamine oleate sclerotherapy measured at the 2nd day postoperatively (P=.007*) (Table 3).

Regarding to lesion size regression in sclerotherapy treated group, a detectable statistical significant difference between the preoperative lesion size and its size following first injection was recorded (P= ≤.001).

Considering the healing quality and time required to the residual ulcer healing following the end of treatment maneuver until obtaining the optimum healing according to Landry healing index,[19] laser treated group showed delay in the speed of healing, that explains the lack of detected statistical significant difference between healing quality after the first week following lesion excision and healing quality after the second week (P1= 0.124). However, when comparing the healing quality after the first week to the healing quality after third week, a statistical significant difference was recorded (P2=0.047).

On the other hand, in the sclerotherapy treated group, a statistical significant difference was observed earlier between the healing quality after the first week

and healing quality after the second week (P1=0.014). When comparing both groups, there were statistical significant differences between both groups regarding the healing quality after first week (P=0.022), after the second week (P=0.044) and after the third week (P=0.044) (Table 4), Furthermore, a significant reduction in the healing time of the resulted residual ulcer associated with sclerotherapy treated group compared to laser treated group (P=0.041) (Table 5).

Regarding the overall treatment time recorded from starting the treatment maneuver until gaining the optimum healing, sclerotherapy showed longer overall treatment time starting from the first application of the sclerosing agent until obtaining the optimum healing of the lesion site with statistical significant difference when compared to laser treated group (P=0.033) (Table 5).

Table (1) Showing Landry healing index and its scoring criteria.

Healing score	Criteria
1 (Very poor)	Tissue color: ≥ 50% of gingiva red Response to palpation: bleeding Granulation tissue: present Treated lesion site is not epithelialized, with loss of epithelium beyond the lesion site Suppuration present
2 (Poor)	Tissue color: ≥ 50% of gingiva red Response to palpation: bleeding Granulation tissue: present Treated lesion site is not epithelialized, with connective tissue exposed
3 (Good)	Tissue color: ≥ 25% and < 50% of gingiva red Response to palpation: no bleeding Granulation tissue: none Treated lesion site shows no connective tissue exposed
4 (Very good)	Tissue color: < 25% of gingiva red Response to palpation: no bleeding Granulation tissue: none Treated lesion site shows no connective tissue exposed
5 (Excellent)	Tissue color: all tissues pink Response to palpation: no bleeding Granulation tissue: none Treated lesion site shows no connective tissue exposed

Table (2) Showing distribution of intraoperative bleeding severity among patients included within both groups

Groups/ Bleeding	Laser treated group (n=8)		Sclerotherapy treated group (n=8)		p-value
	No	**%**	**No**	**%**	
Mild	6	75.0	8	100.0	P=.467
Moderate	2	25.0	0	0	

Table (3) Showing comparison between preoperative and postoperative mean and standard deviation values of summation of S1 and S2 lines used for swelling assessment at the second day postoperatively among patients included within both groups

Groups Visits	Laser treated group (n=8)		Sclerotherapy treated group (n=8)		Test of sig. p-value
	Mean ± SD	**Min-Max**	**Mean ± SD**	**Min-Max**	
Pre-op	215.88± 14.51	195-240	201.62± 16.51	175-223	P=.088
1st visit	216.25± 11.97	195-230	235± 11.86	219-253	P=.007*
2nd visit	216.25± 11.97	195-230	205.12± 16.15	179- 223	P=.140
3rd visit	216.25± 11.97	195-230	202.5± 21.93	175-223	P=.473
4th visit	216.25± 11.97	195-230	175±0	175-175	P=.537

Table (4) Showing comparison between both groups regarding healing quality in the postoperative subsequent three weeks according to landry healing index

Healing		Laser treated group (n=8)		Sclerotherapy treated group (n=8)		p-value
		No	**%**	**No**	**%**	
1st week	very poor	2	25.0	0	0	0.022*
	Poor	4	50.0	0	0	
	Good	1	12.5	3	37.5	
	very good	1	12.5	5	62.5	
2nd week	very poor	2	28.6	0	0	0.044*
	Good	1	14.3	0	0	
	very good	4	57.1	3	37.5	
	Excellent	0	0	5	62.5	
3rd week	Good	2	28.6	0	0	0.044*
	very good	2	28.6	0	0	
	Excellent	3	42.9	8	100.0	

Table (5) Showing comparison of mean and SD values of healing time of the residual ulcer and treatment time among patients included within both groups

Groups Time	Laser treated group (n=8)		Sclerotherapy treated group (n=8)		Test of sig. p-value
	Mean ± SD	**Min-Max**	**Mean ± SD**	**Min-Max**	
Healing time	25.25±10.23	14-40	16.62±3.62	14-21	P=.041*
Treatment time	25.25±10.23	14-40	36.25±8.27	28-49	P=.033*

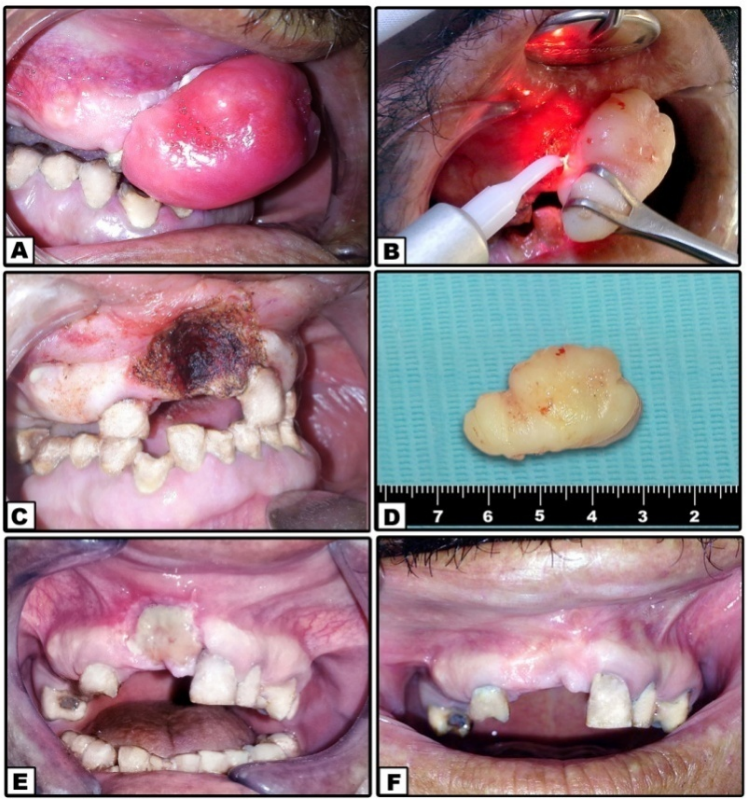

Fig. 1 Laser treated group A, Lesion preoperative, B, During laser excision, C, Char layer formation D, the excised specimen E, 1 week postoperative F, 3 months postoperative

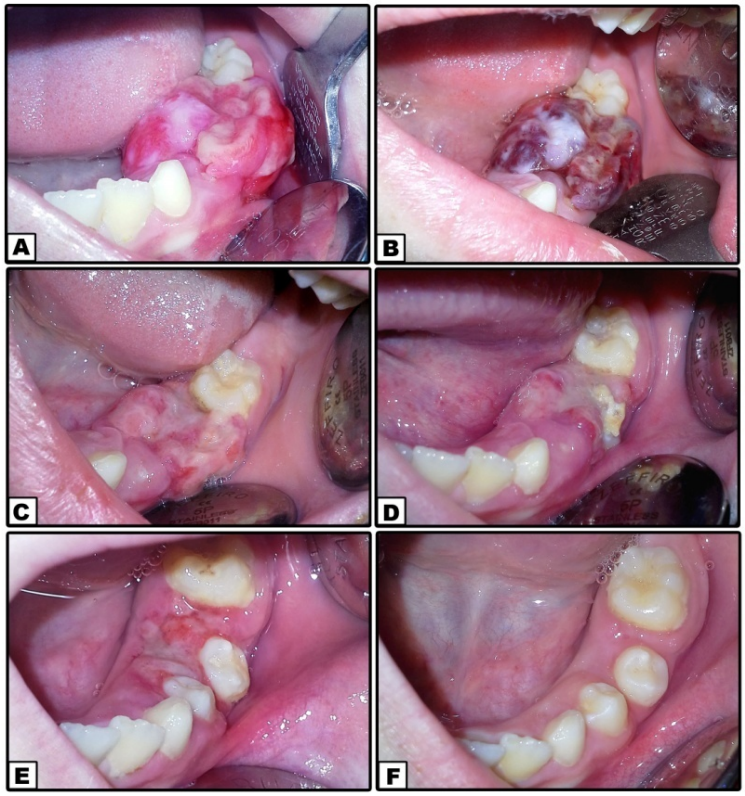

Fig. 2 Sclerotherapy treated group A, Lesion preoperative, B, Immediate after 1st injection C, Post 1st injection D, Post 2nd injection E, Post 3rd injection F, 3 months postoperative

4. Discussion

In our study, two innovated conservative techniques which were reported to be less traumatic with less recurrence rates were compared.[8, 15] The first technique is the treatment using diode laser and the second is sclerotherapy.

Bleeding findings showed detectable increase in the grade of bleeding severity in patients of laser treated group than patients of sclerotherapy group. Our findings showed disagreement with Mahmood & Jasim in 2008 and Azma & Safavi in 2013 who reported no or mild bleeding using diode laser in the treatment of pyogenic granuloma.[14, 15] However, Akbulut et al. in 2013 reported moderate bleeding with diode laser treatment of mucous membrane pemphigoid which needed further suturing to stop the bleeding.[13]

Such controversy can be explained on basis that most of researches published on diode laser treatment of pyogenic granuloma operated on small lesions not exceed 1.5 cm in its maximum dimension.[15] While, in our study larger lesions that measured ≥2cm in its maximum dimension were operated, which were characterized by higher vascularity. Additionally, Colt and Mathur in 2004 assumed that except for Nd:YAG laser, other laser types have less ability for hemostatic cutting of vessels over 0.5mm or 500 micrometer.[20]

Despite the ability of the diode laser to perform such painless surgery, our findings revealed two patients complained of sever postoperative pain as a result to local complication. Such complication can be attributed to the disadvantage of diode laser through lacking depth precision with variable depth penetration of 2-4 mm which can result in thermal injury to the underlying periosteum with subsequent bone exposure and sever uncharacteristic pain especially, in sessile lesions with broad bases. In agreement to our results, Parker in 2007 demonstrated that vital structures located within the range of 0.5-4 mm depth at the way of diode laser beam can be susceptible to thermal damage. Additionally, Parker reported cases of thermal damage to the periosteum, bone and teeth during perceived excision of giant cell granuloma at 5 Watt output power with subsequent bone sequestration and devitalization of the teeth with subsequent need to root canal treatment.[21] On the other hand, in sclerotherapy treated group two patients showed unusual transient moderate pain following the injection which relieved within 1 week. This may be due to accidental overfilling of the lesion with high

injection pressure or deeper injections. In agreement to our results, Hong et al. in 2010 reported post-injection pain which relieved within 1 week. While, Matsumoto et al. in 2001 reported one patient with unusual persistent post-injection pain for 4 weeks.[7, 8]

The comparable swelling response among both groups can be attributed to the ability of the sclerosing agent to induce intense inflammatory reaction at the site of injection which lead to cell damage and subsequent repair process by thrombosis and fibrosis which is the pivotal point in sclerosis and lesion necrosis.[22] Furthermore, Matsumoto et al. in 2001, Johann et al. in 2005 and Carvalho & Neto in 2010 reported same results of postoperative swelling following sclerosing agent injection in treatment of pyogenic granuloma and benign oral vascular lesions.[4, 7, 23]

In sclerotherapy treated group, lesion size showed detectable regression after the 1st injection visit, and so, the amount of sclerosing agent needed to fill the lesion and perform its sclerosing action decreased to a high extent in the following injection visits, which result in more localization of the injected solution, less diffusion and less inflammation when compared to the first injection session; that's what explain the lesser degree of swelling following second, third and fourth injection visits. On the other hand, diode laser has the ability to seal the lymphatic vessels which results in minimal post operative edema.[24]

Regarding healing quality and time of the formed residual ulcer in both techniques after completion of treatment, in laser treated group the ulcer was covered immediately following the excision with char layer as a product of laser vaporization and carbonization. Although, this layer acts as protective and isolative layer over the disinfected ablated surgical field, unfortunately it also retards the epithelial migration and subsequently delays the overall healing process.[25]

Our explanation for treatment time variation between both groups can be attributed to the fact that, diode laser excision is a single treatment visit results in ulceration and charring of the surgical field which is allowed to heal by time. While, sclerotherapy is a stepped technique of expanded treatment time consists of multiple successive injection visits with weekly intervals up to four weeks which results in gradual lesion size regression until full exfoliation of the lesion and starting the healing process of the residual ulcer. In co-ordination to our results, Matsumoto et al. in 2001, Hong et al. in 2010 and Carvalho & Neto in 2010 reported the same results about the prolonged treatment time with variation in the number of injection visits ranging from one injection session up to six injection sessions.[4, 7, 8]

Considering the recurrence during 6 months of follow up, laser treated group showed one patient of unusual recurrence which characterized by rapid recurrent growth of the lesion to its original size within only two weeks after the excision. Asnaashari et al. in 2014 reported the same type of recurrence after 5 days following diode laser excision of lip pyogenic granuloma and called it posthaste outgrow. Asnaashari related this condition to the incomplete excision with removal of the local initiating factor in addition to the high proliferative activity following low level laser application.[26] Asnaashari based his assumption on Kreisler et al. in 2003 who demonstrated in vitro cellular effect of soft tissue laser irradiation on connective tissue proliferation.[27] They stated that considerably higher proliferative activity especially on fibroblasts was evident after low level laser irradiation. Additionally, Hong et al. in 2010 reported recurrences following laser excision of pyogenic granuloma assuming that limited penetration depth of the laser beam may leads to under excision which technically is hard to predict.[8] On other hand, our results of sclerotherapy treated group showed one case of recurrence after two months of follow up. Matsumoto et al. in 2001 disagree with our results who reported 0% recurrence rate following treatment of nine patients complaining of pyogenic granuloma.[7]

5. Conclusion

Although, treatment of pyogenic granuloma using diode laser showed to be reliable and less invasive conservative technique with satisfactory results on the long term, it is relatively sensitive technique needs experienced operator and well adjusted device. On the other hand, ethanolamine oleate sclerotherapy proved to be safer, easier and minimally invasive with less complications and better results especially when the treatment longevity is not a concern.

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