

“A comparative study of Alveogyl and ZOE in dry socket syndrome”

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Abstract: Alveolar Osteitis (dry socket) can be defined as the inflammation of the extraction socket occurring postoperatively within 1-4 days that is usually characterized by intense throbbing pain, accumulation of disintegrated clot and food debris in the socket and malodor. The etiology of the dry socket has not been well-known. However, certain theories suggest that the contributing factors to the etiology that includes early dislodgment of blood clot of extraction site, also any trauma due to surgery, secondary infection, or any nutritional deficiency, or mechanical dislodgement of any clot, also decreased the particularly vascularity, drug-induced includes oral contraceptives, and tobacco-induced. Alvogyl (Septodont, France) is an intra-socket medication for dry socket containing Iodoform (15.8%) as an antimicrobial, Butylparaminobenzoate (25.7%) as an anaesthetic, Eugenol (13.7%) which retards the inflammatory process and also relief the pain by inhibiting the action of prostaglandins and Penghawar (3.5%) as an anti-inflammatory agent. This prospective study is aimed at evaluating the efficacy of Alvogyl in alleviating symptoms of dry socket when compared to the traditional method of ZOE paste. Null hypothesis states that there is no difference between Alvogyl & ZOE in treatment of dry socket. The alternate hypothesis states that Alvogyl is better than ZOE in treatment of dry socket.

Conclusion:- The main objective of dry socket management has been palliative because pain level differs in every person. It is of greater importance to find and also access various parameter to provide us with more detailed compression in relation to its treatment modalities.

In our study by comparing the above parameters between Alveogyl and ZOE, we conclude that Alvogyl has better healing properties and relieves pain at faster rate than ZOE.

Date of Submission: 26-08-2019

Date of Acceptance: 10-09-2019

I. Introduction

Alveolar Osteitis (dry socket) can be defined as the inflammation of the extraction socket occurring postoperatively within 1-4 days that is usually characterized by intense throbbing pain, accumulation of disintegrated clot and food debris in the socket and malodor¹. Crawford in the year 1896 gave the term “Dry socket”^{2,3,4}.

Dry socket is a very common complication that is encountered in the healing phase for extraction. If wound arises within a few days after the extraction. Dry socket is characterized by extreme pain and foul odor, but with no suppuration. On clinical examination, the common clinical signs include the exposed bone with necrosis and sequestration of fragments. Healing of such wounds is extremely slow. The etiology of the dry socket has not been well-known. However, certain theories suggest that the contributing factors to the etiology that includes early dislodgment of blood clot of the extraction site, also any trauma due to surgery, secondary infection, or any nutritional deficiency, or mechanical dislodgement of any clot, also decreased the particularly vascularity, drug induced includes oral contraceptives and tobacco-induced. Other causes include decreased bleeding because of the hemostasis caused by epinephrine or other injectable substances that causes vasoconstriction in the local anesthetic and loss of clot because of rinsing the mouth or sucking the wound⁵. Frequency of alveolar osteitis or dry socket is increased with the cases of excessive traumatic type extraction, particularly in the procedures which involves flap reflection and also excessive amount of bone removal. The most common procedure is the mandibular third molar surgery which involves trimming of thick bone and also splitting of the tooth. Thus it is the commonest site for the occurrence. Several studies indicate that prevention is always the method of choice to decrease the rate of dry socket. These comprise of the use of 0.12% Chlorhexidine mouth wash, the placement of medicated packing into the extraction socket and the prophylactic use of Metronidazole and Lenampicillin, although none of the methods has gained a universal success for treating the dry socket. Usage of the Antibiotic coverage is an effective method to control the effect of the dry

socket but the usage of antibiotic coverage is not so cost-effective so there is a need for the prevention modality that is equally effective and less expensive.

Alvogyl (Septodont, France) is an intra-socket medication for dry socket containing Iodoform (15.8%) as an antimicrobial, Butylparaminobenzoate (25.7%) as an anaesthetic, Eugenol (13.7%) which retards the inflammatory process and also relief the pain by inhibiting the action of prostaglandins and Penghawar (3.5%) as an anti-inflammatory agent.

II. Material And Methods

This prospective randomized study was carried out in this department of oral and maxillofacial surgery, Teerthanker Mahaveer Dental College Moradabad, Uttar Pradesh from 2014 to 2017. A total of forty patients who required treatment of dry socket after extraction were included in the study.

Study Design: Prospective open-label observational study

Study Location: This was a tertiary care teaching hospital based study done in the Department of Oral & Maxillofacial Surgery Teerthanker Mahaveer Dental College Moradabad, Uttar Pradesh.

Study Duration: December 2014 to December 2017.

Sample size: 40 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design. The target population from which we randomly selected our sample was considered 20,000. We assumed that the confidence interval of 10% and confidence level of 95%. The sample size actually obtained for this study was 20 patients for each group. We planned to include 40 patients (Group I- Control, Group II- Cases of 20 patients for each group).

Subjects & selection method:

This prospective randomized studies were carried out in this department of oral and maxillofacial surgery, Teerthanker Mahaveer Dental College Moradabad. A total of forty patients who required treatment of dry socket after extraction were included in the study. Routine blood investigations were done for all the patients and intra-oral periapical radiograph were obtained to exclude presence of root fragment/torus and body/ bony fragments within the socket. All the patients were randomly allocated in two groups. Study group received

Group A (N=20 patients) -Alvogyl paste as an intra-socket medication. This paste is a proprietary preparation containing Iodoform (15.8%) as an antimicrobial, Butylparaminobenzoate (25.7%) as an anesthetic, Eugenol (13.7%) as an analgesic and Penghawar (3.5%) as an anti-inflammatory agent.

Group B (N=20 patients)-The control group received a Zinc Oxide Eugenol (ZOE) as an obtundent dressing.

The patients were blinded to the use of Alvogyl. A standardized procedure for follow-up was observed for all patients as per protocol. All patients in the study routinely receive Tab diclofenac sodium (50 mg orally S.O.S) as rescue medication. Before the insertion of medication in the socket; clinical findings e.g. pain, degree of inflammation and amount of bone exposed was noted.

Inclusion criteria:

1. All patients in good health irrespective of age considerations were included.
2. Dry socket occurring in any extraction site was included.
3. Patients who were willing to take part in study were included.
4. The following criteria of dry socket were considered for inclusion in the study:-
 - a. Symptoms which start on the 3rd to 5th day after extraction of the tooth.
 - b. Loss of blood clot from the socket.
 - c. Severe pain that radiated from the empty dry socket, normally towards the ipsilateral ear and also towards temporal region.
 - d. A clot which initially has a dirty gray seeming appearance which later disintegrated to leave a grey or yellowish grayish bare bone socket devoid of granulation tissue.
 - e. Foul odor
 - f. Confirmation of the diagnosis is made by smoothly sliding a probe to the socket and is extremely sensitive.

Exclusion criteria:

1. Patients who are allergic to components of Alvogyl/ZOE and/or to medications prescribed in the study.
2. Pregnant patients or patients on oral contraceptives.
3. Medically compromised patients.
4. Patients who did not give consent in the department at the procedural time.

Procedure methodology

All the patients were randomly allocated in two groups. The study group received Alvogyl paste as an intra-socket medication (Group A). This paste is a proprietary preparation containing Iodoform (15.8%) as an antimicrobial, Butylparaminobenzoate (25.7%) as an anesthetic, Eugenol (13.7%) as an analgesic and Penghawar (3.5%) as an anti-inflammatory agent. The control group received a Zinc Oxide Eugenol (ZOE) as an obtundent dressing (Group B). The patients were blinded to the use of Alvogyl. A standardized procedure for follow-up was observed for all patients as per protocol. All patients in the study routinely receive Tab diclofenac sodium (50 mg orally S.O.S) as rescue medication. Before the insertion of medication in the socket; clinical findings e.g. pain, degree of inflammation and amount of bone exposed was noted.

Method Of Evaluation:-

(A) Visual Analog Scale

Following each procedure, a questionnaire consisting of Visual Analogue Scale of 10 units concerning pain was marked by the patients as mentioned in the proforma. The patients were asked to answer the questionnaire at first visit after immediate insertion of dressing, third and fifth post-insertion day and subsequent alternate days until healing occurs. Three consecutive readings were taken and the mean of these three readings was the baseline reading for that parameter. Similarly, three readings for each parameter were recorded on the day of reporting of patients, the first day after the insertion of the pack, the third day, fifth day and subsequent alternate days until healing, and the mean of that parameter was compared to baseline reading. The data so obtained was statistically analyzed with the help of independent -t-test and SPSS software as per data requirements. Other factors e.g. number of packs required to alleviate symptom completely and the time to required achieve clinical healing were also be noted.



(B) INFLAMMATION SCORING CRITERIA

Inflammation around the socket was scored according to the criteria given by Soben Peter.⁶

0- Absence of inflammation

1- Mild inflammation, the slight change in color, slight edema, no bleeding on probing

2- Moderate inflammation, redness, edema and hypertrophy bleeding on probing

3- Severe inflammation marked redness and hypertrophy, ulceration, a tendency to spontaneous bleeding.

(C) NUMBER OF SOCKET WALLS EXPOSED

The number of walls of the socket exposed completely or partially on each visit was noted to assess the degree of healing

1- Single wall exposed completely or partially

2- Two walls exposed completely or partially

3- Three walls exposed completely or partially

4- Four walls exposed completely or partially

Statistical analysis:

The statistical procedure was carried out in 2 steps.

1. Data compilation and presentation

2. Statistical analysis

1. Data compilation and presentation:

The whole data was fully asymmetrically combined, it was transformed from proforma that was initially precoded into the computer system and master chart was made in excel sheet. The total data was distributed meaningfully and presented as individual tables along with graphs.

2. Statistical analysis:

Descriptive type of statistical analysis was done for the present study. Results made for continuous measurements and data recorded. It was presented with the help of mean +_SD and also results based on category measurement are denoted in numbers (%). Significance is calculated for 5% level significance. Independent t-test was used for assessing the study parameters on the ordinal scale in 2 or more than two groups.

III. Result

Out of 40 patients (Table 1) 29 – females accounting for 72.5% and only 11 – males i.e. total 27.5%. Patient age ranged from 20 years till 70 years and the mean age is 33.7 years. The maximum number of the patient’s i.e. 20 patients were between the age group of 25 to 40 years. Prevalence for the dry socket was seen to be more in the mandible than that of maxilla i.e. 31:09 in a ratio of 3.4:1

Table 1:-AGE GROUP & GENDER

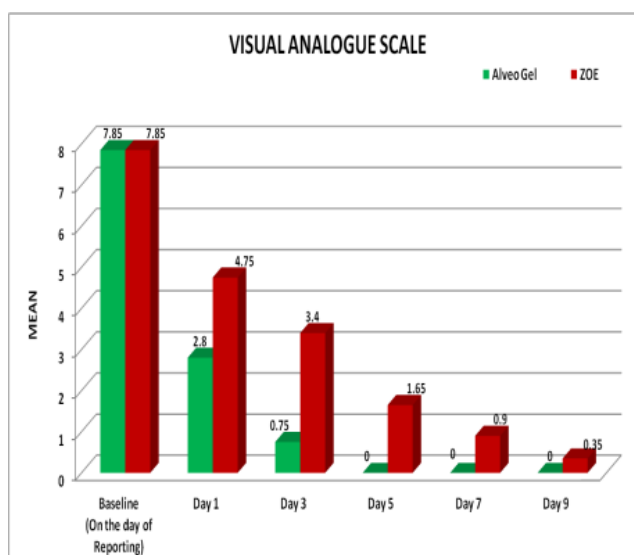
Age group	Male	Female	Total
<25	3	8	11
>25 to <40	3	17	20
>40	5	4	9
Total	11	29	40

Out of a total of 40 sites, 9 occurred in the maxillary arch (22.5%) and 31 occurred in the mandibular arch (77.5%). Dry socket occurred most frequently in mandibular 1st molar region i.e. 18 patients (45%) followed by mandibular 3rd molar region 6 patients (7.5%) and lower mandibular premolar 6 patients (7.5%). There were no cases of dry sockets upper and lower anterior region.

TABLE 2: COMPARISON OF VISUAL ANALOG SCALE IN ALVOGYL/ZNOE

VISUAL ANALOGUE SCALE	ALVEO GEL		ZOE		Independent t – test	p – value
	MEAN	SD	MEAN	SD		
Baseline	7.85	1.089	7.85	1.663	0.00	1.00
Day 1	2.80	2.142	4.75	2.826	-2.459	0.019
Day 3	0.75	1.251	3.40	2.28	-4.556	< 0.001
Day 5	0.00	0.00	1.65	2.059	-3.584	0.001
Day 7	0.00	0.00	0.9	1.774	-2.269	0.029
Day 9	0.00	0.00	0.35	0.875	-1.789	0.082

The VAS scores varied in follow-up period i.e. (P<.001) and the intensity in case of pain lowered in both the groups over a period of time. This decrease was significantly more in the case of Group A when compared to that of Group B. For both, the groups patients did not take the rescue medications i.e. Diclofenac Na 50mg during the treatment. On the 5th day, pain symptoms have completely eliminated in group A, but for group B, 09 patients reported with some degree of pain.



GRAPH : SHOWING VISUAL ANALOG SCALE

Table 3: NO.OF WALLS EXPOSED

No. of walls exposed	Group A	Group B
One wall	4	7
Two wall	13	13
Three wall	3	0
Four wall	0	0

Numbers of walls exposed were considered equal in both the groups. In group A complete healing was noted in all the patients on 5th day compared to 12 patients in group B. On 7th day in group B, 4 patients had either one or two walls exposed.

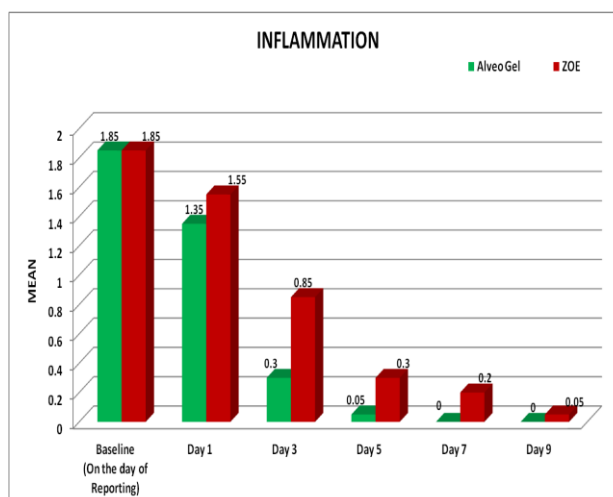
TABLE 4:-COMPARISION OF EXPOSED WALL IN ALVGOGYL/ZNOE

EXPOSED WALL	ALVEOGL		ZOE		Independent t - test	p - value
	MEAN	SD	MEAN	SD		
Baseline	1.95	0.605	1.95	0.224	0.00	1.00
Day 1	1.95	0.605	1.95	0.489	0.00	1.00
Day 3	0.20	0.523	1.00	0.795	-3.76	0.001
Day 5	0.00	0	0.45	2.059	-3.327	0.002
Day 7	0.00	0	0.25	0.55	-2.032	0.049
Day 9	0.00	0	0.05	0.224	-1	0.324

TABLE 5:- COMPARISION OF INFLAMMATION IN ALVGOGYL/ZOE

INFLAMMATION	ALVEOGL		ZOE		Independent t - test	p - value
	MEAN	SD	MEAN	SD		
Baseline	1.85	0.366	1.85	0.366	0.00	1.00
Day 1	1.35	0.587	1.55	0.51	-1.15	0.257
Day 3	0.30	0.47	0.85	0.587	-3.27	0.002
Day 5	0.05	0.224	0.30	0.47	-2.147	0.038
Day 7	0.00	0.00	0.20	0.41	-2.179	0.036
Day 9	0.00	0.00	0.05	0.224	-1.00	0.324

The inflammation decreased significantly over the period of follow-up in both the groups. However, by the 5th day, inflammation had significantly decreased in Group A with only 5 patients showing sign of resolved inflammation as compared to 15 patients in Group B. By 7th day, all patients in Group A had completely resolved inflammation, but 4 patients in Group B had some inflammation still present.



GRAPH : SHOWING INFLAMMATION

IV. Discussion

In 1896, Crawford coined the term dry socket and along with various other terminology have been suggested such as alveolar fibrinolytic osteitis, alveolitis sicca alveolitis, Dolorosa, postoperative alveolitis, alveolalgia, septic socket, necrotic socket, localized osteomyelitis, delayed extraction wound healing which best explains these painful series after tooth extraction. Dry socket is total accounts for 3-4% of among all extractions by Macgregor 1968, however, there are many variations in the result because of tough assessing conditions. While many terms are there which describe the etiology of this condition none is conclusive in its own.⁸

Though the precise etiology and pathogenesis of alveolar osteitis is not fully understood, Birn put forth his hypothesis suggesting that trauma and infection cause inflammation with the resultant release of tissue activators that convert the plasminogen present in the clot to plasmin, which in turn dissolves the clot and the kinins thus released from them cause severe pain.⁶

Macgregor in the year 1968, put forward that difficult extractions related to more inflammation of dry socket. Some etiological causes result in degeneration of clot and infected from bacterial swabs when obtained from these produced a mixed bacterial growth.⁸

The role of bacteria in dry socket have been postulated. Many reports have supported the increasing prevalence of this conditions especially in patients who have poor or compromised oral hygiene or already existing infection or any periodontal disease in an advanced form. When antibacterial measures are taken, its prevalence has decreased thus supporting its relation to bacteria.¹² Nitzan et al have found a high fibrinolytic activity of *treponema denticola* from cultures. Generally, dry socket never occurs during childhood because during this time period this organism has not yet colonized in the mouth.

Many other researchers agree that traumatic extraction plays a very major factor for the formation of dry socket the procedure involving reflecting a flap as well as the division of tooth with trimming of bone have reported in the formation of dry socket.

Sweet & Butler have suggested that 4-5 times increase in this condition i.e alveolar osteitis is seen in patients who underwent 400 transalveolar extractions but smoked with a frequency of half packet cigarettes in 1 day. When compared to those who did not smoke 40% incidence of this condition was seen in patients who smoked on that particular day of the procedure, 20% incidence was observed in patients who consumed more than 1 packet in 1 day.¹⁴

The presence of vasoconstrictor property adrenaline of anesthetic local solutions has also found to be a contributory factor in dry socket.¹⁰

In the present study age, the range was all the patients who reported to us with dry socket and had their extraction done by intra alveolar method. However, all had traumatic extractions done by various trainees in the oral & maxillofacial surgery department. No history of smoking was recorded prior to extraction.

Various studies conducted in the 1970s suggested females were more affected with dry socket. It is already proven that certain pyrogens and certain drugs lead to activation of fibrinolytic activity and hence contributes to dry socket, resulting from clot degeneration.

Macgregor (1968) has concluded that the incidence of AO to be gender-specific, females are more prone than males.⁹

Sanchis JM et al recorded in his study about pain and inflammation during the first to seven days of the postoperative period. The higher incidence of pain recorded after the first six hours, with maximum inflammation one day after 3rd molar removal. A decrease in mouth opening after 48 hours was recorded as 18.5 mm v/s 9.9 mm post seven days. Total pain killer drugs consumption after 48 hrs and 7 days was found to be 2.5 and 3.9 tablets of metamizole. Both groups showed similarity in relation to criteria such as age, distribution, gender, oral status, smoking and difficulty level in the removal of teeth surgically were similar in both groups.¹²

Few authors also concluded that injection of chlortetracycline solution in extraction wound have resulted in less pain and also better healing.

A study by Verbic and Olech, have found that antibiotic use may result in less trismus and swelling but it was failed to be proved.¹²

Vezeau et al concluded that broad-spectrum antibiotics such as tetracycline and clindamycin have proved to be better in preventing dry socket. Also substances, resorbable for example methylcellulose act as a stabilizer of clot., polylactic antibiotics also decreased the occurrence of dry socket. Penicillins are also effective in controlling alveolar osteitis¹². Chapnick & Diamond conducted a study for ruling out the effectiveness of topically applied clindamycin observed effective decreased in the dry socket in lower third molar after irrigation and applying gel form of clindamycin topically.¹⁰

Several kinds of research concluded that the preoperative use of chlorhexidine mouth rinse decreases the occurrence of alveolar osteitis following lower 3rd molars extraction.

Few studies also showed that fibrinolytic nature of dry socket was greatly reduced when PHBA was used topically.¹¹

The local application of the mixture of hydrocortisone and oxytetracycline much impactfully reduced the prevalence of dry socket.¹⁶

The anti-fibrinolytic agent tranexamic acid proved to reduce dry socket when applied topically in the extraction site.¹⁶

A recent study on the reduction of the occurrence of alveolar osteitis in which 200 lower molars were removed bilaterally with eugenol medicament placed at the same time. The contralateral surgical site was not given any dressing.¹¹

Majati SS in 50 patients study concluded the effectiveness of Dextranomer granules in early management of pain. Subjects were randomly assigned to Group A in which ZOE medicament and Group B in which Dextranomer medicament was given. Significant results showed dextranomer as a better medicament with better handling characteristics and no allergic reactions.

Faizel S et al evaluated and compared the effectiveness of Neocone (Polymyxin B sulfate, tyrothricine, neomycin sulfate, tetracaine hydrochloride), and Zinc oxide Eugenol (ZOE) and Alvogyl dressings for the management AO. Patients diagnosed with AO were grouped namely Group A of Alvogyl, Group B of ZOE, Group C of Neocone. Two factors that are healing and relief were assessed and compared Pain. Neocone proved to be a suitable dressing for the management of AO.¹³

In our study patients reporting to the department with dry socket categorized in 2 groups in which Group A patient's obtained Alvogyl as an intra-socket medication. The control Group B received Zinc oxide Eugenol. Pain, inflammation, and bone exposed were evaluated and were studied at first, third, fifth and seventh day post insertion of the pack (ZOE/Alvogyl).

There was a great variation of result in pain in following ($P < .001$) was more decreased in A group. But both the groups patients did not take the rescue medications i.e Diclofenac Na 50mg during the treatment. On the 5th day, the pain completely disappeared in all the patients of the group a, however in group b, 09 patients reported with some degree of pain indicating that Alvogyl gave me better results than ZOE in pain control.¹⁶

The inflammation decreased significantly over the period of follow-up in both the groups. However, by the 5th day, inflammation had significantly decreased in Group A with only 5 patients showing sign of resolved inflammation as compared to 15 patients in Group B. By 7th day, all patients in Group A had completely resolved inflammation, but 4 patients in Group B had some inflammation still present, thus Alvogyl was superior in reducing inflammation around the extraction socket when compared to ZOE. Inflammation decreased more rapidly in Alvogyl probably because of additional anti-inflammatory action of Penghawar. Penghawar fibers give a firm consistency which provides early filling of the socket. Penghawar fibers are the Malayan designation of the lower part of stripes of a large fern found indigenous in Sumatra and used as a hemostatic agent.

Numbers of walls exposed were comparable in both the groups. In group A complete healing was noted in all the patients on 5th day compared to 12 patients in group B. On 7th day in group B, 4 patients had either one or two walls exposed. Alvogyl was better in causing rapid healing of the sockets as the wound completely healed in 5 days in all cases. It may be attributed to the fact that Iodoform has antiseptic and disinfectant properties. Iodoform is an organo-iodine compound with a chemical formula of CHI₃.¹⁷

V. Conclusion

The main objective of dry socket management has been palliative because pain level differs in every person. It is of greater importance to find and also access various parameter to provide us with more detailed compression in relation to its treatment modalities. In our study by comparing the above parameters between Alvogyl and ZOE, we concluded that Alvogyl has better healing properties and relieves pain at a faster rate compared to ZOE.

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Dr. Amit Yadav “A comparative study of Alveogyl and ZOE in dry socket syndrome” *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 18, no. 9, 2019, pp 68-75.