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**Original Research** 

# Prevention of Dry Socket using Chlorhexidine Gel and Ornidazole Gel in Impacted Mandibular Third Molar: A Comparative Randomized Prospective Study on 30 Patients

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## Abstract:

**Background:** To compare the effectiveness of the intra-alveolar application of chlorhexidine gel versus ornidazole gel in prevention of dry socket after surgical extraction of mandibular third molars with difficulty score between 7 and 10.

**Materials and Methods:** *In vivo*, single blind, randomized comparative prospective study was conducted in the Department of Oral and Maxillofacial Surgery of Vyas Dental College and Hospital on 30 patients irrespective of gender, race, caste undergoing surgical extraction of mandibular 3<sup>rd</sup> molar with difficulty score between 7 and 10. All the patients in the age group of 18-60 years, requiring extraction of impacted 3<sup>rd</sup> molar were selected for the study. The patients were divided in three groups on the basis of material used, each group had 10 patients. There were two experimental groups in which chlorhexidine gel or ornidazole gel was placed in the socket after surgical extraction of third molar and one control group in which no gel was placed. All patients were evaluated for mouth opening, facial size pre-operatively and on 3<sup>rd</sup> and 7<sup>th</sup> post-operative day. All patients were also evaluated for pain for the diagnosis of dry socket on 3<sup>rd</sup> and 7<sup>th</sup> post-operative day.

**Results:** The study clearly indicates a definite improvement in mouth opening and swelling (facial size) after placement of chlorhexidine gel or ornidazole gel. This improvement in mouth opening and swelling has effect on pain also and there is decrease in post-extraction pain. Only 1 from 10 patients developed dry socket after placement of chlorhexidine gel and 2 from 10 patients developed dry socket in which nothing was placed, this shows that incidence of dry socket is significantly less on placement of either chlorhexidine gel or ornidazole gel. There is no significant difference between chlorhexidine gel and ornidazole gel and both gels are effective in reducing the incidence of dry socket in patients with difficulty score between 7 and 10.

**Conclusion:** This study indicates that both chlorhexidine gel and ornidazole gel are effective in reducing post-operative complications which are pain, swelling, and reduction in mouth opening. This improvement signifies and highlights the use of chlorhexidine gel and ornidazole gel in the prevention of dry socket after extraction of mandibular third molar. The limitation of the present study is reduced sample size, consisting of only 30 patients.

**Key Words**: Chlorhexidine gel, dry socket, mandibular third molar extraction, ornidazole gel

# Introduction

Dry socket or alveolar osteitis (AO) is a very painful, self-limiting condition which is relatively common complication following tooth extraction. Dry socket was first described in literature in 1896 by Crawford.<sup>1</sup>

According to Blum<sup>2</sup> AO or dry socket is defined as "postoperative pain in and around the extraction site, which increases in severity at any time between the first and third day after the extraction which is usually accompanied by partially or totally disintegration of blood clot within the alveolar socket with or without halitosis". Its incidence varies from 20% to 30% after removal of impacted third molars and 1-70% for all dental extractions.<sup>3,4</sup> The onset of AO is considered to occur 1-3 days after tooth extraction.<sup>5</sup>

Exact etiology of AO has not been firmly established. Currently, two main theories have been proposed for the etiology of AO. Majority of intervention for AO focus on prevention rather than treatment. Several techniques have been used in the prevention of AO. Current preventive measures include antibacterial agents, antiseptics, antifibrinolytics, antiinflammatory agents, and clot support agents.<sup>2</sup>

Antiseptics such as chlorhexidine rinses have proved to be efficient in AO prevention. The introduction of 0.2% chlorhexidine in the form of bio adhesive gel to deliver the active substance has resulted in new lines of research in dry socket prevention.<sup>6,7</sup>

This was a prospective, blind study done to assess and compare the effectiveness of chlorhexidine gel and ornidazole gel placed directly into the surgical socket after removal of the mandibular third molar in preventing incidence of "AO."

## **Materials and Methods**

The present study was undertaken in the Department Oral and Maxillofacial Surgery, Vyas Dental College Jodhpur, after obtaining ethical clearance. This study involved both male and female patients, who were referred to the department for removal of mandibular 3<sup>rd</sup> molar with difficulty score between 7 and 10 on the basis of Pederson difficulty index.

#### Inclusion criteria

All the patient in the age group of 18-60 years, requiring extraction of impacted 3<sup>rd</sup> molar who were willing to be available for the entire period of study were included in the study

## Exclusion criteria

The patients with contraindications for intervention, immunocompromized patients, pregnancy or women in lactating period and those on oral contraceptive, patients allergic to chlorhexidine and ornidazole, patients with any hard or soft tissue pathology and patients who are addicted to or abuse alcohol and or tobacco in any form.

After obtaining a thorough history, patients were examined clinically and were explained about the procedure, its possible complications and the necessary follow-up period involved in the study. The patients who were willing and fulfilled all conditions were enrolled for the study. Informed consent forms were signed by the participants.

# Study design

This is a blind study. A total of 30 patients were included in the study who fulfilled all the inclusion criteria (Sample size = 30). The 30 participants were divided into three equal groups based on "the material placed in the extraction socket." In this group, there were three subgroups. In the sub groups, there were two experimental groups and one control group. All sub groups included 10 patients each.

On the basis of difficulty index the group included all the patients who fall in the given range:

 Group: Very difficult, on the basis of Pederson difficulty index (difficulty index score: 7-10) (n = 30)

Ten patients received chlorhexidine gel, 10 patient received ornidazole gel, and 10 were under control group.

All the patients underwent extraction with the same technique and followed by same post-operative regimen. All the procedure were done under local anesthesia with 2% lignocaine (with 1: 80,000 adrenaline) by the same operator to eliminate any operator bias. All patients were recalled on the  $3^{\rm rd}$  day and  $7^{\rm th}$  day post-operatively for a follow-up study.

The following details were recorded pre-operatively;

- 1. The tooth to be removed
- 2. Type of impaction
- 3. Inter incisal mouth opening
- 4. Facial size
- 5. Pain.

Evaluation was done immediate pre-operative and then on 3<sup>rd</sup> and 7<sup>th</sup> post-operative day. All the patients were subjected to pre-operative investigations which included clinical, radiological, and hematological.

## Surgical technique

The patient was planned for the procedure following all aseptic condition. The patient face was prepared with betadine and was draped. Nerve block was given using 2% lignocaine hydrochloride with 1:80,000 adrenaline. Full thickness mucoperiosteal flap were raised by giving Terrence Ward's 1 or Terrance Ward's 2 incision or an envelope flap. Surgical area exposed. Buccal guttering was done according to Moore and Gilbey's buccal guttering technique. The tooth if necessary was sectioned and the tooth was removed from the socket (Figure 1).

The surrounding bone was smoothened. The wound was gently irrigated with a sterile normal saline solution (approximately 40-50 ml) and checked for any small detached fragments of bone or tooth pieces. The socket was gently dabbed with gauge to remove excess saline. In the experimental groups chlorhexidine gel or ornidazole gel (Figure 2) was squeezed into the socket to completely fill the socket using a disposable syringe from the depth upward before primary closure of the wound (Figures 3 and 4).



Figure 1: Extraction socket after removal of tooth

Wound was closed with 3-0 Mersilk interrupted sutures. Pressure pack was given.

Regular post-surgical instructions were given to all the patients in written. All patients followed the same medicine regime: Tablet diclo  $50 \, \text{mg/TID} \times 3$  days and Warm saline rinse after 24 h of extraction.

On  $3^{\rm rd}$  and  $7^{\rm th}$  post-operative day: The patients were evaluated for signs of dry socket, pain, swelling, and restriction in mouth opening.

#### Results

The study was carried out on 30 patients with impacted mandibular third molars, who reported to our department, requiring surgical extraction of impacted mandibular third molar, with difficulty score between 7 and 10. Following completion of clinical study on the patients, the measurements and data taken from all the patients were tabulated for statistical studies.

For statistical analysis of mouth opening and facial size data was subjected to paired *t*-test and pain data was subjected to Pearson Chi-square.

Graph 1 shows gender distribution of included 17 (56.67%) male subjects and 13 (43.34%) female subjects. Table 1 shows age distribution, mean age in years is 32.02.

Table 2 describes the mean and probability value of mouth opening in three sub groups on  $3^{\text{rd}}$  and  $7^{\text{th}}$  post-operative day. The *P* value for mouth opening is significant in both the groups for both the gels (P < 0.05). The *P* value for

Table 1: Age distribution.								
Based on Case Mean N SD								
difficult index	group							
Group	Chlorhexidine gel	26.20	10	3.938				
	Ornidazole gel	34.00	10	8.485				
	Total	30.10	20	7.580				
SD: Standard deviation								

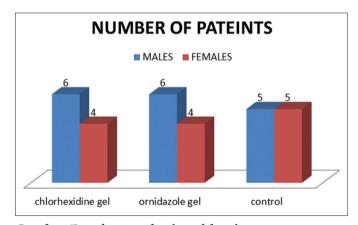
chlorhexidine gel is highly significant as compared to ornidazole gel.

Table 3 describes the mean and probability value of mouth opening in both the groups on  $3^{rd}$  and  $7^{th}$  post-operative day between chlorhexidine gel and ornidazole gel. The P value for both the gels in the group is not significant (P > 0.005).

Table 4 describes the mean and probability value of facial size in both the groups on  $3^{\rm rd}$  and  $7^{\rm th}$  post-operative day. The P value for mouth opening is significant in both the gels (P < 0.05). The P value is highly significant for both the gels on the  $7^{\rm th}$  day. From the P value, it can be concluded that placement of both the gels in extraction socket gives a better result.

Table 5 describes the mean and probability value of facial size on  $3^{\text{rd}}$  and  $7^{\text{th}}$  post-operative day between chlorhexidine gel and ornidazole gel. The P value for both the gels in the group is not significant (P > 0.05). With this P value, it is difficult to comment which gel is more effective.

Table 6 describes the mean and probability value of pain in both the groups on  $3^{\rm rd}$  and  $7^{\rm th}$  post-operative day. The P value for pain is significant for ornidazole group on the  $7^{\rm th}$  day at the same time it is not significant for chlorhexidine gel. The P value on the  $3^{\rm rd}$  day in not significant for both the gel.



**Graph 1:** Distribution of male and female in group

Table 2: Mean and P value of mouth opening.									
Based on difficult	Based on case Mouth opening group pre-extraction		Mouth opening 3 <sup>rd</sup> day post-extraction	Mouth opening 7 <sup>th</sup> day post-extraction	Paired <i>t-</i> test <i>P</i> value				
index		measurement (mm)	measurements (mm)	measurements (mm)	3 <sup>rd</sup> day	7 <sup>th</sup> day			
Group	Chlorhexidine gel	38.90	31.70	37.90	0.000	0.000			
	Ornidazole gel	37.40	28.80	34.90	0.027	0.045			
	Control group	38.90	24.20	30.70					

Table 3: Mean and P value of mouth opening for chlorhexidine gel and ornidazole gel.									
Based on difficult	Based on case group	Mouth opening pre-extraction	Mouth opening 3 <sup>rd</sup> day post-extraction	Mouth opening 7 <sup>th</sup> day post-extraction	Paired <i>t</i> -test  P value				
index		measurement (mm)	measurements (mm)	measurements (mm)	3 <sup>rd</sup> day	7 <sup>th</sup> day			
Group	Chlorhexidine gel	38.90	31.70	37.90	0.195	0.131			
	Ornidazole gel	37.40	28.80	34.90					

Table 4: Mean and P value of facial size.									
Based on difficult index	Based on case group	Facial size (pre)	Facial size (3 <sup>rd</sup> day)	Facial size (7 <sup>th</sup> day)		aired <i>t-</i> test <i>P</i> value			
		_	·		3 <sup>rd</sup> day	7 <sup>th</sup> day			
Group	Chlorhexidine gel	11.7800	12.0680	11.8310	0.004	0.000			
	Ornidazole gel	11.7980	12.1040	11.8770	0.005	0.000			
	Control group	12.1080	13.0760	12.5570					

Table 5: Mean and P value of facial size for chlorhexidine gel and ornidazole gel.									
Based on difficult index	Based on case group	Facial size (pre)	Facial size (3 <sup>rd</sup> day)	Facial size (7 <sup>th</sup> day)	Paired P va				
					3 <sup>rd</sup> day	7 <sup>th</sup> day			
Group	Chlorhexidine gel	11.7800	12.0680	11.8310	0.782	0.656			
	Ornidazole gel	11.7980	12.1040	11.8770					

	Table 6: Mean and P value of pain.										
Based on difficult	Based on case group	Pain (3 <sup>rd</sup> day)			Pain (7 <sup>th</sup> day)			Chi-square (P value)			
index		No pain	Mild	Moderate	No pain	Mild	Moderate	3 <sup>rd</sup> day	7 <sup>th</sup> day		
Group	Chlorhexidine gel	0	6	4	9	1	0	0.019	0.006		
	Ornidazole gel	1	6	3	9	0	1	0.023	0.004		
	Control group	0	1	9	3	7	0	-	-		

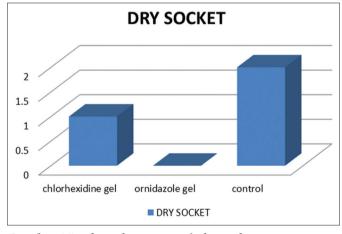
In this study, total 3 patients had dry socket in 30 patients. Out of 3, 1 patient was from case group, 2 patients were from control group (Graph 2).

#### Discussion

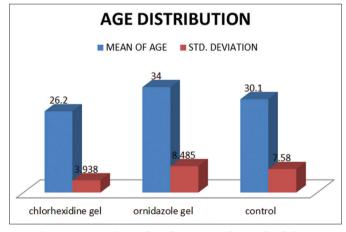
The most common and painful complication in the healing of human extraction wounds is AO, commonly known as dry socket. Alveolar osteities (dry socket), a complication of tooth extraction, is an acute non purulent inflammatory process which is localized in the dental alveolus that produces a delay in wound healing and is characterized by a late onset (2-4 days after the extraction) with intense and irradiating pain and also there is absence of typical inflammatory signs.<sup>8</sup> The main characteristic of the extraction socket is the denuded appearance of its interior (no presence of blood clot) with the bone exposed in the oral cavity which is whitish and is hypersensitive to contact and the mucosa surrounding the socket is tumescent. The more complex and traumatic the extraction, the higher the likelihood of dry socket.

Most literature supports that dry socket rarely occurs in childhood and that incidence increases with the patient's age, although the exact age bracket of highest incidence varies among different papers. <sup>2,9</sup> In this study, three patients had dry socket. Out of three patients, one patient belong to the third decade and two patients belong to fourth decade. From this study, it is difficult to conclude that incidence of dry socket is higher in third and the fourth decade of life because of small sample size.

In this study, we found no correlation between gender, age, site of extraction, and dry socket. The patients who were addicted to or abuse alcohol and or tobacco in any



**Graph 2:** Number of patients with dry socket in a group



**Graph 3:** Mean of age distribution and standard deviation into case groups

form were not included in this study. In this study, 17 male subjects (56.67%) and 13 female subjects (43.34%) were

included (Graph 1). The patients who had participated in the study were in the age range of 18-60 years, with a mean age of 32.02 years in case groups (Table 1, Graph 3). In this study, patients were divided into three groups on the basis of usage of gel (chlorhexidine gel and ornidazole gel). Three sub groups were made and each group had 10 patients. 30 patients had traumatic extraction that is time taken for procedure was more than 40 min because of difficulty index score between 7 and 10. Out of 30 patients, 3 patients had dry socket, Incidentally, 2 patients out of 3 belong to control group. It can be concluded that 67% had dry socket after traumatic extraction (time for procedure >40 min) in which no gel was placed.

In 1977, Legarth<sup>10</sup> performed a study to see the effect of 0.2% chlorhexidine on dry socket prevention and noted a 45% decrease in dry socket in a group of 60 patients. In addition, Tjernberg<sup>11</sup> performed a study and found that only 1 patient in a test group of 30 patients using 0.2% chlorhexidine rinse had AO as compared to 5 of 30 patients in the control group. A study by Krekmanov and Nordenram,<sup>12</sup> published in 1986, found an 11% decrease in the incidence of dry socket in patients who rinsed with a 0.2 % chlorhexidine solution. This contrasts with results published in 1971 by Macgregor,<sup>13</sup> who concluded



Figure 2: Gel used



Figure 3: Placement of ornidazole gel into the socket

that 0.2% chlorhexidine was not of value as a pre-operative antiseptic rinse for oral surgery.

The bio-adhesive 0.2% chlorhexidine gel could improve the action of chlorhexidine since placement of chlorhexidine gel directly into the socket will allow a more direct action on the alveolus, and also we can see the long lasting effect of the gel placed.<sup>14</sup>

Various studies have been done to see the role of metronidazole in the prevention of dry socket and in results was found that that prophylactic metronidazole was found to be effective means of preventing "dry socket" after routine dental extraction.<sup>15</sup>

The antimicrobial activity of ornidazole has been proposed is due to the reduction of nitro group to a more reactive amine group. This amine group attacks the microbial DNA thus inhibiting further synthesis and causing degradation of existing DNA. From the mentioned mechanism of action use of ornidazole as local drug delivery may be an advantageous form of treatment since it would probably eliminate side effects, which occur with systemic dosing. <sup>16</sup>

On the basis of clinical evaluation and statistical analysis we found that in patients where intra alveolar chlorhexidine gel or ornidazole gel was placed there was significant reduction in pain on the 3<sup>rd</sup> post-operative day and 7<sup>th</sup> post-operative day. Mouth opening and facial swelling was also good post-operatively (i.e. approximately same as pre-operative measurements)



Figure 4: Placement of chlorhexidine gel into the socket



Figure 5: Wound closure with 3-0 silk suture in both groups

when compared with control group. In statistical analysis, the probability value (P value) for mouth opening, facial size, and pain in overall comparison of chlorhexidine gel, and control group was less than 0.05 (0.00) which proves it to be statistically significant. Similarly, in statistical analysis the probability value (P value) for mouth opening, facial size, and pain in overall comparison of ornidazole gel, and control group was also less than 0.05 (0.00) which proves it statistically significant. From this it can be concluded that both chlorhexidine gel and ornidazole gel is effective in reducing post-extraction complications.

In overall comparison of chlorhexidine gel and ornidazole gel irrespective of Pederson difficulty index score for mouth opening, facial size, and pain we did not found statistically significant result as probability value (P value) was more than 0.05 (P > 0.05) From this it can be concluded that both the gels are effective in reducing post-extraction complications, but which gel is more effective is difficult to comment.

In our observation, we found that patients were maximally benefited by the placement of ornidazole gel, as none of the patients in this group reported with dry socket.

In this study, three patients developed dry socket, for two patients zinc-oxide eugenol dressing was placed, and for one patient normal saline irrigation was done. All the patients were benefited and no one reported with any complain.

# Conclusion

This study indicates that irrespective of difficulty index both chlorhexidine gel and ornidazole gel are effective in reducing post-operative complications which are pain, swelling, and reduction in mouth opening. This improvement signifies and highlights the use of chlorhexidine gel and ornidazole gel in the prevention of dry socket after extraction of mandibular third molar. The limitation of the present study is reduced sample size, consisting of only 30 patients. It is very important to get the correct and precise idea of root pattern of impacted third molar and its relation with mandibular canal, for this we prefer cone beam computed tomography over intra oral periapical as suggested by various studies also. <sup>17</sup>

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