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Evaluating the Prudential Use of Antibiotic Therapy Concerning Third Molar Surgical Procedures: A Clinical Evidence Based Research

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Abstract:

Aims and Objectives: To assess the role and the prudential use of antibiotics in prevention of postoperative infections following third molar.

Materials and Methods: This randomized prospective double blind clinical study was conducted in the Department of the Oral and Maxillofacial Surgery which includes the clinical parameters of pain, swelling and trismus. The sample population consisted of 24 patients based on inclusion and exclusion criteria. A clinical trial was conducted on the patients indicated for surgical removal of impacted mandibular third molar who were divided in Group-A (post-operative antibiotic) and Group-B (Pre-operative antibiotic) each group contain 12 patients. Ethical clearance was obtained for the study.

Results: The result indicates no significant difference between two groups in pain, swelling and trismus. Within the group significant changes of all clinical parameters were noticed on 2st, 3rd and 7th day post surgical removal of 3rd molar. Swelling was seen to be completely subsided on 7th day post operatively in both the groups with marginally more number of patients complaining of pain and trismus on 7th day post-opertively were reported in GROUP A patients. Post-operative infections were found to be marginally more in GROUP A patients as compared to GROUP B patients which completely subsided on 7th day post surgical procedure following betadine gargle.

Conclusion: Complications mostly inevitable and invariable and are frequent in third molar surgical procedures. Attention to the basic principles of surgery, including proper preparation of the patient, asepsis, haemostasis, use of controlled force, thorough debridement, and meticulous management of both bone and soft tissues can reduce the number and severity of complications. From the present study, although non significant it was believed that single dose pre-operative prophylaxis is a safe way to minimize the infection rate and costs in the hospital setting having marked reduction in swelling and trismus.

Key words: Antibiotics, Mandibular Third Molar, Pain, Trismus, Swelling, Infection, Prophylaxis.

Introduction:

Antimicrobial medicationsidentified as a substance delivered by microorganisms, which specifically suppresses the growth or kills the causative pathogenic microorganisms at low fixations, considered being the most principal creations o 20th century era in the field of medicine and are being prescribed as therapy to a wide range of infections or illness. [1] The role antibiotics in dentistry has been paramount with most usage

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in the infection control phase of odontogenic infections which is used as an adjunct to the surgical therapies owing to the nexus of micro-organisms ecosystem equilibrium of which changes from resilient facultative anaerobes to obligate anaerobes in cases of pulpal and periodontal infections. [2,3] With the advancement in the new class of antibiotics since the discovery of penicillin most of them has been unjudiciously used warranting any rational explanation.[4,5] Therefore present study has been conducted to provide a rational explanation for the use of antibiotic for the cases of third molar surgical procedures considering the various clinical parameters.

Material and Methods

This randomized prospective double blind clinical study was conducted in the Department of the Oral and Maxillofacial Surgery. Assessment of pain, trismus and swelling was done before and after surgical removal of impacted mandibular third molar. The sample population consisted of 24 patients who fulfilled the inclusion and exclusion criteria. A clinical trial was conducted on the patients whom required the surgical removal of impacted mandibular third molar and were voluntarily willing to participate in the study in which patients were divided in to two different groups (each group had 12 patients). Ethical clearance was obtained for the study.

Inclusion criteria were as follows:

- Patients between 15-50 years of age with impacted mandibular third molars were included in the study.
- Patients with American Society of Anesthesiologists(ASA) 1, 2 Category were selected in the study.
- The patients were operated by one operator.
- Patients with clinical signs of pain, swelling and trismus were selected.

Exclusion criteria are as follows:

- Patients with acute pericoronitis or any other acute infection.
- Medically compromised patients.
- Impacted molars with pathology and periapical infection were excluded from the study.
- Patients allergic to Amoxicillin.
- Patients on antibiotic therapy since last 15 days for any reason.

Sample Design

Sample was divided into two groups:

Group A (12 patients) regarded as Group-A in which patient received antibiotic post-operatively (Cap. Amoxicillin 500 mg three times in a day for five days).

Group B (12 patients) regarded as Group-B in which patient receive pre-operative antibiotic (Cap Amoxicillin 2gm) 1 hour before surgery.

Evaluation Criteria

Clinical Parameter:

• Assessment of Swelling: - Assessment of postoperative swelling was done by calculating the differences between pre & postoperative measurements from extra oral reference points. Facial measurements were carried out with silk thread and centimetre ruler. The linear measurements were taken between the angles of the mandible to outer canthus of the eye followed by measurement of tragus of ear to corner of the mouth. Then the measurements were transferred to the centimetre ruler. These measurements were done on 1^{st}, 3^{rd}, and 7^{th} postoperative days.

• Assessment of Pain: - Severity of patient pain perception was assessed via a simplified visual analogue scale (VAS). The patient was required to place a mark on the scale to indicate the pain intensity. These measurements were done on 1^{st}, 3^{rd}, and 7^{th} postoperative days.

• Assessment of Trismus: -Trismus was recorded as the difference in inter-incisal distance at maximum opening pre operatively and on 1^{st}, 3^{rd}, and 7^{th} postoperative days.

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Results

In 24 patients (24 molars), 12 in each group; surgical extraction of the mandibular third molar was done (in group A, 5 females and 7 males and in group B, 4 males and 8 females; Table-1 and Graph-1). Age distribution ranged from 15-40 years as shown in Table-2 and graph 2. Twenty-four impacted mandibular third molars were extracted using the same surgical protocol and the study was a prospective double blind clinical study. Statistical analysis data is presented as mean values and standard deviations (x ± SD).

Table Number 1: Age distribution: The age ranged from 15-40 years.

Age Range	Group A	Group B
15-20	0	1
21-30	8	7
31-40	4	4

Swelling (Table Number 2)

Group-A

Swelling on the 1st day after surgery: Outof 12 patients in group A only one patient had developed severe swelling and remaining 11 patients had developed only mild to moderate swelling on 1st day after surgery.

Swelling on the3rd day after surgery: Out of 12 patients no patient had severe swelling and all patients had mild swelling on 3rd post-operative day.

Swelling on 7th day after surgery: No significant swelling was found in any patient. All patients reported with almost no swelling.

Group A

Swelling			Mean	SD	Mean diff	p value
	Pre-op	C---T	107.83	11.74		
		O---A	108.00	15.37		
	1	C---T	118.42	12.41	10.58	0.00
		O---A	116.75	13.01	8.75	0.00
	3	C—T	113.75	10.57	5.92	0.00
		O---A	113.83	13.07	5.83	0.00
	7th	C---T	109.17	10.63	1.33	0.04
		O---A	109.75	13.77	1.75	0.02

TABLE NUMBER-2

Group-B **(Table Number-3)**

Swelling on the 1st day after surgery: Outof 12 patients in group B only one patient had developed severe swelling and remaining 11 patients had developed only mild and moderate swelling on the 1st day after surgery.

Swelling on the3rd day after surgery: Out of 12 patients one patient had severe swelling and the remaining patients had mild swelling on 3rd post-operative day.

Swelling on 7th day after surgery: No significant swelling was found in any patient. all patients had reported with almost no swelling.

Group B

Swelling			Mean	SD	Mean diff	p value
	Pre-op	C---T	107.00	8.51		
		O---A	107.00	5.05		
	1	C---T	114.92	10.24	7.92	0.00
		O---A	112.83	6.22	5.83	0.00
	3	C—T	113.17	10.53	6.17	0.02
		O---A	112.42	5.35	5.42	0.00
	7th	C---T	108.33	8.38	1.33	0.01

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		O---A	107.00	4.18	0.00	0.50

Table Number-3

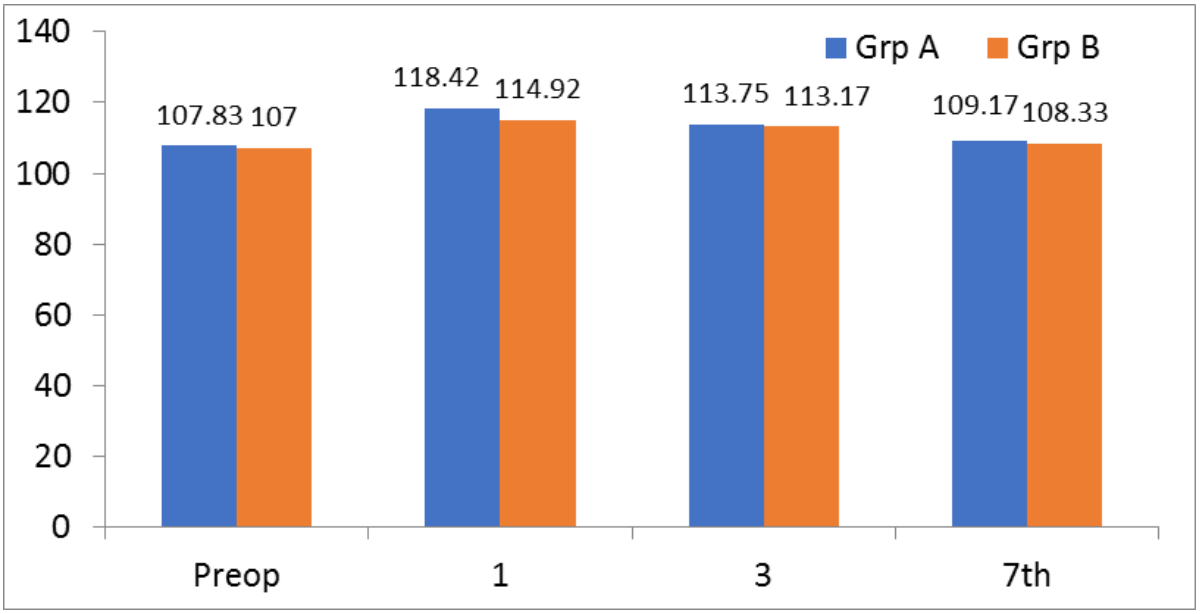
Comparison between Group-A and Group-B: In group I and group II, the results indicate that there is a significant time effect. This means that the swelling score changes over time i.e. swelling score decreased with the passage of time in both groups. Swelling on the first post-operative day was perceptibly but not significantly lesser in Group B; the group that received pre-op antibiotics. The results also indicate that there is no significant difference in swelling in the two groups on 1st, 3rd and 7th day after swelling. p values >0.05(i.e. not significant). (TABLE NUMBER-4, GRAPH NUMBER 1)

Inter-Group Comparison

Swelling			Group A		Group B		
			Mean	SD	Mean	SD	p value
	Pre-op	C---T	107.83	11.74	107.00	8.51	0.844
		O---A	108.00	15.37	107.00	5.05	0.832
	1	C---T	118.42	12.41	114.92	10.24	0.459
		O---A	116.75	13.01	112.83	6.22	0.357
	3	C—T	113.75	10.57	113.17	10.53	0.893
		O---A	113.83	13.07	112.42	5.35	0.731
	7th	C---T	109.17	10.63	108.33	8.38	0.833
		O---A	109.75	13.77	107.00	4.18	0.515

p>0.05 – Not Significant; p<0.05 – Significant; p<0.001–Highly Significant

Table Number-4



Swelling
Graph Number-1

Pain

Group-A: (Table Number 4)

Pre-operative: Three patients in this group had presented with severe pain pre-operatively and nine patients had present with mild to moderate pain or no pain.

Pain on the 1st day after surgery: Only two patients had presented with severe pain post operatively on 1st

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after surgery, seven patients with moderate pain and three patients with mild pain (according to VAS scale)
Pain on the 3rd day after surgery: Only one patient is reported with moderate pain on 3rd post-operative day and remaining eleven patients had presented with mild pain (according to VAS scale)
Pain on the 7th day after surgery: One patient is reported with almost no pain and other patient is also reported with mild pain or no pain.

Pain		Mean	SD	Mean diff	p value
	Pre-op	31.67	24.34		
	1	32.92	10.54	1.25	0.42
	3	25.00	11.28	-6.67	0.16
	7	9.58	4.68	-22.08	0.00

Table Number-4

Group-B (Table Number-5)
Pre-operative: Two patients in this group had presented with severe pain pre-operatively and ten patients is present with mild to moderate pain or no pain.
Pain on the 1st day after surgery: Only two patients presented with severe pain post operatively on 1st after surgery, six patients with moderate pain and four patients with mild pain (according to VAS scale)
Pain on the 3rd day after surgery: Two patients had reported with no pain and two patients had reported with very mild pain and eight patients had reported with moderate pain.
Pain on the 7th day after surgery: Six patients had reported with almost no pain and remaining six patients with very mild pain.

Pain		Mean	SD	Mean diff	p value
	Pre-op	23.33	16.28		
	1	31.67	17.49	8.33	0.08
	3	20.00	14.30	-3.33	0.28
	7	5.00	6.40	-18.33	0.00

Table Number-5

Comparison between Group-A and Group-B: In group I and group II, the results indicate that there is a significant time effect. This means that the pain score changes over time (p-value<0.001). Pain on the third post-operative day was perceptibly but not significantly lesser in Group B; the group that received pre-op antibiotics No statistically significant difference was found between the twotreatment groups (p-value >0.05) after applying repeated measure analysis ofvariance as shown in Table number-6 and graph number-2.

Pain		Group A		Group B		
		Mean	SD	Mean	SD	p value
	Pre-op	31.67	24.34	23.33	16.28	0.335
	1	32.92	10.54	31.67	17.49	0.834
	3	25.00	11.28	20.00	14.30	0.352

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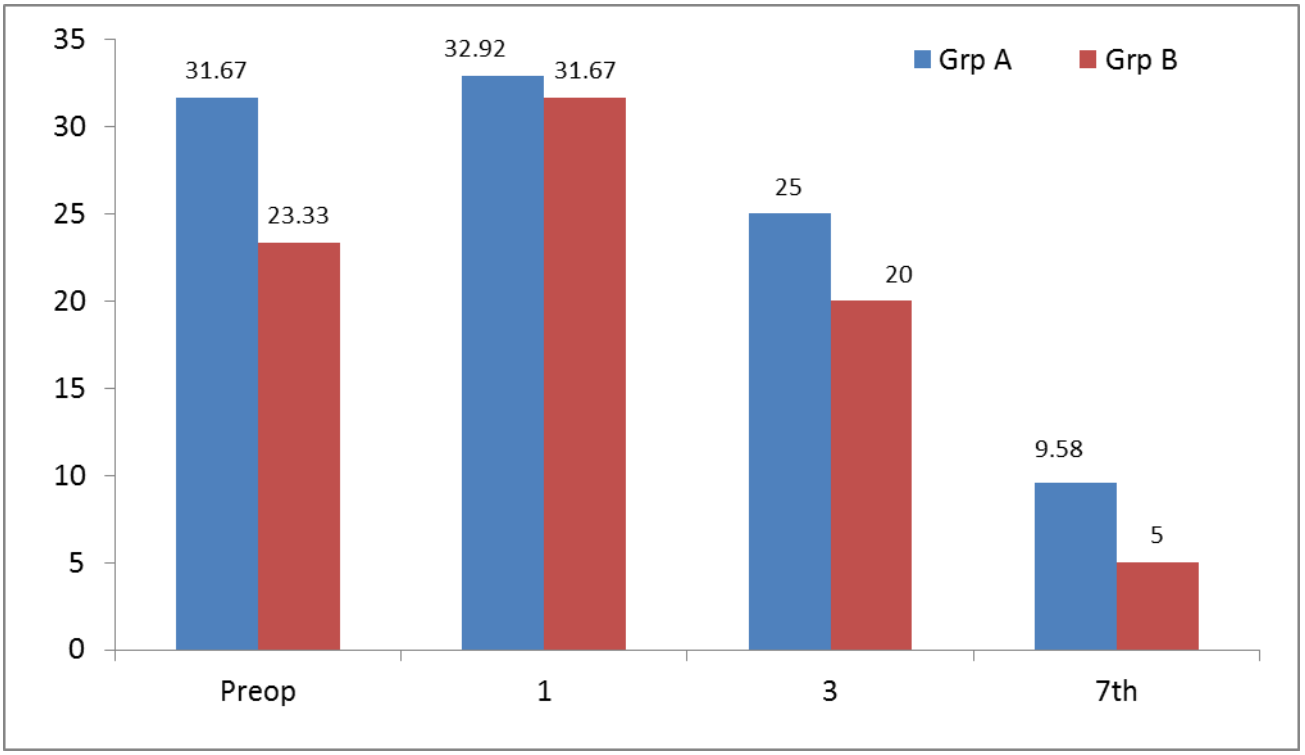
	7	9.58	4.68	5.00	6.40	0.058

Table Number-6



Graph Number-2

Trismus

Group-A (Table Number-7)

Trismus on the 1st day after surgery: There is significant difference is found in mouth opening first day after the surgery six patients in this group does not show any significant difference in mouth opening before and after surgery. Three patients had severe trismus after surgery and three patients had reduced mouth opening.

Trismus on the 3rd day after surgery: Two patients had trismus on 3rd after surgery and ten patients had good mouth opening**.**

Trismus on the 7th day after surgery: Only two patients had significant reduced mouth opening seven day after surgery.

Group A

Trismus		Mean	SD	Mean diff	p value
	Pre-op	37.42	2.50		
	1	26.83	4.37	-10.58	0.00
	3	29.75	3.77	-7.67	0.00
	7	34.25	4.11	-3.17	0.03

Table Number-7

Group B (Table Number-8)

Trismus on the 1st day after surgery: There is significant difference is found in mouth opening first day after the surgery. Four patients had severe trismus first day after surgery and four patients had good mouth opening first day after surgery.

Trismus on the 3rd day after surgery: One patient is reported with severe trismus and two patients with mild trismus while nine patients with good mouth opening.

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Trismus on the 7th day after surgery: No patient reported with trismus on 7th day after surgery in this group

Group B

Trismus		Mean	SD	Mean diff	p value
	Pre-op	37.00	5.29		
	1	26.58	4.72	-10.42	0.00
	3	29.83	4.24	-7.17	0.00
	7	35.58	3.50	-1.42	0.20

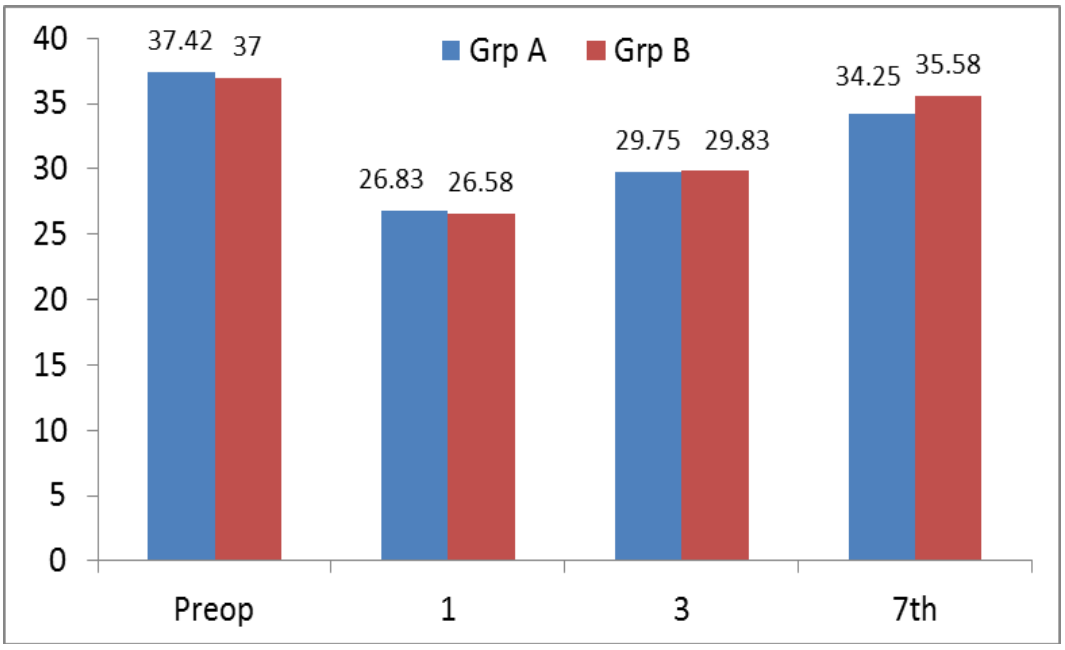
Table Number-8

Comparison between Group-A and Group-B: The results shows that there was time effect (p-value<0.001) and pain changes over time. No statistically significant difference was found between the twotreatment groups (p-value >0.05) after applying repeated measure analysis ofvariance as shown in Table-9 AND GRAPH NUMBER-3.

Trismus		Group A		Group B		
		Mean	SD	Mean	SD	p value
	Pre-op	37.42	2.50	37.00	5.29	0.808
	1	26.83	4.37	26.58	4.72	0.894
	3	29.75	3.77	29.83	4.24	0.960
	7	34.25	4.11	35.58	3.50	0.402

TABLE NUMBER-9

Trismus (Comparison between Group-A and Group-B)



Graph Number-3

Infection: Though the sample size is small, there is marginal reduction in rate of post-operative infection in group-b (Pre-operative antibiotic). Two patients had reported with infection on 1st day after the surgery in Group-A and in Group-B only one patient is reported with the infection on 1st day after surgery. Third day after surgery in both group two patients had reported with infection. These surgical sites were irrigated with betadine and saline and the patients prescribed warm saline gargles five times in a day. Subsequently, there

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was no infection on the seventh day after surgery when patient came for follow-up.

Discussion

The findings in this randomized prospective double blind clinical study were based on periodical clinical examinations and patient's feedback. There was a good correlation between the patients' own assessments of pain on the Visual Analogue Scale with the difficulty of removal of impacted third molar. Most patients, who reported swelling, also had some degree of impaired mouth opening. The methods we used to evaluate pain, swelling, trismus and infection are described in the literature. [4]

Post-operative infection of bone and soft tissues is a common complication that can be reduced with good surgical techniques. Some bacterial contamination of a surgical site is inevitable, either from the patient's own bacterial flora or from the environment. [5]. Antibiotics are commonly administered prophylactically for major and minor surgical procedures. In many cases, antibiotics are prescribed only after the procedure. No intra-operative antibiotic cover is thus achieved which is in conflict with the basic principles of prophylaxis. [6]

In this study we used two groups, group I with single loading dose of 2-gm Amoxicillin 1 hour before surgery and group II with 500 mg of Amoxicillin post operatively thrice daily for five days. Such a randomized controlled trial was required to evaluate the efficacy of antibiotic prophylaxis in third molar surgery. [7]

Most odontogenic infections are poly-microbial and are composed of at least two predominating bacteria, commonly Streptococci (anaerobic gram-positive cocci) and *Neisseria*(anaerobic gram-negative rods). *Jaunay et al in 2000* mentioned that most of the antibiotics are prescribed in relatively low dose over a long period. [8]

Penicillin is still the gold standard in treating dental infections. Penicillin has contributed to a dramatic decrease in mortality in serious odontogenic infections such as Ludwig's angina and diffuse oro-facial cellulites [9]

One of the aims of rationalizing surgical antibiotic prophylaxis is to optimize the use of antibiotics thus minimizing the consequences of misuse. The prevalence of antibiotic resistance in any population is related to the proportion of the population that receives antibiotics, number of antibiotic exposures and also the total antibiotic exposure [10]. In a study, *Namias et al* has shown a statistically significant increase in the frequency of bacteraemia and infections in surgical patients who received prophylactic antibiotics for more than four days in comparison with those who received prophylaxis for one day or less [11].

Side effect most often encountered is penicillin hypersensitivity, which is found in roughly 3-5% of the population. Anaphylactic reactions occur in 0.04-0.011 percent of patients receiving penicillin for prophylaxis. Gastrointestinal tract upset, colonization of resistant or fungal strains, cross reactions with other drugs and other allergies, are also associated with antibiotic therapy. Because of their ineffectiveness against the oral anaerobes, macrolides are no longer considered among the empiric antibiotics of choice for odontogenic infections [12]. Also, penicillin resistance has not been shown to be a significant problem in outpatient odontogenic infections.

In this study we excluded patients who were allergic to penicillin. Four patients reported with infection after surgery in group-A and three patients in Group-B. These surgical sites were irrigated with betadine and saline and the patients prescribed warm saline gargles five times in a day. [13] Subsequently, there was no infection on the seventh day after surgery when patient came for follow-up. Th e period for susceptibility to surgical site infection begins at the time of incision. A number of reports during the past few decades have dealt with the use of antibiotics in third molar surgery. Researchers used different antibiotic regimens. Most researchers used amoxicillin, metronidazole, clindamycin, tinidazole, clavulanic acid and doxycycline *(Falconer, 1992; Gill and Scully 1988)*[14,15] They found infection rates ranging from 1.0% to 27% (Lawler, 2005). [16] However, over all incidence of infection from third molar extraction has been reported to be in the range of 3% to 5% by sushrala et al [17]. It has been suggested by Osborn et al (1985) [18] that the rates of post-operative infection are higher for mandibular bony impactions than for any other type of extractions, as result of increased trauma, denser bone, decrease vascularity, etc. Surgical experience can also influence the rate of secondary infection.The overall results of the present study corresponded well with those previously

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reported by Sisk et al, 1986; Christiaens and Reychler, (2002) with respect to infection and other complications. [19,20]

Goldberg et al (1.8%), Piecuch et al (1.8%) and Figueiredo et al (1.5%) [21,22,23] described the rates of post-operative infection. Dry socket is one of the most common complications associated with third molar surgery. The overall rates of alveolar osteitis vary in the literature from 1% to 30%. The variability of reported percentages can be attributed largely to ambiguous diagnostic criteria.

Numerous studies have supported the fact that increasing age, female gender, oral contraceptives, smoking, surgical trauma and pericoronitis are risk factors for alveolar osteitis, *Alexander (2000), Sekhar (2001) and Bergdahl (2004*) [6,24,25]in their prospective studies compared systemic pre-operative use of metronidazole with placebo and found that the incidence of alveolar osteitis and early post-operative infection to be the same in both groups. Reekie et al (2006) in his double blind study, found no significant difference between the metronidazole and placebo groups. [26]Sanchis et al (2004) [27] used tetracycline compound to prevent dry socket and concluded that intra-alveolar placement of tetracycline compound after the removal of impacted mandibular third molars did not affect the incidence of dry socket. *Nordenram (1973)* found that intra-alveolar tetracycline/neomycin bacitracin cones significantly reduce pain and alveolar osteitis[28]. Swelling is an expected sequel of the 3rd molar surgery. It reaches a maximum level 2 to 3 days post-operatively and normally subsides by the 4th day. It should completely resolve by the 7^{th} - 10^{th} day post-operatively.

Pain after third molar surgery usually begins when the effect of anaesthesia subsides. Effective pain management is regarded as an essential skill of any responsible surgeon. Preoperative systemic analgesics reduce pain by inhibition of central and peripheral pain receptors. Prophylactic analgesic therapy is intended to inhibit the effects of the surgery on the surrounding tissue. Non-steroidal anti-inflammatory drugs (NSAIDS) are proven potent anti-inflammatory/analgesic drugs for acute pain [29] and are widely used for third molar surgery. Most painful problems that require analgesics will be due to inflammation. Pain management drugs include non-narcotic analgesics (e.g., non-steroidal anti-inflammatory drugs, paracetamol) or opiates (i.e., narcotics). Non-steroidal anti-inflammatory drugs (NSAIDs) provide excellent pain relief due to their anti-inflammatory and analgesic action without the central actions and addition potential of opioids. In this study we used Tab. Ketorolac 10mg three times in a day for three days for effective pain management, to be extended in case of pain. Ketorolac is an acetic acid derivative; a potent analgesic but has modest anti-inflammatory activity. In postoperative pain it has equalled the efficacy of morphine, but does not interact with opioid receptors and is free of opioid side effects. Like other NSAIDs, it inhibits prostaglandins synthesis and relieves pain primarily by a peripheral mechanism. In short-lasting pain, it has compared favourably with aspirin. Ketorolac is rapidly absorbed after oral and intramuscular administration. It is highly plasma protein bound and 60% excreted unchanged in urine. Major metabolic pathway is glucuronidation; plasma t½ is 5–7 hours. Ketorolac has been rated superior to aspirin (650 mg), paracetamol (600 mg) and equivalent to ibuprofen (400 mg). [30] The results of the study showed that there were time effect (p-value<0.001) and pain changes over time. No statistically significant difference was found between the two treatment groups (p-value >0.05) after applying repeated measure analysis of variance as shown in the table-7. Trismus is often the result of surgical trauma. It is secondary to masticatory muscle and facial inflammation. Trismus is the body's attempt to prevent additional trauma or pain after third molar surgery . Recognized regimens for treating trismus include ultrasonic therapy, pharmaco-therapeutics and physiotherapy. [31] In this study we found no statistical significance between the two treatment groups regard trismus (p-value >0.001) Injuries to the inferior alveolar and lingual nerve are well recognized complications of third molar surgery. The third molar is close to important structures such as the IAN, lingual nerve, and adjacent second molar. The lower it is, the more difficult it is to extract and more complications may occur during operation or postoperatively. Among them, injury of the inferior alveolar nerve is of most concern for surgeons. Sometimes it is unavoidable and is likely to lead to legal disputes between doctors and patients. The risk of Inferior alveolar nerve injury (IANI) complication depends mainly on the position of the impacted tooth in relation to the mandibular canal (MC) before surgery. The inferior alveolar nerve travels within the mandibular canal in the mandible, and is thus supported by the alveolus and the neurovascular bundle. Anatomically, the inferior alveolar vein is the most superior structure in the canal. Below the vein lies the inferior alveolar artery. Medial to both these

structures lies the inferior alveolar nerve usually. When rotary instruments penetrate the canal, the bleeding will alert the surgeon that the superior aspect of the bony canal has been breached and the vein is injured The incidence of injury to the inferior alveolar nerve after lower third molar extraction was about 0.35 - 8.4%. Within 4 - 8 weeks after surgery, 96% of inferior alveolar nerve (IAN) injuries recover, and the recovery rates are not influenced by gender and only slightly by age. Some injuries may be permanent, lasting longer than 6 months, and with varying outcomes ranging from mild hypoesthesia to complete anaesthesia and neuropathic responses resulting in chronic pain. (Rafael Sarikov et al, 2014 [32] The incidence of neurologic injuries from third molar surgery is related to multiple factors, including the surgeon's experience and proximity of the tooth relative to the inferior alveolar canal. Horizontally impacted teeth are generally more difficult to remove because of the increased need for bone removal and soft tissue manipulation when compared with distoangular or mesioangular impactions with higher incidence of nerve damage (Mostapha et al, 2001; Brann et al, 1999). In this study no patient reported with any kind of nerve injury post operatively. [33,34]

Conclusion

From the results of our study, we believe that single dose pre-operative prophylaxis is a safe way to minimize the infection rate and costs in the hospital setting. Complications invariably occur following the surgical removal of third molars.

Attention to the basic principles of surgery, including proper preparation of the Patient, asepsis, haemostasis, use of controlled force, thorough debridement, and meticulous management of both bone and soft tissues can reduce the number and severity of complications. However, we need a safe and effective analgesic and anti-inflammatory combination after third molar surgery to prevent post-operative pain status. More clinical studies are needed to determine the relative diagnostic efficacy of antibiotics in prevention of postoperative infection following third molar surgery.

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