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# Comparative Efficacy of Amoxicillin Clavulanate and Clindamycin in Management of Resistant Orofacial Infection. Randomized Clinical Trial

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**Abstract:-**
**Purpose of the study: Very often patients present for treatment with acute orofacial infections which have either beeninadequately treated or patients have inappropriately taken multiple courses of antibiotics without resolution of their problem. We wanted to study the efficacy of two basic antibiotics which were effective against beta-lactamase producing organisms, that is Amoxycillin-Clavulinic acid and Clindamycin along with local measures for these resistant infections.**
**This study is conducted to compare the efficacy of Clindamycin and Amoxicillin -Clavulinic acid in the treatment of resistant orofacial infections and propose the use of these drugs empirically as first line of therapy To evaluate the efficacy of Clindamycin which is in limited use for severe odontogenic infections and in infections spreading to the bone. To propose the use of antibiotic empirically in resistant infection.**

**Patients and Methods: Patients with one or more fascial space infections presenting with draining sinus, cellulitis or a consolidated swelling ,patients who received beta lactam antibiotics for three days or more and with unresolved infections were included in this study. Of the forty patients included in the study, twenty received Amoxicillin Clavulinic acid and twenty received Clindamycin .The efficacy was compared based on improvement in clinical symptoms with the use of various parameters like duration of pain, swelling, trismus, pus discharge.**

**Results: In our study both Amoxicillin Clavulinic acid and Clindamycin showed similar good results with complete resolution of infection. The mandibular spaces were more frequently involved as compared to maxilla. The number of days pus discharge in the Clindamycin group was less ( < 3days ) and the improvement of mouth opening was better; both the results being statistically significant.**

**Conclusion: With this study we conclude that both Amoxicillin Clavulinic acid and Clindamycin have proved to be equally effective in resistant orofacial infections. Clindamycin can be used as an empiric drug in resistant orofacial infections and in infections that have potentially spread to bone. For practical implications in patients with acute orofacial infections, infections involving bone and those infections that have not responded to inadequate/inappropriate treatment, Clindamycin can be preferred over Amoxicillin-clavulanate. When Amoxicillin -Clavulanate is used, it may be better to combine it with Metronidazole**

***Keywords:-*** *Odontogenic infection, resistant orofacial infection, Amoxicillin clavulinic acid, Clindamycin, empirical antibiotics.*

## I. INTRODUCTION

Most odontogenic infections in healthy patientsarise as a sequelae to pulpal necrosis caused due tocaries , dentofacialtrauma, periodontal infections and/or pericoronitis.The majority of these are self-limiting and may drain spontaneously. However these infections may spread into the fascial spaces adjacent to the oral cavity and spread aggressively leading to more severe infection. Later these may further spread into the vital systems like central nervous system and respiratory system causing life threatening situation. Hence timely interventions are required to prevent the spread by establishing a patent airway, in addition to debridement, incision and drainage and appropriate antimicrobial therapy. The beta lactamase resistant antibiotics are recommended for the treatment of Orofacial Odontogenic infections because they are effective against the specific bacteria with a very low incidence of adverse effects.

Of late there has been an increase in the number of cases of acute infection that do not respond to commonly used beta lactam antibiotics. Injudicious use of antibiotics and inappropriate dosing regimens may have led to treatment failure and increase in severity of the infections. Patients, who have already taken beta lactams, imidazoles or quinolones for acute odontogenic infection, present with

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unresolved infection for treatment. Antibiotic selection in these patients is difficult and the culture specimens frequently yield false negative results due to suppression of microbial growth. The combination therapy is generally avoided when not specifically indicated, for it may provide an increased opportunity for resistant bacteria to emerge. There is marked increase in the cost of combined therapy as compared to single drug therapy.

## II. MATERIALS AND METHODS

A randomized clinical studywas conducted on patients attending the Department of Oral and Maxillofacial Surgery, M S Ramaiah Dental College and Hospital Bangalore, with orofacial infections. The study included 40 patients who were treated for various orofacial infections following periapical, pericoronal or plate infections. The patients consent and ethical clearance was taken for the study. The patients wererandomly given either one of the either study drugs, Amoxicillin Clavulinic acid (Group 1) or Clindamycin (Group 2).The various parameters which were compared were pain, swelling, pus discharge and trismus. This study included 40patients of either group aged 50yrs and below with one or more fascial space infections presenting with draining sinus, cellulitis or a consolidated swelling or a severe odontogenic infection that had potentially spread to the bone. These patients had received beta lactam antibiotics for three days or more and presented with unresolved orofacial infection. Patients with mild to moderate infections who have not received antibiotics for the same, patients allergic to penicillin and diabetic patients were excluded from the study

## III. METHODOLOGY

Theethical clearance was sort fromthe institutional ethics committee prior to the beginning of the study. We have followed the Helsinki guidelines for the study.

The source of infection was determined byclinical examination wherein case history of the patient followed by general examination for toxic signs and symptoms, local examination of the swelling, determination of fascial spaces involved as carried out and confirmed through Orthopantomograph or intraoral periapical radiographs. Routine necessary hematological and urine investigations were done. The selected patients were informed of the procedure and written consent was taken. In severely dehydrated patients IV Fluids were indicated. The patients were selectedrandomly to receive the study drug, either Clindamycin or Amoxicillin and Clavulinic acid. The drugswere given intravenouslyconsidering the severity of infection. Once the drug was started and the general condition of the patient was stabilized and depending on whether the swellinglocalized or suppurated, incision and drainage was planned. This was followed by removal of source of infection, like extraction of the causative tooth or miniplates removal. The face was prepared and draped. The incision and drainage was done for 35 patients, of which intraoral drainage was established in 28 patients and extraoral drainage in 7 patients. Corrugated rubber drain was placed where extraoral incision was given and ribbon gauze where intraoral incision was placed. They were sutured at site and were removed after 72hrs.

Extractions were carried out in 17 cases in group1 (Amoxicillin and clavulinic acid) and 10 cases in-group 2(clindamycin). Mini plates removal was carried out in 2 cases in group 1 and 4 cases in-group 2. In 2 cases (0ne in each group) curetting of the socket was done. In one case IMF was done following Incision & Drainage and in one case Sequestrectomy and saucerisation was done. Postoperative instructions were given to the patients. Patients continued to receive medications either Amoxicillin and clavulinic acid or clindamycin. The patients were also given Ibuprofen plus paracetamol thrice daily for about 5days along with B-complex and lactobacillus, and jaw physiotherapy. The patients were followed up for up to 10 days until the symptoms improved. The parameters used to assess the efficacy of the study drugs i.e. duration of time taken for the reduction in pain using VAS scale, reduction in swelling using photographs , duration of pus discharge and improvement in mouth opening using caliper to measure mouth opening were recorded and tabulated until the last day of follow up. The incidence of any adverse effects like itching, diarrhorea, vomiting etcduring the study period was noted. Data were entered in windows Excel format. The students t test was used to find the significance of differences between the mean number of days for drug taken, pain present, swelling, pus discharge and improvement of mouth opening between Amoxicillin Clavulinic acid and Clindamycin. Similarly Chi Square and Fisher Exact test were used to find the significance of proportion of above-mentioned parameters between Amoxicillin Clavulinic acid and clindamycin group.The statistical software namely SPSS 11.0 and systat 8.0 were used for the analysis of the data and Microsoft word and Excel have been used to generate graph, table etc.

## IV. RESULTS

A prospective randomized clinical study consisting of forty subjects with unresolvingodontogenic infections, presenting with swelling and pain was undertaken to investigate and comparethe effectiveness of the two drugs Amoxicillin and Clavulinic acid and Clindamycin.

The graphical representation( Fig 1 & Fig 2) shows the common fascial spaces involved . Buccal space was most commonly involved in the two groups followed by submandibular, masseteric , canine,temporal and submental spaces. Five cases of miniplate infection were also included. These spaces werenot mutually exclusive and co existed in some patients.

- **Table 1:** Shows the no.ofdays pus discharge was present in both the groups. Pus discharge was noticed significantly in more no.of days with Amoxicillin and Clavulinic acid (3.30days) as compared toClindamycin (2.40days) with P=0.019. In 60% of patients on Clindamycin, pus discharge was less than 3days (P<0.05) as compared to 75% of patients on Amoxicillin and Clavulinic acid showed pus dischargefor >3 days (P<0.05).

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- **Table 2:** Shows no.of days taken for improvement of mouth opening. The mean no.of days were taken for improvement of mouth opening with Clindamycin (2.78 days)was less as compared to Amoxicillin and Clavulinic acid (3.31 days) with P=0.388. 31% patients with Amoxicillin and Clavulinicacid took 4 to 6 days to show improvement in mouth opening as compared to 11% with Clindamycin(P=0.340).

## V. DISCUSSION

Odontogenic infections are the most common infection of all infections in the oral cavity with the etiology usually being attributed to the oral flora of the mouth and not to the introduction ofnon-resident bacteria. Odontogenic infections are usually polymicrobial, with aerobes initially but however anaerobes generallyout number aerobes by at least fourfold as the infection proceeds. The most commonly isolated aerobic species are alphahemolytic streptococci and the predominant anaerobes are peptostreptococci, Bacteroides speciesfusobacterium nucleatum, actinomyces, peptococcus, eubacterium, treponema etc.[1,2,3] The predominant microorganisms are anaerobes that are resistant to penicillin.[4]

Most acute orofacial infections are predominantly of odontogenic origin, more commonly as a result of pericoronitis, decayed carious teeth with pulpal exposure, periodontitis or complication of dental procedures.[4, 5] In our study the common cause of orofacial infections was pericoronitis, decayed teeth with pulpal exposure, complications of dental procedures, acute osteomyelitis and miniplate infections. Treatment of theseinfections includes surgical drainage and use of antibiotic administration.

Whenever a bacterial population is exposed to antibiotics some of the bacteria will be resistant to the drug. The problem of emerging resistance is the expected result of antibiotic administration. Every antibiotic will eventually become useless because of this phenomenon. It can be delayed by prudent use of specific narrow spectrum antibiotics. Early identification and management of acuteoro facial infections is critical to prevent the rapid systemic involvement which can be life threatening. [6]

Antibiotics are always not necessary in the treatment of infections. Drainage and applications of heat may be enough to enable the patient to overcome the condition and antibiotics must not be prescribed to replace or delay these local measures. Where the infection is spreading or there are signsof systemic involvement such as general malaise, a flushed dry skin or a raised body temperature, theimmediate use of antibiotics is indicated. Unfortunately it is often impossible at this stage to take aculture or where this can be done to wait for results. Antibiotics must then be prescribed blind.[7]

Antimicrobials are neverto be used as an alternate to appropriate surgical drainage and/or debridement, and should only be used asan adjunctive therapy. However, antimicrobial therapy that are started soon after diagnosis and before surgery can shorten the severity and the period of infection and minimizing associatedrisks such as bacteremia. [8]

Historically, penicillins have been used as first line drug in the treatment of odontogenicinfection. Penicillin v is the drug of choice in the treatment of Odontogenic infections. In literature, higherrates ofPenicillin resistance and treatment failures have been reported with the highest rates of Penicillin resistance that have been observed is with the genus Bacteroides[1]. Penicillin resistance in these pathogens hasbeen associated with beta lactamase production. A combination of Amoxicillin and beta lactamaseinhibitor, Clavulinic acid retains activity against beta lactamase producing organisms which are commonlyassociated with odontogenic infections. The Sanford Guide to Antimicrobial therapy recently replacedPenicillin V with Clindamycin as the drug of choice for odontogenic infections. The 1st and 2ndgeneration Cephalosporins have a significantly broader spectrum of activity. Although Cephalosporinsare adequate alternatives to Penicillin in odontogenic infections, they generally lack activity againstBacteroides except for Cefoxitin and Cefotetam.[3,5,9,10,25]

Macrolides have adequate activity against the majority of odontogenic pathogens however they should not be considered as first line therapy and should be reserved for patients allergic to Penicillins.Macrolide antibiotics have the highest number of significant drug interactions of any group. [3,5,9,10]

Quinolones are active against aerobic and facultative gram negative bacilli but they have pooractivity against anaerobes and hence limit their value in the treatment of acute odontogenicinfection.[5,11]

Metronidazole is highly effective against most anaerobes, however it lacks activity against aerobicbacteria. The severe adverse effects with Metronidazole include gastrointestinal upset, metallic taste, centralnervous system stimulation and discolored urine. However it can be used in combination with Penicillinseffectively, although this may lower patient's compliance due to different dosing schedules. [5, 9, 10].

However combining two antimicrobial agents with different sites of action may result in inhibition of theantibacterial effectiveness of one of the drugs (antagonism of antibacterial effect). The disadvantages of combination therapy are risks of toxicity from two or more drugs, development of resistant bacteria,and increased cost to the patient. [12]

Successful management of oral infections are achieved by appropriate timely surgical intervention like establishing drainage, good overall supportive care of the patient and antibiotics.[8] Patients with unresolvedinfection due to inappropriate dosing, misuse of antibiotic, or due to development of bacterial resistanceare often referred to oral surgeons. To effectively administer antimicrobial therapy for a patient,microbiologic estimation of the purulent exudates must be obtained however the empiric

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antimicrobial therapy can be initiated until the culture sensitivity report is available .[9,11,13]

Tomoari Kuriyama et al recommend the primary use of beta lactamase stable beta lactams because they have great effectiveness against prevotella, porphyromonas and fusobacterium. [14]

Although culturing is rarely required in managing odontogenic infection at times it is necessary to resolve a progressive infection. The culturing is indicated in patients who do not respond to the prescribed firstantibiotic even after 48hrs, and the infection progressing to other fascial spaces. [11]

Haug et al in their study found that staphylococcus aureus and coagulase positive staphylococci were the most common gram positive antibiotic resistant bacteria isolated.[15] In our study, most of theculture yielded no growth, however in few cases coagulase positive staphylococcus were reported.

Considering the factors for selection of antibiotics like narrow spectrum, single drug therapy, toxicity, tissue distribution etc. we chose Amoxicillin and clavulinic acid and clindamycin for our study.We have compared the efficacy of these two drugs in resistant orofacial infection.Clavulinic acid a beta lactamase inhibitor retains and enhances the activity of Amoxicillin byinhibiting the beta lactamase producing microorganisms, which are commonly associated withodontogenic infections. This combination has merit in oral infections being active against virtually allanaerobes and oral streptococci, as well as most staphylococcus aureus, E Coli, P merabilis and Klebsiellaspecies. [3, 10, 16]

Clindamycin has excellent activity against gram positive organisms, including anaerobes and beta lactamase producing organisms. Clindamycin's spectrum of coverage and excellent clinical efficacy,paired with the increase in both penicillin resistance and the report of treatment failure with penicillinhas contributed to replacement of penicillin v with Clindamycin as the drug of choice in the management of odontogenicinfections.[3,8,12]

Clindamycin is generally the drug of choice in infections resistant to penicillintherapy. Abscess cavities are not vascular still some penetration of antibiotics into these spaces doesoccur. The antibiotic that best penetrates an abscess is clindamycin. It also penetrates best into boneand is therefore an important consideration in osteomyelitis.[12] In our study we used Clindamycin for2cases where the infection had spread to bone and we found good improvement in the signs andsymptoms and resolution of infection.

In our study forty patients who presented with unresolved infection were included, whorequired treatment for various orofacial infections following periapical, pericoronal or miniplateinfections that were initially treated with antibiotics and had unresolved infections or who presented with severe acute infections.

Edward S Peter et al in their study found that men represented slightly more than women in their study sample with an age of 36 years. [17]. Wenoticed in our study that the male to female distribution however was equal with mean age being 38.20±10.31 and 35.95±12.67 for the two groups respectively.

J Wang A in his study found that mandibular infections were more common as compared to maxillary infections. [18]. This finding correlates with our finding where we found that the most common fascial space involved in the two groups of our study was mandibular buccal space followed by submandibular, masseteric, canine, temporal, parotid and submentalis spaces indicating mandibular infections being more common than maxillary infections.

The patients in our study were given the study drugs randomly. Since the infectionwas severe with toxic signs and symptoms the patients received the drug intravenously. In our study we found that mean number of days the drug Clindamycin had to be given was comparatively more than Amoxicillin and Clavulinic acid with P=0.277.Significantly greater proportion (55%) of the patients had receivedAmoxicillin and Clavulinic acid for three to five days whereas comparable proportion (55%) of the patients had received Clindamycin for 6 to 8 days. Once the drug was started the parameters like the no. of days swelling and pain present, no. of days pus discharged, no. of days taken for improvement in mouth opening, were evaluated.

In our study we noted that suppuration started early with Amoxicillin and Clavulinic acid and prolonged for a longer time (3.30 days) as compared to Clindamycin where suppuration started late andcontinued for a shorter period of time (2.40 days).

Various studies report that the upholder in the management of these infections remains inappropriate empiric antibiotic administration, timely and aggressive Incision and Drainage and surgicallyeradicating the foci of infection. [2, 12]

Once the general condition of the patient stabilized with antibiotics, analgesics and IVfluids, the sources of infection were treated. The various surgical procedures carried out in the treatment of thepatients of the two groups were Incision and drainage, Extraction of the causative tooth or miniplateremoval. In those cases with miniplate infections, the fracture had healed and the miniplates removalwas carried out in order to eliminate the source of infection to prevent any further chances for recurrentinfection. Further improvement in symptoms were noted in the patients, following the surgicalprocedures.

In the study by Gilmore et al and Von Konow et al, they found that the patients in the clindamycin group had ashorter duration of pain, swelling and fever and more favorable laboratory findings. However with nostatistical significance. [20, 21]. In our study we found that swelling and pain lasted for about 3 to 5 days inmaximum number of patients in both groups. However there was no statistical significance noted.

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Shorter duration for improvement in mouth opening was observed with Clindamycin group ascompared to Amoxicillin and Clavulinic acid group. Less mean no. of days were taken for improvement in mouth opening with Clindamycin (2.78 days) as compared to Amoxicillin and Clavulinic acid (3.31days) with P=0.388. 31 patients with Amoxicillin and Clavulinic acid took 4 to 6 days to showimprovement in mouth opening as compared to 11% with Clindamycin (P=0.340). In other studies theoutcome was almost similar in the groups with no statistical significance.

Clindamycin therapy resulted in shorter hospital stay and lower net treatment costs with a slightly higher success rate. [23] Von Konow in his study reported that six of his patients in the Clindamycin group had moderate to severe gastrointestinal discomfort including one case of Clostridium difficile associated diarrhoeawhich was of no statistical significance as compared to the other group.[21] Gilmore et al in his studymentioned that only two of the twenty three patients who received Clindamycin developed diarrhoea.[20]

In our study 1 patientin the Clindamycin group developed diarrhorea, which however is of no statisticalsignificance. We lost follow up with two of our patients.

Gilmore W C et al in a prospective double blind trial compared penicillin and clindamycin in the treatment of moderate to severe orofacial infections of odontogenic origin, with pus discharge. Amongthe 27 patients who received penicillin, 22(81%) had successful outcome and5(19%) had improved outcome. In 28 patients treated with Clindamycin, 23(82%) had a successful outcome and5(18%) had improved outcome. Resistance rates for anaerobic isolates were 8.9% to penicillin and 1.9% to Clindamycin. It was concluded that Penicillin and Clindamycin produced similar good results in treating odontogenic infection when the rate of penicillin resistance among oral anaerobic bacteria is at arelatively low level. [20, 23]

Morton Goldberg confirmed that penicillin and its derivatives are the gold standard antimicrobial agents available for the treatment of orofacial infections. Amoxicillin has been reported tobe successful in Group A beta hemolytic streptococci infection. Clindamycin is effective in 95% of anaerobic infection. [22, 23]. However with this study we conclude that both Amoxicillin and Clavulinic acid and Clindamycinhave proved to be equally effective and can be used as an empiric drug and in resistant orofacialinfections as first line of therapy and also in infections which have potentially spread to bone. Manish Bhagania et al reported in their study that Clindamycin and Penicillin/Metronidazole combination is still considered a clinically effective first line treatment option for treating severe odontogenic infection. [23]

## VI. CONCLUSION

With this study we conclude that both Amoxicillin Clavulinic acid and Clindamycin have proved to be equally effective in resistant orofacial infections. Clindamycin can be used as an empiric drug in resistant orofacial infections and in infections that have potentially spread to bone**.**However the sample size in our study was small although good results were obtained with both Amoxicillin and Clavulinic acid and Clindamycin with no statistical significance. However it shows trend statistically and significance can be obtained with a larger sample size and also by doing a double or triple blind study.

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Table 1: Duration of pus discharge present in both the groups

| No of days | Amoxicillin Clavulinic acid | | Clindamycin | | P value |
|---|---|---|---|---|---|
| | No of patients | % | No of patients | % | |
| < 3 | 3 | 15 | 12 | 60 | 0.030* |
| 3-5 | 15 | 75 | 8 | 40 | 0.025* |
| 6-8 | 2 | 4 | - | - | 0.05 |
| Mean no of days ±SD | 3.30±1.38 | | 2.40±0.88 | | P=0.019* |
| Inference | Significantly more no of days pus discharge seen with Amoxicillin and clavulinic acid (3.30days) as compared to clindamycin (2.40) with P =0.019. In 60% of the patients the pus discharge with clindamycin was less than 3 days ( P<0.05) as compared to 75% of patients with Amoxicillin and clavulinic acid who showed pus discharge for > 3days ( P<0.05) | | | | |

*Significant at 5%

Table 2: Time taken for improvement in mouth opening

| No of days | Amoxicillin Clavulinic acid | | Clindamycin | | P value |
|---|---|---|---|---|---|
| | No of patients | % | No of patients | % | |
| 1-3 | 10 | 62.5 | 12 | 60 | 0.355 |
| 4-6 | 5 | 31.3 | 8 | 40 | 0.340 |
| 6-8 | 1 | 6.3 | - | - | P>0.05 |
| Mean no of days ±SD | 3.31±1.74 | | 2.78±0.67 | | P=0.388 |
| Inference | Less mean number of days were taken for improvement of mouth opening with Clindamycin (2.78 days) as compared to Amoxicillin clavulinic acid (3.31 days) with P=0.388. 31% patients with Amoxicillin clavulinic acid took 4-6 days to show improvement in mouth opening as compared to 11% with Clindamycin ( P=0.340 ) | | | | |

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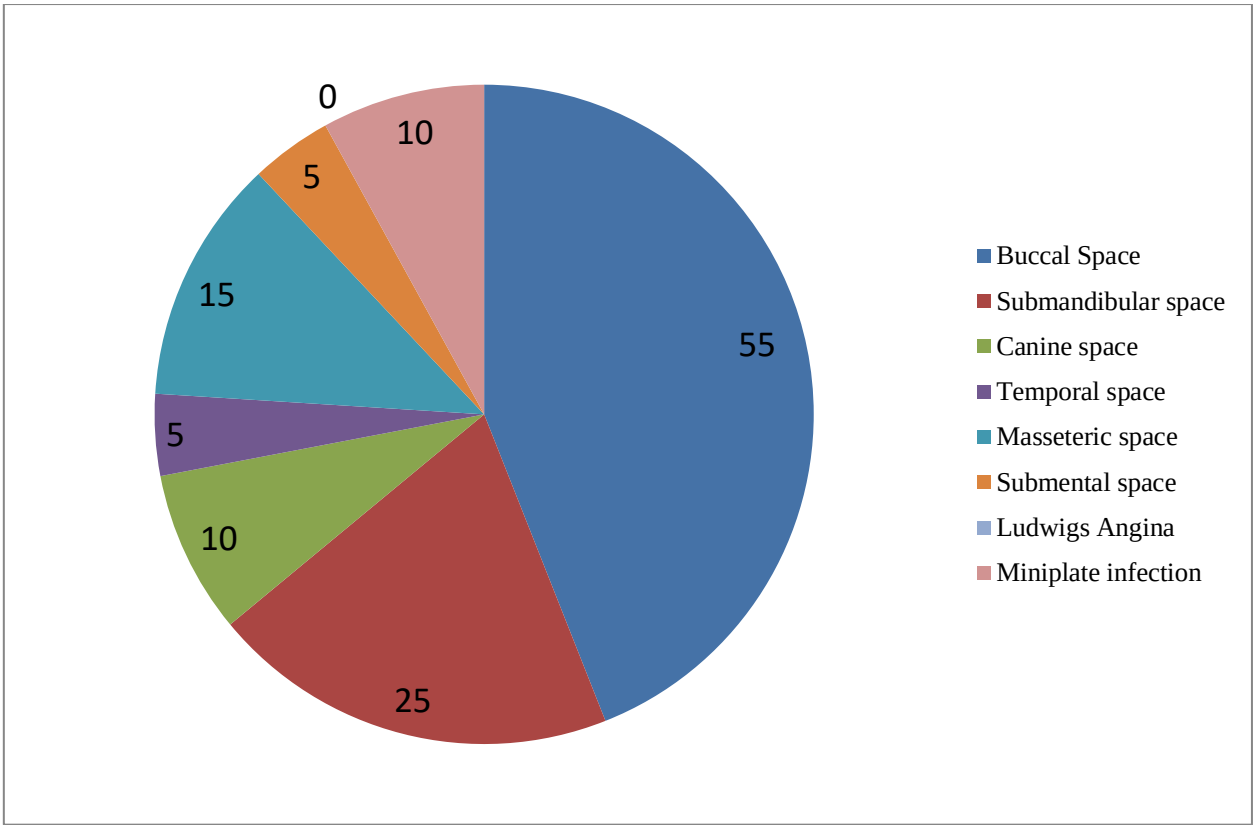


Fig. 1: Graphical representation showing fascial spaces involved in the Amoxicillin Clavulunate group

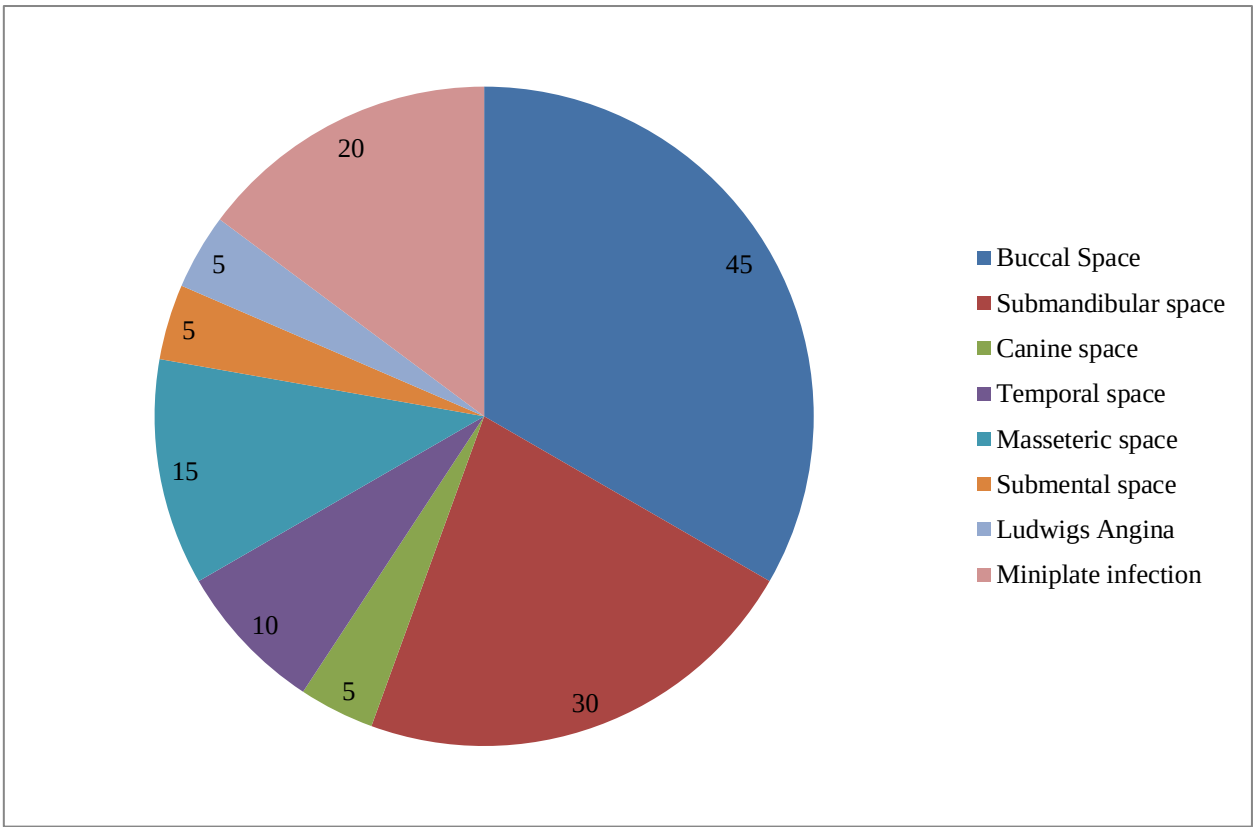


Fig. 2: Graphical representation showing involvement of spaces in Clindamycin group in patients of both the groups