



The International Journal of Therapeutics 2018; 1(1): 66-74.

EVALUATION OF MARKET POTENTIAL FOR IN-SITU GEL CONTAINING ANTIMICROBIAL AND ANTI-INFLAMMATORY AGENT IN PERIODONTAL DISEASE



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ABSTRACT

Objective: The aim of the study is to determine the market potential for *in-situ* gel containing antimicrobial and anti-inflammatory agent.

Methodology: The data obtained from market research carried out by self-administered questionnaire method and personal interview with dentists and pharmacists in Mysore area.

Results: The study revealed that there is an enormous potential for oral local application containing antimicrobial and anti-inflammatory agents in periodontal disease. The results of data analysis study are; it was found that 80% of dentists treat periodontal disease patients with antibiotics and anti-inflammatory drug; and 48% of dentists treats periodontal disease patients with doxycycline and metronidazole; 40% of dentists consider aceclofenac is better for periodontal disease; majority of dentists (60%) preferred local application containing antibiotics and anti-inflammatory agents as a route of administration of in periodontal disease; majority of dentists (80%) prescribe metronidazole oral local application for periodontal disease; and 60% of dentists preferred the local application containing newer classes of broad spectrum antibiotics consider better in periodontal disease.

Conclusion: Overall, the findings from dentists and pharmacists were similar for antibiotics and anti-inflammatory agents with commonly prescribed drugs are aceclofenac, doxycycline and metronidazole for periodontal disease. The local application containing newer classes of broad spectrum antibiotics consider better in periodontal disease This study concluded to have promising potential research to develop *in-situ* gel containing anti-microbial & anti-inflammatory agents with various combinations.

Keywords: Anti-microbial, Anti-inflammatory, Periodontal disease

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INTRODUCTION

The increasing ageing population across the globe and a concurrent increase in demand for enhanced oral care offers huge opportunities for product innovation and differentiation to dental care providers. Moreover, increasing awareness in the developing nations about oral hygiene and new product developments has also given a boost to the market for dental consumables. Rising demand for aesthetic dentistry and growing dental tourism further ensures growth of this market in coming years.^[1]

The global dental consumables market is estimated to grow at a CAGR of 6.8% from 2016 to 2021 to reach USD 35.35 Billion by 2021. Factors such as the rapid rise in geriatric population, growing dental tourism in emerging markets, rising incidences of dental caries and other periodontal diseases, growing disposable incomes rising demand for cosmetic dentistry, and increasing dental care expenditure are the major factors driving the growth of the global dental consumables market.^[2]

There are various oral drug delivery systems available in the market for periodontal disease such as films, chips, gels, fibers, implants.^[3,4]

Periodontal diseases are groups of infections and inflammatory conditions, including gingivitis and periodontitis that affect teeth supporting structures.^[5] Gingivitis can and does occur in all groups, ethnicities, races, genders and socioeconomic levels. These diseases occur when bacteria from dental plaque invade surrounding tissues and from the accumulation of plaque at the gingival margin, which, in turn, induces an inflammatory response. The result is the formation of pockets between gingival and tooth that causes gingival margin retraction and the development of an ideal environment for anaerobic bacteria growth responsible for the disease. The progression of this destructive process can cause tooth loss. More than 90% of adults are having periodontal diseases.^[6,7]

In-situ periodontal gel containing Linezolid with rate controlling polymers which provides a longer duration of action and local antibacterial effect without loss of dosage^[8]. In-situ is a Latin word which means 'In its

original place or in position'. The gelation can be triggered by temperature, pH change, ionic change & also UV induced gelation, Solvent exchange induced gelation. In situ drug delivery system offers advantages such as reduced frequency of administration, improved patient compliance, and comfort. An in situ gel formulation provides an interesting alternative for achieving effective plasma drug concentration, an advantage over conventional delivery systems.^[8]

A site-specific system aims at delivering the therapeutic agent at sufficient levels inside the pocket and at the same time minimizing the side effects associated with systemic drug administration. In conventional mode of drug administration, many drugs do not reach target areas in the body in sufficient concentration because of premature inactivation and excretion. The systemic drug administration has been useful in treating periodontitis but the disadvantage is that, drug is diluted several thousand folds before it reaches the site and exposes the drug to rest of the body parts leads to potential side effects. This problem can be overcome by administering the drug directly to the intended site of action with lesser dose. The local production of prostaglandins and other metabolites of arachidonic acid within the periodontal tissues contribute to alveolar bone resorption in periodontitis. Research findings have shown that inhibitors of prostaglandin production, such as non-steroidal anti-inflammatory drugs (NSAIDs), could affect the course of bone loss in periodontal disease. Data from prospective animal experiments and human studies support this concept, and indicates that NSAIDs can reduce gingival inflammation and reduce alveolar bone resorption. There is also evidence that systemic administration of antibiotics and NSAIDs are effective in altering the progression of certain forms of periodontitis.^[9]

Aceclofenac appears to reduce the intracellular concentration of free arachidonate in leucocytes, perhaps by altering the release or uptake of the fatty acid. Sustained drug delivery systems are able to provide very precise control over drug release for a prolonged period of time eliminating the need for frequent dosing and minimizing side effects, thereby increasing patient compliance and comfort.^[9]

Newer trends like use of mucoadhesive polymers, in situ forming gels, viscosity modifiers, plasticizers etc which can enhance intrapocket retention of drugs have gained considerable attention among researchers and industrialists. Current market is flooded with products such as Periostat, Periochip(®), Atridox(®), Arestin(®), Actisite(®), Dentomycin(®), and Elyzol(®) and generics such as metronidazole, levofloxacin, tetracycline, doxycycline and minocycline for intrapocket delivery. There is a need of novel drugs and delivery systems with better efficacy profiles than the existing compounds.^[9]

Inclusion of novel technologies like films, fibers, in situ forming implants, microparticles, nanoparticles, and liposomes as intra pocket drug delivery has great potential.^[3,10]

Materials and Methods:

Research Methodology

SOURCE OF DATA:

a) Primary source

The data obtained from market research which was carried out by self administered questionnaire method.

Inclusion criteria: Dentists, Registered pharmacists, chemists and druggists, including hospital pharmacists.

Exclusion criteria: Doctors of other specialties and doctors involved in other systems of medicine will be excluded from the survey. Ayurvedic, Homeopathic and Unani retail.

b) Secondary source

Literature survey: Pharma pulse, Text books of pharmacology basics, Pharma biz, Medical journals, CIMS, Pharmaceutical journals and magazines, Internet.

Method of collection data:

1. Preliminary communication with all categories of respondents as mentioned above.
2. Personal interview with all categories of respondents as mentioned above.
3. Sampling technique: Convenience sampling.
4. Sample size: 100 (Doctors + Pharmacists)
5. Sample area: Mysore

A self-administered questionnaire *survey* was conducted to “**Evaluate market potential for *in-situ* gel containing antimicrobial and anti-inflammatory agents in periodontal disease**”

A *survey* was carried out among the Dentists and Pharmacists in Mysore using a pretested questionnaire with 12 questions for Dentists and 10 questions to Pharmacist.

Questionnaire design flow chart:

Questionnaire surveys Evaluate market potential for in-situ gel containing antimicrobial and anti-inflammatory agents in periodontal disease” and discuss questionnaire design, pre-testing, validity establishment, and administration along with data collection and analysis. Steps in questionnaire survey design and administration flow chart shown in Fig-1.

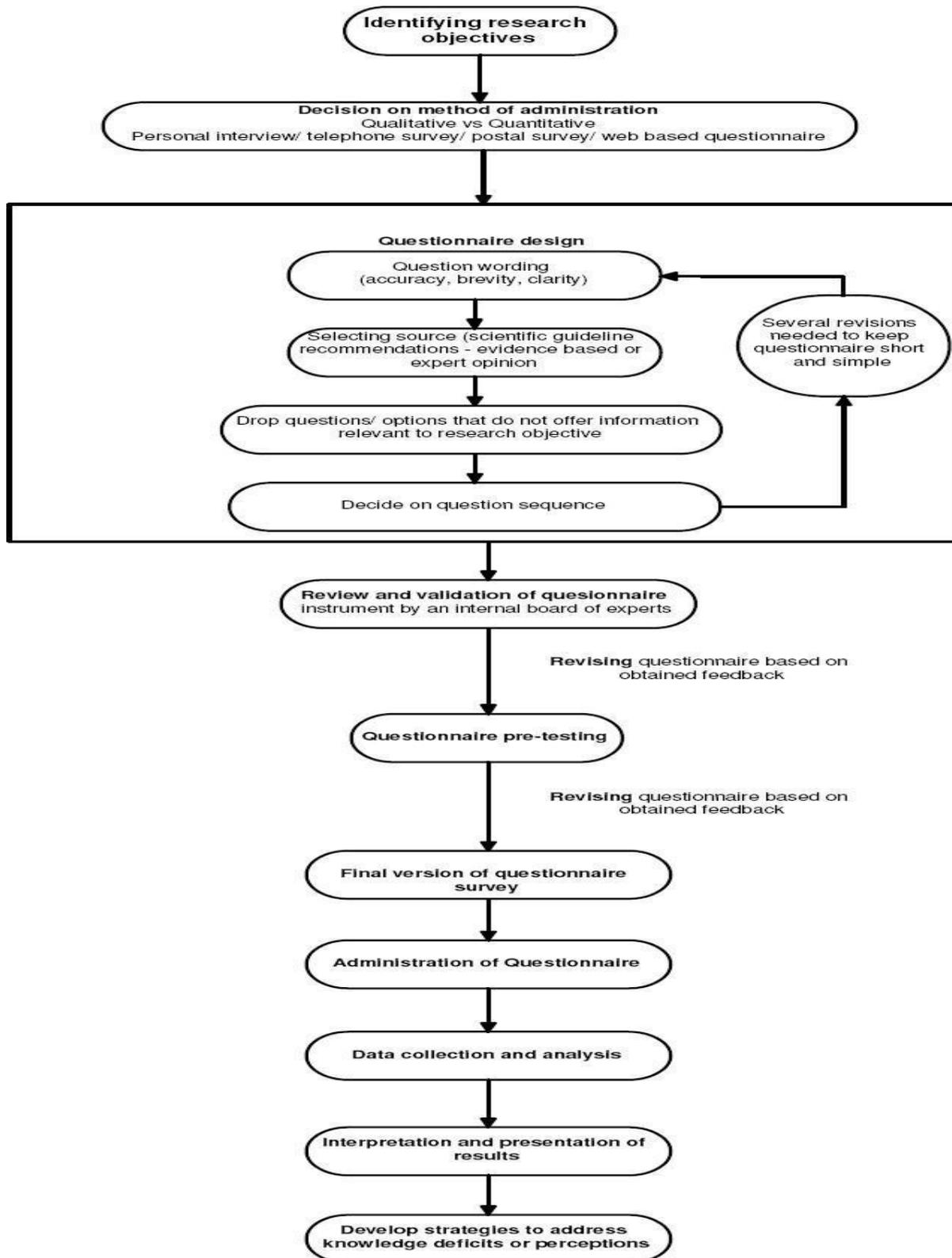


Figure 1: Steps in questionnaire survey design and administration

Pilot study:

During Pilot study the questionnaire were pre-tested by administering structured questionnaire to 03 dentists it was observed during pilot study that all dentists are of the opinion that Question number (4) of dentists' questionnaire should be changed

Hence, the Question No.4 changed as

4. Most commonly prescribed drug for periodontal disease

a. Antibiotics _____

b. Ant-inflammatory drug _____

Also during Pilot study the questionnaire were pre-tested by administering structured questionnaire to 03 pharmacists. All the pharmacists were of the opinion that Question number (2) of pharmacists questionnaire should be changed.

2. Average number of prescriptions from dentists you receive per day for antibiotics and anti-

a. inflammatory agents _____

Hence, the Question No.2 changed as

2. Average number of prescriptions from dentists you receive per day for

a) Antibiotics _____

b) Anti-inflammatory _____

c) Antibiotics and anti-inflammatory (both) _____

Data analysis:

Questionnaire response from dentists:

- 1) Average number of patient treated by Dentist. Majority of dentists treated 1-5 patients/day followed by 6-10 patient/day (results are shown in Table-1)
- 2) Periodontal disease patient treated. Most of the dentists (30%) surveyed treat 1- patients/day (results are shown in Table-2)
- 3) Average number of periodontal disease patient treated subjected to prescription of antibiotics and anti-inflammatory per day. Majority 80% of dentists treats periodontal disease with antibiotics.
- 4) Most commonly prescribed drug for periodontal disease.

A) Total exceeds 100% since multiple responses were given, the respondents results are depicted using Microsoft excel software in Figure 1.

B) 40% of dentists consider Aceclofenac to be better followed by 24% of dentists consider Diclofenac to be better.

5) Preferred route of administration or dosage form for antibiotics and anti-inflammatory. Majority of dentists (60%) preferred local application containing antibiotics and anti-inflammatory is the route of administration considered better.

6) Oral local application prescribed for periodontal disease.

A) Majority of dentists (60%) prescribed Oral local application for periodontal disease

B) Majority of dentists (80%) prescribed metronidazole Oral local application.

7) Advantages of oral local application Majority of dentists (60%) are of opinion that both Patient satisfaction and Better disease cure rate are advantages of oral local application.

8) Disadvantages of local application Majority 50% are of opinion that taste is disadvantage of local application.

9) In terms of safety the antibiotics and anti-inflammatory local application rated as

10) Suggestion for change required in existing Preferred antibiotics and anti-inflammatory local application for periodontal disease. Total exceeds 100% since multiple responses were given the respondents results are depicted using Microsoft excel software in Figure 4.

11) Preferred antibiotics and anti-inflammatory local application for periodontal disease.

Total exceeds 100% since multiple responses were given the respondents results are depicted using Microsoft excel software in Figure 3.

12) Aspects of available dental local applications appeals most.

Majority of dentists (60%) are of opinion that both patient satisfaction and better disease cure rate are advantages of oral local application.

Questionnaire response from pharmacists:

1. Average Number of prescription from dentists received per day.

- Majority of pharmacists (60%) received 1-5 prescriptions from dentists per day (Results are shown in Table-3)
2. Average number of prescriptions from dentists received per day for periodontal disease.

Total exceeds 100% since multiple responses were given, the respondents results are depicted using Microsoft excel software in Figure 5.
 3. Most commonly prescribed local application antibiotics and anti-inflammatory periodontal disease.

Total exceeds 100% since multiple responses were given, the respondents results are depicted using Microsoft excel software in Figure 6.
 4. Most commonly prescribed oral local applications for dental problems

Total exceeds 100% since multiple responses were given, the respondents results are depicted using Microsoft excel software in Figure 7.
 5. Average number of units of oral local applications for dental problems sold per week.

Majority of pharmacists (96%) sells 1-7 units of oral local applications for per week results are shown in table-4
 6. Are you satisfied with
 - a. Sales of oral local applications: Majority of Pharmacists (60%) Satisfied with Oral local application for Periodontal disease.
 - b. Available oral local applications: Majority of Pharmacists (60%) satisfied available Oral local application for periodontal disease.
 - c. Reason for No _____

Majority of Pharmacists (60%) not satisfied with available Oral local application for periodontal disease because of Patient compliance (like, taste, not effective)
 - d. Any suggestions for improvement _____

Majority of Pharmacists (60%) suggested to improve formulation of oral local application to avoid patient compliance (like, taste, not effective)
 7. Most commonly co-prescribed drug with local oral applications. Total exceeds 100% since multiple responses were given , the respondents results are depicted using Microsoft excel software in Figure 8. Maximum percent of Pharmacists rated antibiotics

(80%) and anti inflammatory (90%) local application is good.

8. Most commonly prescribed oral local applications brands by dentists. Total exceeds 100% since multiple responses were given , the respondents results are depicted using Microsoft excel software in Figure 9.
9. Satisfaction level of consumer for above oral local applications. Maximum percent of Pharmacists (60%) surveyed of opinion that satisfaction level of consumer for antibiotics and anti-inflammatory local application is not good followed by (20%) average
10. Suggestions: Majority of Pharmacists (60%) suggested to improve formulation of oral local application with respect to control release, adhesion/ retainability of drug required.

RESULTS AND DISCUSSION

Table-1 Average number patient treated by Dentists

Average No. of patient treated	1-5	6-10	11-15	16-20	21-25
Number of dentists	15	10	10	10	2
Percentage of dentists	30	20	20	20	4

Table-2 Periodontal disease patient treated

Average Number of patient treated	1-5	6-10
Number of dentists	15	10
Percentage of dentists	30	20

Table-3 Average Number of units of oral local applications

Average Number of prescription	1-5	6-10
Number of Pharmacists	30	20
Percentage of Pharmacists	60	40

Table-4 Average Number of units of oral local applications

Average Number of units of oral local applications	1-7	7-14
Number of Pharmacists	48	02
Percentage of Pharmacists	96	04

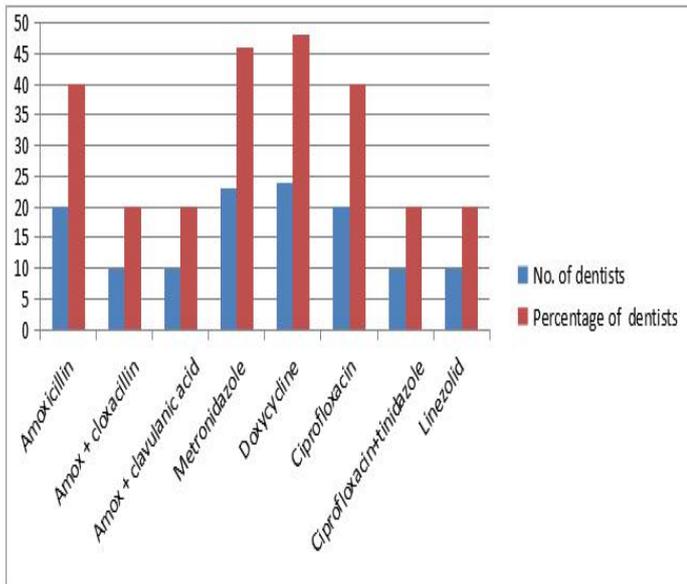


Fig-2 Medications and Number with percentage of Dentists

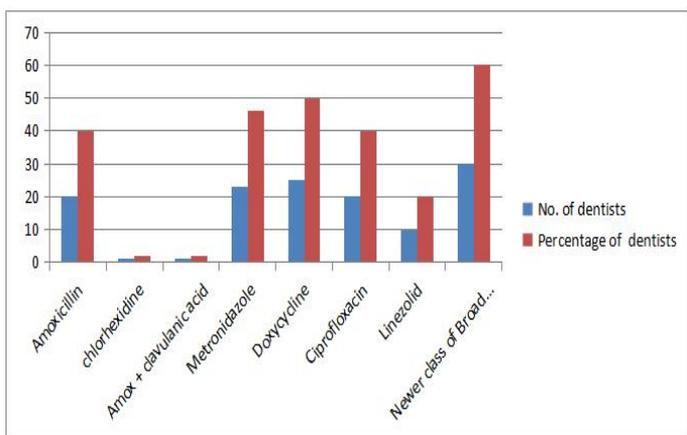


Fig-3 Medications and Number with percentage of Dentists

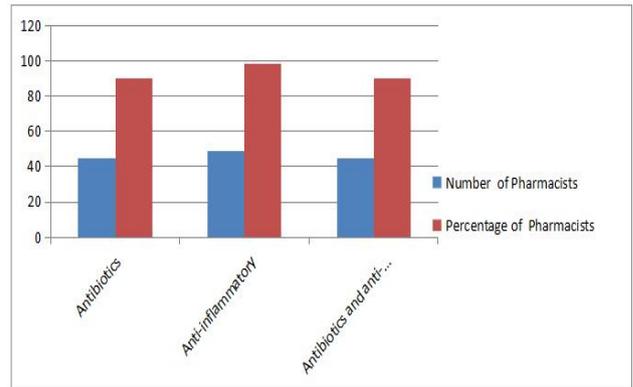


Fig-4 Pharmacists and medications reported

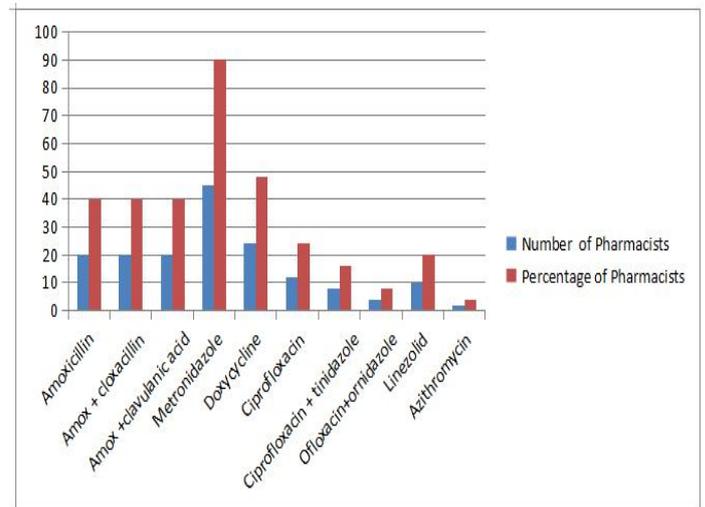


Fig-5 Pharmacists and medications reported

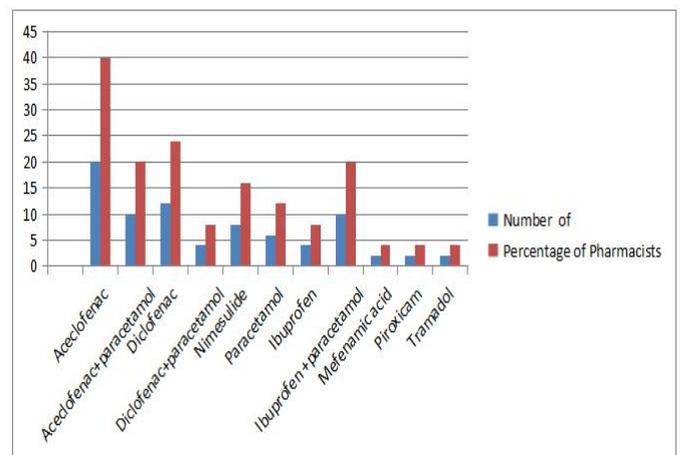


Fig-6 Pharmacists and medication types

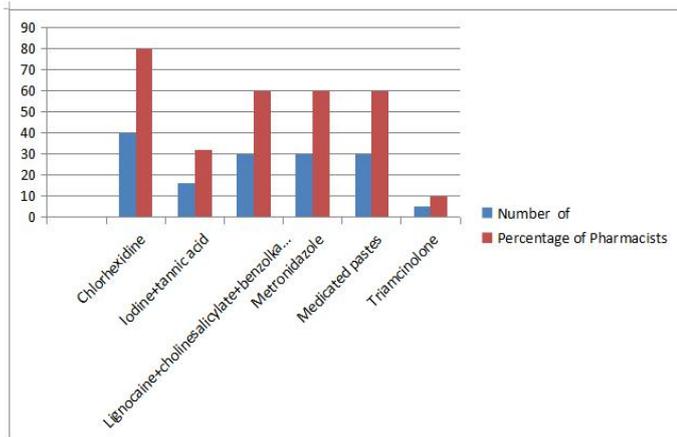


Fig-7 Pharmacists and medications used

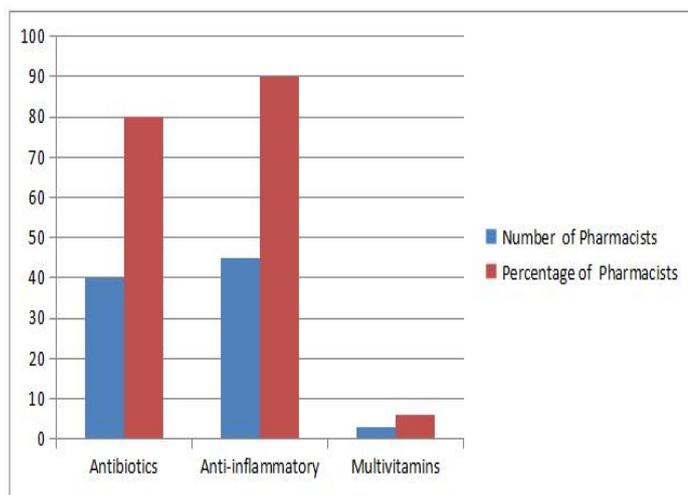


Fig-8 Pharmacists and medication types

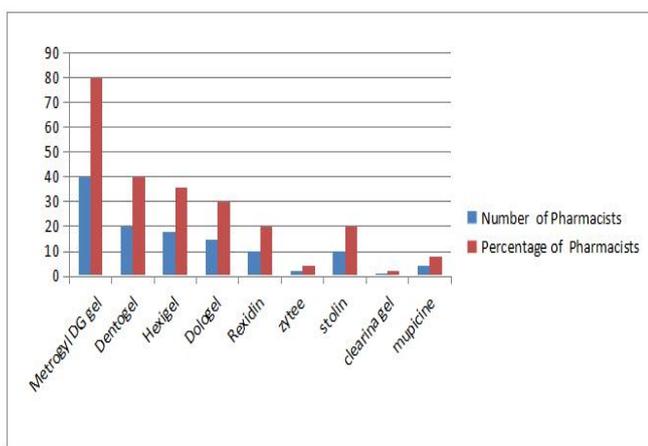


Fig-9 Pharmacists and Percentage with medications

Conclusion

Findings from the responses to questionnaire by both dentists and pharmacists are similar with respect to antibiotics and anti-inflammatory like most commonly prescribed drugs are aceclofenac, doxycycline and metronidazole for periodontal disease.

Literature survey reveals that there are many reports on in-situ gel containing anti-microbial anti-inflammatory agents, however work on in-situ gel containing new class of antimicrobial like linezolid & natural anti-inflammatory agents like placenta for periodontal disease have not been reported. Hence the study after evaluation of market potential for oral application shows promising potential research can be made to develop in-situ gel containing anti-microbial & anti-inflammatory agents and to try various combinations and this study will further contribute to the field of periodontal disease and satisfies the customer need.

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CITE:

Inayathulla, Ahmed GM, Goudnavar P. Evaluation of Market Potential for In-Situ Gel Containing Antimicrobial And Anti-Inflammatory Agent In Periodontal Disease, The International Journal of Therapeutics 2018; 1(1): 66-74.

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