



Original Research Article

Comparative evaluation of the synbiotics, antibiotics and analgesics in post extraction healing of tooth sockets- A randomized control trial

Shweta Singh^{1,*}, Sahana S¹, Sulabh Kumar², N K Gupta³

¹Dept. of Public Health Dentistry, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, India

²Dept. of Prosthodontics, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh, India

³Mayo Hospital, Lucknow, Uttar Pradesh, India



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ABSTRACT

Background: The emergence of antibiotic resistance and its side effects have restricted their use in array of prophylactic options in present scenario. Indeed, some new strategies and alternative therapies like herbal medicines and laser therapies have already minimised the use of antibiotic prevent/cure health related issues or oral diseases. Nowadays many authors are trying to prove influence of synbiotics in oral health maintenance so this study was done to check the usage of synbiotics and its benefits in the post extraction tooth socket.

Aim: The aim of this research is to study the effect of synbiotics supplements on post-surgical complications and oral wound healing after extraction of tooth.

Objectives: To determine the clinical effectiveness and cost-effectiveness of synbiotics over antibiotics and analgesics in post extraction of tooth socket.

Materials and Methods: This study is a randomized controlled trial, parallel group, multicentre trial comparing the efficacy of synbiotics in healing of post extraction sockets that was conducted in three centres of Lucknow city-India including BBD dental college of dental sciences. Three groups were made with 80 patients in each group. The primary outcome measures were observed in each group on 3rd day, 5th day and 7th day.

Results: We could find significant difference between the 3 groups regarding the evaluated parameters. In Table 1 age and gender distribution was observed. Wound related complications like bleeding, swelling and gut flora disturbance at the surgical site was present more in group 2 and group 3 as compared to group 1 which is found statistically significant with p value 0.02, 0.01 and 0.01. In Table 5 the cost analysis during the treatment among the study subjects was noted where statistical significant results were obtained between groups 1 vs group 2; group 1 vs group 3 and group 2 vs group 3 at $p \leq 0.01$.

Conclusion: Since this was a novel approach in comparing the post extraction wound healing and as the results showed a definite positive effect by synbiotics. Further studies with a larger sample and different formulation would be recommended to be put into clinical use.

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1. Introduction

The first probiotic species introduced into research were *Lactobacillus acidophilus* by Hull, et al. in 1984 and *Bifidobacterium bifidum* by Holcomb, et al. in 1991.¹ The term “synbiotic” is used when a product contains

both probiotics and prebiotics. Because the word alludes to synergism, this term is reserved for products in which the prebiotic compound selectively favors the probiotic compound.² The synbiotics have been observed to reduce the risk of certain infectious disease such as certain types of diarrhoea and oral diseases like dental caries, mouth ulcers, gingivitis and periodontal diseases.^{3–5} Despite of this fact, very little information is available in the literature as to

* Corresponding author.

E-mail address: drshweta2005@gmail.com (S. Singh).

the synbiotic management of the patient with oral diseases. Though antibiotics have been used against lot of infections. Synbiotics are specifically selected to not contribute to the spread of antibiotic resistance and not carry transferable antibiotic resistance in the next generation by avoiding over use of antibiotics. This study focuses on contribution of synbiotics for invasive procedures as it may reduce the risk for certain infectious diseases and thereby reduce the need for antibiotics.

The aim of this study is to evaluate whether the antibiotic prophylaxis could be beneficial in preventing post extraction local complications and whether the use of a synbiotic could help reduce the antibiotic gastro-intestinal side effects.

2. Aim

The aim of this research is to study the effect of probiotic supplements (*Lactobacillus reuteri*) with prebiotics on post-surgical complications and oral wound healing after extraction of tooth.

3. Objective

To evaluate whether the use of synbiotics are equally effective as use of antibiotics and could it be beneficial in preventing local complications post extraction.

4. Materials and Methods

The ethical clearance with IEC Code: 01/BBDCODS/IEC/11-2019 was obtained from the Institutional Ethics Committee of Babu Banarasi Das College of Dental Sciences.

The following formula was used to calculate the appropriate sample size $n = z^2pq/d^2$.

Total sample size of 240 people was finalized. After calculation “n” when was equal to 231.59, which was rounded off to 232. To compensate for attrition, the sample size was increased to 240. Patients meeting the inclusion criteria were initially included in this randomized clinical trial and randomly allocated to one of the three experimental groups according to a computer-generated randomization list. The parameters observed during the study were bleeding, pain, swelling and gut flora disruption.

4.1. Inclusion criteria

Uncompromised general health, Non-smokers, No systemic medications, No recent/ongoing episode of antibiotic treatment.

4.2. Exclusion criteria

Any pathological condition associated with the tooth to be extracted detected on radiographs prior to surgery and regular consumers of probiotics and prebiotics.

Synbiotics are available in the form of powder, liquid, gel, paste, granules, capsule or sachets.⁶ In this study we used synbiotics in the form of sachets. Patients were told to use the sachets as mentioned on the packing. Patients were allocated to the group 1 were given Synbiotics (*Bifidobacterium longum*+lactoferrin) and analgesics (sos) for 7 days. Patients allocated to the group 2 received antibiotic + analgesics (sos) and patients allocated to the group 3 received only analgesics (sos) and no antibiotic or synbiotics therapy after the extraction. To evaluate post-extractive complications, controls were performed on day 1, 4 and on 7th day after the extraction.

5. Results

Post extractive complications observed in each group have been prominent but fast to resolve. The antibiotic administration showed a decrease in pain suffered by patients but a higher incidence of gastrointestinal side effects, such as abdominal distension and diarrhoea, which seemed to be relieved by the concomitant use of the synbiotics.

In Table 1 gender and age distribution among the study subjects is shown. Group 1 subjects who were recruited at a mean age of 35.42 ± 9.31 , Group 2 subjects who were recruited at a mean age of 37.62 ± 7.98 and Group 3 were at a mean age of 36.79 ± 10.27 which was significant with p value 0.53.

The Table 2 depicts the wound related parameters and general complications evaluated on day 1 and found relative difference between the groups in variables like bleeding with p value 0.002 and it was found maximum in group 3 patients and minimum in group 1. Pain and swelling were reported maximum again by group 3 and minimum in group 1. Gut flora disruption was statistically significant with p value ≤ 0.01 where none of the patients from group 1 had any problem related to it whereas 16 patients reported suffering on day 1.

Tables 3 and 4 is a table depicting the parameters evaluated on day 4 and 7 subsequently with similar findings as of Table 1 with a statistical significant p value of 0.04.

The cost effective analysis of the therapies tested were evaluated in Table 5. The turkey HSD Post-hoc test analysis was applied to list the difference of cost analysis between the groups. Statistical significant results were obtained between group 1 vs group 2; group 1 vs group 3 and group 2 vs group 3 at $p \leq 0.01$.

It is seen that synbiotics distinctly marked to be a better choice than antibiotics in the inter group comparison.

Table 1: Gender and age distribution among the study subjects

Variables	Group 1		Group 2		Group 3		Chi square	p value
	N	%	N	%	N	%		
Gender								
Male	47	58.75	48	60	44	55.0	2.47	0.53
Female	33	41.25	32	40	36	45.0		
Age	Mean	SD	Mean	SD	Mean	SD	Anova Test	p value
	35.42	9.31	37.62	7.98	36.79	10.27	1.89	0.27

Table 2: Comparison of various wound related parameters and general complications among the study groups at day 1

Variables	Group 1		Group 2		Group 3		Chi square	p value
	Present	Absent	Present	Absent	Present	Absent		
Bleeding	17	63	25	55	38	42	12.64	0.002*
Pain	19	61	26	54	33	47	5.58	0.06
Swelling	8	72	13	67	30	50	19.86	<0.01*
Gut flora disruption	0	80	16	64	9	71	1.04	<0.01*

*: statistically significant

Table 3: Comparison of various wound related parameters and general complications among the study groups at day 4

Variables	Group 1		Group 2		Group 3		Chi square	p value
	Present	Absent	Present	Absent	Present	Absent		
Bleeding	1	79	4	76	7	73	1.13	0.41
Pain	1	79	2	78	10	70	1.29	0.38
Swelling	0	80	0	80	6	74	0.79	0.58
Gut flora disruption	0	80	27	53	8	72	4.78	0.04*

*: statistically significant

Table 4: Comparison of various wound related parameters and general complications among the study groups at day 7

Variables	Group 1		Group 2		Group 3		Chi square	p value
	Present	Absent	Present	Absent	Present	Absent		
Bleeding	0	80	0	80	0	80	0	1
Pain	0	80	0	80	1	79	0.13	0.91
Swelling	0	80	0	80	3	77	0.22	0.78
Gut flora disruption	0	80	6	74	1	79	0.32	0.72

Table 5: Cost analysis during the treatment among the study subjects

Groups	Mean (in Rs)	SD
Group 1	90.58	2.37
Group 2	258.13	2.24
Group 3	27.82	1.47
Anova test		94.79
p value		<0.01*
Tukey HSD Post-hoc Test... Group 1 vs Group 2: Diff=167.5500, 95% CI=166.7800 to 168.3200, p=<0.01* Group 1 vs Group 3: Diff=-62.7600, 95%CI=-63.5300 to -61.9900, p=<0.01* Group 2 vs Group 3: Diff=-230.3100, 95% CI=-231.0800 to -229.5400, p=<0.01*		

*: statistically significant

6. Discussion

Tooth extraction is a very common procedure in oral surgery. Despite this, very little information is available in the literature as to the role of antibiotic management in the patient.

The aim of this study was to evaluate whether the synbiotic prophylaxis could be beneficial in preventing post extraction local complications and whether the use of a synbiotic could help reduce the complications as antibiotics does when procedure is done following proper asepsis. Probiotics are known to benefit both general and oral health of humans. Its oral implications are witnessed in the following: Dental caries, Periodontal diseases, Halitosis, Candidiasis etc.

In oral cavity, probiotics can create a biofilm, acting as a protective lining for oral tissues against oral diseases. Such a biofilm keeps bacterial pathogens off oral tissues by filling a space pathogens would invade in the absence of the biofilm,¹ and competing with cariogenic bacteria and periodontal pathogens growth.⁴

Our data suggest that this synbiotic preparation could have therapeutic potential in oral health possibly through both anti-inflammatory and antimicrobial effects. There are several studies done to find out effect of probiotics and prebiotics on oral health conditions. A study from 2006 suggests that probiotics can reduce symptoms of gingivitis.⁵

Tomoki Maekawa and George Hajishengallis in 2014 and DN Della Riccia et al in 2007 came up with a study where they proved that probiotics have an anti inflammatory properties and help in healing of oral wounds and mouth ulcers.^{7,8}

Of the three groups that were evaluated the synbiotics group posed an equivalent response to that of the antibiotics. Since this was a novel approach in comparing post extraction wound healing and as the results showed a definite positive effect by synbiotics. Further studies with a larger sample and different formulation would be recommended to be put into clinical use.

7. Conclusion

Synbiotics hold a promise in improving oral health. It is been observed that combination of probiotics and prebiotics have proven to be beneficial over the use of antibiotics and analgesics.

The present study holds strong clinical significance as the synbiotics proves to be the antidote for the antibiotics.

8. Source of Funding

None.

9. Conflict of Interest

None.

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Author biography

Shweta Singh, Senior Lecturer

Sahana S, Professor

Sulabh Kumar, Assistant Professor

N K Gupta, Professor and HOD

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