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LSTR 3 Mix MP Therapy and Conventional Root Canal Therapy: A comparative Clinical & Radiological Study for the treatment outcome of Irreversible Pulpitis in Permanent Tooth.

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Background: LSTR therapy is considered as one of the most widely accepted clinical procedure for the treatment of permanent tooth with irreversible pulpitis with minimum destruction of tooth tissue ***Objective:*** To evaluate the clinical and radiographic findings of permanent tooth with irreversible pulpitis by LSTR 3Mix MP therapy and compare with conventional root canal therapy. ***Methods:*** According to inclusion and exclusion criteria, a total of 40 teeth were enrolled in this study, out of which 20 teeth treated with LSTR 3Mix MP Therapy, (Group-I) and the remaining 20 teeth treated with conventional root canal therapy (Group-2). Clinical and radiological Follow up examinations were performed at 3, 6- and 12-months interval to investigate the incidence of postoperative pain, tenderness to percussion, swelling and periodical radiolucency, collected date was analyzed by using Statistical package for Social Science (SPSS) version 17. Statistical analysis was performed by Chi-square test to assess the difference between the clinical outcome of Group 1 and 2; a value of $P<0.05$ was considered as statistically significant. ***Results:*** At 3 months observation period, LSTR and Conventional root canal therapy showed 100% success rate in treating teeth with irreversible pulpits; neither pain nor any tenderness on percussion or post-operative swelling was observed. Radiographic examination also revealed no sign of radiolucent area. At 6 and 12 months following the completion of the treatment, except in one case in each observation period, there results were similar to that of 3 months. One LSTR (5%) and one conventional (5%) therapy reported pain, tenderness on percussion and swelling with peripical lesion. There were no statistical differences between the two groups ($p>0.05$). ***Conclusions:*** It can be concluded that LSTR 3 Mix MP Therapy proved to be effective in treating teeth with irreversible pulpitis; with similar clinical and radiological outcome to conventional root canal treatment within one-year observation period.

KEYWORDS: LSTR, RCT, Irreversible pulpitis

INTRODUCTION

Sterilization of root canal and periraducular region results in good healing of the periradicular region. Bacteria which are present mainly in the root canals and superficial layer of infected root canal wall may be easily removed by conventional root canal treatment. But the bacteria, which remain in the deep layers of root canal dentin, may leak out to periapial region and cause complications. Application of anitbacterial drugs to endodontic lesion in one of the clinical procedures that can be used to sterilized such lesions,

LSTR-3mix therapy is a new biologic approach in the treatment of endodontics with or without periapical involvement by using a mixture of three antibiotics. This concept was developed by the Cariology Research Unit of the Niigata University School of Dentistry Niigata, Japan in 1988. LSTR technique involves the use of three broad spectrum antibiotics namely metronidazole, ciprofloxacin and minocycline. The 3 antibiotics are mixed with Macrogol and Propylene Glycol (MP), which is found to be an excellent vehicle to carry 3mix into the entire dentin through the dentinal tubules and kill all the bacteria in the lesions.

The advantages of LSTR 3 Mix are investigated by many of the previous studies. These studies showed that LSTR therapy could kill all bacteria taken from carious lesions, necrotic pulps; infected root dentin and endodontic lesion of deciduous teeth and also permanent teeth.[1,2] Treatment using 3Mix-MP revealed excellent clinical outcomes.

The composition of bacteria may vary in infected pulp and root canal dentine. A study shows the anaerobic microorganism recovered from carious dentine: 80% are obligate anaerobes from infected pulp; 92% are obligate anaerobes from infected root canal dentin. Obligate anaerobes are sensitive to Metronidazole which has wide bactericidal spectrum against anaerobes. All bacteria cannot be eliminated by Metronidazole alone, even at high concentration thus others drugs are necessary to sterilize the infected dentin. Therefore, Ciprofloxacin and Minocycline were added to eliminate bacteria from infected dental tissues.

The elimination of bacteria reduces infection thereby eliminating inflammation as well as pain of both acute and chronic type. According to Hoshino, 94% of the cases that experienced pain were relieved within 24 hours after use of the LSTR 3 Mix, regardless of the nature and severity of the pain.

To sterilize deep layer of infected root dentine, root canal medicaments should penetrate root canal dentine. The penetration ability into the infected root canal dentin is improved by mixing these drugs with Propylene Glycol and Macrogol to form ointment base. The penetration ability of Propylene Glycol was clearly demonstrated by Cruz et. al.[3]

Repair of damaged tissues can also be expected if lesions are disinfected.4 LSTR has less mechanical instrumentation and root canal and periapical tissue remain untouched. The conventional treatment of irreversible pulpits is to surgical removal of pulp by a pulpectomy procedure2. However, the LSTR hypothesis proposes that the local application antimicrobial agents, such as the LSTR 3Mix-MP combination would disinfect this lesion by eradicating bacteria in dentinal and or pulpal lesions. This treatment procedure was revealed as the treatment of pulpits as LSTR 3Mix-MP save pulp therapy, because most inflamed pulps were saved to be alive instead of the removal of pulp tissue in the conventional endodontic therapy.

Based on the previous studies, it is therefore considered that LSTR therapy provide excellent clinical outcome in treatment of cases with caries dentin extended to pulps, cases with exposed pulps and cases of pulpitis with spontaneous pain. Permanent and primary teeth2 with periradicular lesions have been also successfully treated by 3Mix-MP endodontic therapy. This new pgjigm has been used in the retreatment cases without removal of previous root canal obturating material.

3Mix has not caused any observed pathological changes when placed onto human pulp tissue. [5]it was clearly demonstrated in the previous study that the surviving pulp tissue revealed the pulp function, showed by immunochemical positive recations to Nestin and PGP 9.5. Thus, functioning odontoblasts6 and nerve innervations7 were restored in coronal and redicular pulps a certain period after LSTR 3Mix-Mp treatment. In recent endoodontic study, Banchs and Trope8 have indicated, when the root canal is disinfected using 3Mix-and the inflammatory conditions reversed, the puip tissue can regenerate as the result of revascularization.

The aim of this study was to evaluate the clinical and radiological outcomes of LSTR 3 MIXMP therapy for the treatment of permanent teeth with irreversible pulpitis and compared with that of conventional root canal therapy.

MATERIALS

Study design: Quasi experimental study

Study period: June 2013 to June 2014

Place of study: This study was conducted in Faculty of Dentistry, Department of Conservative Dentistry & Endodontics, Bangabandhu Sheikh Mujib Medical University, Dhaka- 1000, Bangladesh.

Study population: The study population was comprised of patients having permanent tooth with irreversible pulpitis irrespective of sex and tooth numbers.

Sampling method: Purposive sampling technique was employed to select the cases.

Main outcome variable:

1. Post operative pain
2. Tenderness to percussion
3. Swelling
4. Periapical radiolucency

Sample size:

To determine the sample size the following formula was followed:

$$n = \frac{Z^2(p \times q)}{d^2}$$

n= The desired sample size

p= Proportion in the population; if not known, it is regarded as 0.973 (97.3%)

q=1 –p=l00-97.3=2.7%

z=value of standard normal distribution (z distribution) at a given level of significance or at a confidence level.

Here z=l .96 at confidence interval.

e=margin of error5%

Thus, n = $\frac{1.96^2(0.50 \times 0.50)}{(0.05)^2}$ =40.36

Therefore target sample size was 40

40 patients with irreversible pulpitis were selected for this study. They were randomly divided into two groups:

Group 1- contain twenty patients having permanent teeth with irreversible pulpitis treated by LSTR 3 Mix MP Therapy.

Group2- contain twenty patient having permanent teeth with

irreversible pulpitis treated by conventional root canal treatment.

Inclusion criteria:

1. Permanent teeth with irreversible pulpitis due to caries or large restoration
2. Permanent teeth with spontaneous pulpal pain.
3. Permanent teeth with irreversible pulpitis which was restorable.

Exclusion criteria:

1. Permanent teeth with irreversible pulpitis due to trauma,
2. Teeth with abnormal mobility
3. Presence of abnormal periradicular radiolucency.
4. Non restorable tooth.
5. Presence of abnormal periradicular radiolucency.
6. Radiographic evidence of excessive bone loss in furcuation area.

PROCEDURES OF PREPARING AND ORGANIZING MATERIALS:

Study procedure:

Through history taking and radiograph were taken for each case. Those that failed to meet inclusion criteria were rejected. Thus, a total of 40 teeth that fulfilled the inclusion criteria were selected for the study after clinical and radiographical evaluation. The occupation, socioeconomic condition, general health status, drug history and past dental history of the patients, spontaneous pain or pain during the night were obtained by face to face interview and were recorded in prefixed questionnaire by parent. Percussion and pulp sensitivity tests were performed and radiographs were examined to assess pulpal health. Patient's symptoms, clinical signs and radiographic evidences were recorded.

Composition of LSTR agent is as follows:

- Ciprofloxacin
- Minocycline
- Metronidazole

Three antibiotics are mixed with

- Propylene Glycol
- Macrogol.

Preparation of the LSTR 3 Mix MP Therapy:

Metronidazole, Ciproflaxacin and Minocycline were mixed in a proportion of 1:1:1 (by volume). The vehicle, of an ointment consistency, was prepared separately by mixing Macrogol and propylene glycol in ratio of 1:1 by volume. The 3 Mix antibiotics and MP vehicle thoroughly mixed to form 3 Mix-MP in a ratio of 7:1 for standard consistency. For Ciprofloxacin and Metronidazole tablet, the entire coat were removed with a scalpel. The tablet was pulverized using mortar and pestle. For Minocycline which comes in capsules, the powder was segregated. The powder antibiotics were stored and sealed in air tight containers, The propylene glycol and Macrogol were mixed together at a certain consistency so that the mixture tip could be erected (MP). The 3 antibiotics were mixed together with propylene glycol and Macrogol as diluents until a creamy consistency so that it could be divided in small rounded ball that could be erected by the tips of the probes.

Technique of Placement of LSTR3 —mix MP:

Isolation of the tooth was achieved using rubber dam, cotton roll and with the use of saliva ejector. If present previous restoration was removed carious lesion with soft dentine was not removed intentionally unless the access cavity was less than 1.5 mm in depth in dentine. Care was taken not to damage the pulp during the preparation. The dentinal walls of the preparation were treated with 12% EDTA for 1 mm. to remove the smear layer. After drying, a 1 mm diameter ball like particle of 3 mix MP preparations was placed on to the bottom of the caries cavity and using a cotton ball, pressed to a thin layer on the cavity floor. Then, a first layer of GIC (Fujilx) was applied to seal 3mix MP, The cavity was then entirely sealed with the second layer of glass ionomer cement

Technique of conventional root canal therapy:

1. Isolation and disinfection of the tooth.
2. Application of local anesthesia.
3. Prepare the access cavity.
4. Removal of the vital pulp tissue.
5. Establishment the length of tooth or TLD x-ray.
6. Bio-mechanical preparation of the root canal system.
7. Irrigation of the root canal system.
8. Test the trial point or select the master cone.
9. Obturate the canal with Zn-Oxide eugenol sealer and Gutta Percha point by lateral condensation technique and the cavity was filled with fuji ix glassinomer cement.

Follow up:

The patients were recall for clinical and radiographic evaluation at3, 6 and 12 months interval for the assessment of postoperative pain, tenderness on percussion, swelling and periapical radiolucency.

Procedures of collecting data: A clinical checklist were use to record the data.

PROCEDURE OF DATA ANALYSIS:

Collected data was analyzed using Statistical Package for Social Science (SPSS) version 17. Statistical analysis was performed by Chi-square test to assess the difference between the clinical outcome of Group I and II; a value of P<0.05 was considered as statistically significant.

Quality assurance strategy:

Maximum qualities were assured by using disposable and sterilized instruments.

RESULTS

Table 3.1 Distribution of study patients by age (n=40)

Age	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
≤ 10	0	0.0	1	5.0	
11-20	5	25.0	4	20.0	
21-30	9	45.0	14	70.0	
>30	6	30.0	1	5.0	
Mean±SD	27.5±	10.11	24.85±	6.15	
Range(min,max)	12,	46	10,	40	

ns= not significant

P value reached from unpaired t-test

Group 1: Treated by LSTR 3 Mix MP Therapy
Group 2: Treated by Conventional Root Canal Therapy

Table 3.1 shows age distribution of the study patients. It was observed that majority (45.0%) patients age were belonged to 21-30 years in group 1 and 14(70.0%) in group 2, the mean age was found 27.5±10.11 years in group 1 and 24.85±6.15 years in group 2. The mean age difference was not statistically significant (p>O.OS) between two groups.

Table 3.2 Distribution of study patients according to sex (n=40)

Sex	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
Male	7	35.0	8	40.0	0.743^{ns}
Female	13	65.0	12	60.0	

ns= not significant
P value reached from chi square test

Table 3.2 shows sex of the study patients, it was observed that almost two third (65.0 %) patients were female in group 1 and 12(60.0%) patients in group 2. The difference was not statistically significant (p>0.05) between two groups

Table 3.3 Distribution of study patients according to teeth number (n=40)

Teeth number	Group-I (n20)		Group-II (n20)	
	n	%	n	%
Location				
Right Upper	1	5.0	1	5.0
Right Lower	7	35.0	11	55.0
Left Upper	3	15.0	1	5.0
Left Lower	9	45.0	7	35.0
Mandibular 1st molar	13	65.0	12	60.0
Maxillary 1st molar	3	15.0	2	10.0
Mandibular 2^{en} molar	1	5.0	2	10.0
Maxillary Ist premolar	1	5.0	1	5.0
Mandibular 2^{en} premolar	1	5.0	2	10.0
Maxillary 3rd molar	1	5.0	1	5.0

Table 3.3 shows the distribution of the study teeth, it was observed that 1(5.0%) had right upper tooth in group 1 and group 2, respectively. Right lower tooth was found 7(35.0%) in group 1 and 11(55.0%) in group 2. Left upper tooth was found 3(15.0%) in group 1 and 1 (5.0%) in group 2. Left lower tooth was found 9(45.0%) in group 1 and 7(35.0%) in group 2. Mandibular 1st molar was found 13(65.0%) in group 1 and 12(60.0%) in group 2. Maxillary 1st molar was found 3(15.0%) in group I and 2(10.0%) in group 2. Mandibular 2^{en} molar was found 1(5.0%) in group 1 and 2(10.0%) in group 2. Maxillary 1st premolar was found 1(5.0%) in group I and group 2, respectively. Mandibular 2nd premolar was found 1(5.0%) in group 1 and 2(10.0%) in group 2, Maxillary 3rd molar was found 1(5.0%) in group 1 and group 2, respectively.

Table 3.4 Clinical assessment of post operative pain in the study teeth during 12 months follow up (n=40)

Pain status (VAS score)	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
Pre operative					
Present	20	100.0	20	100.0	-
Absent	0	0.0	0	0.0	
First follow up					
Present	0	0.0	0	0.0	-
Absent	20	100.0	20	100.0	
Second follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	
Third follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	

ns= not significant
P value reached from fisher exact test.

Table 3.4 shows the pain status of the study teeth during third follow up and observed that, pain was not found in both group at 1st follow-up. Second and third follow up pain was found one case in group I and group II respectively. The difference was not statistically significant (p>0.05) between two groups.

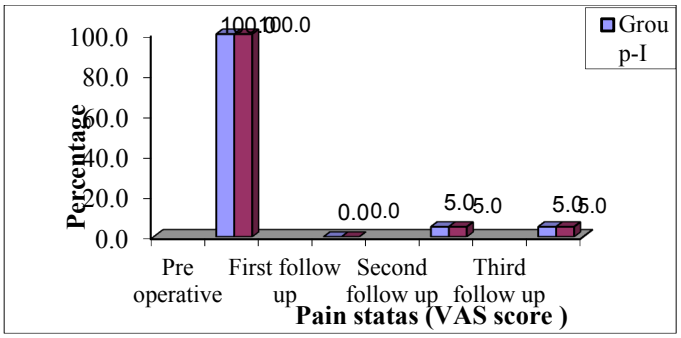

Fig 1: Bar diagram showing clinical assessment of post operative pain in the study teeth during 12 months follow up.

Table 3.5 Clinical assessment of tenderness to percussion in the study teeth during 12 months follow up (n40)

Tenderness	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
Pre operative					
Present	20	100.0	20	100.0	-
Absent	0	0.0	0	0.0	
First follow up					
Present	0	0.0	0	0.0	-
Absent	20	100.0	20	100.0	
Second follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	
Third follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	

ns not significant
P value reached from fisher exact test.

Table 3.5 shows the tenderness of the study teeth during third follow up and observed that, tenderness was not found in both group at 1St follow-up. Second and third follow up
tenderness was found one case in group I and group II respectively. The difference was not statistically significant (p>0.05) between two groups.

Table 3.6 Clinical assessment of swelling in the study teeth during 12 months follow up (n=40)

Swelling	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
Pre operative					
Present	20	100.0	20	100.0	-
Absent	0	0.0	0	0.0	
First follow up					
Present	0	0.0	0	0.0	-
Absent	20	100.0	20	100.0	
Second follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	
Third follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	

ns not significant

P value reached from fisher exact test

Table 3.6 shows the swelling of the study teeth during third follow up and observed that, swelling was not found in both groups at pre operative and 1St follow-up, Second follow up swelling was found one case in group I and group II respectively. Third follow up swelling was found one case in group II. The difference was not statistically significant (p>0.05) between two groups.

Table 3.7 Radiological assessment of periapical radiolucency of the groups at evaluation period (n=40)

X-ray radiolucency	Group-I (n20)		Group-II (n20)		P value
	n	%	n	%	
Pre operative					
Present	20	100.0	20	100.0	-
Absent	0	0.0	0	0.0	
First follow up					
Present	0	0.0	0	0.0	-
Absent	20	100.0	20	100.0	
Second follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	
Third follow up					
Present	1	5.0	1	5.0	0.756^{ns}
Absent	19	95.0	19	95.0	

ns not significant

P value reached from fisher exact test

Table 3.7 shows the X-ray radiolucency of the study teeth during third follow up and observed that, X-ray radiolucency was not found in both groups at pre operative and 1st follow-up. Second and third follow up X-ray radiolucency was found one case in group I and group II respectively. The difference was not statistically significant (p>0.05) between two groups.

DISCUSSION

Endodontic therapy plays an important role in removing bacteria, their by-products and their substrates, by disrupting and destroying the microbial ecosystem through chemical and mechanical methods29. Different drugs and medicaments have also been suggested to accompany these techniques with varying success rate. Besides the use of nonspecific antiseptics, application of antibacterial drugs represents. Based on the previous studies, it is therefore considered that LSTR therapy provide excellent clinical outcome in treatment of cases with caries dentin extended to puips, cases with exposed puips and cases of pulpitis with spontaneous pain. Permanent and primaryteeth2 with periradicular lesions have been also successfully treated by 3Mix-MP endodontic therapy

For further investigation, in this present study, 20 teeth with irreversible pulpitits were treated with LSTR therapy (Group I) and clinical and radiological outcome were assessed at 3, 6, and 12 months intervals and compared with 20 teeth of conventional root canal therapy, in vivo. The methodology followed in this study was originally based on Moral, et. al. and Takushige, et. al. [1,2].

It was found that, all patients had pain during preoprative period. However, at 3- months following the completion of the treatment, group I and group II showed 100% success rate in clinical and radiographic investigation. Neither pain nor tenderness on percussion or postoperative swelling has been detected in any of treated teeth. Furthermore, radiographic examination revealed no sign of radiolucent area. The results between two groups were not statistically significant and were corresponded to that of previous study of Takashige et. al.[2]

At 6 and 12 months observation period, one tooth in LSTR group (5%) and one tooth in Conventional group (5%) reported pain, tenderness on percussion, swelling and periapical radiolucency. Again, the results between two groups were not statistically significant. Incidence of pain, tenderness on percussion, swelling and periapical radiolucency in LSTR group might be due to leakage through coronal restoration. This is supported by Takushige et. al. [1,2] The responsible tooth was then treated by 2w1 application of LSTR 3 Mix MP Therapy. The sign and Symptom was resolved following reapplication of LSTR.

On the other hand, the incidence of pain, tenderness on percussion, swelling and periapical radiolucency in group 2 was not clearly understood from the present study. However, it might be due to incomplete debridement of the root canal system, over instrumentation, chemical irritant in form of intracanal medicaments, irrigating solution get extruded in the perapical tissue. Re-RCT was done in the responsible tooth and the symptom was subsided following treatment.

In similar type of study, Moral et. al. [1] found subsidence of all the post operative clinical symptoms (pain, tenderness to percusion, swelling and sinus) in 85% cases and 17% came back with the clinical symptoms.

In another study of Takushige, et.al. [2] reported that 95.5% cases having good results following a single application of the 3 Mix drug; 3% cases need retreatment and 2% cases pulp become dead (necrosed) but no clinical symptom and discomfort were found. According to Hoshino et al. 94% of these cases that experienced pain was relieved within 24 hours after use of LSTR 3 Mix MP therapy regardless of the nature and severity of pain.

The results of clinical and radiological findings following LSTR and conventional root canal therapy in permanent tooth with irreversible pulpitis were compared in this present study.

Although no significant differences was found in this present study but LSTR therapy is considered as better treatment option for pulpitis with history of spontaneous pain, permanent and primary teeth with periradicular lesion, retreatment cases without removal of previous root canal obturating material. It was confirmed by previous studies.[1,2]

Conventional root canal treatment is as time consuming, hazardous and somewhat destructive method[2]. Tooth becomes brittle because of lack of nutrition supply from the surrounding living tissue.' In endodontics disease bacteria may invade not only dentine but also cementum. Such bacteria are reported to be mainly obligatory anaerobs, it appears to be difficult to eliminate these bacteria using conventional root canal treatrment.

On the other hand, LSTR therapy has following advantages. It is not necessary to remove the entire pulp and bio mechanical preparation of the canal. In LSTR therapy nutrition supply of treated teeth are tried to keep normal and the tooth structure as well as the canal wall need not to make wide.So the teeth having LSTR therapy remain stronger in comparison with those having root canal theraphy 2 It is also demonstrated in situ that LSTR mixture could be carried quickly and efficiently by propylene glycol that penetrate into the periapical lesion and killed all the cultivable bacteria within one day after sterilization by 3 Mix drugs.

Based on the present study and together with the previous studies, it is considered that LSTR therapy can be used as an alternative to conventional root canal therapy because it is simple, cost effective, time saving and reduces the number of appointment time.

LIMITATION OF THE STUDY

1. The study population was selected from one selected hospital in Dhaka city, so that the results of the study may not be reflect the exact picture of the country.
2. The present study was conducted at a very short period of time.
3. Histological analysis was not done.
4. Small sample size was also a limitation of the present study. Therefore, in future further study may be under taken with large sample size and wide range

CONCLUSION

It can be concluded that the clinical and radiological outcome of LSTR 3 Mix MP is similar to conventional root canal therapy in the treatment of permanent teeth with irreversible pulpitis.

RECOMMENDATIONS:

Further research is necessary with long term clinical evaluation and a larger sample size to Confirm the results.

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