JOURNAL OF COMPLEMENTARY MEDICINE RESEARCH

RESEARCH ARTICLE

Comparative Evaluation of Post-Operative Pain Using Endoflas and Endoflas Powder with Turmeric Gel as Obturating Materials for Pulpectomy in Primary Teeth: A Double Blinded Randomized Controlled Trial

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ABSTRACT

Background: Endodontic treatment in children is complex and encompasses occurrence of post-operative pain which needs to be diligently managed for achieving successful treatment outcomes. Occurrence of post-operative pain is multifactorial in origin and every possible preventive measures should be incorporated in the treatment protocols to make root canal treatment effective and painless for children.

Aim: The present study aims to comparatively evaluate the occurrence of post-operative pain on using Endoflas and Endoflas powder with Turmeric gel (EPTG) as obturating materials for pulpectomy in primary mandibular molars.

Materials and Methods: A single-centered double-blinded randomized controlled trial was designed for recruiting children in an age group of 4-9 years with a chief complaint of night pain and requiring pulpectomy procedure were enrolled into the present study. On completion of pulpectomy an immediate post-operative intra-oral periapical radiograph (IOPAR) was obtained to assess the quality of obturation using the modified Coll and Sadrian's criteria. Pre- and post-operative pain assessment was done using the Wong-Baker Faces Pain Rating Scale (WB-FPRS) during the 1st week of follow-up interval.

Results: Highest percentage of optimal fillings (12/60.0%) were found in Endoflas followed by EPTG (8/40.0%) group. Severe degree of post-operative pain was experienced in more number of overfilled children followed by underfilled and optimal filled children. During 1st week of follow-up interval, post-operative pain experience was more in children obturated with EPTG compared to children obturated with Endoflas.

Conclusions: Meticulous management of post-operative pain in children is the essence of successful treatment in paediatric dentistry. Prior knowledge of obturation quality and the resorption status of an obturating material on overfilling can serve as necessary guidelines to alleviate the perceived post-operative pain with effective management. EPTG can thus be suitably used as a promising obturating material in primary teeth.

KEYWORDS:
Endoflas-FS, Endoflas powder with Turmeric gel, Obturating material, Post-operative pain Primary teeth, Pulpectomy.

ARTICLE HISTORY:
Received May 04,2021
Accepted June 10,2021
Published July 16,2021

DOI:
10.5455/ jcmr.2021.12.02.28

VOLUME: 12
ISSUE: 2
ISSN: 2146-8397

INTRODUCTION

International Association for the study of pain (1979) has defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"[1]. Pain has been described more than just a qualitative experience or a set of experiences, but rather considered as a conscious experience or an interpretation of the nociceptive input influenced by memories, emotional, pathological, genetic and cognitive factors [2]. The experience of pain is shaped by a host of psychological factors which has clear emotional and behavioural consequences that eventually influences the development of persistent problems and the outcome of treatment [3]. However this phenomenon of pain perception is utterly more damaging in children affecting their psychological set up and quality of life. Perception of pain in children creates fear, anxiety and undue havoc towards dental treatment resulting in perceived difficulty during behavioural management. Episodes of post-operative pain after endodontic therapy or occurrence of intra-operative pain in children has to be closely scrutinized and anticipated for effective management and developing a positive attitude towards dental treatment.

Post-endodontic pain is governed by a myriad of pre-operative and intra-operative factors and is primarily multifactorial in origin. Most importantly factors such as apical extrusion of debris, irrigants, obturating agent, intracanal medicament, insufficient root canal preparation, existence of periapical pathosis, large apical patency during instrumentation coupled with greater incidence of pre-operative pain perception eventually elevates the experience of post-operative pain [4,5]. Presence of severe pre-operative pain is likely to cause a greater incidence of moderate to severe level of post-operative pain compared to those without any or mild pre-operative pain perception prior to endodontic treatment [6-8]. However occurrence of post-operative pain can be well ascertained by the quality of obturation obtained as well as on using suitable obturating materials with high anti-bacterial, anti-inflammatory and sedative properties for faster resolution of periapical pathosis contributing to early healing of the infected zones leading to lesser or no incidence of post-operative pain.

Pulpectomy in primary teeth is generally undertaken to address diseased teeth with pulpal pathosis and inflammation or teeth indicated for pulpotomy which on clinical exploration exhibits signs of irreversible pulpitis with minimal or no resorption in roots [9]. Post-operative episodes of pain after endodontic therapy in children is inevitable as endodontic intervention in primary teeth is quite challenging and difficult to perform due to its intricate anatomical diversification such as curvature in molar roots, presence of multiple collateral/ accessory canals, narrow and ribbon-shaped architecture of root canals, complexity of apical delta, presence of physiological root resorption and possible damage to the underlying succedaneous tooth bud are some of the few intervening hurdles in performing proper instrumentation of the root canals [10,11]. Moreover endodontics in primary teeth is chemo mechanical in nature necessitating the pivotal role of copious irrigation done during root canal instrumentation rather than only emphasizing on debridement of root canals [12-18]. Hence the role of obturation, judicious selection of obturating agents used and the quality of obturation obtained is highly pivotal for overcoming the several operatory hurdles in the way of successful treatment and also in anticipating the occurrence of post-operative pain leading to its effective and timely management in children [19,20].

A wave of change revolutionizing the field of paediatric endodontics is the emergence of newer obturating materials and herbal medication which can be employed for root canal therapy in primary teeth since these materials encompasses advanced antimicrobial properties which are highly effective in eliminating the existing infection and thereby reducing the burden of elevated post-operative pain perception in children. Endoflas-FS is one such emerging obturating agent known to encompass the beneficial properties of Zinc oxide eugenol (ZOE), Iodoform and Calcium hydroxide [Ca(OH)2] which probably compensate the disadvantages of one individual material with the advantages of the other. One of the unique feature of Endoflas to be used as a root filling material in primary teeth is its pattern of resorption which is limited only to the extruded material beyond the apex and does not occur within the root canals, hence the material is neither resistant to resorption nor does it results in hollow tube effect [21]. The other desirable properties of Endoflas are its broad antibacterial efficacy, hydrophilic nature to be used in humid root canals, firmly adhering to the surface of root canal walls and disinfecting the dentinal tubules [22,26]. The above desirable properties of Endoflas thus makes it a material of choice for primary teeth obturation. Incorporation of herbal medicaments to the existing obturating agents is another important emergence with an increasing trend of use and one such tremendously useful medicinal herb is the "Turmeric". Turmeric popularly known as the "Golden Herb" is a rhizomatous herbaceous perennial plant and comprises of a volatile oil "turmerone" and other colouring agents called "curcuminoids" that consists of "curcumin demethoxycurcumin", "5'-methoxycurcumin" and "dihydrocurcumin" which are found to be the natural antioxidants [22,23]. Curcumin is a highly pleiotropic molecule that influences multiple signalling pathways and has anti-inflammatory, anti-oxidant, anti-microbial, wound healing and radiosensitizing properties [24-27]. Curcumin possesses good anti-bacterial property against a number of Gram positive and Gram negative bacteria [28] which inhibits the bacterial cell division by perturbing the cytokinetic Z-ring through a direct interaction with FtsZ [29]. Curcumin is effective against the most prevalent microbes in deep carious lesions [30] and also against the commonest root canal pathogen E. Faecalis [31-34]. Curcumin also possesses high anti-inflammatory properties and has been shown to regulate numerous transcription factors, cytokines, protein kinases, adhesion molecules, redox status and enzymes which have been linked to inflammation [35-37]. Hence any agent which possesses both anti-bacterial and anti-inflammatory actions can be considered as ideal for

developing into medicaments with a wide range of possible applications in endodontic procedures. However till date in the existing literature, only one clinical trial regarding prevalence of post-operative pain using different pulpotomy agents in pediatric dentistry have been published [38]. So far, all studies on vital pulp therapy or pulpectomy in primary teeth have evaluated the success rate of either the procedure or the capping/obturating materials [38-40] and there is no clinical investigation in pediatric dentistry which assesses post-operative pain perception following the use of various obturating agents for pulpectomy in primary molars.

Hence the present trial aims to comparatively assess the post-operative pain perception following the use of Endoflas and a novel medicament EPTG for pulpectomy in primary mandibular molars.

MATERIALS AND METHODS

Study Design and Ethical Consideration

A single-centered, double-blinded, parallel group, randomized controlled trial was designed for conducting the present trial in the department of Paediatric and Preventive Dentistry, India from September 2018 to January 2019. The trial was approved by the Institutional Scientific Review Board (SRB/MDS/PEDO/18-19/0036) and the Human Ethical Committee (SDC/MDS/18-19/093) in accordance to the standards laid down in the 1964 declaration of Helsinki and its later amendments. Prior to the start of the trial, written informed consent was obtained from the parents/accompanying guardian of the recruited participants. Each stage of the trial was performed and reported according to the CONSORT guidelines [41]. (Figure 1)

Sample size determination and recruitment of participants

A total sample of 40 participants in an age group of 4-9 years with chief complaint of pain and the tooth indicated for pulpectomy on confirmation of clinical and radiographic diagnosis were enrolled into the present trial. Prior to the main study, a pilot trial with 5 participants in each group was taken and the results obtained followed a normal distribution with a post-hoc power of 95% and the estimated sample size was ascertained to be 20 participants in each group. The intern posted recruited children with a chief complaint of night pain in primary mandibular molars indicated for pulpectomy, having atleast 2/3rd of the remaining root length with no evidence of pathological internal or external root resorption and restorable tooth structure were included while children with systemic ailments or special health care needs, lacking potential co-operative ability and those under prolonged medication, antibiotic prophylaxis or functional orthodontic treatment were excluded from the study. Computer generated randomization technique with allocation concealment using sequentially numbered, opaque sealed envelopes was performed by one of the postgraduate for random distribution of recruited participants into group I: Endoflas-FS (20/Control) and group II: EPTG (20/experimental).

Study Tool and Calibration of Participants (Parents/accompanying guardian)

WB-FPRS was used for assessment of both pre-and post-operative pain perception in children (Figure 2). It is a pictorial representation of the discomfort level experienced by children which comprises of six faces, each depicting an expression of pain perception [42,43]. The scale was thoroughly explained and each of the pictorial facial expression depicting a certain level of pain perception was made to understand both to the children and the parents/accompanying guardian. Children were then asked to subjectively rate their pre-operative pain perception into one of the either six representation of facial expression (WB-FPRS). Data pertaining to the pre-and post-operative pain assessment was obtained by another postgraduate who was not the operator and was blinded to the intervention groups.

Clinical procedure

All the clinical procedures were performed by a single trained paediatric dentist to maintain consistent uniformity in the treatment delivered to all the participants. Local anaesthesia using 2% lignocaine with 1:200,000 adrenaline (LOX* 2% ADRENALINE, Neon Laboratories Pvt. Ltd, India) was administered and on complete assessment of subjective as well as objective signs and symptoms of action of local anaesthesia, the tooth indicated for pulpectomy was isolated using rubber dam (GDC Marketing, India). Presence of intra-oral abscess and/or extra-oral swelling and/or draining fistula associated with the tooth indicated for pulpectomy procedure determined the number of sittings to be undertaken for completion of the procedure. Teeth associated with periapical pathosis were treated in two or multiple sittings in order to facilitate complete disinfection of the root canal space [44-48] while teeth free of periapical inflammation or pathosis were treated in a single-sitting visit. Under aseptic condition, a No.330 pear-shaped carbide bur (Mani, Inc, Tochigi, Japan) run in a high-speed handpiece (NSK PANA AIR PA-SU B2) was used for removal of superficial caries and gaining endodontic access to the pulpal chamber. Amputation of coronal pulp was done using a sterile spoon excavator (Hu-Friedy Mfg. Co. LLC) followed by the use of a DG 16 endodontic explorer (Hu-Friedy Mfg. Co. LLC) to locate the root canals in the dentinal map. Instrumentation of all the root canals were performed using the conventional hand K-files. The radicular pulp was removed using a 10 size K-file (Dentsply Maillefer, OK, USA). The remnants of the radicular pulp tissue was removed by copious irrigation using normal saline (Fresenius Kabi India, Pvt. Ltd). Working length determination was done using pre-operative radiographs. The working length was kept 1mm short of the radiographic apex. The hand K-files were used sequentially from No.15 size till No.35 size in a quarter turn push and pull back motion for effective biomechanical preparation. The mesial canals (narrower canals) were instrumented till No.30 size K-files while the wider distal canals were instrumented till No.35 size K-files (apical gauzing). Each K-file was used upto

five teeth in order to maintain uniform preparation in all the samples. During instrumentation, the root canals were frequently irrigated after use of each file, alternatively with 0.9% normal saline (Fresenius Kabi India, Pvt. Ltd) and 2% chlorhexidine (Asep- RC, STEDMAN PHARMACEUTICALS PVT. LTD, India.) while final rinsing was done with normal saline. Finally the prepared root canals were dried using No.15 size sterile paper points (Pearl Dent Co, Ltd., Vietnam) and obturation was performed using the test material of each group.

Obturation using Endoflas-FS (Group I/Control)

20 children recruited to group I were obturated using Endoflas-FS (SANLOR LABORATORIES, COLOMBIA, USA). The material is commercially marketed in powder and liquid (Eugenol) form. A 2:1 powder:liquid ratio was undertaken to achieve the desired medium consistency of using it as an obturating material for pulpectomy. Endoflas powder was dispensed onto the glass slab using a measuring scoop and was slowly incorporated into the liquid eugenol incrementally using an agate spatula by folding technique (manipulation method) to get the desired medium consistency. The prepared material was then carried into the dried root canals in an incremental pattern using a No.20 size hand held reamer (MANI, INC. Japan). Final compaction of the material into the root canals was achieved by compressing the material into the canals using wet cotton pellets technique.

Obturation using EPTG (Group II/Experimental)

20 children recruited to group II were obturated using a mixture of ENDOFLAS powder with CURCUMIN GEL (Curenext ORAL GEL, Abbott pharmacy, India). Curenext oral gel consists mainly of Curcuma longa extract (Rhizome) [10 mg] with gel base and is commercially available in paste form (50 gm). Both endoflas powder and turmeric gel was dispensed onto the glass slab using a measuring scoop. A 3:1 powder:gel ratio was followed to achieve a desired medium consistency by incorporating Endoflas powder into curcumin gel incrementally on a glass slab using a stainless steel spatula by folding technique [49]. The prepared material was then carried into the dried root canals in an incremental pattern using a No.20 size hand held reamer. Final compaction of the material into the root canals was achieved by compressing the material into the canals by using a wet cotton pellet technique.

On completion of obturation in each group, the access cavity was restored using type II Glass Ionomer Cement (Shofu, Shofuinc. Japan) and an immediate post-operative radiograph was obtained to assess the quality of obturation. Final coronal restoration was achieved using a preformed stainless steel metallic crown (SSC) (3M ESPE) luted with type I Glass Ionomer Cement (Shofu, Shofuinc. Japan) either in same or subsequent appointment followed by necessary treatment indicated for other teeth. All the children were prescribed a course of analgesics (Tablet Aceclofenac + Paracetamol) and were advised to continue the medication twice a day for five days despite their pain perception in order to elucidate the exact pain scores on the WB-FPRS.

Assessment of quality of obturation

Quality of obturation was done based on the modified Coll and Sadrian's criteria (1996) as underfilled, optimal filled and overfilled [50]. Two blinded paediatric dentists assessed the post-operative radiographs. Kappa statistics was performed to assess the consistency and reliability of inter-and intra-rater examination of the two blinded investigators which reported a Cronbach's alpha value of 0.76 (moderate level of agreement) between the two examiners.

Assessment of post-operative pain during one week of follow-up

Immediate post-operative pain on the day of procedure (Day 1) was assessed in all the participants using the WB-FPRS and either a printed sheet of WB-FPRS was provided or its image was shared through individual Whatsapp to all the parents/accompanying guardian for ascertaining the level of post-operative pain perception during 1 week of follow-up interval through telephonic conversation. Post-operative pain assessment was obtained by a postgraduate investigator who was not the operator and was blinded to the study groups.

Statistical analysis

Statistical analysis was performed using IBM.SPSS statistics software version 23.0. For descriptive data (i.e; age, gender, tooth type, pre-operative cause of pain, post-operative analgesics consumed, quality of obturation, pre-and post-operative pain assessment) frequency and percentage analysis was done followed by One-way ANOVA and Pearson's Chi-square test to find the level of significance between the two groups. The mean pre-and post-operative pain level during one week of follow-up interval was analyzed using Kruskal-Wallis test followed by Chi-square analysis to find the level of significance between the two groups on different post-operative days. Association of quality of obturation with post-operative pain assessment during one week of follow-up interval was also analyzed using percentage analysis and Chi-square test. A significance level of $p < 0.05$ was set for the present study.

RESULTS

A total of 40 children (21 females and 19 males) in an age group of 4-9 years with a mean age of (5.94 ± 1.026) years were enrolled into the present study. The distribution of the participants with respect to age ($p= 0.467$), gender ($p= 0.342$), distribution of tooth type ($p= 0.632$), pre-operative cause of pain ($p= 0.757$) and post-operative analgesics consumed ($p= 0.598$) showed an equal distribution of participants in both the groups thereby preventing selection bias while insignificant difference in post-operative analgesics consumed reflected no impact of analgesic consumption on the incidence of post-operative pain perception in the recruited children (Table 1).

Highest percentage of optimal fillings (12/60.0%) were found in Endoflas followed by EPTG (8/40.0%) group. Higher percentage of overfillings were found in EPTG (8/40.0%)

followed by Endoflas (3/15.0%) group while more of underfillings were found in Endoflas (5/25.0%) followed by EPTG (4/20.0%) group which showed a statistically insignificant difference (p= 0.204). (Table 2) (Figure 3)

Higher percentage of children recruited into EPTG group (30.4%) had severe pre-operative pain compared to Endoflas group (7.5%). Severe post-operative pain was experienced more in EPTG (41.7%) compared to Endoflas group (9.5%) on day 1, similarly moderate level of post-operative pain was found more in EPTG (42.0%) compared to Endoflas group (9.9%) on day 2. On day 3 moderate pain level was experienced by less number of participants with EPTG (12.2%) followed by Endoflas (7.6%) group while on day 4 moderate pain was experienced in (6.4%) of participants in Endoflas followed by (1.9%) of participants in EPTG group. On day 5 and 6 only mild post-operative pain was experienced by the participants while on day 7 none of the participants experienced any post-operative pain irrespective of the groups (Table 3).

Mean pre-operative pain score was higher in EPTG (2.75 $\pm$ .716) compared to Endoflas (2.65 $\pm$ .745) group while mean post-operative pain score was higher in EPTG compared to Endoflas group on day 1 and 2 while on day 3 and 4 higher mean post-operative score was found in Endoflas group compared to EPTG group. On day 5, 6 and 7 no significant difference was observed in the post-operative pain perception of participants in both the groups. (Table 4) (Figure 4)

On day 1 higher percentage of children with overfilling (51.7%) experienced severe pain followed by underfilled (16.6%) and optimal filled (4.6%) children. On day 2 moderate level of post-operative pain was experienced more in overfilled children (48.5%) compared to underfilled (9.7%) and optimal filled (5.1%) children. Similarly on day 3 (16.6%) of underfilled participants experienced moderate level of post-operative pain compared to optimal filled (8.5%) and underfilled (3.0%) children while on day 4 none of the participants with optimal filling experienced any post-operative pain, only (4.0%) of participants with overfilling and (1.6%) of participants with underfilling experienced only moderate level of post-operative pain. On day 5 only (9.2%) of overfilled children experienced only mild post-operative pain while none of the children with underfilling and optimal filling experienced no post-operative pain while on day 6 very few children (0.8%) with overfilling experienced mild post-operative pain. On day 7 none of the children experienced any level of post-operative pain irrespective of the groups and quality of obturation (Table 5) (Figure 5,6).

DISCUSSION

Management of post-operative pain is highly essential for efficient management of paediatric patients. Anticipation of post-operative pain on the basis of obturation quality and pre-operative history plays an important role in determining the degree of severity in occurrence of post-operative pain. The role of obturation holds high significance not only in management of post-operative pain but also seals all channels of infection which is difficult to achieve through appropriate cleaning and shaping due to the complex architecture of root canal system in primary teeth. Proper obturation of root canals therefore minimizes all potential causes of apical percolation and coronal leakage [51]. The tortuous and ribbon-shaped root canals with multiple accessory root canals in primary teeth makes mechanical debridement highly difficult to achieve complete disinfection of the root canals hence obturation of root canals with appropriate obturating agents is quintessential for obtaining successful treatment outcomes[52-54]. Therefore obturating agents with advanced anti-microbial, anti-inflammatory, biocompatible and resorbable properties are more suitable to be used in primary teeth as quality of obturating materials used plays a pivotal role in determining the prognosis of root canal treatment by eliminating infection in primary teeth [19,20]. In the present study, one of the most recent obturating material Endoflas-FS has been used due to its unique and advanced properties. One of the most important property for an obturating material to be used in primary teeth is the rate of resorption pattern which needs to be synchronous with the physiological rate of resorption of roots in primary teeth. Endoflas is known to neither resist resorption nor results in intra-radicular resorption of obturating material [55]. Hence Endoflas is highly efficacious and suitable to be used in primary teeth as an obturating material. On the other hand EPTG is one of the newer herbal based obturating material with multitude of beneficial properties. The material is known to possess excellent resorbable properties and has been found to show resorption of the extruded obturating material within a time period of 1 week [49,56]. EPTG shows a faster rate of resorption of apically extruded obturating material without causing any resorption within the root canals. EPTG is thus a promising and innovative material to be used as an obturating agent in primary teeth.

In the present study more number of optimal fillings were observed in Endoflas group compared to EPTG however more of overfilled cases were found in EPTG group than in Endoflas group. Underfilled teeth were also more in EPTG group compared to Endoflas group. Due to powder:liquid component of Endoflas, it is convenient to manipulate the material using a definite ratio into a desired consistency to be used as an obturating material, hence compaction of the material into the root canals is easier to achieve more of optimal fillings while use of Turmeric gel with Endoflas powder even though used in a definite ratio may not result in appropriate consistency to properly compact the material into the root canals and hence need to be pushed to obturate along the entire length of root canal resulting in overfilled teeth. On day 1 and 2 more number of children obturated with EPTG experienced higher severity of post-operative pain compared to children obturated with Endoflas. The probable factors responsible for such a finding is the higher number of children with pre-operative history of night pain and higher percentage of over and under filled teeth. Extruded obturating material in the periapex can serve as foreign substance and can initiate severe inflammatory reaction over the pre-existing inflammation resulting in acceleration of post-operative pain. However on day 3

prevalence of post-operative pain was more in Endoflas group compared to EPTG and the probable reason for it is mostly due to the slow resorption pattern of the extruded obturating material compared to the faster rate of resorption of EPTG and similar observation was also observed on day 4. While on day 5 and 6 both the groups showed comparatively similar findings pertaining to post-operative pain however few more children in Endoflas group experienced mild post-operative pain compared to EPTG group. On day 7 none of the children experienced any symptoms of post-operative pain irrespective of their group or quality of obturation. This finding is in accordance to the findings mentioned by Radhakrishna et al, where children after a follow-up of 1 week showed complete resolution of pre-and post-operative pain [49].

On day 1 severe level of post-operative pain was observed in overfilled children followed by underfilled and optimal filled children. One of the important factor which could be responsible for severe post-operative pain perception in underfilled children is that the hollow space in the root canals due to improper obturation can cause seepage of the periapical fluid into the root canals thereby initiating infection and accelerating the severity of post-operative pain. Similar observation was also found on day 2 while on day 3 moderate level of post-operative pain was experienced more in overfilled children followed by optimal filled and underfilled children. Optimally filled children still had a moderate level of post-operative pain on day 3 probably due to their pre-operative history of chronic periapical infection which needs a longer period of time to get alleviated and healed. On day 4 very few children experienced moderate level of pain both overfilled as well as underfilled while optimally filled children experienced no post-operative pain. On day 5 and 6 only few overfilled children experienced very mild level of post-operative pain and on day 7 none of the children experienced any degree of post-operative pain. One of the important contributing factor which can be listed to cause severe post-operative pain in children is that both Endoflas and EPTG consists of Ca(OH)2 and iodoform besides other ingredients and iodoform is known to initiate severe inflammatory reaction on apical extrusion of material [57]. However more of clinical trials with large sample size should be conducted to explore more beneficial properties of this novel medicament (EPTG) and to further substantiate and support the results of the present study.

CONCLUSIONS

Occurrence of post-operative pain in children is an important concept in paediatric dentistry and its proper management is highly essential for developing positive attitude in children towards dental treatment. Earlier anticipation of prevalence of post-operative pain in children with appropriate measures taken to manage it can eventually lead to the success of treatment. EPTG is a newer obturating agent whose further effects on primary teeth needed to be explored and can be used as an alternative obturating material in primary teeth.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest

ACKNOWLEDGEMENT

The authors thank all the participating children and their parents.

FUNDING

Nil

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Table 1: Demographic variables depicting sample size, age, gender, tooth type distribution, pre-operative cause of pain and post-operative analgesics consumed in each group with over-all p-value

Treatment Groups	**ENDOFLAS (Control group) [N = 20]**	**ENDOFLAS POWDER + TURMERIC GEL (Experimental group) [N = 20]**	**Total [N = 40]**	**Over-all p - value**
Age (Years) Mean ± Standard Deviation	5.60 ± 0.883	7.00 ± 1.124	5.94 ± 1.026	0.467
Females N(%)	9 (45.0%)	12 (60.0%)	21 (52.5%)	0.342
Males N(%)	11 (55.0%)	8 (40.0%)	19 (47.5%)	
Tooth type distribution N(%)	Tooth 74 4 (20.0%) Tooth 75 6 (30.0%) Tooth 84 7 (35.0%) Tooth 85 3 (15.0%)	Tooth 74 2 (10.0%) Tooth 75 8 (40.0%) Tooth 84 5 (25.0%) Tooth 85 5 (25.0%)	Tooth 74 6 (15.0%) Tooth 75 14 (35.0%) Tooth 84 12 (30.0%) Tooth 85 8 (20.0%)	0.632
Pre-operative cause of pain Pain on chewing N(%)	8 (25.0%)	7 (35.0%)	12 (30.0%)	0.757
Night pain N(%)	2 (25.0%)	5 (25.0%)	10 (25.0%)	
Pain on intake of hot & cold beverages N(%)	10 (50.0%)	8 (40.0%)	18 (45.0%)	
Post-operative analgesics consumed Mean ± Standard Deviation	3.10 ± 3.855	6.25 ± 2.337	5.01 ± 1.537	0.598
Total N(%)	20 (100%)	20 (100%)	40 (100%)	

Chi - square test, $p \leq 0.05$ [a]Statistically significant values

Table 2: Depicting different Quality of obturation in each group with over-all p-value

Treatment Groups / **Quality of obturation**	**ENDOFLAS (Control group) [N = 20]**	**ENDOFLAS POWDER + TURMERIC GEL (Experimental group) [N = 20]**	**Total [N = 40]**	**Over-all p - value**
Underfilling N(%)	5 (25.0%)	4 (20.0%)	9 (22.5%)	p = 0.204
Optimalfilling N(%)	12 (60.0%)	8 (40.0%)	20 (50.0%)	
Overfilling N(%)	3 (15.0%)	8 (40.0%)	11 (27.5%)	
Total N(%)	20 (100%)	20 (100%)	40 (100%)	

Table 3: Depicting percentage of pre- & post-operative pain assessment using WB-FPRS in both the groups

Pre- & post-operative pain assessment	Wong-Baker FACES Pain Rating Scale (Pain score)	ENDOFLAS (Control group) [N = 20]%	ENDOFLAS POWDER + TURMERIC GEL (Experimental group) [N = 20] %
Pre-operative pain	Mild pain	27.1%	14.3%
	Moderate pain	65.4%	55.3%
	Severe pain	07.5%	30.4%
Post-operative pain (Day 1)	Mild pain	17.7%	11.5%
	Moderate pain		
	Severe pain	72.8% 09.5%	46.8% 41.7%
Post-operative pain (Day 2)	No pain	22.8%	13.2%
	Mild pain	67.3%	44.8%
	Moderate pain	09.9%	42.0%
Post-operative pain (Day 3)	No pain	42.3%	45.3%
	Mild pain	50.1%	42.5%
	Moderate pain	07.6%	12.2%
Post-operative pain (Day 4)	No pain	50.4%	51.4%
	Mild pain	43.2%	46.7%
	Moderate pain	06.4%	1.9%
Post-operative pain (Day 5)	No pain	62.2%	65.8%
	Mild pain	37.8%	34.2%
Post-operative pain (Day 6)	No pain	89.9%	93.2%
	Mild pain	10.1%	06.8%
Post-operative pain (Day 7)	No pain	100.0%	100.0%

Table 4: Depicting mean pre- and post-operative pain level during one week follow-up period in each group with over-all p-value

Treatment Groups / Pre- and post-operative pain assessment	ENDOFLAS (Control group) [N = 20]	ENDOFLAS POWDER + TURMERIC GEL (Experimental group) [N = 20]	Over-all p-value
Pre-operative pain	2.65 ± .745	2.75 ± .716	0.659
Post-operative pain (Day 1)	2.95 ± .826	3.25 ± 1.070	0.445
Post-operative pain (Day 2)	2.25 ± .639	2.40 ± .821	0.678
Post-operative pain (Day 3)	1.80 ± .696	1.75 ± .851	0.678
Post-operative pain (Day 4)	1.45 ± .510	1.35 ± .489	0.602
Post-operative pain (Day 5)	1.20 ± .410	1.20 ± .410	1.000
Post-operative pain (Day 6)	1.00 ± .000	1.00 ± .000	1.000
Post-operative pain (Day 7)	1.00 ± .000	1.00 ± .000	1.000

Kruskal-Wallis test, Chi - square test, [b]Highly Significant at P ≤ .01, [a]Significant at 0.011 < P ≤ .050

Table 5: Depicting association between quality of obturation and post-operative pain during one week of follow-up period with over-all p-value

Quality of Obturation	Post-operative pain (Day 1)			Post-operative pain (Day 2)			Post-operative pain (Day 3)			Post-operative pain (Day 4)			Post-operative pain (Day 5)		Post-operative pain (Day 6)		Postoperative pain (Day 7)
Pain scores	Mild pain	Moderate pain	Severe pain	No pain	Mild pain	Moderate pain	No pain	Mild pain	Moderate pain	No pain	Mild pain	Moderate pain	No pain	Mild pain	No pain	Mild pain	No pain
Underfilling	47.8%	35.6%	16.6%	62.3 %	28.0 %	9.7%	78.1%	18.9%	3.0%	93.2 %	5.2%	1.6%	100. 0%	0.0%	100. 0%	0.0%	100.0%
Optimalfilling	52.1%	43.3%	4.6%	71.1 %	23.8 %	5.1%	82.9%	8.6%	8.5%	95.3 %	4.7%	0.0%	100. 0%	0.0%	100. 0%	0.0%	100.0%
Overfilling	09.7%	38.6%	51.7%	10.7 %	40.8 %	48.5%	44.6%	38.8%	16.6%	46.1 %	49.9 %	4.0%	90.8 %	9.2%	99.2 %	0.8%	100.0%
Over-all p - value	*0.023**			*0.027**			*0.034**			*0.021**			*0.532*		*0.735*		*1.000*

*Chi – square test, $p \leq 0.05$ *Statistically significant values*

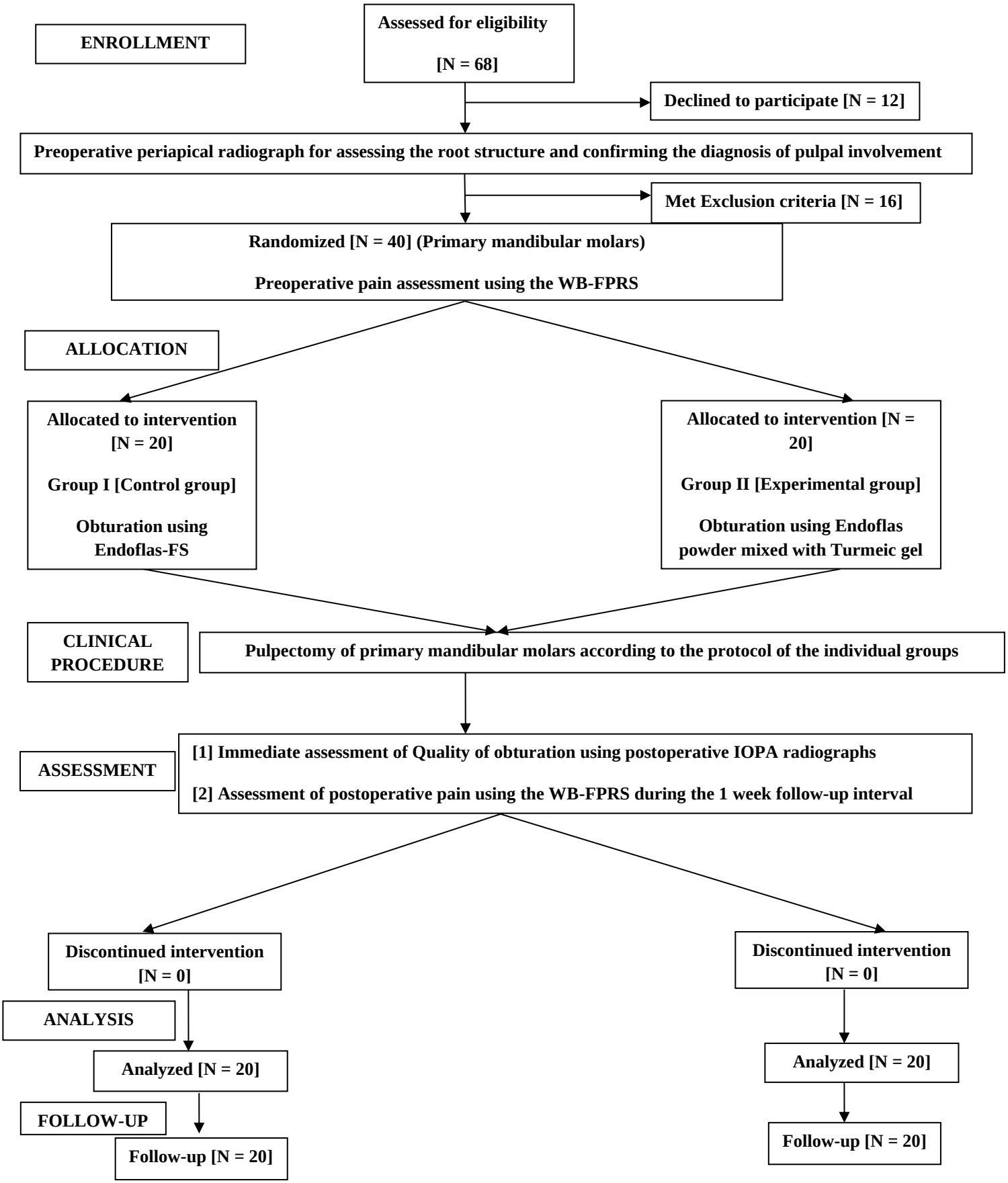

Fig.1: CONSORT flowchart depicting the different stages followed during the double-blinded randomized controlled trial

Fig.2: Depicting Wong-Baker Faces Pain Rating Scale used for pre- & post-operative pain assessment.

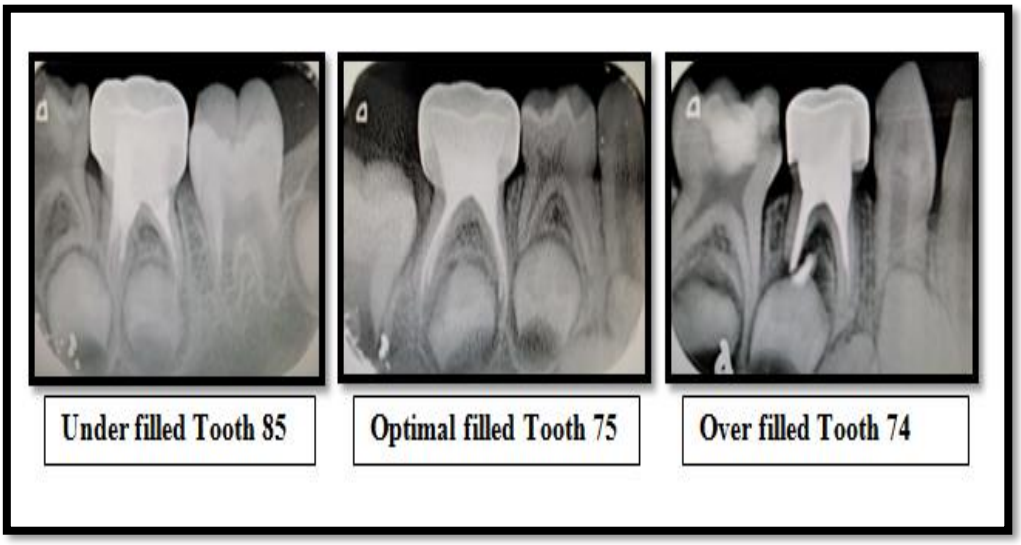

Fig.3: Immediate post-operative IOPA radiograph depicting different levels of quality of obturation according to Coll and Sadrian criteria (1996). [A] Underfilling [B] Optimal filling [C] Overfilling

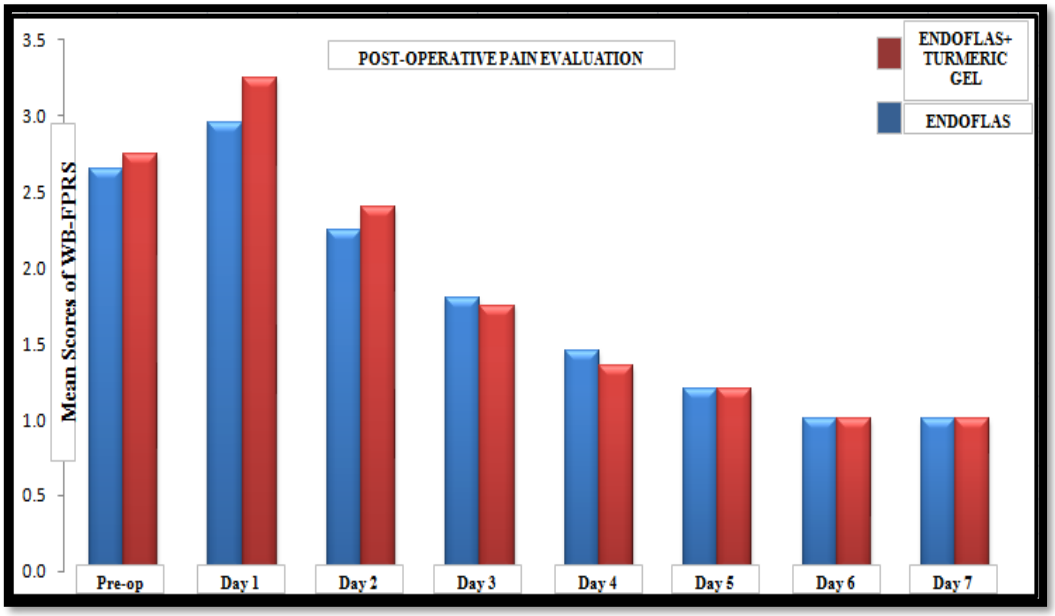

Fig.4: Depicting post-operative pain evaluation using WB-FPRS in both the groups after 1 week follow-up

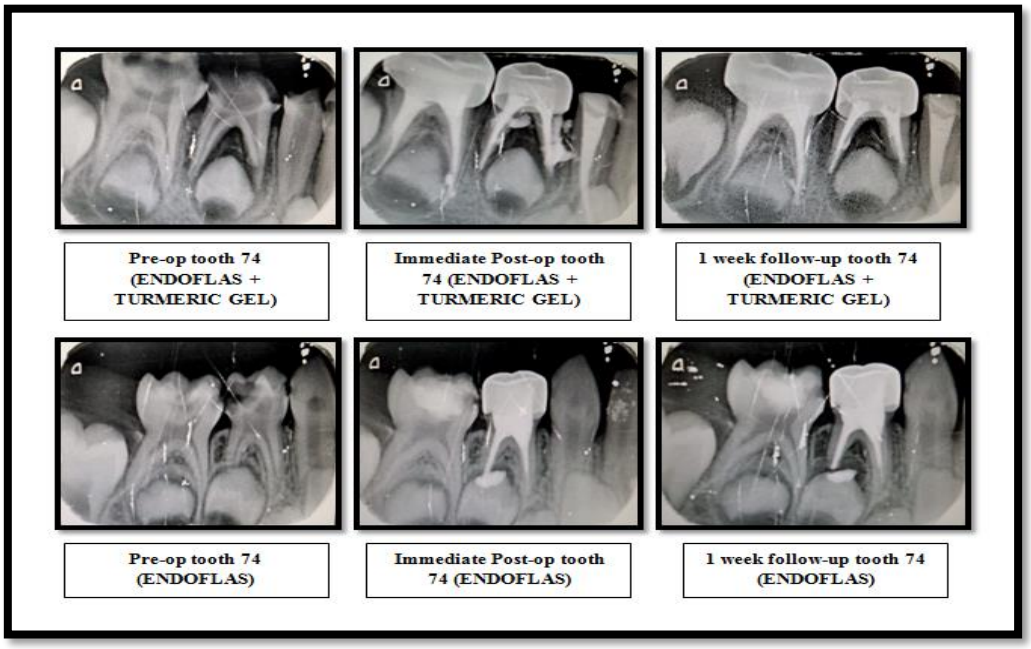

Fig.5: Depicting resorption pattern of obturating material (Endoflas, Endoflas Powder + Turmeric gel) in both the groups after 1 week follow-up

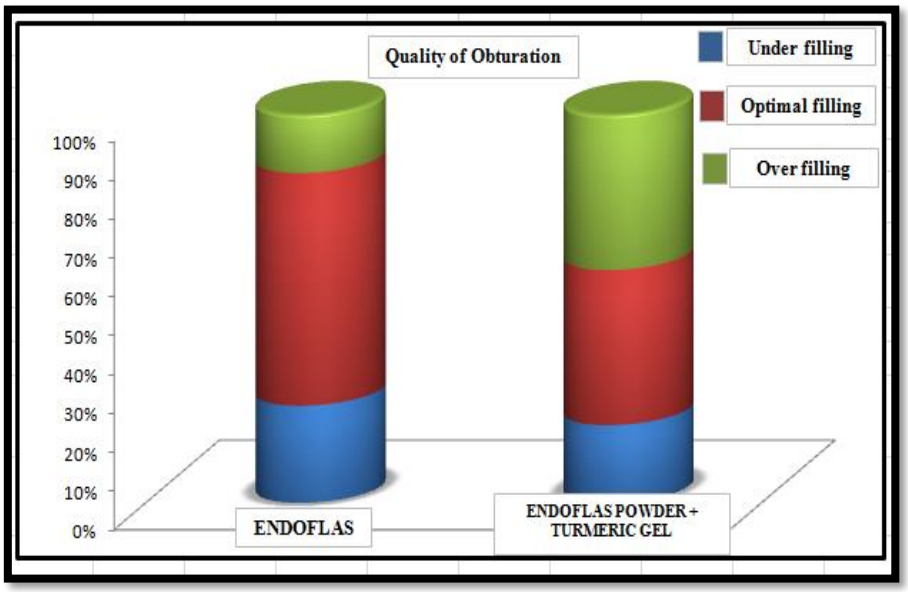

Fig.6: Depicting percentage of quality of obturation in both the groups after 1 week of follow-up