

# Pain Relief Effects and Safety of Transitional Therapy in the Treatment of Posterior Teeth of Pregnant Women with Symptomatic Irreversible Pulpitis and Symptomatic Apical Periodontitis

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**Purpose:** To assess the pain relief effects and safety of transitional therapy (TT) in the treatment of posterior teeth of pregnant women with symptomatic irreversible pulpitis and symptomatic apical periodontitis.

**Methods:** A prospective cohort clinical study was conducted in the Department of Stomatology at Shenzhen Maternity & Child Healthcare Hospital, China, from January 2017 to December 2019. We enrolled 62 pregnant women with acute dental pain caused by posterior teeth with symptomatic irreversible pulpitis or symptomatic apical periodontitis. Among the 62 participants, 34 received TT, and 28 chose nontreatment during pregnancy. We evaluated the pain relief with the verbal numerical rating scale (VNRS) scores of pain perception in the clinical study, as well as the anti-bacterial medicament filling conditions of canals of in vitro models. Moreover, we investigated the safety outcomes, such as gestational age, neonatal head circumference, birth weight, and body length.

**Results:** The VNRS scores of the participants treated with TT were significantly lower than those of the nontreatment group 2 days after treatment ( $P<0.001$ ). TT treated pregnant women experienced significantly more pain decreases in VNRS scores than their counterparts ( $P<0.05$ ). The optimal anti-bacterial medicament filling conditions of canals of in vitro models by TT method were comparable with those of canals instrumented with traditional RCT method. Moreover, no significant differences of safety outcomes were observed between pregnant women of these two groups.

**Conclusion:** The transitional therapy is efficient in alleviating acute dental pain of posterior teeth of pregnant women with symptomatic irreversible pulpitis and symptomatic apical periodontitis, and maintaining painless chains throughout pregnancy with no adverse effects on neonatal birth outcomes.

**Keywords:** symptomatic irreversible pulpitis, symptomatic apical periodontitis, transitional therapy, root canal infection, pregnancy, neonatal outcome

## Plain Language Summary

With greatly simplified the procedure of endodontic treatments, TT successfully relieved pregnant women from acute pain with symptomatic irreversible pulpitis and symptomatic apical periodontitis and maintain them painless throughout pregnancy. The method could safely and efficiently decrease the pain levels of pregnant women without adverse effects on neonatal birth outcomes.

## Introduction

Acute dental pain may be one of the worst types of suffering experienced by women during pregnancy. It directly affects the emotional status, general health and well-being of mothers-to-be, which may have a substantial impact on the status of her fetus.<sup>1</sup> Over half of pregnant women have been reported of experience of dental pain during pregnancy.<sup>2-4</sup> Symptomatic irreversible pulpitis and symptomatic apical periodontitis, as a sequel to microorganism infection of the dental pulp, cause acute dental pain and have been suggested to be associated with adverse pregnancy outcomes

(APOs).<sup>5,6</sup> Thus, the relief of acute dental pain at any time during pregnancy is imperative.<sup>7</sup> The suggested treatment approach for relieving dental pain involves complete chemomechanical disinfection of the root canal system which is known as traditional root canal therapy (RCT), and systemic or local antibiotic treatment.<sup>8</sup> However, RCT is not widely applied in pregnant women due to time-consuming, and complicated procedures with long-term chair side, and safety concerns on X-ray radiation.<sup>9–11</sup> Adjustments are required to arrange the timing and types of endodontic treatment in pregnant women, especially for posterior teeth.<sup>12–14</sup> With chemical disinfection, we mechanically instrumented a preflaring and dredging glide for antibacterial medication to reach the apex location without complete root canal preparation, a method known as transitional therapy (TT), which has been developed to effectively alleviate acute pain due to pulpal or periapical infections. This method was designed to eliminate bacteria from the root canal system without complete preparation and maintain a constant concentration of antibacterial medicament in canals throughout the pregnancy period to prevent reinfection.

With the simplified method, we successfully treated pregnant women who suffered from acute dental pain caused by symptomatic irreversible pulpitis and symptomatic irreversible apical periodontitis without adverse effects. It deserves to be evaluated with a well-designed protocol to certify its pain relief effects and safety. In this study, we assessed pain relief with both objective and subjective indicators. The subjective indicator is pain perception and pain decrease measured by the verbal numerical rating scale (VNRS) score. The objective indicator is the filling condition of antibacterial medicament of root canals, which is used to indicate the state of maintaining painlessness. As we know, the filling condition is closely related with postoperative pain after endodontic treatment. Due to lack of X-ray data *in vivo*, we designed an *in-vitro* canal model with resin blocks to observe the anti-bacterial medicament filling condition.

In this study, we aimed to investigate the pain relief effects and safety of TT in the treatment of posterior teeth of pregnant women with symptomatic irreversible pulpitis and symptomatic apical periodontitis. We hypothesized that TT was a suitable method to alleviate acute pain in posterior teeth with symptomatic irreversible pulpitis and symptomatic apical periodontitis and made it possible to maintain a painless state throughout of pregnancy period.

## Methods

### Participants

Seventy-two pregnant women who came to the dental clinic between 2017 and 2019 in Shenzhen Maternity and Child Health Care Hospital (SMCHH) because of acute dental pain in posterior teeth with symptomatic irreversible pulpitis and symptomatic apical periodontitis were considered. Diagnoses were based on the recommendations of the American Board of Endodontics.<sup>15</sup> Diagnoses will be reaffirmed by an expert in endodontology. All of them were informed about the details of the study and agreed to sign on the informed written consent.

All participants were asked to describe their level of pain using a VNRS initially and 2 days postoperatively.<sup>16</sup> We contacted these participants by phone and excluded those who did not meet the following inclusion criteria for the study: women who eventually had no pregnancy outcome data and those who were not prepared to provide information about the delivery outcome. Ultimately, 62 pregnant women met the inclusion criteria i) with acute local dental pain such as spontaneous pain and/or pain on percussion and palpation; ii) with clinically diagnosis of symptomatic irreversible pulpitis and symptomatic apical periodontitis in posterior teeth; iii) accepting a phone call 2 days after the initial interview and a new appointment in 2 weeks; iv) availability of information of neonatal birth outcomes; v) currently no medical history of taking antibiotics or analgesics; and vi) self-reported systemically healthy prior to pregnancy (eg, fetal congenital aneuploidy or anomaly chronic inflammatory diseases, congenital genetic diseases, metabolic disorders).

### Dental Treatment

Thirty-four pregnant patients were treated with TT, while 28 pregnant patients selected postnatal treatment. Regarding the first visit, most of the patients presented as emergency cases. We removed all the decayed lesions and accessed the pulp cavity with a rubber dam under local anesthesia. The orifices of all the root canals were exposed, and the pulp was disinfected with 3% buffered sodium hypochlorite (NaOCl). Canals were dredged with manual hand file #10 and PathFile files and then instrumented with ProTaper Universal Sx file and irrigated with 0.5% NaOCl solutions (Dakin's Solution

and 15% ethylenediaminetetraacetic acid (EDTA) solution (Apotek Produktion&Laboratorier AB, Sweden)). The canals were then filled with  $\text{Ca}(\text{OH})_2$  paste. We phoned all the subjects 2 days after the initial interview and asked each subject to describe her level of pain using a VNRS. For the second time, we normally removed all  $\text{Ca}(\text{OH})_2$  with a #10 K file and carefully introduced Vitapex paste into the root canal. The cavity was then filled with glass ionomer if the subject showed no discomfort.

## Pain Assessment

All participants were asked to describe their levels of pain using a VNRS sheet consisting of a line from 0 to 10, which was anchored by two extremes “No pain” and “the worst pain”.<sup>17</sup> Pain levels were assigned into four categorical groups: 0, no pain; 1–3 mild pain; 4–6, moderate pain; 7–10, severe pain. The VNRS scores were recorded in a database with appropriate validation procedures.

## Filling Conditions of Canals of in vitro Models

Twenty severely curved simulated canals in resin blocks (Endo Training Block-L, Dentsply Maillefer; taper = 0.02, apical diameter = 0.15, length = 16.5 mm, angle and radius of curvature = 60° and 4.5 mm) were prepared. The working length (WL) was determined to be 1.0 mm short of the apical foramen. After sealing the apical foramen using a small piece of wax, the resin blocks (n = 10 per group) were divided into two groups. In Group A, canals were processed with a simulation treatment called TT. Canals were dredged with PathFile (#13, #17, #19, Dentsply Maillefer, Ballaigues, Switzerland) and preflared with the Sx file of ProTaper Universal (Dentsply Maillefer, Ballaigues, Switzerland). In Group B, canals were dredged with PathFile and instrumented with the ProTaper Universal file (S1, Sx, S2, F1, F2). The procedures were performed by a single operator. Canals were instrumented under constant irrigation/aspiration with distilled water. After root canal preparation, paper tips were used to wipe up waters in canals. Vitapex was carefully introduced to the root canal until 3 mm prior to the WL, and then a postoperative radiograph was taken to determine the extent of filling material in the canals. All areas of voids or failure in the filling were individually measured by the same dentist. The quality of the root canal filling was as follows: underfilling, defined as canals filled more than 2 mm short of the apex; optimal filling, defined as canals having paste ending at the radiographic apex or up to 2 mm short of the apex; and overfilling, defined as any canal showing paste outside the root.<sup>18</sup>

## Safety Outcomes

The neonatal outcomes were recorded via a medical record query system, which included gestational age, birth height, head circumference, and birth weight. For those who delivered outside our hospital, we obtained information by phone.

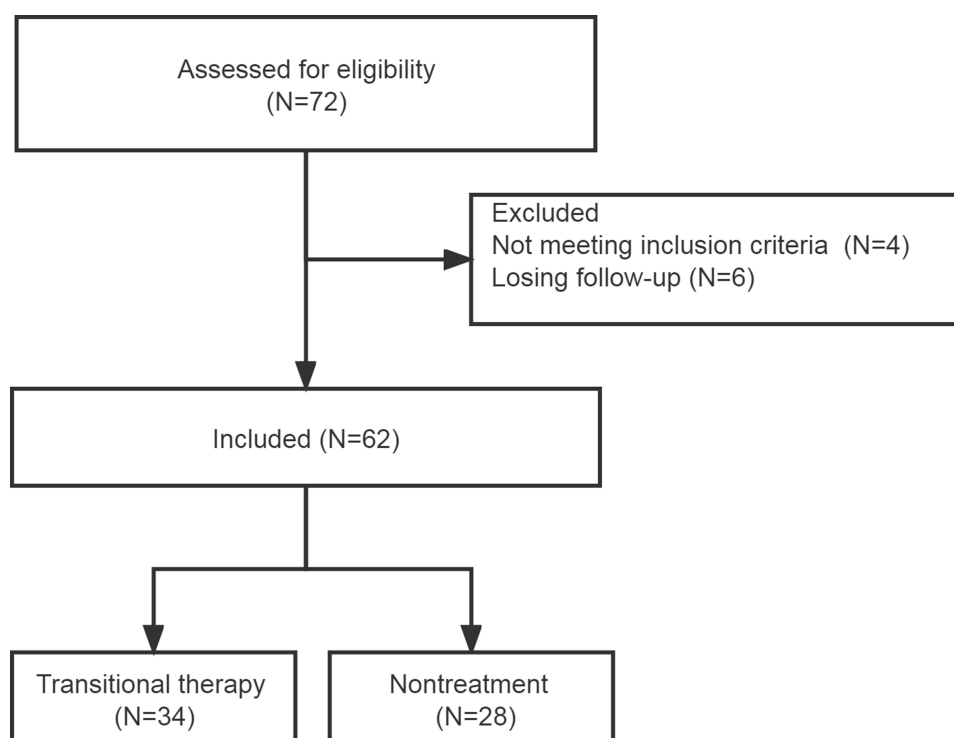
## Statistical Analysis

We compared demographic variables including age, gestational age, and diagnosis, by using *t* test or  $\chi^2$  test when appropriate. Regarding the outcome variables, for continuous data that were distributed normally, we compared them by using a *t* test. For nonnormally distributed continuous data, nonparametric tests and Mann–Whitney tests were used. We analyzed the filling conditions using the  $\chi^2$  test adjusted by Bonferroni statistical methods. We performed statistical calculations by using software (SPSS, IBM, or Epi Info, Centers for Disease Control and Prevention). Differences were considered significant when the *P* value was less than 0.05.

## Results

### Demographic Analysis

Figure 1 shows the participant recruitment process. Out of 62 participants, 20.96% of pregnant women were below 13 weeks of gestation age, 33.87% were between 13 and 21 weeks of gestation age, and 46.77% were above 21 weeks of gestation age, as shown in Table 1. A total of 69.35% of subjects were diagnosed with symptomatic irreversible pulpitis, while 30.6% were diagnosed with necrotic pulp with symptomatic apical periodontitis. There was no significant difference between the transitional group and the nontreatment group in terms of gestational age or diagnosis status.



**Figure 1** Flow chart of the 62 subjects included in the study.

The average age was  $28 \pm 3.50$  years in the transitional group; for the nontreatment group, the average age was  $29.75 \pm 3.12$  years. There was little significance between these two groups. X-ray radiation was refused by participants or their family members. None of the subjects received analgesics or antibiotics.

## Pain Perception and Pain Decrease

We followed-up with all subjects by phone 2 days after the initial visit, and their VNRS was recorded. The median preoperative VNRS was 5.5 in the transitional group and 6.0 in the nontreatment group. There were no significant differences between these two groups at the first visit ( $P=0.051$ ). Two days later, the median VNRS dropped to 0.5 in the transitional group, and the median

**Table 1** Demographic Analysis of Pregnant Women Treated with Transitional Therapy or Nontreatment

Variables	Transitional Therapy (N=34)	Nontreatment (N=28)	P-value
Age (years)	$28.0 \pm 3.5$	$29.7 \pm 3.15$	0.044
Gestational age, N (%)			0.283
<13 weeks	9 (7.5)	3 (25.0)	
13–21 weeks	11 (52.4)	10 (47.6)	
>21 weeks	14 (48.3)	15 (51.7)	
Diagnosis, N (%)			0.060
Symptomatic irreversible pulpitis	27 (62.8)	16 (37.2)	
Symptomatic Apical periodontitis	7 (36.8)	12 (63.2)	

**Notes:** Data are presented as N (%) or  $X \pm SD$ . Differences were compared between groups using t tests or  $X^2$  tests.

VNRS dropped to 3.0 in the nontreatment group. The VNRS scores of the subjects treated with TT were significantly lower than those of the nontreatment group ( $P<0.001$ , Table 2). We also compared the preoperative and postoperative VNRS scores and found a significant pain decrease in VNRS scores in the transitional group ( $P<0.05$ ).

## Filling Condition of Canals of in vitro-Models

As shown in Table 3, there was no significant difference in the optimal filling conditions between Group A and Group B ( $P=0.031$ ). There was a significantly higher percentage of over filling conditions of canals in Group B than that in Group A. There was also a higher percentage of underfilling conditions in Group A compared with Group B.

## Safety Outcomes

Twelve women did not deliver their babies at SMCHH, so we phoned them to obtain such information including delivery gestational age, neonatal birth weight, and major abnormalities. As shown in Table 4, there was no difference between

**Table 2** VNRS Analysis of the Transitional Therapy Group versus the Nontreatment Group

Variables	Transitional Therapy (N=34)	Nontreatment (N=28)	P-value
VNRS, median (IQR)			
Preoperative	5.5 (4.0, 6.3)	6.0 (5.0, 7.0)	0.051
2 days after first visit	0.5 (0, 2.0)	3.0 (2.3, 3.0)	<0.001
Pre/post VNRS difference, (X±SD)	4.6±2.0	3.5±1.7	0.023

**Note:** Data are presented as the median (IQR) or X±SD, and differences were compared between groups using nonparametric Mann–Whitney U-tests or t tests.

**Table 3** Analysis of Preparation Time and Filling Conditions of Simulated Canals in Resin Blocks

Variables	Group A	Group B	P-value
Filling, N (%)			0.031
Optimal filling	4 (40) <sup>a</sup>	3 (30) <sup>a</sup>	
Underfilling	4 (40) <sup>a</sup>	0 (0) <sup>b</sup>	
Overfilling	2 (20) <sup>a</sup>	7 (70) <sup>b</sup>	

**Notes:** <sup>a,b</sup>Represents subsets of group categories. There is no significant difference in the proportion of columns among these categories at the 0.05 level.

**Table 4** Comparison of Variables for Neonatal Birth Outcomes Between the Transitional Therapy and Nontreatment Groups

Variables	Transitional Therapy (N=34)	Nontreatment (N=28)	P-value
Gestational age	39.0 (38.0, 40.0)	39.4 (38.5, 40.0)	0.373
Birth weight	3320.0±383.0	3203.0±435.0	0.263
Body length	50.0 (50.0, 51.0)	50.0 (50.0, 52.3)	0.585
Head circumference	35.0 (33.3, 36.8)	35.0 (34.0, 36.0)	0.913

**Note:** Data are presented as the median (IQR) or X±SD, and differences were analyzed between groups using nonparametric Mann–Whitney U-tests or t tests.

the two groups in terms of delivery gestational age, neonatal birth weight, body length or head circumference. No babies were born with an abnormality, and only one baby was born prematurely.

## Discussion

In this study, transitional therapy was found to be a valuable method that can alleviate the acute pain of pregnant patients suffering from symptomatic irreversible pulpitis and symptomatic apical periodontitis. The patients' pain levels significantly decreased after receiving the TT intervention in 2 days. Notably, a greater decrease in the level of pain was reported in patients in the TT group relative to those in the nontreatment group. There was no significant difference in the variables of neonatal characteristics between the pregnant women treated with TT and those who chose postnatal treatment.

To achieve optimal outcomes after endodontic procedures, the bacterial populations within the root canal should be eliminated or at least decreased to levels compatible with host defense. A balance between microbial aggression and host defense should be established to impede the spread of the infection.<sup>19</sup> In this study, the TT method, which consisted of chemical disinfection and mechanical instrumentation, successfully reduced the load of the microbial population. Moreover, the use of Vitapex inside the canals successfully provided a long-lasting antibacterial environment to heal the periodontal lesions or prevent further infection. No recurrence of infection during the period of pregnancy was observed after TT.

Similar to our study, Wolf et al successfully alleviated moderate or severe pain ( $\text{VNRS} \geq 4$ ) in patients suffering from symptomatic apical periodontitis and presented a cost-effective emergency treatment alternative. There was no significant difference in the level of pain relief between patients treated via removal of necrotic tissue from the pulp chamber (RNT) and those treated with complete chemomechanical disinfection (CMD).<sup>8</sup>

Root canal treatment (RCT) is clearly efficient in relieving dental pain caused by endodontic infection, but it may carry a risk of interappointment flare-up. Interappointment flare-up due to an acute inflammatory reaction may aggravate the pain severity due to mechanical, chemical and/or microbial injury to the pulp or periradicular tissues during RCT procedures.<sup>20</sup> The glide path with NiTi rotary PahtFile leads to less postoperative pain and faster symptom resolution.<sup>23</sup> PathFile systems are good at creating a glide path and decreasing the risk of posterior iatrogenic errors. For the transitional method, we used rubber dams to isolate the infected teeth and local anesthesia to relieve the symptoms and possible pain brought by the dental procedure. Preflaring of the canals with chemical disinfection greatly decreased the bacterial organisms to a susceptible level, which greatly reduced the symptoms of a clinically acceptable grade.

Regarding the safety of dental treatment, Michalowicz and colleagues<sup>16,20</sup> reported pregnancy outcomes for 351 women who received dental and periodontal treatment during pregnancy. The study authors concluded that there is no association between essential dental treatment and an increased risk of experiencing serious medical adverse events or adverse pregnancy outcomes. The study by Aharon Hagai et al,<sup>21</sup> in which 210 pregnancies were included, showed that dental treatment during pregnancy does not represent a major teratogenic risk. Due to the limited number of subjects, our study failed to provide solid evidence for serious adverse pregnancy outcomes, such as fetal/congenital anomalies.

There are some limitations in the study. First, it is not a randomized control trial and therefore it has a selection bias of participants. Variables were collected to calibrate the bias including gestational age, age and diagnosis and little significant difference existed between the two groups. Second, the subjects were recruited from a single female hospital, and a more representative large sample could have been randomly selected from multiple health-care centers in the region.

According to studies on the barriers to delivering dental care to pregnant women, dentists' perceived barriers include the time spent serving pregnant women for less compensation and increased liability.<sup>10,22,23</sup> Pregnant women are also faced with the difficult decision of whether to receive treatment to alleviate acute pain or postpone treatment due to the fear of possible risk. TT provides a short-term way to decrease aggravation due to infection, and it has the potential to be incorporated into emergent treatment options. Establishing a healthy oral environment and maintaining optimal oral hygiene levels are primary objectives for the health of pregnant women and their fetuses. Dental clinicians and faculty



members need to improve their knowledge of effective interventions and dental treatment guidelines to improve the dental care of pregnant women.

## Conclusions

The transitional therapy leads to decreased pain levels in 2 days and maintenance of the painless chain throughout pregnancy with no adverse effects on neonatal birth outcomes. This study suggested that transitional therapy would be a valuable method specific to treating the posterior teeth of pregnant women with symptomatic irreversible pulpitis or symptomatic apical periodontitis.

## Ethics Approval

The study followed all guidelines for ethics in research and abided by the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of Shenzhen Maternity & Child Healthcare Hospital (LLYJ2021-088-051).

## Author Contributions

All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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## Disclosure

The authors report no conflicts of interest in this work.

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