Clinical Oral Investigations (2021) 25:3067–3076
https://doi.org/10.1007/s00784-020-03627-4

ORIGINAL ARTICLE

Comparison of indirect pulp treatment and iRoot BP Plus pulpotomy in primary teeth with extremely deep caries: a prospective randomized trial

Xiaoxian Chen[1] · Hongmei Zhang[1] · Jie Zhong[1] · Wenjuan Yan[1] · Bichen Lin[1] · Meili Ding[1] · Shihua Xue[1] · Bin Xia[2]

Received: 2 August 2020 / Accepted: 7 October 2020 / Published online: 15 October 2020

Abstract

Objectives The purpose of this randomized controlled trial was to compare the 24-month success rates of indirect pulp treatment (IPT) and iRoot BP Plus pulpotomy of primary molars with extremely deep caries.

Materials and methods Generally healthy children aged 3–7 years requiring general anesthesia for treating primary molars with extremely deep caries or reversible pulpitis were recruited. Patients with systemic disease, mental health problems, or manifestations of irreversible pulpitis were excluded. In total, 175 molars were randomized and blinded for either IPT (n = 87) or iRoot BP Plus pulpotomy (n = 88). All teeth were restored with stainless steel crowns and evaluated after 6, 12, 18, and 24 months by two blinded calibrated investigators. Kaplan-Meier survival curves were used to compare the survival rates between the groups. The correlations between success rate and patient characteristics were explored with the Cox proportional hazards model.

Results A total of 168 primary molars in 67 patients (average age: 3.83 years) were evaluated. The cumulative survival probability at 24 months was not significantly different between the IPT (93.8%) and pulpotomy (97.7%) groups (P = 0.238). IPT treatment success was significantly associated with age (odds ratio = 2.347; 95% CI: 1.068–5.156; P = 0.034) and preoperative sensitivity (odds ratio = 9.742; 95% CI: 1.079–87.970; P = 0.043).

Conclusions The 24-month success rates of IPT and iRoot BP Plus pulpotomy performed in primary molars with extremely deep caries were not significantly different. Increasing age and preoperative sensitivity were found to be associated with the cumulative survival probability in IPT-treated primary molars with extremely deep caries. Primary teeth with extremely deep carious lesions without signs of irreversible pulpitis can be treated successfully by either indirect pulp capping or iRoot BP Plus pulpotomy.

Trial registration ChiCTR2000032462

Keywords Indirect pulp treatment · Primary teeth · Pulpotomy · Reversible pulpitis · Vital pulp therapy

✉ Bin Xia
summerinbeijing@vip.sina.com

Xiaoxian Chen
chenxiaox2007@126.com

Hongmei Zhang
2804358@qq.com

Jie Zhong
77704994@qq.com

Wenjuan Yan
yanwenjuan85@163.com

Bichen Lin
stephanlin@bjmu.edu.cn

Meili Ding
bluesky408210@163.com

Shihua Xue
shihuax@163.com

[1] Department of Pediatric Dentistry, First Clinical Division, Peking University School and Hospital of Stomatology, Jia No.37 Xishiku Street, Xicheng District, Beijing 100034, China

[2] Department of Pediatric Dentistry, Peking University School and Hospital of Stomatology, Zhongguancun South Avenue 22, Haidian District, Beijing 100081, China

Introduction

Vital pulp therapy is generally the preferred treatment option for deep dentinal caries in primary teeth, provided the diagnosis of a normal pulp or reversible pulpitis is based on clinical and radiographic evaluations [1]. Indirect pulp treatment (IPT) leaves caries over the pulp and covers it with biocompatible material to stimulate the pulp-dentin complex and produce reparative dentin, thus avoiding pulp exposure, while a pulpotomy removes the infected coronal pulp, leaving the radicular pulp exposed before medicament treatment. The advantages of vital pulp therapy include preservation of the vitality and function of the pulp until exfoliation of the primary teeth [2].

According to the definitions approved by the European Society of Endodontology, deep caries is defined as caries reaching the inner quarter of dentine. In cases of deep caries, there is still a zone of hard or firm dentine between the caries and the pulp, while extremely deep caries penetrates the entire thickness of the dentine, which is radiographically detectable when located on an interproximal or occlusal surface. During operative treatment, there is a risk of pulp exposure in cases of deep caries, which is unavoidable in cases of extremely deep caries [1–4].

In cases of extremely deep caries [1], it is necessary for the clinicians to decide before the operation whether to keep the soft substance at the bottom of the cavity and perform IPT based on the principles of minimally invasive dentistry or to remove all the caries and then carry out the pulpotomy. Once the decision of IPT is made, the caries substance will not be removed completely. The American Academy of Pediatric Dentistry (AAPD) pointed out that IPT is performed in teeth with deep carious lesions approximating the pulp without pulp degeneration [2]. Thus, for extremely deep caries, IPT is indicated in the case of a treated tooth with no pulpitis or with reversible pulpitis. A number of studies have investigated the success rates of IPT and pulpotomy [3, 5–8]; however, these studies were not randomized controlled trials, and they seldom considered the clinical evaluation of IPT or pulpotomy applied in extremely deep caries [4]. The clinical practice guidelines of AAPD highlight the current lack of clinical trials that directly compare IPT and pulpotomy in vital primary teeth with deep carious lesions [2].

Only a few studies have directly compared IPT and pulpotomy, and all of them have been retrospective studies. These studies revealed that IPT success was significantly higher than that of formocresol (FC) pulpotomy (94% vs. 70%) at 3.4 years of follow-up [9, 10] and ferric sulfate pulpotomy at the 48-month follow-up (93.0% vs. 70.4%) [11]. Earlier exfoliation was observed after treatment with FC pulpotomy or ferric sulfate pulpotomy compared with IPT [9, 11].

Meanwhile, concerns have been raised over the application of FC in humans, and alternative materials with better biocompatibility, such as mineral trioxide aggregate (MTA), are the preferred pulpotomy agents [12]. Clinical trials showed that MTA performed better than FC [13–15] or ferric sulfate [16]. IRoot BP Plus (Innovative Bioceramix Inc., Vancouver, Canada) is a more recent bioceramic material that has shown similar favorable results with MTA in dog incisors [17]. Calcium hydroxide has also shown good results in human permanent incisors [18] when used as pulp-capping agent. However, no clinical trial has assessed the effect of iRoot BP Plus in primary teeth pulpotomy.

Considering the drawbacks of calcium hydroxide, such as the high solubility[19], lower strength of calcium hydroxide [20] and insufficient adherence to dentinal walls, multiple tunnel defects in the induced dentin bridges [21], resin-modified glass ionomer (RMGI) IPT was used in the control group. The antibacterial properties of RMGI liners were reported superior to calcium hydroxide [22]. RMGI liners are noted for minimizing post-operative sensitivity in restorations, better strength, fluoride release, and excellent sealing ability[23] and RMGI is the most commonly used material for IPT with high clinical success [3, 24, 25].

This randomized controlled trial aimed to compare the clinical and radiographic success rates of RMGI IPT and iRoot BP Plus pulpotomy in vital primary molars with extremely deep caries, over a 24-month period.

Materials and methods

Subjects

This study utilized a parallel-group, randomized controlled design, and enrolled patients who visited the Department of Pediatric Dentistry, First Clinical Division, Peking University School and Hospital of Stomatology, Peking, China, in the period of 2017–2020. The study protocol was approved by the Peking University School and Hospital of Stomatology Ethical Committee (PKUSSIRB-201840190), and registered at the Chinese Clinical Trial Registry (ChiCTR2000032462). All procedures were conducted in accordance with the ethical standards of the relevant national and institutional committees on human experimentation with the Helsinki Declaration of 1975, as revised in 2008. The parents or legal guardians provided written informed consent.

Using a list of pains, a detailed pain history of every included molar was obtained from the children, and confirmed by their parents. The items measured the history and frequency of tooth pain, sensitivity during eating or brushing, response to extremely cold or hot temperatures, pain due to food impaction, spontaneous pain, pain on chewing, night pain, and use of analgesics. Preoperative sensitivity was defined as a

transient pain triggered by tooth brushing or eating sweet, sour, cold, or hot foods, with the pain disappearing within seconds after removal of the stimulus; without spontaneous pain. The preoperative radiographs were apical radiographs (first choice) or panoramic radiographs (only for uncooperative children). Inclusion and exclusion criteria are presented in Table 1

The sample size calculation was based on two independent sample rates and was performed using the PASS software (NCSS, LLC. Kaysville, UT). According to the success rate of similar materials reported in the literature, the 2-year success rates of RMGI IPT and ProROOT MTA pulpotomy have been previously reported to be 83.3% and 98%, respectively [26, 27]. To account for a desired accuracy of 20%, a significance level of 5%, and a safety margin of 15% to compensate for patient dropouts and changes in treatment interventions, a minimum sample size of 67 teeth in each group was required.

Treatment

Two pediatric dentists screened each patient for inclusion and exclusion criteria during a preoperative oral examination. In the case of disagreement, a consensus was reached through discussion. The kappa value for inter-examiner agreement was 0.75. A computer generated a randomization sequence. Simple randomization (with sealed envelopes) of the included teeth in the treatment groups was performed immediately after patient enrollment. For randomization, in patients with more than one molar included in the study, the sequence employed was as follows: upper-right, upper-left, lower-left, and lower-right. The patients and their parents/guardians, pediatric dentists performing the screening and enrollment procedures, outcome assessors, and anesthesiologists were all blinded to group allocation.

General anesthesia (GA) was conducted in accordance with an established protocol [28]. Three operators, with different educational qualifications (doctoral or master's graduate) and years of experience in clinical pediatric care, performed the operative treatments in this study. Prior to the commencement of the study, the clinical operator was trained to ensure standardization of pulp evaluation and all operative procedures. All operators were calibrated using in vitro teeth with deep caries; this involved selective caries removal in the IPT group, and the bleeding control and pulpotomy procedures including the condensation of a novel bioceramic endodontic material iRoot BP Plus into a pulp chamber in the pulpotomy group, according to the manufacturer's instructions. Intraoral local anesthesia was administered, and a rubber dam was applied during all vital pulp procedures.

The IPT procedure involved the selective removal of soft dentine; peripheral carious enamel and dentine were removed using a large round carbide bur until the hard dentine was reached. A hand excavator was used, and light pressure was applied on the pulp chamber floor to remove the soft dentine so as to avoid pulp exposure and further injury, especially near the pulp cavity (whose location was determined by a radiographic assessment). A layer of resin-modified glass ionomer (Lime-Lite Enhanced Light Cure Cavity Liner, Pulpdent Corporation, Watertown, MA) was applied over the remaining carious dentine.

The iRoot BP Plus pulpotomy procedure involved the complete removal of all caries using a large round carbide bur. An access cavity was prepared using a diamond bur, and the coronal pulp was removed with a sterile sharp spoon excavator. The pulp chamber was rinsed with saline and the health of the radicular pulp was reconfirmed; a sterile cotton pellet moistened in saline was then packed against the radicular pulp stumps to achieve hemostasis. The radicular pulp stump was then covered with a 2-mm thick iRoot BP Plus. Cavit (3 M ESPE, St Paul, MN) and a resin-modified glass ionomer base (lime-Lite enhanced light cure cavity liner, Pulpdent Corporation, Watertown, MA) were then placed.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Generally healthy children aged 3–7 years	1. Patients with systemic disease or mental health problems
2. Ability to communicate with dentists	2. Clinical symptoms of irreversible pulpitis, such as a history of spontaneous, persistent, and/or nocturnal pain
3. Requirement for caries treatment under general anesthesia (GA) due to a lack of cooperativeness	3. Tenderness to percussion or abnormal mobility
4. At least one restorable primary molar diagnosed with extremely deep caries, no spontaneous unprovoked toothache	4. Fistula, or gingival swelling on clinical examination
5. Extremely deep caries was diagnosed using the established criteria of the European Society of Endodontology: Caries penetrating the entire thickness of the dentine, radiographically detectable when located on an interproximal or occlusal surface. Pulp exposure is unavoidable during operative treatment [1]	5. Interradicular or periapical radiolucencies; pathological internal or external root resorption; physiological root resorption;
6. For candidate teeth on the same side, only the maxillary or mandibular teeth were included. The teeth with preoperative sensitivity were distributed in different quadrants.	6. Extensive caries requiring extraction

All vital pulp treated teeth were restored with a light-cured composite resin (Filtek Z250 Universal Restorative, 3 M ESPE, St Paul, MN), followed by a pre-fabricated stainless steel crown (SSC) (3 M ESPE, St Paul, MN).

Follow-up and evaluation

All the patients were recalled for clinical examinations at 6, 12, 18, and 24 months and periapical radiographs were taken at 6, 12, and 24 months. Two blinded, independent, experienced pediatric dentists performed the clinical examinations; two additional dentists performed the radiographic evaluations. Prior to outcome evaluations in this study, the four investigators were calibrated using independent clinical and radiographic assessments of a separate set of 20 primary molars. The intra-examiner reliability (0.85, 0.95, 0.80, and 0.85) of each assessor was calculated using Cohen's kappa statistic. The inter-examiner reliability values for the clinical and radiographic assessments were 0.85 and 0.80, respectively.

The criteria for clinical success were the absence of clinical signs and post-operative symptoms, including pain, gingival abscesses, fistula openings, and abnormal mobility. The criteria for radiographic success included the absence of radiolucencies at the interradicular and/or periapical regions, absence of internal root resorption, and absence of external root resorption that was not compatible with physiological resorption due to the exfoliation process.

Statistical analysis

Statistical analysis was performed using the statistical software SPSS 21.0 (SPSS Inc., Chicago, IL). The differences in success rates between the groups were statistically analyzed using Kaplan-Meier survival curves. Multivariate survival analysis was conducted using Cox proportional hazards regression (forward likelihood ratio model) to identify independent prognostic factors. Independent variables included age, sex, tooth type, location of caries, preoperative sensitivity, color of cavity floor, and pulp exposure after caries removal (nearly or already exposed). A P value < 0.05 with a 95% confidence interval (CI) was considered significant.

Results

A total of 87 and 88 teeth were randomly allocated to the IPT and pulpotomy groups respectively. Twelve patients originally allocated to undergo IPT were switched to the pulpotomy group, as they required the pulpotomy due to pulp exposure at the corner of the tooth, and a large amount of caries remaining on the pulpal axial wall. Five teeth in the pulpotomy group underwent root canal therapy due to the inability to achieve hemostasis of the pulp stump within 5 min. Three patients (six teeth) in the IPT group reported by telephone the absence of any discomfort, and declined further follow-up; we were unable to contact one patient (one tooth) in the pulpotomy group after the initial treatment session. The overall dropout rate was 4%; therefore, a total of 168 molars in 67 children were included in the final analysis (Fig. 1). Patient and clinical characteristics were generally equivalent between the two groups (Table 2). In the pulpotomy group, 67 out of 87 teeth (77%) had exposed pulp, and 20 out of 87 (23%) had nearly exposed pulp with red cavity bottom after caries removal.

The 12 teeth that had been switched to the pulpotomy group and the five teeth in the pulpotomy group which underwent root canal therapy were all confirmed to be radiographically and clinically successful at the 24-month follow-up evaluation. Nevertheless, all statistical analyses were performed with these teeth in their originally allocated groups, in accordance with the modified intention-to-treat (ITT) principle.

Treatment failure was observed in five and two teeth in the IPT and pulpotomy groups, respectively (Table 3). The overall clinical and radiographic success rate for RMGI IPT was 93.8% (76/81) and for iRoot BP Plus pulpotomy was 97.7% (85/87). There were no significant differences in the survival rates between the two groups at 6, 12, 18, or 24 months (Table 4, Figs. 2, 3, and 4). The overall log-rank comparison did not yield a significant difference (P = 0.238).

Sex and tooth position in the arch were excluded as potential determinants of treatment success following univariate analyses. The Cox regression analysis indicated that the success rate of IPT was significantly associated with preoperative sensitivity (odds ratio [OR] = 9.742; 95% CI, 1.079–87.970; P = 0.043) and patient age (OR = 2.347; 95% CI, 1.068–5.156; P = 0.034). No other factors were significantly associated with treatment success (Table 5).

Discussion

The success rates of both IPT and pulpotomy for the management of extremely deep caries approaching the pulp in primary molars were high at the 24-month follow-up (93.8% vs. 97.7%), with no significant differences between the two treatments (notice that the pulp state in all cases was normal or reversible pulpitis). This study confirmed that IPT and pulpotomy could be successful in treating extremely deep primary molars. According to the AAPD guidelines, both IPT and pulpotomy are viable options for treating primary teeth with deep caries lesions and reversible pulpitis [2]. If the pulp is exposed during the excavation of carious dentine, pulpotomy is recommended [2, 29]. The indications of IPT and pulpotomy partially overlap. Often, the treatment plan is determined somewhat subjectively by the doctor. The significance of this study was to provide an objective basis for

Table 2 Patient and clinical characteristics in the two treatment groups

Variables	IPT group (n = 81)		Pulpotomy group (n = 87)		P value
	n	%	n	%	
Sex					
Male	53	62.3	50	57.5	
Female	28	37.7	37	42.5	0.29
Tooth position in the arch					
Maxillary	41	50.6	42	48.3	
Mandible	40	49.4	45	51.7	0.762
Tooth type					
1st primary molar	53	65.4	51	58.6	
2nd primary molar	28	34.6	36	41.4	0.364
Location of caries					
Single	8	9.9	16	18.4	
Double	27	33.3	44	50.6	
Multiple	46	56.8	27	31.0	0.361
Preoperative sensitivity					
Yes	26	29.6	40	43.7	
No	55	70.4	47	56.3	0.066
Color of cavity floor					
Yellow	61	75.3	64	73.6	
Brown	20	24.7	23	26.4	0.796
Age of patients (years)	3.78 ± 1.131		3.99 ± 1.018		0.87
Operator					
Attending physician	35	43.2	42	48.3	
Associate chief physician	46	56.8	45	51.7	0.51

making a treatment decision in cases of extremely deep caries. Some studies have reported a higher long-term success rate for IPT, as well as a more normal exfoliation time, compared to pulpotomy [9, 29, 30].

Our results suggest that preoperative sensitivity was associated with the prognosis of IPT. Preoperative sensitivity refers to reversible pulpitis or partial coronal pulpitis, which might increase the risk of failure in the IPT group, especially for extremely deep lesions in primary teeth. However, despite the risk of failure, the success rate is as high as 93.8%. Thus, clinicians should acknowledge the importance of obtaining an accurate pain history, and the effect of preoperative sensitivity on subsequent IPT failure.

This study revealed that a younger patient age was associated with higher success rates for IPT. Similarly, in a previous retrospective study from our group aimed to evaluate the success rate of mineral trioxide aggregate pulpotomy, we observed a better outcome in younger compared with older children (OR = 1.473, $P < 0.05$) [31]. This finding may be attributed to age-related histological changes in the pulps of primary teeth. The cell densities of coronal odontoblasts, subodontoblasts, and fibroblasts have been found to decrease with age, and these cells undergo morphological changes throughout the aging process of individuals, which may compromise the pulp's ability to resist tooth injury [32]. Younger pulps have a higher reparative ability and an increased resistance to infection; these characteristics decrease naturally with age. Young primary teeth or permanent teeth are considered good candidates for vital pulp treatment (VPT) due to their higher pulpal blood supply, open root apices and pulps free of age-related changes, compared with teeth with closed apices [33]. In children younger than 3.67-year-old treated with IPT, there was no case of failure. Therefore, it is important to take into consideration the patient's age when formulating a treatment plan for the management of deep caries. The results of this study revealed a relationship between the trend of age growth and IPT, and that increased age raised the risk of IPT failure. Future investigations may focus on the pulp aging in children, and a specific study on age and VPT should be conducted. The study reported by Gruythuysen et al. included children of a higher age, which did not influence the results [3]; however, in relation to the age of those children, about 20 to 30% of the permanent teeth treated with IPT were immature at the start of treatment.

Multiple surface cavities had an incidence of 85.71% in this study. To eliminate the recurrent caries and confounding

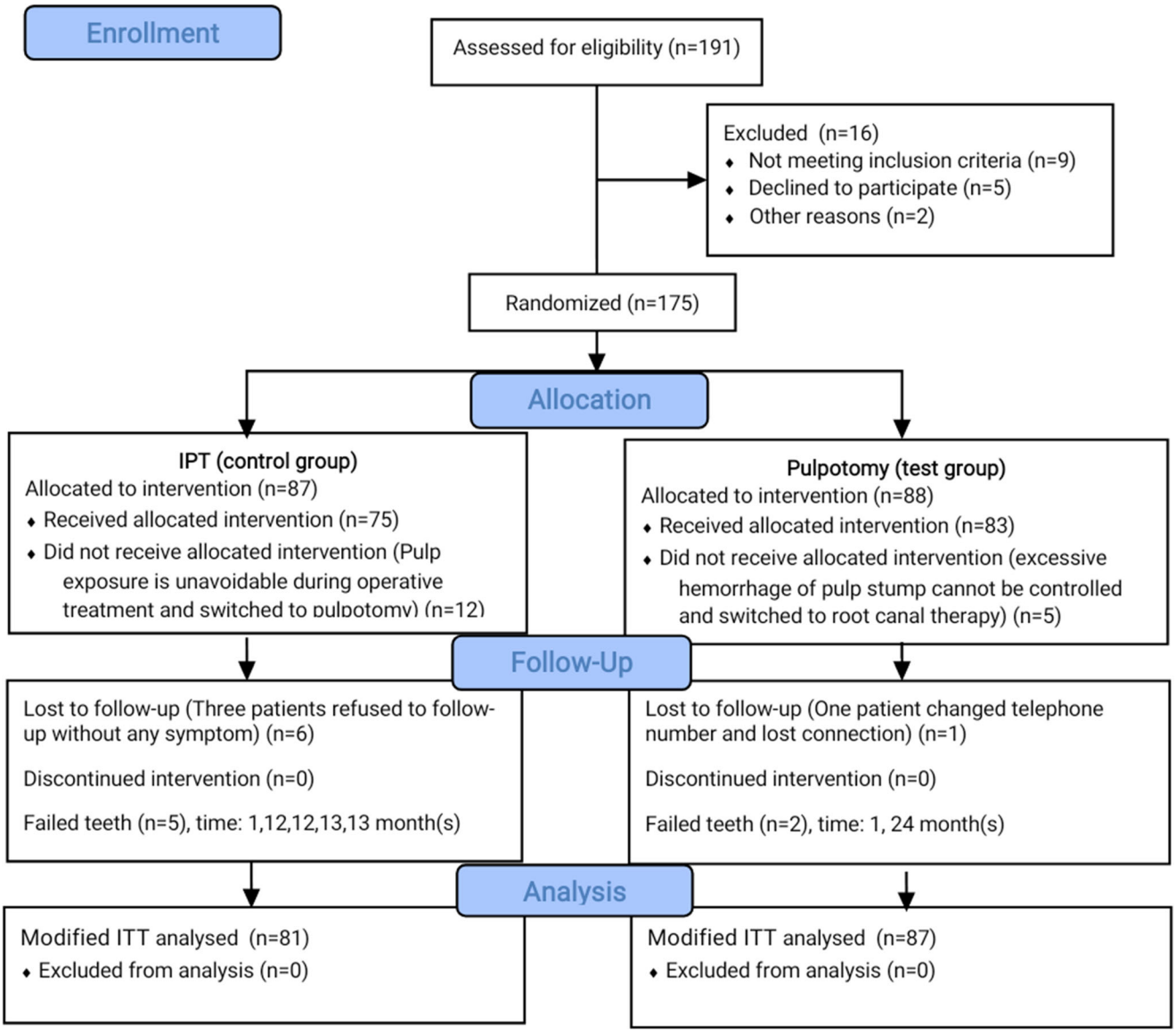

Fig. 1 Consolidated standards of reporting trials flowchart showing the progress of patients through the 24-month study

effects of the quality of restoration on tooth survival, SSCs were placed under GA, immediately following IPT or pulpotomy. The lack of association between the number of carious tooth surfaces and treatment success rate could be attributed to the use of SSCs. Current evidence indicates that the adequate sealing of the remaining infected dentine is of

Table 3 Details of the teeth, which had radiographic failed up to 24 months

Number	Group	Gender	Age	Tooth site	Preoperative pain	Time of failed (months)	Diagnosis when failed	Outcome
1	IPT	M	4	54	Yes	1	CPP	RCT
2	IPT	F	3.67	64	No	12	CP	RCT
3	IPT	F	6.2	85	Yes	12	CPP	Extraction
4	IPT	M	6	75	Yes	13	CPP	RCT
5	IPT	M	4.58	75	Yes	13	CP	RCT
6	Pulpotomy	M	5.5	85	Yes	1	APP	RCT
7	Pulpotomy	F	3.58	54	Yes	24	CPP	Extraction

CPP, chronic periapical periodontitis; *CP*, chronic pulpitis; *APP*, acute purulent pulpitis; *RCT*, root canal treatment

Table 4 Comparison of clinical and radiographic success between treatment groups at 12 months and 24 months

Group (*n*)	Clinical success						Radiographic success					
	12 months			24 months			12 months			24 months		
	N	%	*P*	*N*	%	*P*	*N*	%	*P*	*N*	%	*P*
IPT (81)	76	93.8	0.107	76	93.8	0.264	78	95.7		78	95.7	0.264
Pulpotomy (87)	86	98.8		85	97.7		86	98.8	0.353	86	98.8	

IPT, indirect pulp treatment

utmost importance for IPT and that a suitable restoration is the main determinant of a successful outcome after pulpotomy [3, 6]. A previous study reported higher success rates after IPT with the use of SSCs compared with amalgam restorations [34]. However, another study revealed that successful adhesive filling materials did not influence the survival rate after 3 years (96%) [3]. Therefore, we strongly recommend the placement of SSCs in extensive caries as soon as possible after vital pulp treatment. In cases of one surface (occlusal) carious lesions or if there is enough surrounding tooth structure, an adhesive filling is a viable option.

In this study, pulp exposure was unavoidable during caries excavation in 13.8% of the cases in the IPT group, which was similar to the 12.3% (19/154) in the frequency of pulp exposure during the extremely deep caries treatment reported by Orhan et al. [4] Gruythuysen et al. reported a frequency of 5% of pulp exposures in the IPT group [3], where deep carious lesions were defined as lesions comprising more than two-thirds of the dentin thickness, and the severity of dental caries was lighter than that in the present study. The results of our study showed that the 12 teeth that were switched to the pulpotomy group were all successful. The analyses of this study were based on modified ITT, regardless of which treatment was actually provided; however, the patients who dropped out were not included in the final analyses due to missing outcome data. The use of a modified ITT analysis could have prevented attrition bias and led to an underestimation of the difference in success rates between the two groups [35]. As all teeth that were switched to a different treatment were successfully treated, the success rates of both IPT and pulpotomy may have been overestimated.

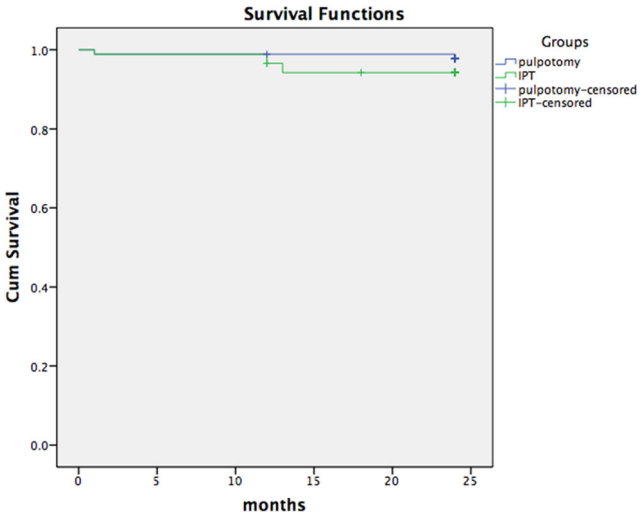

Fig. 2 Cumulative survival rates in the IPT and pulpotomy groups over 24 months of follow-up. IPT, indirect pulp treatment; $P = 0.238$

The complete or non-selective removal of caries for teeth with a normal pulp or reversible pulpitis can be considered overtreatment [36, 37]. Studies of primary dentition have demonstrated the effectiveness of one-step selective caries removal [34, 38] and the Hall technique for sealing caries lesions with an SSC [39]. Low incidences of pulpal necrosis after IPT have been reported in 3% of permanent posterior teeth [33], 4% for primary molars, and 7% for permanent teeth [3]. In this study, 5 out of 81 (6%) IPT treatment teeth showed clinical failure or apical radiolucency. More deep carious lesions were observed compared with a previous report, in which the lesion depth was > 2/3 of the dentine [40]. It is reasonable to assume that more teeth in the present study had severe pulp involvement. In a clinical trial conducted by Gruythuysen et al., the caries detector was applied to distinguish the dentin-enamel junction and a prophy brush with fluoride toothpaste was used [3]. Hence, more conservative caries excavation techniques should be pursued to achieve better outcomes of IPT. Most treatment failures in the IPT group occurred within 1 year, which was in line with the findings of Casagrande et al. [36].

The advantage of pulpotomy is that pulpal health can be reassessed under direct vision after mechanical exposure of the pulp cavity, especially when the pulp is purulent or necrotic, but asymptomatic preoperatively. The possibility of failure due to the misdiagnosis of the pulp state was low. However, the assessment of pulp color and the amount of pulp hemorrhage is a relatively crude and subjective measure [1]. Keles et al. concluded that children who underwent pulpotomy treatment had higher postoperative pain scores and greater need for rescue analgesia than the subjects of the control group, who received only dental fillings [41]. Moreover, the pulpotomy group required a prolonged recovery time and more GA time than IPT. In the light of equivalently high success rates, reduced operation time, less postoperative pain, and normal

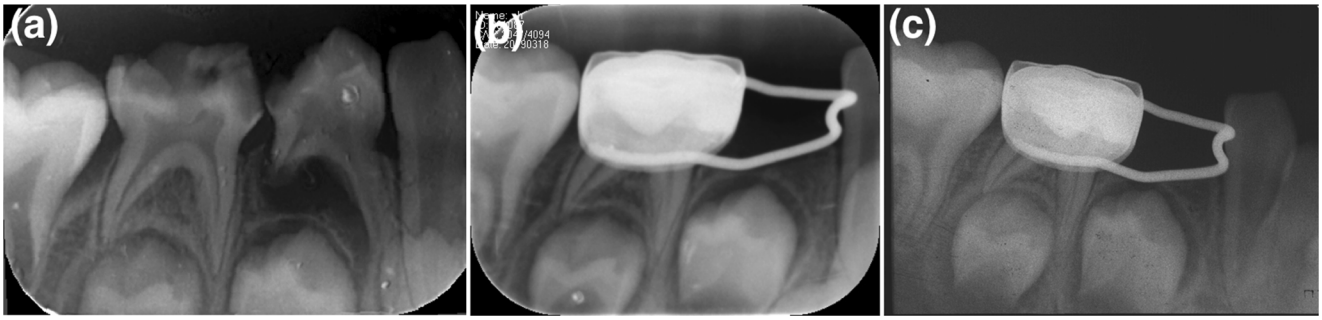

Fig. 3 A lower right second primary molar that underwent indirect pulp treatment with resin-modified glass ionomer. **a** Pre-operative periapical radiograph. **b** Radiographic evaluation at the 12-month follow-up; the procedure was considered successful. **c** Radiographic evaluation at the 24-month follow-up showing a successful outcome

exfoliation time, IPT remained the preferred treatment (over pulpotomy) for extremely deep caries.

iRoot BP Plus is a ready-to-use hydraulic premixed bioceramic modeling material. Studies have demonstrated its biocompatibility and ability to induce mineralization and odontoblastic differentiation when used as a pulp-capping agent [17, 42–44]. It is currently considered to be a suitable alternative to calcium hydroxide for the pulpotomy of permanent incisors [18] as prior studies have reported the formation of reparative dentine bridges as early as 4 to 6 weeks post-treatment, with the absence of tunnel defects [45, 46]. The use of iRoot BP Plus in the present study may have contributed to the high success rate in the pulpotomy group. Our results further support the clinical effectiveness of iRoot BP Plus for the pulpotomy of primary teeth.

Some limitations should be acknowledged in this study. First, the use of GA provided an optimal and controlled environment for clinical treatment, in which the confounding effects of various factors could be eliminated; as such, the treatment success rates may have been overestimated. Second, although the group allocation was performed prior to operative treatment, the individual subjective judgments of the clinicians and the unpredictability of the clinical course resulted in pulpal exposure in 13.8% of the cases in the IPT group; these cases required a pulpotomy and were thus switched to the pulpotomy group. Third, all dentists performing the treatments were specialists in pediatric dentistry; therefore, the success rates may have been different if general dentists had performed the treatments. Fourth, there was a possibility of overtreatment for individual teeth treated with pulpotomy. However, such a possibility was limited to some of the children in this study, and the conclusions are beneficial to a broader range of people in the long run. Future studies should employ a longer observation period and evaluate the specific effects of preoperative sensitivity on long-term treatment success, with the overarching aim of guiding clinical treatment planning for IPT and pulpotomy.

The 24-month success rates of IPT and iRoot BP Plus pulpotomy performed in primary molars with extremely deep caries were not significantly different from each other. Increased age and preoperative sensitivity were found to be associated with a lower cumulative survival probability in IPT-treated teeth. Primary teeth with extremely deep carious lesions without signs of irreversible pulpitis can be treated

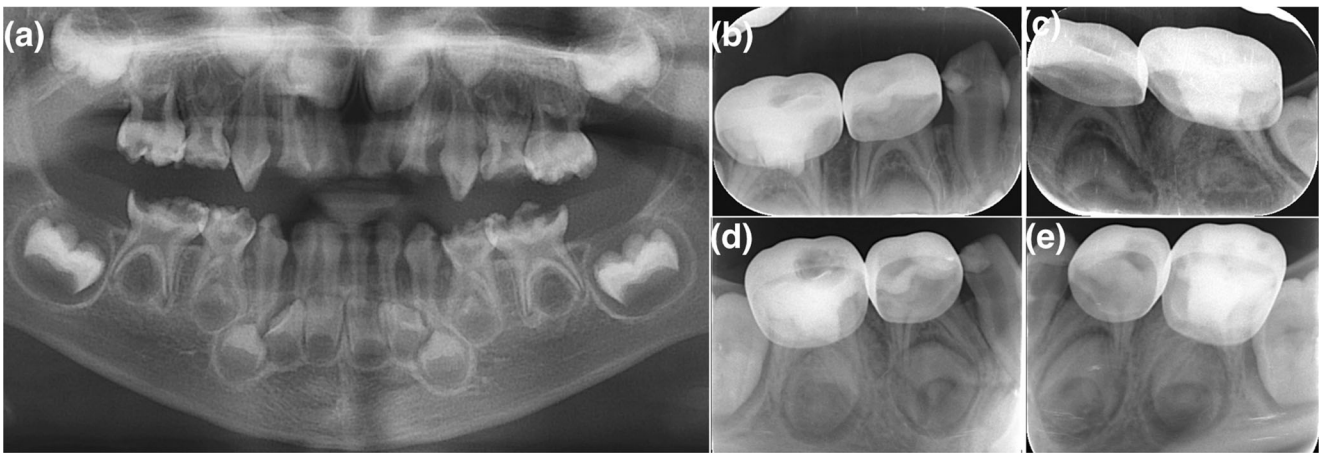

Fig. 4 A 3-year-old girl, who underwent indirect pulp treatment in teeth 74 and 84 with resin-modified glass ionomer, while tooth 75 and 85 underwent iRoot BP Plus pulpotomy. **a** Pre-operative panoramic radiograph. **b** Teeth 84 and 85 were considered successfully treated at the 12-month follow-up. **c** Teeth 74 and 75 were considered successfully treated at the 12-month follow-up. **d** Two-year follow-up showing successful results in teeth 84 and 85. **e** Two-year follow-up showing successful results in teeth 74 and 75

Table 5 The results of the Cox proportional risk regression analyses for treatment success rate

Items	IPT Group				Pulpotomy group			
	B	OR	95% CI	*P*	*B*	OR	95% CI	*P*
Age	0.853	2.347	1.068–5.156	0.034*	0.004	1.004	0.195–5.164	0.997
Preoperative sensitivity	2.276	9.742	1.079–87.970	0.043*	17.234	30,514,936.446	0.000–1.353E+303	0.968
Number of surfaces with caries	0.142	1.153	0.25–5.308	0.855	− 2.653	0.070	0.001–6.578	0.252
Color of cavity floor	13.343	623,413.347	0.00–1.288E+194	0.978	− 2.734	0.065	0.000–15.528	0.328
Exposed or nearly exposed pulp	− 0.405	0.667	0.051–8.640	0.757	− 2.421	0.089	0.004–1.973	0.126
Tooth type (1st or 2nd molar)	− 0.524	0.592	0.060–5.886	0.655	− 0.934	0.393	0.009–17.503	0.630

*$P < 0.05$

IPT, indirect pulp treatment; *CI*, confidence interval; *OR*, odds ratio

successfully by either indirect pulp capping or iRoot BP Plus pulpotomy.

Funding This study was supported by the Fund Program for New Clinical Techniques and Therapies of First Clinical Division, Peking University School and Hospital of Stomatology (NCTT2018020).

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures involving human participants were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The clinical trial was approved by the Peking University School and Hospital of Stomatology Ethics Committee (PKUSSIRB-201840190) and is registered at the Chinese Clinical Trial Registry (ChiCTR2000032462)

Informed consent Informed consent was obtained from all individual participants included in the study.

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