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ORIGINAL RESEARCH

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Potential factors affecting the success rate of indirect pulp therapy in primary molars with deep caries: a retrospective study

Yue Yu[1,†], Siyuan Hao[1,†], Yixin Jin[1], Qiong Zhang[1], Yan Wang[1,*], Jing Zou[1,*]

[1]State Key Laboratory of Oral Diseases & National Center for Stomatology & National Clinical Research Center for Oral Diseases & Department of Pediatric Dentistry, West China Hospital of Stomatology, Sichuan University, 610041 Chengdu, Sichuan, China

***Correspondence**
wangyan1458@scu.edu.cn
(Yan Wang);
zoujing@scu.edu.cn
(Jing Zou)

[†] These authors contributed equally.

Abstract

Indirect pulp therapy (IPT) is a common conservative treatment for deep dental caries. However, the potential risk factors for the prognosis of IPT have not been well studied. This study retrospectively investigated the success rate of IPT in treating primary molars with deep caries and the factors potentially affecting the two-year success rate. A total of 303 primary molars in 202 children (106 boys and 96 girls) were included in this study. These primary molars were identified as having deep caries by clinical and radiographic examinations and were treated with IPT. The factors potentially affecting the IPT success rate were analyzed after two years of follow-up. The results indicated that the two-year IPT success rate was 86% (262/303). The success rate of primary molars with and without stainless steel crowns was 96% (120/125) and 80% (142/178), respectively. Primary molars treated with stainless steel crowns showed a significantly lower risk of failure (hazard ratio (HR) = 0.18, 95% confidence interval (CI): (0.10, 0.34), p = 0.01). There were no significant differences in other factors, including gender (male *vs.* female), age (preschool *vs.* school age), cooperation level (Frankl 2 *vs.* 3 or 4 scales), arch type (maxillary *vs.* mandibular), tooth type (first *vs.* second primary molar), or pulp capping material (calcium hydroxide *vs.* glass ionomer cement). IPT is an effective, conservative treatment modality for primary molars with deep caries. Stainless steel crowns could significantly improve the IPT success rate.

Keywords

Deep caries; Indirect pulp therapy; Primary molar; Potential factors; Stainless steel crown; Success rate

1. Introduction

The 4th National Oral Health Survey in Mainland China reported that the prevalence of primary dental caries in 5-year-old children was as high as 71.9%, 5.9% higher than 10 years ago [1]. Primary dental caries is a significant chronic disease in childhood, and dental pulp infection is possible when caries involve and penetrate the dentin. If deep caries of primary teeth are not treated promptly, tooth tissue defects, pulpal lesions, and periapical infections can occur, ultimately leading to the early loss of primary teeth. The early loss of primary teeth will affect chewing, pronunciation, and the aesthetic functions of primary teeth and lead to malocclusion and disturbances in the eruption of permanent teeth. Therefore, favorable and effective treatment for deep caries in primary teeth is necessary to preserve primary teeth, and the vitality of tooth pulp is of great significance for maintaining the integrity of dentition and children's oral health.

The American Academy of Pediatric Dentistry guidelines recommend vital pulp therapy for children with deep carious lesions in primary teeth. For teeth with deep caries without symptoms of dental pulp degeneration or only reversible pulpitis, the complete removal of decayed tissue may lead to pulp exposure. Indirect pulp therapy (IPT) is a conservative vital pulp procedure performed in deep carious lesions approaching the pulp but without signs or symptoms of pulp degeneration [2]. In IPT, caries on the lateral walls are removed. In contrast, caries approaching the pulp are selectively retained to avoid pulpal exposure and preserve pulp vitality. Then, they are covered with biocompatible materials, and a restorative procedure is undertaken to promote the remineralization of dental tissue and the formation of reparative dentin [3, 4]. Compared to other vital pulp therapy methods, IPT has the advantages of lower medical costs and higher long-term success rates [5]. IPT is also associated with a better primary tooth exfoliation pattern. Farooq *et al.* [6] reported that 38% of primary molars exfoliated earlier than other teeth after formocresol pulpotomy, while IPT molars exhibited normal exfoliation. However, it is difficult to elicit accurate information on pulp symptoms in pediatric dentistry. Correctly diagnosing the pulp status of deep carious lesions in primary teeth is crucial for selecting the best vital pulp therapy [7, 8]. Pulp sensibility and vitality tests

measuring the nerve response rather than assessing the blood flow of the pulp have significant limitations [9]. The lack of accurate electric pulp tests for primary molars has been attributed to the incomplete innervation of the pulp [10]. The clinician's decision must be guided by the macroscopic quality of the carious dentin, remaining dentin thickness, the radiographic extent of the lesion, and the ability to elicit clinical symptoms from the child and determines the success of the treatment [11]. Therefore, exploring the factors affecting the success rate of IPT has become a hot research topic for pediatric dentists.

The success of IPT can be influenced by various risk factors and challenges, including diagnostic accuracy, patient factors, tooth factors, operator skills and experience, and material selection [12–15]. Pediatric patients may have difficulty cooperating during dental procedures, making precise clinical work challenging. Managing behavior and maintaining a dry field can be difficult, affecting the procedure's success. However, younger patients may have more resilient pulp tissues, increasing the likelihood of success. The anatomical morphology of teeth with different dental arches and tooth types varies, possibly resulting in varying degrees of dental pulp involvement by caries and potentially impacting the treatment outcome [16]. The materials used for sealing the cavity after excavation play a role in the success of IPT. If the seal is not established properly, microorganisms can penetrate the pulp space and cause inflammation. Also, a good pulp capping material can promote the remineralization of carious dentin and the formation of reparative dentin [17–20]. Exploring the factors affecting the success rate of IPT could help improve the outcome of IPT.

Thus, the present study retrospectively investigated the success rate of IPT in treating primary molars with deep caries and the factors affecting the two-year success rate, including gender (male *vs.* female), age (preschool *vs.* school age), cooperation level (Frankl 2 *vs.* 3 or 4 scales), arch type (maxillary *vs.* mandibular primary molar), tooth type (first *vs.* second primary molar), stainless-steel crown (yes *vs.* no), and pulp capping material (calcium hydroxide *vs.* glass ionomer cement). We hope that our data could serve as a reference for pediatric dentists to improve the outcome of IPT.

2. Methods

2.1 Subject selection

The present retrospective study reviewed the records of 202 pediatric patients from 01 January 2019, to 31 December 2020, from electronic medical archives in the Department of Pediatric Dentistry, West China Hospital of Stomatology, Sichuan University. The patients were diagnosed with deep caries of primary molars and underwent IPT. Patients were selected according to the inclusion and exclusion criteria.

The inclusion criteria were: (1) Primary molars diagnosed with deep caries based on clinical and radiographic examinations. (2) Teeth treated with IPT. The decayed dentin on the lateral walls of the cavity was removed completely. Part of the decayed dentin on the pulpal walls was preserved and capped with calcium hydroxide or glass ionomer cement. (3) No pulp calcification, internal or external resorption, and radiolucency in the furcal area in the pre-treatment radiographic examination. (4) The succedaneous tooth germ was intact.

The exclusion criteria were: (1) Children who were too young to communicate or with a mental intellectual disability. (2) Teeth with spontaneous pain that could not be relieved after irritant removal. (3) Looseness, pain upon percussion, or pustules or fistulas in the gums upon oral examination. (4) Radiographic examination indicating abnormalities in the root canal, root divergence and periapical tissues, such as pathological internal and external absorption of tooth roots, significant widening of periodontal membranes, and radiolucency in the furcal or periapical areas.

2.2 Data collection

Data, including subjects' medical histories, clinical examination records, radiographic examination results, and treatment records, were collected. The potential factors affecting IPT success or failure included gender (male *vs.* female), age (preschool *vs.* school age), cooperation level (Frankl 2 *vs.* 3 or 4 scales), arch type (maxillary *vs.* mandibular), tooth type (first *vs.* second primary molar), stainless steel crowns (yes *vs.* no), and pulp capping material (calcium hydroxide (Ultra-Blend Plus, Ultradent Products, USA) *vs.* glass ionomer cement (FX-II, Shofu, Japan)).

Clinical and radiographic examinations were performed every six months during the follow-up period. The IPT outcomes in primary molars were determined based on clinical and radiographic examinations. According to the American Academy of Pediatric Dentistry guidelines, the criteria for success were teeth without symptoms and signs, including pain, swelling, abscess, fistula, pathological loosening of the teeth in clinical examinations, and the absence of pathologic external or internal root resorption or other pathologic changes in radiographic examinations. Teeth not meeting the criteria were identified as failures by two pediatric dentists, and disagreements were discussed with another senior pediatric dentist.

2.3 Statistical analysis

A chi-squared test was performed using SPSS 25.0 (SPSS Inc., Chicago, IL, USA) to identify factors associated with the two-year success rate of IPT. Survival analysis was conducted using GraphPad Prism 8 (GraphPad Prism Inc., San Diego, California, USA). The survival curves of the two groups were compared using the log-rank test. We calculated hazard ratios (HRs) and 95% confidence intervals (CIs) to assess risk. The HR was the ratio of the hazard rates corresponding to the risk of failure. A p-value of < 0.05 was regarded as statistically significant.

3. Results

3.1 Subjects and tooth characteristics

Table 1 presents the characteristics of the subjects and teeth treated with IPT. A total of 303 primary molars in 202 children (106 boys and 96 girls) were included in the present study. The mean age of the subjects at the time of treatment was 5 $\pm$ 1.4 years, ranging from 3 to 11 years. The Frankl scale

of 27 patients (including 32 teeth) was 2, and 175 patients (including 271 teeth) had scales of 3 or 4. Concerning tooth location, 123 teeth were maxillary primary molars, and 180 were mandibular primary molars. Regarding tooth type, 163 teeth were first primary molars, and 140 were second primary molars. One hundred and twenty-five teeth had a stainless steel crown, and 178 did not. One hundred and fifty-six teeth received calcium hydroxide pulp capping material, and 147 received glass ionomer cement.

TABLE 1. Characteristics of the included subjects and primary molars.

Characteristics	Success	Failure
Patients (n)	174	28
Age (mean ± SD)	5.03 ± 1.37	4.94 ± 1.42
Gender (male: female)	93:81	13:15
Frankl grade (mean ± SD)	3.34 ± 0.52	3.68 ± 0.35
Primary molars (n)	262	41

SD: standard deviation.

3.2 Success rate and survival analysis

The two-year success rate of IPT was 86% (262/303). The potential factors involved in the success of IPT were analyzed by the chi-squared test (Table 2). The results indicated that stainless steel crowns were significantly associated with the success of IPT ($p = 0.01$). Primary molars treated with stainless steel crowns showed a significantly lower risk of failure than those without IPT. Survival analysis was conducted to further verify the association between stainless steel crowns and the success rate of IPT. The success rate of primary molars with and without stainless steel crowns was 96% (120/125) and 80% (142/178), respectively. Thus, primary molars with stainless steel crowns showed a significantly higher survival rate ($p = 0.01$). HRs were calculated to compare the risk of failure between the two groups. The results revealed that primary molars treated with stainless steel crowns had significantly lower risks of failure (HR = 0.18, 95% CI: (0.10, 0.34)) (Fig. 1).

However, other factors were not significantly associated with IPT success, including gender (male *vs.* female), age (preschool *vs.* school age), cooperation level (Frankl 2 *vs.* 3 or 4 scales), arch type (maxillary *vs.* mandibular), tooth type (first *vs.* second primary molar), and pulp capping material (calcium hydroxide *vs.* glass ionomer cement).

TABLE 2. Potential factors affecting the success rate of IPT were analyzed by the chi-squared test.

Characteristics	Success (n = 262)	Failure (n = 41)	*p*-value
Gender			
Male	136	16	0.13
Female	126	25	
Age			
Preschool	226	36	1.00
School-age	36	5	
Cooperation level			
Frankl 2	30	2	0.28
Frankl 3 or 4	232	39	
Arch type			
Maxillary	105	18	0.73
Mandibular	157	23	
Tooth type			
First primary molar	141	22	1.00
Second primary molar	121	19	
Stainless-steel crown			
Yes	120	5	0.01
No	142	36	
Pulp capping material			
Calcium hydroxide cement	134	22	0.76
Glass ionomer cement	128	19	

4. Discussion

Pediatric dentists have attempted to improve the outcome of IPT in the recent decade. Our study retrospectively investigated the success rate of IPT in treating primary molars with deep caries and the factors potentially affecting the success rate. A total of 303 primary molars in 202 children were included in the present study. The results indicated that stainless steel crowns were significantly associated with IPT success. Primary molars treated with stainless steel crowns showed a significantly lower risk of failure than those without IPT. However, other factors, including gender (male *vs.* female), age (preschool *vs.* school age), cooperation level (Frankl 2 *vs.* 3 or 4 scales), arch type (maxillary *vs.* mandibular), tooth type (first *vs.* second primary molar), and pulp capping material (calcium hydroxide *vs.* glass ionomer cement), were not significantly associated with the success of IPT.

The two-year success rate of IPT was 86% in the present study. The success rate of IPT in the published literature differs with different treatment methods and follow-up durations. Gruythuysen *et al.* [21] reported that the three-year survival rate of IPT was 96% for primary molars and 93% for permanent teeth. However, Covaci *et al.* [22] reported that the survival rate of IPT was 84% using calcium hydroxide. A review by Shang *et al.* [23] reported that the success rate of IPT was between 78% and 93%. The present study found that the two-year survival rate of IPT was 86%. The success rate of primary molars with and without stainless steel crowns was 96% (120/125) and 80% (142/178), respectively, consistent with previous reports. Our study and previous studies indicated that IPT, as a vital pulp therapy method, has a high success rate.

Our data showed that primary molars without stainless steel crowns had a significantly higher risk of failure than those with stainless steel crowns, consistent with previous studies. Al-Zayer *et al.* [24] reported that placing stainless steel crowns after an IPT procedure was significantly more successful than an amalgam restoration. Zahdan *et al.* [25] demonstrated that

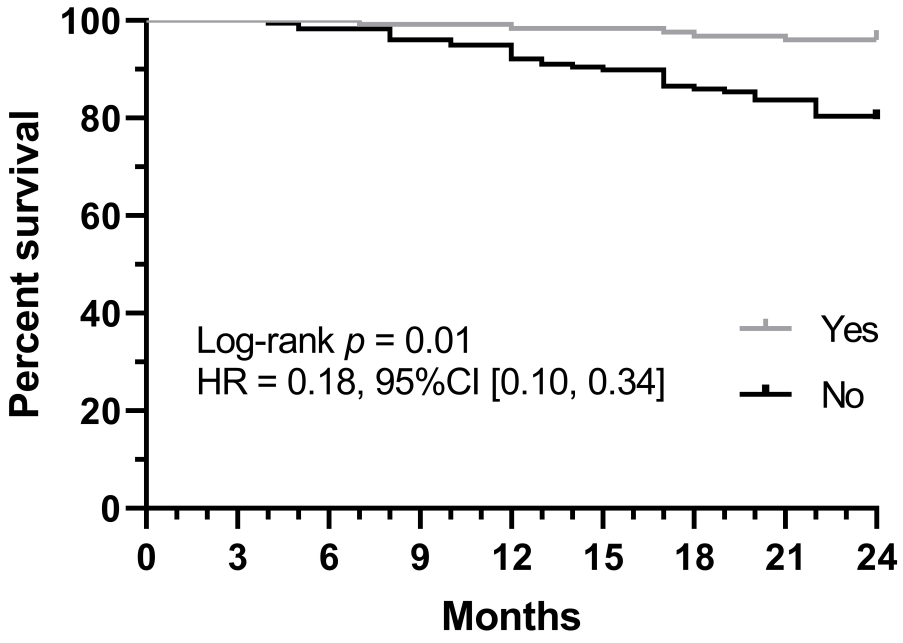

FIGURE 1. Survival analysis plot. Primary molars with stainless steel crowns showed a significantly higher survival rate. HR: hazard ratios; CI: confidence interval.

stainless steel crowns had a higher survival rate than multi-surface composite resin restorations placed in the primary molars of children by students at a pediatric dental clinic. In primary molars with deep caries treated with IPT, teeth restored with stainless steel crowns also survived longer than those restored with composite resin [26]. Concerning other vital pulp therapy procedures, the success rate of teeth restored with stainless steel crowns was also significantly higher than those restored with composite resin. The one-year survival rate of teeth with early childhood caries treated under general anesthesia (including IPT and pulpotomy) was 97.7% and 83.5%, respectively [27]. The published evidence and data from our study indicate that stainless steel crowns could improve the success rate of IPT for primary molars with deep caries.

The sealing ability of the restoration is essential to the success of vital pulp therapy, including IPT. After composite resin restoration, saliva and microorganisms can penetrate the space between teeth and restorative materials and cause microleakage [28]. As microleakage expands, dental plaque leads to secondary caries [29]. Moreover, the dissolution of adhesive agents leads to loosening and restoration loss [30]. Stainless steel crowns can improve the success rate of treatment by protecting restoration, reducing microleakage, and preventing secondary caries [31]. Large lesions or multi-surface lesions in primary molars in children should be treated with stainless steel crowns. The full coverage, increased durability, and longevity of stainless steel crowns protect against future decay [32]. Therefore, we suggest that stainless steel crowns can contribute to better outcomes of primary molars after IPT. The proper selection of restorative materials is vital for IPT since restoration leakage or fracture can lead to pulpal failure.

The present study demonstrated the clinical effectiveness of IPT, independent of the lining material, in treating deep caries of primary molars. American Academy of Pediatric Dentistry guidelines recommend calcium hydroxide, glass ionomer, bonding agents or mineral trioxide aggregate (or any other biocompatible material) as capping materials. The present study used calcium hydroxide or glass ionomer as capping materials, which were reported to be effective in promoting the remineralization of dental tissues and the formation of reparative dentin [33]. The results indicated two-year clinical and radiographic success rates of 86% (134/156) for teeth lined with calcium hydroxide and 87% (128/147) for teeth lined with glass ionomer. The results of the present study are consistent with previous studies. Falster *et al.* [34] performed IPT in 48 primary molars; 83% of teeth treated with calcium hydroxide and 96% treated with only the adhesive resin system exhibited clinical and radiographic success at the two-year follow-up. Marchi *et al.* [35] showed that IPT using calcium hydroxide or glass ionomer as a liner had similar success rates at the 48-month follow-up.

In the present study, neither gender, age, cooperation level, arch type, nor tooth type significantly affected the success of IPT procedures. The authors had expected that more cooperative children would have higher success rates. The explanation may be that all the operators paid attention to the quality of clinical procedures, irrespective of the patient's cooperation level. Moreover, all the included patients had at least a Frankl scale of 2, which means they were reluctant to accept treatment. No patients with a Frankl scale of 1 refused to accept treatment because only outpatients were investigated in this study. These uncooperative patients usually underwent treatment under general anesthesia or sedation. There were inconsistencies among studies concerning arch type and tooth

type [16, 24, 36]. Maqbool found that maxillary deciduous molars and second deciduous molars had a better overall outcome at a 12-month follow-up after vital pulp therapy. The authors attributed the differences in findings between maxillary and mandibular teeth to the fact that maxillary bone has a thinner cortical bone layer, more spongy bone, and a richer blood supply than mandibular bone [16]. The differences between the first primary molars and the second primary molars were explained by the influence of cavity size, root anatomy, and restorability. However, the two studies showed no significant differences [36]. Thus, a larger sample size and longer follow-up studies are needed.

Admittedly, this study had several limitations, and the results should be interpreted with caution. First, the sample size was relatively small, and further large-sample retrospective studies or clinical trials are required. Second, the follow-up duration was short. Further studies should report results with longer follow-ups. Third, since this was a retrospective study with several operators, bias in the selection of treatment for a particular tooth and operator preferences cannot be ruled out. Therefore, randomized, double-blind studies are needed to verify the results.

5. Conclusions

IPT is an effective conservative treatment for primary molars with deep caries. Stainless steel crowns can significantly improve the success rate of IPT.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

YW and SYH—contributed to the overall conceptualization and design of the study. YY, SYH, YXJ and QZ—collected the data and carried out the data analysis. YY and SYH—drafted the manuscript. YW and ZJ—revised the manuscript. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Ethic Committee of West China Hospital of Stomatology, Sichuan University (WCHSIRB-D-2019–085). All the procedures complied with the principles of the Helsinki Declaration. Informed consent was obtained from the legal guardians of children involved in the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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