Pulpa Dentis D30 for Acute Reversible Pulpitis: A Prospective Cohort Study in Routine Dental Practice

Harald Johan Hamre, Dr med; Inge Mittag, Dr med dent; Anja Glockmann, Dipl Biol; Helmut Kiene, Dr med; Wilfried Tröger, Dr rer nat

Background • Pulpa dentis D30 (PD: dental pulp of the calf, prepared in a homeopathic D30 potency) has been used in acute reversible pulpitis for pain relief and to avoid or postpone invasive dental treatment.

Primary Study Objective • To study short-term clinical outcomes of PD therapy for acute reversible pulpitis in routine dental practice.

Methods/Design • Prospective, observational, open-label, single-arm cohort study.

Setting • Eleven dental primary care practices in Germany.

Participants and Intervention • Thirty-two patients starting monotherapy with PD for acute reversible pulpitis without visible or radiological abnormalities. PD was applied as 1-mL submucous injections into the mucobuccal fold, repeated daily as needed.

Primary Outcome Measures • Avoidance of invasive dental treatment (pulp capping, root canal therapy, tooth extraction) and remission of pain, measured on a 0-10 point scale (partial remission: reduction by ≥3 points; complete remission: reduction from ≥4 points to 0-1 points) during the 10-day follow-up period.

Results • Median pain duration was 14.0 days. The patients received a median of two PD applications (range 1-7). A total of 81% (n = 26/32) of patients did not require invasive dental treatment, and 19% (n = 6) had root canal therapy. Remission status was evaluable in 24 patients. Of these, 63% (n = 15/24) achieved pain remission, 58% (n = 14) remitted without invasive dental treatment (complete remission: n = 12, partial remission: n = 2), and 29% (n = 7) had a close temporal relationship between PD and remission (ratio "time to remission after first PD application vs pain duration prior to first PD application" <1:10).

Conclusion • In this study of PD for acute reversible pulpitis, 58% of evaluable patients achieved pain remission without invasive dental treatment. The open-label pre-post design does not allow for conclusions about comparative effectiveness. However, more than one-fourth of evaluable patients remitted with a close temporal relationship between the first PD application and pain remission, suggesting a causal relationship between therapy and remission. (*Altern Ther Health Med.* 2011;17(1):16-21.)

Harald Johan Hamre, Dr med, is a senior research scientist, Anja Glockmann, Dipl Biol, is a medical information specialist, and Helmut Kiene, Dr med, is the director at the Institute for Applied Epistemology and Medical Methodology, Freiburg, Germany. Inge Mittag, Dr med dent, is in private dental practice in Bremen, Germany. Wilfried Tröger, Dr rer nat, is the director of Clinical Research Dr Tröger, Freiburg.

Corresponding author: Harald J. Hamre, Dr med
E-mail address: harald.hamre@ifaemm.de

Acute painful pulpitis (inflammation of the tooth pulp) is one of the most common diagnoses in patients seeking acute dental care.[1-3] Causes of pulpitis include bacterial infections—eg, from caries, dental procedures, trauma, hyperocclusion (the affected tooth hits first when biting)—and chemical or thermal irritants.[4,5] According to symptoms and signs, painful pulpitis is classified as reversible or irreversible. Reversible pulpitis is associated with localized tooth pain of mild to moderate intensity, transient hypersensitivity to electrical or thermal stimuli or sweets, no previous history of pain, and no pain on percussion. Irreversible pulpitis is associated with moderate to severe pain that can be poorly localized, prolonged hypersensitivity, a previous history of pain, and sometimes pain on percussion. Unless treatment of precipitating causes such as hyperocclusion or caries leads to pain remission, painful pulpitis will usually require invasive dental treatment (pulp capping, root canal therapy, or tooth extraction). Reversible pulpitis can be treated by pulp capping, which entails the placing of a protective agent to the exposed pulp (direct capping) or nearly exposed pulp (indirect capping). Irreversible pulpitis requires root canal therapy, including removal of pulp tissue or tooth extraction.[5-8] Notably, the distinction between reversible and irreversible pulpitis is not always clear-cut (eg, different authors describe hypersensitivity to heat as suggestive of reversible[7] or irreversible pulpitis[5-8]), and the correlation between symptoms/signs and histological findings is imperfect.[6]

Pulpa dentis D30 (PD) is a medication used within anthroposophic medicine (AM). PD has been on the market since the 1970s and consists of pulpa dentis of the calf (*Bos taurus*) extracted with glycerol and prepared in a homeopathic D30 potency

TABLE 1 Potentized Organ Preparations Used in Anthroposophic Medicine

Pulpa Dentis D30 is a potentized organ preparation used in anthroposophic medicine (AM). AM is a complementary system of medicine founded by Rudolf Steiner and Ita Wegman.[10] AM involves special artistic and physical therapies and special medications. AM medications are made of mineral, botanical, or zoological origin or are chemically defined substances. All AM medications are manufactured according to Good Manufacturing Practices and national drug regulations; quality standards of raw materials and manufacturing methods are described in the Anthroposophic Pharmaceutical Codex.[9]

AM medications can be prepared in concentrated form or potentized.[9] During potentization, a procedure also used in homeopathy, the original substance is successively diluted, each dilution step involving a rhythmic succussion (repeated shaking of liquids) or trituration (grinding of solids into lactose monohydrate). A D30 potency (also called 30X) has been potentized in a 1:10 dilution for 30 times, resulting in a $1:10^{30}$ dilution. Since potencies beyond D23 do not contain any molecules of the original substance, effects cannot readily be explained by molecular mechanisms. However, a systematic review of in vitro studies found biological effects of potencies ≥D23 in nearly three-fourths of the studies and in more than two-thirds of the studies with highest quality.[11]

Potentized organ extracts from higher animals (potentized organ preparations) were introduced in homeopathy and further developed in AM.[12] Potentized organ preparations are believed to regulate physiological processes in the respective organ from which they are prepared.[13] In acute inflammations organ preparations are typically used in D30 potencies.[14] All potentized organ preparations used in AM are prepared from animals bred on selected biodynamic farms where meat or bone meal has never been used in the diet[15]; there is therefore no risk of prion transmission.

(Table 1).[9] For reversible pulpitis, PD has been used for pain relief and to avoid or postpone invasive dental treatment. PD can be used alone or combined with other AM medications.[16,17] For acute pulpitis, 1 mL PD is injected submucously in the mucobuccal fold adjacent to the affected tooth or applied orally.[17] PD applications may be repeated daily as needed. Costs are approximately 1.0 to 1.5 Euro for a 1 mL ampoule of PD. PD therapy for pulpitis has been evaluated in case reports and retrospective surveys.[18] We here present a prospective observational study of PD as monotherapy for acute reversible pulpitis without visible or radiological abnormalities.

METHODS

Design and Objective

This was a prospective, observational, open-label, single-arm therapy study in a dental primary care setting. The objective was to describe short-term clinical outcomes in patients treated with PD as monotherapy for acute reversible pulpitis without visible or radiological abnormalities.

Participating Dentists

All dentists certified by the Physicians' Association for Anthroposophical Medicine in Germany as AM dentists and working in primary care (n = 34) were invited to participate in the study. In addition, 13 dentists were contacted at AM congresses. Of these 47 dentists, 14 dentists agreed to participate, and 11 dentists recruited patients into the study (certified AM dentists: n = 9, contacted at AM congresses: n = 2). The dentists were regularly using PD for acute reversible pulpitis in their practices.

Eligibility Criteria

Patients seen in routine dental practice with a clinical diagnosis of acute reversible pulpitis were considered for inclusion. Inclusion criteria were

1) age ≥18 years;
2) localized dental pain;
3) sensitivity of the affected tooth to cold, heat, or percussion;
4) pain duration of 2 days to 6 weeks; and
5) starting treatment with PD as monotherapy.

Exclusion criteria were abnormal findings on visual inspection or radiological examination of the affected tooth (such as caries), pain from dysgnathia, trigeminal neuralgia, periodontal pain, marked signs of inflammation of the periodontal tissues, planned invasive dental treatment for pulpitis (pulp capping, root canal therapy, tooth extraction), planned treatment with antibiotics, and planned change in ongoing analgesic medication for the dental pain. All treatment including PD was administered at the discretion of the dentists; the decision to start treatment with PD was not subject to formal assessment.

Clinical Outcomes

Each patient was classified by the following predefined criteria.

Invasive Dental Treatment Avoided. No pulp capping, root canal treatment, or tooth extraction during the 10-day follow-up period after first PD application.

Pain Remission. *No Remission*. Reduction of pain intensity (documented on numeric rating scales from 0 "no pain" to 10 "worst possible pain") by <3 points, no pain reduction, or pain deterioration.

Partial Remission. Reduction of pain intensity by ≥3 points, sustained for at least 2 consecutive days.

Complete Remission. Reduction of pain intensity from ≥4 points immediately before first PD application to 0 or 1 point, sustained for at least 2 consecutive days.

Close Temporal Relationship Between PD and Remission. Complete or partial remission with a ratio "time to remission after first PD application vs pain duration prior to first PD application" <1:10. This criterion was chosen because a close temporal relationship between therapy administration and clinical response, in the absence of adjunctive therapies, suggests a causal relationship between therapy and clinical response. The ratio 1:10 as cutoff point has been suggested by several authors.[19,20]

Perceived Effectiveness of PD. Patients and dentists used ratings of "very effective" or "effective" vs "less effective," "ineffective," or "don't know."

Average pain intensity was calculated for patients with at least two evaluable pain score values before and after first PD application, respectively.

Data Collection

All data were documented with questionnaires returned in sealed envelopes to the study office (dentist questionnaire: returned on Day 10; patient questionnaires: returned on Days 0, 1, and 10). At study enrollment (Day 0) the dentists documented eligibility criteria, smoking, alcohol use, comorbid disorders, and adjunctive therapies for comorbid disorders; the patients documented pain in the past 14 days retrospectively, current pain, and the use of analgesics. During follow-up (Days 1-10), the dentists documented all treatment for pulpitis and adverse events and on Day 10, performed vitality tests with cold stimuli; the patients documented pain intensity in pain diaries; the dentists and patients independently documented analgesic use and on Day 10, the perceived effectiveness of PD. Pain intensity was documented daily; on Days -1, 0, and 1 every 2 hours; and on Day 0 also immediately before the first PD application. Pain quality was documented on Day 0, using eight predefined descriptors.

The patient follow-up responses were not available to the dentists. The dentists and patients received no financial or other compensation for study participation or use of PD.

The data were entered twice by two different persons into Microsoft Access 97 (Microsoft Corp, Redmond, Washington). The two datasets were compared and discrepancies resolved by checking with the original data.

Quality Assurance and Adherence to Regulations

The study was registered with the National Association of Statutory Health Insurance Physicians and the Federal Institute for Drugs and Medical Devices and conducted according to the Declaration of Helsinki and the International Conference on Harmonisation Good Clinical Practice guidelines. Written informed consent was obtained from all patients before enrollment. Because of the observational noninterventional nature of the study, approval by an ethics committee was not required.

Data Analysis

The data analysis (SPSS 14.0.1, SPSS Inc, Chicago, Illinois) was performed on all patients fulfilling the eligibility criteria. Missing values for pain intensity during sleep or for other reasons were replaced with mean values of the individual patient in the respective period (Day -1, Day 0 before PD, Day 0 after PD, Day 1, from first day with pain to PD, from PD to last day with pain); missing data for other outcomes were not replaced. *T*-test was used for paired continuous data.

RESULTS

Patient Recruitment and Follow-up

A total of 108 patients with a clinical diagnosis of acute reversible pulpitis were assessed for eligibility. Of these patients, 32 fulfilled all eligibility criteria and were included in the analysis; 76 patients were not included. Reasons for exclusions were the following: planned other treatment for pulpitis (n = 69), no localized dental pain (n = 2), pain duration <2 days (n = 3), and pain duration >6 weeks (n = 2). The five patients with pain duration <2 days or >6 weeks fulfilled all other eligibility criteria and received PD, and their ineligibility was detected after completion of the study documentation; none of these patients had invasive dental treatment, and four patients were evaluable for remission: complete remission (n = 1), partial remission (n = 2), no remission (n = 1).

The patients were enrolled from November 14, 2002, to August 15, 2003. The number of enrolled patients per dentist was one patient (n = 4 dentists), two to four patients (n = 5), and seven patients (n = 2). The dentist questionnaire (returned on Day 10) was available for all 32 patients; the patient questionnaires (returned on Days 0, 1, and 10) were available for 32, 28, and 25 patients, respectively. Pain remission status was evaluable in 24 patients, while eight patients had incomplete documentation of pain levels before (n = 3) or after (n = 7) first PD administration.

Baseline Data

Sociodemographics. Mean age was 42.6 ± 13.4 years (range 19-79 years); 23 of 31 evaluable patients were women. The patients smoked regularly (n = 4/28 evaluable patients) or occasionally (n = 2), or did not smoke (n = 22). Alcohol was consumed regularly (n = 1/26), occasionally (n = 14), or never (n = 11).

Dental Treatment Preceding Pulpitis. The dental pain had occurred after dental treatment in 22% (n = 7/32) of patients: preparation for crown (n = 1), placement of crown or bridge (n = 3), placement of ceramic inlay (n = 3). The interval between dental treatment and the first PD application was 4 to 5 days (n = 4) and 12 to 25 days (n = 3).

Pulpitis Leading to Recent Dental Treatment. The dental pain had led to unsuccessful dental treatment in 6% (n = 2/32) of patients: direct capping (n = 1) and placement of composite filling (n = 1). The interval between dental treatment and the first PD application was 15 and 7 days, respectively.

Dental Pain. The most frequently affected teeth were 14, 15, and 26 (each n = 3 patients) and 17, 24, 36, 37, and 46 (each n = 2). Pain duration prior to the first PD application was 2 to 6 days (n = 8/29 evaluable patients), 7 to 13 days (n = 6), 14 to 27 days (n = 7), and 28 to 42 days (n = 8), with a median duration of 14.0 days (interquartile range 5.5-31.5 days, mean 17.9 ± 13.5 days). Pain intensity immediately before the first PD application was 0 to 3 points (n = 6/29 evaluable patients), 4 to 6 points (n = 17), and 7 to 9 points (n = 6). Most common pain descriptors, with multiple responses possible, were "dull" (n = 12/32 patients), "persistent" (n = 10), "abruptly occurring" (n = 8), "gnawing" (n = 5), and "slowly swelling and subsiding" (n = 5).

Comorbidity. A comorbid disorder was present in 28% (n = 8/29) of evaluable patients. The most frequent comorbid disorders were hypertension (n = 3 patients) and psoriasis (n = 2).

Treatment

Treatment With PD and Analgesics. On Day 0, PD therapy

was administered to all 32 patients. The total number of PD applications, including the first application, was one (n = 9 patients), two (n = 12), three to four (n = 10), and seven (n = 1), with a median of two applications per patient (interquartile range 1-3). All PD applications were submucous injections, except for three patients who had PD orally on Day 0; two of these subsequently had one submucous PD injection on Day 3, and the third had no PD injections and was also not evaluable for remission status. Analgesics were used by nine patients (paracetamol [acetaminophen], acetylsalicylic acid, or ibuprofen: n = 6, codeine-containing analgesic: n = 1, homeopathic analgesics: n = 2).

Invasive Dental Treatment. A total of 19% (n = 6/32) of patients had root canal therapy, which was administered on Days 0-1 (n = 2), Days 4-6 (n = 3), and Day 11 (n = 1). No patients had pulp capping or tooth extraction.

Other Treatment for Pulpitis. A total of 16% (n = 5/32) of patients had other treatment for pulpitis. Two patients had dental treatment of the affected tooth (filling replaced on Day 1, polishing on Day 10), and three patients had other AM medications for pulpitis (A-70 orally on Day 0, Periodontium/Silicea comp injected together with PD on Days 2 and 9, respectively).

Clinical Outcomes

Avoidance of Invasive Dental Treatment. A total of 81% (n = 26/32) of patients did not require invasive dental treatment during follow-up. Vitality testing with cold stimuli was performed on Day 10 on these patients (n = 23 evaluable patients); the tooth was found to be vital in all 23 cases.

Pain Remission. A total of 63% (n = 15/24) of evaluable patients achieved pain remission, and 58% (n = 14/24) remitted without invasive dental treatment (complete remission n = 12, partial remission n = 2; examples in Figure 1). In the 14 patients with complete or partial remission without invasive dental treatment, time from first PD application to remission was 0 to 2 hours (n = 6 patients), 1 day (n = 2), 2 to 4 days (n = 3), and 5 to 8 days (n = 3); the ratio "time to remission after first PD application vs pain duration prior to first PD application" was <1:10 in seven patients and ≥1:10 in seven patients (Figure 1, patients 1 and 2). Remission status in the five patients who also had other treatment for pulpitis was complete remission on Day 7 (n = 1: filling replacement on Day 1, further PD injections on Day 3 and 4; see Figure 1, Patient 4), partial remission on Day 5 (n = 1: tooth polishing on Day 10), no remission (n = 1: A-70 on Day 0), and not evaluable (n = 2: Periodontium/Silicea comp).

Average Pain Intensity. Average pain intensity was calculated in patients with at least two evaluable pain score values before and after first PD application, respectively (n = 26 evaluable patients, Figure 2). Average pain intensity was approximately 4.3

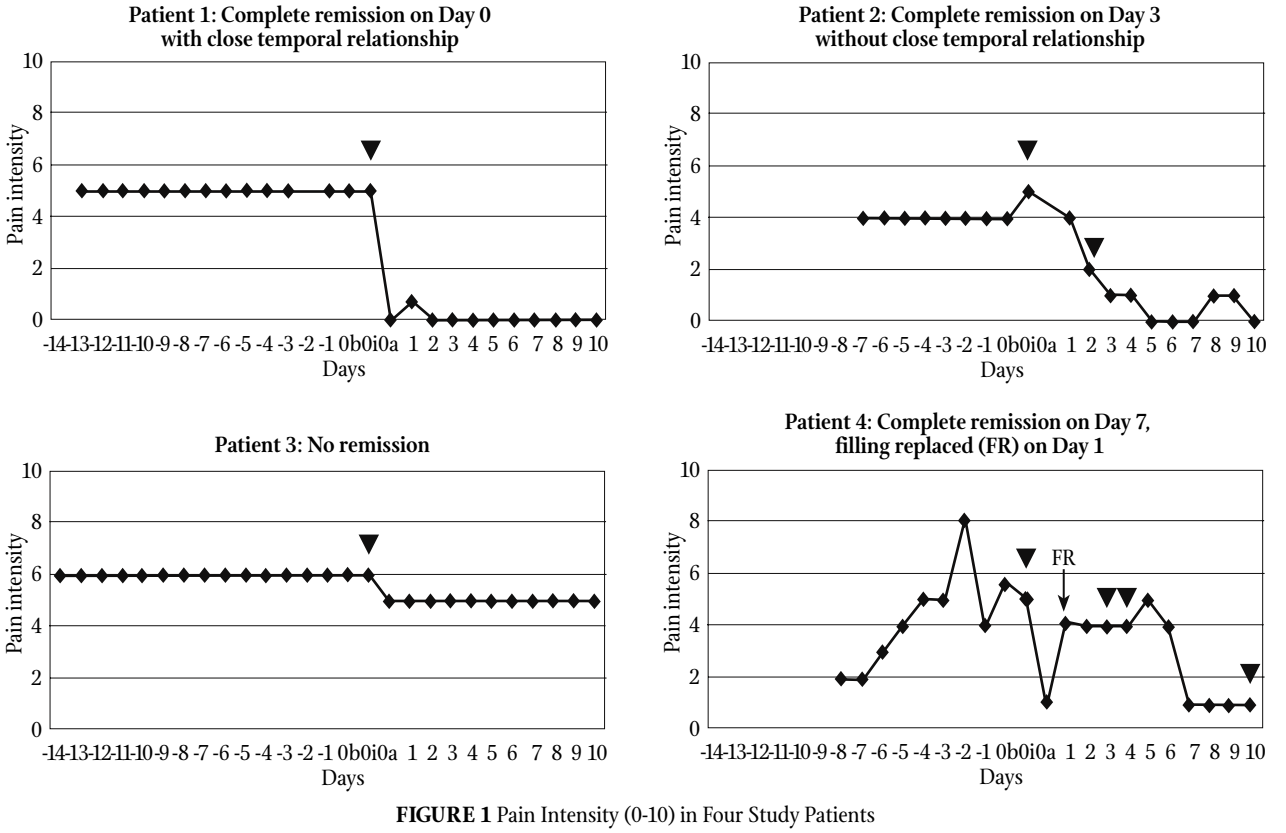

FIGURE 1 Pain Intensity (0-10) in Four Study Patients

Complete remission, no remission, close temporal relationship (see definitions in text). ▼ indicates Pulpa dentis application; 0b and 0a, intensity on Day 0 before and after first the Pulpa dentis application, respectively (average of score values documented every 2 h); 0ib, intensity immediately before first the Pulpa dentis application.

TABLE 2 Clinical Outcomes

Item	%	N
1. Invasive dental treatment (pulp capping, root canal therapy, tooth extraction) avoided	81%	26/32
2. Partial or complete remission	63%	15/24
3. 1 + 2	58%	14/24
4. 1 + 2 + Close temporal relationship between Pulpa dentis application and remission (see Methods for details)	29%	7/24
5. Pulpa dentis very effective or effective (patient rating on Day 10)	75%	18/24
6. Pulpa dentis very effective or effective (dentist rating on Day 10)	79%	23/29

points during Days -6 to -1, peaked at 5.15 ± 1.97 points immediately before first PD application (Figure 2, Day 0ib) and dropped to 3.10 ± 2.26 points on Day 0 after first PD application (Figure 2, Day 0a, average of score values documented every 2 hours), with a mean difference from Day 0ib to Day 0a of 2.05 points (95% confidence interval [CI] 1.15-2.95, $P < .001$). The corresponding difference in patients who did not require invasive dental treatment was 2.23 points (95% CI 0.51-1.16, $P < .001$, n = 21 evaluable patients, Figure 2). Pain intensity decreased further during Days 3 to 10.

Further outcomes are presented in Table 2. Adverse events did not occur during follow-up.

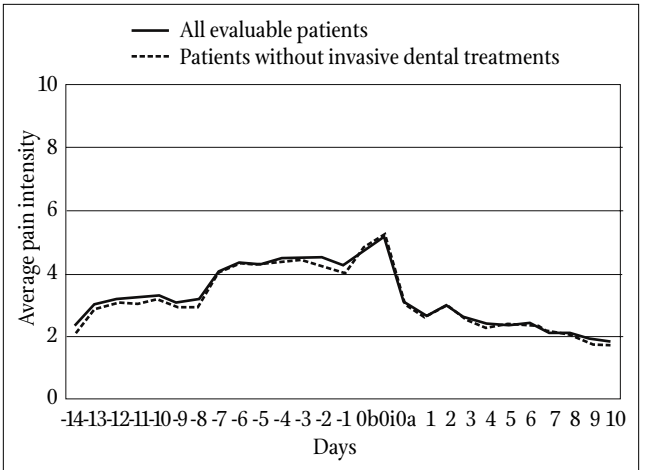

FIGURE 2 Average Pain Intensity (0-10)

Patients with at least two score values before and after first application of Pulpa dentis (all evaluable patients: n = 26, patients without invasive dental treatment: n = 21). 0b and 0a indicate intensity on Day 0 before and after first the Pulpa dentis application, respectively (average of score values documented every 2 h); 0ib, intensity immediately before first the Pulpa dentis application.

DISCUSSION

Main Findings

This is the first prospective study of PD for pulpitis. We studied 32 consecutive patients with a clinical diagnosis of acute reversible pulpitis without visible or radiological abnormalities where PD was administered for pain relief and to avoid invasive dental treatment. The latter goal was reached in 81% of patients. More than half the evaluable patients had complete or partial pain remission without invasive dental treatment, more than one-fourth had a close temporal relationship between the first PD application and pain remission, and one-fourth remitted within 2 hours after the first PD application.

Strengths and Limitations

Strengths of this study include a detailed assessment of treatment and pain outcome and a high representativeness. One-fourth of certified AM dentists working in primary care in Germany participated, and all eligible patients were enrolled. These features suggest that the study to a high degree mirrors the use of PD as monotherapy among AM dentists in primary care. It should be noted, however, that only one-third of the patients with acute reversible pulpitis seen by the participating dentists started PD as monotherapy (apart from analgesics) and were eligible for this study, whereas two-thirds required other treatment (eg, root canal therapy or other AM medications) and were not eligible. Compared to all patients treated for acute pulpitis in dental primary care, the study sample is therefore selected in two aspects: patients were seen by a subgroup of dentists offering AM therapy, and patients were deemed not to require immediate invasive dental treatment.

A limitation of the study is the small sample size. Also, since the study was open-label, it cannot distinguish between biological effects of PD and other possible effects from receiving injections (nonspecific physiological effects of an injection, placebo effects, observation bias), but this issue may be less important in emergency dental care. Pain intensity in the days prior to study inclusion was documented retrospectively and may be affected by recall bias.

Because the study did not have a control group, one has to consider other causes for the observed pain improvement apart from PD, such as adjunctive therapies. However, invasive dental treatment was required by only 19% of patients, and the remaining 81% had a significant and sustained pain improvement. Other adjunctive therapies were administered to five patients, but in only one of these the adjunctive therapy was followed by a documented remission, after an interval of 6 days (Figure 1, Patient 4).

Regression to the mean from study inclusion at symptom peaks is another factor to be considered. Average pain levels were stable in the last week before inclusion and increased by 0.85 points on Day 0 before first PD application (Figure 2). This increase may be due to egression from the mean[21] but may also represent true clinical deterioration. Correspondingly, regression to the mean could explain a maximum of 0.85 points of the subsequent average improvement.[21]

Natural recovery is also to be considered: Pulp inflammation may be spontaneously reversible, probably related to a host of factors that mediate the inflammatory response.[4] Therefore, spontaneous remission of pain, although unlikely to affect more

than half of study patients within a 10-day observation period, cannot be totally excluded.

Clinical outcomes also were assessed in individual patients, whereby more than half of evaluable patients had pain remission without invasive dental treatment for a condition where such treatment is usually considered mandatory,[6,7] and more than one-fourth remitted with a close temporal relationship between PD administration and remission (time to remission from first PD application <1:10 of pain duration prior to PD application), suggesting a causal relationship between treatment and remission.[19,20]

The 10-day follow-up period of this study would seem sufficient to assess acute pain relief but is short in regard to avoidance of root canal treatment and tooth extraction. Without long-term follow-up data, one cannot be certain that pain remission following PD application indicates a permanent inflammation reversal. Also, the inclusion criterion of pain duration of at least 2 days may have been unduly restrictive and not representative for clinical practice.

Because no universally accepted criteria for the diagnosis of acute reversible pulpitis exist,[5-8] study inclusion was based on a clinical diagnosis, which may vary across settings.

Clinical Implications in Context of the Published Literature

Complementary and alternative noninvasive therapies for acute reversible pulpitis seem to be little studied. A Medline search using the keywords *pulpitis* and *complementary therapies* yielded only two publications, and these did not refer to acute reversible pulpitis but to other topics (root canal therapy,[22] chronic pulpitis[23]). Acupuncture is used for dental pain, and a systematic review of controlled studies concluded that acupuncture can alleviate dental pain,[24] but the studies included in the review did not evaluate acute pulpitis but dental pain from other causes (experimental pain, drilling, tooth extraction, oral surgery).

The results of this study suggest that PD can effectively reduce pain in acute reversible pulpitis without visible or radiological abnormalities. PD therapy also could possibly reduce the need for invasive dental treatment such as pulp capping, root canal therapy, and tooth extraction. Invasive dental treatment usually is considered necessary to control pain in acute pulpitis but was avoided in 81% of study patients. However, due to the short follow-up period, this finding should be interpreted with caution.

Advantages of PD therapy are the easy administration, suitable for emergency care; the low cost; and the possibility to assess response from day to day and to switch to invasive dental treatment if a satisfactory response does not occur.

CONCLUSIONS

In this study, PD was administered as monotherapy for acute reversible pulpitis without visible or radiological abnormalities. More than half the patients achieved pain remission without invasive dental treatment such as pulp capping, root canal treatment, or tooth extraction. The open-label, pre-post design of the present study does not allow for conclusions about comparative effectiveness. However, more than one-fourth of patients remitted with a close temporal relationship between the first PD application and pain remission, suggesting a causal relationship between therapy and remission.

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