

ORIGINAL REPORT: EPIDEMIOLOGIC RESEARCH

Patient-Centered Dentinal Hypersensitivity Treatment Outcomes: Results from the National Dental PBRN

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Abstract: *Dentinal hypersensitivity (DH) can have a significant impact on oral health and functioning, and it is a clinical symptom commonly managed by dentists during routine clinical practice. DH symptoms are typically elicited by otherwise innocuous, nonpainful stimuli applied to exposed dentin (e.g., tactile stimuli, warming or cooling temperatures or air puffs). Treatment approaches have sought to directly target the dentinal pulp tissues or close dentinal tubules via dental office care and treatment services (fluoride varnishes, glutaraldehydes, bonding agents, sealants, oxalates, or lasers) or home care services (toothpastes or dentifrices containing fluoride or potassium nitrate compounds). The purpose of this prospective multicenter cohort study was to assess how community-based dentists from*

the National Dental Practice-Based Research Network (National Dental PBRN) manage DH and whether the effectiveness of DH treatments can be assessed in those settings. A total of 171 dentists recruited 1862 subjects with DH from their existing patients. Dentists then recommended and provided DH treatment as appropriate. Treatment choice was at the discretion of the dentists. Patients rated their DH pain at baseline and 1, 4, and 8 wk during the course of their treatments. They used pain intensity and unpleasantness visual analog scales and 4 labeled magnitude scales and rated their satisfaction with treatment after 8 wk. Patients were provided reminders postbaseline via email, texting, or voice mail. These patient-centered outcomes served as the principal measures for the assessment of treatment because treatments sought

to alleviate DH symptoms. The patients with DH who reported pain reduction from dentist-provided treatments (glutaraldehyde/HEMA [hydroxyethyl methacrylate] compounds, oxalates, and bonding agents), dentists' advice and counseling regarding oral habits and diet, and patient-applied fluoride toothpaste reported a concomitant positive rating of satisfaction with DH treatments. The results from this study support the feasibility of engaging network practices to assess the effectiveness of clinical DH treatments.

Knowledge Transfer Statement: *National Dental PBRN dentists provide a range of procedures to treat dentinal hypersensitivity. In this large nonrandomized study designed to assess clinical care and to capture patient-reported outcomes, about 60% of patients reported improvement*

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in pain. This study demonstrated the feasibility of engaging network dentists and their patients to assess treatment effectiveness. Future studies will explore the feasibility of imposing randomization and measuring patient compliance with treatment in the manner that this treatment is provided.

Keywords: National Dental Practice-Based Research Network, dentin sensitivity, pain, primary health care, clinical study, patient satisfaction

Introduction

Dentinal hypersensitivity (DH) is a clinical symptom that can have a significant impact on oral health and functioning. It is characterized as a sharp and short-acting pain typically elicited by thermal, tactile, or osmotic stimuli that are not normally perceived as painful (Dababneh et al. 1999). The prevalence of DH has ranged from 8% to 57% (with the large range likely related to differences in diagnostic criteria), principally afflicting middle-aged individuals and females (Dababneh et al. 1999; Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). As such, the occurrence of DH pain may influence food and drink choices as well as the performance of oral hygiene procedures.

DH diagnosis is established by the presence of dentinal pain in the absence of other potential sources of the pain, including dental caries, tooth fractures, or other painful conditions that may produce similar painful symptoms. The eliciting of pain by otherwise innocuous, nonpainful stimuli is similar to findings following injuries to the skin. Following trauma, unmyelinated C and small-diameter myelinated A δ fibers undergo sensitization with increased responsivity to nonnoxious stimuli as inflammatory mediators bind with small-diameter afferent nerve fibers (Fried et al. 2011). So, in the presence of dental caries, it is possible that similar mechanisms of sensitization may explain DH pain symptoms. However, DH frequently

occurs in the absence of inflamed dentin, so inflammation is not likely the culprit. Another possible explanation, the hydrodynamic theory of dentinal sensitivity (Brännström 1963), proposes that the movement of fluids within dentinal tubules stimulates pulpal nerves in response to physical stimuli, such as warming and cooling temperatures and air puffs; however, tactile stimuli are not likely to alter fluid movement. Other reported theories fail to fully explain why a variety of stimuli evoke DH pain.

Clinical approaches to the management of DH address the problem of exposed dentin, the presumed site responsible for DH symptoms. The exposed dentin can be the result of 1) tooth wear following erosion related to acidic beverages or food or endogenous sources; 2) abrasion of tooth surfaces following mechanical stimulation; or 3) abfraction that results from degradation of the tooth structure in the cervical region, likely related to compressive and tensile stresses associated with occlusal function and gingival recession. Treatment approaches have sought to directly target the dentinal pulp tissues or close the dentinal tubules (Holland et al. 1997; Orchardson and Gillam 2006).

Common recommended treatments include home care or dental office care and treatment services that seek to occlude dentinal tubules or destroy vital tissue within the tubules. Home care services include toothpastes and dentifrices containing fluoride or potassium nitrate compounds. Dental office care/treatment services include dental sealants, varnishes, and restorations or more potent versions of the home care approaches, such as fluoride varnishes, glutaraldehydes, bonding agents, (potassium) oxalates, or lasers (Orchardson and Gillam 2006). Clinical management of DH may also involve counseling when diet or oral habits are viewed as contributing factors.

The purpose of this study was to assess the how dentists from the National Dental Practice-Based Research Network (National Dental PBRN) manage DH in routine clinical practice

and to assess the feasibility of engaging network practices to assess treatment effectiveness. Dentists recruited subjects with DH from their existing patients and documented clinical measures relevant to DH consistent with the study protocol. They then recommended and provided DH treatment, as appropriate. Treatment choice was at the discretion of the dentists. Patients rated their DH pain during the course of their treatments and rated their satisfaction with treatment after 8 wk. These patient-centered outcomes, including ratings of pain levels and satisfaction with treatment, served as the principal measures for the assessment of treatment because treatments sought to alleviate patient DH pain. In addition to determining statistically significant reduction in pain to assess treatment effectiveness, we assessed the percentage of patients who achieved “clinically significant pain reduction” (Farrar et al. 2000; Robinson et al. 2005) across all treatments. The incorporation of this latter measure provided a patient-centered assessment of treatment that is clinically meaningful and provides a valid measure of treatment effectiveness.

Results from this study provided initial assessments of DH treatment effectiveness (treatment performance under “real world” conditions) rather than treatment efficacy (performance under controlled circumstances that would typically include randomization of treatments and treatment controls; Revicki and Frank 1999; Godwin et al. 2003).

Methods

Community-based patients (≥ 19 y) with DH symptoms were recruited by 171 National Dental PBRN clinicians in a prospective multicenter cohort study that assessed patient-centered outcomes (pain and patient satisfaction with treatment) following dentist-recommended DH treatments (Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). The design and structure of the network have been described

Table 1.
Patient Cumulative Accrual by Month.

Month	Patient Accrual, <i>n</i>	
	Monthly	Cumulative
April 1 to 30, 2015	35	35
May 1 to 31, 2015	144	179
June 1 to 30, 2015	306	485
July 1 to 31, 2015	328	813
August 1 to 31, 2015	411	1,224
September 1 to 30, 2015	301	1,525
October 1 to 31, 2015	236	1,761
November 1 to 30, 2015	116	1,877
December 1 to 31, 2015	1	1,878

elsewhere (Gilbert et al. 2013; <http://www.nationaldentalpbrn.org>). Network dentists were invited to enroll in the study from March to the end of July 2015. A total of 171 dentists completed the requisite network training regarding human subjects and conflict of interest and completed the informed consent. Characteristics of the participating dentists, including demographics, practice location, and type, and their treatment preferences for DH have been reported (Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). Patient recruitment commenced in network practices from April 2015 until the end of December 2015 (see Table 1). Of the 1,862 enrolled patients, 92% ($n = 1,713$) completed their follow-up appointments by the end of May 2016. Females represented 74% of the patients. The patients' sociodemographic characteristics have been described elsewhere (Kopycka-Kedzierawski, Meyerowitz, Litaker, Heft, et al. 2017). More than 85% of patients reported that their current DH symptoms had lasted for >1 mo (36.2% from 1 mo to 1 y, 46.6% for >1 y).

Prior to recruiting patients to the study, dentists completed an online questionnaire that queried background information regarding how they routinely

and most frequently diagnose DH and what treatment modalities they routinely use to manage DH (Table 2; Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). Given the objectives of the study, dentists' delivery of clinical procedures for DH was conducted per their usual routine and not standardized. This report conforms with the STROBE guidelines (Strengthening the Reporting of Observational Studies in Epidemiology) for the conduct and dissemination of observational studies.

Dentists identified subjects with DH (patients self-reported as having sensitive teeth) from among their patients who satisfied the following inclusion criteria: age ≥ 19 y; ≥ 1 tooth diagnosed with DH (excluding third molars); access to a telephone and willingness to be contacted over the course of the study via text message, email, or telephone (based on their preference) related to the study by the practice, regional coordinator, and the Westat Coordinating Center; and willingness to provide the name and contact information of an individual living at another location who could contact the patient if he or she could not be reached. DH diagnosis was not standardized and was established by the dentist. The most commonly

Table 2.
Dentist-Recommended Treatments for Dentinal Hypersensitivity by Frequency of Mention.

Treatment
Fluoride
Fluoride gel
Fluoride varnish
Fluoride paste
Fluoride rinse
OTC potassium nitrate toothpaste
Glutaraldehyde/HEMA
Bonding agents
Sealants
Restorative treatments
Lasers
Oxalates
No treatment ^a

HEMA, hydroxyethyl methacrylate; OTC, over the counter.

^aReceived dentists' advice and counseling regarding habits.

reported DH diagnosis methods were as follows: patient report confirmed by clinical examination (48%), pain in response to an air blast (26%), and pain in response to scratching dentin with a dental explorer (12%; Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). The exclusion criteria included having a medical condition that could affect the reliable reporting of DH symptoms (e.g., cognitive impairments), having a chronic pain condition (e.g., temporomandibular disorders or fibromyalgia), having other dental or pulpal pain, or taking recent (i.e., within the previous week) analgesic medications (e.g., nonsteroidal anti-inflammatory or narcotic drugs) >3 times per week.

At the baseline visit, dentists completed the clinical history form and indicated their treatment choice. Patients in the study completed a dental history form, which included sociodemographic

information, and rated their DH pain using visual analog and labeled magnitude (LM) scales (described later). Patients also rated their DH pain 1, 4, and 8 wk later. They also rated their satisfaction with treatment at the 8-wk session. These tasks were completed online, or the paperwork was mailed to the regional coordinators.

Measures

DH Pain

Patients rated their DH pain at baseline prior to treatment and then after the initiation of treatment at 1, 4, and 8 wk. They were asked to rate the DH that they experienced within the past day (24 h) using 2 visual analog scales (VASs; Price et al. 1983) of pain intensity and unpleasantness and 4 LM scales. For the VASs, they rated 1) their pain intensity by placing a vertical line on a horizontal 100-mm line with the end points “not painful” and “most intense pain imaginable” and 2) their unpleasantness by placing a vertical line on a horizontal 100-mm line with the end points “not unpleasant” and “most unpleasant sensation imaginable.”

Patients also rated the DH qualities using LM scales developed for this clinical condition (Cunha-Cruz et al. 2013; Heaton et al. 2013). For the LM ratings, patients placed vertical lines on 4 horizontal 100-mm lines, each of which included descriptive terms to assess the “duration,” “intensity,” “tolerability” and “pain description” of the DH pain. The lower end point for each of these measures is “no pain.”

Satisfaction with Treatment

Patients rated their satisfaction with DH treatment at 8 wk after the initiation of treatment by placing a vertical line on a 100-mm horizontal line with the end points “dissatisfied” and “completely satisfied.”

For all scales, the measures were recorded as the distances from the lower end point to the vertical lines. All forms used in the study are publicly available at <http://www.nationaldentalpbrn.org/study-results/management-of-dentin-hypersensitivity.php>.

Data Analysis

Primary analyses were conducted with the 2 VASs and 4 LM scales as outcome variables for the 13 treatment items listed in Table 2, including “no treatment.” “No treatment” principally included dentists’ advice and counseling regarding modifying toothbrushing rigor and type of toothbrush or toothpaste, reduction in the ingestion of acidic foods and drinks, or discontinuation of tooth-whitening products (Kopycka-Kedzierawski, Meyerowitz, Litaker, Heft, et al. 2017).

Analyses of pain scale scores were conducted with mixed linear models to account for correlated observations due to clustering within dentists and repeated measurements within patients. An unstructured correlation matrix was modeled. Terms representing dentist and patient were included as random effects. Fixed effect terms were included for time, treatment, and the interaction of time and treatment.

Treatment groups were based on each patient’s having received or not received a specific treatment recommendation or combination of treatment recommendations. The comparison group for each analysis included all patients who did not receive the particular recommendation.

Comparisons among estimated marginal group and interaction means were conducted with Šidák’s (1967) adjustment for multiple comparisons. Exploratory analyses to characterize associations among scores from the pain scales were conducted with correlation analyses and factor analyses, separately by week of observation. Analyses were implemented with SAS 9.4 (SAS Institute Inc.).

Results

At baseline, 1,862 eligible patients enrolled, and 1,645 (88.3%), 1,701 (91.4%), and 1,696 (91.1%) completed the 1-, 4-, and 8-wk follow-up sessions, respectively. Patient characteristics are more comprehensively described elsewhere (Kopycka-Kedzierawski, Meyerowitz, Litaker, Heft, et al. 2017). The patients were predominantly female

(74%), and the mean (SD) ages were as follows: females, 44.4 y (13.6) and males, 45.7 y (13.6). Patients had 4.2 (4.8) sensitive teeth predominantly associated with gingival recession (70.2%) or visible dentin (53.6%). Approximately half (890 of 1862, 48%) received recommendations for 1 treatment modality, and 35% received recommendations for a combination of 2 treatment modalities.

Table 3 reports the mean baseline DH pain ratings recorded for the 4 LM scales and 2 VASs. Patients recorded their DH pain at baseline, 1 wk after treatment or treatment commenced, 4 wk, and 8 wk. A factor analysis of the patients’ ratings of their DH with the 4 LM scales and the 2 VASs indicated that the LM ratings were highly correlated with the VAS measures, so only the pain intensity and unpleasantness VAS ratings were used for the treatment outcome analyses.

To provide for tests of effectiveness, each DH treatment was compared separately against all other treatments. Table 4 provides results for the pain intensity and unpleasantness ratings analyses. Significant DH pain improvement was demonstrated following 3 dentist-provided treatments—glutaraldehyde/HEMA (hydroxyethyl methacrylate) compounds, oxalates, and bonding agents—and patient-applied fluoride toothpastes. In addition, patients who received dentists’ advice and counseling regarding habits and diet reported DH pain reduction.

Patients assessed their treatment satisfaction at 8 wk only. Models including baseline pain score, treatment, and satisfaction suggest that 8-wk satisfaction and baseline pain were associated with change in pain score but treatment type was not. A reduction in pain was associated with higher satisfaction scores. The single measurement of satisfaction at 8 wk does not provide information regarding whether high satisfaction might drive a decrease in pain. The Pearson correlations between satisfaction and each VAS pain change score are about -0.21 , indicating that a higher satisfaction rating is associated with more negative

Table 3.
Baseline Dentinal Hypersensitivity Pain Ratings Based on the 4 Labeled Magnitude Scales and 2 Visual Analog Scales.

Scales	Ratings, mm
Labeled magnitude scales	
Duration	44.1 (16.0)
Intensity	49.4 (19.1)
Tolerability	36.8 (16.9)
Description	50.2 (26.5)
Visual analog scales	
Pain intensity ^a	40.4 (23.4)
Unpleasantness ^b	43.2 (23.9)

^aEnd points: “not painful” and “most intense pain imaginable.”

^bEnd points: “not unpleasant” and “most unpleasant sensation imaginable.”

change scores. Based on the correlation, satisfaction explains about only 4% of the variability of change in pain score.

Pain VASs and similar measurement scales provide individual pain measures that allow for statistical tests of group pain treatment effectiveness. Several investigators have suggested that in comparing groups of patients, a statistically significant reduction in pain does not necessarily mean that the pain reduction is “clinically important” for an individual patient (Farrar et al. 2000; Robinson et al. 2005). Robinson et al. (2005) demonstrated that pain reduction of 56% represented clinically significant pain reduction in patients with chronic pain experiencing their symptoms for >1 mo (mean = 92.9 mo). We determined the percentage of our study patients achieving the 56% pain reduction threshold suggested by Robinson et al. as reflecting treatment success from the patient perspective. Approximately 60% of enrolled patients received clinically important pain reduction (VAS intensity = 61.8%, VAS unpleasantness = 61.1%).

Discussion

The results from this study support the feasibility of engaging network practices to assess the effectiveness of clinical DH treatments. The preferred

primary treatments for DH as chosen by the study dentists were over-the-counter potassium nitrate toothpaste (48% of dentists) and fluoride formulations (38% of dentists). They also reported using glutaraldehyde/HEMA products, bonding agents, sealants, and oxalates and providing advice to patients regarding diet and oral habits (Kopycka-Kedzierawski, Meyerowitz, Litaker, Chonowski, et al. 2017). The patients with DH who reported pain reduction from dentist-provided treatments—glutaraldehyde/HEMA compounds, oxalates, and bonding agents as well as advice and counseling regarding habits and diet—and patient-applied fluoride toothpaste reported a concomitant positive rating of satisfaction with DH treatment. Furthermore, approximately 60% of patients reported “clinically significant pain relief” (pain reduction >56% on the VASs).

Pain symptoms fluctuate temporally due to changes in pain perceptions related to sensations and cognitions about events associated with the sensations (Staud et al. 2010; O’Brien et al. 2011). Beyond applying treatments that alter the local environments and recommending changes in behaviors that might affect DH local factors, factors other than dental treatment may influence posttreatment pain

reports. These factors provide potential confounds in studies that are assessing interventions provided by multiple dentists where pain report is an outcome measure, because there are differences among dentists in the information that they provide to patients. Furthermore, it is important to understand that outcome of a treatment involves the full context of treatment, including the treatment choice as well as the dentist’s explanation of the causes of the DH, the treatment choice, and the likely resolution of the problem. As such, counseling provides the patient with a plausible explanation for the cause of the pain, expectations for the future course of the underlying cause of the pain, and ways to deal with the DH symptoms (Price et al. 2005). This is an important issue that requires standardization among dentists in treatment studies.

VASs of pain intensity and unpleasantness provided reliable patient-centered pain outcomes for assessing DH treatment. The patients also rated their DH using LM scales. The baseline-rated VAS and LM pain scores were approximately twice as large as those reported by Cunha-Cruz et al. (2013; VAS pain, 19.9 [20.4]; LM intensity, 25.2 [23.7], LM duration, 20.7 [18.9], LM tolerability, 15.8 [16.5], LM pain description, 27.3 [28.6]). Their patients rated their DH on a 100-mm VAS with the end points “no pain” and “worst pain imaginable” in response to a 1-s air blast from a dental air-water syringe. The differences in rated DH pain among our patients might be due to the fact that their baseline pain was reported by patients and not evoked by the dentists; thus, their spontaneous pain levels may have been greater.

The patient LM ratings from study patients consistently covaried with the VAS measures. As such, they were not included in the assessment of DH treatment outcomes. Furthermore, the VAS pain measures were valid assessments in that pain reduction predicted patient satisfaction with treatment.

Strengths of the present study included the use of clinical dental practices for data collection with a standardization of patient enrollment, patient records, and

Table 4.

Visual Analog Scale “Pain Intensity” and “Unpleasantness” Comparisons between Those Having Received and Not Received the Specific Treatment Recommendations.

Treatment	Patients, <i>n</i>	Pain Intensity		Unpleasantness	
		<i>F</i> Statistic	<i>P</i> Value ^a	<i>F</i> Statistic	<i>P</i> Value ^a
Fluoride	63	0.16	0.9219	0.85	0.4645
Fluoride gel	115	1.03	0.3766	1.31	0.2697
Fluoride varnish	515	1.13	0.3341	1.46	0.2237
Fluoride paste	314	4.48	0.0039	1.42	0.2364
Fluoride rinse	97	0.35	0.7858	0.86	0.4587
OTC potassium nitrate toothpaste	923	1.56	0.198	1.01	0.3868
Glutaraldehyde/HEMA	98	3.12	0.0251	4.71	0.0028
Bonding agents	89	6.69	0.0002	5.61	0.0008
Sealants	6	1.53	0.2049	2.28	0.078
Restorative treatments	151	1.58	0.1918	1.29	0.2769
Lasers	13	0.31	0.82	0.55	0.6451
Oxalates	76	1.99	0.1134	2.84	0.0366
No treatment	96	8.60	<0.001	10.30	<0.001

HEMA, hydroxyethyl methacrylate; OTC, over the counter.

^aTreatment × week.

outcomes measures. However, the goals of the study were to assess how network dentists identify and treat DH pain in the practice setting and to demonstrate the feasibility of engaging network practices for assessing DH treatment effectiveness.

The National Dental PBRN provides a diverse “real world” setting for the conduct of clinical studies whose outcomes can affect clinical dental practice. The present study demonstrated the value of this structure for the conduct of an initial study of DH treatment effectiveness. Future studies may explore the feasibility of imposing randomization, engaging patients as their own treatment controls, and measuring patient compliance with the treatment as actually provided in routine clinical practice by network dentists.

Author Contributions

M.W. Heft contributed to the conception, design, data analysis, and interpretation, drafted and critically

revised the manuscript; M.S. Litaker, contributed to data analysis and interpretation, drafted and critically revised the manuscript; D.T. Kopycka-Kedzierawski, contributed to conception, design, and data acquisition, drafted and critically revised the manuscript; C. Meyerowitz, S. Chonowski, R.L. Yardic, R. Mungia, contributed to conception, design, and data acquisition, critically revised the manuscript; V.V. Gordan, contributed to design, critically revised the manuscript; G.H. Gilbert contributed to the conception and design, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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