Development and preliminary evaluation of a new screening instrument for atypical odontalgia and persistent dentoalveolar pain disorder.

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Abstract:

Aim: To develop and preliminarily evaluate a new screening instrument for Atypical Odontalgia (AO) or Persistent Dentoalveolar Pain Disorder (PDAP). To evaluate the instrument's performance in detecting AO/PDAP amongst a heterogeneous group of orofacial pain conditions and pain-free controls and empirically compare its performance with an established neuropathic screening instrument (S-LANSS) which is the best available standard.

Methods: The study design was cross-sectional; subjects recruited included a convenience sample of pain free controls (n=21) and four groups of orofacial pain conditions: AO/PDAP (n=22); Trigeminal Neuralgia (n=21); Temporomandibular Disorder (n=41); and Acute Dental Pain (n=41). The instrument's internal reliability and factor structure were examined alongside its sensitivity and specificity and ROC-determined threshold score.

Results: The 9 AO/PDAP specific items were found to moderately correlate with the S-LANSS ($r=0.58$; $p<0.01$). The 14-items of the full instrument were examined using exploratory factor analysis and reduced to ten items in a two-factor structure that explained 96% of the variance. This 10-item final instrument had a ROC area of 0.77 (95% CI: 0.67; 0.88), sensitivity of 77% (95%CI: 55; 92%), and specificity of 69% (95%CI: 60; 77%) with an intentionally higher false-positive rate than false-negative rate. In contrast, the S-LANSS exhibited sensitivity of 32% (95%CI: 14;55%) and specificity of 78% (95%CI: 70;85%) with less-optimal false-positive versus false-negative rates.

Conclusion: This preliminary study shows the new screening instrument for AO/PDAP merits progression to field testing.

Introduction

Pain related to the teeth (odontogenic pain) is the most common orofacial pain, estimated to affect between 8-12% of individuals in developed countries (Lipton *et al.* 1993, Steele *et al.* 2011). Odontogenic pain is primarily inflammatory in nature (Berman & Rotstein 2016) and the underlying dental disease that produces odontogenic pain often necessitates an invasive procedure resulting in deafferentation, e.g. root canal treatment or tooth extraction. Both root canal treatment and extraction are common practice in developed countries: U.S. ~20 million endodontic procedures and ~55 million tooth extractions (American Dental Association Survey 2007); U.K. ~600,000 endodontic procedures and ~1.3 million extractions (NHSDigital 2016).

Dental treatments requiring deafferentation result in a small number of patients experiencing persistent, post-procedural, non-odontogenic pain **localised** in the tooth site (Marbach 1993, Nixdorf *et al.* 2012). Uncertainty exists whether this pain was actually present before the deafferentation procedure due to reports of the phenomenon in the absence of deafferentation (Schnurr & Brooke 1992, Ram *et al.* 2009) . When this phenomenon follows a deafferentation procedure it is presumed to be largely of neuropathic origin (Baad-Hansen 2008) and has been referred to variously as: atypical odontalgia (AO) (Woda & Pionchon 1999, IHS 2004, Ram *et al.* 2009), Persistent DentoAlveolar Pain disorder (PDAP) (Nixdorf & Moana-Filho 2011, Nixdorf *et al.* 2012), phantom tooth pain (Marbach 1978), and painful post traumatic trigeminal neuropathy (PPTTN, International Classification of Headache Disorders 3 [ICHD-3]) (Benoliel *et al.* 2012a, Benoliel *et al.* 2012b,

IHS 2013, IHS 2018). Given the uncertainty regarding its nomenclature, pathophysiology, and disease course, the two most common terms used in the literature to refer to the phenomenon will be used throughout this paper: Atypical Odontalgia and Persistent Dentoalveolar Pain disorder (AO/PDAP).

Individuals experiencing AO/PDAP following deafferentation procedures are unlikely to experience pain reduction with endodontic non-surgical retreatment, or further surgical intervention (Marbach 1978, Oshima *et al.* 2009). It is important, therefore, to identify AO/PDAP cases early in their course thereby preventing any further dental treatments that are irreversible, ineffective, and may contribute to worsening morbidity (Durham & Nixdorf 2014, Durham & Nixdorf 2014). A brief standardized AO/PDAP screening instrument would be a practical way to begin the process of identification of putative AO/PDAP cases. This approach would parallel similar approaches to screening for other conditions in medicine and dentistry (Maizels *et al.* 2006, Price *et al.* 2010, Schiffman *et al.* 2014). Screening instruments for neuropathic pain in medical clinics have become accepted clinical practice due to a number of factors including the inherent complexity of diagnosing neuropathic pain (Bennett *et al.* 2007). The same complexity exists within dental clinics and orofacial pain and therefore it is likely that dental practice could similarly benefit from a such a screening instrument.

To date, three studies have examined the use of general (i.e. not restricted to orofacial conditions) neuropathic pain screening instruments in screening

orofacial pain (Klasser *et al.* 2011, Elias *et al.* 2014, Herrero Babiloni *et al.* 2017). In patients with a post-traumatic inferior alveolar or lingual nerve injury, the PAINdetect instrument lacked sensitivity for trigeminal neuropathy (Elias *et al.* 2014). Two other studies used a modified version of the Self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) questionnaire (Klasser *et al.* 2011, Herrero Babiloni *et al.* 2017) with its performance being superior to PAINdetect but still lacking sufficient sensitivity and specificity in AO/PDAP.

The orofacial region has unique symptom characteristics and nociception from this region is mainly conducted by the trigeminal nerve. Given that the trigeminal nerve innervates specialized structures and has unique somatosensory properties, nociception from the orofacial region may be perceived, interpreted and/or reported differently than nociception from other persistent pain conditions elsewhere in the body (Schnurr & Brooke 1992, Dworkin 1999, Bereiter *et al.* 2000). This may account for the limitations apparent in the adaptation of more generic whole-body neuropathic screening instruments, such as S-LANSS, into the dental setting (Herrero Babiloni *et al.* 2017). Given this, an ongoing programme of work (Durham *et al.* 2013, Durham & Nixdorf 2014) has examined the characteristics and impacts of AO/PDAP from the patient's perspective in order to identify items for a self-report screening instrument (Durham *et al.* 2013). The aim of the current study was to develop and preliminarily evaluate the screening instrument's performance in detecting AO/PDAP amongst a heterogeneous group of orofacial pain conditions and pain-free controls and empirically compare its

performance with an established neuropathic screening instrument (S-LANSS) which is the best available standard.

Materials and Methods

Ethical approval was obtained (University of Minnesota IRB: 1104S98353) and written, informed consent obtained from all participants. The present report follows the Standards for Reporting of Diagnostic Accuracy (STARD) (Bossuyt *et al.* 2003).

Participants and procedures

This study was cross-sectional and utilised a convenience sample of AO/PDAP patients, three other orofacial pain conditions, and a pain-free control group. The three groups of other orofacial pain conditions were: temporomandibular disorders (TMD), trigeminal neuralgia, and acute dental pain. The three other orofacial pain conditions were chosen on the basis of the likelihood that they may mimic AO/PDAP and thereby provide a more exacting test of the screening instrument. All of the TMD and TN patients, and the majority of AO/PDAP patients were recruited from the TMD, Orofacial Pain and Dental Sleep Medicine Clinic (University of Minnesota, USA). Two of the AO/PDAP patients were recruited from private orofacial pain practice (Minneapolis-Saint Paul, MN). Patients experiencing acute dental pain were recruited from a private endodontic practice, (Minneapolis-Saint Paul, MN). The pain-free controls were recruited by approaching accompanying persons at the School of Dentistry (University of Minnesota, MN) and people in the university community.

The following inclusion criteria applied to all study participants:

- Eighteen years of age or older;

- Ability to converse fluently in English;
- Met the diagnostic criteria for the respective group assignment.

The exclusion criteria for the study were:

- Unable to provide informed consent;
- Any history of trauma to the orofacial region throughout their life course;
- Any history of TMJ surgery or intra-articular steroid injection;
- Any lifetime history of a major systemic illness related to altered pain sensitivity, for example fibromyalgia or other widespread bodily pains (even if resolved).

Assignment to the AO/PDAP group was based on each participant meeting the diagnostic criteria for AO, PDAP, and PPTTN (Table e1, Appendix) and having all other potential causes of the pain phenomenon excluded by appropriate (clinical) investigation (Woda & Pionchon 1999, IHS 2004, Nixdorf & Moana-Filho 2011, Nixdorf *et al.* 2012, IHS 2013, IHS 2018). Classification was performed by an experienced board-certified clinicians who were trained and calibrated in a previous study (Nixdorf *et al.* 2015).

For the other three orofacial pain conditions, reference standard criteria were followed. Assignment to the painful TMD sample was based on myalgia, myofascial pain, or arthralgia, according to Diagnostic Criteria for TMD (DC/TMD) (Schiffman *et al.* 2014). Assignment to the acute dental pain group was based on the diagnostic criteria of Gutmann *et al*. (2009) pertaining to

irreversible pulpitis and/or symptomatic apical periodontitis applied by a specialist board-certified endodontist (Nixdorf *et al.* 2015). Assignment to the Trigeminal Neuralgia sample was based on use of the ICHD-II Diagnostic Criteria for the diagnosis of Classical Trigeminal Neuralgia (IHS 2004). Pain-free controls confirmed that they had no pain in the face, mouth, teeth, jaws, or ears in the last three months; and had not sought dental treatment within the last three months.

A total of six instruments, including the AO/PDAP screening instrument, were presented individually to the participants in a predetermined randomised sequence (permuted block). Putative participants were flagged by the clinical team to research team members uninvolved in the patient's care and they then gave a standardised explanation of the instruments to the participant. Participants were recompensed $20 U.S. for the time it took to complete the instruments.

Measures and instruments

A case report form was completed by the clinical team, recording individuals' socioeconomic/demographic status and clinical diagnosis. Besides the AO/PDAP screening instrument, the modified Self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) was also completed as a reference to allow an empirical comparison for the performance of the AO/PDAP screening instrument. S-LANSS was chosen in preference to the next most common generic neuropathic pain-screening

instrument because it has good sensitivity and specificity for general neuropathic pain (Bennett *et al.* 2005) whereas the PainDETECT demonstrated poor sensitivity for trigeminal neuropathy (Elias *et al.* 2014).

The putative full fourteen-item AO/PDAP screening instrument examined in this study is outlined in supplemental Figure e1. Nine of its fourteen items were constructed from the recurring themes in a previously reported qualitative research study regarding patients suffering from AO/PDAP (Durham & Nixdorf 2014). These nine items ("AO/PDAP specific items" Q1,6-11,13-14, in Figure e1) were worded to mirror the terms used by participants in the qualitative study in order to ensure sufficient face validity for American English speakers. The remaining five items (Q2,3,4,5,12), giving rise to the 14-item instrument, were added based on expert opinion of two board-certified orofacial pain clinicians (JD & DRN) in order to increase the specificity of the instrument in relation to the other common orofacial pain conditions (TMD, TN, Acute dental pain). The AO/PDAP screening instrument was given a standard bipolar scoring system of: -2 strongly disagree to 2 strongly agree, with neither agree nor disagree scored as 0. Items 3,4,5, and 12 were reverse scored. A simple sum of the item scores was used to generate a summary score.

The S-LANSS used in the study was adapted for use intra-orally (Klasser *et al.* 2011), by relating each S-LANSS item to intraoral tissues as described in full by Herrero Babiloni *et al*. (2017). The scoring system and threshold values

for a positive response to the items (≥12) remained the same as the original S-LANSS (Bennett *et al.* 2005), consistent with Klasser *et al*. (2011).

Data management and analysis

All data were inputted into Microsoft Excel (Microsoft Excel 2010, Microsoft Corporation, Redmond, Washington) by research team members uninvolved in the participants' care and the data were then crosschecked for concordance (DRN/JD). There were no missing data in the subjects who comprised the sample used for analysis. Simple descriptive statistics and inferential parametric statistics were used to examine the data. For between-group comparisons, family-wise Bonferroni correction to the p-value was used. In all other cases, the significance level was set to alpha=0.05. All analyses were performed using STATA release 13 (Stata Statistical Software. StataCorp LP, College Station, TX, USA). The analyses were divided into two phases: in the first phase, only the 9 AO/PDAP specific items were assessed, while in the second phase, all 14 items were included in the analyses.

Phase 1 – internal reliability (Cronbach's alpha) was calculated for the nine AO/PDAP specific items. Exploratory factor analysis was then used to identify whether these nine AO/PDAP specific items were unidimensional. The exploratory factor analysis was conducted using principal factor analysis with a polychoric correlation matrix and excluding the control group (as they have no orofacial pain). The number of factors to be retained was determined from the point of inflexion in the scree plot and a second exploratory factor analysis

retaining all factors with an eigenvalue>1.0 provided a comparison analysis. Finally, in Phase 1, the ability of the AO/PDAP specific items to differentiate cases (those with AO/PDAP) from all comparison groups was examined. We used the standard bipolar simple scoring system to calculate a summary score for the nine AO/PDAP specific items and then used this score in a ROC analysis to determine the most appropriate threshold for a positive screening for AO/PDAP (a 'true positive') and its resultant sensitivity and specificity. This performance was empirically compared to that of the S-LANSS in determining an AO/PDAP case from a comparator. Convergent validity of the summary score of the nine AO/PDAP specific items and the S-LANSS' summary score was also assessed using a Pearson correlation.

Phase 2 - the putative full 14-item AO/PDAP screening instrument was subject to another exploratory factor analysis using the same principal factor approach and matrix. Poorly performing items (i.e. those with factors loadings $<\pm 0.4$ (Matsunaga 2010) or cross-loadings of $\geq\pm 0.4$ on two or more factors) were removed. Once the final item list was established, a new ROC analysis of the revised items' summary score was computed to determine the threshold for a positive screening for AO/PDAP and its resultant sensitivity and specificity.

Results

The sociodemographics of the sample and their diagnoses are provided in Table 1. The patients were predominately female (72%), with a mean age of 49 (SD±16) years old. Table e2 in the appendix contains specific details on the characteristics of the AO/PDAP cohort. The mean summary standard score per instrument by condition is shown in Table 2 and a one-way ANOVA demonstrated that the conditions differ in their AO/PDAP screening instrument score. Supplemental Table e3 displays the mean scores by item of the AO/PDAP screening instrument.

Phase 1 - Cronbach's alpha for the nine AO/PDAP specific items using a simple summary score was 0.83. The exploratory factor analysis returned a single-factor solution that explained 61% of the total variance (Table 3 and Table e4 for polychoric correlation matrix) even after exploring other factor structures with oblique rotation. Items 6 and 9 did, however, have very poor loadings on the single factor.

The AO/PDAP specific nine-item simple summary score moderately correlated with the S-LANSS summary score ($r=0.58$; $p<0.01$). The ROC analysis for the AO/PDAP specific items' summary score demonstrated the optimum threshold as ≥3 (ROC area=0.71; 95%CI: 0.60-0.81). The sensitivity and specificity for the AO/PDAP specific items at this threshold and that of the S-LANSS at its standard threshold along with their confidence intervals with the true positive being a clinically-determined AO/PDAP diagnosis are shown

in Table 4. Compared to the AO/PDAP specific nine-item summary score, S-LANSS had better specificity (78%) but lower sensitivity (32%).

Phase 2 – Following the addition of the five expert-derived items the exploratory factor analysis of the now 14-item instrument returned a three-factor structure with a weak third factor (Eigen value 1.02) explaining 87% of the variance. Three factors were retained and oblique rotation performed (Table e5 appendix) and subsequently two items were removed for weak loading on all factors: item 7 “times when pain intensity increases”, and item 12 “better with over-the-counter pain medications…”. Re-running the exploratory factor analysis on the remaining 12 items demonstrated a two-factor structure explaining 82% of the variance (Table e6 appendix).

An iterative process explored the remaining factor structures related to the other items that either: had loaded heavily on the third factor (items 5 “best described as sharp, stabbing, or electrical” and 6 “generally a dull ache”); or cross-loaded in the three-factor model (items 1 “pain never stops” and 9 “able to locate the pain accurately”). The factor structure that best explained the majority of the variance (96%) was a two-factor model that dropped items 6 and 9 in addition to items 7 and 12 that had been dropped in the previous iteration. The remaining 10-item screening instrument is shown in the appendix (Table e7) and a final version for clinical use is shown in Figure e2 .

The ROC area of the 10-item finalised AO/PDAP screening instrument was 0.77 (95%CI: 0.67; 0.88) and demonstrated the optimum threshold for the summary score as ≥1. The 10-item AO/PDAP screening instrument (appendix figure e2) improved the point estimates of sensitivity and specificity of the instrument compared to the AO/PDAP specific nine-item version (Table 4) with Cronbach's alpha calculated at 0.83.

Discussion

In this study, development of the AO/PDAP screening instrument and a preliminary evaluation of its performance in detecting cases of AO/PDAP in a convenience sample was performed. Our results suggest that the final 10-item AO/PDAP screening instrument measures 2 constructs and has modest sensitivity of 77% (95% CI: 55%-92%) and specificity of 69% (95% CI: 60%-77%). Empirically this compares favourably to the S-LANSS: sensitivity 32% (95% CI: 14%-55%), specificity 78% (95% CI: 70%-85%), and the nine AO/PDAP-specific items within the screening instrument also had a moderate convergent validity with the S-LANSS ($r=0.58$; $p<0.01$). The sensitivity and specificity point estimates suggest that as long as the AO/PDAP screening instrument is *used with prudence* alongside standard clinical investigation and examination it represents one way by which those without orofacial pain expertise can increase their diagnostic suspicion of AO/PDAP following treatments involving deafferentation.

The challenge of screening for AO/PDAP involves differentiating between multiple and potentially comorbid conditions producing pain within the orofacial region. A useful screening tool must contain items identifying key (diagnostic) features of the condition in question. With AO/PDAP, this is more challenging, as the disorder is underreported, poorly understood, and the idiosyncrasies of the condition had not been accurately detailed before recent qualitative research (Durham & Nixdorf 2014). This qualitative research helped define the key recurrent characteristics of the pain associated with AO/PDAP, which were then used to help produce the AO/PDAP-specific items

within the screening instrument. These characteristics are covered elsewhere (Durham *et al.* 2013), but briefly they are: constant nature; low intensity with variability producing acute exacerbations; pressure-like phenomenon felt deep within bone or tooth; adjunctive features such as itchiness, prickling, or tingling.

As a preliminary evaluation of the screening instrument this study has limitations. The methodology used didn't seek to confirm content validity; however the nine items derived from patients (Durham & Nixdorf 2014) do provide a patient-centred approach. The other properties that are yet to be examined include face validity, test-retest reliability, and responsiveness to change. Further validity studies are required in other languages in order to ensure that the constructs of each statement remain semantically and culturally relevant to the target population; this is particularly relevant given the complex symptom characteristics. Future studies will also provide independent datasets with which to re-examine the current study's estimates of the instrument's sensitivity and specificity as it is possible given the current study refined and tested the instrument using the same dataset the estimates of sensitivity and specificity may be inflated.

The study remuneration was provided as a token of our appreciation of the time participants spent completing the study documentation. It is conceivable, however, that despite its low value it influenced individuals' responses, but we

believe this is unlikely given they were unaware of which questionnaires related to which condition. Despite recruiting for a considerable period of time and offering a gratuity, the limited number of individuals (n=22) in the AO/PDAP group is indicative of its low prevalence and therefore the difficulty of recruiting such individuals. A future direction to address both sample size and cultural differences would be to conduct such research across countries with the participation of multiple clinical research groups, such as with the use of a registry of patients suffering from AO/PDAP. The convenience sample was selected to give the instrument the broadest and most exacting evaluation but does not replicate the reality of everyday clinical practice. It is conceivable that the point estimates of sensitivity and specificity for the instrument may increase or decrease in routine practice settings hence further field testing is required. Furthermore any future field testing should seek to control bias in a rigorous manner.

At present, the authors suggest that the AO/PDAP screening instrument, produces sufficient sensitivity and specificity (77% and 69% respectively), to represent a step-forward for identifying putative AO/PDAP cases that may need specialist examination prior to any further investigation or intervention. The AO/PDAP screening instrument will, however, be *prone to false positives* and practitioners should bear this in mind when using it and ensure they use all the clinical information at their disposal before making a putative positive screen for AO/PDAP using the finalised ten item screen shown in Appendix Figure e2. It may be that with the recent emergence of the utility of qualitative sensory testing in differentiating AO/PDAP from controls (Baad-Hansen *et al.*

2013a, Baad-Hansen *et al.* 2013b) that the combination of somatosensory changes (gain or loss in cold, light touch, pin-prick) detected by qualitative sensory testing chairside and the use of the screening instrument may present an opportunity for a step change in the diagnosis of AO/PDAP which currently is a diagnosis of exclusion.

In a general dentistry setting, the use of the AO/PDAP screening instrument is particularly desirable because dentists are comfortable diagnosing odontogenic pain but generally may be less comfortable with non-odontogenic pains. The current psychometric properties of the AO/PDAP screening instrument represent an acceptable trade-off between sensitivity and specificity as they will help decrease morbidity through non-productive dental treatment for a problem that is no longer dental. The authors would recommend, therefore, that best use of the AO/PDAP screening instrument is as an adjunct to the regular diagnostic process when signs, symptoms, and investigations do not clearly indicate an odontogenic or TMD as source for the patient's "tooth" pain complaint. Given the nature and origins of the screening instrument it will screen for any of AO, PDAP, or PPTTN as the samples used in its development included participants who fitted the criteria for all of these conditions.

Conclusion

Given the current options available to help with identifying AO/PDAP early in its course following deafferentation treatments the AO/PDAP Screener has

sufficient sensitivity and specificity to begin field testing on a larger and multinational scale. It must, however, be used alongside careful and appropriate clinical examination and investigation.

Author Contributions

J. Durham & D. R. Nixdorf secured funding, led study conception and design, provider oversight during data collection, contributed to interpretation of data and drafted and critically revised the manuscript. S.J. Stone, R. Ohrbach, L.Robinson contributed to data analysis and interpretation and drafted and critically revised the manuscript.

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Conflicts of interest

The Authors declare that there are no conflicts of interest.

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Supporting information

There is an appendix document which contains 2 figures and 7 tables in order to give the reader further details on both the instrument and the data collected. This singular word document is meant for viewing online via the journal's website.

Tables

Table 1 – Sample socioeconomic and demographic status

	Control n=21	AO/ PDAP n=22	TN n=21	TMD n=41	ADP n=41	Total n=146
Gender n(%)						
Female	13(62)	20(91)	14(67)	35(85)	23(56)	105(72)
Male	8(38)	2(9)	7(33)	6(15)	18(44)	41(28)
Age Mean(SD)	45(14)	52(12)	60(18)	45(17)	48(12)	49(16)
Race n(%)						
White	19(90)	22(100)	20(95)	37(90)	32(78)	130(89)
Black or African American	0(0)	0(0)	0(0)	2(5)	3(7)	5(3)
Other	2(10)	0(0)	1(5)	2(5)	6(15)	11(8)
Income n(%)[a]						
<$10,000	2(10)	2(9)	5(24)	10(24)	3(7)	22(15)
$10,000-$29,999	3(15)	2(9)	2(10)	12(29)	3(7)	22(15)
$30,000-49,999	4(20)	6(27)	6(29)	3(7)	11(27)	30(21)
≥$50,000	11(55)	12(55)	8(38)	16(39)	24(59)	71(49)
Level of education n(%)						
Pre High and High School	0(0)	5 (23)	3 (14)	7 (17)	6 (15)	21 (14)
Some college	2(10)	1(5)	7(33)	13(32)	13(32)	36(25)
College degree	4(19)	6(27)	5(24)	18(44)	14(34)	47(32)
Advanced or graduate degree	15(71)	10(45)	6(29)	3(7)	8(20)	42(29)
Dental Insurance n(%)						
Uninsured	7(33)	1(5)	8(38)	7(17)	4(10)	27(18)
Insured	14(67)	21(95)	13(62)	34(83)	37(90)	119(82)

[a] 1 individual did not declare their income bracket

TN – Trigeminal neuralgia; TMD - Temporomandibular Disorders; ADP – Acute Dental Pain; AO/PDAP – Atypical Odontalgia/Persistent DentoAlveolar Pain Disorder

Table 2 – Mean scores by instrument and by pain condition

Clinical diagnosis	AO/PDAP screening instrument* [95% CI]	S-LANSS Mean Score [95% CI]
Control	-7.05 [a,b]	0 [c]
	[-8.07; -6.02]	[0.00; 0.00]
AO/PDAP	6.73[a]	10.59 [c]
	[4.53; 8.93]	[7.83; 13.35]
TN	0.86 [b]	9.52 [c]
	[-1.02; 2.73]	[6.45; 12.59]
TMD	3 [b]	7.27 [c, d]
	[1.54; 4.46]	[5.17; 9.37]
ADP	1 [b]	11.05 [c, d]
	[-0.47; 2.47]	[8.93; 13.17]

* Full fourteen item version of AO/PDAP Screener mean simple summary score using bipolar scoring

[a]One-way ANOVA with post hoc Bonferroni correction significantly higher scores in AO/PDAP cases compared to controls, ADP ($F(4,141)=36.52$, $p<0.001$)

[b]One-way ANOVA with post hoc Bonferroni correction significantly higher scores in TN, TMD, and ADP cases than in controls ($F(4,141)=36.52$, $p<0.001$).

[c]One-way ANOVA with post hoc Bonferroni correction significantly higher scores in AO/PDAP, TN, TMD, and ADP cases than in controls ($F(4,141)=12.77$, $p<0.0001$);

[d]One-way ANOVA with post hoc Bonferroni correction significantly higher scores in ADP cases compared to TMD cases ($F(4,141)=12.77$, $p<0.05$).

TN – Trigeminal neuralgia; TMD - Temporomandibular Disorders; ADP – Acute Dental Pain; AO/PDAP – Atypical Odontalgia/Persistent DentoAlveolar Pain Disord

Table 3 – Principal factor analysis for nine AO/PDAP specific items using standard bipolar scoring system

Item	Principal factor analysis	
	Factor loading	**Uniqueness**
1. This pain never stops; it seems to always be there.	0.52	0.73
6. This pain is generally a dull ache.	0.06	0.99
7. There can be times when the pain intensity increases (pain attack) and then it returns to its usual level.	0.44	0.81
8. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.	0.32	0.90
9. I feel I am able to locate the pain accurately, for example to a particular tooth or small area in my mouth.	0.08	0.99
10. This pain feels like it is deep within the tooth or jaw bone.	0.54	0.71
11. This pain feels like a pressure within the tooth or jaw bone	0.53	0.72
13. This pain is difficult for me to describe to others.	0.51	0.74
14. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.	0.28	0.91

Kaiser-Meyer-Olkin measure of sampling adequacy = 0.827

Bartlett's test of sphericity $\chi^2 = 407.18$; *df=36; p=0*

Table 4 – Sensitivity and specificity of AO/PDAP screening instrument in 9 and 10 item forms, and S-LANSS summary score

	Sensitivity		Specificity	
	Point estimate	95% CI	Point estimate	95% CI
AO/PDAP-specific nine items simple summary score using bipolar scoring system (threshold ≥3)	68%	45% 86%	58%	49% 67%
AO/PDAP screening instrument (10 items) simple summary score using bipolar scoring system per item (threshold ≥1)	77%	55% 92%	69%	60% 77%
S-LANSS (threshold ≥12)	32%	14% 55%	78%	70% 85%

Supplemental information and appendix:

Supplementary Figure e1 - Full fourteen item AO/PDAP Screener

1. This pain never stops; it seems to always be there.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

2. This pain moves around, sometimes it seems to be mainly in one area and at other times it seems to be in other areas.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

3. This pain is a throbbing type of pain.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

4. This pain wakes me up at night.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

5. This pain is best described as sharp, stabbing, or electrical bouts of pain that are intense, brief in duration (lasting for seconds or less).

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

6. This pain is generally a dull ache.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

7. There can be times when the pain intensity increases (pain attack) and then it returns to its usual level.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

8. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

9. I feel I am able to locate the pain accurately, for example to a particular tooth or small area in my mouth.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

10. This pain feels like it is deep within the tooth or jaw bone.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

11. This pain feels like a pressure within the tooth or jaw bone.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

12. This pain is made better with taking over the counter “pain medications”, such as ibuprofen.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

13. This pain is difficult for me to describe to others.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

14. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

Supplementary Figure e2 – Finalised ten item AO/PDAP screener for clinical use.

- Please leave **NO** question unanswered

- Please **CIRCLE** your response to the question using the response options provided underneath each question: strongly disagree, disagree, neither agree nor disagree, strongly agree, agree

1. This pain never stops; it seems to always be there.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

2. This pain moves around, sometimes it seems to be mainly in one area and at other times it seems to be in other areas.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

3. This pain is a throbbing type of pain.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

4. This pain wakes me up at night.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

5. This pain is best described as sharp, stabbing, or electrical bouts of pain that are intense, brief in duration (lasting for seconds or less).

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

6. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

7. This pain feels like it is deep within the tooth or jaw bone.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

8. This pain feels like a pressure within the tooth or jaw bone.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

9. This pain is difficult for me to describe to others.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

10. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.

STRONGLY DISAGREE DISAGREE NEITHER AGREE NOR DISAGREE AGREE STRONGLY AGREE

There are NO more questions to answer in this booklet, thank you

For office use (**remove this text prior to issuing the instrument to patients**):

Scoring instructions:

-2 to 2 for strongly disagree to strongly agree for all items except for 3, 4, and 5 where reverse scoring is used (*i.e*. strongly agree is -2 and strongly disagree is 2).

To calculate the total score for the AO/PDAP screening instrument we recommend the simple sum method whereby the response scores of all items are summed. The threshold for a positive screen is ≥1.

The interpretation of the AO/PDAP screening instrument's threshold score being met or exceeded is that it is **not** likely that the pain is from an odontogenic or TMD cause. Therefore, neuropathic or idiopathic aetiologies may be present and further investigation is warranted.

Below is a scored example of the AO/PDAP screening instrument *(* indicates reverse scoring item*):

Item	**Response given**	**Score**
1	Strongly agree	2
2	Agree	1
3*	Neither agree nor disagree	0
4*	Disagree	1
5*	Strongly disagree	2
6	Neither agree nor disagree	0
7	Strongly disagree	-2
8	Strongly agree	2
9	Neither agree nor disagree	0
10	Strongly agree	2
Total score (sum)		8

Interpretation of score: Exceeds threshold of 1 and therefore patient's pain is **not** likely to be of odontogenic or TMD aetiology.

Supplementary Table e1 – Diagnostic criteria for Atypical odontalgia (AO), Persistent Dentoalveolar Pain disorder (PDAP), and Painful Post Traumatic Trigeminal Neuropathy (PPTTN) (IHS 2004, Nixdorf *et al.* 2012, IHS 2013, IHS 2018)

Condition	**Summary of diagnostic criteria as they relate to phenomenon of interest for this study**
Atypical odontalgia	1. Pain is localized to a tooth that is present in the mouth or has recently been extracted. 2. Pain has been present for the last 4 to 6 months or has returned periodically in the same form over the last period of months or years. 3. Pain is continuous throughout all or part of the day except during sleep. 4. The pain has no major paroxysmal character. 5. Clinical or radiographic examination does not reveal any obvious cause of pain.
Painful Post Traumatic Trigeminal Neuropathy	A. Facial and/or oral pain in the distribution(s) of one or both trigeminal nerve(s) and fulfilling criterion C B. History of an identifiable traumatic event to the trigeminal nerve(s), with clinically evident positive (hyperalgesia, allodynia) and/or negative (hypoaesthesia, hypoalgesia) signs of trigeminal nerve dysfunction C. Evidence of causation demonstrated by both of the following: 1. pain is localized to the distribution(s) of the trigeminal nerve(s) affected by the traumatic event 2. pain has developed < 6 months after the traumatic event D. Not better accounted for by another ICHD-3 diagnosis.
Persistent dentoalveolar pain (PDAP) - Secondary	1. Persistent pain (at least 8hrs per day for ≥15days per month). Present for ≥3 months 2. Localised in the dentoalveolar region(s) 3. Not caused by another disease or disorder 4. In close temporal relationship to a causal event (e.g. dental procedures, facial trauma, infection,…) 5. Sensory abnormality present or absent

Supplementary Table e2 - Characteristics of AO/PDAP cohort and final screener score

Case id*	Age	Gender	Level of education	Tooth site. Universal/USA system (FDI/Canadian system)	Dental Arch	Tooth Type	Deafferentation preceding pain	RCT of painful tooth	Total n of RCT to painful tooth	Painful tooth extracted prior to clinic visit	Finalised 10 item screener summary score‡
1	66	Female	Advance/Graduate Degree	9 (21)	Mx	Central incisor	Yes	Yes	1	No	1
2	51	Female	Advance/Graduate Degree	9 (21)	Mx	Central incisor	Yes	Yes	2	Yes	3
3	28	Female	Advance/Graduate Degree	19 (36)	Mn	1st molar	No†	No	0	No	**-8**
4	28	Male	College Degree	3 (16)	Mx	1st molar	Yes	Yes	1	Yes	9
5	66	Female	High School	Missing data							4
6	42	Female	College Degree	14 (26)	Mx	1st molar	Yes	Yes	1	Yes	3
7	57	Female	Advance/Graduate Degree	5 (14)	Mx	1st premolar	Yes	Yes	4	Yes	3
8	49	Female	Advance/Graduate Degree	5 (14)	Mx	1st premolar	Yes	Yes	3	No	5
9	63	Female	High School	11 (23)	Mx	Canine	Yes	Yes	2	No	9
10	59	Female	Advance/Graduate Degree	4 (15)	Mx	2nd premolar	Yes	Yes	1	No	**-1**
11	58	Female	High School	7 (12)	Mx	Lateral incisor	Yes	Yes	1	Yes	**0**
12	37	Female	College Degree	14 (26)	Mx	1st molar	No†	No	0	No	2
13	60	Female	College Degree	13 (25)	Mx	2nd premolar	Yes	Yes	2	No	**-1**
14	35	Female	College Degree	Missing data							1
15	65	Male	Some College	10 (22)	Mx	Lateral incisor	Yes	Yes	2	Yes	2
16	56	Female	Advance/Graduate Degree	9 (21)	Mx	Central incisor	Yes	Yes	2	No	**-4**
17	57	Female	High School	29 (45)	Mn	2nd premolar	Yes	Yes	2	No	8
18	46	Female	Advance/Graduate Degree	3 (16)	Mx	1st molar	Yes	Yes	1	Yes	9
19	64	Female	Advance/Graduate Degree	3 (16)	Mx	1st molar	Yes	Yes	1	No	1

Case id*	Age	Gender	Level of education	Tooth site. Universal/USA system (FDI/Canadian system)	Dental Arch	Tooth Type	Deafferentation preceding pain	RCT of painful tooth	Total n of RCT to painful tooth	Painful tooth extracted prior to clinic visit	Finalised 10 item screener summary score‡
20	66	Female	High School	12 (24)	Mx	1st premolar	Yes	Yes	2	No	5
21	48	Female	Advance/Graduate Degree	7 (12)	Mx	Lateral incisor	Yes	Yes	2	No	5
22	42	Female	College Degree	14 (26)	Mx	1st molar	Yes	Yes	2	Yes	3

RCT – Root canal treatment; Mx – maxillary dentition; Mn Mandibular dentition.

** All cases were of white ethnic origin and all had cone-beam computed tomography of the painful site/tooth and also a brain and face MRI to exclude other pathology.*

†Both of these cases had experienced a traumatic event affecting the tooth in question within 3-6 months of the pain beginning and therefore fitted PPTTN diagnostic criteria (Appendix table e1)

‡ Scores of individual cases from the finalised 10 item screener (Figure e2). Emboldened figures are where the case failed to meet the threshold for a positive screen (≥1). Given the heterogeneity of the phenomenon under investigation and the idiosyncratic nature of the experience and description of pain this variation is to be expected.

Supplementary Table e3 – Simple ordinal mean scores by item of AO/PDAP screener

Study group	**Control**		**AO/PDAP**		**TN**		**TMD**		**ADP**	
Item number	Mean score	95% Confidence interval	Mean score	95% Confidence interval	Mean score	95% Confidence interval	Mean score	95% Confidence interval	Mean score	95% Confidence interval
1	-3.62	[-4.17;-3.07]	2	[1.01;2.99]	-0.67	[-1.96;0.63]	0.24	[-0.68;1.17]	0	[-0.85;0.85]
2	1.9	[1.71;2.10]	0.55	[-0.12;1.21]	-0.52	[-1.21;0.16]	-0.07	[-0.54;0.40]	-0.1	[-0.55;0.35]
3	1.9	[1.71;2.10]	0.18	[-0.38;0.74]	0.24	[-0.34;0.81]	0.05	[-0.41;0.51]	-0.54	[-0.95;-0.12]
4	1.9	[1.71;2.10]	0.32	[-0.20;0.84]	0.29	[-0.34;0.92]	0.41	[0.00;0.83]	-0.32	[-0.78;0.14]
5	1.9	[1.71;2.10]	1.18	[0.66;1.71]	-1.24	[-1.73;-0.74]	0.54	[0.11;0.97]	0.27	[-0.18;0.71]
6	-3.81	[-4.21;-3.41]	1.82	[0.87;2.76]	-0.19	[-1.26;0.88]	1.61	[0.98;2.24]	0.98	[0.27;1.68]
7	-1.9	[-2.10;-1.71]	0.45	[-0.17;1.08]	1.05	[0.48;1.61]	0.68	[0.32;1.05]	0.9	[0.54;1.27]
8	-1.9	[-2.10;-1.71]	-0.45	[-1.00;0.09]	-0.1	[-0.63;0.44]	-0.39	[-0.79;0.01]	-0.66	[-0.95;-0.37]
9	-1.71	[-2.15;-1.28]	0.59	[-0.09;1.27]	0.76	[0.19;1.34]	1.1	[0.75;1.45]	1.02	[0.63;1.42]
10	-3.81	[-4.21;-3.41]	2.09	[1.12;3.06]	0.86	[-0.35;2.06]	1.27	[0.51;2.03]	1.95	[1.30;2.61]
11	-1.9	[-2.10;-1.71]	0.45	[-0.11;1.01]	-0.29	[-0.92;0.34]	0.27	[-0.13;0.67]	0.71	[0.39;1.02]
12	1.62	[1.25;1.99]	0.36	[-0.19;0.92]	1	[0.57;1.43]	-0.05	[-0.36;0.26]	-0.56	[-0.91;-0.21]
13	-3.05	[-3.84;-2.25]	0.91	[-0.24;2.06]	0.57	[-0.55;1.69]	-0.2	[-1.04;0.65]	-1.17	[-1.88;-0.47]
14	-1.71	[-2.04;-1.39]	-0.32	[-0.95;0.31]	-0.62	[-1.17;-0.07]	-1	[-1.35;-0.65]	-0.61	[-0.98;-0.24]

AO/PDAP – Atypical odontalgia/persistent DentoAlveolar Pain disorder; TN – Trigeminal Neuralgia; TMD – Temporomandibular Disorder; ADP – Acute dental pain

Supplementary Table e4 – Polychoric correlation matrix from exploratory factor analysis of 9 AO/PDAP specific items

Item number from the original 14	1	6	7	8	9	10	11	13	14
1	1.00								
6	0.24	1.00							
7	0.15	0.01	1.00						
8	0.07	0.05	0.31	1.00					
9	0.16	0.19	0.14	-0.20	1.00				
10	0.36	0.12	0.19	-0.10	0.28	1.00			
11	0.21	-0.09	0.14	0.12	0.03	0.51	1.00		
13	0.34	-0.05	0.27	0.33	-0.26	0.06	0.18	1.00	
14	0.09	-0.23	0.20	0.20	-0.09	0.03	0.11	0.26	1.00

Supplementary Table e5 – Rotated exploratory factor analysis of putative full fourteen item screener explaining 87% of variance

Item and number	Factor Loading			Uniqueness
	Factor 1	Factor 2	Factor 3	
1. This pain never stops; it seems to always be there.	0.20	***0.52***	*0.51*	0.50
2. This pain moves around, sometimes it seems to be mainly in one area and at other times it seems to be in other areas.	**0.67**	-0.12	-0.04	0.57
3. This pain is a throbbing type of pain*	-0.25	**-0.47**	0.13	0.60
4. This pain wakes me up at night*	-0.30	**-0.44**	0.15	0.57
5. This pain is best described as sharp, stabbing, or electrical bouts of pain that are intense, brief in duration (lasting for seconds or less).*	-0.03	-0.07	**0.75**	0.40
6. This pain is generally a dull ache.	0.03	0.18	**0.60**	0.65
7. There can be times when the pain intensity increases (pain attack) and then it returns to its usual level.	0.26†	0.29†	-0.20†	0.71
8. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.	**0.59**	0.03	-0.02	0.63
9. I feel I am able to locate the pain accurately, for example to a particular tooth or small area in my mouth.	***-0.51***	*0.42*	-0.04	0.70
10. This pain feels like it is deep within the tooth or jaw bone.	-0.23	**0.74**	0.07	0.50
11. This pain feels like a pressure within the tooth or jaw bone	0.01	**0.58**	-0.10	0.63
12. This pain is made better with taking over the counter “pain medications”, such as ibuprofen.*	0.10†	-0.12†	0.17†	0.96
13. This pain is difficult for me to describe to others.	**0.65**	0.05	0.16	0.60
14. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.	**0.35**	0.04	-0.19	0.79

†Poorly performing item across all factors.
*Items are reverse scored
Expert derived items are:2,3,4, & 5
Emboldened figures are strongest factor loading for item
Italicised figures indicate cross-loading on more than one factor

Supplementary Table e6 – Exploratory factor analysis with oblique rotation of interim twelve item screener (items 7 and 12 dropped because of very poor loadings) explaining 82% of the variance

Item and number	Factor Loading		Uniqueness
	Factor 1	Factor 2	
1. This pain never stops; it seems to always be there.	0.30	**0.53**	0.63
2. This pain moves around, sometimes it seems to be mainly in one area and at other times it seems to be in other areas.	**0.47**	-0.32	0.68
3. This pain is a throbbing type of pain*	**-0.61**	-0.14	0.60
4. This pain wakes me up at night*	**-0.65**	-0.09	0.57
5. This pain is best described as sharp, stabbing, or electrical bouts of pain that are intense, brief in duration (lasting for seconds or less).*	-0.39†	0.34†	0.73
6. This pain is generally a dull ache.	-0.16	**0.43**	0.79
8. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.	**0.51**	-0.19	0.70
9. I feel I am able to locate the pain accurately, for example to a particular tooth or small area in my mouth.	-0.15	**0.44**	0.79
10. This pain feels like it is deep within the tooth or jaw bone.	0.31	**0.61**	0.54
11. This pain feels like a pressure within the tooth or jaw bone	**0.50**	0.33	0.64
13. This pain is difficult for me to describe to others.	**0.51**	-0.11	0.73
14. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.	**0.42**	-0.20	0.78

*Items are reverse scored
†Poorly performing item across all factors.
Expert derived items are:2,3,4, & 5
Emboldened figures are strongest factor loading for item

Supplementary Table e7 - Exploratory factor analysis with oblique rotation of ten item screener (items 6,7, 9 and 12 dropped in first factor analysis because of very poor loadings [7 &12] and cross-loading [6 &9]) explaining 96% of the variance

Item and number	Factor Loading		Uniqueness
	Factor 1	Factor 2	
1. This pain never stops; it seems to always be there.	-0.01	**0.56**	0.69
2. This pain moves around, sometimes it seems to be mainly in one area and at other times it seems to be in other areas.	**0.60**	-0.15	0.66
3. This pain is a throbbing type of pain*	**-0.44**	-0.36	0.60
4. This pain wakes me up at night*	**-0.51**	-0.31	0.57
5. This pain is best described as sharp, stabbing, or electrical bouts of pain that are intense, brief in duration (lasting for seconds or less).*	**-0.45**	0.12	0.81
8. This pain gets worse with changes of atmospheric pressure, for example during bad weather, scuba diving, airplane travel.	**0.61**	-0.06	0.64
10. This pain feels like it is deep within the tooth or jaw bone.	-0.12	**0.71**	0.52
11. This pain feels like a pressure within the tooth or jaw bone	0.15	**0.58**	0.59
13. This pain is difficult for me to describe to others.	**0.48**	0.09	0.74
14. Some words that might help describe my pain include peculiar: itchy, tingling, or prickling feelings.	**0.46**	-0.02	0.79

*Items are reverse scored
Expert derived items are:2,3,4, & 5
Emboldened figures are strongest factor loading for item

References

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