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The impact of structured plaque control for patients with gingival manifestations of oral lichen planus: a randomized controlled study

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Clinical relevance

Clinical guidelines suggest that patients with oral lichen planus should improve their oral hygiene. Systematic reviews have suggested that patient-centered outcome measures be used in oral lichen planus outcome studies.

Principal findings

A structured plaque control intervention was more effective than control in improving the oral health related quality of life for subjects with gingival oral lichen planus.

Practical implications

This study provides support to the existing clinical guidelines that recommend optimizing oral hygiene for patients with oral lichen planus. Structured plaque control should form part of the first line treatment for patients presenting with gingival lesions.

The impact of structured plaque control for patients with gingival manifestations of oral lichen planus: a randomized controlled study

Abstract

Aim: To evaluate the impact of a structured plaque control intervention on clinical and patient-centered outcomes for patients with gingival manifestations of oral lichen planus.

Materials and methods: Eighty-two patients were recruited into a 20-week randomised controlled trial. The intervention was structured plaque control comprising powered tooth brushing and inter-dental cleaning advice. Control subjects continued with their normal dental plaque control regimen. The primary outcome measure was the oral health impact profile (OHIP) with secondary outcomes of pain, plaque index, mucosal disease score and cost-effectiveness.

Results: Overall the intervention patients showed statistically significant improvements in OHIP sum ordinal and dichotomous scores compared with control. There were improvements in the functional limitation, psychological discomfort and physical disability domains at 4- and 20-weeks and in the psychological disability domain at 20-weeks. The intervention was successful in reducing plaque compared to control ($p < 0.001$) and improvements were observed using the mucosal disease indices at the 4- and 20-week follow ups ($p < 0.001$).

Conclusion

A structured plaque control intervention was effective in improving the oral health related quality of life and clinically observed gingival lesions. This study provides evidence to include intensive plaque control within patients' initial and on-going management.

Introduction

Gingival manifestations are commonly seen in the erosive, ulcerative and atrophic forms of oral lichen planus (OLP) (Jadinski and Shklar, 1976, Scully and Porter, 1997, Leao et al., 2008, Lo Russo et al., 2009). The lesions vary in extent and severity from mild localized patches to widespread intense erythema and ulceration with areas of spontaneous haemorrhage (Scully and Porter, 1997). The symptomatology of milder presentations may include sensitivity to spicy or acidic foods or discomfort with particular dentifrices. The more severe presentations of the disease are likely to be symptomatic, painful and have significant impact on patients' lives (Cheng et al., 2012). Interventions are generally initiated based on controlling symptoms; the current recommended clinical pathway suggests that following diagnosis, initial treatment should focus upon controlling oral hygiene, avoid precipitating factors (e.g. drugs, foods, chemicals) and provide reassurance (Lodi et al., 2005, Thongprasom et al., 2003, Thongprasom et al., 2011). Improving plaque control as a conservative strategy has been the subject of increasing interest, but there remains limited evidence for the effectiveness of this intervention and, as a result, topical corticosteroids remain the first line treatment (BSOM, 2010, Holmstrup et al., 1990, Lo Russo et al., 2008, Guiglia et al., 2007, Lopez-Jornet and Camacho-Alonso, 2010, Salgado et al., 2013).

It is important for clinicians to understand the disease from the patient's perspective so that treatments are proportionate to the reported symptoms. Pain scores are easy to administer and may provide some insight, but they do not capture other symptoms, which might be more pertinent. These might include challenges with eating, in particular avoiding particular foods that may exacerbate symptoms, chronic soreness, frequency of ulcers, aching, general discomfort or even changes in mood. Over the last 20 years there has been a shift to understand the effect that diseases impact upon patients' lives. The rationale being that newly developed treatment strategies should address the issues that are important to patients. Patient-based outcome measures have been developed to measure the consequences of impaired oral health from the patient's perspective, frequently referred to as oral health related quality of life.

These instruments have been subsequently evaluated for reliability and consistency and are frequently used in clinical studies as primary or secondary outcome measures. Rarely have patient-based outcome measures been used to evaluate interventions for oro-mucosal diseases including OLP, and those that do, generally use it as a secondary outcome measure (Hegarty et al., 2002, McGrath et al., 2003, Gorouhi et al., 2007, Lopez-Jornet et al., 2009, Riordain and McCreary, 2010, Salgado et al., 2013). It has been recommended that future evaluations should include pain symptoms, report adverse effects of treatment and include cost-effectiveness with lengthy follow-up periods to evaluate long-term benefit (Lodi et al., 2012). In this paper we report outcomes from a 20-week randomized controlled trial evaluating the impact of plaque control on gingival oral lichen planus from the patient's perspective.

Aim

To evaluate the impact of a structured plaque control intervention on clinical and patient-centered outcomes for patients with gingival manifestations of oral lichen planus.

Methods

Study design

The study was conducted at Newcastle Dental Hospital, UK in accordance with ICH good clinical practice (GCP) between February 2011 and May 2012, a favourable ethical opinion was provided by Sunderland Research Ethics Committee, UK (Ref. 10/H0904/48). The design, (study overview, sample size, recruitment, randomisation and examiner calibration) has previously been described (Stone et al., 2013).

Briefly: a parallel group, longitudinal randomized controlled trial (RCT) was conducted to evaluate the effectiveness of a structured plaque control programme. Inclusion criteria were: adult patients aged 18 years and above; willing and able to complete questionnaires; able to provide consent, newly referred or under review at Newcastle Dental Hospital with a provisional diagnosis of OLP with clinical signs of gingival involvement. Exclusion criteria

were: unable to attend for the additional appointments prior to biopsy; unable to complete questionnaires (large print format were made available for those with visual impairment, alternatively questionnaires would be read by a researcher); involved in a research study within the previous 28 days. All subjects whose diagnosis of OLP was not previously confirmed by biopsy and histopathological analysis had this performed along with direct immunofluorescence and blood tests where appropriate (BSOM, 2010). The intervention group received structured oral hygiene instruction using a powered toothbrush, Sonicare *FlexCare+* HX6942/20 (Philips Oral Healthcare Inc. Bothell, WA, USA) with interdental cleaning aids, either appropriately sized TePe[®] extra soft interdental brushes (TePe Munhygienprodukter, Sweden) ranging from ISO size 1-6 or Oral-B dental floss (Procter & Gamble, UK). All products were provided for the complete duration of the study along with standardised toothpaste for all subjects (Pronamel[®], GlaxoSmithKline, Brentford, Middlesex, UK). The control group was asked to continue with their normal plaque control regimen and did not receive this additional intervention or advice. Follow up was carried out at 4 and 20 weeks, compliance was not formally recorded. Clinical record forms were coded and anonymised, each participant was assigned a study number, participant information was kept confidential and individual subject records contained only sufficient data to allow identification of the participants throughout the study.

Oral health-related quality of life was the primary outcome measure in this study. It was measured using the 49-item version of the Oral Health Impact Profile (OHIP-49), which has been shown to be reliable, valid and responsive to clinical change (Locker and Allen, 2002). Participants were asked to rate each of the responses on a 5-point Likert scale. Responses were coded 0 (never), 1 (hardly ever), 2 (occasionally), 3 (fairly often), and 4 (very often). The OHIP was self-administered but checked for completeness to ensure no missing data points (Guyatt et al., 1993). The questionnaire items provide information about the frequency (burden) by which participants had experienced specific impacts in the month preceding completion of the questionnaire; OHIP does not aim to measure severity. Short reference periods have been used with OHIP successfully in the past (Sutinen et al., 2007) and in clinical trials (Allen et al.,

2001), therefore a 4-week reference period was used at all appointments to allow evaluation of change over the course of the study. Secondary outcomes included visual analogue scales for pain, global transition scores and validated clinical indices for mucosal disease and plaque control along with evaluation of cost-effectiveness (Silness and Löe, 1964, Slade and Spencer, 1994, Stone et al., 2013, Escudier et al., 2007). The data for the secondary outcomes have been previously reported with the exception of global change scores (Stone et al., 2013). These were included at each follow-up visit to provide some overall context to the subjects' symptoms and also to provide validity to the OHIP data.

Analytic plan

The primary outcome measure for this study was overall sum OHIP score and by domain. No weightings were to be applied to the OHIP data, sum OHIP data were used (Allen and Locker, 1997). Overall sum OHIP (ordinal) data were used in statistical analysis to examine both intervention and control groups, ordinal data were used to examine each OHIP domain. Data was also dichotomised by grouping subjects reporting items frequently often or very often (coded 1), and those reporting items occasionally, hardly ever and never (coded 0). These data were summarised and analysed to further differentiate negative impacts on quality of life for intervention and control subjects.

Descriptive statistics were produced for each of the primary and secondary outcomes according to treatment received. Statistical analysis of the data including parameter and 95% confidence interval (CI) estimation was accomplished using SAS software. For age and gender, continuous variables p-values were calculated by t-test and chi-squared for categorical variables. Comparisons for the primary outcome measure, OHIP and clinical parameters between treatment groups were performed using ANOVA for baseline and ANCOVA for the 4-week and 20-week follow-ups. The p-values are based on a mixed model F-test (H_0 =both intervention and control treatments equal). The population to be analysed comprised all randomised subjects with a baseline and at least one post-baseline OHIP evaluation, those without were excluded from the analysis. Minor differences to those previously reported may exist based on the way in which those with missing data points were handled. Global change scores were

calculated and analysed using Mann Whitney U statistic, assuming an abnormal distribution.

Results

Recruitment for the study ran from February 2011 to June 2012. 120 patients were invited to participate, 82 accepted, were enrolled and randomised, (39 intervention and 43 control subjects). 3 intervention and 2 control subjects were lost to follow up. One subject failed to attend visit 2 but was retained through to visit 3. 79 of the 82 participants data were analysed.

The mean age for all randomised subjects was 61.4 years at the time of enrolment; the gender balance of 18.3% males to 81.7% females reflected the greater number of females with oral lichen planus in the wider population. The numbers of subjects taking concomitant topical steroid medication was evenly distributed in both control and intervention groups (n=23). Three participants were taking concomitant systemic steroids (prednisolone); two in the intervention group and one in the control group. Recruitment selection bias was not considered to be significant.

A summary of the baseline and follow-up OHIP data is presented in Table 1. There were no significant differences between the groups in baseline demographics or for any other parameter at baseline ($p>0.05$). The groups had similar baseline mean OHIP sum scores 49.66 (ordinal) and 6.55 (dichotomous) for the intervention group and 49.39 (ordinal) and 6.71 (dichotomous) for the control group. At week 4 and week 20 the distributions shift with both groups showed a reduction in OHIP ordinal scores overall. The shift for the intervention group was more than the control group. Both groups contained subjects who experienced net negative change (post-baseline minus baseline) in OHIP ordinal and dichotomous scores. The negative net change in ordinal scores indicated subjects experiencing an overall improvement in given domain, taking into account both the improvement and deterioration to individual statements. Negative net change in dichotomous scores indicates an overall decrease in the impacts that happened “fairly often” or “very often” from baseline, taking into account some impacts happened more frequently, and some happened less frequently. The intervention group experienced greater negative net change in

both ordinal and dichotomous scores indicating improvements in oral health related quality of life these differences were statistically significant at the 4-week ($p=0.022$) and 20-week ($p=0.004$) follow-up.

Evaluation of the individual domain scores provides further insight into the range of impacts that oral lichen planus has on a subject's quality of life. Statistical output for each domain was undertaken using ordinal data and presented in Table 1.

Those domains with significant differences between the intervention and control groups at 4 and 20 weeks respectively were functional limitation ($p=0.022$; $p=0.014$), psychological discomfort ($p=0.007$; $p=0.002$) and physical disability ($p=0.014$; $p=0.004$). The psychological disability domain showed significant differences at the 20-week ($p=0.003$) but not at the 4-week follow up ($p=0.435$). There were no significant correlations in the social disability ($p=0.763$; $p=0.811$) and handicap domains ($p=0.858$; $p=0.224$) at either time point and a constant although not statistically significant effect was observed in the physical pain domain ($p=0.059$, $p=0.052$).

Global change

Global change scores, recorded on a 5-point Likert scale, were coded positively for improvements and negatively for deteriorations in symptoms: Improved a lot (2), improved slightly (1), stayed the same (0), become slightly worse (-1), become a lot worse (-2). Results are displayed in Table 2. At week 4 the mean global change with 95% CI was 1.03 (0.86, 1.38) for the intervention group indicating that the subjects in that group felt that their symptoms improved slightly. The control group still showed a positive mean global score [0.26 (-0.02, 0.53)] and there were statistically significant differences between the two groups ($p<0.001$) at the 4-week follow-up. At the 20-week follow-up the difference in improvements between the groups from the 4-week time point was not statistically significant ($p=0.067$) suggesting that the greatest effect came in the intervention group in the time initially following the intervention.

Effect sizes

The effect of treatment was examined using Cohen's d (Table 3). Interpretation of effect sizes differs but it is generally agreed that those values above 0.2 are

seen to be having a small treatment effect, above 0.5 to have a moderate effect and above 0.8 to have a large effect.

Moderate treatment effects were seen in the intervention group for OHIP ordinal scores at week 4 (0.61) and week 20 (0.74). Moderate treatment effects were also observed in the intervention group for pain (VAS) both at the 4-week (0.52) and 20 weeks (0.70). Large effect sizes were observed in the interventions group for PI at week 4 (1.47) and week 20 (1.56). A moderate effect was seen in Escuder's oro-mucosal disease index at week 4 (0.75) and a large effect at week 20 (1.01). Small changes were observed for the control group in OHIP scores and VAS scores at 4 and 20 weeks. No effect was observed in PI for the control group at any time point. These can be used alongside the surrogate measures of health (clinical indices) and subjective measures of health (OHIP) in an attempt to provide comprehensive assessment of the effect of the intervention.

Discussion

The evaluation of the effectiveness of a structured plaque control programme used tools that were both objective and subjective measures of health and disease. For context, clinical evaluation of the intervention was based on Plaque Index (Silness and Løe, 1964) and the Escudier index (Escudier et al., 2007). In this study the mean Plaque Index scores reduced for the intervention group by 39.5% at the 20-week follow up compared to a marginal improvement of 4.1% control group. The intervention was, therefore successful in reducing plaque compared to control and was sustained to the end of the study at 20 weeks ($p < 0.001$). Clinical improvements were observed using the Escudier indices at the 4- and 20-week follow up ($p < 0.001$).

The mean OHIP ordinal scores at baseline were 49.7 for the intervention and 49.4 for the control group. In the original validation studies for OHIP involving older adults, the mean sum OHIP ordinal score was 31.5 (Slade, 1998). The subjects with gingival manifestations of oral lichen planus in this study reported more frequent impacts at baseline indicating poorer oral health related quality of life. It is important though to examine the individual domains to determine the social impact of the disease. The physical pain domain in OHIP contains statements that relate to the frequency that subjects experienced painful gums, sore spots and discomfort when eating. These symptoms are commonly reported in outpatient clinical settings therefore, it is reasonable to assume that this domain would have the potential for change. Although improvements in the domain score were observed, they were not statistically significant from the control group ($p > 0.05$). The VAS scores for pain were also not statistically different at the 4- and 20- week follow up ($p > 0.05$). Pain might therefore not be significantly affected by the intervention or perhaps the symptoms that have the greatest effect on quality of life do not include pain. In the functional limitation domain there were significant differences between the control and intervention groups ($p = 0.012$, $p = 0.014$). This domain contains statements relating to appearance, difficulty chewing, taste and digestion. It may be that improvements in clinical signs of inflammation then bring about these secondary outcomes measured in this and other domains. The largest differences between groups

were observed with the psychological discomfort and physical disability domains. The psychological discomfort domain relates to being worried, self-conscious, miserable, concerned about appearance and tension. Perhaps the intervention is, by resolving inflammation, reducing symptoms, so that subjects are consequently being less concerned about their oral health. There may also be some positive effect by which participating in the study affects this domain; particularly a study that monitors subjects more frequently than through their conventional clinical pathway. This may be particularly important when examining a cohort of patients with a potentially pre-malignant diagnosis (Holmstrup, 2010). Within the physical disability OHIP domain, which contains statements relating to being unable to brush teeth, avoidance of eating and unsatisfactory diet, there were statistical differences between the groups in favour of the intervention group at week 20 ($p=0.004$). It is impossible to tell, without further adjunctive qualitative interviewing, which part of the intervention was the most important: the advice and reassurance, or the provision of appropriate aids that facilitate the perceived improvements in this domain. Comparatively few impacts were observed in the final three domains: psychological disability, social disability and handicap. This suggests that oral lichen planus does not have large disabling effects but carries significant psychological impact associated with the diagnosis and chronic discomfort. Anxiety has previously been strongly associated with the initiation of oral lichen planus and frequent observation and monitoring during a clinical study may go some way to alleviating this anxiety (Vallejo et al., 2001)

Studies have suggested that painful atrophic mucosa may discourage patients from brushing effectively, additionally it has been reported that powered tooth brushing can cause minor gingival abrasions (Erpenstein, 1985, Robinson et al., 2005). The intervention therefore had the potential to exacerbate the lesions particularly with the friable, atrophic nature of the gingival tissue. It has been suggested that plaque removal would potentiate new lesions resulting from mechanical trauma, however this hypothesis lacked evidence (Hermann, 1963). Contrary to the thoughts of Erpenstein, (1985) the results of this study showed that the structured advice and products provided to the subjects facilitated

improvements in plaque control, brought about improvements in the severity of the OLP lesions and improved subjects' oral health related quality of life; the intervention did not result in any adverse outcomes and analysis of its cost-effectiveness has previously been reported (Stone et al., 2013).

Conclusions

A structured plaque control intervention was effective in improving the oral health related quality of life and clinically observed gingival manifestations of oral lichen planus. This study provides evidence to include intensive plaque control within patients' initial and on-going management. Intensive plaque control should, therefore, become an important initial phase of treatment, which can be delivered pre-referral by general dentists and dental hygienists.

	Intervention (SE) n=38	Baseline Control (SE) n= 41	Difference	P-value	Intervention (SE) n=38	Week 4 Control (SE) n=40	Difference	P-value	Intervention (SE) n=36	Week 20 Control (SE) n=41	Difference	P-value
Sum OHIP ordinal	49.66 (4.47)	49.39 (4.30)	0.27	0.966	34.62 (2.31)	42.19 (2.25)	-7.57	0.022	30.95 (2.81)	42.26 (2.63)	-11.31 (3.85)	0.004
95% CI	40.76, 58.56	40.82, 57.96	-12.09,12.62		30.01, 39.22	37.70, 46.68	-14.00, -1.15		25.35, 36.55	37.02, 47.51	-18.99, -3.64	
Sum OHIP dichotomous	6.55 (0.98)	6.71 (0.95)	-0.15	0.910	3.13 (0.51)	5.20 (0.49)	-2.07	0.005	2.51 (0.64)	4.94 (0.60)	-2.43	0.007
95% CI	4.59, 8.51	4.82, 8.59	-2.87, 2.57		2.12, 4.14	4.22, 6.18	-3.48, -0.66		1.23, 3.79	3.74, 6.14	-4.19, -0.68	
Functional limitation	10.53 (0.87)	9.80 (0.83)	0.72	0.550	7.71 (0.52)	9.40 (0.50)	-1.69	0.022	6.95 (0.55)	8.85 (0.51)	-1.89	0.014
95% CI	8.80, 12.25	8.14, 11.47	-1.67, 3.12		6.68, 8.74	8.40, 10.40	-3.12, -0.25		5.87, 8.04	7.83, 9.87	-3.39, -0.40	
Physical pain	13.68 (0.88)	14.34 (0.85)	-0.66	0.593	9.63 (0.65)	11.38 (0.64)	-1.75	0.059	9.68 (0.77)	11.77 (0.72)	-2.09	0.052
95% CI	11.93, 15.44	12.65, 16.03	-3.10, 1.78		8.33, 10.93	10.11, 12.64	-3.56, 0.07		8.14, 11.22	10.33, 13.21	-4.20, 0.02	
Psychological discomfort	7.79 (0.83)	7.93 (0.80)	-0.91	0.905	4.84 (0.48)	6.68 (0.46)	-1.84	0.007	4.12 (0.56)	6.63 (0.52)	-2.51	0.002
95% CI	6.14, 9.44	6.34, 9.52	-2.43, 2.16		3.89, 5.79	5.76,7.60	-3.17, 0.52		3.01, 5.23	5.58, 7.67	-4.04, -0.98	
Physical disability	7.97 (0.91)	7.51 (0.88)	0.46	0.716	5.36 (0.57)	7.38 (0.56)	-2.03	0.014	4.65 (0.61)	7.18 (0.57)	-2.53	0.004
95% CI	6.16, 9.79	5.76, 9.26	-2.06, 2.98		4.21, 6.50	6.27, 8.50	-3.63, 0.43		3.44, 5.87	6.04,8.32	-4.20, -0.86	
Psychological disability	5.76 (0.79)	5.68 (0.76)	0.08	0.942	3.99 (0.44)	4.48 (0.43)	-0.49	0.435	3.21 (0.56)	4.89 (0.53)	-1.68	0.032
95% CI	4.19, 7.33	4.17, 7.20	-2.10, 2.26		3.11, 4.88	3.62, 5.34	-0.17, 0.75		2.08, 4.33	3.84, 5.94	-3.22, -0.15	
Social disability	1.39(0.49)	1.90 (0.47)	-0.51	0.458	1.41 (0.24)	1.31 (0.23)	0.10	0.763	1.26 (0.29)	1.16 (0.27)	0.10	0.811
95% CI	0.42, 2.37	0.96, 2.84	-1.86, 0.85		0.94, 1.89	0.85, 1.77	-0.56, 0.77		0.68, 1.83	0.62, 1.70	-0.69, 0.89	
Handicap	2.53 (0.58)	2.22 (0.56)	0.31	0.705	1.65 (0.29)	1.58 (0.28)	0.07 (0.40)	0.858	1.17 (0.32)	1.70 (0.30)	-0.53	0.224
95% CI	1.37, 3.68	1.11, 3.33	-1.30, 1.91		1.08, 2.22	1.02, 2.14	-0.72, 0.87		0.54, 1.80	1.11, 2.29	-1.39, 0.33	

Table 1. Sum OHIP scores for ordinal and dichotomous data and Sum OHIP data by domain. P-values are based on a mixed model F-test (H_0 =both treatments equal). Difference = Mean of treatment difference (intervention - Control).

Visit	Treatment	n	Mean (SD)	95% CI	p-value
Week 4	Intervention	38	1.03 (1.03)	0.86, 1.38	<0.001
	Control	40	0.26 (0.85)	-0.02, 0.53	
Week 20	Intervention	36	0.94 (1.15)	0.56, 1.33	0.067
	Control	40	0.44 (1.14)	0.07, 0.81	

Table 2. Descriptive statistics for global change scores. Respondents were asked to consider their symptoms since the previous visit and indicate if they had improved a lot, improved slightly, stayed the same, become slightly worse or become a lot worse. Positive values indicate treatment improvement and negative values indicate deterioration in symptoms. P-value based on Mann Whitney U statistic, as the data were not normally distributed.

Outcome measure	Follow up	Group	Mean pre-treatment (SD)	Mean post-treatment	Effect size
OHIP-ordinal	Week 4	Intervention	49.66 (24.86)	34.55	0.61
		Control	49.39 (29.82)	42.25	0.24
	Week 20	Intervention	49.66 (24.86)	31.64	0.74
		Control	49.39 (29.82)	41.66	0.26
OHIP-dichotomous	Week 4	Intervention	6.55 (4.91)	3.03	0.72
		Control	6.71 (6.97)	5.30	0.20
	Week 20	Intervention	6.55 (4.91)	2.56	0.74
		Control	6.71 (6.97)	4.90	0.26
Pain (VAS)	Week 4	Intervention	3.34 (2.07)	2.27	0.52
		Control	3.36 (2.23)	2.95	0.18
	Week 20	Intervention	3.34 (2.07)	1.85	0.70
		Control	3.36 (2.23)	2.49	0.38
Plaque Index	Week 4	Intervention	1.42 (0.36)	0.89	1.47
		Control	1.45 (0.34)	1.44	0.03
	Week 20	Intervention	1.42 (0.36)	0.86	1.56
		Control	1.45 (0.34)	1.47	-0.06
Escudier oro-mucosal disease index	Week 4	Intervention	31.12 (9.62)	23.93	0.75
		Control	27.97 (8.07)	28.46	-0.06
	Week 20	Intervention	31.12 (9.62)	21.40	1.01
		Control	27.97 (8.07)	25.65	0.29

Table 3. Unadjusted mean pre- and post-treatment values, standard deviations and Cohen's *d* effect sizes. It is generally accepted that *d* values of 0.2 represent small change, 0.5 represent moderate change and those >0.8 represent large change. Negative values represent deterioration from baseline.

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