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Cost-effectiveness of personalised plaque control for managing the gingival manifestations of oral lichen planus: a randomised controlled study

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Clinical relevance

Scientific rationale for study

Guidelines suggest that patients with gingival manifestations of oral lichen planus (OLP) should improve their oral hygiene. There is a lack of robust evidence to support this guidance. Systematic reviews have recommended that health economic evaluation should be evaluated in future randomised controlled trials.

Principal findings

Personalised plaque control was more effective than control in the treatment of the gingival manifestations of oral lichen planus. This was cost-effective and patients valued the treatment in excess of its cost.

Practical implications

Understanding the clinical impact and cost-effectiveness of treatments will allow stakeholders to make informed decisions about alternative treatment strategies. Standardised outcome measures will allow direct comparisons to be made.

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Abstract

Aim: To undertake cost-effectiveness and cost benefit analyses of an intervention to improve oral health in patients presenting with the gingival manifestations of oral lichen planus (OLP).

Materials and Methods: 82 Patients were recruited to a 20-week randomised controlled trial. The intervention was personalised plaque control comprising powered tooth brushing and interdental cleaning advice. The primary outcome measure was the oral health impact profile (OHIP) with secondary outcomes of pain, plaque index, mucosal disease score and cost-effectiveness. Private cost data and stated willingness to pay (WTP) values for treatment were obtained from intervention patients at 20 weeks.

Results: 81% of intervention patients showed improvement in both plaque index and mucosal disease score at 20 weeks compared to 30% of controls that continued with their usual plaque control regimen. All intervention group patients stated a positive WTP value. The mean net value of the treatment was £172 compared to the incremental cost of the treatment estimated at £122.75. The cost-effectiveness analysis resulted in an incremental cost-effectiveness ratio of £13 per OHIP point.

Conclusions: The tailored plaque control programme was more effective than control in treating the gingival manifestations of oral lichen planus. The programme is cost effective for modest values placed on a point on the OHIP scale and patients generally valued the treatment in excess of the cost.

Introduction

Gingival manifestations are most commonly seen in the erosive, ulcerative and atrophic forms of oral lichen planus (OLP) (Jadinski and Shklar, 1976, Scully and Porter, 1997, Stoopler et al., 2003, Leao et al., 2008, Lo Russo et al., 2009). The condition is often symptomatic with the extent of the gingival involvement varying from chronic epithelial desquamation, erythema, and erosion to blistering of the attached and marginal gingiva (Prinz, 1932, Scully and Porter, 1997, Guiglia et al., 2007).

Symptomatic ulcerative or erosive gingival involvement has the potential to compromise effective plaque control (Lo Russo et al., 2009). It is recognised that whilst good plaque control does not bring about complete resolution, it may reduce the frequency of the symptoms of OLP (Guiglia et al., 2007, Holmstrup et al., 1990, Erpenstein, 1985, Lopez-Jornet and Camacho-Alonso, 2010). Further, most guidelines and reviews have recommended that as part of the initial treatment the optimisation of plaque control may prevent periodontal damage (Lo Russo et al., 2008).

Current evidence suggests that topical corticosteroids should be the first line treatment, but there is no universally agreed second line treatment such as short courses of systemic corticosteroids (Cribier et al., 1998, Carrozzo and Gandolfo, 1999, Eisen, 2002, Eisen et al., 2005, Lodi et al., 2005, Al-Hashimi et al., 2007, Scully and Carrozzo, 2008, Carrozzo and Thorpe, 2009, BSOM, 2010, Cheng et al., 2012). Factors that have been found to expedite improvement of symptomatic lesions include reassurance, avoidance of exacerbating factors such as certain foods, avoidance of smoking, alcohol and improving plaque control (Ramon-Fluixa et al., 1999, Thongprasom et al., 2003, Thongprasom et al., 2011). The outcomes of the two most recent systematic reviews of interventions for treating oral lichen planus have recommended an evaluation of cost-effectiveness of treatments should take place (Zakrzewska et al., 2005, Lodi et al., 2012).

Economic evaluation of treatment strategies requires the comparison of outcomes from alternative treatments alongside a comparison of their costs (Antczak-Bouckoms and Weinstein, 1987). Economic evaluation seeks to ascertain whether the marginal change in outcome from the introduction of a new treatment justifies the marginal change in cost. If

this is the case the introduction of the new treatment programme will lead to a more efficient allocation of health care resources. Given that the over-riding aim of healthcare is (or should be) to improve patients' wellbeing by maximising their quality of life, the patient's valuation of the outcome of their treatment is the prime consideration when selecting an outcome measure (for economic evaluation). This should be guided by consideration of which measures best capture the patient's experience of their oral health.

In medicine, health related quality of life is often measured in Quality Adjusted Life Years (QALYs) assessed from standardised questionnaires such as the EQ-5D-3L; under certain assumptions, valuations derived from these measures represent the underlying value of life in compromised health states compared against life in full health (EuroQol, 2013). In principle these 'utility' measures could be applied to dental interventions however, they are unlikely to be sensitive to important considerations of oral health such as chewing ability, or aesthetic considerations. In the absence of a suitable measure of the underlying value or utility of dental treatment, a specific measure such as the oral health impact profile (OHIP), provides an indication of the likely impact of changes in oral health on a patient's quality of life (Slade and Spencer, 1994). Careful use of mapping algorithms have been proposed to provide comparisons between OHIP and generic utility measures of health status but risks do exist in under- or over-estimating the severity of the condition (Brazier et al., 2010, Brennan and Spencer, 2006). An economic evaluation using change in OHIP is a cost-effectiveness analysis (CEA), it does not attempt map OHIP to a utility score (Weinstein and Stason, 1977).

An alternative approach to valuing health outcomes is to ask patients to place a monetary valuation on their outcome, their maximum willingness-to-pay (WTP) for the treatment they have received (Vernazza et al., 2010). This allows a cost-benefit analysis (CBA) of the value of a treatment or programme. In private decision-making we undertake these valuations to decide whether to make a purchase; we seek to maximise our happiness from our budget by buying the combination of goods and services we value most highly. In principle, WTP values capture the potential alternative uses of those resources (money), and if the WTP value exceeds the cost then the purchase will increase wellbeing. In the public sphere, this tenet only holds if budgets across all sectors of the economy are flexible so that resources can be taken from their least productive role and redistributed as necessary. In the real

world in which budgets are fixed, CBA can be used for decision making across programmes provided the costs and benefits of each programme are known and the correct decision making framework is applied (Birch and Donaldson, 1987).

The aim of this study, therefore, was to undertake a CEA and CBA of an intervention to improve oral health in patients presenting with gingival manifestations of OLP.

Methods

Study design

A parallel group, longitudinal, randomised controlled trial (RCT) was conducted to evaluate the effectiveness of a personalised plaque control programme. The intervention group received personalised oral hygiene instruction using a powered toothbrush, Sonicare *FlexCare+* HX6942/20 (Philips Oral Healthcare Inc. Bothell, WA, USA) with instructions to brush for 2 minutes. They were also provided 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). The control group were asked to continue with their normal plaque control regimen and did not receive any advice. At baseline, all subjects (control and intervention) received a prophylaxis, this comprised a polish of the teeth using a cup and prophylaxis paste, they were also issued with standardised toothpaste (Pronamel®, GlaxoSmithKline, UK). Full periodontal assessments were not performed as part of the study protocol and the prophylaxis did not include scaling or root planing.

The primary outcome measure was the oral health impact profile (OHIP) with secondary outcomes: visual analogue scale (VAS) for pain, global transition scales and validated clinical indices for mucosal disease and plaque control (Slade and Spencer, 1994, Silness and Loe, 1964, Escudier et al., 2007). Clinical outcomes were assessed at baseline, 4 weeks and 20 weeks. The study was conducted in accordance with ICH Good Clinical Practice (GCP), a favourable ethical opinion was provided by Sunderland Research Ethics Committee, UK.

Patients were recruited from oral medicine and periodontal clinics at Newcastle Dental Hospital between February 2011 and May 2012. 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.

Patients were provided with an information sheet, a further appointment was made or further time given to consider involvement. 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). Participation in the study was designed to fit within the patient's standard clinical care pathway.

Sample size was determined using OHIP as the primary outcome measure, with pain, clinical indices and cost-effectiveness being secondary outcomes. The minimally important difference, the smallest difference between groups of an outcome that patients perceive as having a beneficial effect, was used to calculate the standard deviation and subsequently the number of subjects required in the study (Allen et al., 2009, John et al., 2009). Powering the study at 80% using a standard deviation of 10.49, 49 subjects in each group were required to detect a difference with confidence at the 95% level (Allen et al., 2009, John et al., 2009). The attrition rate was expected to be high (Hewitt et al., 2010). To allow for 20% dropout rate (non-compliance with the protocol and loss to follow up) the *a priori* estimate of subjects was 118. 120 patients who attended oral medicine consultant diagnostic clinics were invited to participate into the study, 82 accepted and were enrolled into the study (39 intervention and 43 control subjects). 3 intervention subjects and 2 control subjects were lost to follow up; a decision to terminate enrolment was based upon a pragmatic decision based upon low recruitment rates.

Randomisation using sealed opaque envelopes was carried out in blocks of 10 to ensure roughly similar numbers of participants in each group. These envelopes were opened in front of the subject by the researcher following consent and enrolment into the study and after the baseline records had been recorded.

Calibration of the clinical examiner was undertaken to ensure reliability of the clinical outcome measures. Silness and Löe plaque index and the clinical components of the Escudier index measure on an ordinal scale, therefore a weighted Cohen's Kappa statistic was used to assess the agreement between two ratings after adjusting for chance (Cohen, 1968). The weighted Cohen's Kappa for Silness and Löe = 0.80 [95% CI 0.75, 0.84]; Escudier index site score 0.96 [95%CI 0.83,1.00] and activity score 0.78 [95%CI 0.63,0.91].

At the final assessment (20 weeks) the intervention group were asked to complete a short questionnaire, which recorded out of pocket payments and lost work time relating to treatment during the study. They were also asked to state their maximum WTP to purchase the powered toothbrush in an open-ended valuation exercise. The valuation was preceded by the patients being given cards representing a range of prices [£1 to £2000] and asked to consider whether they would pay the amount listed on each card. This exercise is frequently undertaken as an aid to the valuation of health services in contingent valuation studies.

Estimation of costs

Although oral hygiene aids were provided free as part of the trial this would not be the case in routine practice and hence the economic evaluation included these costs. The cost of the toothbrush was set at the current price of £95. The cost of the remaining interdental aids was estimated at £23.50. The costs of toothpaste provided to both intervention and control groups were ignored. For the CEA the difference across the two groups in toothpaste cost is likely to be zero. For the CBA it was assumed that patients would purchase toothpaste whether or not they participated in the intervention and that any additional toothpaste costs could be ignored. The time input for the plaque control programme, delivered by a dental hygienist was estimated to be approximately 5 minutes. The estimated total cost of an hour of patient contact time including all overheads for a dental hygienist working in General Dental Practice was £51 (PSSRU, 2011). The cost for 5 minutes was then calculated at £4.25.

Travelling and time costs were collected for patients in the treatment arm but not the control arm. For the CEA the costs for both arms of the study were assumed to be the same and would consequently net out of the calculation of cost-effectiveness. For the CBA,

where costs were compared with the benefits of treatment for patients in the treatment arm, travel and time costs were included. Patients in the treatment arm were asked to report estimates of travel costs including car parking. They were also asked to report the total time spent attending treatment sessions and their gross salary (in bands of £10,000). The assumption was made that patients worked full time for 1750 hours a year and we estimated hourly costs of patient time at the mid salary band value divided by 1750. Valuing the time of non-working patients is contentious but it is highly unlikely that these patients value their time at zero (Brouwer and Koopmanschap, 1998). Unemployed patients were assigned to the band £0 – £10,000 and retired patients to the band £10,000 - £20,000 to assign a value to their time.

Data analysis for clinical outcomes

Comparison of clinical outcome measures across treatment groups at baseline was undertaken using ANOVA. Comparison of clinical outcomes across treatment groups at 4 week and 20 week follow-up was undertaken using ANCOVA in which adjustment for the baseline measure of the relevant clinical outcome measure was undertaken (Frison and Pocock, 1992).

Data analysis for Cost-effectiveness

The cost-effectiveness of the intervention was assessed using reported OHIP scores and is presented in the form of a Cost-Effectiveness Acceptability Curve (CEAC) (Fenwick et al., 2004). The CEAC indicates the likelihood that the intervention is cost-effective given the uncertainty of data and the value placed on the outcome measure. The amount patients were WTP for the intervention was measured in the treatment group and the likelihood that the benefits exceed the cost of treatment is reported, again allowing for uncertainty of data.

The CEA utilised a summary score obtained from differences in OHIP responses obtained at baseline and at the 20-week follow-up for each patient. The OHIP contains 49 items with five possible responses to each question (Never/Hardly ever/Occasionally/Fairly often/Very often). Responses were assigned a value from zero (Never) to four (Very often) and the values for each patient summed. Given the small size of the trial differences in baseline characteristics across the treatment and control arms were anticipated. Consequently, an ordinary least squares (OLS) regression model was used to estimate the treatment effect

and control for baseline characteristics with age, sex and baseline OHIP score were pre-specified. The following baseline covariates were included if they improved model fit as judged by Akaike's Information Criteria (AIC) (Akaike, 1974): mean plaque index; pain as measured using a VAS; and the site score, severity score and activity score of the Escudier Index. Age and baseline covariates were treated as continuous variables and fractional polynomials were used to specify the appropriate relationship with the dependent variable (OHIP summary score at 20 weeks) (Sauerbrei and Royston, 1999). Again, AIC was used to guide selection of polynomial functions but with an emphasis on parsimony. The model was specified prior to addition of the treatment assignment dummy.

A complete case analysis (patients with data at baseline and 20 week follow-up) was undertaken in the base case analysis. To allow for sampling uncertainty the data were bootstrapped. Bootstrapping provides an empirical measure of the distribution of a statistic derived from multiple sampling with replacement from the trial population. It avoids making parametric assumptions; the distribution of OHIP scores at 20 weeks was clearly skewed. The pre-specified model for OHIP at 20 weeks was fitted to each of a thousand bootstrap re-samples and the coefficient on the dummy for the treated group (β_t) obtained. The net monetary benefit of treatment (Stinnett and Mullahy, 1998) was then calculated for each of the bootstrap re-samples as:

Net monetary benefit = $\lambda * \beta_t$ - mean cost of treated group + mean cost of control group
(where λ is the threshold WTP for one OHIP point).

The Net monetary benefit calculation was repeated for integer values of λ from zero to £100. The resulting dataset contained 101 net monetary benefit estimates corresponding to each threshold WTP value from zero to £100 for all 1000 bootstrap re-samples (101,000 values in total). The proportion of the 1000 bootstrap re-samples for which the net monetary benefit of the intervention ($\lambda * \beta_t$) exceeded zero was then plotted for the range of values of λ from 0 to £100. The resulting CEAC plots the likelihood that the intervention is cost-effective given the value the decision maker places on a unit change in outcome (OHIP in this case).

Sensitivity analysis

The proportion of missing data was relatively small, arising from loss to follow-up of five patients. The impact that these missing data might have on the treatment effect was investigated by undertaking an analysis of all patients after multiple imputation of missing data (White et al., 2011). Multiple imputation was undertaken using chained equations. Each of the covariates listed in Table 1 was included and data at all three visits (baseline, 4-week and 20-week) were included. Polynomial transformations of the baseline covariates, which were part of the final model, were also included. Covariates were log transformed where this led to a noticeable improvement in non-normally distributed data. Where log transformation failed to yield a distribution that appeared approximately normal, covariates were imputed using predictive mean matching. Ten imputations were undertaken. The final model was then fitted to the ten imputed datasets and the treatment effect estimated from each dataset was combined using Rubin's rules (Rubin, 2004).

Data analysis for Cost Benefit Analysis

The CBA assessed whether patients receiving the treatment judged it to be worth more than the cost. Patient travelling and time costs were added to the treatment cost (toothbrush plus accessories plus hygienist time) to determine the total cost of treatment for each patient. This value was subtracted from each patient's stated maximum WTP for the treatment to determine the net value of the treatment. The mean and median net value of treatment is reported along with the range. In addition, the proportion of patients with a net value of treatment above zero is reported. The data were bootstrapped to allow for sampling uncertainty. The bias corrected and accelerated confidence interval around the mean net value of treatment derived from 1000 bootstrap resamples is reported.

Results

Raw data

The clinical and quality of life data for the intervention and control patients at baseline and follow up are presented in Table 1. The groups are broadly similar at baseline although the severity and activity scales of the Escudier Index indicate more widespread lesions at baseline in the treatment group. Three patients in the treated group and two in the control group were lost to follow-up at 20 weeks. Differences in the clinical measures in favour of

the treated group are significant at the 4-week assessment. These differences are maintained at the 20-week assessment. Differences in the quality of life measures are clinically significant and statistically significant after adjusting for baseline measurements reflecting the greater variance in the quality of life data.

At the 20-week follow-up 89% of the intervention group showed an improvement from baseline in mucosal disease scores; 92% showed an improvement in plaque index; and 81% showed an improvement in both scores. In the control group 53% of patients showed an improvement in mucosal score; 43% showed an improvement in plaque index and only 30% improved on both measures.

Estimation of treatment effect

The optimised OHIP model included age; sex; a linear and quadratic term for baseline OHIP summary score; the reciprocal of the Escudier Index site score squared; the reciprocal of the Escudier Index site score multiplied by the natural log of site score; the severity and activity subscales of the Escudier index; and Plaque Index. Table 2 reports the treatment effect without controlling for patient characteristics, after controlling for age, sex and OHIP score at baseline and after fitting the final model. The size of the treatment effect is not markedly different after controlling for baseline characteristics. The significance of the treatment effect is markedly increased after controlling for baseline OHIP summary scores. Much of the variance in OHIP summary scores at the 20-week assessment is explained by the difference in baseline OHIP summary scores.

Table 2 also shows the treatment effect estimated in the sensitivity analyses. After fitting the final model to the multiply imputed data the coefficient is essentially unchanged from the complete case analysis. After fitting the model to the subsample of patients who improved on both clinical measures (29 treated and 12 control patients) the value is consistent with that estimated on the complete sample, but the treatment effect is no longer statistically significant.

Cost-effectiveness analysis

The treatment effect on the 20-week OHIP summary score estimated from the bootstrapped data was -9.34 ($p = 0.008$, 95%CI -16.28 to -2.40). The incremental cost of the treatment was £122.75 resulting in an Incremental Cost-effectiveness Ratio of £13 per OHIP

point (95%CI £8 to £51). The CEAC is presented in Figure 2. Below a value of £10 per OHIP point the intervention is evidently not cost-effective. At £20 per OHIP point there is an 80% likelihood that the intervention is cost-effective given the uncertainty resulting from the sample size. This likelihood exceeds 95% if the value placed on each OHIP point exceeds £33.

Cost benefit analysis

Private cost data and stated WTP values for treatment were obtained from all 36-intervention patients at the 20-week follow-up; all patients stated a positive maximum WTP value (range £65 to £1500). Out of pocket costs for patients were generally small. The net value of treatment ranged from -£97 to £1339. The mean was £172 (CI £88 to £282); the median was £69 (CI £24 to £124); and the inter-quartile range was £2 to £194. Three quarters of the sample stated a maximum WTP in excess of the total cost of treatment.

Discussion

The results indicate that a tailored plaque control programme is more effective than the control in managing patients with gingival manifestations of OLP. At 20 weeks patients in the treatment arm showed significantly better scores on each of the clinical measures when compared against those in the control arm. Patients reported better OHIP scores in the intervention group compared to those in the control arm, these differences were significant after controlling for baseline OHIP scores. The intervention was more expensive than the control treatment. Consequently, the intervention can only be considered cost-effective if a sufficient premium is placed on the improvement in outcomes. The CEA indicates that a relatively modest premium of £13 per OHIP point is sufficient for the intervention to be considered cost-effective. However, at this value considerable uncertainty remains in that assessment. This uncertainty recedes as the value placed on the outcome increases. Above £33 per OHIP point there is 95% certainty that the intervention is cost-effective.

The cost-benefit analysis indicates that the benefit of the intervention as perceived by patients exceeded the cost. The majority of patients in the treatment arm valued the treatment in excess of the cost, and the mean value was significantly more than the cost. Hence the cost-benefit analysis would indicate that the treatment is cost-effective when compared to no treatment.

Limitations and potential sources of bias

The number of patients in the trial fell below the *a priori* estimate, a *post hoc* power calculation was carried out to assess the power of the study and its ability to draw conclusions. The study was found to be over-powered at 36 subjects per group. Recruitment and retention rates were sufficient to establish a statistically significant improvement in OHIP summary score for the intervention compared against control. The significant difference in clinical indicators in favour of the intervention supports this finding. Loss to follow-up was relatively small, and whilst there is possible bias, the sensitivity analysis in which missing data were imputed would indicate no significant impact on the results. Bootstrap resampling ensured that uncertainty arising from the sample size was accounted for in the determination of the treatment effect, and facilitated the presentation of results in the form of a CEAC. This is the currently recommended methodology by the National Institute for Health and Clinical Excellence (UK) in its guidance for health technology assessment (Kenward and Carpenter, 2007). Without WTP data from the control group valuing their treatment the cost-benefit analysis cannot ascertain whether the treatment is cost-effective when compared against the control intervention.

Examiner blinding was not carried out in this study which may have introduced some bias. This was minimised by allocating the subjects after their baseline records were recorded. At follow up, formal blinding was not carried out, however subjects did not report their allocation to the examiner and further advice was not provided.

It remains possible that further improvement beyond 20 weeks may have occurred. We did not assess this and we cannot be certain that the differences between treatment and control groups are maintained beyond 20 weeks. Improvement in oral health in both groups between baseline and 4 week follow-up is, however, much greater than the further improvement seen between 4 and 20 weeks, suggesting that further changes beyond 20 weeks are likely to be small. It may be necessary to provide further motivation to patients to ensure that oral health maintenance routines are maintained.

Whilst the intervention is clinically effective it is cost-effective only if sufficient value is placed on the outcome. A value of £13 per OHIP point appears reasonable; the resulting

value placed on transition from the worst possible to the best possible oral health on the OHIP scale would be £2548. Nevertheless, it is far from evident that all patients would value their oral health this high. It should also be noted that we have assumed an equal value for each point on the OHIP summary score when this is unlikely to be the case. The OHIP gives an indication of the impact of a patient's oral health on their wellbeing but, unlike the QALY, it is not a utility measure. Whilst the CBA indicated patients valued their treatment in excess of the cost, stated WTP may be greater than either the actual or ability to pay (Harrison and Rutstrom, 2002).

Utility measures in dentistry

A recent editorial in the Journal of Clinical Periodontology questioned the value of CEA in dentistry and argued in favour of CBA (Listl and Birch, 2013). The authors concerns related to the lack of information on overall budget impact conveyed by the ICER and the lack of appropriate reference values or acceptability thresholds against which the ICER might be compared to judge cost-effectiveness. Whilst the former argument is certainly a limitation of the ICER, additional analysis to estimate budget impact is feasible within a CEA framework. The latter argument reflects the wider challenge in health care decision making of identifying current provision at the margin of efficiency. This challenge is not negated by CBA; costs and benefits of currently provided services still need to be estimated if a comparison with a candidate programme is to be undertaken. However, the value of CEA in dentistry is limited by the lack of a universally applied measure of oral health quality of life analogous to the QALY.

It would be difficult to create a utility measure from the full OHIP questionnaire as it potentially specifies 1.78×10^{34} different oral health states. A simplified oral health related quality of life scale could, however, form the basis of a utility measure for oral health. The upper anchor for the scale would be the absence of problems on any of the dimensions of the scale. This would not necessarily equate to a full dentition, rather to ideal functioning and aesthetics, and an absence of pain. The lower anchor for the scale might be the state of edentulousness. This would be the equivalent of death on the QALY scale used in measuring health related quality of life. States worse than being edentulous are clearly possible, as are health states 'worse than death'. Generation of values for each oral health state specified by the instrument would require a population survey using methods such a

Standard Gamble or Time Trade-Off, and possibly regression modelling. The generation and general application of a utility measure in clinical trials in dentistry would provide a tool to gauge the benefit of interventions from the patients' perspective and allow comparison of interventions across different clinical areas. The establishment of an acceptable threshold WTP value for a unit change in this utility measure would allow more definitive assessment of the cost-effectiveness of dental interventions.

Conclusions

The tailored plaque control intervention was more effective than control in treating the gingival manifestations of OLP. There were statistically significant improvements in OHIP, plaque control and lower Escudier index scores for the intervention group. Most patients valued it in excess of the cost and the mean value of the intervention was significantly more than the cost. Comparison against standard practice using an OHIP summary score indicates that the intervention is cost-effective assuming a relatively modest valuation of at least £13 per OHIP point.

Tables and Figures

	Intervention	Control	Difference (p-value)*
<i>Baseline</i>			
Number of patients	39	43	
Age	61.2 (9.9)	61.6 (11.8)	-0.4 (0.87)
Sex (proportion of women)	0.85	0.79	0.06 (0.52)
Pain (VAS)	3.34 (2.07)	3.36 (2.23)	-0.02 (0.97)
Plaque index	1.47 (0.34)	1.51 (0.35)	-0.04 (0.64)
Escudier Index (site score)	10.87 (2.52)	10.42 (2.18)	0.45 (0.39)
Escudier Index (severity score)	14.90 (5.59)	12.86 (4.30)	2.04 (0.07)
Escudier Index (activity score)	16.87 (7.03)	14.00 (5.26)	2.87 (0.04)
OHIP summary score	49.49 (24.56)	48.67 (29.34)	0.81 (0.89)
<i>4 weeks</i>			
Number of patients	38	40**	
Pain (VAS)	2.27 (1.66)	2.95 (2.06)	-0.68 (0.06)
Plaque index	0.99 (0.35)	1.50 (0.35)	-0.51 (<0.0001)
Escudier Index (site score)	9.45 (2.65)	10.63 (2.20)	-1.18 (0.0001)
Escudier Index (severity score)	10.79 (5.04)	13.58 (4.38)	-2.79 (<0.0001)
Escudier Index (activity score)	11.74 (6.10)	15.08 (5.99)	-3.34 (<0.0001)
OHIP summary score	34.55 (23.84)	43.05* (31.02)	-8.50 (0.016)
<i>20 weeks</i>			
Number of patients	36	41	
Pain (VAS)	1.85 (1.72)	2.49 (2.04)	-0.64 (0.07)
Plaque index	0.98 (0.38)	1.54 (0.33)	-0.56 (<0.0001)
Escudier Index (site score)	9.14 (2.55)	10.28 *** (2.55)	-1.14 (0.0005)
Escudier Index (severity score)	9.69 (5.23)	12.03 *** (3.72)	-2.33 (0.0002)
Escudier Index (activity score)	10.42 (5.98)	12.83 *** (4.69)	-2.41 (0.0001)
OHIP summary score	31.64 (23.06)	41.66 (28.87)	-10.02 (0.004)

Table 1 Pre-treatment characteristics and raw outcome data. Statistics reported are mean values with standard deviation in parentheses unless otherwise stated.

* p values for baseline measures are derived from ANOVA; p values for outcomes at 4 and 20 weeks are derived from ANCOVA with control for the relevant measure at baseline.

** Response available for only 39 patients for OHIP summary score for control group at 4 week assessment.

***Response available for only 40 patients for each Escudier Index subscale for control group at 20 week assessment.

Covariates	Treatment effect	95% CI	p value	Adj. R squared	AIC
None	-10.02	-22.14 to 2.11	0.10	0.02	726.0
Age, sex, baseline OHIP	-10.00	-17.65 to -2.34	0.01	0.62	656.6
Full model	-9.34	-17.04 to -1.64	0.02	0.64	656.4
Full model after imputing missing values	-9.35	-16.81 to -1.54	0.02	-	-
Full model applied to subsample showing clinical improvement	-6.06	-19.31 to 7.19	0.36	0.52	

Table 2 Model diagnostics and treatment effect (difference in OHIP score at 20 weeks) estimated from ordinary least squares regression analysis (base case and sensitivity analyses).

Figure 1 Study overview alongside the conventional clinical treatment pathway. If required, further investigations were performed to confirm diagnosis. 120 participants were approached, 8 did not meet the inclusion and exclusion criteria, 30 declined to participate. 82 patients were enrolled, 39 patients were randomly allocated to intervention and 43 to control arms of the study. The study length was set at 20 weeks with a review at 4 weeks. One patient was unable to attend for review at 4 weeks but did not withdraw and attended appointment 3.

Figure 2 A cost-effectiveness acceptability curve (CEAC). The incremental cost of the treatment was £122.75 resulting in an Incremental Cost-effectiveness Ratio of £13 per OHIP point (95%CI £8 to £51). Below a value of £10 per OHIP point the intervention is evidently not cost-effective. At £20 per OHIP point there is an 80% likelihood that the intervention is cost-effective, this likelihood exceeds 95% if the value placed on each OHIP point exceeds £33.

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