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What's new for the clinician?
- excerpts from and summaries of recently published papers

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1. Effectiveness of three different oral moisturizers in palliative care patients

SF Kvalheim, MC Marthinussen, DF Haugen, E Berg, GV Strand, SA Lie.
Randomized controlled trial of the effectiveness of three different oral moisturizers in palliative care patients. Eur J Oral Sci. 2019; 127: 523-30.

Saliva is crucial for maintaining optimal oral health. Healthy individuals produce resting (unstimulated) whole saliva at a rate of 0.3 - 0.4 ml min^{-1}. The subjective feeling of xerostomia is thought to occur when less saliva is secreted than the amount of water lost from the mouth by evaporation and by absorption through the oral mucosa.[1]

Mucin-rich resting saliva lubricates mucous membranes and teeth, and stimulated saliva plays an important role in mastication, speech, swallowing, and digestion. Constituents such as lactoferrin, peroxidase, and histatin contribute to salivary antimicrobial, antiviral, and antifungal properties.[1]

In individuals with failing salivation, these important properties of saliva in the oral cavity are reduced or absent, causing dry and sore mucous membranes, delayed wound healing, rapid development of caries and erosion, fungal infections of the mouth and throat, discomfort, pain, and problems using dentures.[1] Dry mouth can also lead to swallowing difficulties, speech disturbances, loss of appetite, dehydration, and malnutrition, thus having a negative effect on diseases and contributing to reduced quality of life, particularly in life's final phase.[1]

Many patients in palliative care (Palliative care is the active treatment and care for patients with incurable diseases and short life expectancy) have received treatment or medications that may have adverse effects on oral health which commonly manifests as dry mouth or xerostomia. A range of different products are used in an effort to alleviate the symptoms of dry mouth. There are several commercially available mouthwashes and gels.

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Kvalheim and colleagues (2019)1 sought to test the efficacy of three moisturizers [17% watery solution of glycerol, oxygenated glycerol triester (OGT), and a newly developed product (Salient)] was compared] in a randomised clinical trial (RCT).

The trial was designed to answer the following question: Do any of the three agents improve xerostomia, reduce pain and discomfort, and improve ability to talk in palliative care patients? The hypothesis was that there was no difference in efficacy between 17% glycerol, OGT, and Salient.

MATERIALS AND METHODS

The study was designed as an RCT with a crossover design. All patients were treated with three oral-care products.

Thirty patients were recruited from two palliative care units in Norway. Eligibility criteria for participants were: xerostomia (subjective feeling of dry mouth); in institutionalized palliative care; curative treatment of existing diseases completed or terminated; WHO performance status ≥III (corresponding to Karnofsky Performance Status Score of 30%–40% (i.e., only capable of limited self-care, confined to bed or chair more than 50% of wake time); cognitively functioning, capable of and willing to give written consent, capable of giving responses to a limited questionnaire; and expected to remain at the care centre for a minimum of 3 days.

Patients who had previously been treated with chemotherapy and/or radiotherapy to the head and neck region were excluded.

The project leader assigned the participants to the interventions. The intervention was, in general, carried out after morning routine care and breakfast. Each product was applied at the same time of day to avoid the risk that diurnal variation in health status might influence the outcome.

If the patient agreed to participate, he/she answered a short questionnaire, which contained the primary outcome measures of subjective xerostomia, discomfort and pain, and speech problems.

These measures were recorded on a 5-point ordinal Likert scale at three points in time: before the intervention; immediately after the intervention; and 2 h after the intervention. In addition, evaluations of taste and application method of the products used were recorded on a 3-point ordinal scale. After all products had been applied and procedures completed (2 h after the last intervention, normally on day 3), patient preference of the three products was recorded on a 4-point nominal scale on the same questionnaire. At the same time, the patients were asked to comment freely on the products and procedures.

The products were presented in neutral containers without labels, ensuring that the patients were blinded as to their content. The dentist who carried out the intervention could not be similarly blinded because of the differences in application methods for the three products. The three products compared in this study were: (i) a 17% watery solution of glycerol, (ii) Oxygenated glycerol triester (OGT) and, (iii) Salient.

The total duration of the intervention was thus normally 3 days. The night following each application was considered a washout period, after which a new product could be applied.

RESULTS

Of the 30 patients, 17 (57%) were female (mean age = 68 yr.) and 13 were male (mean age = 69 yr.). The main diagnosis was cancer in 28 (93%) of the patients; 12 (40%) had WHO performance status III and 18 (60%) had status IV.

Relative to baseline recordings, all products produced improvements immediately after the intervention. At this time, a higher number of respondents treated with glycerol reported no or minimal oral dryness (indicated by the green shades of the columns) compared with respondents treated with OGT.

Two hours after intervention, the effect of glycerol had decreased relative to the other two products (in fact, had reverted to baseline), whereas the effects of OGT and Salient largely persisted.

Relative to baseline recordings, all products impacted significantly in reducing the occurrence of speech problems immediately after intervention. At this time, there were no significant differences between the products. Two hours after the intervention, the effect of glycerol had dropped by a larger amount than that of the two other products and was no longer different from baseline, whereas the effects of OGT and Salient largely persisted.

No statistically significant carry-over effect was discovered for xerostomia, discomfort and pain, or speech problems (smallest $P = 0.13$).

Whereas 22 (73%) of the 30 patients reported that the application method of glycerol was agreeable, only a few felt that about Salient. OGT occupied an intermediate position between glycerol and Salient.

In terms of taste, OGT was disliked by 23 (77%) of 30 patients. For the other products, most respondents reported a neutral taste. The majority of patients (19/30, 63%) preferred glycerol ($P < 0.001$). The corresponding numbers for Salient and OGT were six (20%) of 30 and three (10%) of 30, respectively. Two of the patients preferred not to use any of the three products. There was no association between the preferred product and on which day the preferred product was applied ($P = 0.48$).

All patients commented on the treatment received. The remarks concerning xerostomia, taste, application method, and preferred product mirrored those reported above. The sticky, glutinous consistency of Salient was mentioned by 18 (60%) of 30 patients. In addition, 11 (37%) of 30 patients characterized the taste of OGT as strange, strong, oily, rancid, nauseating, or disgusting.

Others (4/30, 13%) were dissatisfied with the use of a small spoon when dispensing Salient, and an equal number of patients commented that the most important factor for their well-being was oral care in itself; that is, getting help with brushing their teeth and cleaning the mucosa.

CONCLUSION

Within the defined limitations of this study, the researchers conclude that none of the three tested products was found to be clinically completely adequate. The 17% concentrationof glycerol had the most positive effect immediately after application, but little or no effect 2 h thereafter.

OGT and Salient had a long-lasting effect, but were nevertheless not preferred by the patients - probably because of the disagreeable taste of the former and the unpleasant, sticky consistency of the latter.

Implications for practice

The glycerol solution was preferred by this group of patients but its effect was short-lived effect. However, this can be compensated for by frequent applications. Additionally, glycerol is relatively cheap and is easily available at most pharmacies without a prescription.

Reference

1. Kvalheim SF, Marthinussen MC, Haugen DF, Berg E, Strand GV, Lie SA. Randomized controlled trial of the effectiveness ofthree different oral moisturizers in palliative care patients. Eur J Oral Sci. 2019; 127: 523-30.

2. Bisphenol A in human saliva and urine before and after treatment with composite resin restorative materials

TLL Berge, GB Lygre, SA Lie, CH Lindh, L Björkman.
Bisphenol A in human saliva and urine before and after treatment with dental polymer-based restorative materials. Eur J Oral Sci. 2019; 127: 435-44.

There is considerable concern among scientists and the public about the hormone-mimicking properties of many chemical components of plastics, including those found in dental composites[1]. The commonly used Bis-GMA resin uses one of the most controversial of these, Bisphenol-A (BPA).

Bisphenol A (BPA) is a synthetic chemical substance, produced in large quantities and widely used in the production of polycarbonate plastics, epoxy resins, dental monomers, thermal paper, and numerous other products.[1] Responsible composite manufacturers claim that there is no unreacted BPA in dental resins, and that it takes high temperatures – several hundred degrees – to liberate free BPA. Other critics say that, in fact, the ester bonds in resins are subject to hydrolysis, and BPA can be liberated in measurable quantities.[1]

BPA levels in human populations have been associated with reproductive abnormalities, adverse developmental effects, metabolic disease, and breast cancer, among other health conditions.[1] There is wide interest in the sources of BPA exposure. The primary source of human exposure is assumed to be through the diet because BPA can leach into food and beverages from containers made of polycarbonate plastic or lined with epoxy resin coatings.[1] However, results from studies have indicated human exposure also from numerous non-dietary sources, including dust and indoor air, thermal paper, cosmetics, and dental materials.[1]

Berge and colleagues (2019)[1] reported on a study that sought to quantify BPA concentrations in saliva and urine, before and after treatment with dental polymer-based restorative materials, to assess if placement of these materials is associated with increased BPA levels in saliva and urine.

MATERIALS AND METHODS

Twenty patients, aged between 16 and 40 years old, without any known diseases or medications at the time of the study and in need of at least one dental restoration, involving two or more tooth surfaces, with a polymer-based restorative material were included.

Individuals with removable dentures, dental splints, and those who currently were undergoing orthodontic treatment, individuals who had received polymer-based dental fillings during the previous 3 months were excluded. Smokers, snuff users, and drug abusers were also excluded.

One dentist recorded the number of tooth surfaces previously filled with tooth-coloured restorative materials. The same dentist also provided the dental treatment. The treatment was performed according to standardized procedures and materials used at the clinic. The cavities were restored with a widely used filling material (Tetric EvoCeram) which contained Bis-GMA. The bonding procedure and the application of filling material were carried out according to the manufacturers' instructions.

For each participant, a new compule with filling material was used. The material was applied in incremental layers of <2.0 mm, and each layer was cured for 20-30s. Care was taken to avoid application of excessive amounts of material. Any surplus was removed and put back into the compule. Each compule was weighed before and after treatment, using an analytical balance.

The amount (weight in g) of polymer-based material used in each participant was estimated by the difference between the two measurements. The curing lamp emitted 600-700 mW cm^{-2} light intensity at a range of 440-460 nm. The lamp was controlled prior to each treatment using a hand-held curing radiometer. After curing, the fillings were polished according to standard procedures using polishing diamond burs, polishing disks, and silicone polishers.

The restorations differed in size depending on the tooth size and the extent of the prepared lesion. To adjust for differences, each filling surface was given scores from 1 to 3, depending on its area. Small restorations were given the lowest score of 1. Restorations of intermediate size, typically the approximal or occlusal surfaces of Class II restorations in premolars, were given a score of 2. The highest score, 3, was used for molars to denote restorations extending over the total occlusal fissure pattern or over the approximal surface of Class II restorations.

The scores for all polymer-based filling surfaces treated in each patient were summed and yielded the variable 'filling points'. The tooth surfaces treated and the estimated 'filling points' were recorded.

All treatment sessions were scheduled in the morning before 9 AM. Each participant provided a total of five 2 ml saliva samples and four 100 ml urine samples. The first saliva and urine samples were collected immediately before treatment, after a 10 h fast.

Sampling of a second saliva sample was started 10 min after placement of the polymer-based fillings, and subsequent saliva and urine samples were collected 1 h, 24 h, and 1 wk. after placement of the fillings. On each day of sampling, the participants also answered questions regarding consumption of canned and microwaved food during the previous week and within the previous 24 h.

To reduce exposure from other potential sources of BPA, the participants were instructed to abstain from eating, drinking, and brushing their teeth for at least 10h prior to sampling.

Only tap-water was allowed for drinking. The participants were asked not to use lip balm or lipstick during the same period. To identify possible contamination during sampling, transport, and storage, field blanks were collected using ultra-pure water instead of saliva and urine. The field blanks were treated like the NA, not applicable.

RESULTS

The saliva samples collected 10 min after treatment showed a statistically significant increase in BPA levels compared with the pre-treatment samples. The concentrations remained significantly elevated 1 h, 24 h, and 1 wk. after placement. After the immediate post-treatment increase, the concentration of BPA in saliva decreased exponentially. In saliva, no conjugated BPA was detected. Pre-treatment levels of BPA in saliva were low, and the mean value was estimated to be 0.11 ng ml^{-1}.

Before treatment, 11 (55%) of 20 participants had salivary BPA levels below the limit of detection (0.1 ng ml^{-1}). In one saliva sample collected before treatment, the BPA concentration was more than 100 times higher (11.6 ng ml^{-1}) than the mean value and more than 100 SD from the mean of the remaining 19 samples.

This saliva sample was excluded from the statistical analysis because it was probably contaminated. One participant had breakfast before the sample time point 1 wk. after treatment, and thus the samples collected from this participant at this time point were not included in the statistical analysis.

The levels of BPA concentrations in saliva were confirmed by analysing nine samples in a laboratory. Secondary explorative analysis showed that the number of filling points was associated with the BPA levels in saliva, 24 h ($P = 0.011$) and 1 wk. ($P = 0.029$) after treatment.

However, neither the number of filling surfaces nor the amount (weight) of dental polymer-based material placed was associated with the salivary BPA concentration at any time point (all $P > 0.05$). Moreover, there were no statistically significant associations between the other covariates tested and the salivary BPA levels at the different time points.

Before treatment, 19 (95%) of 20 participants had detectable levels of BPA in their urine. There were no statistically significant differences between urinary BPA levels before and after placement of the dental polymer-based restorations. The BPA levels in the urine samples collected 1 h after treatment did not show a statistically significant association with the BPA level in the saliva samples collected 10 min after treatment.

All field blanks had BPA concentrations below the detection limit.

CONCLUSIONS

The findings in this study confirm that placement of dental polymer-based restorative materials may cause a substantial increase in the concentration of salivary BPA after treatment. The results indicate that exposure to BPA is relatively short and transient. After 1 wk., the concentration of BPA in saliva was only slightly elevated compared with the levels before treatment. This study did not show changes in the BPA concentration in urine after treatment with a dental polymer-based restorative material.

Implications for practice

The findings of this study confirm that composite materials do contribute to raised salivary levels of BPA. This can be of concern if the patient has exposure to BPA from other sources such as plastic bottles, etc.

Reference

1. Berge, TLL, Lygre, GB, Lie, SA, Lindh, CH, Björkman, L. Bisphenol A in human saliva and urine before and after treatment with dental polymer-based restorative materials. Eur J Oral Sci. 2019; 127: 435-44.