Analgesic Efficacy of Aloe Vera and Green Tea *Mouthwash* After Periodontal **Pocket Reduction Surgery: A Randomized Split-Mouth Clinical Trial**

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	Abstract						
	Objectives: The aim of this study was to assess the efficacy of aloe vera and green						
	tea mouthwash for reducing pain after periodontal pocket reduction surgery.						
	<i>Methods</i> : This randomized, split-mouth, double-blind, cross-over clinical trial was						
	carried out on 45 patients between 25 and 50 years of age requiring pocket reduction						
	surgery. Patients underwent bilateral surgeries in two sessions. After the first						
	surgery, the patients were randomized to receive either mouthwash or placebo for 10						
	days; then, each group used the other product for the same time period. The						
	parameters assessed following each procedure were the numeric pain rating scale						
	(NPRS) and number of painkillers taken by patients to alleviate postoperative pain.						
	Also, patients were requested to report side effects, if any, after using the						
	mouthwash.						
	<i>Results</i> : The reported postoperative pain score was significantly lower after using						
	the aloe vera and green tea mouthwash compared to the placebo only in the first						
	postoperative day (P=0.002). Furthermore, number of analgesic tablets used in the						
	first postoperative day was significantly lower than that in the control group						
	(<i>P</i> =0.007).						
	Conclusion: Our results indicated that patients experienced significantly less early						
	postoperative pain when they used aloe vera and green tea mouthwash. Thus, its						
	application can be recommended to decrease pain after periodontal pocket reduction						
	surgery.						
	Key Words: Aloe vera gel; Green tea extract polyphenone E; Mouthwashes; Pain;						
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Introduction

Pain is inevitable after surgical procedures. Severity of pain after periodontal surgery depends on several factors such as type of surgical procedure, surgeon's knowledge about the anatomy of surgical site, poor handling of tissues, poor infection control, increased duration of surgery and sex and psychological state of patients (1).

Periodontal surgery often includes elevating a flap, gingival grafting or gingivectomy procedures. Postoperative pain experienced during the first three days after surgery is considered normal. Pain should gradually diminish during the healing phase (2). Among periodontal surgeries, resective osseous surgery is expected to cause the highest postoperative pain (3). Patients often complain of pain, swelling and trismus,

which negatively affect their quality of life after surgery (4). Therefore, patient compliance may become compromised during the postoperative period (5).

Postoperative pain management is performed aiming to completely prevent or decrease pain to tolerable levels for patients with minimal side effects (1). There are a number of pain relief protocols after such operations, but none of them are ideal. The most common protocol for elimination of postoperative pain consists of non-steroidal anti-inflammatory drugs (NSAIDs) (6-8). Inhibition of COX enzyme activity is the main mechanism of action of NSAIDmediated analgesia; by inhibiting Cox enzyme, production of prostaglandins and other inflammatory mediators is decreased in the injured tissue. Prostaglandins are responsible for pain, fever and vasodilatation in response to trauma (9, 10). But some side effects have been reported following the administrating of NSAIDs, such as gastrointestinal bleeding, cardiovascular complications and platelet dysfunction (11, 12). Another major drawback of these medications is that they also inhibit the beneficial effects of prostaglandins, which can be hazardous for patients with underlying diseases or pregnant women (13-16).

In order to prevent the above-mentioned adverse effects, clinical researchers are looking for alternative options with better safety profile and acceptable efficacy. Nowadays, herbal medications have gained increasing popularity and include a wide range of therapeutic agents that show promising efficacy for periodontal diseases. Aloe vera is one of the most extensively studied herbs in dental and oral health studies (17, 18).

Aloe vera has different formulations with favorable anti-inflammatory, anti-microbial and analgesic properties, which have been confirmed in vitro, and also in animal and clinical studies (17, 19-23). Wound healing properties of aloe vera products have been demonstrated in both animal and clinical studies as well; these properties are and important in medical surgical procedures (18, 24). Aloe vera mouthwash formulations have shown optimal efficacy for painful oral conditions such as ulcers, gingivitis and mucositis (23, 25, 26).

Anti-inflammatory and analgesic effects of green tea products containing polyphenols have been studied for years and confirmed in many studies (27-30). Green tea mouthwash has been previously produced and tested in clinical studies (31,32). It has been shown to be effective in prevention of dental plaque and carries. Decrease in bacterial count and acid production in the oral cavity were also noted following the use of green tea mouthwash (31, 32). Also, multiple studies approved the safety have of these mouthwash formulations (33-37).

Considering all the above, combination of these two herbal products may provide a synergistic analgesic effect useful for management of pain after periodontal surgery. No previous study has assessed the analgesic effects of these two substances in combination with each other especially after periodontal surgery. Thus, the aim of this study was to assess the efficacy of aloe vera and green tea mouthwash for reducing pain after periodontal pocket reduction surgery.

Methods

This randomized, split-mouth, double-blind, cross-over clinical trial was carried out on patients referred to the Department of Periodontology of Mashhad University of Medical Sciences.

The study was carried out in accordance with the ethical principles for medical research on human established by the Helsinki protocol in 1964. The Ethical Committee of Mashhad University of Medical Sciences approved the study protocol (ethical acceptance code: IR.MUMS.SD.REC.1394.107) and all patients signed written informed consent forms. This clinical trial was registered in the Iranian Registry of Clinical Trials (IRCT2016082029432N1 ID). According to previous studies with similar design in a similar setting, sample size more than 29 patients was found to be acceptable for this study (38, 39).

Medical and dental history of patients was taken and clinical examinations such as periodontal probing were conducted in all quadrants to assess the amount of clinical attachment loss and pocket depth. Furcation involvement and bleeding on probing were also assessed. Radiographic evaluation was also performed to assess bone loss and its severity. Accordingly, patients requiring periodontal pocket reduction surgery were detected.

Forty-five patients were selected between 25 and 50 years of age, who needed bilateral resective pocket reduction surgery. They all gave their informed consent for enrolment in the study. Patients with uncontrolled systemic diseases who could not undergo such surgeries, patients who only suffered from gingivitis and those with preoperative dental or maxillofacial pain were excluded from the study. The procedure was explained to the patients in detail and their informed consent was obtained.

All 45 patients were scheduled to undergo two-step pocket reduction surgery bilaterally. Surgeries were performed by the same qualified surgeon. In each individual, the first surgical procedure was followed by using aloe vera and green tea mouthwash, and the second procedure (control) was followed by use of a placebo solution. Both the experimental and placebo mouthwashes were produced in Mashhad School of Pharmacy laboratories. Herbal mouthwash consisted of 10g aloe vera extract gel, 20mL concentrated fusion of 250g/L green tea suspension, 5g propylene glycol and methylparaben and propylparaben as preservatives, all diluted with sterile water to reach the volume of 1L. Both herbal mouthwash and placebo solutions were distributed in similar brown opaque plastic bottles. The order of the two interventions was randomly assigned by flipping a coin. Secondary surgeries were performed at least 10 days after the first procedure. Surgical pack was not placed on the surgical site in order to maximize the efficacy of mouthwash. For the treatment arm, patients had to rinse their mouth with 15mL of herbal mouthwash twice a day (once in the morning and once in the evening) for a period of 10 days after each surgical procedure. The study protocol also involved assessing NSAID intake in the first 10 days postoperatively; all patients were prescribed 400mg ibuprofen (Gelofen®, Daana Pharma Co, Tabriz, Iran) as painkiller in order to minimize bias.

The predictor variable was type of mouthrinse used. The outcome variable was self-reported pain based on the NPRS and number of analgesics used, during first and second post-operative 10-day periods.

Each patient was given a randomized bottle of mouthwash after the surgery. Neither the surgeon nor the patient were informed about the type of mouthwash. A form was given to each patient in order to record pain intensity on a scale from 0 (no pain) to 10 (worst pain) each morning before using any painkiller and after rinsing the mouthwash, and also to write down the number of painkillers used during each day. Moreover, the patients were told to report any side effect or discomfort experienced after using the mouthwashes.

Results

Thirty out of 45 enrolled patients completed the protocol and 15 were dropped out due to inadequate compliance. The mean age of patients was 42.6 ± 6 years. According to paired sample t-test, there was a significant difference in pain score between the mouthwash and placebo groups in the first day after surgery (P=0.001) but there was no statistically significant difference for the days after (Table 1, Figure 1).

According to Wilcoxon test, there was a significant difference in pain scores between the first and second postoperative days in the placebo group (P<0.001), but no significant difference was shown in pain scores between the first and second post-operative days in the mouthwash group (P>0.05).

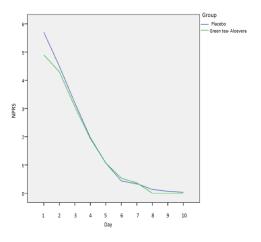


Figure 1- Changes in pain score (numerical pain rating scale or NPRS) during 10 postoperative days

Table 1- The mean and standard deviation of pair scores in the two groups at unrefert time p											
Group											Friedman
	One	Two	Three	Four	Five	Six	Seven	Eight	Nine	Ten	's test results
Placebo mouthwash	5.70± 2.60	4.50± 2.60	3.20± 2.27	1.97± 1.79	1.07± 1.66	0.43± 1.04	0.33± 0.71	0.13± 0.35	$\begin{array}{c} 0.07 \pm \\ 0.25 \end{array}$	0.03± 0.18	$\begin{array}{c} 0.03\pm\\ 0.18 \end{array}$
Aloe-Tea mouthwash	4.90± 2.63	4.30± 2.31	3.07± 2.07	1.93± 1.72	1.07± 1.60	$\begin{array}{c} 0.53 \pm \\ 0.90 \end{array}$	$\begin{array}{c} 0.37 \pm \\ 0.77 \end{array}$	$\begin{array}{c} 0.00 \pm \\ 0.00 \end{array}$	$\begin{array}{c} 0.00 \pm \\ 0.00 \end{array}$	$\begin{array}{c} 0.00 \pm \\ 0.00 \end{array}$	X [*] =221 P<0.001
Results of paired samples t- test and Wilcoxon	P= 0.001	P [*] = 0.496	P= 0.728	P [*] = 0.751	P= 0.977	P= 0.629	P= 0.902	P= 0.046	P= 0.157	P= 0.3.17	X [*] =207 P<0.001

Table 1- The mean and standard deviation of pain scores in the two groups at different time points

*Results of paired samples t-test.

Discussion

The aim of this study was to assess the analgesic efficacy of aloe vera and green tea mouthwash after periodontal pocket surgery. Statistical analysis revealed a statistically significant correlation between the use of aloe vera and green tea mouthwash and the perceived postoperative pain, as identified by means of NPRS.

Pain is the among most common complications after periodontal surgeries. Even though postoperative pain is normally resolved three days after surgery (2), physicians have the duty to decrease patients' pain and discomfort as much as possible (15). In order to achieve this goal, several measures have been developed in the minimize vears to tissue recent traumatization and soothe the pain by use of least toxic remedies during periodontal procedures. As an example, low level laser therapy has gained popularity as a novel orosurgical approach with lower rates of postoperative complications including pain (40, 41). However, these modern techniques are generally associated with higher treatment costs for patients. As a favorable inexpensive substitute, application of herbal products with proven analgesic and healing properties, which are abundantly available, be would а reasonable choice for management of post-surgical pain (42).

Anti-inflammatory and analgesic effects of green tea products have been previously confirmed (27-29, 43). Also, the efficacy of aloe vera extract in reducing the symptoms of inflammation and its anti-bacterial effects have been documented (17, 19-23). Several studies have approved the safety of these substances (33-36); but no previous study has evaluated the analgesic effects of these two components, combined with each other, especially after periodontal surgery and the current study is the first to assess this topic. In our study, none of the patients reported any discomfort or side effect after using the herbal mouthwash.

The nature of pain makes its objective measurement impossible. Studies have shown that perception of pain may differ from one person to another according to age, sex and psychological state (44, 45). In our study, a split-mouth design was chosen so each participant acted as his/her own control in order to lessen the confounding factors. Also in our trial, all surgeries were performed by the same surgeon in order to minimize the effect of surgeon's experience and skills on the results of the study.

Pain assessment in this study was done NPRS. Ferreira-Valente using and colleagues (46) reported that the NPRS has the highest responsiveness among pain intensity rating scales. It is also simple and does not need any instrument for recording and obtaining the data. Therefore, we chose this method for assessment of pain intensity. Statistical analysis revealed significant differences in pain scores and number of analgesics taken during the first postoperative day, but not for the rest of the evaluation period. This could be related to the natural spontaneous alleviation of pain after the first day (47, 48). As the highest discomfort and pain is experienced by patients in the first 12 hours after surgery (47), administration of this mouthwash can be useful, regardless of the results on the next days. Another conjecture about the analgesic effects of aloe vera and green tea mouthwash can be due to its antiseptic and anti-viral effects (49-51) since bacterial

infection or activity of herpes simplex type 2 virus at the surgical site are also among the reasons for postoperative pain (2, 52).

The current study had some limitations. Due to ethical considerations, patients could not be refrained from using painkillers after the surgery. Therefore, they were asked to record the number of painkillers taken during each day. To maximize the local effect of mouthwash, periodontal surgical pack was not placed at the site of surgery, which could have resulted in further exposure of surgical site to irritants. However, this way we tried to optimize both the treatment and the trial as much as possible.

Conclusion

Our study showed that using aloe vera and green tea mouthwash significantly decreased the perceived pain during the first week after periodontal surgical procedure. Thus, its application can be recommended to decrease pain after periodontal pocket reduction surgery. The required number of NSAIDs needed to relieve postsurgical pain would be less as such and thus their side effects.

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Conflict of interest: "None Declared"

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