



Clinical evaluation of photodynamic therapy efficacy in the treatment of oral leukoplakia



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Summary

Background: The aim of the study was clinical evaluation of photodynamic therapy efficacy in the treatment of oral leukoplakia lesions.

Methods: Twenty-three consecutive patients aged 21–79 were included to the study. In all patients 44 homogeneous, flat leukoplakia lesions were clinically diagnosed and confirmed histopathologically. Photodynamic therapy was performed with the use of Photolon[®] photosensitizer, containing 20% Chlorine-e6 and 10% dimethyl sulfoxide and a semiconductor laser, with power up to 300 mW and a wavelength of 660 nm. Ten illumination sessions were conducted with the use of superficial light energy density of 90 J/cm².

Results: At baseline the mean size of leukoplakia lesion was 6.5 ± 5.10 cm² while after photodynamic therapy 3 ± 2.99 cm². Significant reduction (on average by 53.8%) of leukoplakia lesions sizes was observed after therapy. Twelve (27.27%) lesions had been completely cured, 22 (50%) partially cured, although 10 (22.73%) lasted unchanged. The efficacy of PTD was comparable in women and men irrespective of age. There have been no adverse site effects during therapy noted.

Conclusions: Within the limits of the study it can be concluded that photodynamic therapy with the use of Chlorine-e6 can lead to considerable reduction of oral leukoplakia lesions size thus may be useful in clinical practice. However there is a need of further studies on larger number of cases and longer follow-up time.

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Introduction

Oral leukoplakia (OL) is a common pathology of mucosa with carcinogenic potential with 0.1–17% risk of cancerous transformation or even four times higher when erythroplakia coexistence is observed [1,2]. According to different authors OL occurs in 0.2–11.7% or 9.7% of population, three times more often in males aged between 40 and 60 [3–6]. It was estimated that occurrence of OL in males below 30 years of age is less than 1% and increases to 8% over 70 years of age and to 2% in females 70 years of age and older [1].

Etiology of OL is not clearly established. Smoking, alcohol abuse, lasting mechanical injuries, *Candida albicans* infection and differences of local galvanic potentials are reported as the most important cause factors [2,3]. OL can accompany systemic disorders like hormonal disturbances, gastric juice secretion, diminished saliva secretion or iron deficiency anemia. It is also stated that EBV, HPV (16 and 18 types), HSV and HIV viruses significantly influence OL development and carcinogenic transformation [7].

As its etiology cannot be established, treatment is difficult and shows insufficient efficacy [8,9]. In recent years photodynamic therapy (PDT) has been introduced as a new and alternative treatment method of OL. PDT uses light that has a definite wavelength to activate the photosensitizer accumulated in the cells [10,11]. One of the novel photosensitizers is chlorine derivative which chemical structure corresponds to a partially reduced porphyrin moiety. This pigment has been already applied in the treatment of pre-cancerous lesions [12].

The purpose of the study was a clinical evaluation of the efficacy of photodynamic therapy with the use of Chlorine-e6 in the treatment of oral leukoplakia.

Materials and methods

Study design

Study was performed in group of patients who have been referred to Department of Periodontal and Oral Mucosa Diseases Medical University of Białystok due to examined oral mucosa lesions by general practitioners. The study protocol was planned in accordance with the Helsinki Declaration of 1975 and was reviewed and approved by the local ethical committee (Ethics Committee Nr.: R-I-002/188/2009). All patients in the project signed a detailed informed consent form.

Inclusion criteria

1. Presence of at least one clinically and histopathologically diagnosed lesion of oral homogenous flat leukoplakia.

Exclusion criteria

1. Coincidence systemic disorders.
2. Allergy to the photosensitizer.
3. Age below 18.
4. Smoking 10 or more cigarettes per day.

Twenty-three consecutive, generally healthy, patients (16 women and 7 men) aged 21–79 were included in the study. Six of patients (3 women, 3 men) were smokers (less than 10 cigarettes per day). In the group of patients 44 lesions of homogenous flat oral leukoplakia were clinically and histopathologically diagnosed. Thirty-eight lesions were observed on cheeks and lips, 6 on gums and tongue. Before treatment regular scaling and root planning was performed as well as all causative local factors possibly influencing on oral mucosa status were eliminated. All patients also received proper oral hygiene, non-irritating diet and smoking discontinuation instructions.

Patients received photodynamic therapy with the use of Chlorin-e6 as a photosensitizer. The appointments were scheduled at 2-week intervals, but no longer than for 10 sessions. As there was no early response to the treatment, all patients had to undergo 10 PDT sessions. The treatment efficacy was assessed macroscopically by one experienced investigator (SS) at 1, 2, 5 and 10 appointments. Changes in the lesion sizes were monitored at the respective PDT sessions and measured (in mm) using a calibrated periodontal probe PCPUNC15 (Hu-Friedy, IL, USA). All lesions were classified into one of five groups according to their size:

- Group 0 – lack of evident lesions.
- Group 1 – a lesion smaller than 3 cm².
- Group 2 – a lesion from 3 cm² to <6 cm².
- Group 3 – a lesion from 6 cm² to <10 cm².
- Group 4 – a lesion from 10 cm² to <15 cm².
- Group 5 – a lesion >15 cm².

In order to analyze age-related data, four age groups were distinguished: 30–45, 46–60, 61–75 and over 75 years.

Any potentially negative aspects of photodynamic therapy from the patient's point of view were also investigated. The patients were asked to assess the character of pain and burning or pricking sensations associated with PDT using a 0–3 scale.

Treatment

To perform PDT, Chlorin-e6 was used as a photosensitizer. Commercially available Photolon® (Haemato, Poland) contains: 20% Chlorine-e6 and 10% dimethyl sulfoxide. The gel was applied directly onto the lesion and the surrounding healthy mucosa one hour before illumination, using an occlusive dressing according to own method. A sheet of nonwoven fabric, exceeding the lesion in size by 5–10 mm, was carefully covered with a 1–2 mm layer of the photosensitizer. Next, saliva was removed from the vicinity of the lesion and the prepared fabric was placed on dried mucosa. Another layer was composed of a polyethylene sheet, of the same size as the nonwoven fabric. Finally, the dressing was additionally stabilized with a few layers of sterile gauze.

PDT was performed using a semiconductor laser Haemato LS PDT 660 (Haemato, Poland). Application of 660 nm wavelength was transmitted to the lesion via an optical fiber equipped with a diffuser tip. The laser power from the end of the optical fiber did not exceed 300 mW. A series of illumination was performed using superficial light energy density of 90 J/cm².

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