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A randomized clinical trial of oral hygiene care programmes during stroke rehabilitation

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ABSTRACT

Objectives: The objectives of this study were to evaluate and compare the effectiveness of an advanced oral hygiene care programme (AOHCP) and a conventional oral hygiene care programme (COHCP) in improving oral hygiene, and reducing gingival bleeding among patients with stroke during outpatient rehabilitation.

Methods: Subjects were randomized to receive (i) the COHCP comprising a manual toothbrush, toothpaste, and oral hygiene instruction, or (ii) the AOHCP comprising a powered toothbrush, 0.2% chlorhexidine mouthrinse, toothpaste, and oral hygiene instruction. Dental plaque, gingival bleeding, and other clinical oral health outcomes were assessed at baseline, the end of the clinical trial, and the end of observation period. Development of infectious complications was also monitored.

Results: Participants of both programmes had a significant reduction in the percentages of sites with moderate to abundant dental plaque ($p < 0.001$) and with gingival bleeding ($p < 0.05$). Those in the AOHCP had significantly less plaque and gingival bleeding than those in the COHCP controlling for other factors at the end of the clinical trial period (both $p < 0.001$) and the observational period (plaque: $p < 0.05$, gingival bleeding: $p < 0.01$).

Conclusions: Although both oral hygiene care programmes were effective in terms of plaque and gingival bleeding control, the AOHCP was more effective than the COHCP in reducing dental plaque and gingival bleeding.

Clinical significance: This study highlighted the value of oral hygiene programmes within stroke outpatient rehabilitation and provides evidence to advocate for the inclusion of oral hygiene care programmes within stroke outpatient rehabilitation for patients with normal cognitive abilities.

1. Introduction

Stroke, as the predominant cause of permanent disability among older people, is a “rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 h or longer, or leading to death, with no apparent cause other than of vascular origin” [1]. A marked increase in the absolute number of stroke survivors, and the level of disabled-adjusted-life-years (DALYs) caused by stroke has occurred since 1990 [2]. This places a great burden on health and social care systems in many countries, particularly those with limited financial resources.

Post-stroke deficits (motor, sensory, perceptual, and cognitive) are often pronounced and prolonged with considerable impact on daily functioning, including oral self-care [3]. A number of orofacial functional impairments following stroke include decreased salivary flow, lip force, and chewing efficiency, which in turn affect the ability to clear food debris out of the oral cavity [4]. Consequently, oral hygiene is often exacerbated with significantly increased levels of plaque [5]. Dental plaque does not only lead to a number of plaque-induced oral diseases (e.g. dental caries, periodontal disease, and peri-implantitis) [6], but also can be a reservoir for oral opportunistic pathogens which has been proved to be associated with pneumonia [7]. In addition, associated gingival bleeding as a result of poor oral hygiene may give rise to bacteremia with potentially life-threatening consequences [8].

Outpatient rehabilitation service is critical to the well-being of stroke survivors in the long term, and determines whether they can

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return back to their 'normal' social life [9]. Of key concern is to reduce the risk of developing pneumonia which has been reported to lead to a threefold risk of death [10]. Therefore, there has been growing advocacy to integrate oral hygiene care programme within outpatient stroke rehabilitation [11]. The use of mechanical and chemical agents to control dental plaque levels and reduce gingival bleeding has been proposed; however, there is limited evidence of the effectiveness or evidence of superiority of different oral hygiene programmes. The rationale to choose oral self-care instead of assisted care is firstly because the patients during outpatient stroke rehabilitation have already regained part of their functional abilities. Because of improved hand function, oral self-care is not as challenging as in acute phase. The second reason is that those patients were community-dwelling instead of living in institutions, and their care givers were mostly family care givers who are not professional care givers. Assisted oral care will exert extra burden on family care givers in addition to taking care of their daily life.

To this end this study aimed to compare the effectiveness of an advanced oral hygiene care programme (AOHCP) to a conventional oral hygiene care programme (COHCP) in controlling plaque levels and reducing gingival bleeding among patients with stroke who had normal cognitive abilities during outpatient rehabilitation.

2. Methods

The study was approved by the *Institutional Review Board of the University of Hong Kong* (IRB reference number: UW 12-090), and registered at the *Hong Kong Clinical Trial Register* (Certificate for Clinical Trial No.: 003900). This study was a randomized, single-blind, parallel-group clinical trial of 3-month duration. An observational period of 3 months was conducted after the end of the clinical trial. The study site was the *Mrs Ng Wah Memorial Day Outpatients Centre*, Tung Wah Hospital (TWH) in Hong Kong SAR. Following discharge patients with stroke who have sustained functional impairments were referred to this centre for further rehabilitation involving multidisciplinary team. The length of outpatient rehabilitation varied depending on severity of impairment. Stroke patients were the main users of the outpatient rehabilitation services and formed the source population for this study. The following inclusion and exclusion criteria were applied: (1) being admitted to the outpatient rehabilitation programme within six months; (2) having moderate to severe functional disability – *Barthel Index* (BI) scores of < 70; (3) not being edentulous; (4) no more than mild cognitive impairment – *Mini Mental State Examination* (MMSE) > 18; (5) being able to follow a one-step command (as an assessment of communication); (6) no indwelling naso-gastric feeding tubes. Patients who fulfilled the criteria were provided with information on potential benefits and adverse effects of the interventions, the procedures, and the anticipated outcomes of this study. At the next follow-up appointment participants who agreed to participate were asked to provide their written informed consent. Patients were recruited and screened by an experienced dental surgery assistant in the study team.

Sample size was calculated based on intended ability to detect a significant difference in the primary outcome variable – the level of dental plaque between two groups at three-month review. In a previous observational study conducted among stroke sufferers [12], the mean percentage of moderate to abundant plaque was 89.51% (standard deviation [SD] = 18.73) at baseline and 66.67% (SD: 32.58%) after 6 months without any specific oral hygiene intervention, yielding a change by a value of around 20%. On the basis of this study, we proposed a difference in the percentage of moderate to abundant plaque of at least 20% between the two intervention groups with the standard deviation being set at 30%. Then the number of study subjects would require 38 per group, based on 80% power and the statistical significance level set at 0.05. Anticipating a 20% dropout rate over the course of the clinical trial, the initial sample size for each treatment group was proposed as 47 patients per group (94 subjects in total). Participants were block randomized with a group size of 4 (ABBA) to receive one of two oral hygiene care programmes: (1) A conventional oral hygiene care programme (COHCP) – supply of a manual toothbrush (Oral-B® Pro-Health All-In-One), a standardized tooth paste (Colgate® Maximum Cavity Protection), and oral hygiene training or (2) an advanced oral hygiene care programmes (AOHCP) – supply of a powered toothbrush (Oral-B® AdvancePower™ 400 series), 0.2% *chlorhexidine gluconate* mouth rinse (Corsodyl®), a standardized tooth paste (Colgate® Maximum Cavity Protection), and oral hygiene training. The randomized sequence was computer generated by the project supervisor. The allocation sequence number of each subject was concealed in an opaque envelope and provided to a nurse at the rehabilitation centre who was independent of the research team. After randomization and baseline assessment, intervention commenced immediately and lasted for three months. Appointments were made for the 3-month review. After the 3-month review, no study articles were provided to subjects. Another follow-up assessment appointment was scheduled at the end of 6 months for each subject.

After intervention assignment, all subjects attended a one-to-one oral hygiene training conducted by a dental surgery assistant who was not involved in the clinical assessments. Firstly, participants were given a standardized oral hygiene pamphlet provided by the Department of Health, and the practice of oral hygiene was demonstrated on tooth block models. Following on this, each subject was instructed to present their oral hygiene practice and brush their teeth in a systematic way. Training sessions lasted approximately 30 min. For those assigned to AOHCP, they were provided with specific manufacturer's instructions regarding the use of powered toothbrush. In addition, they were provided with a 3 months' supply of mouthrinse and were instructed to rinse twice daily with 10 ml of the mouth rinse (at least 30 min after brushing). The oral hygiene training was conducted in a separate room away from clinical assessments so that assessors were blind to which group the subjects were assigned to.

The primary outcome was oral hygiene status at the end of clinical trial as assessed by the *Silness and Löe Plaque Index* (PI) [13], and gingival bleeding at the end of clinical trial as assessed by *Gingival Bleeding Index* (GBI) [14]. The secondary outcome was oral hygiene status and gingival bleeding at 6 months. The PI was charted on all permanent teeth and assessed at six sites per tooth. The criteria for the Silness and Löe PI were as following: 0 = No plaque detected with probe; 1 = Plaque not visible by unaided eye but detectable with probe; 2 = Moderate amount of plaque. Plaque visible to unaided eye; 3 = Abundance of plaque. The percentage of tooth sites with moderate to abundant plaque (PI score: 2 or 3) was calculated for each subject. The GBI was charted on all permanent teeth and assessed at six sites per tooth. The criteria for GBI were: 0 = No bleeding after probing; 1 = Presence of bleeding within 10 seconds after probing. The percentage of bleeding sites (GBI score: 1) was calculated for each subject. At each study visit, ~10% of the subjects were randomly selected for reevaluation of the plaque index and gingival bleeding index, and the intra-rater reliabilities were assessed. Other clinical oral health outcomes included dental caries experience, periodontal health, oral mucosa conditions, and dental prosthesis status were recorded according to *WHO Basic Oral Healthy Survey Guidelines* [15]. In order to evaluate the adverse effect of chlorhexidine during the study period, the amount of calculus and tooth staining were examined. The height of calculus (unit: millimetre) was measured at the three sites of the lingual surfaces of six anterior lower teeth (mesial, central, and distal) by a periodontal probe [16]. The mean of the total amount of calculus formed on all six lingual surfaces was calculated for each subject. Tooth stain was scored both for intensity and area by the *Lobene Extrinsic Tooth Stain index* [17] by recording presence of stating in on the labial surfaces of the 12 anterior teeth in terms of (i) area: code 0 = no stain detected, code 1 = stain up to 1/3 of the gingival region, code 2 = stain over 1/3 to 2/3 of the gingival region, code 3 = stain over 2/3 of the gingival region; and (ii) intensity: 0 = no stain, 1 = light