Understanding Photobiomodulation (cont'd) Thursday, April 15, 2010, 12:05 p.m. – 12:25 p.m., Breakout Session Student Scholarship Award Presentation

310-DM7 – Efficacy of 640-nm Diode Laser Treatment for Prevention of Oral Mucositis in Pediatric Cancer Patients

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Oral mucositis is a morbid and costly side effect of cancer treatment in pediatric patients. No preventive or therapeutic methods have been validated for this condition. Recent evidence has shown that exposure of tissues to low-power (soft) lasers can promote wound healing *in vitro* and *in vivo*. Several studies testing the efficacy of laser for the reduction of incidence, duration, and/or severity of cancer therapy-induced oral mucositis have been performed. Results of these studies have been encouraging but most authors agree that this subject requires more clinical study. Generally, there is a paucity of studies that address preventive measures for therapy-induced mucositis in pediatric cancer patients.

Objectives of our study:

- 1. To test the hypothesis that laser application during cytotoxic therapy will reduce incidence, severity, and duration of oropharyngeal mucositis in pediatric cancer patients.
- 2. To study the duration of hospital stay of children treated for malignancy.

We have tested a promising and relatively novel approach to prevention of therapy-induced mucositis in children receiving cytotoxic treatment for malignant diseases. This strategy has been successful in adults and, if confirmed, may become the standard of care for oral mucositis in pediatric cancer patients. Prevention of oral mucositis and/or reduction in its signs and symptoms can significantly improve the quality of life of the patients, reduce the hospitalization costs, and, most importantly, increase the survival rate of these patients.

Materials and Methods: We performed a prospective, randomized, double-blind study of the effect of diode He-Ne laser therapy on incidence, severity, and duration of oral mucositis in pediatric cancer patients. Eight subjects were between the ages of 3 and 18 years with a diagnosed malignancy who underwent chemotherapy at the Hematology/Oncology Department, The Children's Hospital (TCH), Birmingham, Alabama. Laser exposure started on the first day of chemotherapy and continued each day of the cytotoxic treatment (4 to 7 days). Daily treatment lasted 15-30 minutes. We used a 640-nm diode laser (Scalar Wave Laser, Loveland, Colo., USA) with a fiber-optic and handpiece attachment for clinical application. This instrument is light and portable and can be used at the bedside. The participants were able to sit or lie in supine position while the laser procedure was performed. The participants wore protective wavelength-specific eye goggles. Sterile plastic protective sleeves were used to cover the laser handpiece. We irradiated the buccal, labial, soft palate, and floor of the mouth mucosa on half of the mouth. The side that was treated was randomly selected. Each area was irradiated for 40 seconds. The energy density was 4.5 J for each cm² of exposed tissue. This dose has been selected based on previous studies. The contralateral side received a sham treatment for the same amount of time, with the laser turned off. To reduce bias, neither the patient nor the examiners knew which side was treated. For incidence, duration, and severity of mucositis we used a student T-test for paired

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variables to compare OMAS (Oral Mucositis Assessment Scale) and FACES (Wong-Baker FACES Pain Rating Scale) scores from the treated vs. untreated sides of the mouth at each encounter point. Number of days of hospitalization were compared to the historical control group and were tested for correlation with mucositis scores. Subjects were matched by age, gender, type of malignancy, and chemotherapy protocol. Chi-square and Fisher's exact tests were used for these analyses.

Results: Only 2 children developed ulcerative mucositis. However, mean oral mucositis (p = 0.27) and pain (p = 0.62) scores failed to show statistical significance between the treated and untreated sides. Similarly, total hospital days for treated children were not different from the control.

Conclusions: To our knowledge, this is one of very few studies to test laser effects for cytotoxic therapy-induced mucositis in a pediatric population. Soft laser exposure was well tolerated in pediatric cancer patients and oral mucositis incidence was very low. Larger studies are needed to support the routine use of these devices for mucositis prevention.

This presentation discusses investigational devices that have not yet received U.S. FDA approval or clearance for the specified clinical indications, or describes off-label uses.

Biography: Dr. Adar Ben-Amy is a 2002 Graduate Tel Aviv University School of Dentistry and completed a Pediatric Dentistry Residency at the University of Alabama School of Dentistry in 2009.

Disclosure: Dr Ben-Amy has no commercial or financial interest relative to this presentation.

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