Use of Photobiomodulation for Alveolar Repair in Patients Submitted to Dental Extraction after Radiotherapy in the Head and Neck Region: Double-blind Randomized Pilot Study.

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INTRODUCTION

Delayed alveolar repair after dental extraction, with eventual bone exposure, is a frequent finding in patients irradiated in the head and neck region. An adequate control of alveolar healing is important to prevent osteoradiationecrosis (ORN). When a tooth extraction is indicated in irradiated patients, there is no consensus on adequate management. In this scenario, we evaluated the efficacy of PBM on alveolar mucosal healing following dental extractions in individuals treated for head and neck tumors with radiation therapy.

Table 1 – Baseline clinical features.

Variables	G1 (n=19):	G2 (n=21):	Total	p-value
	N (%) or Mean ± Standard Deviation			
Sex				
Male	15 (78.9)	14 (66.7)	29 (72.5)	0.488 ¹
Female	4 (21.1)	7 (33.3)	11 (27.5)	
Age	58.2 ± 11.2	54.5 ± 10.2	56.2 ± 10.7	0.326 ³
Symptom duration (months)	7.2 ± 5.5	9.8 ± 9.2	8.5 ± 7.7	0.466 ³
Localization of Primary Tumor				
Mouth and Bottom Lip	3 (21.1)	11 (52.4)	14 (37.5)	0.015 ²
Extra Oral	16 (78.9)	10 (47.6)	26 (62.5)	
Staging				
Stage I/II	12 (63.2)	17 (81.0)	29 (72.5)	0.293 ¹
Stage III/IV	7 (36.8)	4 (19.0)	11 (27.5)	
Treatment modality				
Surgery and Radiotherapy	12 (63.2)	16 (76.2)	28 (70.0)	0.013 ²
Surgery, Radiotherapy and Chemotherapy (12 sessions)	5 (26.3)	- (-)	5 (12.5)	
Radiotherapy	2 (10.5)	5 (23.8)	7 (17.5)	
Time from radiation therapy (months)	66.8 ± 52.9	76.1 ± 66.2	71.7 ± 59.7	0.641 ³
Dose				
Up to 65Gy	14 (58.3)	10 (41.7)	24 (60.0)	0.249 ²
>65Gy	5 (31.0)	11 (69.0)	16 (40.0)	
Irradiated Field				
Mandible	15 (78.9)	10 (47.6)	25 (62.5)	0.068 ²
Maxilla	1 (5.3)	6 (28.6)	7 (17.5)	
Maxilla and Mandible	3 (15.8)	5 (23.8)	8 (20.0)	

1- Exact Fisher Test; 2 -Verisimilitude Ratio Test; 3- Non-parametric Mann Whitney Test

METHODS

Forty dental extraction were performed at least 6 months following RT-HN according to the study group: PBM (n=19): dental extraction + PBM and SHAM (n=21): dental extraction + sham PBM. All patients received prophylactic antibiotics and the surgical alveoli underwent primary closure. PMB parameters were: 808 nm, 40mW, 100J/cm², 70s, 2.8 J/point and area of 0,028cm². The primary outcome was complete mucosal lining at 14 days, and the secondary outcomes were the presence of infection, as well as post-operative pain and consumption of analgesics at 7 days. The patients were evaluated every 7 days during a time interval of 28 days.

RESULTS

Alveolar mucosal lining was shown to be faster in PBM, and at D14 18/19 (94.7%) patients evolved with complete alveolar mucosal lining. PBM patients reported post-operative pain less frequently at D7 (21.1% x 66.7%, p=0.005), and also used less analgesics (at D7 - 21.1% x 66.7%, p=0.005).

Table 2 - Distribution of pain variables (pre- and post-operative); infection (pre- and post-operative); administration of analgesic agents, bone exposure and alveolar mucosa lining

Variables	G1 (n=19):	G2 (n=21):	Total	p-value
	n(%)			
Pre-operative pain				
No	6 (31.6)	13 (61.9)	19 (47.5)	0.067 ¹
Yes	13 (68.4)	8 (38.1)	21 (52.5)	
Post-operative Pain				
D7	4 (21.1)	14 (66.7)	18 (45.0)	0.005 ¹
D14	- (-)	2 (9.5)	2 (5.0)	0.488 ¹
Analgesic Administration (days)				
D7	4 (21.1)	14 (66.7)	18 (45.0)	0.005 ¹
Pre-operative infection				
No	18 (94.7)	20 (95.2)	38 (95.0)	1.000 ¹
Yes	1 (5.3)	1 (4.8)	2 (5.0)	
Bone exposure (presence in millimeters)				
D21	- (-)	1 (4.8)	1 (2.5)	1.000 ¹
D28	- (-)	1 (4.8)	1 (2.5)	1.000 ¹
Alveolar Mucosa lining				
D7				
G1	- (-)	19 (90.5)	19 (47.5)	0.000 ²
G2	17 (89.5)	2 (9.5)	19 (47.5)	
G3	2 (10.5)	- (-)	2 (5.0)	
D14				
G1	- (-)	2 (9.5)	2 (5.0)	0.000 ²
G2	1 (5.3)	19 (90.5)	20 (50.0)	
G3	18 (94.7)	- (-)	18 (45.0)	
D21				
G2	1 (5.3)	16 (76.2)	17 (42.5)	0.000 ¹
G3	18 (94.7)	5 (23.8)	23 (57.5)	
D28				
G2	- (-)	1 (4.8)	1 (2.5)	1.000 ¹
G3	19 (100.0)	20 (95.2)	39 (97.5)	

1 - Exact Fisher Test; 2- Verisimilitude ratio test

Table 3 - Relative Risk (RR) measurements, Absolute Risk Reduction (ARR), Number Necessary for Treatment (NNT) of variables: Post-operative pain in time D7 and alveolar mucosa lining in time D14

Variables	RR	ARR	NNT
	(IC95)	(IC95)	(IC95)
Post-operative Pain			
D7	0.316 (0.126 - 0.794)	0.456 (0.184 - 0.729)	2.192 (1.372 - 5.445)
Alveolar Mucosa lining			
D14	0.053 (0.008 - 0.355)	0.947 (0.847 - 1.048)	1.056 (0.954 - 1.181)

1- Exact Fisher Test; 2 - Verisimilitude Ratio Test; CI95= Confidence Interval of 95%, RR=Relative Risk, ARR = Absolute Relative Risk; ARR=Absolute Risk Reduction; NNT=Number Necessary to Treat

CONCLUSIONS

PBM demonstrated a beneficial effect in mucosal healing of dental extraction sockets following HN-RT. Larger RCTs are necessary to establish PBM as standard of care for managing these surgical sites.

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