BETHANECHOL USED TO PREVENT SALIVARY GLAND DYSFUNCTION PATIENTS SUBMITTED TO RADIOACTIVE IOIDINE THERAPY – A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED STUDY

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Introduction

Symptoms related to salivary gland damage are one of the most frustrating complications after radioactive iodine (^{131}I) therapy. The objectives of this prospective trial were to evaluate the efficacy of the prophylactic use of bethanechol on reducing sialadenitis symptom through presence of pain and swelling in salivary glands; hyposalivation; xerostomia symptom and also to evaluate the quality of life score using University of Washington Quality of life 4 questionnaire (QOL-UW).

Patients and Methods

This double-blind, prospective clinical trial was conducted between July 2016 to March 2017. A total of 50 patients with with primary differentiated thyroid carcinoma were randomized before ^{131}I therapy and allocated into two groups (Table 1):

Table 1- Clinical characteristics of 50 patients.

Variables	Category	Grupo Bethanechol (n=26)		Grupo Placebo (n=24)		p
		N	%	N	%	
Gender	Male	12	46,2	07	29,2	0,216
	Female	14	53,8	17	70,8	
Age (years)	≤ 37	9	34,6	9	37,5	0,433
	38 – 55	12	46,2	12	50	
	56 – 75	5	19,2	3	12,5	
Diagnosis	Papillary	25	96,2	22	91,7	0,602
	Follicular	01	3,8	02	8,3	
^{131}I dose (mCi)	≤ 125	13	50	12	50	0,676
	126 – 150	11	42,3	10	41,7	
	>150	2	7,7	2	8,3	

Bethabechol and Placebo

Both therapies were administered one tablet (25 mg tablets) taken twice a day beginning 2 hours after ^{131}I therapy and continued until 1 month after the end of treatment.

Xerostomia Assessment, Whole Saliva Collection, Sialadenitis and QOL questionnaire

These evaluations were performed in FOUR phases:

- Baseline
- 10 days after ^{131}I therapy
- 30 days after ^{131}I therapy
- 90 days after ^{131}I therapy

ALEXANDER et al. 1998; CAGLAR et al. 2002. NEWKIRK et al. 2000. SILBERSTEIN 2008. JAGUAR 2015.

Results

Bethanechol therapy was generally well tolarated. No patient was drop out to this study due to adverse effect.

Xerostomia Complaint

Bethanechol group presented significantly lower complaints of dry mouth on 10 (p=0.047) and 30 (p=0.003) days compared with placebo. Interestingly, bethanechol patients who received ^{131}I dose > 125 mCi, showed better xerostomia indices when compared to placebo with same dose.

^{131}I-induced sialadenitis

Salivary gland pain and swelling were more frequent among placebo patients at 10 days (p=0.047).

Salivary Flow

Comparasion of the groups by whole unstimullated saliva, no statistical difference was found in any phases.

QOL questionnaire

Placebo group presented worse score related to activity (p=0.034), saliva (p=0.05) and humor (p=0.05) at 10 days, taste (p=0.05) and saliva (p=0.05) at 1 month. Interestingly, placebo patients who presented xerostomia, edema and pain in salivary glands, showed worse geral mean scrore at 10 and 30 days after ^{131}I therapy (Figure 1).

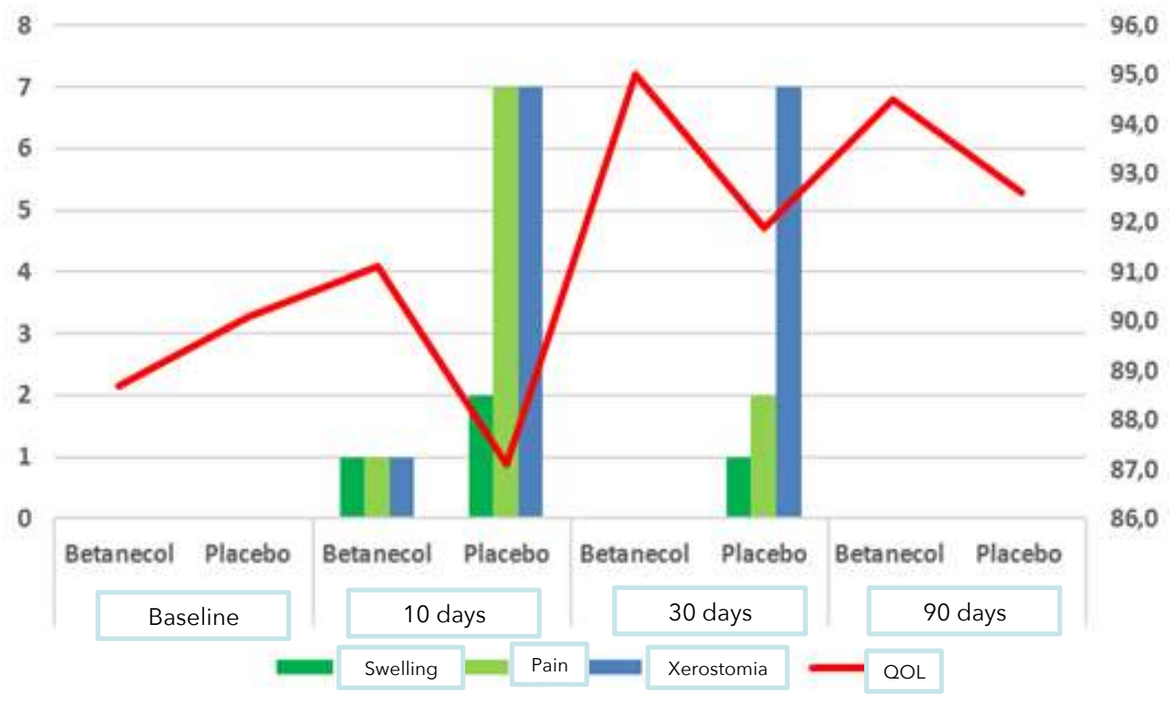

Figure 1- Association of xerostomia, swelling and pain in salivary glands with QOL .

Conclusion

Bethanechol during ^{131}I therapy is safety and contributes to decrease the acute salivary gland damage and complaint of xerostomia. with greater improvement in the patient's quality of life.