APBI with 3D-CRT vs WBI after conserving surgery (IRMA trial): interim cosmetic and toxicity results

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Purpose and background

To report interim **cosmetic** and **toxicity** results in patients enrolled from *5 italian centers* in the randomized IRMA trial

IRMA trial

Multicentric randomized trial (Italy, Netherlands, Spain, Switzerland, Israel)

Non inferiority study (APBI vs WBI)

Primary Objective: Local control (incidence of ipsilateral recurrences)

Secondary Objectives: OS, Cosmesis, Toxicity.

Matherial and methods

Patients

- Age ≥ 49 years
- Invasive breast cancer < 3 cm, pN0-1
- Unifocal disease
- Negative resection margins

Treatment

3D-CRT APBI: 38.5 Gy in 10 fractions twice daily

WBI: standard fractionation (1,8-2 Gy/fr) or hypofractionated (2,5 Gy/fr)

Adjuvant systemic therapy according to institutional guidelines

Matherial and methods

Follow-up and outcomes

Evaluation	Basal	During RT	End of RT	At 6 wks	At 3 months	At 6 months	At 1 year
Visit	x		x	x	x	x	X (b)
Weight	x				x	x	x
Disease status	x		x	x	x	x	x
Mammography	x						X (a)
Breast CT	x						
Toxicity (c)	x	x	x	x	x	x	X (b)
Photographs	x				x	x	X (d)
Cosmetic evaluation (Patient)	x				x	x	X (d)
Cosmetic evaluation (Radiotherapist)	x					x	X (d)

After first year:
every 6 months for the first 3 years
then annually for at least 10 years

Toxicity: RTOG scale

Definition of cosmetic result:

A) Excellent: minimum difference in relation to the untreated breast in volume
B) Good: slight asymmetry in the volume or form of the treated breast
C) Fair: difference in the volume and form of the breast treated.
D) Poor: pronounced modification of the aspect of the breast treated in over 1/4 of the breast tissue

Results

Patient characteristics

March 2007 - December 2013: **983 pts enrolled - 5 italian centers** (425 *Bologna Bellaria*, 240 *Modena*, 163 *Reggio Emilia*, 101 *Bologna S. Orsola*, 54 *S.G.Rotondo*)

Median FUP: 5 years

Characteristic	WBI (n=506)	APBI (n=477)
Mean Age (SD, range)	64.4 (8.6, 49-87.5)	64.1 (8.2, 49-86)
CHT pre-RT (%)	84 (16%)	83 (17.4%)
OT (%)	409 (80.8%)	379 (79.4%)

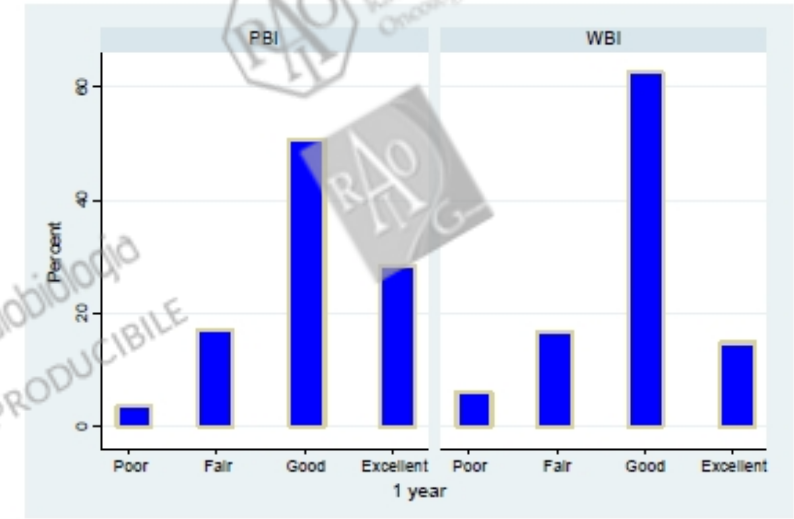
TNM classes	PBI	WBI
	N. (%)	N. (%)
T1N0	384 (80.5)	406 (80.2)
T2N0	30 (6.3)	37 (7.3)
T1N1	56 (11.7)	54 (10.7)
T2N1	7 (1.5)	9 (1.8)

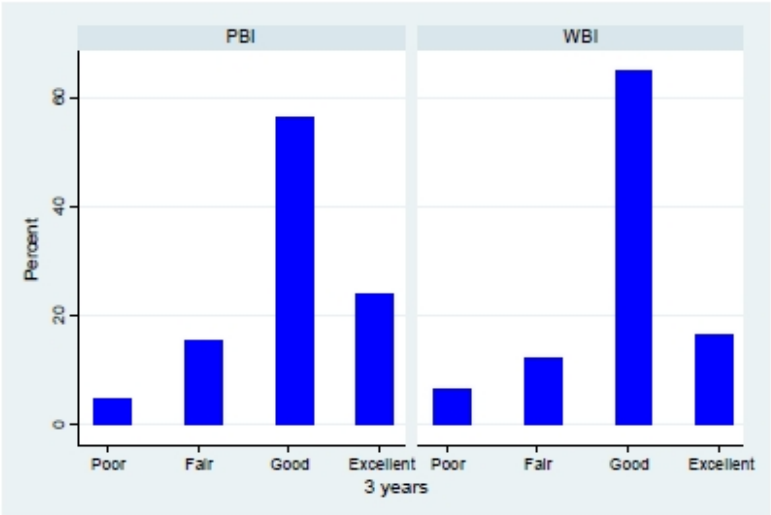
Results

Cosmetic outcome

Phys \ Pts	Poor/fair	Good/excell
Poor/fair	95 (87.16%)	53 (9.25 %)
Good/excell	14 (12.84%)	520 (90.75%)

Cohen's K = 0.68





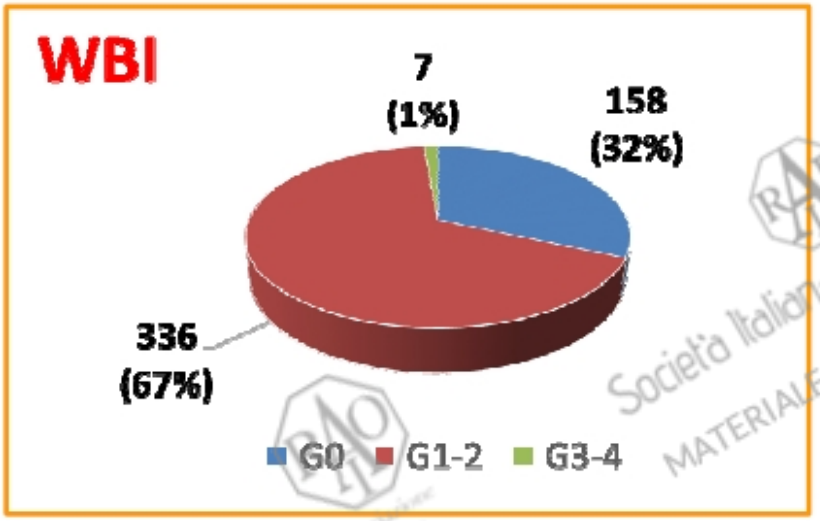
Results

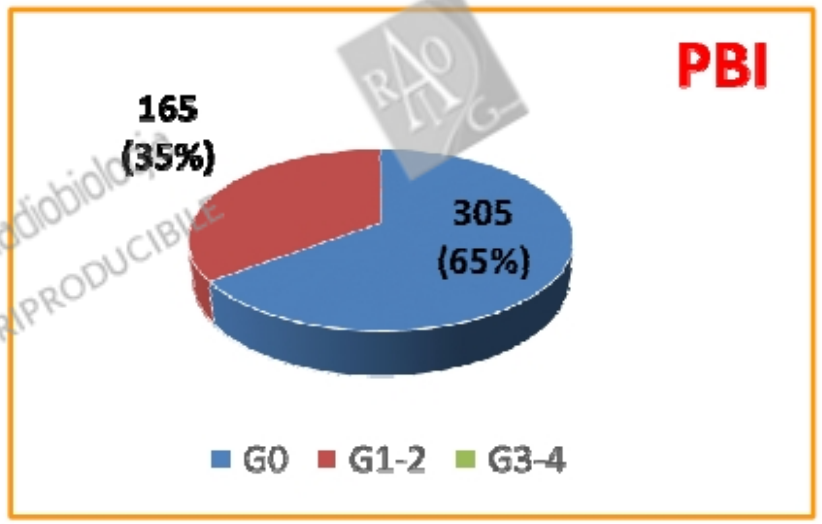
Adverse cosmesis

Time	WBI	APBI	APBI-WBI Difference (%)	95% CI	P
Patients					
1 year	58 (17.5%)	51 (14.5%)	-3 %	-8.4 to 0.2	0.2
2 years	39 (12.8 %)	39 (12.5%)	- 0.3 %	-5.5 to 4.9	0.9
3 years	37 (13.2%)	44 (14.6%)	1.4 %	-4.2 to 7	0.6
Physician					
1 year	75 (22.6%)	73 (20.8%)	- 1.8 %	-7.9 to 4.3	0.5
2 years	58 (19 %)	62 (19.9 %)	0.9 %	-5.3 to 7.1	0.7
3 years	51 (18.2 %)	60 (19.9 %)	1.7 %	-4.6 to 8	0.6

Results

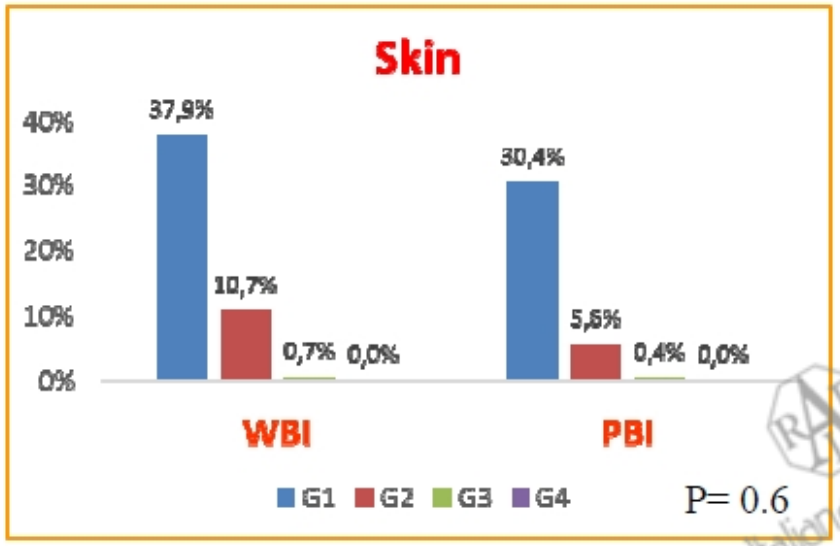
Skin acute toxicity

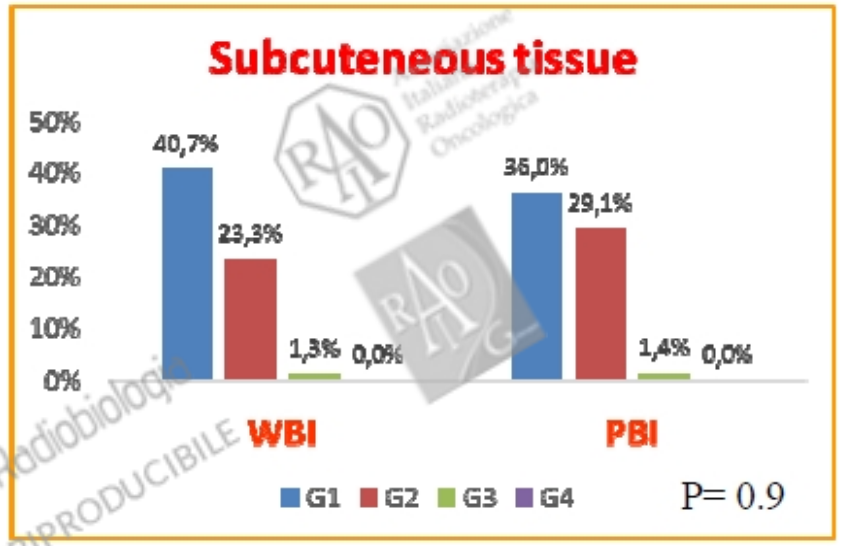


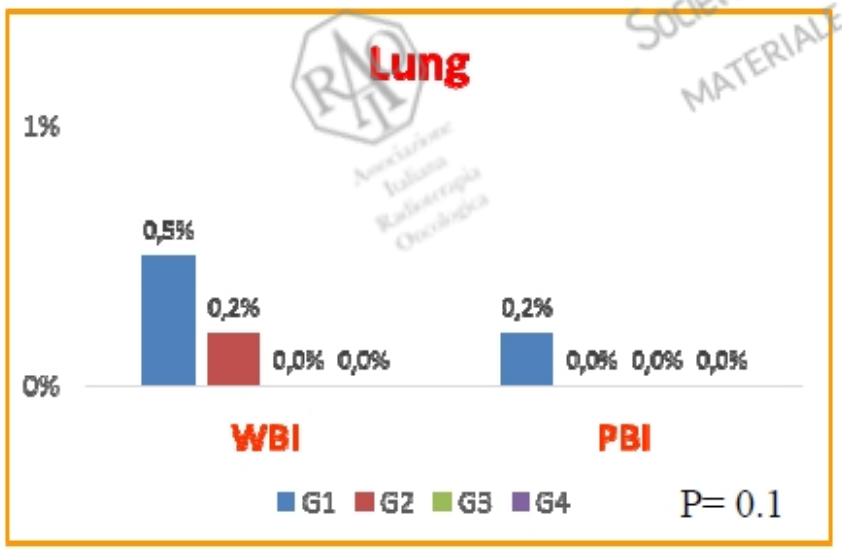


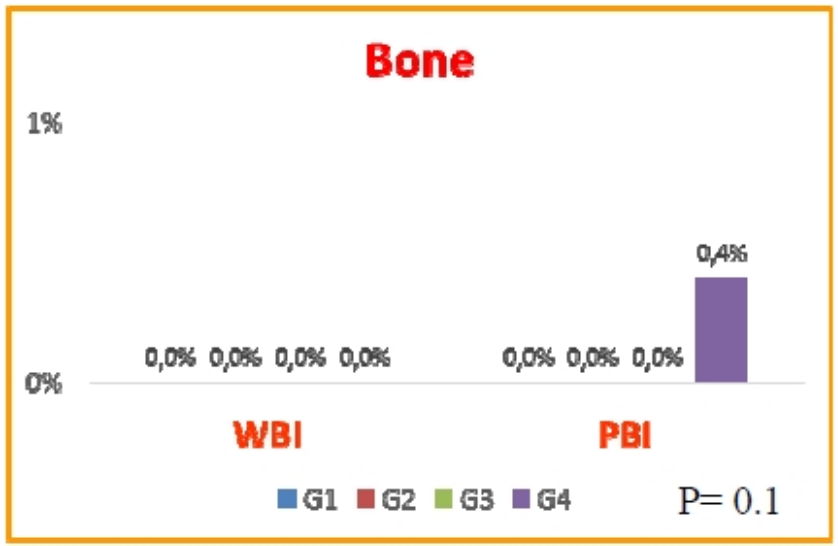
P <0.05

Late toxicity

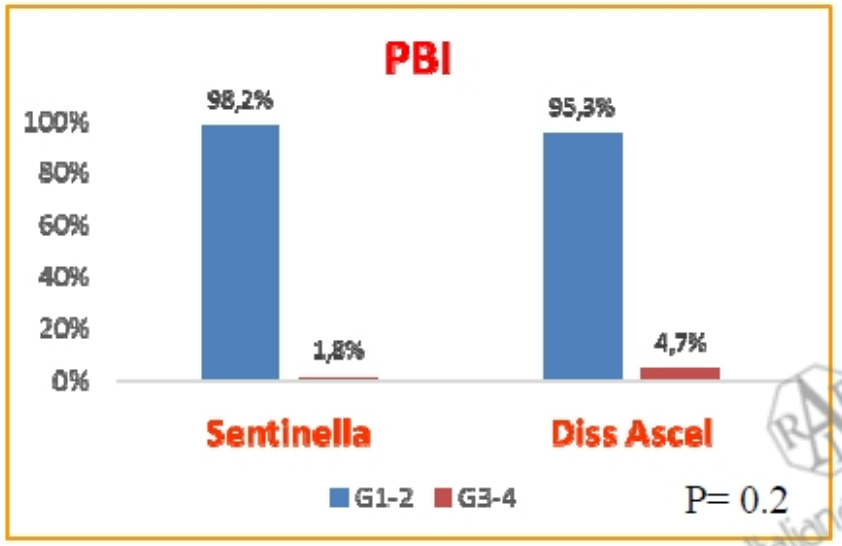




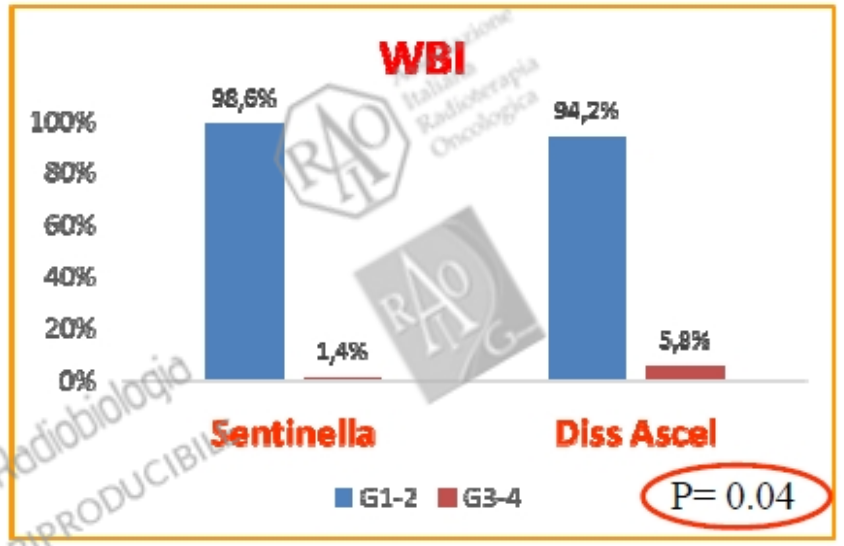


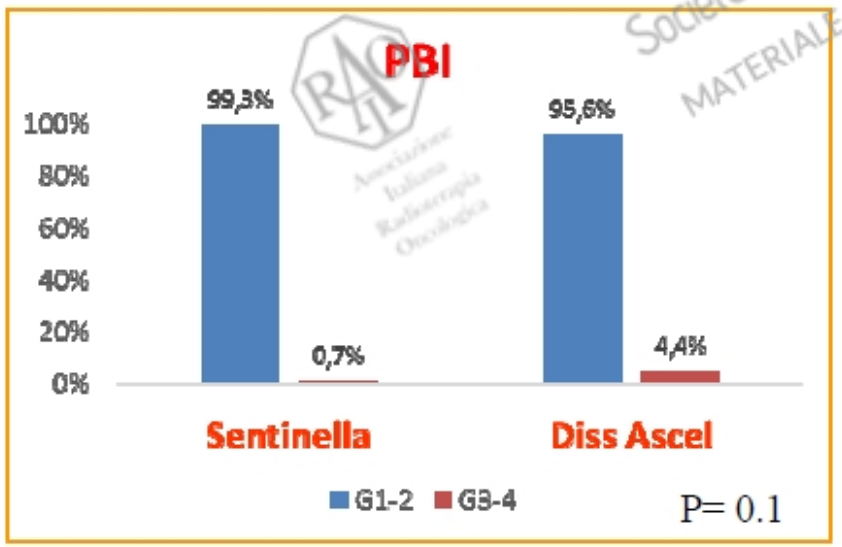


Late toxicity

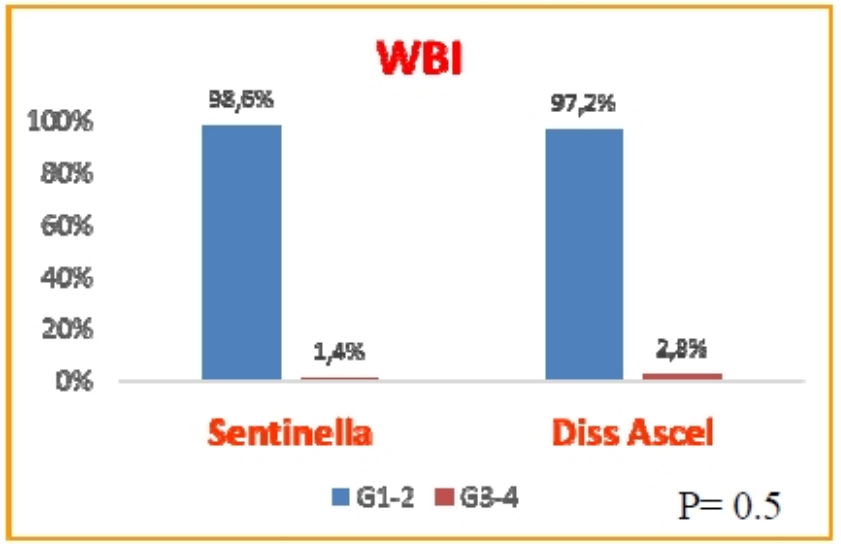


Subcuteneous tissue

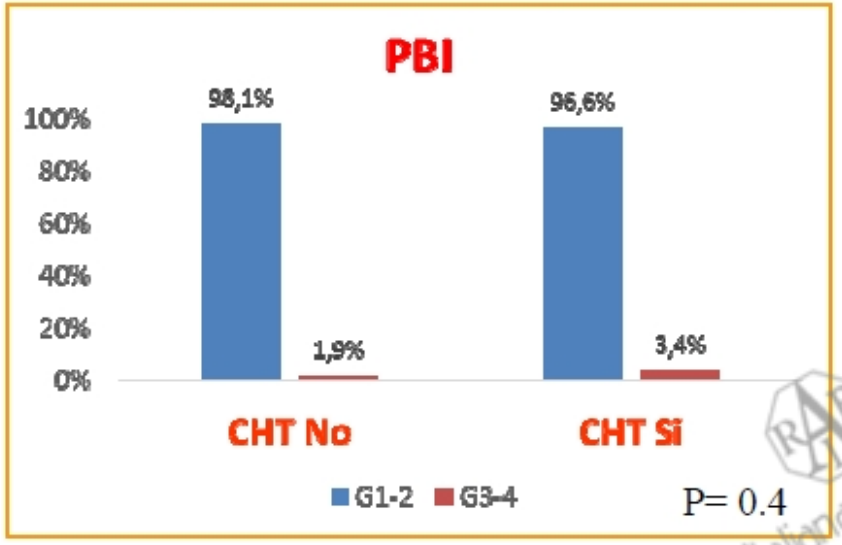




Skin



Late toxicity



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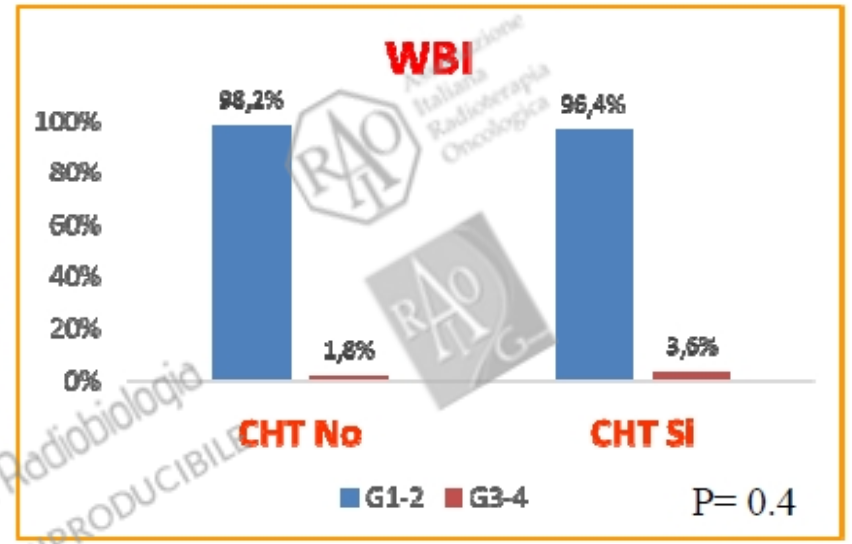

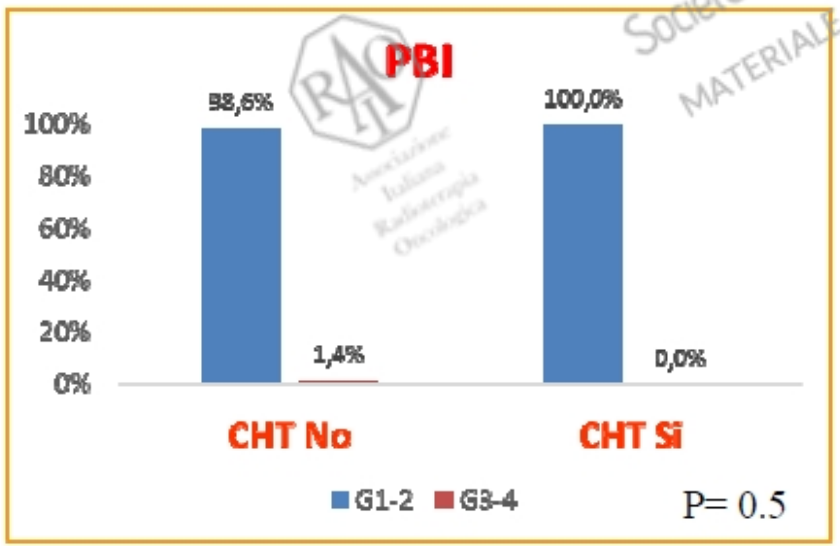

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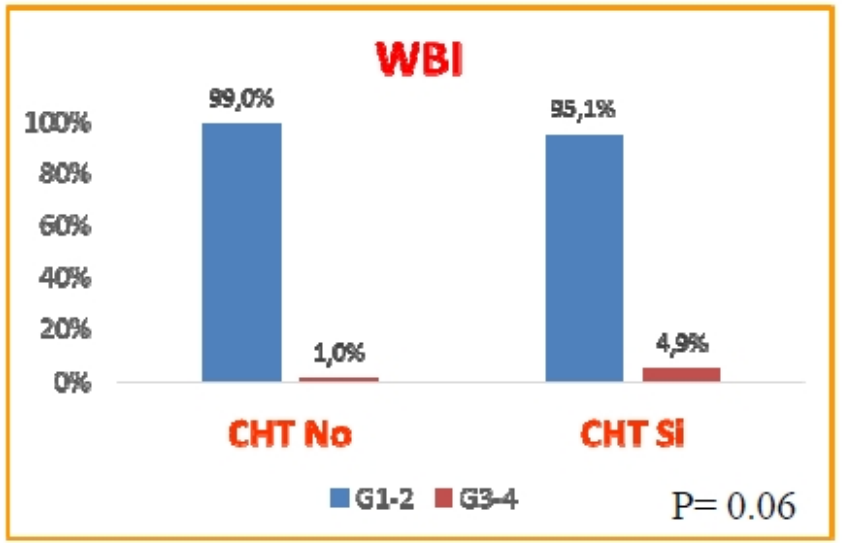

Conclusion

APBI with 3D-CRT resulted in *better acute toxicity* and *similar late toxicity* and *good/excellent cosmetic results* compared with standard WBI.

Additional follow-up is needed to confirm these results.

Acknowledgements

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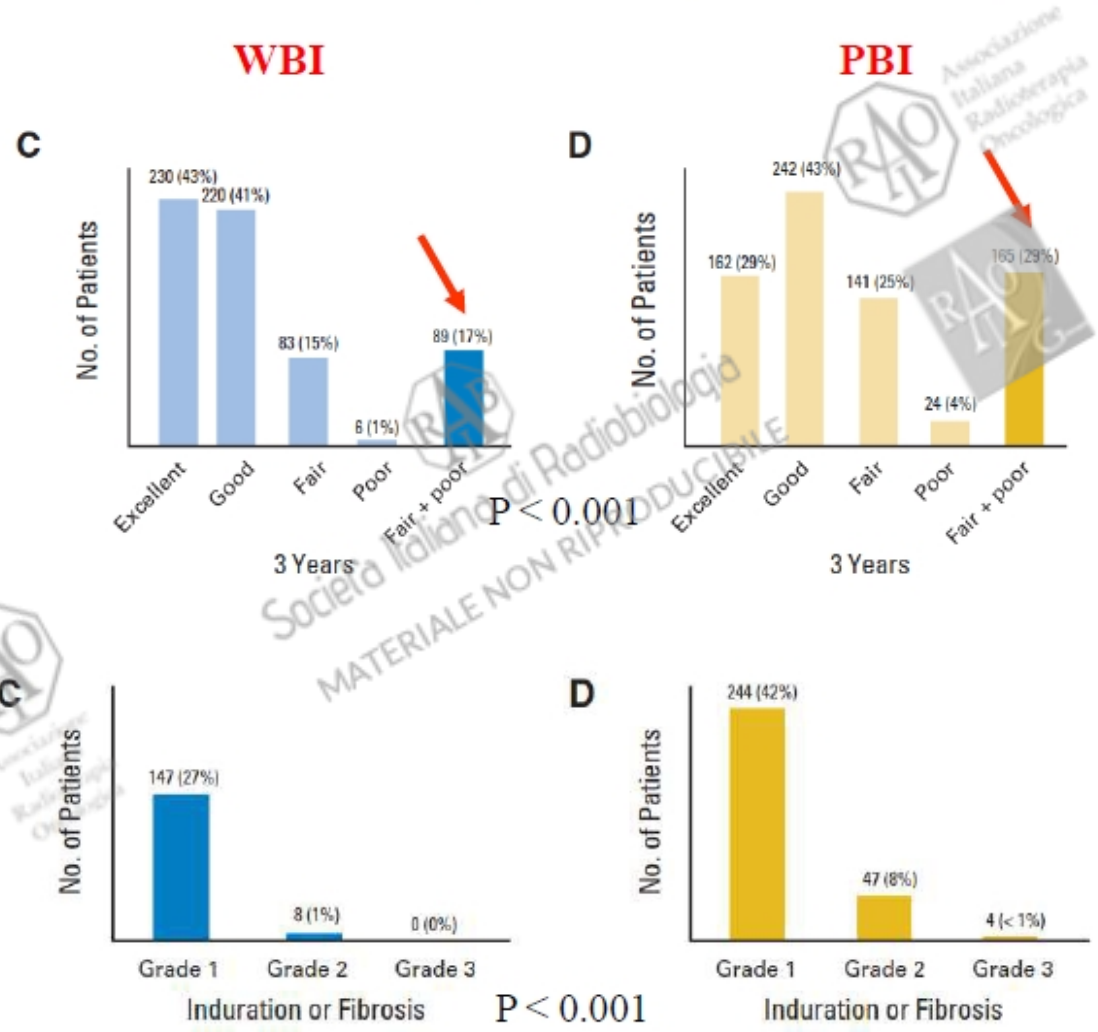
Discussion



Olivotto I. A., et al. *J Clin Oncol* **2013;** 31: 4038-45