

NSABP B-39/ RTOG 0413

Behavioral and Health Outcomes  
(BAHO): *Quality of Life*

# *Quality of Life Endpoints*

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- Cosmesis
- Breast related symptoms
- Fatigue
- Perceived convenience-of-care

# *QOL: Primary hypotheses*

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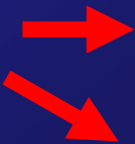
- **Cosmetic** results from PBI after lumpectomy will be comparable to WBI 3-years following treatment.
- **Fatigue** will be less for patients undergoing PBI compared to WBI

# *QOL: Secondary Hypotheses*

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- **Treatment related symptoms** at the end of radiotherapy will be less for patients undergoing PBI.
- **Perceived convenience of care** will be greater for patients undergoing PBI

# *QOL Sub-study*

- Sample size : 964  482 Chemotherapy  
482 No Chemo
- Chemotherapy expected to impact QOL
- Two separate analyses for QOL:
  - Patients who receive Chemotherapy
  - Patients who do not receive Chemotherapy

# QOL- Cosmesis

## QOL:

Baseline

Last day treatment

4 weeks post treatment

1 year

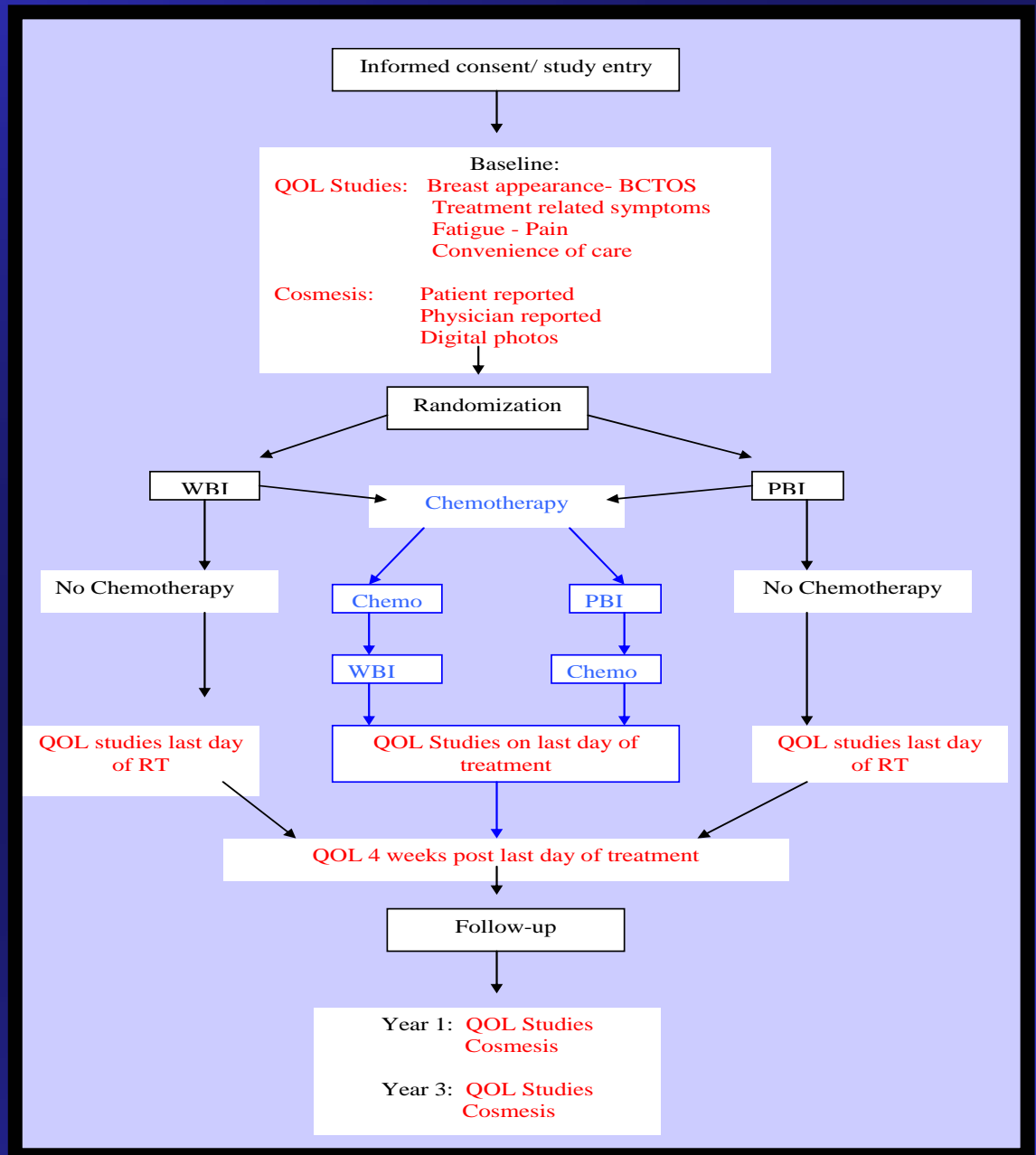
3 year

## Cosmesis:

Baseline

1 year

3 year



# *QOL Studies: Treatment related Symptoms*

By circling one (1) number per line, please indicate how much you have been bothered by each of the following problems during treatment.

	Not bothered at all	A little bit bothered	Some- what bothered	Bothered quite a bit	Bothered very much
Fever or shivering (shaking, chills)....	0	1	2	3	4
Swelling of breast (breast feels larger).....	0	1	2	3	4
Breast heaviness.....	0	1	2	3	4
Breast warm to touch.....	0	1	2	3	4
Breast skin is red.....	0	1	2	3	4
Breast skin is tanned.....	0	1	2	3	4
Breast skin or area around nipple is pale in color.....	0	1	2	3	4
Breast skin is flaking or peeling.....	0	1	2	3	4
Bleeding or fluid leakage from breast	0	1	2	3	4
Breast itching.....	0	1	2	3	4
Blisters on the breast (or breast skin moist and raw).....	0	1	2	3	4
Coughing.....	0	1	2	3	4
Difficulty breathing.....	0	1	2	3	4
Muscle aches.....	0	1	2	3	4
Rib or chestwall pain.....	0	1	2	3	4
Infections.....	0	1	2	3	4
Slow healing of breast wounds...	0	1	2	3	4
Visible small blood vessels (spider veins).....	0	1	2	3	4
Pockmarks or puncture wounds on breast.....	0	1	2	3	4
Thickening of breast skin.....	0	1	2	3	4
Hardening of breast.....	0	1	2	3	4
Breast or nipple numbness.....	0	1	2	3	4
Sharp shooting pains or twinges in the breast.....	0	1	2	3	4

# *QOL Studies*

## BCTOS: Breast Cancer Treatment Outcome Scale

	Difference between treated and untreated breast and area			
	None	Slight	Moderate	Large
1. Breast size.....	1	2	3	4
2. Breast texture (hardening) .....	1	2	3	4
3. Arm heaviness.....	1	2	3	4
4. Nipple appearance.....	1	2	3	4
5. Shoulder movement .....	1	2	3	4
6. Arm movement .....	1	2	3	4
7. Breast pain.....	1	2	3	4
8. Ability to lift objects.....	1	2	3	4
9. Fit of shirt sleeve.....	1	2	3	4
10. Breast tenderness.....	1	2	3	4
11. Shoulder stiffness.....	1	2	3	4
12. Breast shape.....	1	2	3	4
13. Breast elevation (how high the breast is).....	1	2	3	4
14. Scar tissue.....	1	2	3	4
15. Shoulder pain.....	1	2	3	4
16. Arm pain.....	1	2	3	4
17. Arm swelling.....	1	2	3	4
18. Breast swelling.....	1	2	3	4
19. Arm stiffness.....	1	2	3	4
20. Fit of bra.....	1	2	3	4
21. Breast sensitivity.....	1	2	3	4
22. Fit of clothing.....	1	2	3	4



# QOL Studies: Fatigue and Pain

HOW MUCH OF THE TIME DURING TREATMENT	All of the time	Most of the time	Some of the time	A little of the time	None of the time
1. Did you feel full of life?	1	2	3	4	5
2. Did you have a lot of energy?	1	2	3	4	5
3. Did you feel worn out?	1	2	3	4	5
4. Did you feel tired?	1	2	3	4	5

5. Rate your pain at its worst during treatment. (Circle one number.)

0	1	2	3	4	5	6	7	8	9	10
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No pain Pain as bad as you can imagine

6. Rate your pain at its least during treatment. (Circle one number.)

0	1	2	3	4	5	6	7	8	9	10
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No pain Pain as bad as you can imagine

7. Rate your pain on average during treatment. (Circle one number.)

0	1	2	3	4	5	6	7	8	9	10
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No pain Pain as bad as you can imagine

8. Rate how much pain you have right now. (Circle one number.)

0	1	2	3	4	5	6	7	8	9	10
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No pain Pain as bad as you can imagine

9. Are you currently receiving treatments or taking medications for your pain?

Circle one: Yes No

# ***QOL STUDIES: Convenience of Care***

Example:

1. To what extent has your treatment **disrupted** your normal daily activities?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A lot

2. To what extent has your treatment **disrupted** your normal recreational activities?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A lot

3. To what extent has your treatment **disrupted** your normal activities with your family and friends?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A lot

4. To what extent has your treatment **disrupted** your normal sleep pattern?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A lot

5. To what extent has your treatment **reduced** your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A lot

# *Cosmesis Evaluation*

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## Three methods

- Patient reported
- Physician reported
- Digital photos

# *Cosmesis:*

## *Patient and physician reported scale*

1	<b>EXCELLENT:</b> when compared to the untreated breast or the original appearance of the breast, there is minimal or no difference in the size or shape of the treated breast. The way the breast feels (its texture) is the same or slightly different. There may be thickening, scar tissue or fluid accumulation within the breast, but not enough to change the appearance.
2	<b>GOOD:</b> there is a slight difference in the size or shape of the treated breast as compared to the opposite breast or the original appearance of the treated breast. There may be some mild reddening or darkening of the breast. The thickening or scar tissue within the breast causes only a mild change in the shape or size.
3	<b>FAIR:</b> obvious differences in the size and shape of the treated breast. This change involves a quarter or less of the breast. There can be moderate thickening or scar tissue of the skin and the breast, and there may be obvious color changes.
4	<b>POOR:</b> marked change in the appearance of the treated breast involving more than a quarter of the breast tissue. The skin changes may be obvious and detract from the appearance of the breast. Severe scarring and thickening of the breast, which clearly alters the appearance of the breast, may be found.

Same scale as RTOG 9517 and RTOG 0319

# *Cosmesis:* *Digital photos*

- Hands on hips
  - both breasts
- Close-up
  - treated breast
- Independent Panel review
- RTOG Database



/12/04







10 mo post mq

1 1-98-55







10 mo post mp  
1-18-05

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