

Clinical Study (Dec '11) Correlation with biopsy proven cancers

Study Site: Bryn Mawr Hospital, Pennsylvania, USA
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 Duration: Oct 2009 - Oct 2011

Background

NoTouch BreastScan (NTBS) is a non-invasive, non-radiation based imaging tool that measures and compares thermal markers in the breasts using dual infrared cameras and computer software analysis. This study evaluated NTBS results as a predictor of breast cancer in symptomatic patients undergoing minimally invasive breast biopsy due to suspicious mammogram, ultrasound and/or MRI findings.

Inclusion Criteria

- Female age >18 years at the time of enrollment
- Suspicious mammography, ultrasound and/or MRI findings

Results by Size & Grade

Of the 178 patients retrospectively evaluated using NTBS (version 2), 22 were excluded due to erroneous data, resulting in a total of 156 patients. 44 patients had 46 positive breast biopsies and 112 had 116 negative biopsies. Overall results are as follows:

Sensitivity	Specificity	NPV	PPV
87%	48%	90%	40%

Size Analysis	# Cases	Sensitivity
< 1cm	16	88%
1 to 2cm	10	90%
> 2cm	7	100%
Unknown	13	n/a

Grade Analysis	# Cases	Sensitivity
Grade 1	11	91%
Grade 2	16	81%
Grade 3	16	88%
Unknown	3	n/a

Please refer to the attached spreadsheet for clinical details on the positive breast biopsy cases.

Serial #	Type	Grade	Size	Details
1	DCIS	2	0.20	0.2 DCIS largest focus
2	IDC/DCIS	2	n/a	invasive ductal carcinoma: well differentiated
3	IDC	2	2.00	nuclear grade 2 surrounding DCIS: cribriform type and intermediate grade 2 cm grade 2
4	DCIS	1	1.50	1.5 DCIS solid cribriform no necrosis identified grade 1 (low)
5	IDC/DCIS	2	2.6	RIGHT: 2.6 cm IDC; DCIS present comedo cribriform micropapillary solid grade 3; overall grade 2
6	IDC/DCIS	2	3	LEFT: 3cm IDC; DCIS present cribriform solid grade 2; overall grade 2
7	IDC	1	1.00	1 cm invasive ductal grade 1
8	DCIS	3	1.4	1.4 cm DCIS solid comedo extensive comedonecrosis present grade 3
9	DCIS	3	0.00	solid and cribriform types with punctate necrosis and nuclear grade 3
10	DCIS	1	0.6	0.6 cm Inv papillary cancer; cribriform DCIS grade 1 present; overall grade 1
11	IDC/DCIS	1	1	1 cm IDC; DCIS cribriform grade 1 present; overall grade 1
12	IDC/DCIS	3	1.1	1.1 cm IDC; DCIS comedo grade 3 present; overall grade 3
13	IDC	1	1.7	1.7 cm IDC; grade 1
14	IDC/DCIS	2	0.8	0.8 IDC; DCIS cribriform grade 2; overall grade 2
15	DCIS	3	n/a	solid cribriform comedo DCIS grade 2/3
16	DCIS	2	0.6	0.6 cm solid cribriform grade 2 (intermediate)
17	PHY	n/a	n/a	excluded b/c phyllodes
18	IDC/DCIS	1	1.5	1.5 cm IDC and DCIS solid cribriform with focal necrosis present; overall grade 1
19	IDC	1	1.8	1.8 cm; grade 1
20	DCIS	3	n/a	grade 2 - 3 and cribriform
21	IDC/DCIS	3	0.6	0.6 IDC; DCIS present comedo grade 3; overall grade 3
22	DCIS	3	n/a	DCIS intermediate/high grade comedonecrosis
23	DCIS	3	n/a	high grade DCIS comedo type
24	IDC/DCIS	2	0.4	0.4 cm IDC with DCIS grade 3 with expansive comedonecrosis present; overall grade 2
25	DCIS	3	4	4 cm DCIS solid grade 3
26	DCIS	2	0.5	0.5 cm DCIS cribriform grade 2
27	DCIS	2	0.1	0.1 cm DCIS micropapillary grade 2
28	IDC	3	n/a	poorly differentiated
29	DCIS	n/a	0.2	0.2 DCIS
30	IDC	3	n/a	INVASIVE, POORLY DIFFERENTIATED DUCTAL CARCINOMA. LYMPHATIC INVASION NOTED
31	IDC/DCIS	1	1.7	1.7 cm IDC; DCIS of solid cribriform type grade 2; overall grade 1
32	IDC	1	0.2	0.2 IDC; no DCIS present; overall grade 1
33	IDC	2	0.9	0.9 cm and an additional 0.7cm nodule in posterior add margin; overall grade 2 (intermed); no DCIS present in final;
34	IDC/DCIS	1	0.4	invasive ductal 0.4 cm grade 1(low) necrosis not identified and cribriform DCIS present
35	IDC	n/a	n/a	
36	DCIS	2	0.3	0.3 DCIS solid cribriform comedo type intermediate (2) grade
37	MUC/I	1	0.1	well diff mucinous <0.1cm; DCIS also seen cribriform and solid type with intermediate grade (2); overall grade 1
38	DCIS	3	0.5	solid comedo DCIS HIGH GRADE (3); 0.5 cm extensive necrosis present
39	DCIS	2	n/a	nuclear grade 2 solid and cribriform
40	IDC/DCIS	3	3.00	INVASIVE DUCTAL CARCINOMA, POORLY DIFFERENTIATED, 3 CM SIZE.
41	IDC/DCIS	2	3.9	LYMPHOVASCULAR INVASION PRESENT
42	IDC	3	2.7	3.9 IDC and solid DCIS present grade 3 (high); overall grade 2
43	IDC/DCIS	2	n/a	INVASIVE DUCTAL CARCINOMA, 2.7 CM, GRADE 3. lymphovascular invasive identified
44	DCIS	3	n/a	IDC moderately diff with high grade DCIS with focal comedonecrosis
45	IDC	2	0.25	DUCTAL CARCINOMA IN SITU, NUCLEAR GRADE 3, SOLID SUBTYPE COMPRISES
46	IDC	3	1.5	LEFT: 0.25 intermediate grade (2) invasive ductal necrosis not identified 1.5 invasive pleomorphic carcinoma overall grade 3