

SUPPLEMENTARY MATERIAL

Predictive value and clinical utility of centrally-assessed ER, PgR and Ki-67 to select adjuvant endocrine therapy for premenopausal women with hormone receptor-positive, HER2-negative early breast cancer: TEXT and SOFT trials

Breast Cancer Research and Treatment

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I. Tables and Figures

Table S1. Characteristics of the patients with and without invasive tumor material assessed versus by central pathology review (CPR) in the IBCSG Central Pathology Office, of the 5707 patients in the TEXT and SOFT intention-to-treat (ITT) populations.

Characteristic	CPR Review				All ITT Patients	
	No		Yes		N	%
	N	%	N	%		
<i>N ITT Patients</i>	889	100	4818	100	5707	100
Cohort						
No chemotherapy SOFT	234	26.3	1185	24.6	1419	24.9
No chemotherapy TEXT	160	18.0	893	18.5	1053	18.5
Chemotherapy TEXT	249	28.0	1358	28.2	1607	28.2
Prior chemotherapy SOFT	246	27.7	1382	28.7	1628	28.5
Age at randomization						
<35	94	10.6	488	10.1	582	10.2
35-39	164	18.4	831	17.2	995	17.4
40-44	295	33.2	1535	31.9	1830	32.1
45-49	289	32.5	1514	31.4	1803	31.6
≥50	47	5.3	450	9.3	497	8.7
<u>Locally-determined characteristics</u>						
No. nodes positive						
N0	508	57.1	2864	59.4	3372	59.1
N 1-3	279	31.4	1379	28.6	1658	29.1
N 4+	102	11.5	575	11.9	677	11.9
Tumor size (path.; cm)						
Unknown	40	4.5	61	1.3	101	1.8
≤2 cm	577	64.9	3018	62.6	3595	63.0
>2 cm	272	30.6	1739	36.1	2011	35.2
Tumor grade						
Unknown	32	3.6	59	1.2	91	1.6
1	173	19.5	1071	22.2	1244	21.8
2	490	55.1	2532	52.6	3022	53.0
3	194	21.8	1156	24.0	1350	23.7
Vessel invasion (lymphatics and/or blood vessels)						
Unknown	74	8.3	248	5.1	322	5.6
No	568	63.9	3141	65.2	3709	65.0
Yes	247	27.8	1429	29.7	1676	29.4
HER2 status						
Unknown	28	3.1	98	2.0	126	2.2
Negative	751	84.5	4138	85.9	4889	85.7
Positive	110	12.4	582	12.1	692	12.1
Hormone receptor status						
ER+ / PgR+	777	87.4	4260	88.4	5037	88.3
ER+ / PgR-	75	8.4	422	8.8	497	8.7
ER+ / PgR unknown	11	1.2	50	1.0	61	1.1
ER- / PgR+	22	2.5	82	1.7	104	1.8
ER- / PgR-	2	0.2	4	0.1	6	0.1

Characteristic	CPR Review				All ITT Patients	
	No		Yes		N	%
	N	%	N	%		
ER and PgR unknown	2	0.2	-	-	2	0.0
Estrogen receptor (ER) status						
Unknown	2	0.2	-	-	2	0.0
Negative (<10%)	24	2.7	86	1.8	110	1.9
Positive (≥10%)	863	97.1	4732	98.2	5595	98.0
Progesterone receptor (PgR) status						
Unknown	13	1.5	50	1.0	63	1.1
Negative (<10%)	77	8.7	426	8.8	503	8.8
Positive (≥10%)	799	89.9	4342	90.1	5141	90.1
<u>Centrally-determined values</u>						
Hormone receptor status						
Not determined	-	-	44	0.9	-	-
Negative (ER and PgR <1%)	-	-	64	1.3	-	-
Positive (ER and/or PgR ≥1%)	-	-	4710	97.8	-	-
HER2 status						
Not determined	-	-	42	0.9	-	-
Negative	-	-	4388	91.1	-	-
Positive	-	-	388	8.1	-	-

Figure S1. Flow diagram of the 4115 patients included in the TEXT and SOFT HR+/HER2- analysis population.

Abbreviations: E=exemestane; HR+=hormone receptor-positive; HER2-=HER2-negative; ITT=intention-to-treat; OFS=ovarian function suppression; SOFT=Suppression of Ovarian Function Trial; T=tamoxifen; TEXT=Tamoxifen and Exemestane Trial;

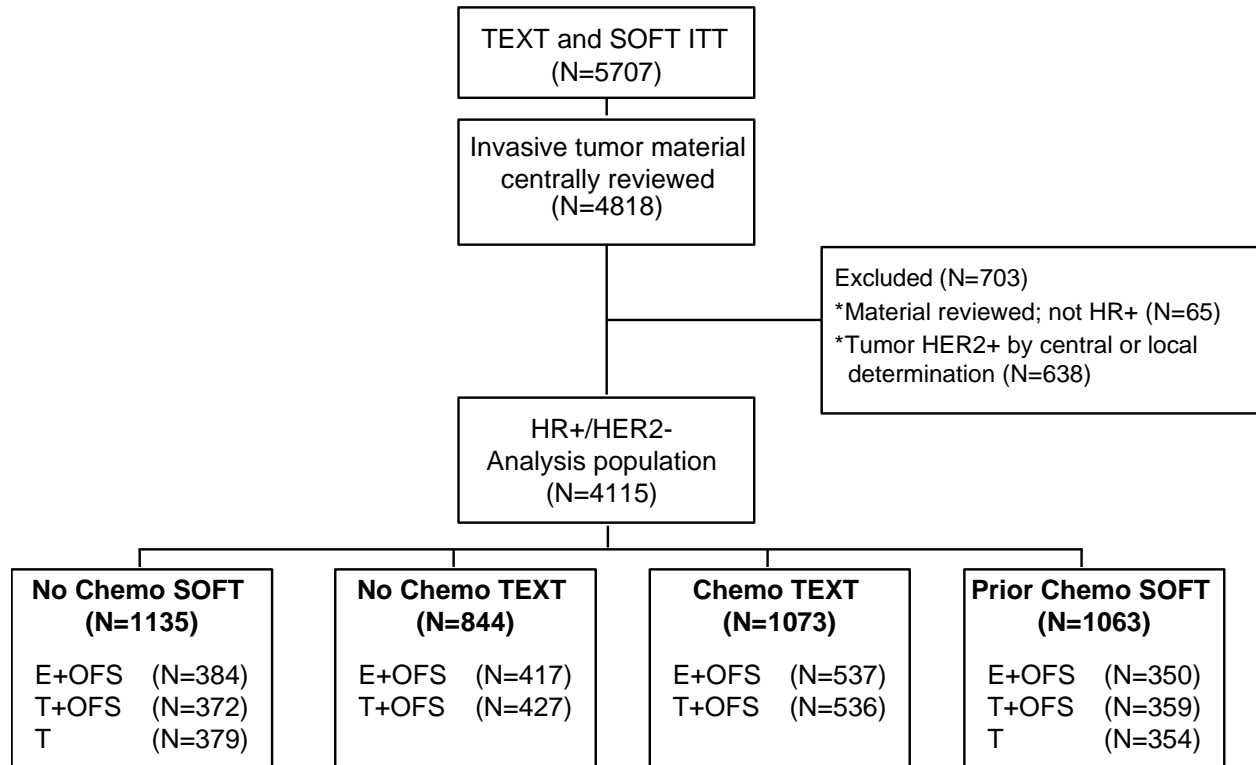
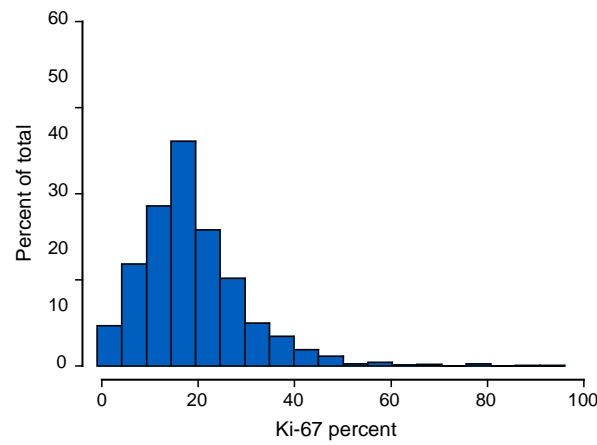
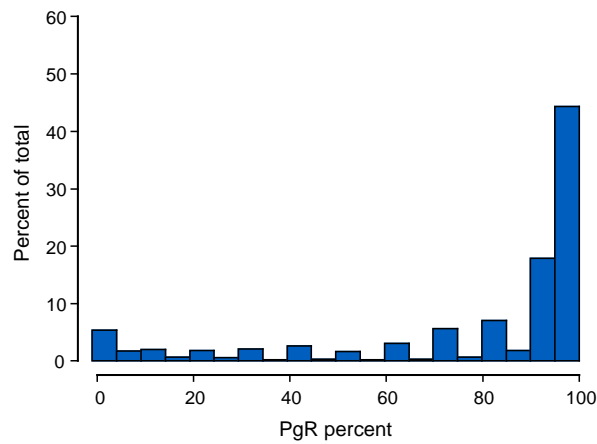
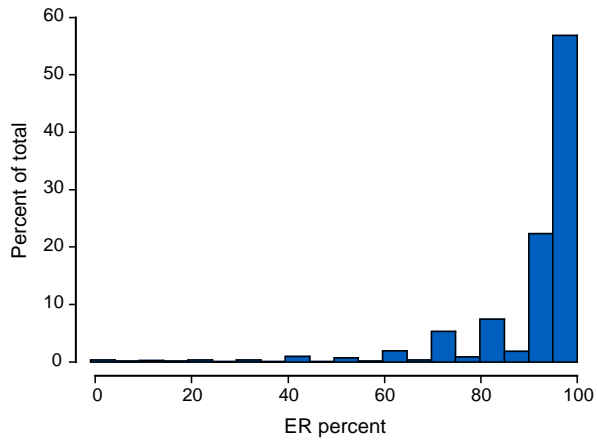


Figure S2. Distribution of estrogen receptor (ER), progesterone receptor (PgR) and Ki-67 expression in the HR+/HER2- analysis population overall.



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