

IMPORT HIGH SEROMA STUDY TABLES

Table 1: Summary of univariate analyses: associations between baseline characteristics and moderate/marked change in breast appearance at 3 years in the case-control population in IMPORT HIGH

Characteristics	Cases [Patients reporting moderate/marked change in breast appearance at 3 years] N=231 (%)	Controls [Patients reporting none/mild change in breast appearance at 3 years] N=231 (%)	Univariate analyses OR (95% CI)	P value
Age years Median (IQR)	N=231 49 (45-52)	N=231 49 (45-57)	0.98 (0.96-0.996)	0.019
Treatment group				
Control	84/231 (36)	77/231 (33)	1	
Test group 1	62/231 (27)	74/231 (32)	0.77 (0.49-1.21)	0.258
Test group 2	85/231 (37)	80/231 (35)	0.97 (0.63-1.50)	0.905
Tumour size (cm)	N=231 2.1 (1.6-2.8)	N=231 1.7 (1.3-2.5)	1.27 (1.07-1.50)	0.005
Tumour grade				
Grade 1	24/231 (10)	17/231 (7)	1	
Grade 2	99/231 (43)	93/231 (40)	0.75 (0.38-1.49)	0.418
Grade 3	108/231 (47)	121/231 (52)	0.63 (0.32-1.24)	0.182
Lymph nodes				
Positive	77/231 (33)	70/231 (30)	1	
Negative	154/231 (67)	161/231 (70)	0.87 (0.59-1.29)	0.485
Tumour location				
Central	38/230 (17)	29/230 (13)	1	
Upper outer quadrant	106/230 (46)	114/230 (50)	0.71 (0.41-1.23)	0.222
Upper inner quadrant	47/230 (20)	48/230 (21)	0.75 (0.40-1.40)	0.364
Lower outer quadrant	25/230 (11)	24/230 (10)	0.79 (0.38-1.67)	0.543
Lower inner quadrant	14/230 (6)	15/230 (7)	0.71 (0.30-1.71)	0.447
CTV boost volume in cc Median (IQR)	N=161 15.4 (7.5-24.6)	N=166 11.6 (6.4-18.6)	1.02 (1.00-1.03)	0.008
Axillary surgery				
No	3/231 (1)	3/231 (1)	1	
Yes	228/231 (99)	228/231 (99)	1.00 (0.20-5.0)	>0.99
Post-op infection				
No	189/231 (82)	207/229 (90)	1	
Yes	42/231 (18)	22/229 (10)	2.10 (1.20-3.63)	0.009
Post-op haematoma				
No	202/231 (87)	219/229 (96)	1	
Yes	29/231 (13)	10/229 (4)	3.14 (1.49-6.61)	0.003
Smoking status				
Never smoker	123/231 (53)	141/229 (62)	1	
Current smoker	41/231 (18)	21/229 (9)	2.24 (1.25-3.99)	0.006
Previous smoker	67/231 (29)	67/229 (29)	1.15 (0.76-1.74)	0.520

Cardiovascular disease				
No	218/229 (95)	210/226 (93)	1	
Yes	11/229 (5)	16/226 (7)	0.66 (0.30-1.46)	0.307
Adjuvant chemotherapy				
No	75/231 (32)	83/231 (36)	1	0.433
Yes	156/231 (68)	148/231 (64)	1.17 (0.79-1.71)	
Baseline HADs anxiety				
Normal (0-7)	133/214 (62)	154/218 (71)	1	
Borderline (8-10)	38/214 (18)	46/218 (21)	0.96 (0.59-1.56)	0.858
Case (11+)	43/214 (20)	18/218 (8)	2.77 (1.52-5.03)	0.001
Baseline HADs depression				
Normal (0-7)	167/215 (78)	184/217 (85)	1	
Borderline (8-10)	30/215 (14)	26/217 (12)	1.27 (0.72-2.24)	0.405
Case (11+)	18/215 (8)	7/217 (3)	2.83 (1.15-6.95)	0.023
Body Image Scale*	N=210	N=215	1.06 (1.03-1.09)	<0.001
Median (IQR)	9 (4-15)	5 (1-11)		
Breast Size***^				
Small	57/140 (41)	69/152 (45)	1	
Medium	52/140 (37)	66/152 (43)	0.95 (0.58-1.58)	0.854
Large	31/140 (22)	17/152 (11)	2.21 (1.11-4.39)	0.024
Surgical deficit**				
Small	86/140 (61)	119/152 (78)	1	
Medium	39/140 (28)	28/152 (18)	1.93 (1.10-3.37)	0.021
Large	15/140 (11)	5/152 (3)	4.15 (1.45-11.86)	0.008
Seroma				
No	161/202 (80)	173/205 (84)	1	
Yes	41/202 (20)	32/205 (16)	1.38 (0.83-2.29)	0.219
Seroma volume (cc)	N=198	N=203	#1.21 (1.02-1.44)	0.032
Median (IQR)***	20.3 (6.8-46.1)	13.6 (7.4-19.0)		
Breast density~				
Rank 1	88/201 (44)	70/204 (34)	1	
Rank 2	51/201 (25)	57/204 (28)	0.71 (0.44-1.16)	0.175
Rank 3	50/201 (25)	51/204 (25)	0.78 (0.47-1.29)	0.330
Rank 4	12/201 (6)	26/204 (13)	0.37 (0.18-0.78)	0.009
Mean dose in Gray	N=192	N=197	1.08 (1.02-1.14)	0.009
	45.1 (43.2-49.2)	44.0 (42.4-48.6)		
Maximum dose in Gray	N=192	N=197	1.01 (0.97-1.05)	0.532
	66 (65-74)	66 (65-74)		

*IQR=interquartile range * Higher scores for body image scale indicate more problems (possible range 0-30). **Breast size and surgical deficit scored on baseline photographs (data not available for all patients as all patients in PROMs sub-study did not participate in the photographic sub-study). ***For seroma volume, patients without seroma included in analysis with zero volume. # Seroma volume assessed per 10cc. ~Data from 2 patients missing due to inability to assess contralateral breast and implants. Rank 1=no or sparse distribution of fibroglandular tissue, 2=small dispersed clusters of fibroglandular tissue, 3=large cluster of fibroglandular tissue and 4=mainly fibroglandular tissue. ^Breast size also assessed using whole breast PTV volume. Data for diabetes mellitus, hypertension and collagen vascular disease not shown as few patients with available data.*

Table 2: Summary of multivariable analyses: associations between baseline characteristics and moderate/marked change in breast appearance at 3 years

Characteristics	Multivariable analyses Adjusted OR* (95% CI)	P value
Age	0.98 (0.96-1.01)	0.243
Tumour size	1.43 (1.13-1.82)	0.003
Post-op infection No Yes	1 1.45 (0.68-3.07)	0.335
Post-op haematoma No Yes	1 5.96 (2.20-16.11)	<0.001
Smoking status Never smoker Current smoker Previous smoker	1 2.25 (1.06-4.74) 1.15 (0.67-1.97)	0.034 0.613
Baseline HADs anxiety Normal (0-7) Borderline (8-10) Case (11+)	1 0.70 (0.37-1.32) 2.17 (0.97-4.87)	0.273 0.060
Baseline HADs depression Normal (0-7) Borderline (8-10) Case (11+)	1 0.90 (0.42-1.93) 1.93 (0.53-6.99)	0.778 0.317
Body Image Scale	1.04 (1.00-1.09)	0.044
Whole Breast PTV volume	1.00 (0.99-1.00)	0.226
Seroma volume	1.01 (0.99-1.04)	0.209
Breast density Rank 1 Rank 2 Rank 3 Rank 4	1 0.63 (0.34-1.16) 0.86 (0.44-1.68) 0.41 (0.16-1.08)	0.134 0.662 0.070
Mean dose to whole breast in Gray	1.05 (0.98-1.13)	0.190

* Odds ratios adjusted for all variables shown in the table. Rank 1=no or sparse distribution of fibroglandular tissue, 2=small dispersed clusters of fibroglandular tissue, 3=large cluster of fibroglandular tissue and 4=mainly fibroglandular tissue