

Real World Analysis of the Clinical and Economic impact of the 21-gene recurrence score in Invasive Lobular Early Stage Breast Carcinoma (ESBC) in Ireland.

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Background

- Breast cancer is the most common malignant tumour diagnosed in Irish women, with 3000 new cases diagnosed per year, of which 10-15% are invasive lobular carcinoma (ILC).¹
- Irish Registry data suggest 26% of stage I and 59% of stage II ESBC receive adjuvant chemotherapy (CT).¹
- The 21-gene recurrence score assay is a validated genomic tool that has improved the selection of patients for chemotherapy in hormone receptor positive (HR+), lymph node negative (NO) ESBC.²
- A previously published national study suggested a 57% net reduction in CT administration in ESBC patients with the use of 21-gene test.
- The impact of the 21-gene test on chemotherapy administration in ILC is poorly defined.

Objectives

- Assess the change in CT recommendations in ILC with 21-gene test use.
- Assess the economic impact of 21-gene test use on the Irish healthcare system

Methods

- From October 2011 to February 2019, a retrospective, cross-sectional observational study was conducted on HR+, NO ESBC pts with invasive lobular subtype who had 21-gene testing in Ireland.
- Data was collected from electronic patient records.
- For the decision impact analysis, a survey of Irish breast medical oncologists presumed that, without 21-gene testing, CT would be recommended to patients with histological grade (G) 2 and 3 tumours and not to those with G1 tumours.
- Following TAILOR-x results, pts were classified as low risk (RS<25) and high risk (RS>25). Pts ≤50 years were classified low risk (RS 0-15), intermediate risk (RS 16-25), and high risk (RS>25).³
- Descriptive statistics were used.
- Cost data were obtained from the National Healthcare Pricing Regulatory Authority.

Results

- 166 pts with ILC were identified.
- Mean age at diagnosis was 59 years.
- Mean tumour size was 2.3cm (range 0.7cm-5.8cm).
- The majority of pts (n=152, 92%) had G2 tumours. Seven pts (4%) had G3 tumours.
- Most pts were >50yrs (n=137, 83%), 29 (17%) pts were ≤50 years
- RS ≤25 was identified in 92.2% (153)pts, RS>25 in 7.2% (12)pts and RS unknown 1 patient.
- In the 12pts with RS>25, all 12 had G2 disease, 6(50%) pts had a tumour size greater than 3cm and 8(66.7%) pts had tumours that were PR negative.

1. Change in CT administration following 21-gene test use

- Seven G1 pts were assumed to have a negative pre-test recommendation and 159 pts had a positive pre-test CT recommendation.
- Post 21-gene testing 124 pts (74.5%) had a change in CT decision; all were a change from CT to hormone therapy.
- Post test, 35 pts (22%) received CT.
- Of pts treated with CT, 3(9%) had RS 0-15, 19(54%) had RS 16-25, 12 (34%) had RS >25 and 1(3%) was unknown.
- Eight pts (23%) that received CT were age ≤50.
- The most common CT regimen administered was docetaxel plus cyclophosphamide (TC).

Table 1: Clinical characteristics and treatment received by RS. BCS=breast conserving surgery. RS=recurrence score

	Total (n)	RS 0-15 (%)	RS 16-20 (%)	RS 21-25 (%)	RS 26-100 (%)	Missing (%)
LNO	166	75 (45.2)	45 (27.1)	33 (19.9)	12 (7.2)	1 (0.6)
Mean age	59	57	60	60	61	48
Age <50	29	16 (55.0)	6 (21.0)	5 (17.0)	1 (3.5)	1 (3.5)
Age >50	137	59 (43.1)	40 (29.2)	27 (19.7)	11 (8.0)	0 (0.0)
LVI+	11	6 (54.5)	2 (18.2)	3 (27.3)	0 (0.0)	0 (0.0)
LVI-	99	45 (45.4)	28 (28.3)	17 (17.2)	8 (8.1)	1 (1.0)
LVI Unknown	56	24 (42.9)	15 (26.8)	13 (23.2)	4 (7.1)	0 (0.0)
Stage IA	80	36 (45.0)	24 (30.0)	13 (16.2)	6 (7.5)	1 (1.3)
Stage IIA	72	31 (43.1)	19 (26.4)	17 (23.6)	5 (6.9)	0 (0.0)
Stage IIB	2	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)
Unknown	12	7 (58.3)	2 (16.7)	2 (16.7)	1 (8.3)	0 (0.0)
Grade 1	7	3 (42.9)	4 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)
Grade 2	152	68 (44.7)	39 (25.6)	32 (21.1)	12 (7.9)	1 (0.7)
Grade 3	7	4 (57.1)	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)
BCS	125	55 (44.0)	33 (26.4)	28 (22.4)	9 (7.2)	0 (0.0)
Mastectomy	41	20 (48.8)	12 (29.3)	5 (12.2)	3 (7.3)	1 (2.4)
CT received	35	3 (8.6)	4 (11.4)	15 (42.8)	12 (34.3)	1 (2.9)

Table 2: Patients aged ≤50 : age, grade (G), RS score, chemotherapy (CT)

	Total	RS 0-15	RS 16-20	RS 21-25	RS 26-100	Missing
40-50	28	15	6	5	1	1
30-39	1	1	0	0	0	0
G1	1	1	0	0	0	0
G2	27	14	6	5	1	1
G3	1	1	0	0	0	0
CT	8	2	1	3	1	1

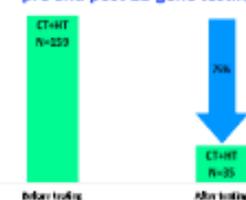
2. Economic impact of 21-gene test on Irish Health Care System

- The use of 21-gene test achieved a 75% reduction in chemotherapy use.
- This resulted in savings of €900,000 in treatment costs.
- With the deduction of assay cost, the net savings totalled approximately €400,000.

Figure 1: CT cost calculation

Parameter	Cost
CT incl. administration costs per regimen	€2,380.84
G-CSF x4 cycles	€4,177.52
Adverse events	€756.00
Total	€7,313.84

Chemotherapy recommendation pre and post 21-gene testing



Conclusions

- There is limited evidence demonstrating the benefits of 21-gene test in ILC.
- In our study, the use of the test has resulted in a 75% reduction in chemotherapy use in an Irish ILC patient population and a substantial cost saving (greater than €400,000) in the Irish Healthcare System.

References

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