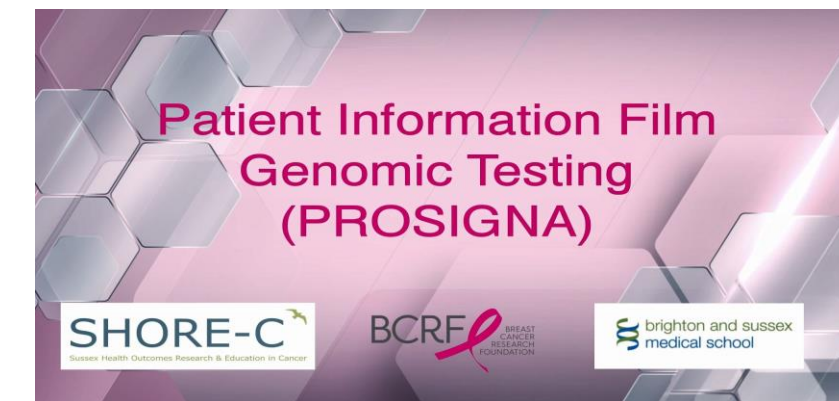
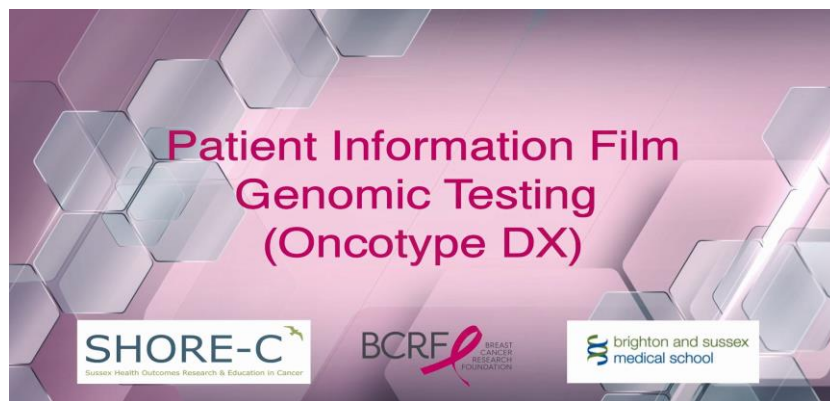


Background

Discussions with patients about gene expression profiling (GEP) tests can be challenging. Patient Information Leaflets (PILs) designed to help often contain complex medical terminology. We developed two 8-minute films to aid BC patients' knowledge & understanding about Prosigna or OncotypeDX. The films use patient friendly language, simple graphics & visuals with a voice over explaining the test process and implications of results.



Initial evaluation in women **without** BC showed that a majority preferred the films to leaflets; furthermore, knowledge was significantly higher following film viewing compared to that after reading the PIL.¹ We report an RCT examining the utility of the films given to women **with** early-stage BC awaiting GEP results.

Methods

1. Consenting patients with ER positive BC in whom the need for chemotherapy was unclear completed 3 questionnaires (STAI anxiety trait/state & Intolerance of Uncertainty (IoU))
2. Then randomised to **Group A** (standard hospital information [leaflets/verbal info]) or **Group B** (standard info + relevant GEP film)
3. Researchers interviewed patients about their knowledge of key facts concerning testing & risk of recurrence results & those in Group B provided feedback about the film
4. Patients completed 2 further questionnaires (STAI anxiety state & the decisional conflict scale) following their GEP results consultations
5. Clinicians completed IoU once and a satisfaction questionnaire following each GEP results consultation

1° outcome: knowledge about GEP testing & risk of recurrence results

- 2° outcomes:**
- a) patients' decisional regret
 - b) impact of anxiety & IoU on decision-making
 - c) satisfaction with the GEP test result discussions (both patient & clinician)

230 patients seen by 82 clinicians from 18 centres

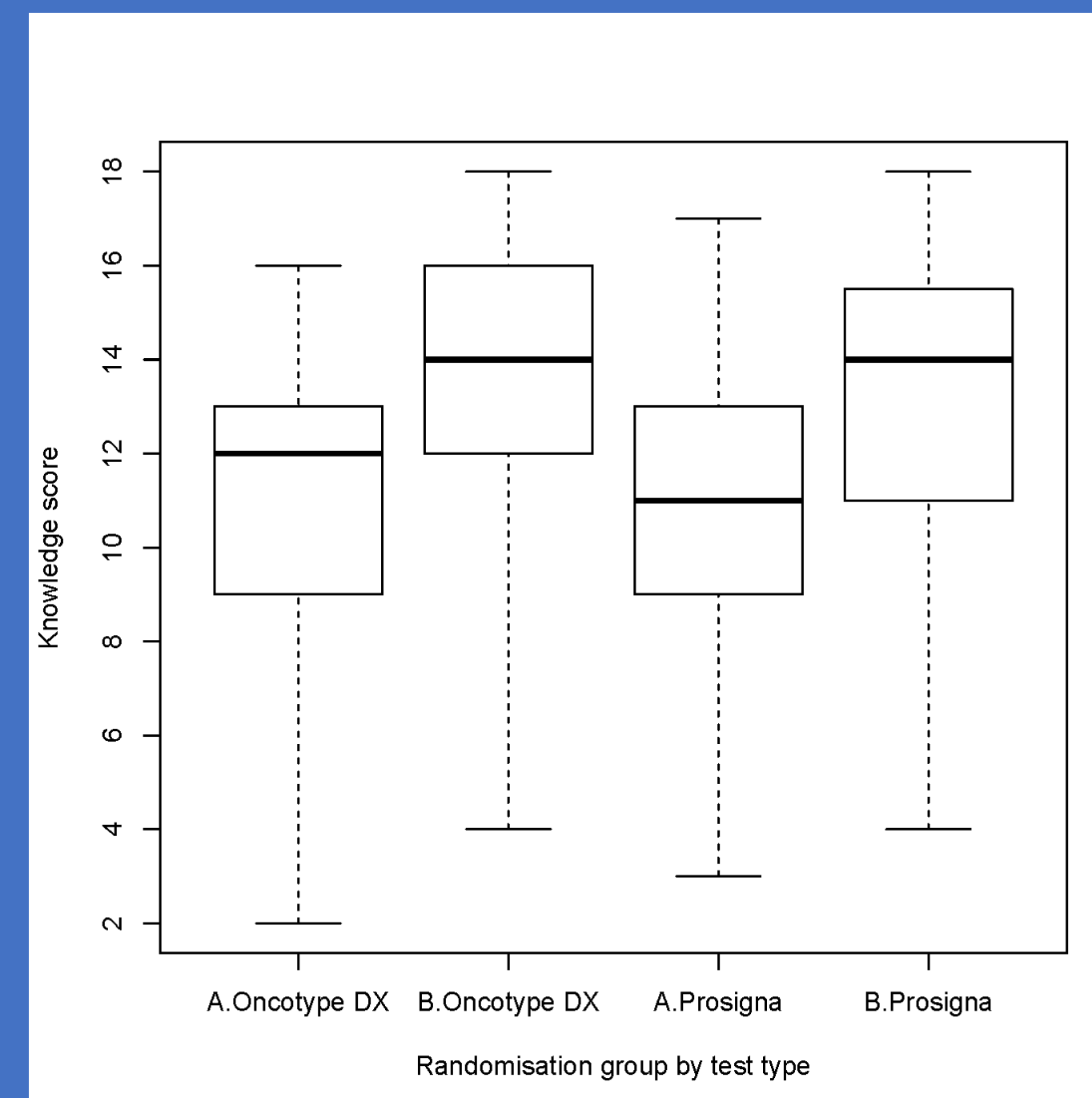
Baseline Characteristics	Group A Standard Information (n=106)	Group B Standard Information + film (n=124)	Total (n=230)
Test type			
OncotypeDx	54 (51%)	66 (53%)	120 (52%)
Prosigna	52 (49%)	58 (47%)	110 (48%)
Age (mean; sd yrs)	58.6 (10.7)	57.8 (10.5)	58.2 (10.6)
Education			
Low	52 (49%)	58 (47%)	110 (48%)
Medium	12 (11%)	26 (21%)	38 (16%)
High	42 (39%)	40 (32%)	82 (36%)
STAI Trait (mean; sd)	40.2 (10.4)	39.7 (10.1)	39.9 (10.2)
STAI State	41.4 (12.5)	41.8 (12.6)	41.6 (12.5)
IoU (mean; sd)	29.5 (9.0)	28.2 (8.6)	28.8 (8.8)

Treatment decisions

162/230 (70.4%) opted for endocrine therapy (ET) alone, 65/230 (28.3%) ET + chemotherapy; 3 (1.3%) undecided

Results

1° outcome: Linear regression model adjusted for age, education & recruitment site showed higher knowledge in Group B than Group A (estimated mean diff of 2.5, 95%CI:1.7- 3.4 p<0.001)



Boxplot of median knowledge score by randomisation group & test type

2° outcomes

- Trend for clinicians to report that patients in Group A asked more difficult questions (10.4% v 2.4%), more unexpected questions (7.5% v 3.2%) & consultations took longer (12.6% v 8.2%)
- Patients' decisional regret scores were low irrespective of group or GEP test (60% patients had scores of 0)
- No impact of anxiety or IoU scores on decision-making

Group B feedback

- Patients viewed films a mean of 1.75 times (range 1-5)
- 51% on smartphones, 49% computers, tablets, laptops
- 110/124 (89%) provided feedback about the film, the majority of which 90/110 (82%) was extremely positive

'I had more confidence about the test after watching the film. It helped my understanding.'

'...it was really, really, helpful, so glad I said yes to this study.'

'...I think it should be given to everyone having the test as it put my mind at rest.'

'It was small & relevant, like a bikini, covered all the important bits! Narrator had a nice, calming voice. Ending with summary was good.'

'Well put together & easier to understand (than what the dr said), so informative.'

- 31/110 (28%) made neutral or constructive comments mainly about finding the music & introduction too long

Conclusions

- Patient information films significantly improved knowledge about GEP tests and recurrence risk results compared to standard verbal and written information
- Patients valued the films, which enabled them to have shorter, more informed discussions
- Versions are available from the authors in Spanish, Italian, French, Urdu, Hindi, Gujarati, Punjabi & Bengali

Reference 1) Fallowfield et al. Br Ca Res & Tmt. 2022;192:265-271

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