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Poor Prognostic Factors and their Impact on Treatment Patterns and Outcomes for Women with Hormone Receptor-positive, Human Epidermal Growth Factor (HR+/HER2-) Advanced Breast Cancer (aBC) in Canada

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Background

- In 2017 it was estimated that breast cancer was the most common cancer among Canadian women [1].
- The aim of the current study is to investigate the impact of poor prognostic factors in HR+/HER2- aBC patients in Canada on treatment patterns and outcomes.
- Previous findings from Di Leo, A et al (2018) showed that presence of liver metastases, high tumour grade, having an ECOG score of 1-3, a progesterone receptor-negative (PgR-) status and a treatment free interval (TFI) of <36 months between end of adjuvant endocrine therapy and recurrence to advanced/metastatic disease were poor prognostic factors in HR+/HER2- advanced breast cancer patients that received endocrine therapy + abemaciclib [2].

Methods

- Real world data were drawn from the aBC Disease Specific Programme™ - a point in time survey administered to oncologists who completed patient record forms for the next 10 HR+/HER2-aBC patients with whom they consulted in Q3 2018 in Canada. The DSP methodology has been published and validated previously [3-5].
- Patient inclusion criteria within the analysis were: age ≥18 years; a physician-confirmed diagnosis of advanced (stage IIIb/c or IV) breast cancer; not currently enrolled in a clinical trial; and receiving an active drug treatment at time of study.
- Cohorts within our analysis comprised of HR+/HER2- advanced breast cancer patients with and without poor prognostic factors (presence of liver metastases at time of survey, high tumour grade at breast cancer diagnosis, ECOG score of 1-3 at time of survey, a progesterone receptor-negative (PgR-) status at time of survey and a treatment free interval (TFI) of <36 months). The number of prognostic factors patients had were also analysed.
  - TFI was calculated from the end of adjuvant treatment to the start of 1st line advanced treatment.
- Outcomes including life expectancy, treatment status, response to treatment and activities of daily living (ADL) were subjective to each physician. ADL options included 'no decrease in ADL', 'mild decrease in ADL', and 'Moderate decrease in ADL'.
- Statistical methods included descriptive statistics including mean, standard deviation, median, bases and percentages.

Results

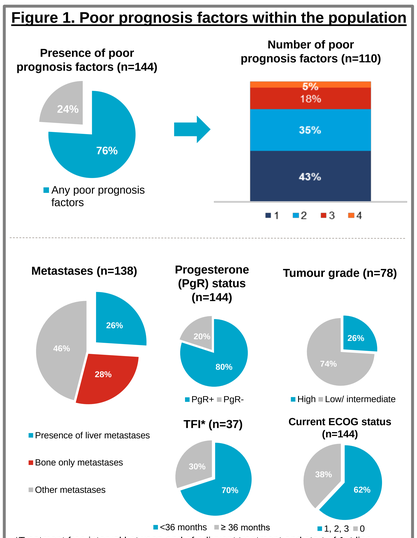
Demographics

- Data analysis was conducted on 144 patients diagnosed with HR+/HER2- aBC. 60% of patients were on their 1st line of therapy at time of data collection, 29% on their 2nd line and 9% were on 3rd line or later. Patient characteristics are shown on tables 1 and 2. In total, 24% of patients had 0 poor prognostic factors, 33% had 1 and 43% had 2+ [figure 1].
- When comparing individual poor prognostic factors, patients with high tumour grade (+/- other poor prognostic factors) and presence of liver metastases (compared to bone only metastases) experienced lower age at time of study and a higher proportion were on long term sick leave from full time work [table 2].
- Patients with an ECOG of 0 at time of study and PgR+ status were less likely to be on long term sick leave from full time work.
- Patients with TFI <36 months had a better ECOG score at initial breast cancer diagnosis (0 = 65% vs 36%) than those with a TFI >=36 months.

Treatment patterns

- Overall, the most common 1L regimen received was Letrozole (28%) followed by letrozole + palbociclib (26%). 49% of patients experienced partial response with only 3% experiencing a full treatment response.

Figure 1. Poor prognosis factors within the population



*Treatment free interval between end of adjuvant treatment and start of 1st line advanced treatment (months)

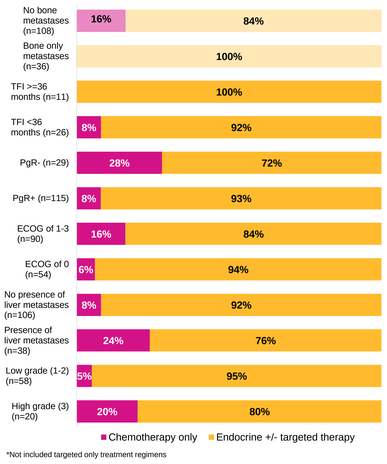
CONCLUSION

- **Results from this analysis provide insights into the impact of poor prognostic factors in the HR+/HER2- aBC population in Canada in terms of treatment patterns and outcomes.**
- **Chemotherapy use was higher and outcomes were worse in patients with poor prognostic factors.**
- **This analysis illustrates an unmet medical need for HR+/HER2-advanced breast cancer patients with poor prognostic factors.**

Table 1

	Total	Number of poor prognostic factors				
		0	Any	1	2	3-4
Patient age, n	**144**	**34**	**110**	**47**	**38**	**25**
Mean (SD) [Median]	64.5 (12.81) [65.5]	64.1 (12.97) [64.0]	64.7 (12.81) [66.0]	68.0 (10.65) [68.0]	64.0 (12.75) [64.5]	59.4 (15.02) [62.0]
Employment status, n, (%)	**142**	**32**	**110**	**47**	**38**	**25**
Employed (full/part time)	19 (13)	11 (34)	18 (16)	9 (19)	4 (11)	5 (20)
Homemaker	24 (17)	3 (9)	21 (19)	12 (26)	8 (21)	1 (4)
Retired	62 (44)	15 (47)	47 (43)	22 (47)	13 (34)	12 (48)
On long term sick leave	22 (15)	1 (3)	21 (19)	2 (4)	12 (32)	7 (28)
Menopausal status, n, (%)	**144**	**34**	**110**	**47**	**38**	**25**
Post-menopausal	127 (87)	30 (88)	97 (88)	44 (94)	34 (89)	19 (76)
Diagnosis stage, n, (%)	**140**	**32**	**108**	**45**	**38**	**25**
IIIb-IV	67 (48)	19 (59)	48 (44)	25 (56)	14 (37)	9 (36)
Current stage, n, (%)	**144**	**34**	**110**	**47**	**38**	**25**
IV	138 (96)	32 (94)	106 (96)	44 (94)	37 (97)	25 (100)
Current ECOG status, n, (%)	**144**	**34**	**110**	**47**	**38**	**25**
0	54 (38)	34 (100)	20 (18)	12 (26)	7 (18)	1 (4)
1-3	90 (62)	-	90 (83)	35 (74)	31 (81)	24 (96)
ADL, n, (%)	**144**	**34**	**110**	**47**	**38**	**25**
No decrease	65 (45)	30 (88)	35 (32)	16 (34)	14 (37)	5 (20)
Mild decrease	68 (47)	4 (12)	64 (58)	27 (57)	21 (55)	16 (64)
Moderate decrease	11 (8)	-	11 (10)	4 (9)	3 (8)	4 (16)

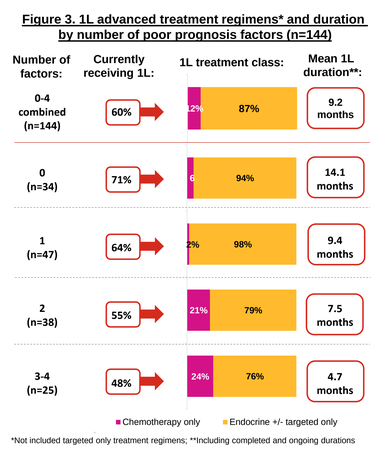
Figure 2. Type of poor prognosis factors by treatments received at 1st line for ABC (n=143*)



*Not included targeted only treatment regimens

- The time from end of 1L to start of 2L was only 14.8 days. Patients that went onto 2nd line (2L) received mostly endocrine only therapy (61%) followed by hormone + targeted (18%) and chemotherapy only (18%). The average duration of 2L treatment (including those still on 2L) was 8.6 months.
- For patients with any poor prognostic factors (n=110) vs those without (n=34), the most common regimens at 1L were letrozole (25% vs 35%) and letrozole + palbociclib (24% vs 32%); the use of chemotherapy at 1L was (14% vs 6%) and the duration of 1L therapy (including ongoing treatment) was longer in patients with poor prognostic factors (14.1 vs 7.7 months).
- Figure 2 shows 1L treatment patterns by type of poor prognostic factor.
- Figure 3 shows 1L treatment received overall by class as well as duration by total population and number of poor prognosis factors.

Figure 3. 1L advanced treatment regimens* and duration by number of poor prognosis factors (n=144)



*Not included targeted only treatment regimens; **Including completed and ongoing durations

Outcomes

- Comparing those with increasing number of poor prognostic factors [0, 1, 2, 3, 4], life expectancy (mean [SD months]) at time of study decreased (43.7 [19.07], 39.1 [21.51], 47.3 [57.34], 32.4 [17.90], 20.2 [20.72]), physicians opinion on patient ADL showed higher levels of both mild or moderate decrease in ADL, and disease progression increased (6%, 11%, 26%, 35%, 60%).
- Patients with high grade disease had much lower life expectancy of those with a low/intermediate grade disease (29.1 vs 44.9 months). Those with liver metastases had a lower life expectancy than those without liver metastases and those with bone metastases (32.8 vs 44.0 vs 45.0 months); they were also more likely to have a progressive disease (32% vs 14% vs 14%).

Limitations: Limitations include the data being physician-reported; thus, no measures were clinically or independently validated. Data were not adjusted for age, stage of disease and other possible confounders. Sample size for subgroups also constitutes a limitation when interpreting the data. Duration data included patients that were still on line of therapy.

Table 2

	Tumour grade		Presence of liver metastases		Bone only metastases		ECOG status		Progesterone status		TFI (months)	
	High (3)	Low (1/2)	Yes	No	No	Yes	1-3	0	-ve	+ve	<36	≥36
Patient age, n	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
Mean (SD) [Median]	56.4 (15.77) [58.0]	65.7 (10.36) [66.5]	60.4 (13.61) [61.5]	66 (12.24) [66.0]	63.2 (13.03) [63.0]	68.6 (11.34) [71.0]	65.7 (13.26) [67.0]	62.6 (11.89) [63.0]	62 (15.18) [62.0]	65.2 (12.13) [66.0]	63.2 (11.00) [62.0]	67.2 (8.98) [66.0]
Employment status, n (%)	**19**	**55**	**38**	**99**	**103**	**34**	**88**	**49**	**28**	**109**	**26**	**11**
Employed (full/part time)	2 (10)	11 (19)	7 (18)	22 (21)	26 (24)	3 (8)	11 (12)	18 (33)	8 (28)	21 (18)	5 (19)	3 (27)
Homemaker	1 (5)	13 (22)	5 (13)	19 (18)	15 (14)	9 (25)	20 (22)	4 (7)	3 (10)	21 (18)	2 (8)	4 (36)
Retired	7 (35)	24 (41)	16 (42)	46 (43)	43 (40)	19 (53)	40 (44)	22 (41)	11 (38)	51 (44)	11 (42)	4 (36)
On long term sick leave	9 (45)	7 (12)	10 (26)	12 (11)	19 (18)	3 (8)	17 (19)	5 (9)	6 (21)	16 (14)	8 (31)	-
Menopausal status, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
Post-menopausal	13 (65)	53 (91)	30 (79)	97 (92)	94 (87)	33 (92)	80 (89)	47 (87)	24 (83)	103 (90)	24 (92)	11 (100)
Diagnosis stage, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
IIIb-IV	8 (40)	23 (40)	15 (39)	52 (49)	47 (44)	20 (56)	41 (46)	26 (48)	20 (69)	47 (41)	-	-
Current stage, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
IV	20 (100)	56 (97)	38 (100)	100 (94)	102 (94)	36 (100)	86 (96)	52 (96)	28 (97)	110 (96)	26 (100)	11 (100)
Current ECOG, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
0	9 (45)	21 (36)	8 (21)	46 (43)	40 (37)	14 (39)	-	54 (100)	4 (14)	50 (43)	8 (31)	3 (27)
1-3	11 (55)	37 (64)	30 (79)	60 (57)	68 (63)	22 (61)	90 (100)	-	25 (86)	65 (57)	18 (69)	8 (73)
Life expectancy (months)	**17**	**45**	**34**	**88**	**91**	**31**	**78**	**44**	**26**	**96**	**22**	**11**
Mean (SD) [Median]	29.1 (19.2) [24.0]	44.9 (17.5) [48.0]	32.8 18.3) [30.0]	44.0 (39.5) [36.0]	45.0 (38.7) [36.0]	39.5 (21.5) [48.0]	42.5 (42.0) [36.0]	40.0 (17.8) [36.0]	39.0 (66.2) [36.0]	48.0 (20.1) [36.0]	51.3 (18.2) [36.0]	37.6 (14.3) [60.0]
Disease status, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
Progressing	8 (40)	8 (14)	12 (32)	15 (14)	22 (20)	5 (14)	19 (21)	8 (15)	7 (24)	20 (17)	12 (46)	1 (9)
ADL, n (%)	**20**	**58**	**38**	**106**	**108**	**36**	**90**	**54**	**29**	**115**	**26**	**11**
No decrease	9 (45)	26 (45)	12 (32)	53 (50)	47 (44)	18 (50)	17 (19)	48 (89)	12 (41)	53 (46)	9 (35)	4 (36)
Mild decrease	6 (30)	32 (55)	23 (61)	45 (42)	53 (49)	15 (42)	62 (69)	6 (11)	14 (48)	54 (47)	15 (58)	6 (55)
Moderate decrease	5 (25)	-	3 (8)	8 (8)	8 (7)	3 (8)	11 (12)	-	3 (10)	8 (7)	2 (8)	1 (9)

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Disclosures: Alex Rider, Abigail Bailey and Katie Lewis are employed by Adelphi Real World. Christopher Lenhu and Diego Novick are employed by Eli Lilly.

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