360 Health Analysis (H360) – A comparison of key performance indicators in breast cancer management across health institution settings

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Abstract

Background

The increased focus on quality indicators (QIs) and the use of clinical registries in real-world cancer studies have led to higher compliance with therapeutic standards and increased patient survival. The European Society of Breast Cancer Specialists (EUSOMA) defined QIs to assess compliance with current standards in breast cancer care.

Methods

This population-based retrospective study is part of the H360 Health Analysis (H360) project - Phase 2 and represents the first comprehensive assessment of the quality of breast cancer care in different hospital settings in Portugal. Its aim is to describe compliance with EUSOMA-defined QIs in breast cancer management in different hospital settings (public vs. private; general hospitals vs. Oncology centers) and thereby assess equity in the provision of care across health institutions. To do so, a set of key performance indicators (KPIs) was selected based on EUSOMA and previously identified QIs. Secondary data were retrieved from patients' clinical records. Compliance with target KPIs in different stages of disease across the considered hospital settings was compared with minimum and target EUSOMA standards.

Results

A total of 259 patient clinical records were assessed. In stage I, II, and III disease, eighteen KPIs met target EUSOMA standards, five met minimum standards, and eight failed to meet minimum standards. Compliance with KPIs varied according to the type of hospital (particularly concerning diagnosis) and stage of the disease.

Conclusions

Study results show that, although most QIs meet EUSOMA standards, there is room for improvement regarding diagnostic and therapeutic procedures. There are differences in the clinical practice across health institutions, particularly between Oncology centers and general hospitals regarding diagnosis and KPI compliance among disease stages. These findings should be addressed in future studies in a coordinated effort to improve the quality of breast cancer care nationally.

Background

Although the incidence of breast cancer varies across European countries, the lifetime risk of having the disease for women is approximately 1 in 10 globally (1). Breast cancer represents a substantial health burden for both the individual and society.

Setting performance measures in cancer, known as key performance indicators (KPIs), is a highly recognized mechanism of monitoring and measuring the quality of care delivered in health centers and enables to accurately compare cancer centers and identify areas for improvement. KPIs are increasingly becoming a requirement in the delivery of health care in most institutions around the world (2).

The European Society of Breast Cancer Specialists (EUSOMA) provides a voluntary certification process for breast centers, which ensures multidisciplinary care and minimum standards of care. EUSOMA defined quality indicators (QIs) to assess compliance with current care standards through a systematic evidence search and expert consensus. Predefined QIs have been estimated for 22 EUSOMA-certified breast centers – including in Portugal – from 2006 to 2015, with minimum standards of care achieved in 8 of 13 main QIs in 2006 and in all QIs in 2015. Compliance with guidelines, reflected by better performance in QIs, significantly improved over the years in EUSOMA-certified breast centers (1, 3). These indicators may be useful for identifying gaps and areas for quality improvement at local and national level (4).

360 Health Analysis (H360) is a multiphase project that aims to provide a comprehensive picture of breast cancer management in Portugal by retrieving real-world data from Portuguese hospitals. After project presentation and a literature review of the subject in H360 Phase 1, project Phase 2 aimed to assess the performance of the Portuguese health system in breast cancer management by comparing the reality of different hospitals and cancer centers in the country. H360 Phase 2 comprised two stages: Stage A retrieved secondary data from patients' clinical records for measuring KPIs in breast cancer, and Stage B retrieved primary data from patients, health care professionals, and hospital decision-makers about the patient journey within the health system. The final goal is to put forward a national consensus with an action plan on how to improve breast cancer management in Portugal (5).

The present analysis concerns project Phase 2 - Stage A and focuses on the assessment of KPIs in breast cancer screening, diagnosis, treatment, staging, and follow-up.

Methods

This was a retrospective study in a sample of Portuguese hospitals. A set of KPIs was established based on QIs previously identified by EUSOMA and based on performance measures according to Khare SR *et al.* 2016 (2, 3). Data were collected from the clinical records of patients randomly assigned in each participating hospital until the predefined sample size for each hospital was achieved.

Study inclusion criteria comprised (i) women with a diagnosis of breast cancer, (ii) ≥ 18 years of age, (iii) with a first cancer diagnosis, (iv) with breast cancer diagnosis ≥ 6 months and ≤ 5 years ago. No exclusion criteria were defined. Sampling was randomly conducted by study investigators.

The pool of selected hospitals included general hospitals and Oncology centers, and public and private hospitals.

Based on a sample of 10 hospitals and a 1.72% prevalence of breast cancer in Western Europe, (6) the initially estimated sample size ranged between 263 and 332 patients. Considering a bilateral test with a

0.05 probability of type I error and a 0.95 potency, the estimated sample size using G*Power® software was 300 patients.

Data descriptive analysis was performed through absolute and relative frequencies (qualitative variables) or mean and standard deviation (quantitative variables).

KPI compliance with minimum and target standards defined by EUSOMA in different disease stages was statistically evaluated based on the proportion of patients (and 95% confidence interval [CI]) with compliance in each KPI (3). KPI compliance according to the type of hospital and disease stage was assessed using Pearson Chi-Square or Fisher's exact test.

Data analysis was performed using IBM SPSS® version 26, adopting a 0.05 significance level.

This study was approved by the Administration Boards of participating hospitals following approval by the respective Ethics Committees, and its design and conception were the strict responsibility of study investigators.

Results

Of 10 hospitals initially selected, three were excluded due to successive bureaucratic and Ethic and Data Protection Commission delays, making a final sample of seven hospitals.

The target number of QIs retrieved from clinical records in each hospital was 40. The study sample was evenly distributed among hospitals and disease stages.

KPI compliance – Descriptive analysis

QIs were evaluated for a total of 259 patients in the seven hospitals included in the study (Table 1). Hospitals 1 and 2 were Oncology centers; hospital 3 was a general university hospital; hospitals 4, 5, and 6 were general hospitals; and hospital 7 was the only private hospital in the sample. Some general hospitals were district hospitals.

Table 1
– Number of patients included according to hospital and disease stage

Hospitals	Stage I	Stage II	Stage III	Stage IV
Hospital 1	10	10	10	10
Hospital 2	10	9	7	10
Hospital 3	10	10	10	10
Hospital 4	10	11	10	10
Hospital 5	10	10	10	7
Hospital 6	10	10	10	11
Hospital 7	2	11	0	10

The planned number of patients was met in four of the seven hospitals, with the remaining hospitals achieving 58–93% of the accrual target. Patients' clinical records were assessed for compliance with a total of 31 KPIs (Table 2).

Table 2
– KPI compliance according to disease stage

KPI										
	Stage I, II, and III								Metastatic setting	
	Total (Stage I, II, and III)		Stage I		Stage II		Stage III			
	N	n (%)	N	n (%)	N	n (%)	N	n (%)	N	n (%)
Screening and diagnosis										
1. Without signs or symptoms (%)	184	64 (34.8)	59	31 (52.5)	69	26 (37.7)	56	7 (12.1)	67	11 (16.4)
2. With signs or symptoms (%)	186	121 (65.1)	60	28 (46.7)	70	44 (62.9)	56	49 (87.5)	67	55 (82.1)
3. Proportion of women with breast cancer who preoperatively underwent: (%)										
3.1. Mammography	191	190 (99.5)	62	62 (100)	72	72 (100)	57	56 (98.2)	68	66 (97.1)
3.2. Physical examination	191	157 (82.2)	62	50 (80.6)	72	60 (83.3)	57	47 (82.5)	67	55 (82.1)
3.3. Ultrasound of both breasts and axillae	191	189 (99.0)	62	61 (98.4)	72	72 (100)	57	56 (98.2)	68	66 (97.1)
4. Anatomopathological diagnosis (%)										
4.1. Fine-needle aspiration	191	48 (25.1)	62	16 (25.8)	72	13 (18.1)	57	19 (33.3)	66	21 (31.8)
4.2. Core-needle biopsy	191	149 (78.0)	62	44 (71.0)	72	61 (84.7)	57	44 (77.2)	68	58 (85.3)
4.3. Surgical biopsy	191	35 (18.3)	62	13 (21.0)	72	10 (13.9)	57	12 (21.1)	66	2 (3.0)

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
5. Proportion of women with breast cancer (invasive or *in situ*) with preoperative histologically or cytologically confirmed malignant diagnosis (%)	189	182 (96.3)	62	57 (91.9)	71	70 (98.6)	56	55 (98.2)	-	-
6. Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: *(%)*										
6.1. Histological type	184	178 (96.7)	58	54 (93.1)	70	69 (98.6)	56	55 (98.2)	66	66 (100)
6.2. Grade	183	175 (95.6)	58	52 (89.7)	69	68 (98.6)	56	55 (98.2)	66	65 (98.5)
6.3. ER & PgR expression	183	173 (94.5)	58	53 (91.4)	69	66 (95.7)	56	54 (96.4)	66	65 (98.5)
6.4. HER2 amplification	182	171 (94.0)	58	53 (91.4)	69	64 (92.8)	55	54 (98.2)	66	65 (98.5)
7. Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded in the surgical specimen: *(%)*										
7.1. Histological type	172	171 (99.4)	61	61 (100)	67	66 (98.5)	44	44 (100)	-	-
7.2. Grade	167	164 (98.2)	60	59 (98.3)	66	66 (100)	41	39 (95.1)	-	-
7.3. ER & PgR expression	170	143 (84.1)	61	47 (77.0)	66	57 (86.4)	43	39 (90.7)	-	-
7.4. HER2 amplification	169	142 (84.0)	61	47 (77.0)	66	56 (84.8)	42	39 (92.9)	-	-

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
7.5. Pathological stage (pT and pN, or ypT and ypN in case of PST)	170	157 (92.4)	61	57 (93.4)	67	60 (89.6)	42	40 (95.2)	-	-
7.6. Size in mm of the invasive component	169	151 (89.3)	61	55 (90.2)	66	60 (90.9)	42	36 (85.7)	-	-
7.7. Peritumoral vascular invasion	167	144 (86.2)	60	55 (91.7)	65	54 (83.1)	42	35 (83.3)	-	-
7.8. Distance to the nearest radial margin	161	143 (88.8)	58	56 (96.6)	63	54 (85.7)	40	33 (82.5)	-	-
8. Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters were recorded: *(%)*									-	
8.1. Dominant histological pattern	59	58 (98.3)	24	23 (95.8)	23	23 (100)	12	12 (100)	-	-
8.2. Size in mm	59	41 (69.5)	24	18 (75.0)	23	15 (65.2)	12	8 (66.7)	-	-
8.3. Grade	59	46 (78.0)	24	20 (83.3)	23	19 (82.6)	12	7 (58.3)	-	-
8.4. Distance to the nearest radial margin	57	36 (63.2)	23	13 (56.5)	22	13 (59.1)	12	10 (83.3)	-	-
9. Time interval of 6 weeks from the date of the first diagnostic examination in the breast center to the date of surgery or treatment start	181	57.7 (35.4) 4-180	58	67.5 (35.0) 14–180	70	54.4 (36.0) 7-153	53	51.2 (33.2) 4-175	59	48.9 (27.8) 9-121
10. Proportion of cancer cases preoperatively examined by MRI (%)	188	99 (52.7)	61	20 (32.8)	71	41 (57.7)	56	38 (67.9)	-	-

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
11. Proportion of cancer cases referred to genetic counseling (%)	181	39 (21.5)	62	8 (12.9)	67	16 (23.9)	52	15 (28.8)	59	12 (20.3)
Treatment										
1. Proportion of cancer patient cases discussed in multidisciplinary group meeting *(%)*	190	190 (100)	61	61 (100)	72	72 (100)	57	57 (100)	68	67 (98.5)
2. Proportion of patients (invasive cancer only) who received a single (breast) surgery for the primary tumor (excluding reconstruction) (%)	161	135 (83.9)	52	45 (86.5)	64	52 (81.3)	45	38 (84.4)	-	-
3. Proportion of patients with invasive cancer and clinically negative axilla who only underwent SLNB (%)	128	116 (90.6)	54	52 (96.3)	55	51 (92.7)	19	13 (68.4)	-	-
4. Proportion of patients with invasive cancer who underwent axillary clearance with excision of at least 10 nodes	130	59 (45.4)	33	6 (18.2)	47	17 (36.2)	50	36 (72.0)	-	-
5. Proportion of patients with invasive breast cancer (M0) who received postoperative RT after surgical resection of the primary tumor and appropriate axillary staging/surgery in BCT setting (%)	149	117 (78.5)	57	48 (84.2)	58	49 (84.5)	34	20 (58.8)	-	-

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
6. Proportion of patients with axillary lymph node involvement (pN2a) who received post-mastectomy RT to the chest wall and all (non-resected) regional lymph-nodes (%)	35	29 (82.9)	1	0 (0.0)	6	4 (66.7)	28	25 (89.3)	-	-
7. Proportion of patients (excluding BRCA1 and BRCA2 patients) with invasive breast cancer no larger than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment (%)	140	92 (65.7)	58	47 (81.0)	57	35 (61.4)	25	10 (40.0)	-	-
8. Proportion of patients with invasive breast cancer who underwent axillary clearance (%)	182	71 (39.0)	61	7 (11.5)	69	23 (33.3)	52	41 (78.8)	-	-
9. Proportion of patients with invasive breast cancer pN0 who did not undergo axillary clearance (%)	105	87 (82.9)	54	47 (87.0)	36	31 (86.1)	15	9 (60.0)	-	-
10. Proportion of patients with endocrine-sensitive invasive cancer who received endocrine therapy (%)	155	151 (97.4)	57	54 (94.7)	58	57 (98.3)	40	40 (100)	-	-
11. Proportion of patients without endocrine-sensitive invasive cancer who did not receive endocrine therapy (%)	35	30 (85.7)	5	4 (80.0)	15	11 (73.3)	15	15 (100)	-	-

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
12. Proportion of patients with ER-negative (T > 1 cm or node +) invasive carcinoma who received adjuvant chemotherapy (%)	32	21 (65.6)	5	4 (80.0)	14	8 (57.1)	13	9 (69.2)	-	-
13. Proportion of patients with HER2-positive (IHC 3 + or *in situ* hybridization-positive) invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab (%)	25	23 (92.0)	6	5 (83.3)	10	9 (90.0)	9	9 (100)	-	-
14. Proportion of patients with HER2-negative invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who did not receive adjuvant trastuzumab (%)	160	154 (96.3)	53	51 (96.2)	61	58 (95.1)	46	45 (97.8)	-	-
15. Proportion of patients with HER2-positive (IHC 3 + or *in situ* hybridization positive) invasive carcinoma (T > 1 cm or N+) treated with adjuvant chemotherapy (%)	27	14 (51.9)	6	4 (66.7)	11	6 (54.5)	10	4 (40.0)	-	-
16. Proportion of patients with inflammatory breast cancer or locally advanced non-resectable ER-negative carcinoma who received neoadjuvant chemotherapy (%)	68	46 (67.6)	5	0 (0.0)	15	12 (80.0)	48	34 (70.8)	-	-

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

KPI										
Staging and follow-up										
1. Proportion of women with stage I breast cancer who did not undergo baseline staging tests (liver US, chest X-ray, and bone scan) (%)	60	32 (53.3)	60	32 (53.3)	-	-	-	-	-	-
2. Proportion of women with stage III breast cancer who underwent baseline staging tests (liver US, chest X-ray, and bone scan) (%)	55	50 (90.9)	-	-	-	-	55	50 (90.9)	-	-
3. Proportion of asymptomatic patients who underwent routine annual mammography screening and 6/12-month clinical evaluation in the first 5 years after primary surgery (%)	173	169 (97.7)	60	60 (100)	69	66 (95.7)	44	43 (97.7)	-	-
4. Proportion of women with breast cancer diagnosis with direct access to a breast care nurse specialist for information and support regarding treatment-related symptoms and toxicity, follow-up, and rehabilitation after initial treatment (%)	189	187 (98.9)	61	59 (96.7)	72	72 (100)	56	56 (100)	67	66 (98.5)

BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; KPI, key performance indicator; MRI, magnetic resonance imaging; n, number of patients with compliance to the respective KPI; N, number of patients evaluated for the KPI; PgR, progesterone receptor; PST, primary systemic treatment; RT, radiotherapy; SLNB, sentinel lymph node biopsy; US, ultrasonography

Table 2

Screening

Analysis of screening KPIs showed that approximately one-third of patients (34.8%) were diagnosed through a screening exam, hence without symptoms at diagnosis.

Diagnosis

Two-thirds of patients with breast cancer stages I-III and 82% of patients with metastatic disease were symptomatic at the time of diagnosis. Almost all patients underwent mammography and ultrasound exam at diagnosis. Core biopsy was the method of choice for histological diagnosis in most patients (71 – 85% of patients, depending on stage). Histological type, grade, expression of hormone receptors, and human epidermal growth factor receptor 2 (HER2) amplification were evaluated in most biopsies performed (> 90%). These parameters were also evaluated on the surgical specimen for most patients (77 – 100%), in addition to stage, size, lymphovascular invasion, and margins for invasive and *in situ* components. Approximately half of patients with localized disease underwent breast magnetic resonance imaging (MRI) before surgery. One-fifth of patients were referred to genetic counseling, even in metastatic setting. Time from the diagnostic biopsy to initial breast cancer surgery or systemic treatment varied between 4 and 180 days.

Treatment (stages I–III)

The cases of all patients with localized disease were discussed in multidisciplinary group meeting.

More than 90% of patients with early-stage breast cancer (stages I or II) and 68% of patients with stage III breast cancer and clinically negative axillary nodes underwent sentinel node biopsy. Regarding localized tumors, the higher the stage, the higher the percentage of patients who underwent axillary clearance (at least 10 lymph nodes). On the other hand, 83% of pN0 patients did not undergo axillary clearance.

Almost all patients underwent a single surgery (excluding reconstruction) for their primary tumor. Most patients (83%) with axillary lymph node involvement (≥ pN2a) received post-mastectomy radiotherapy (RT) to non-resected regional lymph nodes and chest wall. Among patients with invasive breast cancer no larger than 3 cm in total size (including ductal carcinoma *in situ* [DCIS] component), 66% underwent breast-conserving surgery as primary treatment.

Almost all patients (97%) with endocrine-sensitive invasive cancer received endocrine therapy, and 66% of patients with hormone receptor (HR)-negative (T > 1 cm or node-positive) invasive carcinoma received adjuvant chemotherapy.

Ninety-two percent of patients with HER2-positive (immunohistochemistry [IHC] 3 + or *in situ* hybridization-positive) invasive carcinoma (T > 1 cm or node-positive) treated with chemotherapy received adjuvant trastuzumab.

Staging and follow-up

Half of patients with stage I disease did not undergo baseline staging tests during initial staging, as opposed to 90% of patients with stage III disease. Almost all patients were referred to nurse counseling at the time of primary treatment.

After curative treatment, almost all patients underwent routine annual mammography screening and clinical evaluation at 6—12 months in the first five years after primary surgery.

KPI compliance with target EUSOMA standards in all localized disease stages

KPIs were assessed and compared with target EUSOMA standards. KPI compliance with minimum and target EUSOMA standards in breast cancer stages I—III disease is detailed in Table 3. Some KPIs in this study were adapted and hence had no corresponding target standard as per EUSOMA definition, so they were not statistically compared with QIs.

As shown in Table 3, a total of 19 diagnosis, treatment, staging, and follow-up KPIs achieved the target and six the minimum EUSOMA standards, whereas 15 KPIs did not meet minimum EUSOMA standards.

Table 3

Diagnosis

Full compliance with EUSOMA standards was observed in women with breast cancer who preoperatively underwent mammography – 99.5% (95% CI 97–100) – and ultrasonography of both breasts and axillae – 99% (95% CI 96–100). However, minimum standards were not met for the physical examination.

Full compliance with EUSOMA standards was also observed for preoperative histology- or cytology-confirmed malignant diagnosis – 96% (95% CI 94–99) –, as well as for descriptive histological parameters (histological type, grade, estrogen receptor [ER], and progesterone receptor [PgR] expression, and HER2 amplification).

Regarding the pathological report of the surgical specimen, histological type and grade met the target standards – 99.4% (95% CI 98–100) and 98.2% (95% CI 96–100), respectively – and pathological stage (pT and pN, or ypT and ypN in case of PST) met only the minimum standards. All the remaining parameters failed to meet predefined EUSOMA standards. For non-invasive cancers, only the dominant histological pattern report met the target standard – 98.3% (95% CI 95–100%) –, with the remaining parameters falling below minimum standards.

Treatment

All stage I—III breast cancer cases were discussed in multidisciplinary group meeting. Considering surgical parameters, KPI compliance with standards was met for patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy – 90.6% (95% CI 86–96) – and for patients with invasive breast cancer pN0 who did not undergo axillary clearance – 82.9% (95% CI 76–90). Minimum standards were met for patients with invasive cancer who received a single surgery for the primary tumor – 83.9% (95% CI 78–90) – and for patients with invasive breast cancer < 3 cm (total size, including DCIS component) who underwent breast-conserving treatment as primary treatment (excluding BRCA1 and

BRCA2 patients) – 65.7% (95% CI 58–74). Patients with invasive cancer who underwent axillary clearance did not meet the minimum criteria of at least 10 excised nodes.

Regarding RT, the proportion of patients with pN2a involvement who received post-mastectomy RT to the chest wall and all non-resected regional lymph nodes met target EUSOMA standards – 82.9% (95% CI 70–95). However, the proportion of patients with invasive breast cancer who received postoperative RT after surgical resection of the primary tumor and appropriate axillary staging/surgery in the setting of breast-conserving therapy fell below minimum standards.

For systemic therapy, two out of seven KPIs met target standards: proportion of patients with endocrine-sensitive invasive cancer who received endocrine therapy – 97.4% (95% CI 95–100) – and proportion of patients with HER2-positive invasive carcinoma (T > 1 cm or node-positive) treated with chemotherapy who received adjuvant trastuzumab – 92% (95% CI 81–103). The minimum standard was met for the proportion of patients with HER2-negative invasive carcinoma (T > 1 cm or node-positive) treated with chemotherapy who did not receive adjuvant trastuzumab – 96.3% (95% CI 93–99) – and for the proportion of patients with ER-negative disease invasive carcinoma (T > 1 cm or node-positive) who received adjuvant chemotherapy – 65.6% (95% CI 49–82). The remaining three parameters evaluating systemic therapy failed to meet the minimum standards.

Staging and follow-up

Regarding staging and follow-up KPIs, the target standard was 99%, and the minimum standard 95%. Except for women with stage I breast cancer who did not undergo baseline staging tests, all three remaining KPIs met minimum standards (two of which met target standards).

KPI compliance with target EUSOMA standards according to disease stage

KPI compliance with target EUSOMA standards according to disease stage was achieved for most KPIs. The analysis was not performed for some KPIs due to the small sample size in some disease stage parameters.

Compliance with target EUSOMA standards in stage I disease was not achieved for the following KPIs: proportion of patients with invasive cancer who underwent axillary clearance with at least 10 excised nodes; proportion of patients with invasive breast cancer who received postoperative RT after surgical resection of the primary tumor and appropriate axillary staging/surgery in the setting of breast-conserving treatment; and proportion of patients with stage I breast cancer who did not undergo baseline staging tests (Table 4).

Table 4

For invasive and non-invasive cancers with prognostic/predictive parameters recorded in the surgical specimen, not all parameters met target standards.

In stage II disease, minimum EUSOMA standards were not achieved for the following KPIs: proportion of patients with invasive cancer cases with ER and PgR expression and HER2 amplification recorded in the surgical specimen, and proportion of patients with report of peritumoral vascular invasion and distance to nearest radial margin (Table 5). The latter also failed to achieve the minimum standards in non-invasive cancer cases (together with size in mm). In addition, also the proportion of patients with invasive cancer who underwent axillary clearance with at least 10 excised nodes, the proportion of patients without endocrine-sensitive invasive cancer who did not receive endocrine therapy, and the proportion of patients with HER2-invasive carcinoma (T > 1 cm or node-positive) treated with adjuvant chemotherapy failed to meet minimum EUSOMA standards.

Table 5

In stage III disease, minimum EUSOMA standards were not met for the following KPIs: proportion of patients with invasive cancer cases with peritumoral vascular invasion and distance to nearest radial margin recorded in the surgical specimen, as well as size and grade in non-invasive cancer cases; proportion of patients with invasive cancer and clinically negative axilla who only underwent sentinel lymph-node biopsy; proportion of patients with invasive cancer cases who underwent axillary clearance with at least 10 excised nodes; proportion of patients with invasive breast cancer who received postoperative RT after surgical resection of the primary tumor and appropriate axillary staging/surgery in breast-conserving treatment setting; and proportion of patients (excluding BRCA1 and BRCA2 ones) with invasive breast cancer no larger than 3 cm (total size, including DCIS component) who underwent breast-conserving treatment (Table 6).

Table 6

KPI compliance according to the type of hospital and disease stage

The analysis of KPI compliance according to the type of hospital (general hospital vs. Oncology center) and disease stage is reported in Tables 7 and 8, respectively. Regarding the type of hospital, the most statistically significant differences between general hospitals and Oncology centers concerned diagnostic parameters, namely lower use of core biopsy and higher reporting of grade, ER and PgR expression, HER2 amplification, pathological stage definition, and distance to nearest radial margin in non-invasive cancers in the first compared to the latter. The proportion of patients (invasive cancer only) who received a single breast surgery (excluding reconstruction) for the primary tumor was the only treatment parameter showing differences in KPI compliance according to the type of hospital (90% in general hospitals vs. 71.9% in Oncology centers). KPI compliance according to disease stage showed statistically significant differences in some parameters, most of which were treatment-related (Table 8).

Table 7
— KPI compliance according to type of hospital

	Oncology centers	General hospitals	p
	n (%)	n (%)	
SCREENING AND DIAGNOSIS			
2.2 - Proportion of women with breast cancer who preoperatively underwent: Physical examination	54 (94.7)	103 (76.9%)	0.006
3.1 - Anatomopathological diagnosis: Fine-needle aspiration	5 (8.8)	43 (32.1)	0.001
3.2 - Anatomopathological diagnosis: Core-needle biopsy	51 (89.5)	98 (73.1)	0.021
3.3 - Anatomopathological diagnosis: Surgical biopsy	3 (5.3)	32 (23.9)	0.005
6.4 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: HER2	48 (87.3)	123 (96.9)	0.019*
7.2 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: Grade	37 (92.5)	127 (100.0)	0.013*
7.3 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: ER and PgR expression	25 (58.1)	118 (92.9)	< 0.001
7.4 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: HER2 amplification	25 (58.1)	117 (92.9)	< 0.001
7.5 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: Pathological stage (pT and pN, or ypT and ypN in case of PST)	32 (74.4)	125 (98.4)	< 0.001*
7.8 - Proportion of invasive cancer cases for which the following prognostic/predictive parameters were recorded: Distance to the nearest radial margin	41 (100.0)	102 (85.0)	0.007*
8.4 - Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters were recorded: Distance to the nearest radial margin	20 (83.3)	16 (48.6)	0.016
TREATMENT			
2 - Proportion of patients (invasive cancer only) who received a single (breast) surgery for the primary tumor (excluding reconstruction)	41 (71.9)	94 (90.4)	0.005
FOLLOW-UP			

ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PgR, progesterone receptor; PST, primary systemic treatment US, ultrasonography

*Fisher's exact test

	Oncology centers	General hospitals	p
	n (%)	n (%)	
2 - Proportion of women with stage III breast cancer who underwent baseline staging tests (liver US, chest X-ray, or bone scan)	12 (70.6)	38 (100.0)	0.002*
ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PgR, progesterone receptor; PST, primary systemic treatment US, ultrasonography			
*Fisher's exact test			

Table 8
— KPI compliance according to disease stage

	Stage I	Stage II	Stage III	p
	n (%)	n (%)	n (%)	
SCREENING AND DIAGNOSIS				
1 - Without signs or symptoms	31 (52.5)	26 (37.7)	7 (12.5)	< 0.001
10 - Proportion of cancer cases preoperatively examined by MRI	20 (32.8)	41 (57.7)	38 (67.9)	< 0.001
TREATMENT				
3- Proportion of patients with invasive cancer and clinically negative axilla who only underwent SLNB (%)	52 (96.3)	51 (92.7)	13 (68.4)	0.001
4- Proportion of patients with invasive cancer who underwent axillary clearance with excision of at least 10 nodes	6 (18.2)	17 (36.2)	36 (72.0)	< 0.001
5- Proportion of patients with invasive breast cancer (M0) who received postoperative RT after primary tumor surgical resection and appropriate axillary staging/surgery in BCT setting (%)	48 (84.2)	49 (84.5)	20 (58.8)	0.006
7- Proportion of patients (excluding BRCA1 and BRCA2 patients) with invasive breast cancer no larger than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment (%)	47 (81.0)	35 (61.4)	10 (40.0)	0.001
8 - Proportion of patients with invasive breast cancer who underwent axillary clearance (%)	7 (11.5)	23 (33.3)	41 (78.8)	< 0.001
9- Proportion of patients with invasive breast cancer pN0 who did not undergo axillary clearance (%)	47 (87.0)	31 (86.1)	9 (60.0)	0.040
BCT, breast-conserving treatment; DCIS, ductal carcinoma *in situ*; MRI, magnetic resonance imaging; RT, radiotherapy; SLNB, sentinel lymph node biopsy				
*Fisher's exact test				

Table 7

Table 8

Discussion

Numerous studies have examined the quality of care in breast cancer. Several were conducted before 2003, when guidelines and treatments differed from those currently in use, with only a few recent studies conducted at population level (7–10).

Assessment of the performance of the health system in breast cancer management requires measuring compliance to standards of care in real life. To our knowledge, the present multicenter study represents one of the very few in the literature evaluating QIs in breast cancer care. In 2019, three population-based studies focusing EUSOMA QIs in breast cancer management were conducted in Slovenia, France, and Norway (4, 11, 12). In these studies, most EUSOMA KPIs concerned non-metastatic disease stages. Due to this fact, the metastatic stage has been underrepresented in studies and was also not assessed for most parameters in the present one. The results of the referred studies are difficult to extrapolate to Portuguese patients due to differences in the structure of health systems between countries. For instance, the Portuguese health system has some distinguishing features, as the relevance of the public sector (which is accessible and free of charge for all cancer patients), provider's freedom of choice regarding the selection of treatment options, and no limitation on the use of services.

The seven hospitals included in this study varied in organizational characteristics (general hospitals and Oncology centers, central and regional hospitals, public and private hospitals) and number of breast cancer patients annually admitted. The EUSOMA criteria for QIs are precise in their specifications and data selection regarding minimum and target standards (3). These standards should be met regardless of hospital differences. Accordingly, the present study evaluated compliance with QIs as a whole and sought to compare Oncology centers and general hospitals as the two main hospital categories.

QIs selected in this study referred to screening, diagnosis, treatment, and follow-up. KPIs were mostly extracted and adapted from EUSOMA guidelines but also from a study by Khare SR and colleagues addressing important QIs, including the proportion of breast cancer patients presented to multidisciplinary tumor boards at any time after diagnosis (as opposed to the stricter EUSOMA definition that restricts multidisciplinary boards to pre and postoperative setting) (2, 3, 13). In addition, following population-based studies from other countries, a screening KPI was added in an effort to understand how many patients were diagnosed while being asymptomatic (4, 10, 12).

Some QIs were subdivided into several KPIs, with the aim of retrieving more detailed information on how breast cancer care is provided in the hospitals included. For example, the "proportion of women with breast cancer who preoperatively underwent mammography, physical examination, and ultrasound of both breasts and axillae" parameter was subdivided into three independent KPIs focusing on mammography, physical examination, and ultrasound.

Overall, some unexpected and interesting results were found when analyzing data retrieved from this study.

Hospital performance in breast cancer screening and diagnosis

Results from this study showed that approximately one-third of patients were diagnosed through screening exams. However, it should be noted that data were collected regardless of patients' age (in

Portugal, screening is indicated between the ages of 50 and 69 years), and hence a lower percentage than expected was obtained.

Overall, the proportion of invasive cancer cases for which histological type, grade, ER and PgR expression, and HER2 amplification was reported was over 95%, which agrees with EUSOMA target standards. However, this was not observed regarding the surgical specimen. We believe this is in part because it is not mandatory to specifically repeat ER/PgR expression and HER2 amplification in the surgical piece for patients with previous assessment of these parameters in biopsy. Pathological *in situ* data also failed to meet EUSOMA standards. However, while some parameters were considered risk factors in the past (such as distance to the nearest radial margin), reference to a free tumor margin is currently considered sufficient.

The proportion of cancer cases preoperatively examined by MRI was considerably higher than EUSOMA target standards. However, we hypothesize that this proportion is overestimated, as all patients were included regardless of the therapeutic strategy (namely women receiving neoadjuvant systemic therapy). Also, approximately one-fifth of patients were referred for genetic counseling, when EUSOMA target is 5%.

Hospital performance in breast cancer treatment

EUSOMA standards for surgical procedures were globally met. EUSOMA consensus was based on a meta-analysis including 28,162 patients from 33 studies examining the relationship between margin width and local control (14). Two-thirds of consensus participants/advisors recommended an average reoperation rate of less than 20% in 2020 (3). The proportion of patients with invasive cancer who received a single surgery (excluding reconstruction) for the primary tumor was similar to that reported in most European studies, with re-excision rates of approximately 16% (8, 9, 15). American studies reported higher rates (25–40%), and a Norwegian study reported a lower re-excision rate of 6% (12, 16). However, a significant difference was found between general hospitals and Oncology centers regarding distance to the nearest radial margin in non-invasive cancer cases. When evaluating the axillary approach, the proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy was above 90%, complying with target EUSOMA standards and representing a higher proportion than in several European studies (4, 11). The proportion of patients with invasive breast cancer pN0 who did not undergo axillary clearance also met target EUSOMA standards. However, when evaluating patients with invasive cancer who underwent axillary clearance with at least 10 excised nodes, results from this study fell short of target EUSOMA standards (3, 13). Future studies should address this issue to investigate whether it is a national or regional issue, and strategies directed at improving QIs should be implemented.

The proportion of patients with invasive breast cancer who received postoperative RT after surgical resection in the setting of breast-conserving therapy fell below minimum EUSOMA standards, diverging from European studies, in which higher rates (92—98%) were reported (4, 11, 12). In the US, RT after breast-conserving therapy is less frequent (80%) and presents geographic disparities (17, 18). These disparities should also be addressed in future studies, including in Portugal, to investigate whether they represent a

national issue or are hospital-specific. Acknowledging this unmet QI can be a starting point for the implementation of strategies by health professionals and hospital administrations.

Concerning antineoplastic endocrine therapy, this study's results agree with those from previous studies (4, 8, 9, 11, 15, 19) and indicate a lack of compliance with guidelines, which recommend endocrine therapy for all endocrine-positive breast cancers except small tumors (pT1aN0) (20). We believe that the low compliance identified may be related to patient-related factors or tumor characteristics (very early-stage disease, weak hormone receptor positivity) and to harm/benefit ratio. On the other hand, the proportion of patients without endocrine-sensitive invasive cancer who did not receive endocrine therapy did not meet target EUSOMA standards. The interpretation of this result is not straightforward due to the low number of patients with ER- and PgR-negative histology included in this study.

Compliance with adjuvant chemotherapy recommendations was generally low, which can be partly explained by the use of neoadjuvant chemotherapy, largely implemented in recent years, particularly in breast tumors with aggressive phenotype (triple-negative or HER2-positive). This hypothesis is reinforced by the low number of patients eligible for KPI assessment. Furthermore, it also explains the low proportion of patients with HER2-positive disease treated with adjuvant chemotherapy. Compliance with adjuvant trastuzumab was high in this study (92%), as expected.

The proportion of patients with inflammatory or locally advanced non-resectable ER-positive carcinoma who received neoadjuvant chemotherapy was lower than expected according to recent data.

Hospital performance in breast cancer staging and follow-up

Current guidelines recommend imaging assessment only for staging of patients with symptomatic early and stage III breast cancer (20) due to the exceedingly low probability (0.3–1.2%) of distant occult metastases in stage I-II disease (3). In the present study, compliance with target EUSOMA standards in stage III disease staging was very high, contrary to what happened in stage I disease. However, the fact that it was not possible to distinguish between asymptomatic and symptomatic stage I disease may hamper data interpretation. This lack of compliance with target standards in early disease may also be partially explained by patient- and physician-related factors, namely patient-driven physician behavior of ordering unnecessary tests and fear of malpractice litigation. Given the costs and morbidity associated with unnecessary tests, an investment should be made in educating both patients and physicians to perform only the necessary tests.

The main differences in KPI compliance between general hospitals and Oncology centers regarded diagnosis. These included, for instance, lower use of core biopsy and higher reporting of tumor grade, ER/PgR expression, and HER2 amplification, pathological stage, and distance to nearest radial margin in non-invasive cancers in general hospitals. Treatment KPIs were generally similar between both types of hospital, except for the proportion of patients with invasive cancer who received a single breast surgery

(excluding reconstruction) for the primary tumor, which showed higher compliance with standards in general hospitals, reaching the target standard defined by EUSOMA.

Differences in KPI compliance among hospitals may be related to patient and tumor characteristics but also to hospital and physician characteristics. Indeed, diagnostic and surgical procedures may vary according to clinical practice and organizational factors. Regional differences partly drive differences in the types of hospital represented in the region and variations in the provision of health care between hospital services, namely in screening, access to some treatments [e.g., RT], and coordination care. Patient characteristics and physician preferences may also partly explain some of the observed differences. However, compliance with quality standards of care should be met regardless of the number of patients referred to each hospital, type of hospital, or geographic region. In this study, differences in KPI compliance according to disease stage mainly concerned treatment, as different stages are treated differently. Additionally, as expected, most asymptomatic patients were associated with earlier disease stages.

Study limitations

This study has limitations that should be acknowledged, starting with its retrospective nature, which limited data collection to what is documented in clinical records. On the other hand, it would be desirable to have a higher number of clinical records included to allow the analysis of disease stage according to individual hospitals, on the one hand, and comparisons between hospitals, on the other. The fact that only one private hospital was included also represents a study limitation, as it hampered the analysis of breast cancer management in the private sector. Consequently, it can be argued that results from this study should be adjusted for case mix (differences in patient populations) to validate comparisons.

It was not possible to retrieve information on hereditary breast cancer or exclude these cases from the analysis, which may have had an impact (although unlikely significant) when comparing Portuguese and EUSOMA QIs in this study.

Another study limitation was the assessment of metastatic patients, as some were stage IV and others were primarily locally treated and then progressed to metastatic disease. The heterogeneity of this subgroup in the study hampered result interpretation and the analysis of most treatment parameters.

Future studies with a larger sample size addressing the asymmetries reported in this study are desirable, as they may potentially provide additional insights into which KPIs should be extensively explored and which measures should be implemented to improve KPIs by disease stage and hospital. The implementation of KPI measures on the National Oncology Registry (Registo Oncológico Nacional [RON]) is of particular interest to retrieve a national picture of breast cancer management. The inclusion of a comprehensive patient population would enable measuring outcomes and their variation between hospitals according to compliance with QIs.

Conclusion

The relevance of monitoring the performance of breast-treating centers in disease management through a set of QIs is largely demonstrated by numerous initiatives undertaken at national and international level.

EUSOMA QIs are an essential aspect of the voluntary European certification process, based on the EUSOMA 'Requirements of a specialist Breast Centre' document (1, 3, 13).

The present study provides the first comprehensive overview of breast cancer quality of care at population level in Portugal. Globally, QIs met the EUSOMA standards for diagnosis and treatment of non-metastatic breast cancer, but there is room for improvement.

This study provides relevant insights into how breast cancer care in Portugal performs in relation to European standards and could be used as a starting point for further analyses on how to improve the clinical practice of breast cancer management. Additionally, its results may contribute to update the national practice guidelines. Implementing KPI assessment on the National Oncologic Registry could provide more extensive and detailed data on breast cancer quality of care nationally.

Abbreviations

BCT - breast-conserving treatment

CI - confidence interval

DCIS - ductal carcinoma in situ

ER - estrogen receptor

EUSOMA - European Society of Breast Cancer Specialists

H360 - 360 Health Analysis

HER2 - human epidermal growth factor receptor 2

HR - hormone receptor

IHC - immunohistochemistry

KPI - key performance indicator

MRI - magnetic resonance imaging

PgR - progesterone receptor

PST - primary systemic treatment

QI - quality indicator

RON - Registo Oncológico Nacional (National Oncology Registry)

RT - radiotherapy

SLNB - sentinel lymph node biopsy

US - ultrasonography

Declarations

Ethics approval and consent to participate

This study was approved by the Administration Boards of participating hospitals following approval by the respective Ethics Committees:

Ethics Committee of Centro Académico de Medicina de Lisboa (CAML) of Centro Hospitalar Universitário Lisboa Norte

Ethics Committee of Universidade do Algarve (CEUAlg) of Centro Hospitalar Universitário do Algarve

Comissão de Ética para a Saúde (CES) of Hospital do Espírito Santo de Évora

Ethics Committee of Universidade de Trás-os-Montes e Alto Douro (CE-UTAD) of Centro Hospitalar Trás-os-Montes e Alto Douro

Ethics Committee of Instituto Português de Oncologia de Coimbra (IPO – Coimbra)

Ethics Committee of Instituto Português de Oncologia do Porto (IPO – Porto)

Ethics Committee of Hospital da Luz

The study's design and conception were of the strict responsibility of study investigators.

All methods were performed in accordance with the relevant guidelines and regulations in accordance with the Declaration of Helsinki. All patients provided written informed consent prior to any study-specific procedure.

Consent for publication

Not applicable.

Availability of data and materials

The dataset generated and analyzed in the current study is not publicly available due to European Union general data protection regulations. They can be provided by the corresponding author, upon reasonable request, after approval by the local Government responsible for assessing the impact on data protection and by the study's Institutional Ethics Committees.

Competing interests

None to declare.

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Authors' contributions

Concept - L.C., R.B.L., F.P.

Design - L.C., R.B.L.

Data collection - I.B.R., S.C., P.M.S.

Data analysis – I.B.R., S.C., P.M.S., L.T., S.S.

Data interpretation - I.B.R., S.C., P.M.S.

Manuscript writing - I.B.R., S.C., J.C.S., P.M.S.

Critical review - L.C., I.B.R., S.C., J.C.S., P.M.S., J.R., R.D., F.S., N.A., J.L.F.

The work reported in the paper has been performed by the authors, unless clearly specified in the text.

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Tables

Tables 3 to 6 are available in the Supplementary Files section.

Supplementary Files

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- Table3.docx
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