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Data Article

Dataset on growth factor levels and insulin use in patients with diabetes mellitus and incident breast cancer

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ABSTRACT

Growth factor profiles could be influenced by the utilization of exogenous insulin. The data presented shows the relationship between pre-existing use of injectable insulin in women diagnosed with breast cancer and type 2 diabetes mellitus, the growth factor profiles at the time of breast cancer diagnosis, and subsequent cancer outcomes. A Pearson correlation analysis evaluating the relationship between growth factors stratified by of insulin use and controls is also provided.

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TGF
VEGF
Insulin
Breast cancer
Diabetes
Cancer outcomes
Cancer prognosis

Specifications Table

Subject area	Clinical and Translational Research
More specific subject area	Biomarker Research, Cancer Epidemiology
Type of data	Tables
How data was acquired	Tumor registry query was followed by vital status ascertainment, and medical records review Luminex®-based quantitation of growth factors (epidermal growth factor, fibroblast growth factor 2, vascular endothelial growth factor, hepatocyte growth factor, platelet-derived growth factor BB, and tumor growth factor-β) from plasma samples was conducted. A Luminex®200™ instrument with Xponent 3.1 software was used to acquire all data
Data format	Analyzed
Experimental factors	Growth factors were determined from the corresponding plasma samples collected at the time of breast cancer diagnosis
Experimental features	The dataset included 97 adult females with diabetes mellitus and newly diagnosed breast cancer (cases) and 194 matched controls (breast cancer only). Clinical and treatment history were evaluated in relationship with cancer outcomes and growth factor profiles. A growth factor correlation analysis was also performed.
Data source location	United States, Buffalo, NY - 42° 53′ 50.3592″N; 78° 52′ 2.658″W
Data accessibility	The data is with this article

Value of the data

- This dataset represents the observed relationship between injectable insulin use, circulating growth factors at breast cancer diagnosis and outcomes.
- Reported data has the potential to guide future research evaluating insulin-induced growth factor modulation in breast cancer.
- Our observations may assist future studies in evaluating the relationship between insulin safety and effectiveness and growth factors production in cancer.

1. Data

Reported data represents the observed association between use of injectable insulin preceding breast cancer and the growth factor profiles at the time of cancer diagnosis in women with diabetes mellitus (Table 1). Data in Table 2 includes the observed correlations between growth factors stratified by type 2 diabetes mellitus pharmacotherapy and controls. C-peptide correlation with each of the studied growth factors is presented in Table 2, however details regarding its determination from plasma, association with cancer outcomes and use of injectable insulin has been previously reported by us [1].

Table 1
Growth factor associations with insulin use.

Biomarker	Biomarker grouping	Concentration (ng/ml)	Control	No insulin	Any insulin	Unadjusted p-value (MVP)			
						p^1	p^2	p^3	Global test
EGF (ng/ml)	Median (25– 75th)	–	20.26 (12.25–37.04)	28.70 (16.55–56.15)	31.50 (17.62–54.76)	0.002 (0.019)	0.049 (0.140)	0.920 (0.930)	0.003 (0.023)
	Quartiles	1.60–13.61	57 (29.4%)	12 (15.8%)	3 (15.0%)	0.021	0.360	1.000	0.080
		13.79–23.29	51 (26.3%)	17 (22.4%)	5 (25.0%)				
		23.70–44.72	47 (24.2%)	20 (26.3%)	5 (25.0%)				
		45.35–382.99	39 (20.1%)	27 (35.5%)	7 (35.0%)				
	OS-Based Optimization	1.60–113.10	189 (97.4%)	69 (90.8%)	19 (95.0%)	0.042 (0.120)	0.450 (0.870)	1.000 (0.550)	0.060 (0.270)
		116.01–382.99*	5 (2.6%)	7 (9.2%)	1 (5.0%)				
	DFS-Based Optimization	**1.60–5.20***	12 (6.2%)	4 (5.3%)	1 (5.0%)	1.000 (0.950)	1.000 (0.980)	1.000 (0.730)	1.000 (0.990)
		5.39–382.99	182 (93.8%)	72 (94.7%)	19 (95.0%)				
FGF-2 (pg/ml)	Median (25–75th)	–	16.15 (4.32–34.43)	22.00 (4.83–44.44)	17.39 (10.04–94.06)	0.230 (0.210)	0.160 (0.070)	0.450 (0.470)	0.220 (0.100)
	Quartiles	1.60–4.18	49 (25.3%)	19 (25.0%)	4 (20.0%)	0.480	0.180	0.470	0.360
		4.76–17.34	51 (26.3%)	16 (21.1%)	6 (30.0%)				
		17.51–39.78	52 (26.8%)	18 (23.7%)	2 (10.0%)				
		40.30–1147.64	42 (21.6%)	23 (30.3%)	8 (40.0%)				
	OS-Based Optimization	**1.60–10.15***	72 (37.1%)	27 (35.5%)	6 (30.0%)	0.810 (0.810)	0.530 (0.300)	0.640 (0.620)	0.810 (0.620)
		10.21–1147.64	122 (62.9%)	49 (64.5%)	14 (70.0%)				
	DFS-Based Optimization	**1.60–14.61***	87 (44.8%)	34 (44.7%)	7 (35.0%)	0.990 (0.810)	0.400 (0.370)	0.440 (0.430)	0.690 (0.630)
		14.68–1147.64	107 (55.2%)	42 (55.3%)	13 (65.0%)				
HGF (pg/ml)	Median (25– 75th)	–	289 (129–439)	342 (107–554)	347 (218–539)	0.250 (0.790)	0.100 (0.320)	0.490 (0.220)	0.180 (0.500)
	Quartiles	13.02–130.22	50 (25.8%)	21 (27.6%)	2 (10.0%)	0.028	0.360	0.170	0.060
		130.72–312.56	52 (26.8%)	16 (21.1%)	5 (25.0%)				
		314.96–472.00	53 (27.3%)	12 (15.8%)	7 (35.0%)				
		505.37– 6728.77	39 (20.1%)	27 (35.5%)	6 (30.0%)				
	OS-Based Optimization	13.02–1148.76	188 (96.9%)	73 (96.1%)	19 (95.0%)	0.710 (0.780)	0.500 (0.860)	1.000 (0.850)	0.640 (0.970)
		1169.11–6728.77	6 (3.1%)	3 (3.9%)	1 (5.0%)				
	DFS-Based Optimization	13.02– 919.06	185 (95.4%)	70 (92.1%)	17 (85.0%)	0.370 (0.910)	0.090 (0.350)	0.390 (0.170)	0.110 (0.560)
		920.11–6728.77	9 (4.6%)	6 (7.9%)	3 (15.0%)				
PDGF-BB (pg/ml)	Median (25– 75th)	–	2055 (615–5402)	1178 (200–2939)	1955 (317–3824)	0.019 (0.015)	0.470 (0.150)	0.480 (0.590)	0.060 (0.039)
	Quartiles	60–414	43 (22.2%)	22 (28.9%)	7 (35.0%)	0.200	0.260	0.200	0.190
		440–1618	47 (24.2%)	24 (31.6%)	2 (10.0%)				

Table 1 (*continued*)

Biomarker	Biomarker grouping	Concentration (ng/ml)	Control	No insulin	Any insulin	Unadjusted *p*-value (MVP)			
						p^1	p^2	p^3	Global test
		1660–4332	49 (25.3%)	16 (21.1%)	7 (35.0%)				
		4355–15480	55 (28.4%)	14 (18.4%)	4 (20.0%)				
	OS-Based	**60–2687**	109 (56.2%)	55 (72.4%)	13 (65.0%)	0.015	0.450	0.520	0.046
	Optimization	2694–15480	85 (43.8%)	21 (27.6%)	7 (35.0%)	(0.007)	(0.120)	(0.580)	(0.020)
	DFS-Based	**60–10400**	186 (95.9%)	72 (94.7%)	20 (100%)	0.740	1.000	0.580	0.790
	Optimization	10944–15480	8 (4.1%)	4 (5.3%)	0 (0%)	(0.560)	(0.150)	(0.220)	(0.380)
TGF-β (pg/ml)	Median (25– 75th)	–	3007 (1996–4053)	3425 (2413–4608)	4096 (3039–4903)	0.032 (0.380)	0.029 (0.510)	0.410 (0.630)	0.018 (0.550)
	Quartiles	453–2151	57 (29.4%)	14 (18.4%)	2 (10.0%)	0.150	0.048	0.450	0.060
		2155–3157	52 (26.8%)	18 (23.7%)	3 (15.0%)				
		3183–4303	43 (22.2%)	20 (26.3%)	9 (45.0%)				
		4311–12026	42 (21.6%)	24 (31.6%)	6 (30.0%)				
	OS-Based	**453–5545**	176 (90.7%)	64 (84.2%)	17 (85.0%)	0.130	0.420	1.000	0.230
	Optimization	5557–12026	18 (9.3%)	12 (15.8%)	3 (15.0%)	(0.430)	(0.480)	(0.990)	(0.710)
	DFS-Based	**453 –1881**	42 (21.6%)	10 (13.2%)	2 (10.0%)	0.120	0.380	1.000	0.190
	Optimization	1907–12026	152 (78.4%)	66 (86.8%)	18 (90.0%)	(0.220)	(0.510)	(0.750)	(0.390)
VEGF (pg/ml)	Median (25– 75th)	–	95.07 (40.78–189.51)	111.90 (45.66–226.14)	96.26 (64.90–291.86)	0.300 (0.460)	0.380 (0.710)	0.910 (0.980)	0.450 (0.650)
	Quartiles	1.60–43.56	52 (26.8%)	17 (22.4%)	4 (20.0%)	0.680	0.660	0.570	0.770
		44.52–97.48	51 (26.3%)	17 (22.4%)	7 (35.0%)				
		97.87–192.64	45 (23.2%)	21 (27.6%)	3 (15.0%)				
		194.47–4197.81	46 (23.7%)	21 (27.6%)	6 (30.0%)				
	OS-Based	**1.60–37.94***	45 (23.2%)	14 (18.4%)	3 (15.0%)	0.390	0.580	1.000	0.620
	Optimization	38.42–4197.81	149 (76.8%)	62 (81.6%)	17 (85.0%)	(0.370)	(0.420)	(0.800)	(0.480)
	DFS-Based	**1.60–37.94***	45 (23.2%)	14 (18.4%)	3 (15.0%)	0.390	0.580	1.000	0.620
	Optimization	38.42–4197.81	149 (76.8%)	62 (81.6%)	17 (85.0%)	(0.370)	(0.420)	(0.800)	(0.480)

* Overall survival (OS)- and disease-free survival (DFS)-optimized growth factor ranges associated with poorer outcomes are represented in bold. BLQ=below limit of quantitation. p^1=pairwise comparison of controls with the no insulin group, p^2= pairwise comparison of controls with the any insulin group, and p^3=pairwise comparison of the no insulin and any insulin groups. Global Test=significance test across all groups. MVP=*p*-value of the multivariate adjusted analysis. Epidermal growth factor (EGF), fibroblast Growth Factor 2 (FGF-2), hepatocyte growth factor (HGF), platelet-derived growth factor BB (PDGF-BB), tumor growth factor (TGF), vascular endothelial growth factor (VEGF).

2. Experimental design, materials and methods

Evaluation of growth factor profile association with injectable insulin use and BC outcomes was carried out under two protocols approved by both Roswell Park Cancer Institute (EDR154409 and NHR009010) and the State University of New York at Buffalo (PHP0840409E). Demographic and clinical patient information was linked with cancer outcomes and growth factor profiles of

Table 2
Growth factor correlations by insulin use.

Compared Biomarkers		Group	Unadjusted Correlation			Adjusted Correlation		
			Pearson Correlation	95% Confidence Interval	p-value	Pearson Correlation	95% Confidence Interval	p-value
C-Peptide	EGF	All Subjects (n=291)	-0.098	-0.210 to 0.018	0.096	**-0.136**	**-0.247 to -0.020**	**0.021**
		Controls (n=194)	-0.104	-0.242 to 0.037	0.147	-0.141	-0.278 to 0.001	0.051
		No Insulin (n=77)	-0.104	-0.321 to 0.123	0.365	-0.064	-0.289 to 0.167	0.584
		Any Insulin (n=20)	**-0.476**	**-0.758 to -0.042**	**0.029**	-0.414	-0.746 to 0.083	0.089
C-Peptide	FGF-2	All Subjects (n=291)	**-0.161**	**-0.271 to -0.047**	**0.006**	**-0.178**	**-0.288 to -0.064**	**0.002**
		Controls (n=194)	-0.122	-0.259 to 0.019	0.089	-0.125	-0.263 to 0.017	0.083
		No Insulin (n=77)	**-0.224**	**-0.426 to 0.000**	**0.049**	-0.209	-0.417 to 0.021	0.072
		Any Insulin (n=20)	**-0.540**	**-0.793 to -0.127**	**0.011**	-0.427	-0.753 to 0.068	0.079
C-Peptide	HGF	All Subjects (n=291)	0.035	-0.080 to 0.150	0.549	0.006	-0.109 to 0.122	0.913
		Controls (n=194)	**0.173**	**0.033 to 0.306**	**0.016**	**0.165**	**0.024 to 0.300**	**0.0219**
		No Insulin (n=77)	0.050	-0.176 to 0.271	0.663	-0.006	-0.234 to 0.223	0.962
		Any Insulin (n=20)	-0.361	-0.693 to 0.097	0.110	-0.363	-0.718 to 0.142	0.142
C-Peptide	PDGF-BB	All Subjects (n=291)	-0.111	-0.223 to 0.004	0.058	-0.093	-0.206 to 0.023	0.116
		Controls (n=194)	-0.087	-0.176 to 0.105	0.618	-0.082	-0.222 to 0.060	0.254
		No Insulin (n=77)	-0.15	-0.362 to 0.076	0.190	-0.138	-0.355 to 0.094	0.240
		Any Insulin (n=20)	0.359	-0.100 to 0.691	0.112	0.319	-0.191 to 0.693	0.202
C-Peptide	TGF-β	All Subjects (n=291)	0.063	-0.053 to 0.177	0.285	0.018	-0.098 to 0.133	0.767
		Controls (n=194)	-0.036	-0.176 to 0.105	0.618	-0.064	-0.205 to 0.078	0.375
		No Insulin (n=77)	0.145	-0.082 to 0.357	0.206	0.135	-0.096 to 0.353	0.248
		Any Insulin (n=20)	0.195	-0.271 to 0.587	0.403	0.215	-0.296 to 0.631	0.398
C-Peptide	VEGF	All Subjects (n=291)	**-0.127**	**-0.238 to -0.012**	**0.030**	**-0.136**	**-0.247 to -0.020**	**0.021**
		Controls (n=194)	-0.096	-0.233 to 0.046	0.184	-0.095	-0.234 to 0.047	0.189
		No Insulin (n=77)	**-0.244**	**-0.444 to -0.021**	**0.031**	-0.216	-0.423 to 0.014	0.063
		Any Insulin (n=20)	-0.367	-0.697 to 0.090	0.103	-0.267	-0.663 to 0.245	0.291
EGF	FGF-2	All Subjects (n=291)	**0.730**	**0.672 to 0.780**	**<0.001**	**0.734**	**0.675 to 0.783**	**<0.001**
		Controls (n=194)	**0.717**	**0.641 to 0.779**	**<0.001**	**0.725**	**0.650 to 0.786**	**<0.001**
		No Insulin (n=77)	**0.709**	**0.577 to 0.805**	**<0.001**	**0.724**	**0.594 to 0.817**	**<0.001**
		Any Insulin (n=20)	**0.895**	**0.750 to 0.958**	**<0.001**	**0.907**	**0.755 to 0.966**	**<0.001**
EGF	HGF	All Subjects (n=291)	**0.311**	**0.203 to 0.411**	**<0.001**	**0.291**	**0.182 to 0.394**	**<0.001**
		Controls (n=194)	0.107	-0.034 to 0.244	0.137	0.087	-0.055 to 0.226	0.229
		No Insulin (n=77)	0.002	-0.222 to 0.226	0.984	0.025	-0.204 to 0.252	0.829
		Any Insulin (n=20)	**0.902**	**0.765 to 0.961**	**<0.001**	**0.909**	**0.760 to 0.967**	**<0.001**
EGF	PDGF-BB	All Subjects (n=291)	-0.023	-0.138 to 0.092	0.694	-0.007	-0.123 to 0.108	0.900
		Controls (n=194)	0.016	-0.125 to 0.157	0.824	0.009	-0.133 to 0.151	0.898
		No Insulin (n=77)	-0.010	-0.233 to 0.214	0.931	-0.107	-0.328 to 0.124	0.361
		Any Insulin (n=20)	-0.136	-0.546 to 0.326	0.563	-0.124	-0.571 to 0.379	0.630

Table 2 (*continued*)

EGF	TGF-β	All Subjects (n=291)	**0.196**	**0.082 to 0.304**	**<0.001**	**0.172**	**0.058 to 0.282**	**0.003**
		Controls (n=194)	**0.191**	**0.052 to 0.323**	**0.007**	**0.165**	**0.023 to 0.300**	**0.022**
		No Insulin (n=77)	0.181	-0.045 to 0.389	0.113	0.205	-0.024 to 0.414	0.077
		Any Insulin (n=20)	0.067	-0.387 to 0.495	0.775	0.123	-0.379 to 0.570	0.632
EGF	VEGF	All Subjects (n=291)	**0.621**	**0.545 to 0.687**	**<0.001**	**0.627**	**0.552 to 0.693**	**<0.001**
		Controls (n=194)	**0.621**	**0.526 to 0.700**	**<0.001**	**0.627**	**0.533 to 0.706**	**<0.001**
		No Insulin (n=77)	**0.683**	**0.542 to 0.787**	**<0.001**	**0.691**	**0.549 to 0.794**	**<0.001**
		Any Insulin (n=20)	**0.648**	**0.288 to 0.847**	**0.001**	**0.686**	**0.307 to 0.877**	**0.001**
FGF-2	HGF	All Subjects (n=291)	**0.138**	**0.024 to 0.249**	**0.018**	**0.133**	**0.018 to 0.245**	**0.023**
		Controls (n=194)	0.003	-0.138 to 0.144	0.965	-0.004	-0.146 to 0.138	0.955
		No Insulin (n=77)	-0.157	-0.368 to 0.069	0.17	-0.128	-0.347 to 0.103	0.274
		Any Insulin (n=20)	**0.761**	**0.480 to 0.900**	**<0.001**	**0.817**	**0.554 to 0.932**	**<0.001**
FGF-2	PDGF-BB	All Subjects (n=291)	0.059	-0.056 to 0.173	0.328	0.070	-0.046 to 0.184	0.234
		Controls (n=194)	0.124	-0.017 to 0.261	0.0835	0.117	-0.026 to 0.254	0.108
		No Insulin (n=77)	0.012	-0.212 to 0.236	0.916	0.011	-0.218 to 0.239	0.923
		Any Insulin (n=20)	-0.061	-0.490 to 0.392	0.795	0.034	-0.454 to 0.506	0.897
FGF-2	TGF-β	All Subjects (n=291)	**0.127**	**0.012 to 0.239**	**0.030**	**0.120**	**0.005 to 0.233**	**0.041**
		Controls (n=194)	0.054	-0.087 to 0.194	0.453	0.048	-0.095 to 0.189	0.509
		No Insulin (n=77)	0.216	-0.009 to 0.419	0.058	**0.234**	**0.006 to 0.439**	**0.043**
		Any Insulin (n=20)	-0.061	-0.490 to 0.392	0.795	-0.035	-0.507 to 0.453	0.892
FGF-2	VEGF	All Subjects (n=291)	**0.805**	**0.760 to 0.842**	**<0.001**	**0.805**	**0.760 to 0.842**	**<0.001**
		Controls (n=194)	**0.845**	**0.780 to 0.881**	**<0.001**	**0.845**	**0.799 to 0.881**	**<0.001**
		No Insulin (n=77)	**0.787**	**0.683 to 0.859**	**<0.001**	**0.785**	**0.678 to 0.859**	**<0.001**
		Any Insulin (n=20)	**0.832**	**0.617 to 0.932**	**<0.001**	**0.834**	**0.591 to 0.939**	**<0.001**
HGF	PDGF-BB	All Subjects (n=291)	0.057	-0.058 to 0.171	0.328	0.074	-0.042 to 0.188	0.208
		Controls (n=194)	0.093	-0.048 to 0.231	0.195	0.087	-0.056 to 0.226	0.233
		No Insulin (n=77)	0.186	-0.039 to 0.394	0.103	0.221	-0.007 to 0.428	0.056
		Any Insulin (n=20)	-0.063	-0.492 to 0.390	0.790	-0.105	-0.558 to 0.395	0.623
HGF	TGF-β	All Subjects (n=291)	**0.116**	**0.001 to 0.228**	**0.048**	0.091	-0.025 to 0.205	0.122
		Controls (n=194)	0.113	-0.028 to 0.250	0.116	0.099	-0.043 to 0.238	0.170
		No Insulin (n=77)	0.210	-0.015 to 0.414	0.065	0.188	-0.043 to 0.399	0.107
		Any Insulin (n=20)	0.017	-0.429 to 0.456	0.944	0.071	-0.424 to 0.533	0.784
HGF	VEGF	All Subjects (n=291)	0.034	-0.081 to 0.149	0.562	0.032	-0.084 to 0.147	0.584
		Controls (n=194)	0.031	-0.110 to 0.171	0.666	0.025	-0.118 to 0.166	0.736
		No Insulin (n=77)	-0.174	-0.383 to 0.052	0.127	-0.126	-0.344 to 0.196	0.283
		Any Insulin (n=20)	**0.548**	**0.139 to 0.797**	**0.009**	**0.650**	**0.246 to 0.861**	**0.003**
PDGF-BB	TGF-β	All Subjects (n=291)	**-0.120**	**-0.232 to -0.005**	**0.040**	-0.103	-0.216 to 0.012	0.080
		Controls (n=194)	**-0.145**	**-0.280 to -0.004**	**0.044**	**-0.155**	**-0.290 to -0.013**	**0.032**
		No Insulin (n=77)	0.007	-0.217 to 0.231	0.952	0.054	-0.176 to 0.279	0.644
		Any Insulin (n=20)	-0.212	-0.598 to 0.255	0.363	-0.264	-0.661 to 0.248	0.296

Table 2 (*continued*)

PDGF-BB	VEGF	All Subjects (n=291)	0.078	-0.037 to 0.192	0.182	0.081	-0.035 to 0.195	0.168
		Controls (n=194)	**0.143**	**0.003 to 0.279**	**0.045**	0.138	-0.004 to 0.275	0.056
		No Insulin (n=77)	0.035	-0.190 to 0.257	0.758	0.009	-0.220 to 0.237	0.934
		Any Insulin (n=20)	0.070	-0.385 to 0.497	0.768	0.221	-0.290 to 0.635	0.385
TGF-β	VEGF	All Subjects (n=291)	0.100	-0.016 to 0.212	0.089	0.098	-0.018 to 0.211	0.096
		Controls (n=194)	0.044	-0.098 to 0.184	0.542	0.040	-0.103 to 0.181	0.583
		No Insulin (n=77)	0.139	-0.088 to 0.352	0.227	0.172	-0.059 to 0.385	0.141
		Any Insulin (n=20)	-0.016	-0.455 to 0.430	0.946	-0.006	-0.485 to 0.476	0.981

Significant correlations are displayed in bolded text. The differences that are only significant in either adjusted or unadjusted correlations are further denoted by an outline. Epidermal growth factor (EGF), fibroblast Growth Factor 2 (FGF-2), hepatocyte growth factor (HGF), platelet-derived growth factor BB (PDGF-BB), tumor growth factor (TGF), vascular endothelial growth factor (VEGF).

corresponding plasma specimen harvested at BC diagnosis and banked in the Roswell Park Cancer Institute Data Bank and Bio-Repository.

2.1. Study population

All incident breast cancer cases diagnosed at Roswell Park Cancer Institute (01/01/2003 – 12/31/2009) were considered for inclusion (n=2194). Medical and pharmacotherapy history were used to determine the baseline presence of diabetes.

2.2. Inclusion and exclusion criteria

All adult women with pre-existing diabetes at breast cancer diagnosis having available banked treatment-naïve plasma specimens (blood collected prior to initiation of any cancer-related therapy - surgery, radiation or pharmacotherapy) in the Institute's Data Bank and Bio-Repository were included.

Subjects were excluded if they had prior cancer history or unclear date of diagnosis, incomplete clinical records, type 1 or unclear diabetes status. For a specific breakdown of excluded subjects, please see the original research article by Wintrob et al. [1].

A total of 97 female subjects with breast cancer and baseline diabetes mellitus were eligible for inclusion in this analysis.

2.3. Control-matching approach

Each of the 97 adult female subjects with breast cancer and diabetes mellitus (defined as “cases”) was matched with two other female subjects diagnosed with breast cancer, but without baseline diabetes mellitus (defined as “controls”). The following matching criteria were used: age at diagnosis, body mass index category, ethnicity, menopausal status and tumor stage (as per the American Joint Committee on Cancer). Some matching limitations applied [1].

2.4. Demographic and clinical data collection

Clinical and treatment history was documented as previously described [1]. Vital status was obtained from the Institute's Tumor Registry, a database updated biannually with data obtained from the National Comprehensive Cancer Networks' Oncology Outcomes Database. Outcomes of interest were breast cancer recurrence and/or death.

2.5. Plasma specimen storage and retrieval

All the plasma specimens retrieved from long-term storage were individually aliquoted in color coded vials labeled with unique, subject specific barcodes. Overall duration of freezing time was accounted for all matched controls ensuring that the case and matched control specimens had similar overall storage conditions. Only two instances of freeze-thaw were allowed between biobank retrieval and biomarker analyses: aliquoting procedure step and actual assay.

2.6. Luminex® assays

A total of 6 biomarkers (epidermal growth factor, fibroblast growth factor 2, vascular endothelial growth factor, hepatocyte growth factor, platelet-derived growth factor BB, and tumor growth factor-β) were quantified according to the manufacturer protocol. The following Luminex® biomarker panels were utilized in this study: TGFB-64K (tumor growth factor-β), HCYTOMAG-60K (platelet-derived growth factor BB), and HAGP1MAG-12K (epidermal growth factor, fibroblast growth factor 2, vascular endothelial growth factor, and hepatocyte growth factor) produced by Millipore Corporation, Billerica, MA. C-peptide determinations were done according to the manufacturer protocol as previously reported [2].

2.7. Biomarker-pharmacotherapy association analysis

Biomarker cut-point optimization was performed for each analyzed biomarker. Biomarker levels constituted the continuous independent variable that was subdivided into two groups that optimized the log rank test among all possible cut-point selections yielding a minimum of 10 patients in any resulting group. Quartiles were also constructed. The resultant biomarker categories were then tested for association with type 2 diabetes mellitus therapy and controls by Fisher's exact test. The continuous biomarker levels were also tested for association with diabetes therapy and controls across groups by the Kruskal–Wallis test and pairwise by the Wilcoxon rank sum. Multivariate adjustments were performed accounting for age, tumor stage, body mass index, estrogen receptor status, and cumulative comorbidity. The biomarker analysis was performed using R Version 2.15.3. Please see the original article for an illustration of the analysis workflow [1].

Correlations between biomarkers stratified by type 2 diabetes mellitus pharmacotherapy and controls were assessed by the Pearson method. Correlation models were constructed both with and without adjustment for age, body mass index, and the combined comorbidity index. Correlation analyses were performed using SAS Version 9.4.

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Transparency document. Supplementary material

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