

Financial toxicity and the economic cost of breast cancer therapy

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Abstract: Breast cancer. given its natural history, can be present for many years resulting in significant cost to insurers as well as patients with costs not covered by the patients' insurance plans. Breast cancers tends to be diagnosed in the most productive times of a patient's life disrupting both family life and employment. Because of the dependence on employment-based insurance coverage, financial toxicity has entered the lexicon of care of patients with breast cancer. Objective measures of toxicity include costs not borne by insurance companies while subjective measures of toxicity include the psychological stress of having to deal with having to deal managing a household budget and determining which bills to pay. Costs not covered by insurance companies such as child care and travel to and from treatment appointments can add to the psychological stress patient's encounter. Insurance, income and insurance status all play a role in financial toxicity. Unfortunately, financial toxicity is not limited to only those countries without some form of universal health insurance coverage. Financial discussions will need to occur between patients and caregivers in the future as cost of care increases. A switch to a tax-funded universal healthcare system with a universal set of benefits may be needed to decrease the incidence of financial toxicity in women with breast cancer.

Keywords: Breast cancer; radiotherapy; financial toxicity

Received: 01 October 2020; Accepted: 26 February 2021; Published: 30 December 2021. doi: 10.21037/abs-20-122 **View this article at:** http://dx.doi.org/10.21037/abs-20-122

Introduction

The increasing cost healthcare has come under greater scrutiny from patients and insurers. This increasing cost has put pressure on the patient's family budget as insurers are trying to shift costs onto patients. Patient involvement in treatment decision making has increased cost of care and has entered into these discussions. This review article explores the financial toxicity patients and their families are experiencing trying to cope with rising health care cost especially how it relates to breast cancer treatment.

Studies reporting on financial distress or toxicity in cancer patients have increased recently after first entering the medical lexicon in 2011 (1). Financial toxicity or distress can be thought of as the unintended objective financial burden on and subjective financial distress experienced by cancer patients secondary to their treatment. This distress can occur acutely during active treatment or after the patients enter the survivorship stage of their disease. Objective financial burden includes the direct and indirect cost of care not reimbursed by health insurance. Direct costs would include items such as co-pays, deductibles and other out of pocket expenses such as travel to and from treatment centers while receiving care or paying for childcare while attending treatment sessions not fully reimbursed by insurance. Indirect cost of care would include the opportunity cost of having medical treatment and would include the cost of not being able to engage in meaningful employment as well as informal caregiver cost not reimbursed by insurers as well. Objective financial burden affects the subjective financial distress patients experience. Subjective financial distress would include erosion of savings due to continued out of pocket expenses and concern about the effectiveness of coping strategies available to be used by

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patients (1).

A systematic review of the available literature detailing financial toxicity from 2013 to 2016 found 25 studies covering 47 monetary, objective and subjective indictors of financial toxicity (2). The authors reported 28-48% of patients reported financial toxicity using monetary measures while 16-73% experienced financial toxicity using subjective measures (2). Being female, having low income, young age, and receiving adjuvant therapies were factors associated with financial toxicity. A more recent review of the available databases up to 2018 concerning data on cancer related financial distress experienced by adult patients resulted in 41 publications based on 40 studies (3). The majority of the studies were conducted after 2010 and occurred in the United States (US). In addition, the majority of the studies were of patients with breast cancer (n=10), followed by colorectal cancer (n=6), lung cancer (n=6) and prostate cancer (n=6) (3).

Cost of breast cancer care

The incidence of new breast cancer cases has been relatively stable over the last number of years at around 125/100,000 (4). There will be 276,480 new breast cancer cases diagnosed in 2020 with a 2.4% and 3.5% probability of women between 50–59 and 60–69 being diagnosed with breast cancer respectively (4). This diagnosis can come at a time of great impact to women both in terms of income but a critical time of raising and caring for a family.

Cancer care cost has increased as more treatment combinations have become available and as these newer therapies have resulted in extended survival. An analysis of women between 18-44 years old with newly diagnosed breast cancer using 2006 MarketScan® data found an average incurred cost of \$19,435 of additional direct medical costs attributable to breast cancer treatment when compared to same aged women without breast cancer (5). Women in active treatment incurred \$52,542 in additional medical expenditures per person, mostly outpatient costs with an additional \$1,048 in prescription drug costs (5). A similar study among young Medicaid aged women with breast cancer found an unadjusted difference in total monthly medical costs were four times higher in women with breast cancer when compared to women without breast cancer, (\$3,492 vs. \$850, P<0.01) (6).

Furthermore, an earlier analysis of administrative health care claims data of over 10,000 women \geq 18 years of age from 5 US health plans found a mean per patient per month

(PPPM) cost of breast cancer care of \$2,896 (median \$1,940) with the majority of cost attributable to hospitalizations (7). A retrospective review of cost of breast cancer care in the military health system found an average per capita total cost for breast cancer care was \$66,300 [standard error (SE) \$9,200] over a 3.31-year of follow-up period (8). Cost of care differed between site of service with services provided in VA facilities costing less when compared to purchased services from an outside facility. As expected, costs increased with increasing stage of disease.

These studies have shown the incremental direct cost of breast cancer treatment but have not included the indirect costs of treatment such as time away from work, the opportunity cost of treatment or cost paying for childcare while patients are having treatment. Needless to say the cost of breast cancer care, both to the patient and their families can negatively affect the family budget.

In addition, given the long natural history of breast cancer, cost of care once the cancer has metastasized can be significant. An incidence-based cost-of-illness model was developed simulating patients with metastatic breast cancer through treatment, palliative care and death over a 5-year period. With an annual incidence of metastatic breast cancer in the US in 2007 to be 49,674, the total discounted cost to society attributable to metastatic breast cancer was \$12.2 billion for the incident cohort or \$98,571 per patientyear (9). Lost productivity accounted for approximately 21% of the total cost calculated to be \$2.6 billion over 5 years or \$21,153 per patient-year.

In an effort to reduce health care expenditures by shifting costs to patients, insurance companies have implemented high deductibles for certain medications. Insurance companies hypothesize by shifting the cost of care to patients, they can reduce demand and limit their expenditures. Lu *et al.* reported on the switch to a high deductible health plan in insured women with early-stage breast cancer age 25-64 which did not result in a significant change in the use of adjuvant hormonal therapy (10). The authors concluded the lack of significant changes in adjuvant hormone use was related to the modest increase in overall hormone cost, the availability of low-cost generic tamoxifen, and patient awareness of the medication prolong life and health.

Breast cancer care cost concern is not limited to the US, even in countries with universal healthcare coverage. Healthcare cost was evaluated from data from Galway University Hospital in Ireland to assess changing patterns of care cost and survival in women treated for breast cancer. After adjusting for inflation, the average cost per patient rose from $\notin 14,710$ (95% CI, $\notin 13,398$ to $\notin 16,022$) in 1995–1996 to $\notin 30,405$ (95% CI, $\notin 28,620$ to $\notin 32,189$) in 2005–2006 before declining in 2011–2012 $\notin 14,458$ (95% CI, $\notin 13,343$ to $\notin 15,572$) with improvements seen in survival (11). The authors postulate the centralization of services achieving economies of scale and greater adherence to protocols associated with the deployment of multidisciplinary teams improving survival rates. Reduction in medication and radiotherapy cost also had a significant impact on the overall decrease in cost. In addition, higher utilization of breast-conservation surgery was also associated with a reduction in cost. Similar cost of care analyses in patients with breast cancer have also occurred in Italy, France, and Vietnam among other countries (12-14).

Radiotherapy cost

The omission of radiotherapy for low-risk luminal A breast cancer was investigated in women aged ≥ 60 years with T1N0ER+Her2- breast cancer in Ontario. The cost of adjuvant breast radiotherapy per case was estimated at \$6,135.85 per case while the cost of Ki-67 was \$114.71 translating into an annual saving of about \$2.0 million if radiotherapy was omitted for all low-risk luminal A breast cancer patients in Ontario and \$5.1 million across Canada (15). Another cost analysis investigated the potential cost savings by using a more hypofractionated course of therapy in a cohort of women with T1-2 breast cancer identified from the National Cancer Database treated with lumpectomy. The majority of patients were treated with conventional radiotherapy while only 13.3% of patients received a hypofractionated course of treatment with 1.1% receiving accelerated partial breast radiotherapy (16). The estimated annual cost savings from using a hypofractionated course of treatment compared to a conventional course of treatment was calculated to be \$164.0 million, a 39% reduction (16).

The use of intensity modulated radiation therapy (IMRT) following lumpectomy in early-stage breast cancer was investigated with the Surveillance, Epidemiology and End Results (SEER) records women ≥ 66 years old. In multivariable analysis, left-sided breast cancer, living in a large metropolitan, living in a census tract with \leq \$90,000 median income, neutral or favorable local coverage determination and free-standing treatment facility were associated with receipt of IMRT (17). Cost of care was \$8,499 greater expenditure in women receiving IMRT versus conventional radiation therapy in the year after

diagnosis in this cohort of women. An analysis of 23,127 women with non-metastatic breast cancer undergoing radiotherapy was investigated in a SEER analysis from 2000 to 2009. Median cost of radiotherapy was \$8,100 (\$6,700– \$9,700) with an increased cost of radiotherapy associated with the occurrence of treatment-related toxicity, ipsilateral breast recurrence or breast cancer-related mortality (18). Therefore, more intensive or expensive treatment did not result in improved outcome.

Financial toxicity among women with breast cancer

Financial strain was examined across three different geographic diverse samples of women with breast cancer using online surveys. Women who were older, married and had a bachelor's degree were less likely to experience financial strain. Financial strain ranged from 12.1% among older, married and college-educated women to 81% among women who were younger, unmarried and lacked a college education (19). Financial toxicity was only measured in one sample, Sample 3, and was present in 26.1% of the participants. Subjective financial distress was associated with more severe symptoms of depression, anxiety, worse physical symptom burden and perceived health (19).

Cost of care is becoming an important factor in patient's choice of treatment. An analysis of 607 women from the Army of Women and Sisters Network with stage 0 to III breast cancer completed an 88-item survey evaluating the impact of cost on surgical decisions and patient-reported financial arm after breast cancer surgery (20). The majority of women were white, having insurance either private or Medicare (95%), college educated and household incomes more than \$74,000. They found 28% of women reported costs of treatment influenced their surgical decision. Costs were found to affect decision making with regards to breast preservation at incomes of \$45,000/year. In addition, 35% reported financial burden as a result of their treatment. Not surprisingly, 78% of women did not discuss cost of care with their treatment team. Patients having bilateral mastectomy with or without reconstruction had a higher incurred debt, significant to catastrophic financial burden, treatmentrelated financial hardship, and altered employment (20). Financial toxicity, however, was not found to be increased in a cohort of women undergoing contralateral prophylactic mastectomy in a single-institution propensity-matched analysis using the Comprehensive Score for financial Toxicity (COST) instrument (21).

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Country	Tax-funded	Social insurance	Compulsory private insurance	Voluntary private insurance	Out of pocket expenses
Canada	72	2	0	10	17
Germany	14	64	7	1	14
Ireland	73	1	0	12	14
United Kingdom	79	0	0	3	18
United States	39	12	34	0	15

Table 1 Health financing by type of revenue as percentage of total revenue

A survey of women with early-stage breast cancer identified through population-based sampling from two SEER regions reported 21.5% of white, 22.5% of Asian, 45.2% of blacks, and 35.8% of Latina patients had to cut down on spending on non-medical items such as food (22). Debt from treatment was reported by 27.1% of white, 58.9% of black, 33.5% of Latinas and 28.8% of Asian patients. In addition, 14% reported lost income that was $\geq 10\%$ of their household income and 17% of patients reported spending $\geq 10\%$ of their household income on outof-pocket medical expenses (22). Loss of homes was more prevalent among black and Latina patients.

Women with metastatic breast cancer may be at the most risk of developing financial toxicity during their treatment course. Women can have received multiple courses of treatment given the long natural history of breast cancer. An analysis of financial toxicity was performed among women receiving care at an urban outpatient clinic of women who have had breast cancer at least 10 years. The majority of women [143/145] had health insurance either private or government provided (23). Women with low-level income had household income which did not meet basic needs and had difficulty paying for basic needs. In addition, worse financial toxicity was associated with worse quality of life.

Breast cancer patients can experience financial toxicity before, during or after treatment. A survey was sent to 751 women treated for breast cancer of whom 136 (18.1%) returned the survey (24). The majority of respondents were Caucasian and diagnosed with stage I or II breast cancer. The respondents reported significantly worse financial status after diagnosis compared to prior to diagnosis, with the distress highest during treatment. Financial distress remained high even after treatment, with higher distress after treatment significantly more likely to be reported in patients with lower social support during treatment (24).

Financial toxicity in breast cancer patients is not unique

to the US. A cross-sectional study of 166 patients with stage 0-III breast cancer was undertaken using the financial Toxicity Comprehensive Rating Scale (COST-FACIT) tool in a low-middle income area of China. Patients scoring below the median financial toxicity score were more likely to be younger, live in a lower household income, live in rural areas, having lower medical insurance or be unemployed. To cope with financial toxicity 78.8% of women decreased their non-medical expenses at different levels, borrowed money, or reduced or quit treatment (25). An Egyptian study of women with breast cancer reported a high need for financial assistance with 80% having difficulty affording medications. Employment was less after the diagnosis of breast cancer, 15.3% after compared to 32.7% prior to diagnosis. Almost 50% of patients had difficulties securing food and nearly 33% found difficulty affording transportation (26).

Potential reasons for financial toxicity prevalence in the US

The overwhelming majority of studies [30/43] published on financial toxicity in cancer patients have come from the US while 4 were conducted in France, 2 from Ireland and one from the UK (3). The reason for this may be tied to the US healthcare system and how care is provided and reimbursed when compared to other countries. Table 1 shows revenues of health care financing schemes as a % of total revenue in select countries for 2018, the year the latest data are available, according to the Organisation for Economic Co-operation and Development (OECD) (https://stats. oecd.org/Index.aspx?DataSetCode=SHA#). There are clear differences in how healthcare is funded among these selected countries explaining why more studies of financial toxicity are from the US, with a free-market insurance system, compared to the rest of the world with a usual set of universal benefits tied to some form of tax-funded

insurance. Canada has a tax financed National Health Insurance (NHI) providing near universal coverage. Tax financed health care provides the majority of funding also in Ireland and the United Kingdom (UK). Private insurance in the free market is the main source of financing health care in the US while it provides supplementary funding in the UK and Canada. Private health insurance is usually obtained to cover services not covered by NHI or in some countries like the UK may be used to provide easier access to some services therefore allowing citizens with higher income to "jump the line". Germany has a Social Health Insurance system with wage-linked payments to social insurance funds with a small percentage of the population having private health insurance.

Tax funded revenue sources come either from direct or indirect taxes. Direct taxes are levied on individuals and firms through income type taxes but could also include inheritance or corporate taxes. Indirect taxes are levied on products and services and are included in the price of the product, such as value added taxes (VAT). This type of tax financed system is relatively straightforward especially in those countries with universal access to health care. Social insurance, as is seen in Germany, includes those funds raised through mutual or non-government public bodies with contributions generally linked to wages. The US has the highest percentage, a little more than a third, of health care financing provided by private health insurance while the other countries use voluntary private insurance as a supplement to coverage provided by the tax-funded care. Compulsory private insurance is tied to employment making provision of healthcare tenable in difficult economic conditions. The association of healthcare and employment makes job switching difficult as patients may not want to lose healthcare coverage when switching jobs especially if they have a pre-existing condition, such as cancer.

One of the major differences between the countries highlighted in *Table 1* is the type of healthcare systems and potentially the expectations of the patient population in those countries. Canada, Germany, Ireland and the UK have some form of universal coverage of healthcare. Universal healthcare coverage ensures all residents are assured access to some pre-defined minimum level of healthcare coverage as determined by each country. This minimum number of services covered may not include all healthcare demanded by all residents of the country but usually includes a minimum provision of services, especially preventive care type services. Patients could then decide to purchase additional insurance for services not covered in the basic package. By limiting care to a predefined package of benefits the governments can regulate healthcare costs while using the remainder of the tax revenue for other governmental programs. In addition, some countries may have introduced regulations to limit the types of medications available and limit the introduction of new technologies to further control healthcare expenditures. In addition, patients in these countries may be accustomed to queues for diagnostic scans, surgeries or other treatments to control supply.

A greater percentage of healthcare in the US is funded through private health insurance. The number of services provided through private insurance are dependent for the most part by the type of plan patients have purchased. Some insurance plans allow diagnostic tests and other procedures without pre-authorization while lower cost plans limit the amount of tests or medication used to control costs. There is an increasing prevalence of insurance companies using benefit management programs which use published guidelines to reduce cost by limiting testing, procedures and care. There are, in addition, a greater number of testing centers and specialists reducing queue times in the US when compared to the other countries mentioned above. Healthcare financing differences between the US and other countries and patient perception probably plays a major role in financial toxicity experienced by patients in these countries.

Insurance's role in the incidence of financial toxicity was noted in an analysis of 74 observational studies compiling over 590,000 patients (27). Multiple socioeconomic factors were independent risk factors for financial toxicity in cancer patients. Lack of health insurance was associated with increased odds of financial toxicity with patients lacking any drug or health insurance coverage having twice the odds of experiencing financial burden with cancer treatment compared to patients with health insurance (27). Lower income, unemployment or job change and lower education also were independent risk factors for worse financial burden. There was no mention of an association of lower income, education and unemployment on with insurance status.

Financial toxicity, however, has also been reported in a country with universal health coverage. Data from the ACTION study in Malaysia, an upper-middle-income country with universal health coverage, covering 1,662 newly diagnosed solid and non-solid tumors was analyzed for factors influencing financial toxicity. Overall, 1,294 cancer survivors were included in the study after excluding

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patients lost to follow-up and who died. The majority of the patients in the cohort were patients with breast cancer (33%), hematologic malignancies (22%), GI cancers (20%), female reproductive cancers (6.3%) mouth and oropharyngeal cancers (7.1%), respiratory cancers (8.0%), and other malignancies (8.0%) (28). The overall incidence of financial toxicity of cancer survivors at 1-year was 51% ranging from 33% in Ministry of Health hospitals to 65% in public university hospitals and 72% in private hospitals. Out-of-pocket expenses contributed to 18% of the financial toxicity which increased to 51% after inclusion of nonmedical payments for goods and services related to cancer care (28). Low-income status, type of hospital, and lack of health insurance were strong predictors of financial toxicity.

Conclusions

Financial distress is a real and emerging symptom for women with breast cancer. Insurance is an important aspect of why financial toxicity may develop, especially in the US. Multiple studies have pointed to lack of insurance, under employment and low-income status as important determinants of financial toxicity. The long natural history of breast cancer makes patients susceptible for developing financial toxicity over the life-time of their disease. A switch to a tax-funded universal healthcare system with a universal set of benefits may be needed to decrease the incidence of financial toxicity in women with breast cancer at least in the US which depends upon insurance without a universal set of benefits tied to employment. Unfortunately, there have been significant barriers from many sectors within the US healthcare system throughout the years to prevent this from happening.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (William Small Jr. and Parul Barry) for the series "Advancements and Opportunities for Breast Irradiation" published in *Annals of Breast Surgery*. The article has undergone external peer review.

Conflicts of Interest: The author has completed the ICMJE

uniform disclosure form (available at http://dx.doi. org/10.21037/abs-20-122). The series "Advancements and Opportunities for Breast Irradiation" was commissioned by the editorial office without any funding or sponsorship. The author has no other conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/abs-20-122

Cite this article as: Konski AA. Financial toxicity and the economic cost of breast cancer therapy. Ann Breast Surg 2021;5:35.

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