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Financial toxicity in patients with gynecologic malignancies: a cross sectional study

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ABSTRACT

Objective: To evaluate financial toxicity and assess its risk factors among patients with gynecologic cancers.

Methods: This is a cross sectional study that included 2 survey tools, as well as patient demographics, disease characteristics, and treatment regimen. Financial toxicity is measured by validated Comprehensive Score for Financial Toxicity (COST) tool. Participants were also asked to complete a 55-question-survey on attitudes and perspectives surrounding cost of care. Descriptive statistics was used to report patient demographics. Spearman's rank correlation was calculated to assess the relation between financial toxicity and patient/disease related variables. Graphpad Prism Software Version 8.0 was used for analyses.


Results: A total of 50 patients with various gynecologic malignancies were enrolled. Median COST score was 20.5 (range, 1–33). Sixty-five percent of the patients reported being in debt due to their cancer care and 4% filed bankruptcy. Correlation analysis showed that COST score was correlated with age ($r=-0.3$, $p=0.028$), malignancy type ($r=0.3$, $p=0.039$) and income ($r=0.3$, $p=0.047$). Ovarian cancer patients had significantly less financial toxicity (median COST score=23) when compared to patients with other gynecologic malignancies (median COST score=17, $p=0.043$). When scores were dichotomized into low (score ≥ 22) and high toxicity (score < 22), 58% (29/50) of the patients were noted to have high financial toxicity. Enrollment to a clinical trial did not significantly alleviate financial burden.

Conclusion: Financial toxicity is a significant burden even among highly insured gynecologic oncology patients. Age, malignancy type and income were correlated with high financial burden.

Keywords: Financial Stress; Ovarian Cancer; Uterine Cancer; Cervix Cancer; Vulva Cancer; Vagina Cancer

INTRODUCTION

According to American Cancer Society, there were 17 million new cancer cases and 9.5 million cancer-related deaths worldwide in 2018 [1]. These numbers are projected to be 27.5 million and 16.3 million, respectively by 2040 [1]. The United States (US) is currently the fifth country with

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Presentation

This study was presented as a poster at The Society of Gynecologic Oncology Annual Meeting on Women's Cancer, which was held in March 2021.

Synopsis

Financial toxicity is a growing problem, however, data is very limited. This is a cross sectional study that included two survey tools, as well as patient demographics, disease characteristics, and treatment regimen. Sixty-five percent of the patients reported being in debt due to their cancer care and 4% filed bankruptcy. Correlation analysis showed that COST score was correlated with age, malignancy type and income.

Conflict of Interest

No funding was received to assist with the preparation of this manuscript. Burak Zeybek, Emily Webster, Natalia Pogolian, Joan Tymon-Rosario, Alan Balch, Gary Altwerger, Mitchell Clark, Gulden Menderes, Masoud Azodi, Elena Ratner, Peter E Schwartz, Vaagn Andikyan have nothing to disclose. Dr Huang is in advisory board of Glaxo Smith Kline and Bristol Myers Squibb, outside the submitted work. Dr Santin's work has been funded by U01 CA176067-01A1 grants from NIH, CA-16359 grant from the NCI and grants from Deborah Bunn Alley Foundation, Tina Brozman Foundation, Discovery to Cure Foundation, SU2C and Guido Berlucchi Foundation, and by Immunomedics, Inc. Dr Santin also declares research funding support from Institution from Puma, Gilead, Immunomedics, Synthron, and Tesaro and non-financial support (ie, reagents) from Genentech/Roche, Merck, Boehringer Ingelheim, Genentech, Array BioPharma Inc,

highest cancer incidence rate after Australia, New Zealand, Ireland and Hungary, with the age-standardized rate of 352.2 per 100,000 [2]. This rate is 468 per 100,000 in Australia, which has the highest cancer incidence in the world [2]. As expected, these large numbers translate into large amount of costs for the countries' healthcare systems, especially for the US. In a study that investigated the medical care costs associated with cancer survivorship in the US, annualized average cancer-attributable costs were \$183 billion in 2015 and these costs are expected to \$246 billion by 2030—an increase of 34% [3]. Overall medical costs were highest among those who died from cancer in the end-of-life phase, followed by those in the initial and continuing phases of medical care, including the costs of oral prescription drugs. Considerable variation was seen in costs by cancer site and stage [3].

It is inevitable that at least some part of these large costs will be reflected on patients. Financial toxicity is becoming a growing problem among cancer survivors than ever before, as personalized treatments has started to replace the traditional 'one-size-fits-all' approach. The evolution of new generation cancer treatments such as immune therapies and targeted biologics are currently being used in various cancer types either as monotherapy or in combination with cytotoxic chemotherapy agents [4-6]. The list price of these new treatments can be dramatically expensive leading to higher deductibles and copayments for the patients [7-9]. In addition to treatment costs, survivors also suffer from the expenses of long-term follow-ups, side effects of various therapies and loss of at least some of the employment-based insurance benefits due to inability to work that leads to exacerbation of the financial toxicity [10].

Although awareness of healthcare costs and financial burden associated with cancer patients are increasing among health professionals, the number of studies is still very few that address the issue [11-13]. The economic sequelae of each cancer type should be assessed separately to further explore the problem. Patients with gynecologic malignancies comprise a significant portion of cancer cases in the US with approximately 110,000 new cases annually [14]. In this study, we sought to measure the financial toxicity, identify risk factors and assess cost-coping strategies in patients with gynecologic cancers.

MATERIALS AND METHODS

The Institutional Review Board (IRB) at Yale School of Medicine approved the study (IRB Protocol Identification No. 2000028321). Patients, who presented to the gynecologic oncology clinic at an academic center for their treatments and/or follow-ups, were asked to participate in the study. Patients then met with a member of the research team, who explained the study and answered any questions. After the informed consent was signed, a unique research study identification number was assigned and demographic and clinical information from the medical record such as age, diagnosis, treatment type, and comorbidities were collected in a deidentified manner along with the study ID number.

1. Survey design

This cross-sectional study included 2 surveys. The Comprehensive Score for Financial Toxicity (COST) is a validated tool that uses responses to 11 items to generate a composite measure of financial burden ranging from 0 to 44; zero representing high financial toxicity [11]. Patients were also dichotomized into 2 groups based on their COST scores to have low (score ≥ 22) or high (score < 22) financial burden [12]. The second survey is Patient Survey

AstraZeneca, ImmunoGen. Dr Huang is in the advisory board and consultant for Glaxo Smith Kline and Bristol Myers Squibb.

Author Contributions

Conceptualization: S.P.E., S.A.D., A.V.; Data curation: W.E., P.N., T.R.J.; Formal analysis: Z.B.; Investigation: Z.B., W.E.; Methodology: A.G., C.M., H.G., S.P.E., S.A.D., A.V.; Resources: B.A., A.G., C.M., M.G., A.M.; Supervision: R.E.S.; Writing - original draft: Z.B.; Writing - review & editing: A.G., C.M., M.G., H.G., A.M., A.V.

on Attitudes and Perspectives Surrounding Cost of Care, which is developed by Patient Advocate Foundation (PAF). PAF is a national non-profit 501(c)3 organization that provides direct case management services and financial assistance to patients and caregivers. These include helping people navigate the health care system, working with health care providers, payers and employers to assure that patients have access to affordable care, financial and co-pay assistance and teaching self-advocacy to patients and caregivers. Patient Survey on Attitudes and Perspectives Surrounding Cost of Care includes 55 questions that evaluates the demographics of the patients, diagnosis, financial hardship that patients encounter related to their diagnosis and treatments, information that patients would like to receive regarding the costs of the treatments, their insurance type and their income (**Data S1**). Estimated time to complete both surveys was 20 minutes. Surveys were administered once to assess financial toxicity in these patients. All of the participants responded to both surveys. Responses to individual statements/questions ranged from 92%–100% for COST survey statements and 67%–100% for Patient Survey on Attitudes and Perspectives Surrounding Cost of Care.

2. Statistical analyses

Descriptive statistics were used to report patient demographics. Mann-Whitney U and χ^2 tests were used to compare continuous and categorical variables, respectively. Correlation matrix with Spearman's rank correlation test was calculated to assess the relation between financial toxicity and patient/disease related variables. Graphpad Prism Software Version 8.0 was used for analyses.

RESULTS

The characteristics of the patients are summarized in **Table 1**. Median age at diagnosis was 64.5 years (range, 38–84 years). Median time since cancer diagnosis was 24 months (range, 1–144 months). All patients underwent cancer surgeries except 2 patients with stage III and IV cervical cancer, who were treated with chemoradiation. A total of twenty patients (40%) received radiation therapy. Ninety percent of the patients (45/50) received systemic therapy: 30% (15/50) received chemotherapy only, 24% (12/50) chemotherapy and targeted therapy, 12% (6/50) chemotherapy and immunotherapy, and 24% (12/50) received all 3 forms of systemic therapies (chemotherapy, immunotherapy, and targeted therapy) during their disease course. Out of 45 patients, who received systemic treatment, 34% (17/50) received 1 line, 22% (11/50) received 2 lines, 20% (10/50) received 3 lines, 6% (3/50) received 4 lines, 4% (2/50) received 5 lines and 4% (2/50) received 7 lines. Forty percent (20/50) of the patients were enrolled in clinical trials over the course of their disease. Median lines of systemic therapy were 2 (25%–75% percentile, 1–3 lines; range, 1–7 lines) prior to enrollment in a clinical trial. The malignancies and related International Federation of Gynecology and Obstetrics stages are summarized in **Table 2**.

Median COST score was 20.5 (range, 1–33). Correlation analyses showed COST score was correlated with age ($r=-0.3$; $p=0.028$), malignancy type ($r=0.3$, $p=0.039$) and income ($r=0.3$, $p=0.047$). Ovarian cancer patients had significantly less financial toxicity (median COST score=23) when compared to patients with other gynecologic malignancies (median COST score=17, $p=0.043$) (**Table 1**). Interestingly, 36% of ovarian cancer patients reported annual income of >\$100,000 whereas 5% of patients with other gynecologic cancers reported so ($p=0.024$). There was no correlation between the COST score and number of lines of systemic therapy ($r=0.26$, $p=0.069$). When scores were dichotomized into low (score ≥ 22) and high toxicity (score <22), 58% (29/50) of the patients were noted to have high financial toxicity.

Table 1. Characteristics of patients enrolled in the study

Variables	Ovarian cancer (n=24)	Other gynecologic cancers (n=26)	p-value*
COST score (median)	23	17	0.043
Race			
White	78	77	
African American	18	15	
Hispanic	0	4	
Asian	4	4	
Disease stage			
I	13	48	0.008
II	4	4	
III	26	33	
IV	57	15	0.002
Age at diagnosis (median)	62	62	
Performance status			
0	61	67	
1	30	30	
2	9	3	
Insurance			
Private	87	75	
Medicare with supplement	13	7	
Medicare	0	7	
Medicaid with supplement	0	4	
Medicaid	0	7	
No. of dependents (median)	2	2	
Income			
<\$50,000	28	42	
\$50,000–\$99,000	36	52	
>\$100,000	36	5	0.024

Values are given as a percentage.

*Only p-values that are statistically significant are mentioned in the table.

Table 2. Malignancies and related International Federation of Gynecology and Obstetrics stages of patients enrolled in the study

Type of Malignancy	Stage I	Stage II	Stage III	Stage IV
Ovarian	3 (13)	1 (4)	6 (25)	14 (58)
Uterine	12 (60)	0	6 (30)	2 (10)
Cervix	2 (50)	1 (25)	1 (25)	0
Vulva	0	0	1 (100)	0
Vagina	1 (100)	0	0	0

Values are presented as number (%).

Enrollment to a clinical trial did not significantly alleviate financial burden. Patients, who were enrolled in clinical trials, had a median COST score of 23, while the median score was 18 in patients, who were not enrolled in clinical trials ($p=0.256$). There was no correlation between COST scores and race, insurance type, number of dependents, stage of disease, performance status, type of treatment (surgery, radiation, medical), number of medical comorbidities (hypertension, cardiovascular disease, cerebrovascular disease, pulmonary disease, diabetes, thyroid disease, psychiatric disease, deep venous thrombosis/pulmonary embolism) and time since cancer diagnosis.

With regards to source of financial hardship, laboratory tests, insurance related costs (coinsurance, copayments or deductibles), and logistics and work-related issues (transportation, lost wages, time off from work, lodging or caregivers) were the highest contributors (**Fig. 1**). On a scale of 1 to 10 (10 most severe), 46% rated the hardship as 1–3, 33% as 4–6 and 22% as ≥ 7 . Two patients (4%) had to file bankruptcy due to their medical care costs, 4 (8%) had to use credit cards or bank loans that they would not otherwise have

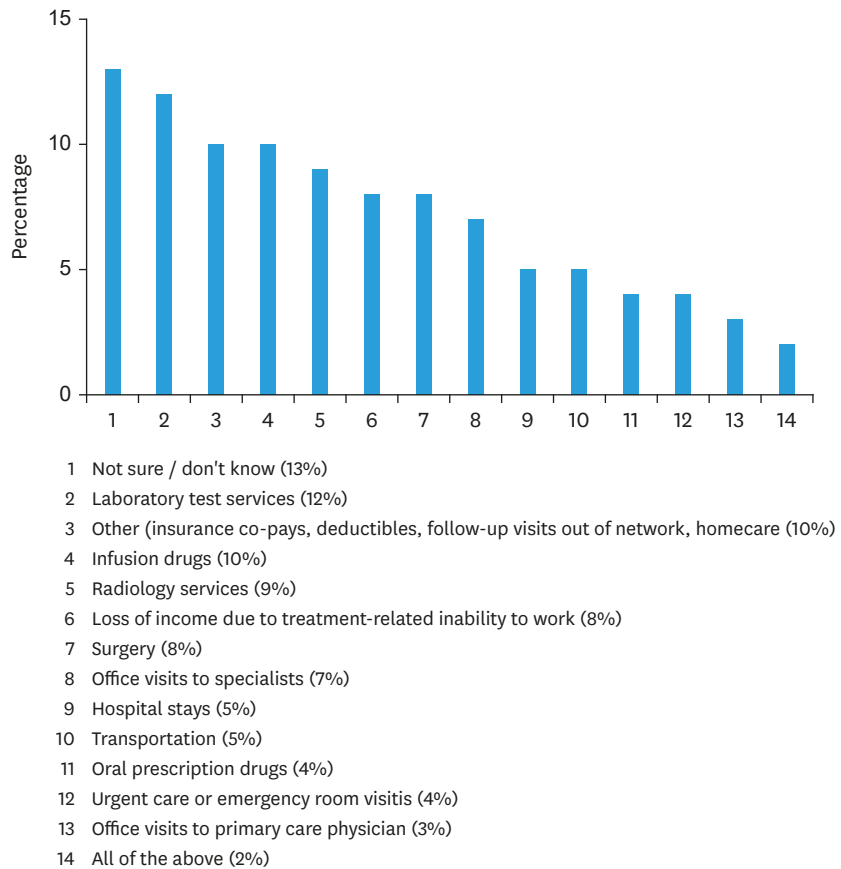


Fig. 1. Contributors to financial hardship.

used and 4 had to borrow from family/friends because of financial toxicity of their cancer care. Patient reported affordability of the costs is summarized in Fig. 2. Sixty-five percent of the patients reported that they were in debt due to their cancer care: fifteen percent reported

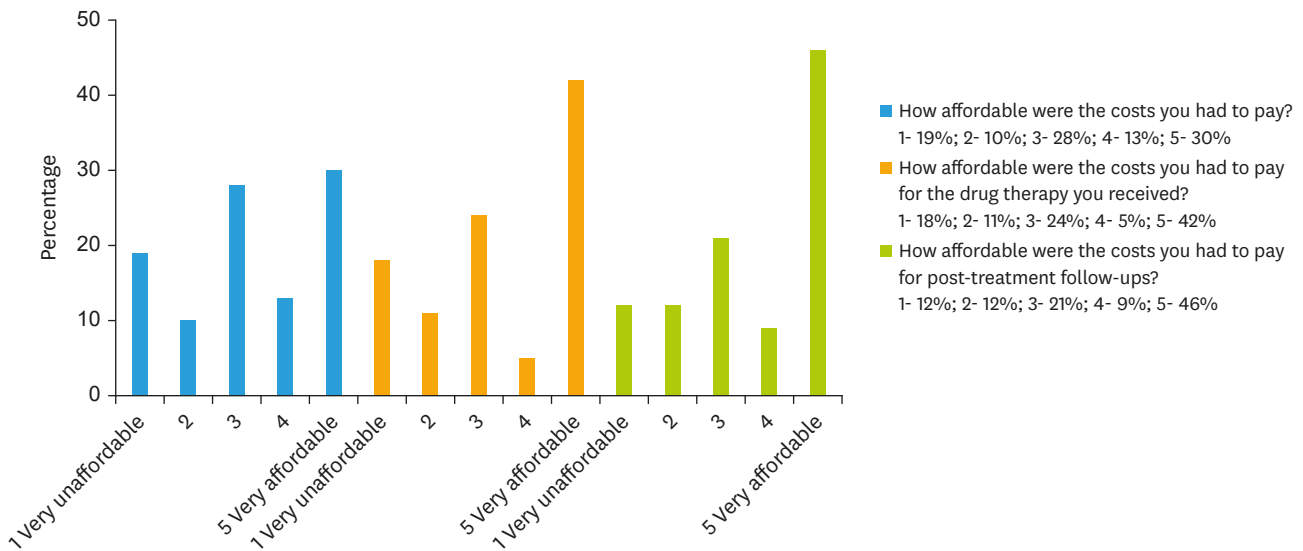


Fig. 2. Patient reported affordability of the costs.

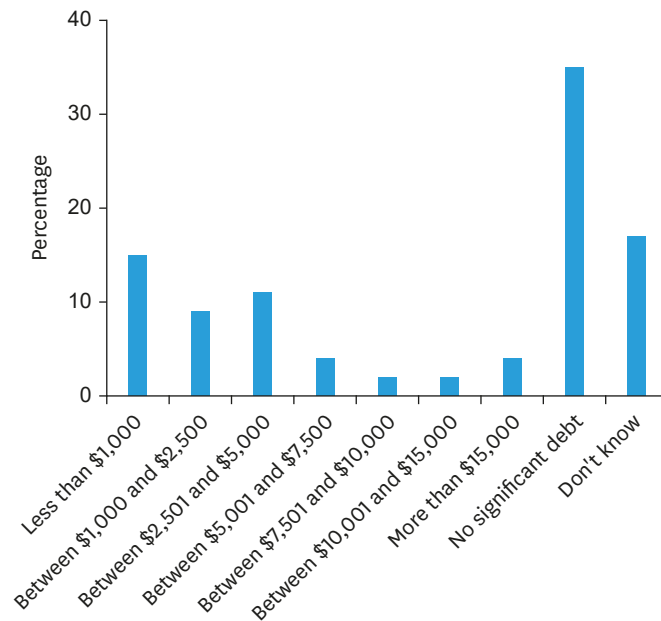


Fig. 3. Estimates that patients currently owe for total healthcare costs.

debt less than \$1,000, 9% between \$1,000 and \$2,500, 11% between \$2,501 and \$5,000, 4% between \$5,001 and \$7,500, 2% between \$7,501 and \$10,000, 2% between \$10,001 and \$15,000 and 4% more than \$15,000. Seventeen percent did not know the amount. Thirty-five percent of the patients reported no significant debt (**Fig. 3**).

When patients are asked what impact the financial hardship had on their medical care in the last 12 months, one patient responded that she shifted care to a different treatment location, one stopped/postponed treatment and one changed the way she paid for her care (e.g. insurance to charity care). Thirty-one patients (84%) reported no impact on medical care out of thirty-seven, who responded the question. The impact of the financial hardship on patients' financial situation in the last 12 months is summarized in **Fig. 4**.

DISCUSSION

In the present study, we sought to investigate the financial toxicity among patients with various gynecological malignancies. To be able to do so, we used 2 questionnaires; the first one was the validated COST survey and the second one was Patient Survey on Attitudes and Perspectives Surrounding Cost of Care. Overall median COST score was 20.5. When we dichotomized the scores into low (score ≥ 22) and high toxicity (score < 22), 58% (29/50) of the patients were noted to have high financial burden. We found that COST scores were correlated with age, malignancy type and income. Ovarian cancer patients had significantly less financial toxicity (median COST score=23) when compared to patients with other gynecologic malignancies (median COST score=17, $p=0.039$). This might be due to the fact that ovarian cancer patients in our study reported higher annual income, when compared to others (Annual income $> \$100,000$; 36% vs. 5%, $p=0.024$). Enrollment to a clinical trial did not significantly alleviate financial burden. Different than prior studies, in which younger age was found to be a significant predictor for financial distress, older age was correlated with

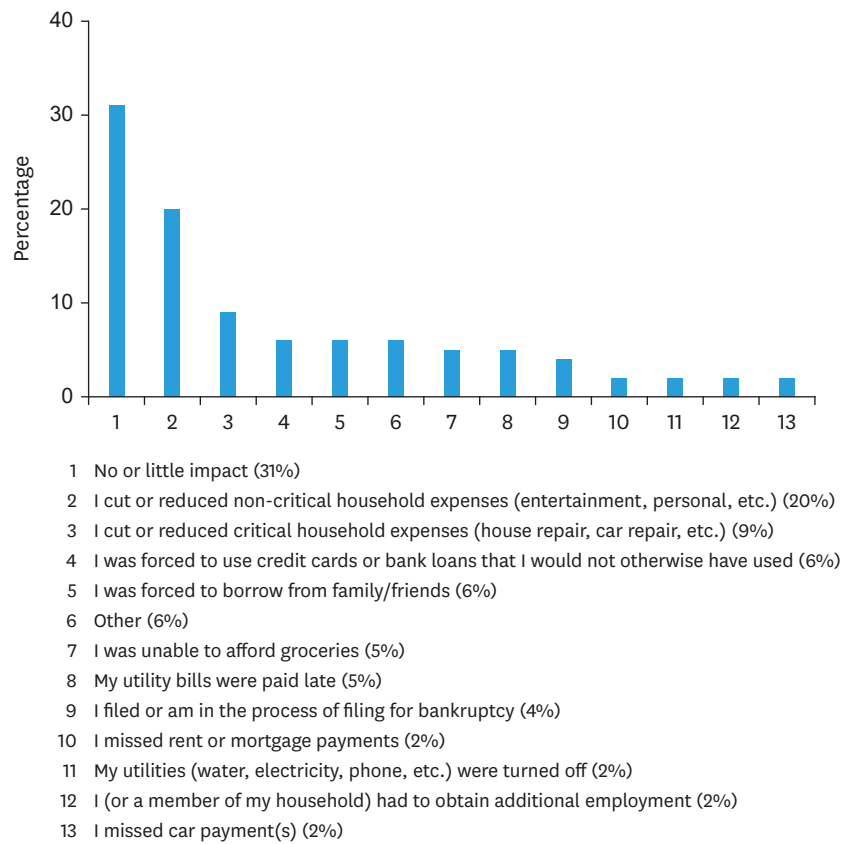


Fig. 4. The impact of financial hardship on patients' financial situation in the last 12 months.

worse financial hardship in our study [15-18]. This might be due to the fact that there was an inverse correlation between age and income in our patient cohort ($r=-0.3$, $p=0.032$).

Currently the COST is the only validated survey that assesses financial hardship in cancer patients. It was developed from an analysis of 155 patients with various cancers in a multi-step process, in which all patients had health insurance coverage [11]. Most of them were private or employer purchased (62%) followed by Medicare with or without supplement (32%). The median household income was \$63,500 and the median COST score was 21 (score range, 3–44; mean±standard deviation, 22.5±11.3). In a later study that included 233 patients with advanced cancer receiving chemotherapy (oral, intravenous or both), COST values were found to be correlated with income, psychosocial distress and health-related quality of life [12]. In our study, 78% of the patients (39/50) had private insurance, while 16% had Medicare and 8% had Medicaid. The median household income was between \$70,000 and \$79,999. We also found that higher income was correlated with less financial burden.

The term 'financial toxicity' is much broader than the patient's out-of-pocket expenses due to medical costs. In addition to services for treatment, it also includes non-medical costs that include transportation, pay cuts, as well as job losses due to staying away from work for extended periods [19]. According to U.S Bureau of labor statistics, 46% of low-income and 27% of private industry workers do not have paid sick leave benefits [20]. Psychological distress is also one of the most important aspects of financial toxicity that includes the stress from anxiety due to cancer diagnosis and its various effects. These were

emphasized in a systematic review, in which, Altice et al. [21] conceptualized the financial hardship in 3 domains in cancer survivors: material conditions (e.g., out-of-pocket costs, productivity loss, medical debt, or bankruptcy), psychological response (e.g., distress or worry), and coping behaviors (e.g., skipped medications) [21]. The authors found that the majority of the studies (82%, n=37) in the literature reported financial hardship as a material condition, while only 7% (n=3) and 16% (n=7) reported psychological response and behavioral measures, respectively. In our study, we investigated all these 3 domains in depth with 2 surveys specifically in the gynecologic cancer cohort. The psychological response domain was assessed with COST survey, while Patient Survey on Attitudes and Perspectives Surrounding Cost of Care was used to investigate the other domains in more detail. Logistics (transportation and travel costs related to treatment) and work-related issues (loss of income due to inability to work because of treatment) were among the highest contributors (13% total) to the financial hardship in addition to laboratory tests (12%), insurance co-pays and deductibles (10%) for our patients. Overall, about two thirds of our patients (65%) in the study reported some sort of debt for healthcare costs (**Fig. 3**). The most common coping behavior was to reduce non-critical household expenses (entertainment, personal, etc.) (20%) followed by to cut down critical household expenses (house repair, car repair, etc.) (9%). Thirty percent of the patients reported 'no or little impact' (**Fig. 4**).

There are very few studies that assess financial toxicity and cost issues specifically in gynecologic oncology cohort. In the study by Boubberhan et al., [22] 240 patients with various gynecologic cancers completed COST tool and a self-reported overall health assessment. Government sponsored health insurance, lower income, and treatment with chemotherapy were significantly associated with high financial toxicity. Overall, 55% of the patients had private insurance as opposed to 80% of the patients in our cohort. Despite a lower private insurance rate, their median COST score was higher when compared to ours (29 vs. 22). At least some part of this finding may reflect that 20% (n=40) of their cohort was benign. Suidan et al. [23] investigated cost estimates of different primary management strategies in ovarian cancer by using the MarketScan database. Among patients, who received neoadjuvant chemotherapy and those who underwent primary debulking, mean adjusted total costs were \$113,660 and \$107,153 (p<0.001), respectively. However, mean out-of-pocket costs were lower for neoadjuvant chemotherapy (\$2,519 vs. \$2,977 (p<0.001)). In terms of various forms of chemotherapy treatments, total cost was highest for intraperitoneal/intravenous chemotherapy (\$121,761), followed by intravenous dose-dense (\$115,099) and intravenous standard (\$105,047) (p<0.001). Out-of-pocket costs for these were \$2,838, \$3,405, and \$2,888 (p<0.001), respectively. When bevacizumab was added to the treatment, both total and out-of-pocket costs increased significantly; \$171,468 with vs. \$104,482 without bevacizumab (p<0.001), \$3127 with vs. \$2,898 without bevacizumab (p<0.001), respectively. In another study that assesses financial hardship in gynecologic oncology cohort, Liang et al. [24] evaluated 121 patients within 8 weeks of starting new line of systemic therapy (chemotherapy, targeted therapy and/or immunotherapy) by using COST survey. Fifty-four percent of participants screened positive for financial distress; 37% experiencing mild, 16% moderate, and 1% severe. Fifty percent reported income <\$40,000, 74% had private insurance, 20% had only public insurance, and 7% were uninsured. Age <65 years and income <\$40,000 were associated with increased odds of screening positive for financial distress. The difference of this study when compared to others [12,16] and ours is that authors categorized financial distress based upon a proposed grading scale: mild (COST score, 14–25), moderate (COST score, 1–13), and severe (COST score, 0) financial distress. If our cohort was categorized based on this grading scale, 58% of the patients would have had mild and 16% would have

had moderate financial distress. None of the patients' COST score was zero in our study. Currently, there is no defined threshold in terms of a COST score to define the severity of financial toxicity and these values differ across the studies [12,16].

Our study has limitations. The patients are from a single tertiary care center, which may not represent other geographic regions or institutions. As in other survey studies, non-response bias might be present leading to overestimation of the facts found in this study. Also, all participants had some form of insurance coverage, not representing women with low income and undeserved patient population. Furthermore, the majority of the participants were white, making it impossible to draw conclusions about underrepresented groups such as African American, Hispanic and Asian individuals. Strengths of the study include the use of an additional survey besides COST tool that assesses the financial hardship in more depth whether it was related to out-of-pocket costs, loss of productivity or combination of both. By using it, our study also assesses the specific costs that contributed most to financial hardship and impact of the hardship on financial situation specifically in gynecologic oncology cohort.

In conclusion, financial toxicity is a significant burden even among highly insured gynecologic cancer patients. Higher income and younger age are correlated with less financial hardship. Increased awareness of physicians and cost coping strategies are needed to optimize quality of care.

SUPPLEMENTARY MATERIAL

Data S1

PAF launch: RWJF-avalere patient survey on attitudes & perspectives surrounding cost of care

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