

## A Prospective Observational Study on ADRS of Chemotherapy in Breast Cancer Patients and Their Quality Of Life Improvement in a Tertiary Care Hospital

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**ABSTRACT:** This research paper is about assessing the health-related quality of life by using EORTC QLQ-C30 and EORTC QLQ-BR23 and the adverse effects of chemotherapy in breast cancer patients. In tertiary care hospitals, we gathered information from 70 patients. Although breast cancer is typically thought of as a disease that primarily affects women, our study shows that it can also impact men. Premenopausal women in this age range of 40–49 years account for the highest percentage of those with breast cancer in the study population (30%). A total of 21 ADRs were recorded from 70 patients. The most common ADRs were nausea, alopecia, weight loss, and insomnia. Naranjo's causality assessment showed 71.1% possible (score 4) and 28.9% probable (score 5-6). A total of 30.9% of ADRs are preventable nausea, vomiting, and constipation. Compared to elder age groups, women in the 30-39 age bracket do the least well on a functional scale.

**KEYWORDS:** Breast cancer, cancer chemotherapy, adverse drug reactions, quality of life, women's health.

### I. INTRODUCTION

Carcinoma of the breast is a malignancy originating from breast tissue.<sup>[1]</sup> Breast cancer statistics from the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) programme show that there will likely be 268,600 new cases in 2019, making up 15.2% of all cancer cases, while there will likely be 41,760 deaths, making up 6.9% of all cancer deaths.<sup>[2]</sup>

The Risk factors of breast cancer are Early menarche (before age 12 yrs), Nulliparity, and late age at first birth are considered Endocrine factors. On the other hand Saturated fat and meat intake, Higher BMI, Obesity, and Alcohol consumption

are the Environmental factors. Breast cancer is genetically caused by mutations in either BRCA1 or BRCA2. TP53, CHK2, PTEN, and ATM are the other genes identified with hereditary breast cancer. Breast cancer's etiopathogenesis is characterized by the development of invasive tumors as a result of numerous molecular changes at the cellular level.<sup>[1]</sup>

Since the discovery of curative treatments for fatal malignancies such as lymphomas, leukemia, and testicular tumors, the area of cancer chemotherapy has experienced a significant transformation. Chemotherapy has undergone a revolution with the introduction of newer medications since it is used as part of a multimodal strategy to treat various malignancies.<sup>[3]</sup>

Anti-neoplastic agents are the most frequently occurring class of medications to result in ADRs. According to a study conducted in Southern India in addition to the prior findings, a more recent analysis of the global trends in ADRs over ten years revealed that high-income nations reported greater ADRs for anticancer and immunomodulating drugs. Additionally, ADRs have a major impact on both health costs and human lives.

Cancer patients experience physical and psychological distress which harms their quality of life (QOL).<sup>[5]</sup> According to the World Health Organization, it is "the condition of one's existence as a result of the interaction of numerous circumstances, including those affecting one's health, happiness, and other qualities like physical comfort and a fulfilling employment, social, education and intellectual achievements, individual liberties, justice, and expression."<sup>[6]</sup> Factors that affect the QOL and mental health of patients are low socioeconomic status, stage of disease, age,

and having had chemotherapy.<sup>[6,7]</sup> Late breast cancer diagnosis has a detrimental impact on patient's quality of life in terms of their health.<sup>[8]</sup> An in-depth investigation is required to pinpoint aspects of living quality in terms of health that can help doctors improve care for patients with breast cancer. Therefore, the goal of the current study was to evaluate patients with breast cancer's quality of life in terms of their health using the EORTC QLQ C-30 and EORTC QLQ BR-23.

## II. METHODS AND MATERIALS

A Prospective observational study conducted in Oncology Department, St. Ann's Hospital, Fathimanagar, NIT post, Warangal.

After receiving the ethical committee's approval from the hospital following the Helsinki declaration, this study was conducted over six months on 70 patients who were histopathologically confirmed to have breast cancer. All participants gave their informed consent before being included in the study. According to Klug et al., cancer survivors are people who have lived for more than two years after receiving a cancer diagnosis.<sup>[5]</sup> Breast cancer survivors are selected based on the subsequent inclusion requirements: patients who are >20 years of age diagnosed of having breast cancer. Exclusion criteria: patients who have not completed treatment and whose stage of cancer is unknown.

The patient demographic characteristics are statistically analyzed. Student's t-test analysis has been used to compare tables with two groups, and analysis of variance in one direction has been used to examine tables containing greater than two groups (ANOVA). The data is considered statistically significant if  $P < 0.05$  with confidence interval 95%.

Patient demographic details namely Age, Sex, diagnosis, suspected ADRs, and treatment details (Drug, dose, strength, frequency, date of starting and stopping) were collected using a specially designed data collection form. Naranjo's scale has been used to assess the relationship between ADR and the drug which contains 10 inquiries that are addressed as Yes, No, or Do not know. For each response a different point value (-1, 0, +1 or +2) is given. Below is a condensed version of the 10 questions:

- Exist any conclusive prior accounts of this response?
- Was the adverse event brought on by the drug administration?

- Did stopping the medication or using a particular antagonist make the side effect better?
- Did the adverse reaction return after the medicine was administered again?
- Were there any further potential causes for the reaction?
- Did the adverse reaction come back after receiving the placebo?
- Were dangerous levels of the substance found in the blood or other fluids?
- Did the reaction get worse as soon as the dose was raised? Or did the reaction get worse when the dosage was cut back?
- Did the patient previously experience a similar response to the medication or a related substance?
- Any additional unbiased evidence that supported the adverse effect?

Links to the real ADR likelihood scale form and instructions for completing it are provided below. Total scores might vary between -4 and +13; a reaction is deemed certain if it is a 9 or above, probable if it is a 5 to 8 or higher, possible if the value is between 1 and 4, and questionable if it is a score of 0 or less.

After patient consent was obtained, a questionnaire survey was conducted. The questionnaires used are EORTC QLQ-C30 and EORTC QLQ-BR23. The QLQ-C30 contains 30 questions, on the functioning scale there are 5 groups of questions namely physical functioning (five questions), role functioning (two questions), emotional functioning (four questions), cognitive functioning (two questions), and social functioning (two questions); two questions on global health, while twelve questions on symptoms namely nausea and vomiting (two questions), fatigue (three questions), difficulty breathing (one question), insomnia (one question), lack of appetite (one question), constipation (one question) and financial difficulty (one question).

The EORTC QLQ-BR23 consists of eight questions comprising four groups of questions on functioning, namely body image (four questions), sexual functioning (two questions), sexual enjoyment (one question), and future perspective (one question); and 15 questions on the symptoms or problems frequently experienced by patients with breast cancer, namely side effects from treatment (seven questions), symptoms related to the breasts (four questions), symptoms related to the arms and shoulders (three questions), and hair loss (one question).

A high score on a symptom dimension (0-100) denotes a lot of symptoms, whereas a high score on the global health status (i.e., total QOL score) and functioning dimension (0-100) signifies a high degree of QOL and functioning.

### III. RESULTS

#### Demographic Characteristics of Respondents

During 6 months study, 70 QOL questionnaires were received from breast cancer patients and a total of 21 ADRs were received. Of the total 70 patients, 1(1%) was male and 69 (99%) were females. A higher percentage of our study population belonged to the age range of 40-49years (30%). Out of 54 cases, the majority of cases were HTN i.e., 25(44.64%), 14(25%) were DM, and about 5(8.92%) were both DM and HTN. Hepatitis B in one male case. About 6(7.1%) were with thyroid and 1(1.78%) with both thyroid and DM. Histopathological evaluation (HPE) a critical component in the management of patients with tumor was performed in all 70 cases of which invasive duct cell carcinoma grade III were 62(88.57%), grade II 6(8.51%) and grade I in 2 (2.42%) cases.

Immunohistochemistry (IHC), is a unique staining procedure used to determine whether or not cancer cells have HER2 receptors and/or hormone receptors on their surface on fresh or frozen breast tissue retrieved during biopsy. The highest number 58(83%) cases were E+P+, Progesterone positive (P+) were 7 (10%), E- P- were 5(7.14%), and estrogen (E+) only 1(1.42%).

69 of the 70 patients underwent mastectomy surgery before chemotherapy and radiation therapy, while one patient underwent surgery after chemotherapy and radiation therapy.

About 8 cycles of chemotherapy (32.86%) with a gap of 21 days for each cycle which include 4 drugs Cyclophosphamide, Doxorubicin, Paclitaxel, and Fluorouracil with different doses, and the route of administration of these drugs in intravenous was

given to all the 70 patients and 25 cycles of radiation therapy (32.86%) were followed by chemotherapy. Of all the cases discussed 1(0.46%) case was with the treatment of chemotherapy, radiation therapy, and brachytherapy (**table 1**).

#### Analysis of ADRs with suspected drugs

A total of 21 ADRs (**table 2**) were recorded from 70 patients. 18.45% of cases of nausea and vomiting are reported in our settings. Constipation was seen in 2.97% of patients. It is noteworthy to mention that the presentation of constipation observed in the patients was of grade 1 type. There were 26.6% of patients with anorexia. Overall, 17.85% of our population had alopecia. We have seen from the present evaluation that the drug regimen consisting of paclitaxel, was associated with numbness (2.97%). about 11% of patients experienced insomnia, and 8.3% experienced pain at the surgical site.

On analyzing the causality assessment of the ADRs by Naranjo's score, 29.9% of cases showed probably and 70.1% showed a possible association. In our study population, all 21 ADR cases were managed symptomatically and these patients recovered fully with no further untoward reactions.

#### Health-related QOL depending on age

Tables 2 and 3 show, respectively, how age affects the correlation between QOL symptom scores and functioning scores. The patients of the age group between (30-39yrs) showed significantly poorer QOL outcomes compared to other age groups. The mean overall well being score for a group (30-39yrs) is 54.1 (SD5.86), while the older group  $\geq 70$ yrs is 63.8 (SD11.3). Nausea and pain in the tumor area are high in the young age group (30-39yrs) compared to elder age category. Only the following showed statistical significance: financial impact (P=0.01), social functioning (P=0.043), pain (P=0.0430), and appetite loss (P=0.030).

**Table 1: Patient Demographic details**

<b>Age (Yrs)</b>	<b>no. of cases (n=70)</b>	<b>Percentage (%)</b>
<b>30-39</b>	10	14.28
<b>40-49</b>	21	30
<b>50-59</b>	15	21.42
<b>60-69</b>	19	27.14
<b>≥70</b>	4	5.17
<b>Comorbidities</b>		
<b>Hypertension</b>	25	44.64
<b>Diabetes</b>	14	25
<b>Hepatitis B</b>	1	1.78
<b>Thyroid</b>	6	10.71
<b>DM+ HTN</b>	5	8.97
<b>DM+ TB</b>	1	1.78
<b>DM+ Thyroid</b>	1	1.78
<b>Thyroid+ CAD</b>	1	1.78
<b>Surgeries</b>		
<b>Hysterectomy</b>	11	31.4
<b>Tubectomy</b>	18	51.42
<b>TAH</b>	5	14.28
<b>Vasectomy</b>	1	2.85
<b>Histopathological Examination</b>		
<b>Grade I</b>	2	2.42
<b>Grade II</b>	6	8.51
<b>Grade III</b>	62	88.57
<b>Immunohistochemistry</b>		
<b>E+</b>	1	1.42
<b>E+ P+</b>	58	83
<b>P+</b>	7	10
<b>E- P-</b>	5	7.14
<b>Plan of treatment</b>		
<b>Chemotherapy</b>	70	32.86
<b>Radiation therapy</b>	70	32.86
<b>Neoadjuvant chemotherapy</b>	1	0.46
<b>HDRT (brachytherapy)</b>	1	0.46
<b>CT+RT</b>	70	32.46
<b>CT+RT+HDRT</b>	1	0.46
<b>Type of Treatment</b>		
<b>AC-paclitaxel</b>	69	97.18
<b>FAC-paclitaxel</b>	1	1.4
<b>CMF</b>	1	1.4

**Table 2: List of ADRs due to chemotherapy**

<b>ADRs</b>	<b>No. of cases</b>	<b>Percentage</b>
<b>Nausea</b>	31	18.45
<b>alopecia</b>	30	17.85
<b>pain</b>	14	8.33
<b>Weight loss</b>	38	22.6
<b>GI irritation</b>	3	1.78
<b>numbness</b>	5	2.97
<b>insomnia</b>	20	11.9
<b>vertigo</b>	1	0.6
<b>Dry mouth</b>	1	0.6
<b>arthritis</b>	5	2.98
<b>swelling</b>	4	2.98
<b>anemia</b>	1	0.6
<b>Metallic taste</b>	1	0.6
<b>constipation</b>	5	2.97
<b>Lightheadedness</b>	1	0.6
<b>Oral ulcer</b>	2	1.19
<b>allergy</b>	3	1.78
<b>recurrence</b>	1	0.6
<b>Micturition</b>	1	0.6
<b>fever</b>	1	0.6

The results of the current study reported that the age group 30-39 yrs had worse body image functioning and future perspectives. Younger age group 30-39yrs are more upset about hair loss (SD32.1).

**Health-related QOL depending on stage**

Tables 5 & 6 show, respectively, how symptom and functioning scores correlate with stage. Patients with advanced illness stages had the

lowest ratings across all functional scales. Patients with advanced-stage disease performed worse on the symptom scale than those with stages I and II, with a average score of 33. (SD 22.5). Patients with advanced-stage illnesses had the weakest performance on the symptoms scale, with an average score of 33 (SD 22.5). P = 0.049 for loss of appetite was extremely significant due to disease's advanced stage.

**Table 3: European Organization for Research and Treatment of Cancer 30-item Quality of Life Questionnaire scores (n=70)**

	Age(mean ±SD)					P value
	30-39 years (10)	40-49 years (21)	50-59 years (15)	60-69 years (19)	≥70 years (5)	
<b>Functioning scales</b>						
Global score	54.1±5.86	61.49±13.01	63.8±11.3	62.7±16.01	63.8±11.3	0.566
Physical functioning	77.9±13.5	77.9±15.2	78.6±6.7	79.2±7.88	90.4±5.8	0.260
Emotional functioning	84.9±5.2	88.8±7.65	84.4±4.31	815.±7.63	86.6±7.48	0.027
Role functioning	70.7±20.1	69±21	62.7±19.3	63.5±20.2	63.5±20.2	0.779
social functioning	79.9±7.04	73.7±8.46	82.1±4.3	79.9±12.7	73.2±9.14	0.043
Cognitive functioning	84.9±9.4	78.2±7.8	77.7±14.9	70.15±24.5	69.4±16.7	0.1506
<b>Symptom scales</b>						
Fatigue	19.9±17.1	21.6±26.3	24.4±26.6	26.2±26.21	33.3±29.7	0.854
Nausea	16.6±23.5	21.6±27	24.4±26	6.13±16.84	11.08±13.5	0.156
Dyspnea	0±0	0±0	0±0	0±0	0±0	-
Pain	29.9±10.5	9.5±15.04	8.88±15.2	1.7±7.63	13.32±18.23	0.0430
Insomnia	19.9±28.0	29.9±18.3	28.8±21.3	31.5±20.66	39.9±36.4	0.561
Appetite loss	20.1±17.3	23.3±15.2	24.4±15.2	10.5±15.9	33.3±23.5	0.030
constipation	6.6±14	7.9±17.5	4.4±17.1	10.5±24.9	13.3±29.7	0.891
Diarhea	0±0	0±0	0±0	0±0	0±0	-
Financial impact	29.63±10.47	16.66±16.66	48.81±20.86	42.85±23.33	57.14±23.33	0.01

P values for questionnaire items related to functions and symptoms : EORTC QLQ-C30 concerning various age ranges. With a significant P-value of 0.05, the study's CI was set at 95%. Each group's patient makeup is indicated in

parenthesis. EORTC QLQ-C30: European Organization for Research and Treatment of Cancer 30-Item Quality of Life Questionnaire, N/A: Not available, CI: Confidence interval, SD: Standard deviation..

**Table 4: Quality of Life Questionnaire Breast Cancer-23 scores (n=70)**

	Age(mean ±SD)					P value
	30-39 yrs (10)	40-49 yrs (20)	50-59 yrs (19)	60-69 yrs (15)	≥70 yrs (5)	
<b>Functioning scales</b>						
Body image	60.4±17.9	62±20	63.9±14.1	62.2±12.5	65.1±16.5	0.907
Sexual functioning	62±20	N/A	N/A	N/A	N/A	-
Sexual enjoyment	N/A	N/A	N/A	N/A	N/A	-
Future perspectives	33.3±15	36.4±29.6	37.7±17.9	38±29.1	83.3±0	0.0862
<b>Symptom scales</b>						
Systemic therapy side effects	16.1±26.2	33.3±31.6	32.9±17.8	34.03±5.6	36.3±28.9	0.576
Breast symptoms	1.1±0	1.6±7.4	2.2±8.5	3.5±10.5	5.5±13.5	0.7408
Arm symptoms	4.4±5.7	8.8±14.6	8.1±11.4	7.01±12.3	12.9±16.3	0.747
Upset by hair loss	46±32.1	39.9±29.7	31.08±26.6	33.3±27.1	27.7±32.7	0.0596

P values for questionnaire items related to functions and symptoms : QLQ-BR23 concerning various age ranges. With a significant P-value of 0.05, the study's CI was set at 95%. Each group's

patient makeup is indicated in parenthesis. SD: Standard deviation, N/A: Not available, CI: Confidence interval, QLQ-BR23: Quality of Life Questionnaire Breast Cancer-23.

**Table 5: European Organization for Research and Treatment of Cancer 30-item Quality of Life questionnaire scores (n=70)**

	Stage(mean ±SD)			P value
	I	II	III	
<b>Physical scale</b>				
Global functioning	63.8±11.3	62.7±16.0	59.9±13.9	0.856
Physical functioning	81.9±9.8	78.5±15.9	78.8±2.74	0.909
Emotional functioning	69.4±15	64.8±20.5	57±22.5	0.639
Role functioning	79.9±10	77.4±14.5	76.2±16.9	0.1664
Social functioning	75±23.3	71.6±16.2	67.2±24.2	0.8395
Cognitive functioning	83.3±0	79.1±14.6	70.5±20	0.0403
<b>Symptom scale</b>				
Fatigue	24.9±11.8	20.6±9.14	33.2±19.6	0.0512
Nausea	16.6±0	22.1±8.6	24.9±15	0.057
Dyspnea	0±0	5.55±3.5	12.3±21.9	0.503
Pain	19.3±31	8.3±11.7	13.8±22.1	0.8135
Insomnia	8.3±11.7	27.7±22.3	31.6±21.4	0.874
Loss of appetite	16.6±23.5	24.9±29.3	33.3±22.5	0.474
Constipation	0±0	8.3±13	13.9±21.3	0.462

P values for questionnaire items related to functions and symptom: EORTC QLQ-C30 concerning the stage of illness at presentation. With a significant P-value of 0.05, the study's CI was set at 95%. Each group's patient makeup is indicated in

parenthesis. N/A: Not available, CI: Confidence interval, SD: Standard deviation, EORTC QLQ-C30: European Organization for Research and Treatment of Cancer 30-Item Quality of Life Questionnaire.

**Table 6: Quality of Life Questionnaire Breast Cancer-23 scores (n=70)**

	Stage(mean ±SD)			P value
	I (2)	II (6)	III (61)	
<b>Functioning scales</b>				
Body image	66.6±11.8	63.8±12.5	60.5±16.8	0.798
Sexual functioning	NA	NA	NA	-
Sexual enjoyment	NA	NA	NA	-
Future perspectives	83.3±0	27.7±32.7	41.6±27.7	0.0446
<b>Symptom scales</b>				
Systemic therapy side effects	8±11.3	27.7±30.6	36.1±28.6	0.058
Breast symptoms	0±0	2.7±6.7	5.06±7.67	0.6205
Arm symptoms	4.4±5.7	8.8±14.6	12.9±16.3	0.840
Upset by hair loss	33.3±0	27.5±13.5	46.7±24.46	0.1428

P values for questionnaire items related to functions and symptom: QLQ-BR23 concerning stage of illness at presentation. With a significant P-value of 0.05, the study's CI was set at 95%. Each group's patient makeup is indicated in parenthesis. N/A: Not available, CI: Confidence interval, SD: Standard deviation, QLQ-BR23: Quality of Life Questionnaire Breast Cancer-23.

Patients with Advanced stage disease have worse future perspectives, with an average score of 41.6 (SD 27.7) when compared to early-stage disease with a statistical significance of  $P=0.0446$ .

#### IV. DISCUSSION

The practice of cancer medicine today has been profoundly impacted by the availability of treatment for many malignancies that were once fatal. Adjuvant chemotherapy has demonstrated that it prolongs life and prevents disease recurrence. Even with these, several anti-neoplastic medications have a narrow therapeutic range and higher potential for side effects such as nausea, vomiting, anemia, alopecia, pancytopenia, neutropenia, constipation, diarrhea, and fatigue.<sup>[4]</sup> To clarify the side-effect profile of a medicine, documentation, and reporting of ADRs become essential. This might aid in averting such events in the future. A noble, moral medical profession demands truthful, unbiased data on medications. Only a robust drug safety monitoring program can make this happen.<sup>[3]</sup>

A total of 21 ADRs were recorded from 70 patients. The elderly population is more prone to the development of ADRs during treatment. A total of 18.45% of cases of nausea and vomiting are reported in our population. Nevertheless, with the use of a 5-hydroxytryptamine 3 antagonist, the incidence of nausea significantly decreased though they have failed to prevent it completely. It is noteworthy to mention that grade I type of constipation was observed in 2.97% of patients and was managed with laxatives and proper counsel on dietary modification. Drugs used in cancer can alter an individual metabolism through changes in taste and it leads to weight loss. Therefore, symptoms of anorexia are seen in 22.6% of patients. In our study, a total of 17.85% of patients suffered from alopecia. We have seen from the present evaluation that the drug regimen consisting of paclitaxel, was associated with numbness (2.97%), about 11% of patients experienced insomnia, and 8.3% experienced pain in the surgical site.

On analyzing the causality assessment of the ADRs by Naranjo's score, we noticed that 29.9% of cases showed probability and 70.1% showed a possible

association. The majority of the ADRs reported in this study were mild. All 21 ADR cases in our study were managed symptomatically and all of these patients recovered fully with no further untoward reactions.

According to various studies younger women report more psychological morbidity than older women, following a breast cancer diagnosis. Given the increase in the number of young women diagnosed with breast cancer, there is interest in several recent studies focusing on this population, particularly young women.<sup>[9]</sup>

In comparison to premenopausal and older age groups, the functional scale global health outcomes for younger breast cancer survivors aged 30-39 were significantly worse. The average global health score in the 40-49 years age group turned out to be 63.5 and 59.9 in the >70 years age group. Statistical significance was found for Emotional functioning ( $P=0.027$ ), Social functioning ( $P=0.043$ ), Pain ( $P=0.0430$ ), Appetite loss ( $P=0.030$ ), and financial impact ( $P=0.01$ ). In a similar study by Neelam Sharma et al., they revealed that the statistical significance in younger age groups was physical functioning  $P = 0.0003$ .<sup>[6]</sup>

On the EORTC QLQ BR 23, the results of the present study showed that the highest mean scores were observed in body image and future perspectives when compared to other functioning scales. Due to cultural barriers, sexual functioning and sexual enjoyment receive a score of zero. Women in India, mainly in rural regions, were unable to discuss sexual functioning in public.

Patients with Advanced stage disease have worse QOL when compared to stage I and Stage II. These results are in concordance with the findings of a study done by Neelam Sharma et al., in patients with breast cancer.<sup>[6]</sup>

#### LIMITATIONS OF THE STUDY

The main issue faced during the study was time. The social environment and cultural barrier of a nation have an impact on how well patients are perceived, so the results from overseas studies may not be entirely relevant to our patients. Our research contributes significantly to the Indian point of view.

#### V. CONCLUSION

The examination of ADRs related to cancer chemotherapy in a hospital setting provides information on the origin, seriousness, and preventability of the discovered ADRs. It might also raise awareness among the treating doctors, helping to stop ADRs from happening again to the same



patient. The recurrence of ADRs following chemotherapy cycles can be avoided with proper evaluation of ADRs. Our study highlighted the typical ADRs of anticancer medications as well as their causes, seriousness, and preventability. Our extensive surveillance has helped to discover the ADRs early and improve the treatment outcomes.

The current investigation concluded that younger age groups had lower health-related QOL than older age groups. Breast cancer is considered one of the social taboos. Women are reluctant to ask for help in evaluating their breast cancer and to speak up. A vast campaign to raise public awareness of health concentrating on women is required with a special focus on tribal and rural people.

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#### Conflicts of interest

There are no conflicts of interest.

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