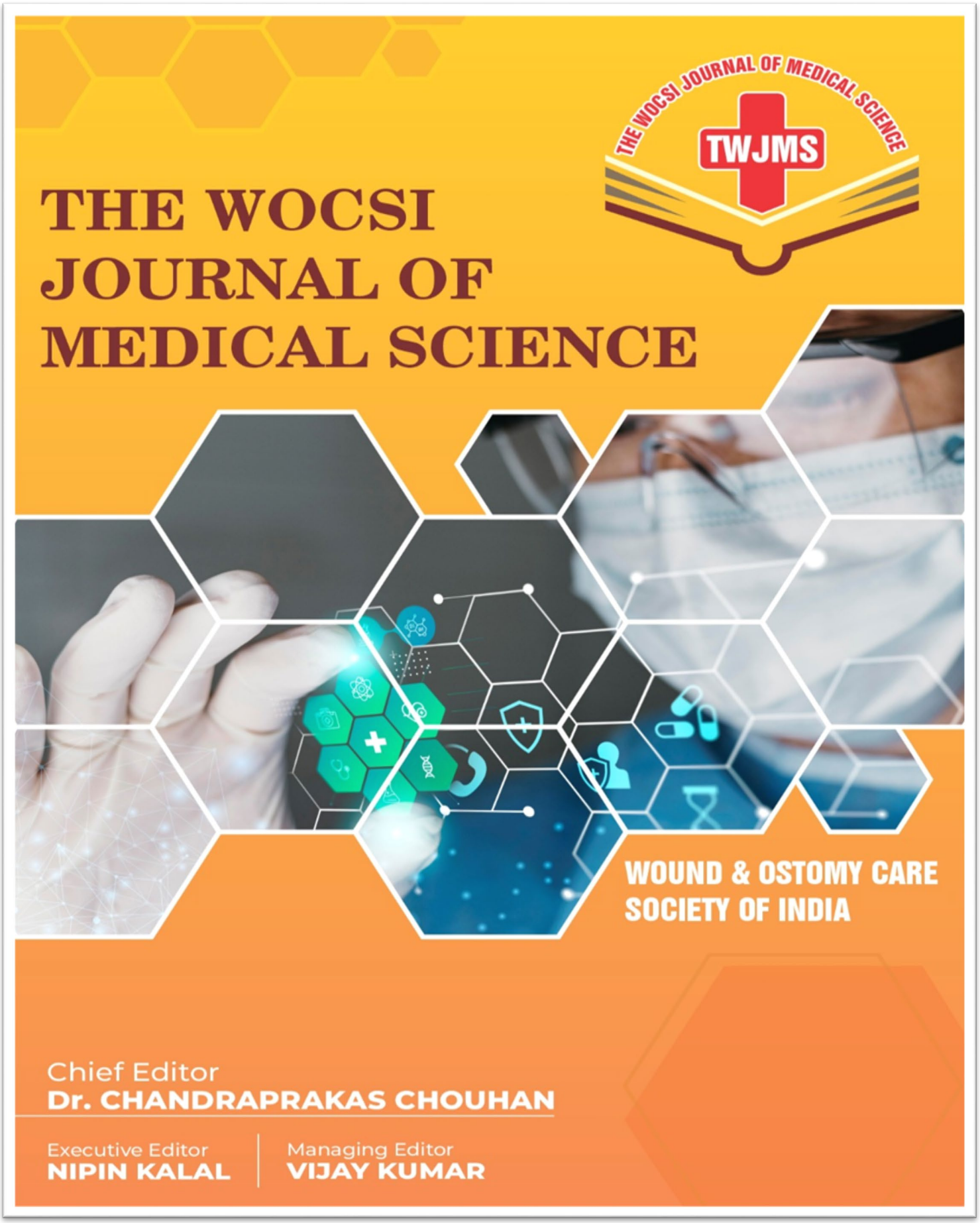
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Psychological Concerns Individuals With Hereditary Cancer and Their Immediate Family Members Seeking Medical Care At A Tertiary Care Hospital In India

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Abstract:

Introduction: Cancer susceptibility is more prevalent in individuals with a familial background. However, on a national level, the field of clinical genetic services and the psychological effects of suspected familial cancer on patients and their relatives is still emerging. Furthermore, it is uncertain whether genetic testing and counseling (GTC) can effectively address the common psychological challenges linked to cancer.

Purpose: The objective of this research endeavor was to examine the correlation between GTC (Genetic Testing and Counseling) and psychological concerns such as anxiety, depression, and distress among individuals with hereditary cancers and their immediate family members.

Methods: This preliminary study involved the participation of 100 patients who visited the GTC center at the All India Institute of Medical Sciences, along with their relatives. Demographic information was collected at the beginning and after undergoing GTC, and validated questionnaires were utilized to assess the psychological issues of interest. Generalized estimating equations, which accounted for clustering within individuals, were employed to analyze the association between GTC and the three psychological concerns.

Results: Out of the total participants, 96 were female patients, with 60% having breast cancer and 26% having ovarian cancer. Among the patients, the odds of experiencing anxiety, depression, and distress were found to be lower after undergoing GTC, when compared to before. These findings were statistically significant for distress (OR: 0.37; 95% CI: 0.21, 0.68). Although not statistically significant, GTC led to a 40% reduction in distress among the relatives (0.60; 0.29, 1.24).

Conclusions: Our results offer preliminary evidence supporting the potential protective effect of GTC in reducing psychological distress related to hereditary cancers among both patients and their immediate family members. We recommend conducting a larger longitudinal study in the future to further investigate these associations and confirm our findings.

Keywords: hereditary cancer, psychological issues, patients, relatives

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INTRODUCTION

Cancer, a group of diseases characterized by the uncontrolled growth and spread of abnormal cells, is responsible for one in seven deaths worldwide. In low- and middle-income countries, it ranks as the third leading cause of death after cardiovascular diseases, infectious diseases, and parasitic diseases. It has been established that individuals with a family history of cancer are more susceptible to developing the disease. While some familial cancers are a result of a combination of genetic and environmental factors, others are solely caused by inherited genetic mutations[1-2]. These inherited genetic mutations play a significant role in approximately 5 to 10 percent of all cancer cases. Over the past decade, various hereditary cancer syndromes have been identified, including familial adenomatous polyposis, hereditary breast and ovarian cancer syndrome (due to BRCA1/2 mutations), hereditary non-polyposis colorectal cancer, and Li Fraumeni syndrome [3]. Anxiety and depression are common psychological issues among cancer patients and their relatives, with a prevalence of around 50%. These symptoms have a negative impact on the lives of both patients and their families[4]. Relatives often experience severe emotional distress, significant fatigue, sleep disturbances, and difficulty maintaining focus and energy throughout the cancer treatment process. Many of these symptoms are indicative of depression [5]. In 2012, there were 14.1 million new cancer cases reported worldwide, excluding non-melanoma skin cancers. Of these cases, 57% (8 million) occurred in economically developing countries. India alone reported over 1 million new cancer cases annually. Additionally, an estimated 600,000-700,000 cancer-related deaths were recorded in the same year[6]. As of 2018, there were approximately 18 million cancer cases globally, with lung and breast cancer being the most common types, including hereditary forms[7]. Despite this, clinical genetic services and the psychological impact of suspected familial cancer on patients and relatives are still emerging fields with limited development[8]. The level of understanding regarding genetic risk-related information remains uncertain due to the complexities involved in communication. Consequently, it is also unclear whether genetic counseling can effectively address psychological issues such as anxiety, depression, and distress[9]. In order to bridge this gap, we have established a center at the All India Institute of Medical Sciences (AIIMS), the country's leading medical institute. This center collaborates with Oncology OPDs to receive referrals from patients. The purpose of this paper is to examine the impact of a familial cancer diagnosis or suspicion on the psychological well-being of patients and their family members.

METHODS

Sample and setting: The study sample consisted of patients with hereditary type of cancers and their first degree relatives. The study participants were primarily enrolled either referred to the newly established GTC center at AIIMS, by the treating physician. Some participants were enrolled after they visited the center after finding about it from the pamphlets placed within AIIMS. To be eligible to participate, the participants had to be at least 18 years of age and provide informed consent to enroll in the study. Those with previous history of mental health disorders were excluded from this study. The intended sample size for this pilot project was 100 patients and relatives each. This was based on the estimates produced by previous research efforts. This

effort was able to enroll 100 patients and 52 first degree relatives in the final study sample.

Variables: At baseline, demographic, and cancer and its treatment-related information (name, age, gender, religion, marital status, education, occupation, residential address, cancer type, and cancer-treatment related information) was obtained. The psychological issues of interest i.e. anxiety, depression, and distress were respectively assessed using three pre-validated questionnaires i.e. Generalized Anxiety Disorder (GAD)-7[10], Patient Health Questionnaire (PHQ)-9[11], and Distress Thermometer (DT) [12], each of which obtained information on a Likert scale. Post-counselling, the psychological issues were re-assessed after one month using the same tools. Anxiety and depression were eventually coded as 'no' if the levels reported were less than five and 'yes' if these were equal to or greater than five. Distress was coded as 'no' if it lied between zero and three and 'yes' if it was equal to four or greater. This was done because of the low cell counts.

Analysis: Descriptive statistics (frequencies and percentages) for the study exposures within each of the outcomes of interest are provided. The crude and multivariable analysis compared the outcomes of interest in the post-counselling phase as compared to pre-counselling. The multivariable models were adjusted for cancer type and age. Generalized estimating equations accounting for within-person clustering and with independent working correlation matrix were used. Note that for the regression models, the analyses were only limited to the two hereditary cancers i.e. breast and ovary. All analyses were conducted in SAS statistical software[13].

Table 1: Frequencies and proportions of patients across demographic and cancer-related characteristics by the psychological outcomes of interest (n=100)

RESULTS

Table 1 shows the respective proportion of participants with the psychological issues of interest before and after counselling for each of the study characteristics. In general, as compared to the respective proportion before, after counselling the proportion of adults with the psychological issues i.e. anxiety, depression, and distress were lower. However, the proportions varied by the characteristic under consideration as shown in Table 1.

Table 2 shows that among the 52 first degree relatives, again, in general we observed a reduction in the proportion of respondents who had the psychological issues after counselling as compared to the proportion who had the former before counselling. For example,among those with anxiety before counselling, 43%, while post counselling, the proportion of females with anxiety was 36%. On the other hand, among those with anxiety in the pre and post-counselling phase respectively, 57% and 64% were males. The proportions also varied by cancer type with those with accompanying a patient with breast cancer having lower proportion of psychological issues after counselling and those with ovarian cancer having higher proportions.

Chi-squared tests revealed that overall, there was a significant difference in the outcomes between and pre- and post-genetic counselling proportions ($P<0.05$) among patients. Among relatives, there was significant difference among the former for depression and distress, but not anxiety ($p=0.06$).

Characteristics	Pre-test anxiety		Post-test anxiety		Pre-test depression		Post-test depression		Pre-test DT		Post-test DT	
	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Gender												
Female	24 (92.3)	72 (97.3)	30 (88.2)	59 (100.0)	23 (95.8)	73 (96.1)	32 (88.9)	57 (100.0)	18 (90.0)	78 (97.5)	36 (92.3)	53 (98.2)
Male	2 (7.7)	2 (2.7)	4 (11.8)	0 (0.0)	1 (4.2)	3 (4.0)	4 (11.1)	0 (0.0)	2 (10.0)	2 (2.5)	3 (7.7)	1 (1.9)
Religion												
Hindu	20 (76.9)	64 (86.5)	28 (82.4)	50 (84.8)	19 (79.2)	65 (85.5)	29 (80.6)	49 (86.0)	16 (80.0)	68 (85.0)	34 (87.2)	44 (81.4)
Others	6 (23.1)	9 (12.2)	6 (17.6)	8 (13.6)	5 (20.8)	10 (13.2)	7 (19.4)	7 (12.3)	4 (20.0)	11 (13.8)	5 (12.8)	9 (16.7)
Marital status												
Married	21 (80.8)	65 (89.0)	21 (80.8)	65 (87.8)	20 (83.3)	66 (86.8)	30 (83.3)	50 (87.7)	17 (85.0)	69 (86.3)	34 (87.2)	46 (85.2)
Unmarried/divorced/widower	5 (19.2)	8 (10.8)	5 (14.7)	8 (13.6)	4 (16.7)	9 (11.8)	6 (16.7)	6 (10.5)	3 (15.0)	10 (12.5)	5 (12.8)	7 (13.0)
Education												
High school or less	11 (42.3)	46 (62.2)	15 (44.1)	35 (59.3)	11 (45.8)	46 (60.5)	16 (44.4)	34 (59.6)	9 (45.0)	48 (60.0)	20 (51.3)	30 (55.6)
Graduate	7 (26.9)	14 (18.9)	11 (32.4)	10 (17.0)	6 (25.0)	15 (19.7)	11 (30.6)	10 (17.5)	5 (25.0)	16 (20.0)	8 (20.5)	13 (24.1)
Post-graduate	8 (30.8)	14 (18.9)	8 (23.5)	14 (23.7)	7 (29.2)	15 (19.7)	9 (25.0)	13 (22.8)	6 (30.0)	16 (20.0)	11 (28.2)	11 (20.4)
Occupation												
Professional/ Business	4 (15.4)	5 (6.7)	4 (11.8)	5 (8.5)	3 (12.5)	6 (7.9)	4 (11.1)	5 (8.8)	3 (15.0)	6 (7.5)	4 (10.3)	5 (9.3)

Unskilled/field worker	5 (19.2)	9 (12.2)	6 (17.7)	8 (13.6)	4 (16.7)	10 (13.2)	6 (16.7)	8 (14.0)	5 (25.0)	9 (11.3)	4 (10.3)	10 (18.5)
Housewife	16 (61.5)	58 (78.4)	22 (64.7)	45 (76.3)	16 (16.7)	58 (76.3)	24 (66.7)	43 (75.4)	12 (60.0)	62 (77.5)	29 (74.3)	38 (70.4)
Retired/unemployed/student	1 (3.9)	2 (2.7)	2 (5.9)	1 (1.7)	1 (4.2)	2 (2.6)	2 (5.6)	1 (1.8)	0 (0.0)	3 (3.8)	2 (4.8)	1 (2.0)
Residential location												
Rural	7 (26.9)	30 (40.5)	5 (14.7)	9 (26.5)	8 (33.3)	29 (38.2)	12 (33.3)	21 (38.2)	5 (25.0)	32 (40.0)	14 (35.9)	19 (35.2)
Urban	19 (73.1)	42 (56.8)	25 (73.5)	25 (73.5)	16 (66.7)	45 (59.2)	24 (66.7)	34 (61.8)	15 (75.0)	46 (57.5)	24 (61.5)	34 (63.0)
Cancer specific characteristics												
Cancer type												
Breast	12 (46.2)	48 (64.9)	14 (41.2)	41 (64.5)	11 (45.8)	49 (64.5)	14 (38.9)	41 (71.9)	8 (40.0)	52 (65.0)	19 (48.7)	36 (66.7)
Ovary	10 (38.5)	16 (21.6)	7 (20.6)	17 (1.7)	7 (29.2)	19 (25.0)	9 (25.0)	15 (26.3)	6 (30.0)	20 (25.0)	8 (20.5)	16 (29.6)
Others	4 (15.4)	10 (13.5)	13 (38.2)	17 (28.8)	6 (25.0)	8 (10.5)	13 (36.1)	1 (1.8)	6 (30.0)	8 (10.0)	12 (30.8)	2 (3.7)
Illness duration												
Upto 1 year	8 (30.8)	18 (24.3)	9 (26.5)	15 (25.5)	11 (45.8)	15 (19.7)	11 (30.6)	13 (22.8)	6 (30.0)	20 (25.0)	11 (28.2)	13 (24.1)
More than 1 year	18 (69.2)	56 (75.7)	25 (73.5)	44 (74.6)	13 (54.2)	61 (80.3)	25 (69.4)	44 (77.2)	14 (70.0)	60 (75.0)	28 (71.8)	41 (75.9)
Treatment duration												
Upto 1 year	8 (30.8)	18 (24.3)	9 (26.5)	15 (25.4)	11 (45.8)	15 (19.7)	11 (30.6)	13 (22.8)	6 (30.0)	20 (25.0)	11 (28.2)	13 (24.1)
More than 1 year	18 (69.2)	56 (75.7)	25 (73.5)	44 (75.6)	13 (54.2)	61 (80.3)	25 (69.4)	44 (77.2)	14 (70.0)	60 (75.0)	28 (71.8)	41 (75.9)
Clinical approach												
0	1 (3.9)	4	5 (14.7)	0	2	3	5	0	2 (10.0)	3	5 (12.8)	0

		(5.4)		(0.0)	(8.3)	(4.0)	(13.9)	(0.0)		(3.8)		(0.0)
1	25 (96.2)	67 (90.5)	29 (85.3)	56 (94.9)	22 (91.7)	70 (92.1)	31 (86.1)	54 (94.7)	18 (90.0)	74 (92.5)	33 (84.6)	52 (96.3)
Total	26	74	34	59	24	76	36	57	20	80	39	54
Missing values are not shown												

Table 2: Frequencies and proportions of first degree relatives across demographic and cancer-related characteristics by the psychological outcomes of interest (n=52)

	Psychological outcomes of interest n(column %)											
	Pre-test anxiety		**Post-test anxiety**		**Pre-test depression**		**Post-test depression**		**Pre-test DT**		**Post-test DT**	
Characteristics	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Gender												
Female	4 (26.7)	16 (43.2)	10 (41.7)	10 (35.7)	6 (31.6)	14 (42.2)	9 (36.0)	11 (40.7)	7 (25.0)	13 (54.2)	15 (37.5)	5 (41.7)
Male	11 (73.3)	21 (56.8)	14 (58.3)	18 (64.3)	13 (68.4)	19 (57.6)	16 (64.0)	16 (59.3)	21 (75.0)	11 (45.8)	25 (62.5)	7 (58.3)
Religion												
Hindu	11 (73.3)	29 (78.4)	18 (75.0)	22 (78.6)	14 (73.4)	26 (78.8)	20 (80.0)	20 (74.1)	21 (75.0)	19 (79.2)	31 (77.5)	9 (75.0)
Others	4 (26.7)	8 (21.6)	6 (25.0)	6 (21.4)	5 (26.3)	7 (21.2)	5 (20.0)	7 (25.9)	7 (25.0)	5 (20.8)	9 (22.5)	3 (25.0)
Marital status												
Married	7 (46.7)	19 (51.4)	16 (66.7)	10 (35.7)	8 (42.1)	18 (54.6)	11 (44.0)	15 (55.6)	13 (46.4)	13 (54.2)	20 (50.0)	6 (50.0)
Unmarried/divorced	8 (53.3)	18 (48.7)	8 (33.3)	18 (64.3)	11 (57.9)	15 (45.5)	14 (56.0)	12 (44.4)	15 (53.6)	11 (45.8)	20 (50.0)	6 (50.0)

Education												
High school or lower	2 (13.3)	7 (18.9)	4 (16.7)	5 (17.9)	4 (21.1)	5 (15.2)	3 (12.0)	6 (22.2)	2 (7.1)	7 (29.2)	4 (10.0)	5 (41.7)
Graduate	8 (53.3)	22 (59.5)	14 (58.3)	16 (57.1)	9 (47.4)	21 (63.6)	17 (68.0)	13 (48.2)	17 (60.7)	13 (54.2)	25 (62.5)	5 (41.7)
Post-graduate	5 (33.3)	8 (21.6)	6 (25.0)	7 (21.2)	5 (20.0)	8 (29.6)	9 (32.1)	4 (16.7)	11 (27.5)	2 (16.7)	11 (27.5)	2 (16.7)
Occupation												
Professional/ Business	2 (13.3)	9 (24.3)	5 (20.8)	6 (21.4)	3 (15.8)	8 (24.2)	4 (16.0)	7 (25.9)	6 (21.4)	5 (20.8)	10 (25.0)	1 (8.3)
Unskilled/field worker	6 (40.0)	9 (24.3)	6 (25.0)	9 (32.1)	6 (31.6)	9 (27.3)	9 (36.0)	6 (22.2)	10 (35.7)	5 (20.8)	10 (25.0)	5 (41.7)
Housewife	1 (6.7)	7 (18.9)	4 (16.7)	4 (14.3)	3 (15.8)	5 (15.2)	3 (12.0)	5 (18.5)	2 (7.1)	2 (25.0)	5 (12.5)	3 (25.0)
Retired/unemployed/student	6 (40.0)	12 (32.4)	9 (37.5)	9 (32.1)	7 (36.8)	11 (33.3)	9 (36.0)	9 (33.3)	10 (35.7)	8 (3.3)	15 (37.5)	3 (25.0)
Residential location												
Rural	4 (26.7)	14 (37.8)	5 (20.8)	13 (46.4)	6 (31.6)	12 (36.4)	7 (28.0)	11 (40.7)	6 (21.4)	12 (50.0)	12 (30.0)	6 (50.0)
Urban	11 (73.3)	23 (62.3)	19 (79.2)	15 (53.6)	13 (68.4)	21 (63.6)	18 (72.0)	16 (59.3)	22 (78.6)	12 (50.0)	28 (70.0)	6 (50.0)
Cancer specific characteristics												
Cancer type												
Breast	7 (46.7)	14 (37.8)	14 (58.3)	7 (25.0)	11 (57.9)	10 (30.3)	13 (52.0)	8 (29.6)	14 (50.0)	7 (29.2)	17 (42.5)	4 (33.3)
Ovary	5 (33.3)	3 (8.1)	2 (8.3)	6 (21.4)	4 (21.1)	4 (12.1)	2 (8.0)	6 (22.2)	5 (17.9)	3 (12.5)	5 (12.5)	3 (25.0)
Others	3 (20.0)	20 (54.1)	8 (33.3)	15 (53.6)	4 (21.1)	19 (57.6)	10 (40.0)	13 (48.2)	9 (32.1)	14 (58.3)	18 (45.0)	5 (41.7)
Total	15	37	24	28	19	33	25	27	28	24	40	12
Missing values are not shown												

Table 3: Association between pre genetic counselling and post counselling scores, controlling for cancer type and age

Exposures	Anxiety		Depression		Distress	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Patients						
Crude	0.95	0.62, 1.46	0.64	0.39, 1.07	0.37	0.21, 0.68
*Adjusted	0.95	0.62, 1.46	0.64	0.38, 1.07	0.37	0.20, 0.68
Relatives						
Crude	1.42	0.68, 3.00	1.00	0.47, 2.15	0.60	0.29, 1.24
*Adjusted	1.05	0.44, 2.50	1.00	0.45, 2.22	0.60	0.29, 1.24
Non-hereditary cancers were excluded from these analyses *Adjusted for cancer type and age						

Table 3 shows that among patients, as compared to pre-genetic counselling, post-genetic counselling, the odds of having anxiety, depression, and distress were lower. For example, there was a 5% lower odds of anxiety post counselling (95% CI: 0.62, 1.46). However, the estimates were only significant for distress where after counselling as opposed to before, there were 63% lower odds (CI: 0.20, 0.68) of the former. Next, among the first degree relatives, as compared to pre-counselling, post-counselling estimates for anxiety show that although insignificant, relatives had slightly greater odds of experiencing the former (OR: 1.05; CI: 0.44, 2.50). For the same, the odds of experiencing distress were lower (OR: 0.60; CI: 0.29, 1.24)

DISCUSSION

Genetic counseling is a relatively recent development in India, with the first graduate level training program being introduced in 2003. However, there are variations and limitations among the institutions that offer these services[14]. As a result, genetic counseling services in India remain fragmented. This pilot research project aimed to establish the first genetic counseling center at the country's leading medical institute. The study also focused on addressing psychological symptoms in patients with familial cancer and their immediate family members. Overall, our findings indicated that counseling was effective in significantly reducing distress among patients. Although a reduction in distress was also observed among relatives, it was not statistically significant.

A previous study[15] conducted in North India among breast cancer patients found that 37% of them experienced anxiety, while 28% experienced depression. In contrast, 55% of women with ovarian cancer reported mild or greater depressive symptoms[16]. When considering only those with breast or ovarian cancer, over 70% of those who had anxiety or depression at the beginning of the study had breast cancer, and over 20% had ovarian cancer.

A previous meta-analysis of controlled trials revealed that, in general, genetic counseling had no significant impact on hereditary cancer-related anxiety (long-term pooled difference = 0.05 U; -0.21, 0.31) and worry (-0.14; -0.35, 0.06)[9]. Another study also reported similar results, finding that among women affected by breast cancer, those who received genetic counseling had comparable levels of psychological distress to those who did not receive counseling[17].

Another randomized controlled trial[18] investigating the impact of breast cancer risk counselling on distress among those with familial history reported that controlling for education level, those who received counselling had significantly lower distress than those who did not. Anxiety and distress was assessed among 412 women at risk of and those that had a previous history of familial cancer in a previous research effort[19]. While no significant change in anxiety levels were observed, worry about breast cancer reduced after a short term follow up and also at 6 months follow up. Also, no changes in worry about ovarian cancer were observed in general.

Our results showed that among patients, GTC had a significant protective effect against the psychological issues; however, this was just only significant for distress. Among relatives also post-counselling, although insignificant, there was a 40% reduction in the odds for distress. There was no association between counselling and anxiety or depression in our study, both among patients and their relatives.

Limitations: This was a pilot study and therefore had a small sample size. Another limitation was that the

survey was self-administered which could have resulted in potential information bias.Collapsing the psychological outcomes categories into no and yes could have resulted in information loss as well. This study also lacked a control group and only did one group analysis.

CONCLUSIONS

This initial research endeavor aimed to address the lack of knowledge in GTC-related research in India. Our findings offer initial evidence supporting the potential protective effect of GTC in alleviating psychological distress among cancer patients and their immediate family members. Although we did observe a protective effect of GTC in reducing depression among patients, it was not statistically significant. Therefore, we recommend conducting a larger longitudinal study to further investigate this association. Additionally, future studies should examine the impact of treatment and gender-specific genetic counselling[20].

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