

Nav-GISM Model Navigation for Adult GI Cancer Patients: A Game Changer in Patient Satisfaction to Logistics and Treatment Adherence - A Randomized Trial

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Abstract: Background: Patient navigation had improved the diagnostic follow up, early treatment and increased patient satisfaction among cancer patients. However, inadequacy of evidences on how a nurse led navigation clinic would change cancer patients' satisfaction to navigator, logistics and medication adherence. Objective: To assess the effect of nurse led navigation clinic on satisfaction to navigator; logistics and medication adherence of GI cancer patients. Materials and methods: In this randomised controlled trial, 90 GI cancer patients were randomly allocated into control (usual care) group and intervention (usual care plus nurse led navigation -NLN) group. Nav-GISM model navigation provided information about facilities and procedures available in centre (logistics of care); importance of the medication adherence, home care, management of chemotherapy side. The outcome measures were assessed using the patient satisfaction to navigator scale, Adherence to Medication and Refill Scale. Results: The patient satisfaction to logistics (median 54) as well as to navigator (median 46) was significantly high in intervention group compared to control group ($p < 0.001$) after the nurse led navigation. Medication adherence (100%) had increased from 50% to 73.33% in intervention group ($p=0.017$) during follow up. No change in anxiety identified. Conclusion: Adding nurse led navigation to usual care can significantly increase patient satisfaction to logistics of care and medication adherence. Implication nursing oncology practice: The NLN will significantly reduce the treatment drop outs among the cancer patients by facilitating easy access to various services, care coordination, reinforcing follow-up and supportive care throughout cancer trajectory.

Keywords: nurse led navigation, patient satisfaction, logistics, medication adherence, GI cancer

1. Background

An exponential rise in cancer incidence has been reported globally since past 5-10 years. According to Global Cancer Statistics, cancers of colorectum (9.6%) and stomach (4.9%) are the third and the fifth most common cancers (incidence) ⁽¹⁾. Indian statistics has projected an estimated incidence of 14,61,427 cancer cases in 2022. ⁽²⁾ Unfortunately, the lack of care coordination contributes to treatment delay, drop out, morbidity and mortality. Often cancer patients couldn't fit into the complex cancer care in hospital setting due to a lack of relevant information or complex instructions provided; and inadequate attention to their emotional and social problems. ⁽³⁾ Further, the long wait time leads to poor treatment or medication adherence. ⁽⁴⁾ It was recommended that linking patients with a care navigator to better care coordination and logistic support to reduce treatment dropouts. ⁽³⁾

The concept of nurse led patient navigation is naive and promising. An oncology nurse navigator (ONN) is a professional RN with oncology specific knowledge who provides information and resources to facilitate informed decision making and timely access to quality health and psychosocial care throughout all phases of cancer continuum (The Oncology Nursing Society [ONS] (2017)). ⁽⁵⁾ The navigation includes guiding through screening, post-screening and assisting patients to undergo various investigations and

adherence to oral chemotherapy at home. ⁽⁶⁾ In the Canadian Breast Cancer Initiative, navigators proactively directed patients through treatment by scheduling appointments, facilitate treatment by providing information, support, and encouragement. ⁽⁷⁾ The number of days from first visit to any kind of intervention has significantly reduced (- 15 days, $p = 0.009$) after the addition of oncology navigation nurse into the team (Russell M. Howerton Laura M Enomoto, Joyce Fenestemaker, et. al 2017) ⁽⁴⁾ Also, there was a significant reduction in anxiety, depression and significant improvement of satisfaction with the cancer related care with the added services of ONN, among newly diagnosed cancer patients. (Evan K Cobraet al. 2017) ⁽⁸⁾

C Allary, A Bourmaud, F Tinquaut, M Oriol, J Kalecinski, V Dutertre et. al (2016) ⁽⁹⁾ developed a protocol for randomized controlled trial- ColoNav: patient navigation for colorectal cancer screening in deprived areas based on the conceptual model of PN intervention developed by Fiscella (2014). When patient education, care facilitation and education by the GI Nurse Navigator on 3 weekly follow up was included, 89% of patients were contacted within 2 days (mean 1.7, range 0-20), 57% of patients completed the staging within 5 days (mean 6.2 days, range 0-40) (Mary May, Coralyn Woldhuis, Wendy K Taylor, Laurence E Mchill (2014)). ⁽¹⁰⁾

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Thomas S, Glynne-Jones R. Chait I (1997)⁽¹¹⁾ found that 72% of patients were completely satisfied with the access to the clinic, reassurance, continuity of care and information. The adjuvant treatment adherence rates were more than 75% and 62% among the cancer patients completed radiation treatment and received written resource information plus usual care (enhanced usual care [EUC]) and written information plus patient navigation (TPN) over 12 months (Kathleen Ell, Betsy Vourlekis, Bin Xie, et. al (2009)⁽¹²⁾.

Approximately 59% adherence rate was observed in hormonal therapy adherence in both groups. In a prospective parallel group randomised controlled trial Susan Krikorian, Susan Pories, Gary Tataronis, et.al (2019)⁽¹³⁾ 90-100% medication adherence was found in both the pharmacist education intervention versus a nurse led intervention (control group) on medication adherence to oral anticancer agents.

After being diagnosed with cancer, patients had to undergo various investigations to complete the workup and to begin with a definitive treatment option like chemotherapy radiation therapy or surgery. But often they could not complete half of the tests due to lack of knowledge and guidance.⁽¹⁴⁾ Moreover, adherence to the prescribed treatment- oral chemotherapeutic drugs or post-chemotherapy supportive drugs was also less. This often led to poor response to treatment or occasionally severe side effects. Hence this study aims to study patient satisfaction to navigation in terms of treatment effectiveness and interpersonal communication as well as the extent to which nurse navigators address patients' needs from the patients' perspectives.⁽¹⁵⁾

2. Aim of the Study

To assess the effectiveness of nurse led navigation (NLN) on patient satisfaction to logistics of care and to the interpersonal factors of navigator, treatment adherence among adult oncology patients attending out-patient unit in a tertiary care centre. As a secondary outcome effect on anxiety also assessed.

3. Materials and Methods

The Navigation of Gastro Intestinal System Malignancy (Nav GISM model) nurse led navigation was conducted in a single tertiary care centre. Institute ethical committee permission obtained for the study- AIIMS.IECPG/240/3/2022. CTRI No-CTRI/2022/09/045171. The intervention was tailored based on the navigation conceptual model developed by Fiscella (2014)(16,16). Nav GISM model facilitated the logistical services to patients to complete various investigations and reinforce compliance with the treatment prescribed to them through giving information and education about the appointment system for chemotherapy and tests, getting tests done, report collection. Also, a comprehensive education of drug effects, care during chemotherapy, transportation assistance (railway ticket concession) and referring to available social support system (in Hindi or English) was included. This might increase adherence to medication as well. Secondly, the acclimatisation to treatment trajectory, the anxiety would reduce in the due course.

Study participants:

Adult GI cancer patients visiting OPD, whose first chemotherapy cycle was yet to be started and prescribed any of the three-weekly regimen (CapOX, CapIRI or Pacli Carbo) were invited for the study. Total 90 patients were randomly allocated into control and intervention group based on computer generated random numbers in 1:1 ratio. The sample size was calculated using the G power 3.4.0 with 80 % power and 0.05 level of significance, considering an expected attrition rate of 10% and expected improvement of 20% in outcome variables (satisfaction and treatment adherence) as per pilot study results.

Study Design

In this pre-test and post-test randomized control group design, the intervention arm received both usual care and NLN while the control arm received only usual care, at first contact and at 3 weeks follow up. The pre-test was taken at base line and after 3 weeks of intervention.

The patients in intervention group were directed by word of mouth, through health workers or by self to the NLN room twice weekly. The researcher (ONN) screened (medical records and OPD cards of patients) in GI cancer clinic. After obtaining the informed consent, the ONN collected the baseline sociodemographic and clinical data, and pre- test done using PSN-L(Patient satisfaction to navigation-Logistics), PSN-I(Patient satisfaction to navigation-investigator)⁽¹⁷⁾, ARMS(Adherence to Refills and Medication Scale)⁽¹⁸⁾ and HAM-A (Hamilton Anxiety Scale) questionnaires. The Oncology Nurse Navigator (ONN) had given the intervention to the NLN group, which took 20 -30 minutes per patient. Thereafter the patients were verbally guided to the respective treatment areas for completion of usual care. After the intervention the patients were asked questions to ensure their understanding and re-emphasised medication adherence and follow up with recommended tests results (as per individual patient's prescription card). A second meeting was fixed verbally on the given follow up date in OPD. Phone number was collected to confirm patient's visit on the scheduled date. Whereas the control group was direct to the usual care areas without NLN.

Intervention

ONN explained in detail about the disease, stage, prescribed treatment and its duration; side effects of chemotherapy, home care management of side effects and need of follow up. They were guided to the different investigation rooms and emphasised that completing the investigations on time is detrimental for disease control and prevention of complications. The oral anticancer drug and other supportive treatment was explained to increase medication adherence using the prescription card. The information on social and financial support system available was given along with red-flags during treatment and emergency contact number.

NLN was supported by various flash cards to give a detailed explanation of the disease, location of tumor and its extent. A booklet for home care management was provided to both groups to reinforce the treatment adherence after post-test.

Usual care

Usual care was the routine services (prescriptions of investigations and chemotherapy, Performance status assessment, monitoring side effects of chemotherapy) given by the medical oncologist.

Pilot study

A feasibility study was conducted among 20 (10 in control arm and 10 in intervention arm) GI cancer patients attending day care.

The enrollment, allocation, intervention, usual care and follow up of patients into the study has reported through the CONSORT flow diagram (figure 2).

Statistical Analysis

All recorded data were coded and entered into Microsoft excel sheet latest version. Data were analysed using IBM SPSS version 26. Intention to treat analysis was done using last observation carry forward technique.⁽¹⁹⁾ Descriptive statistics- frequency, mean, median and inter quartile range were used to summarize the patient characteristics and clinical information. Continuous variables were assessed for normality with Kolmogorov Smirnov and Shapiro wilks test. The data were found non normally distributed since the p value was above 0.05 in the above tests. Inferential statistical tests applied include Fishers exact test, Mann Whitney U test, Wilcoxon signed rank sum test, Pearson chi-square test and Stuart Maxwell test. For all the tests, $p < 0.05$ was considered as significant.

4. Results

Both the groups were homogeneous and comparable on various demographic variables like age, gender, elementary education, monthly income, employment status, family type and administration of medication at baseline, $p < 0.05$ (Table-1). No significant intergroup difference observed on clinical variables at baseline (F test). Most patients were prescribed for CAPOX regimen (chemotherapy) as a neoadjuvant ($n=22$) modality. Most of the patients ($n=38$) did not have any comorbidity. Nearly half of the patients ($n=20$) were accompanied by their spouses. More than 90% of patients fell below poverty line (BPL) and did not have any health insurance (Table-2).

The patient satisfaction to logistics was homogeneous in intervention and control group at baseline. After 3 weeks, the NLN group showed significant improvement in patient satisfaction to logistics ($p < 0.001$). Also, the patient satisfaction to navigator was significantly high among patients underwent NLN comparing to the usual care group ($p < 0.001$).

After the NLN 100% medication adherence had increased from 48% to 73% ($p=0.017$) and wherein the rise was 45% to 49% among the usual care group ($p=0.82$, statistically non-significant).

After the intervention 4.44% and 11.11% patient's anxiety in control group and intervention group respectively had reduced to zero (statistically non-significant).

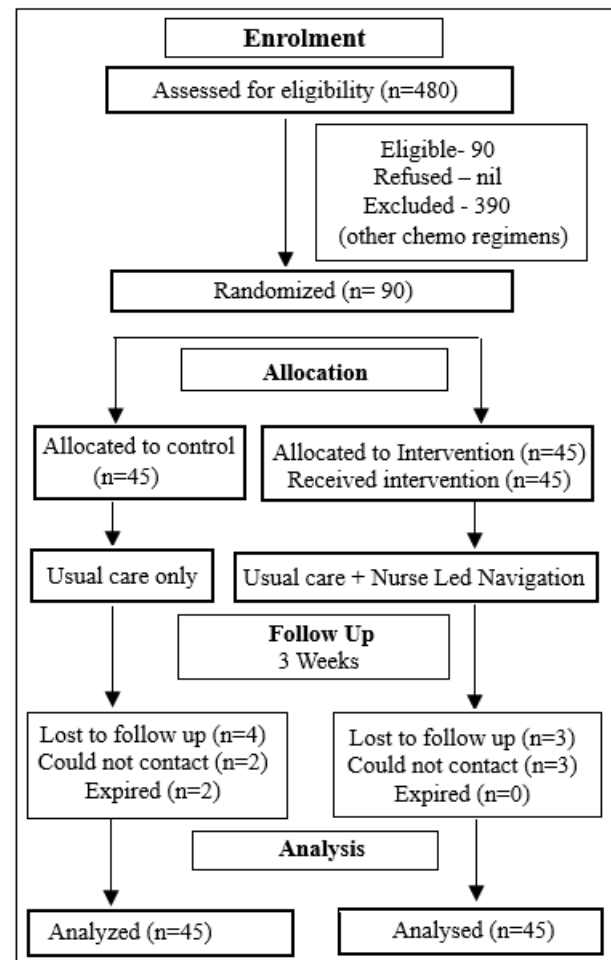


Figure 1: Consort diagram

5. Discussion

This study results contributes to the literature on nurse led navigation which is a promising intervention to facilitate optimal care in an existing oncology unit. The patient navigation had early diagnosis, reduced anxiety and increased satisfaction with care (Ferrante M Jeanne, 2008)(20). In another study done by Berglund et al (2015)²² identified that >90% of patients visited the oncology nurse led out -patient clinic rated nurses' interpersonal manners and the care at the clinic as "good", which is consistent with this study.

The medication adherence rate was 87% to 94% among navigated group Kathleen Ell et al (2009)⁽¹²⁾, but the high adjuvant treatment adherence was attributed to the treatment funding and surveillance along with the navigation intervention, which was lacking in current study. Similar to the findings of Gamze Tokdemir and Sultan Kav (2017)(22), the Nav GISM model incorporated individualised education and follow up had increased the medication adherence and self-efficacy among cancer patients.

Anxiety might have been affected by different confounding variables like side effects of chemotherapy, financial constraints, poor performance status, fatigue. Moreover 3 weeks was a quiet shorter duration to assess effects on anxiety as it takes longer time to bring any significant change in the anxiety level of patients. Even after finishing the study period, patients often called for logistical assistance which indicates

that navigation is crucial for maintaining the continuity of cancer care.

6. Strengths and Limitations

A scientifically sound tool was used to develop the intervention. Also, the control group received intervention at the end of the trial. However, binding was not possible due to lack of additional human resources.

7. Implications and Recommendations

The NLN can be incorporated in nursing curriculum to enhance the knowledge and skill of student nurses. NLN in oncology OPDs will improve the treatment adherence and hence will reduce the health care burden. Nursing administrators can utilise the skill set of specialised oncology nurses in cancer care coordination in NLN clinics. Conducting further multicentric studies will enhance the generalisability of the study results.

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Table 1: Socio demographic characteristics of GI cancer patients in control group and intervention group (n=90)

Variable		Frequency (%) control (n ₁ =45)	Frequency (%) intervention (n ₂ =45)	p value
Age Median (IQR)		49(15)	56(16)	
Sex	Male	21(46.67)	26(57.78)	0.399
	Female	24(53.33)	19(42.22)	
Marital status	Married	42(93.33)	42(93.33)	0.999
	Unmarried	3(6.67)	3(6.67)	
Education status	Elementary	17(37.77)	20(44.45)	0.882
	Secondary	7(15.55)	5(11.11)	
	Higher secondary	15(33.33)	15(33.33)	
	Graduation and above	6(13.33)	5(11.11)	
Monthly income				0.09
Less than 10000		29(64.44)	25(55.56)	
10000 to 20000		11(24.44)	13(28.89)	
20000 to 40000		1(2.22)	6(13.33)	
40000 and above		4(8.89)	1(2.22)	
Occupation	Employed	5(11.11)	7(15.56)	0.329
	Unemployed	40(88.89)	36(80)	
	Student	0(0.00)	2(4.44)	
Type of family	Nuclear	40(88.89)	42(93.33)	0.754
	Extended	5(11.11)	3(6.67)	
Medication administered by				0.669
Self		28(62.22)	25(55.56)	
Family member		7(37.78)	19(42.22)	
Others		0(0)	1(2.22)	

Fisher's exact test, (p<0.05)

Table 2: Clinical variables of patients in control group and intervention group (n=90)

Variable		Frequency (%) control, n ₁ =45	Frequency (%) intervention, n ₂ =45	p value*
Diagnosis	Ca Gall bladder	3(6.67)	4(8.89)	0.784
	Ca Pancreas	0	1(2.22)	
	Periampullary	1(2.22)	4(8.89)	
	Ca Esophagus	12(26.67)	9(20.00)	
	Ca Stomach	15(33.33)	12(26.67)	
	Ca Rectum	5(11.11)	7(15.56)	
	Pseudomyxoma	6(13.33)	7(15.56)	
Stage	LAMN	2(4.44)	1(2.22)	0.999
	Stage 1	0	0	
	Stage 2	7(15.56)	7(15.56)	
	Stage 3	23(51.11)	24(53.33)	
Duration of illness Min max		1 -12 months	1- 12 months	
Medication prescribed	Capox	28(62.22)	32(71.11)	0.464
	Gemox	4(8.89)	5(11.11)	
	Pacli Carbo	13(28.89)	8(17.78)	
	Cap Iri	0	0	
Intent of treatment	Adjuvant	9(20)	14(31.11)	0.432
	Neoadjuvant	22(48.89)	19(42.22)	
	Palliative	14(31.11)	12(26.66)	
ECOG	1	10(22.22)	15(33.33)	0.074
	2	28(62.22)	18(40)	
	3	6(13.33)	12(26.67)	
	4	1(2.22)	0	
Comorbidity	Hypertension	3(6.67)	3(6.67)	0.999
	Diabetes	3(6.67)	3(6.67)	
	Thyroid	1(2.22)	0	
	Nil	38(84.44)	39(86.67)	
Accompanied by	Parent	18(40)	15(33)	0.926
	Spouse	20(44.44)	23(51.11)	
	Children	2(4.44)	3(6.67)	
	Any other person	5(11.11)	4(8.89)	
Financial status	BPL	41(91.11)	38(84.44)	0.999
	APL	4(8.89)	7(16.66)	
Health insurance	No	41(91.11)	38(84.44)	0.999
	Yes	4(8.89)	7(15.56)	

*F test

Table 3: Effect of nurse led navigation on patient Satisfaction with navigator among control and intervention group, (n= 90)

Satisfaction	Control(n=45) Median (Q1, Q3)	Intervention (n=45) Median (Q1, Q3)	p value ^{aa}
Pre test	43(41-43)	42(41-43)	0.324
Post test	43(42-44)	45(44-45)	<0.001*
p value ^a	0.467	<0.001*	

^{aa} Mann -Whitney U test

^a-Wilcoxon signed rank test

*p <0.05 is considered statistically significant; 2- sided test is applied.

Table 4: Effect of nurse led navigation on patient Satisfaction with Logistics among control and intervention group, n=90

Satisfaction	Control(n ₁ =45) Median (Q1, Q3)	Intervention(n ₂ =45) Median (Q1, Q3)	p value ^{aa}
Pre test	45(41-47)	46(44-47.5)	0.136
Post test	46(43-50)	54(50-58.8)	<0.001*
p value ^a	0.004*	<0.001*	

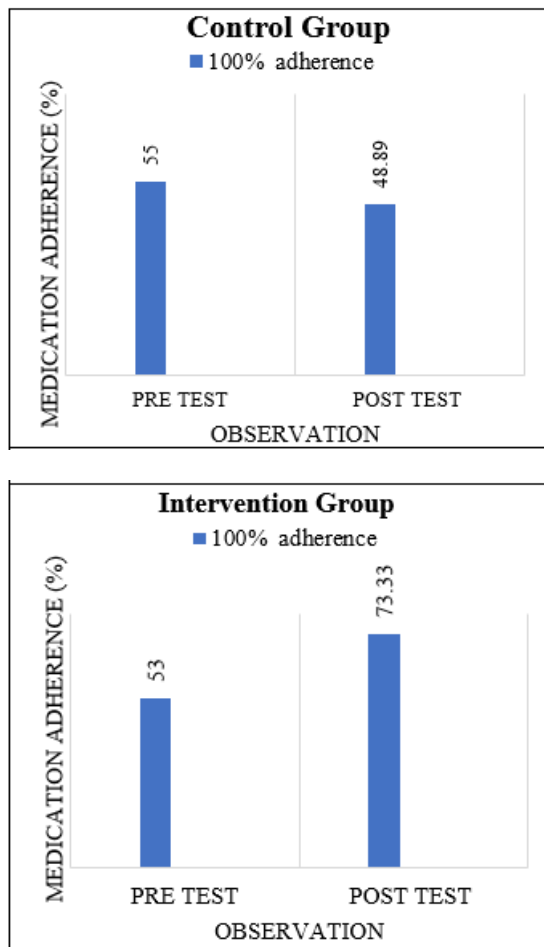
^{aa} Mann -Whitney U test^a-Wilcoxon signed rank test^{*}p <0.05 is considered statistically significant; 2- sided test is applied.

Figure 2: Medication adherence among patients in control group and intervention group at baseline (pre-test) and follow up (post- test)