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## Impact of Patient Counseling on Medication Adherence, Beliefs and Satisfaction about Oral Chemotherapies in Patients with Metastatic Cancer at a Super Specialty Hospital

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### ABSTRACT

The primary aim of this study was to assess the impact of patient counseling by comparing the levels of patient's medication adherence to oral chemotherapies in patients with metastatic cancer. Sixty patients were randomized into usual care and intervention care group. Their medication adherence was assessed by Medication Adherence Rating Scale (MARS). The belief about the medication was measured by Belief about Medication Questionnaire (BMQ). Patient's satisfaction about medication was assessed by Satisfaction with Information about medicine scale (SIMS). All the three scales were assessed at baseline and during their subsequent appointments and at end visit. Sixty patients were included for the final data analysis. No statistical significant difference between the groups with respect to socio-demographic characteristics. No patients were in stage I and II category. According to MARS criteria, adherence rate was improved from 83.4-96.6%. The BMQ-necessity scale and concern scale was related in a negative and positive way to medication adherence, respectively. Significant increase in the SIMS score was observed in both part 1 and 2 and as well as in total score in the intervention care group from baseline to end visit. At the end of the study, intervention group patients had shown a greater improvement in the MARS, BMQ and SIMS score than the usual care group patients. However, by considering the small sample size, future studies are warranted to explore changes in adherence rate with time and clinical impact of non-adherence.

**Key words:** Patient counseling, medication adherence, compliance

### INTRODUCTION

Adherence is defined as, an extent to which a patient's behavior coincides with the medical advice. Adherence of a patient to medication over a long period of time is usually determined by the individual's perception of the risks, benefits and costs of the intervention (D'Amato, 2008). Adherence of a patient to his/her medications is a complex and multifaceted issue that can substantially alter the outcomes of the therapy. Physicians generally assume that the patients are taking drugs as, they prescribed. If in case, a patient is non-adherent to medications, it may lead to misinterpretation of drugs' therapeutic effect and further it guides to unnecessary diagnostic testing, hospitalizations and changes in dose or regimen (Blaschke *et al.*, 2012).

With the development of oral chemotherapy, the delivery of drugs has changed from an inpatient to an outpatient unit. Yet the degree to which patients actually take the medications as prescribed remains unknown. Studies have been reported that medication adherence rate for a chronic disease, such as cancer chemotherapies have been shown to be conspicuously low and more often not more than 40-50% (Gutierrez-Casares *et al.*, 2010; Bhattacharya *et al.*, 2012). Providing adequate information about medications to patients helps them to understand the importance of medications and improves their adherence behavior, which helps in achieving the desired therapeutic goals. It was also found that educated patients have a better social functioning and have better overall quality of life (Husson *et al.*, 2011). The present study was conducted to assess the impact of patient counseling on medication adherence of oral chemotherapy and beliefs, patients' satisfaction about medication in cancer patients.

## **MATERIALS AND METHODS**

**Study protocol and criteria:** A prospective observational study was conducted at the Medical Oncology department in the Sri Ramachandra Hospital, Sri Ramachandra University, Porur, Chennai, Tamil Nadu, India. The study has got Institutional Ethics Committee approval and written informed consent was obtained from all the study patients. Patients of either gender, aged above 18 years and patients taking oral chemotherapies were included in the study. Patients unwilling to participate were excluded.

**Sample size calculation:** Considering  $\alpha$  error at 0.05 and 80% power ( $1-\beta = 0.8$ ) of study with the standard deviation ( $\sigma$ ) of 0.05 using 1:1 ratio of paired sample t test, 60 patients must complete the study.

**Study design:** Patients meeting the study criteria were recruited and randomized into control and test through simple randomization technique i.e., patients with odd serial number were put into control arm and patients with even serial number were put into the test arm. At the time of enrolment, data pertaining to demographics, educational level, socio-economic status, past medical and medication history, alcohol and smoking history, duration of therapy, whether patients belong to curative or palliative condition were collected in a specially designed data collection form.

Structured patient education, including Patient Information Leaflet (PIL) was provided to intervention care group patients at the baseline visit. Usual care group patients received patient education and PIL at the final visit. At baseline, during follow-up and at the end visit, assessment of medication adherence was done by using Medication Adherence Rating Scale (MARS). The MARS is a self-report tool to determine the willingness and ability to take oral medication every day. The patient should be asked to respond to the statements in the questionnaire by circling the answer which best describes their behaviour or attitude towards their medication during the past week (Thompson *et al.*, 2000; Timmers *et al.*, 2014). The belief about the medication was measured by using Belief about Medication Questionnaire (BMQ). The BMQ consists of two ve-item scales assessing patients' beliefs about the necessity of prescribed medication for controlling their disease and their concerns about potential adverse consequences of taking it. Scores obtained for individual items within both scales are summed (Horne *et al.*, 1999; Neame and Hammond, 2005). Patient satisfaction about medication was assessed by using satisfaction with information about medicines scale (SIMS). The SIMS is a tool to assess the extent to which the information needs of individual patients have been met. The instrument contains two subscales: Patients'

satisfaction with information about the action and usage of their medication in items 1-9 and the potential problems of medication in items 10-16 (Horne *et al.*, 2001; Babikako *et al.*, 2011).

**Statistical analysis:** Data were expressed as Mean±SD. The probability value less than 0.05 was considered for statistical significance. Demographic characteristics like age and gender, baseline and final visit data were used to assess response rates by comparing usual care and intervention group. Student's t test was used for the comparisons within the groups. One-way ANOVA Bonferroni multiple comparison test was used for the comparisons between groups using graph pad prism version 4.03, GraphPad Software, Inc. (USA).

## RESULTS AND DISCUSSION

Among the consecutive patients who were screened during the study period, 80 patients were found to be eligible for the study and 13 patients were excluded from the study due to various reasons like cognitive impairment (5 patients), patients with less than 18 years old (4 patients), known to have psychiatric disorders (3 patients), inability to understand spoken words due to hearing impairment (1 patient). Finally, 60 patients completed all the follow-up visits and their data were included in the final analysis (Fig. 1). Baseline characteristics like age, gender, literacy, socio-economic statuses, co-morbidities, type of cancer and stage of cancer are shown in Table 1. The mean age of patients in the study was 42.85 years (±13.92) with almost equal gender distribution (Male 51.66%, Female 48.34%). Most of the patients were lower middle class and no patient was in stage I or II category.

Number of responses for each factor indicating attitude towards medication is shown in Table 2. As far as MARS score is concerned, equal response is observed at baseline in both control and intervention group patients. However, at the end visit, intervention care group patients had

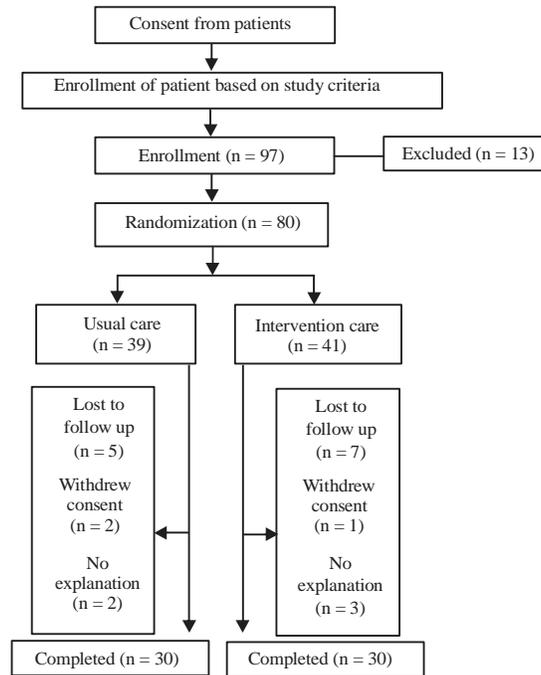


Fig. 1: Flow of patients in the study

Table 1: Socio-demographic characteristics of study patients'

| Characteristics              | Usual care |       | Intervention care |       |
|------------------------------|------------|-------|-------------------|-------|
|                              | No.        | %     | No.               | %     |
| Age (in years)               | 42.37      | 12.87 | 43.33             | 14.96 |
| Male                         | 17         | 56.66 | 14                | 46.66 |
| Female                       | 13         | 43.33 | 16                | 53.33 |
| <b>Literacy</b>              |            |       |                   |       |
| Literate                     | 4          | 13.30 | 5                 | 16.60 |
| Illiterate                   | 26         | 86.70 | 25                | 83.40 |
| <b>Socio-economic status</b> |            |       |                   |       |
| Upper                        | 4          | 13.40 | 5                 | 16.60 |
| Upper middle                 | 11         | 36.60 | 7                 | 23.40 |
| Lower middle                 | 15         | 50.00 | 12                | 40.00 |
| <b>Co-morbidities</b>        |            |       |                   |       |
| Hypertension                 | 4          | 13.40 | 3                 | 10.00 |
| Diabetes mellitus            | 5          | 16.60 | 2                 | 6.60  |
| Chronic kidney disease       | 1          | 3.40  | 0                 | 0.00  |
| None                         | 20         | 66.60 | 25                | 83.40 |
| <b>Type of cancer</b>        |            |       |                   |       |
| Relapsed/recurrent GI cancer | 19         | 63.40 | 6                 | 20.00 |
| Hematological cancer         | 3          | 10.00 | 6                 | 20.00 |
| Gynecological cancer         | 1          | 3.40  | 3                 | 10.00 |
| Breast cancer                | 5          | 16.60 | 14                | 46.60 |
| Head and neck cancer         | 0          | 0.00  | 1                 | 3.40  |
| Penile cancer                | 2          | 6.60  | 0                 |       |
| <b>Stage of cancer</b>       |            |       |                   |       |
| Stage I                      | 0          | 0.00  | 0                 | 0.00  |
| Stage II                     | 0          | 0.00  | 0                 | 0.00  |
| Stage III                    | 1          | 3.40  | 6                 | 20.00 |
| Stage IV                     | 29         | 96.60 | 24                | 80.00 |

Table 2: Summary of patients' responses to medication adherence rating scale

| Questions  | Usual care   |    |               |    | Intervention care |    |               |    |
|--|--------------|----|---------------|----|-------------------|----|---------------|----|
|  | Baseline (n) |    | End visit (n) |    | Baseline (n)      |    | End visit (n) |    |
|  | Yes          | No | Yes           | No | Yes               | No | Yes           | No |
| Do you ever forget to take medication?                   | 2            | 28 | 2             | 28 | 3                 | 27 | 0             | 30 |
| Are you careless at sometimes about taking medication?   | 0            | 30 | 0             | 30 | 0                 | 30 | 0             | 30 |
| When I feel better, I stop taking medication             | 0            | 30 | 0             | 30 | 1                 | 29 | 0             | 30 |
| When I feel worse, I stop taking medication              | 4            | 26 | 3             | 27 | 2                 | 28 | 1             | 29 |
| I take medication only when sick                         | 0            | 30 | 0             | 30 | 0                 | 30 | 0             | 30 |
| It is unnatural for my body and mind to be controlled by | 12           | 18 | 11            | 19 | 5                 | 25 | 4             | 26 |
| Thoughts on medication are clearer                       | 25           | 5  | 25            | 5  | 26                | 4  | 30            | 0  |
| Can prevent getting sick                                 | 29           | 1  | 29            | 1  | 24                | 6  | 30            | 0  |
| I feel weird on medication                               | 22           | 8  | 22            | 8  | 17                | 13 | 17            | 13 |
| I feel tired and sluggish when I take medication         | 17           | 13 | 17            | 13 | 19                | 11 | 19            | 11 |

better response than the usual care group patients as shown in Table 2. Adherence rate is improved from 83.4-96.6% and non-adherence is reduced from 16.6-3.4%. Various reasons mentioned for being non-adherence is that patients stopped taking medicines when they felt improved, stopped taking medicines, when they felt worsened and they forgot to take medicines (Table 3).

Regarding beliefs about medicines, BMQ-necessity scale was related in a negative way to medication adherence, while BMQ-concern scale was related positively (Table 4). There was a significant increase in the SIMS score in the intervention care group from baseline to end visit both in part 1 (information about the action and usage of medication) and in part 2 (information about potential problems of medication), as well as for the total score (Table 5).

Table 3: Pattern of adherence among the study patients

| Pattern of adherence                              | Usual care     |      |           |      | Intervention care     |    |           |      |
|---|----------------|------|-----------|------|-----------------------|----|-----------|------|
|   | Baseline       |      | End visit |      | Baseline              |    | End visit |      |
|   | No.            | %    | No.       | %    | No.                   | %  | No.       | %    |
| Adhered   | 25             | 83.4 | 25        | 83.4 | 24                    | 80 | 29        | 96.6 |
| Non-adhered                                       | 5              | 16.6 | 5         | 16.6 | 6                     | 20 | 1         | 3.4  |
| Reason for non-adhered                            | Usual care (n) |      |           |      | Intervention care (n) |    |           |      |
| Stopped taking medicines, when they felt improved | 0              |      |           |      | 1                     |    |           |      |
| Stopped taking medicines, when they felt worsened | 3              |      |           |      | 2                     |    |           |      |
| Forgot to take medicines                          | 2              |      |           |      | 3                     |    |           |      |

Table 4: Summarized scores of BMQ questionnaire

| Questions   | Usual care (Mean±SD) |                         | Intervention care (Mean±SD) |              |
|---|----------------------|-------------------------|-----------------------------|--------------|
|   | Baseline             | End visit               | Baseline                    | End visit    |
| <b>BMQ necessity</b>  |                      |                         |                             |              |
| My current health depends on my medicines                     | 4.03±0.41            | 4.03±0.41 <sup>ns</sup> | 4.00±0.00                   | 4.33±0.47*   |
| My life would be impossible without medicines                 | 2.40±0.93            | 2.40±0.93 <sup>ns</sup> | 2.38±0.72                   | 2.40±0.88    |
| Without my medicines, i would be very sick                    | 3.86±0.81            | 3.86±0.81 <sup>ns</sup> | 3.60±0.89                   | 4.21±0.30*   |
| My health in future will depend on my medicine                | 3.76±0.85            | 3.76±0.85 <sup>ns</sup> | 3.46±0.89                   | 4.10±0.30**  |
| My medicines protect me from becoming worse                   | 3.76±0.72            | 3.76±0.72 <sup>ns</sup> | 3.63±0.85                   | 4.13±0.18**  |
| <b>BMQ concern</b>  |                      |                         |                             |              |
| Having to take medicines worries me                           | 3.16±1.02            | 3.23±1.06 <sup>ns</sup> | 2.90±1.09                   | 2.26±0.69**  |
| I sometimes worry bout the long term effects of my medicines  | 3.30±0.98            | 3.20±1.06 <sup>ns</sup> | 3.10±1.09                   | 2.53±1.08**  |
| My medicines re mystery to me                                 | 3.20±0.19            | 3.20±1.09 <sup>ns</sup> | 3.16±1.05                   | 2.56±0.97**  |
| My medicines disrupt my life                                  | 2.60±0.93            | 2.60±0.93 <sup>ns</sup> | 2.60±0.95                   | 2.13±0.50**  |
| I sometimes worry bout becoming too dependent on my medicines | 3.83±0.64            | 3.83±0.64 <sup>ns</sup> | 3.80±0.61                   | 2.73±0.98*** |

Data expressed as Mean (SD), ns: Non significant, \*p<0.05, \*\*p<0.01 and \*\*\*p<0.001

Table 5: Summarized scores for SIMS questionnaire

| Questions   | Usual care (Mean±SD) |                         | Intervention care (Mean±SD) |                         |
|---|----------------------|-------------------------|-----------------------------|-------------------------|
|   | Baseline             | End visit               | Baseline                    | End visit               |
| What your medicine is called?                         | 0.20±0.40            | 0.24±0.45 <sup>ns</sup> | 0.26±0.44                   | 0.73±0.44***            |
| What your medicine is for?                            | 0.83±0.37            | 0.89±0.37 <sup>ns</sup> | 0.66±0.47                   | 0.93±0.25**             |
| What it does?   | 0.30±0.47            | 0.40±0.49 <sup>ns</sup> | 0.26±0.44                   | 0.90±0.30***            |
| How it works?   | 0.10±0.30            | 0.20±0.40 <sup>ns</sup> | 0.03±0.18                   | 0.46±0.50***            |
| How long it will take to ct?                          | 0.10±0.30            | 0.20±0.40 <sup>ns</sup> | 0.06±0.25                   | 0.70±0.46***            |
| How you can tell if it is working?                    | 0.50±0.50            | 0.50±0.50 <sup>ns</sup> | 0.20±0.40                   | 0.76±0.43***            |
| How long you will need to be on your medicine?        | 0.03±0.18            | 0.06±0.25 <sup>ns</sup> | 0.26±0.44                   | 0.76±0.43**             |
| How to use your medicine?                             | 1.00±0.00            | 1.00±0.00               | 1.00±0.00                   | 1.00±0.00               |
| How to get further supply?                            | 1.00±0.00            | 1.00±0.00               | 0.96±0.18                   | 1.00±0.00               |
| Whether the medicine has any side effects?            | 0.56±0.50            | 0.60±0.49 <sup>ns</sup> | 0.66±0.47                   | 0.90±0.30**             |
| What re risks of getting side effects?                | 0.30±0.46            | 0.30±0.46 <sup>ns</sup> | 0.23±0.43                   | 0.80±0.40***            |
| What to do if you experience side effects?            | 0.86±0.34            | 0.70±0.46 <sup>ns</sup> | 0.36±0.49                   | 0.90±0.30***            |
| Whether you can drink alcohol while taking medicine?  | 1.00±0.00            | 1.00±0.00               | 1.00±0.00                   | 1.00±0.00               |
| Whether the medicine interferes with other medicines? | 0.00±0.00            | 0.03±0.40 <sup>ns</sup> | 0.00±0.00                   | 0.76±0.43***            |
| Whether the medication will make you feel drowsy?     | 0.66±0.47            | 0.73±0.44 <sup>ns</sup> | 0.80±0.40                   | 0.86±0.34 <sup>ns</sup> |
| What you should do if you forget to take dose?        | 0.10±0.30            | 0.36±0.49               | 0.20±0.40                   | 0.76±0.43**             |

Data expressed as Mean (SD), ns: Non significant, \*p<0.05, \*\*p<0.01 and \*\*\*p<0.001

Compliance advocates that the patient is passively following the physician’s orders and the treatment plan is not based on an established therapeutic agreement between the patient and the physician. As the patient autonomy increases now-a-days, the term, compliance is being replaced with the term, adherence in the recent literatures. The most commonly quoted definition of adherence is the extent to which a person’s behavior coincides with medical or health advice (Greenberg, 1983). During the literature review, we could relatively find few studies which have

focused on adherence to oral chemotherapy, because the majority of chemotherapy has been delivered intravenously in hospitals (Walter *et al.*, 2013; Ruddy *et al.*, 2009). The present study aimed to examine the medication adherence behavior to oral metastatic chemotherapies on cancer patients in south Indian population.

Since, cancer is professed as a serious life threatening disease, one would expect a higher rate of adherence and yet some patients adjust their doses without informing their clinicians. For instance, some cancer patients may exhibit devotion to self-administered medication, increasing the dose because of perceived ineffectiveness or because they believe more is better. Often unrecognized by clinicians, this practice can lead to a substantial increase in toxicity. Conversely, a cancer patient may decrease the dose because of actual or perceived toxicity. Patients taking very expensive oral agents may also reduce their dose to delay the need to refill the costly drug.

Zivin *et al.* (2009) reported that as drug expenditures continue to rise, which resulted in financial burden on patients, often let them to skip pills and avoid filling prescriptions in order to save cost. Nekhlyudov *et al.* (2011) stated that the cost related medication adherence was similar in those with cancer and without cancer. However, in the present study non-adherence was not related to cost as the cost of medication were covered in the insurance scheme.

There was an increase in the trend of non-adherence in the stage III and IV cancer, probably because of patient's misconceptions about treatment results or felt worse when they took the medication. Capecitabine was most commonly prescribed drug for different types of cancer in this study. It showed adherence rates of 85%, whereas the study done by Winterhalder *et al.* (2010) stated that a high self-reported complaints rate of 91% with capecitabine therapy, which was given as either monotherapy or as a part of combination regimen.

Among the study population, 18.3% patients were non-adhering to the medications for the reasons like being forgetfulness, felt better or felt worse or took medication only when they were sick. This is in concurrent to the study conducted by Winter halder *et al.* (2010) in which the authors reported forgetfulness 9% as the major reason for non-compliance. The unintentional non-adherence was reported by 8.3% of the patients and 10% showed intentional non-adherence, whereas the study carried out by Atkins and Fallow field (2006) had remonstrated that majority of patients reported unintentional non-adherence was reported in 83.8% but approximately 16.6% of cancer patients have not taken their medications intentionally.

A number of interventions are available to support the patients in remembering to take their medication. For example cues may be used, such as coordinating dosing with meals or daily rituals, reminder charts, which record the medication to be taken and timings to be reported (Kelly and Giordano, 2011; Raynor *et al.*, 1993). The use of technology such as text messaging and mobile telephone reminders also show improvement in adherence to prescribed therapy (Cramer, 1998). In this study, repeated patient education and counseling were adopted for the intervention group as a tool for improving medication adherence with appearance of the need for increasing information provision.

Both the groups of the study population were assessed for belief about medication. About 6% of the study population had disbelief about medication. But after counseling there was a significant increase in the mean scores in the intervention group except one question "my life would be impossible without the medication" which did not show significant increase, similarly in the study done by Bhattacharya *et al.* (2012), which showed less belief in that same question.

According to the study done by Bhattacharya *et al.* (2012), 42.9% were dissatisfied about medication and concluded that there is a need for increasing information provision about

medication. In our study population, about 54% of the patients were not satisfied with the information provided in both the groups about the medication. In the intervention group after patient education a significant increase in mean scores was observed for the questions like how it works, how long it will take to act, whether the medicine interferes with any other medicines and what to do if you miss a dose. Several studies through SIMS reported improved adherence with the provision of information.

In a study of patient adherence to chemotherapy for breast cancer carried out at Sussex, United Kingdom, 55% of patients receiving oral chemotherapy were non-adhered to medications either unintentionally (due to forgetfulness) or intentionally (due to drug side effects) (McGurk *et al.*, 2006). Few studies that have focused specifically on adherence to oral antineoplastic agents in adults have yielded variable results. In the largest published study of adherence in adult oncology patients, Siegel *et al.* (2012) followed 108 patients with newly diagnosed hematologic malignancies and assessed adherence to oral self-administered daily Allopurinol and intermittent Prednisone and to monthly scheduled appointments.

Lebovits *et al.* (1990) studied the adherence in breast cancer patients who had taken Cyclophosphamide and/or Prednisone. The author concluded that 43% patients were non-adherent. In the present study, 16.6% of patients non-adhered to their medication in both usual care and intervention care group due to several reasons like patients stopped taking medicines when they felt improved, stopped taking medicines when they felt worsened or they forgot to take medicines. After a structured patient counseling by a clinical pharmacist, the non-adherence rate is reduced greatly. However, the limitations of the study were that the study did not include Stage I and II patients and had a small sample size. Future studies may be required to explore changes in adherence rate with time and clinical impact of non-adherence.

## **CONCLUSION**

This preliminary study had explored the changes in adherence rate and had identified the barriers for non-adherence. At the end of the study, intervention group patients had shown a greater improvement in the MARS, BMQ and SIMS score than the usual care group patients. Thus the study concludes that comprehensive patient education has shown to enhance adherence to oral chemotherapy.

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