Adverse event management in chemotherapy cancer patients



Results

RESULTS

In this prospective interventional study conducted at the KMCH hospital during a period of December 2013 to July 2014, a total of 63 cancer patients who received chemotherapy from the comprehensive cancer center of the hospital were included in the study.

ASSESSMENT OF PATIENT CHARACTERISTICS

The demographic details among the subjects revealed that most of the cancer cases fall in the age group of 40-59, having 52. 38% patients in this age group followed by 34. 92% patients in the age group of ≥ 60 years old [Table 2 & Figure 1]. Out of this, the majority of patients receiving chemotherapy were females, 55. 55% whereas males were only 44. 44%. [Table 3 & Figure 2]

Evaluation of the subjects based on their education level revealed that out of the total population 66. 66% falls in the category of educated while 33. 33% were uneducated. [Table 4 & Figure 3] On analysing the subjects based on their diagnosis, gastrointestinal (GI) cancers (33. 33%) were found to be the most common diagnosis followed by breast cancer (17. 46%). [Table 5 & Figure 4]

Assessment of comorbidities revealed hypertension (22. 22%) as the most common comorbidity seen amongst our subjects, closely followed by diabetes mellitus (19. 04%). [Table 6 & Figure 5]

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Among the different types of adverse effects documented the predominant

types consisted of fatigue (84. 12%) and insomnia (68. 25%). [Table 7 &

Figure 6]

ASSESSMENT OF IMPROVEMENT IN PATIENT'S QoL

Study population: 63

Analysis: Friedman's Test

This analysis was carried out for evaluating the change in QoL of the patients

as part of the adverse event management given from pre-intervention

assessment to first and second review of the patients. We found that

adverse event management had a significant effect on the QoL of the

patients with regard to global health status, functional scales, symptom

scales and symptom and limitation scales (P < 0.001) except cognitive

function and financial difficulties. [Table 8 and Figure 7]

Global Health Status/QoL:

The global health status showed a significant change with improvement from

1. 02 in the pre-intervention assessment to 2. 04 and 2. 94 in the first and

second reviews respectively. This change was statistically significant with a

P-value of 0. 0001.

Functional Scales:

The assessment of functional scales showed that the physical functioning of

the cancer patients improved with time. During the pre-intervention

assessment, the mean rank was 1. 24 which then increased to 2. 29 & 2. 48 over the next 2 reviews respectively. The improvement was significant with the P-value of 0. 0003. The scale of role functioning also varied clearly with time, it improved from 1. 34 during the initial assessment to 2. 16 and 2. 50 at follow-up visits. This change was statistically significant with the P-value of . 0001.

The emotional functioning scale increased from an initial value of 1. 54 in the initial assessment to 2. 07 and 2. 39 at the subsequent visits respectively. This improvement was statistically significant with a P-value of 0. 0002. Also, the social functioning showed a significant improvement in the score from an initial value of 1. 41 at the initial assessment to 2. 17 and 2. 42 over the follow up period of first and second review respectively. This change was statistically significant with a P-value of 0. 0001.

Symptom Scales:

On assessing the symptom scales, symptom in the form of fatigue decreased over the study period from an initial value of 2. 86 at the initial assessment to 1. 78 and 1. 37 in the subsequent reviews. This change was statistically significant with a P-value of 0. 0001. The symptom scale of nausea and vomiting also showed a significant improvement from 2. 60 at pre-intervention assessment to 1. 95 and 1. 45 in the follow up period which was statistically significant with a P-value of 0. 0003. The pain symptomatology decreased from a value of 2. 52 in the initial assessment to 1. 87 and 1. 61 during the follow up period. This was a statistically significant improvement with a P-value of 0. 0003.

The symptom scale of dyspnoea also decreased from the initial value of 2. 37 to 1. 93 in the first review and 1. 71 during the second review, which was a statistically significant change with a P-value of 0. 0001. As far as symptomatology in the form of insomnia is concerned, it decreased from the initial value of 2. 67 in the pre-intervention assessment to 1. 83 and 1. 49 in the subsequent reviews with a statistically significant change which gives a P-value of 0. 0002. When symptom in the form of appetite loss was assessed, it showed a marked decrease from a mean rank of 2. 52 at the initial assessment to 1. 85 and 1. 63 during the first and second reviews respectively. This improvement was statistically significant with the P-value 0. 0001.

The symptom scale of constipation improved over the study period from an initial mean of 2. 37 to 1. 88 and 1. 75 in the subsequent follow ups of first and second review which was a statistically significant change with a P-value of 0. 0001 while diarrhoea also decreased from a mean rank of 2. 22 at initial assessment to 1. 93 in the first review and 1. 85 during the second review. This change was statistically significant with a P-value of 0. 0002.

Symptom and Limitation Scales:

Limited normal eating or drinking habits of the patients also decreased from a mean rank of 2. 72 in the pre-intervention assessment to a value of 1. 94 and 1. 33 in the successive assessments. This improvement was statistically significant with a P-value of 0. 0003. The symptom in the form of sore mouth improved over the study period from an initial value of 2. 17 to 1. 95 and 1.

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87 in the next 2 consecutive reviews which was a statistically significant

change with a P-value of 0. 0004.

Limitation in the activities due to adverse effects also showed a significant

improvement from an initial value of 2, 60 to 1, 97 and 1, 44 in the following

2 reviews respectively. This progress was statistically significant with a P-

value of 0, 0003. Knowledge about infection and its prevention showed a

noteworthy improvement in the study period. The value decreased from 2.

98 in the initial assessment to 1. 72 and 1. 30 in the subsequent reviews

which was a statistically significant change with a P-value of 0. 0002.

Difficulty in managing symptoms also showed a drastic improvement from

an initial value of 2.96 in the pre-intervention assessment to 1.73 and 1.31

in the next 2 reviews with a statistically significant change at a P-value of 0.

0001.

ASSESSMENT OF PATIENT'S QoL AGAINST AGE

Study Population: 63

Analysis: One-way ANOVA

The patient's QoL against age was assessed in order to determine whether

age has any influence on the adverse event management and we found that

age has significant role in global health status, functional scales as well as on

symptom scale and symptom and limitation scales (P < 0.05). But out of

these, for a few scales like cognitive functioning, pain, dyspnoea, insomnia,

appetite loss, constipation, diarrhoea, financial difficulties and sore mouth

we were not able to find any influence of age. [Table 9]

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Global Health Status:

In our study, the global health status was found to have a significant improvement among the age group of 18-39 during reviews 1 (P=0.035) and 2 (P=0.003).

Functional Scales:

Physical functioning was at its higher side in the age group of 18-39 from the initial assessment (P=0.043) and the functioning was significantly improved and maintained during the successive reviews (P=0.0001). Role functioning was found to be higher in the age group of 40-59 from the pre-intervention assessment (P=0.004) which was found to have improved during the first review (P=0.0001) and this improvement was sustained over the second review (P=0.0001) as well. At the same time, emotional functioning showed a significant improvement during the first review (P=0.0003) among this age group which was further maintained in the subsequent review. Social functioning also showed a significant change among the population above 59 years by the second review (P=0.0002).

Symptom Scales:

Symptom in the form of nausea and vomiting was seen mostly in the age group of 40-59 years. It showed a significant reduction from the initial assessment (P=0.023) to first review (P=0.011) and the improvement was upheld in the second review. The normal eating or drinking habits were also significantly reduced (P=0.018) highly among this group of patients which was considered to be secondary to the high level of nausea and vomiting

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experienced. The symptom was further improved during the subsequent

follow ups but the change was not statistically significant.

Fatigue was most commonly seen among the \geq 60 age group and it showed

a significant reduction from the initial assessment (P= 0.026) to first review

(P= 0.039) and second review (P= 0.0002).

Symptom and Limitation Scales:

Limitation in the activities due to adverse effects showed a significantly high

reduction in the patients of 18-39 age group during their second review (P=

0. 026). And, in the knowledge regarding infection, its prevention and

management, patients among the 40-59 age group also showed a

statistically significant improvement during their second review (P= 0.022).

In addition, management of symptoms based on the instructions given had

also shown a significant improvement among this group of patients from

review 1 (P = 0.047) to review 2 (P = 0.004).

ASSESSMENT OF PATIENT'S QoL AGAINST COMORBIDITIES

Study Population: 63

Analysis: Independent t-test

Among our study population, 25 patients presented with comorbidities. The

purpose of this analysis was to check whether comorbidity plays any role in

adherence management and we found that it only has a significant effect on

the normal eating or drinking habits as well as on awareness about infection

and management of symptoms (P < 0.05). Comorbidity was found to have

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no significant role in global health status and rest of the functional and

symptom scales. [Table 10]

Patients with comorbidities showed a significantly normal eating or drinking

habits during the baseline assessment (P= 0.002) and was improved further

during the study period. In the knowledge regarding infection, its prevention

and management, the patients without comorbidities showed a significant

improvement during review 1 (P= 0.009) which was sustained in review 2

(P= 0.014) as well. Also, this category of patients showed a significant

ability to manage the symptoms with the instructions given which was found

to be improved during their first review (0. 007).

ASSESSMENT OF PATIENT'S QoL AGAINST EDUCATION

Study Population: 63

Analysis: Independent t-test

This analysis was performed to determine whether education has a role in

the adverse event management and we found that patients with education

shows significant improvement in physical functioning, role functioning,

fatigue, appetite loss, limitation of activities and awareness about infection

(P < 0.05) compared to patients without education who also shows

improvement but the change was not significant enough.

In educated patients, physical functioning was higher from the baseline

assessment (P= 0. 015) which was further maintained throughout the first

review (P= 0. 030) and second review. Role functioning was also higher and

maintained among this group from the initial assessment (P= 0, 008). The

symptom fatigue also shown a remarkable improvement by second review (P=0.006) alongside knowledge about infection (P=0.039). Appetite loss shown a reduction during first review (P=0.010) which was further improved and maintained throughout the follow up period while limitation in activities were considerably low from the baseline assessment (0.032) which was sustained throughout the study period. [Table 11]

EVALUATION OF THE ADVERSE EVENT MANAGEMENT

The evaluation is done using results of quality of life assessment as well as through patient interviews during their reviews. The patients were asked about the usefulness of the adverse event management and tools provided and they were also asked to report the tips they had used.

Among our subjects, the symptom of nausea was found among 39 patients [Table 12] and vomiting was seen among 32 patients [Table 13]. They had shown a considerable improvement throughout the study period and most of them were able to report at least one tip they had used. The tip that had been reported by most patients were " If the smell of food bothers you, let the food cool down before you eat it" and also the patients started taking the anti-emetics prescribed even on days they were experiencing less severe nausea or vomiting.

Out of the study population 48 were found to experience fatigue and the symptom was improved and the improvement was sustained throughout the study period. "Listen to your body, rest when you tired" and "do activities that are most important" were the tips used by most of the patients [Table 14]. Appetite loss was another symptom experienced by 32 of the subjects

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which further improved during the study period. "Drink soups that are easy to swallow" was the tip mostly reported, closely followed by "watch television while you eat". [Table 15]

About 24 of the patients experienced constipation [Table 16] while 15 had diarrhoea [Table 17]. The symptoms were improved during the follow up period and the patients were able to report the tips they had used and found beneficial. Most of the patients tried including more fruits and vegetables into the diet and also as instructed when the symptom was severe they consulted the physician and taken the medication.

Among the study population 12 had mouth sores which improved over time and most of them had tried the mouth wash recipe and drinking through straw as per the tips provided to them [Table 18]. As far as the identification, prevention and management of infection was concerned, most of the study population was found to be lacking any knowledge in these, which then increased considerably during the study period with the information provided regarding the infection [Table 19].