Determinants of Prescribing Practices of Opioids Analgesics in Cancer Patients at Oncology Units, Teaching Hospital, Kandy.

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ABSTRACT: In spite of having advanced, effective and newer treatment modalities cancer has become a most deadly and devastating disease among the other spectrum of chronic diseases across the globe and is the second highest leading cause of death in Sri Lanka. (National Health Bulletine , 2018). Objectives of this study were to determine the factors affecting prescribing practices of opioids analgesics in cancer patients at oncology units, Teaching Hospital, Kandy and assess the level of pain score of patients admitted. Also we assessed the level of satisfaction of cancer patients on services provided by the hospital.Lack of continuous supply of opioids, frequent quality failures of opioid drugs, lack of adverse event reporting system, lack of knowledge in palliative care among staff, irrational authoritative attitudes of staff, non-opportunity to attend important meetings, heavy work load, lack of adequate staff and lack of knowledge on pain assessment were the contributing factors which affect the prescribing practices of health care professionals.Introduction of cancer pain management protocol including pain assessment method and incorporation of pain assessment into the in-service training curriculum of medical officers would be a successful remedy in cancer pain management.

KEY WORDS: Cancer pain, Determinants, Opioids, Prescribing practices

I.   INTRODUCTION

Background : In spite of having advanced, effective and newer treatment modalities cancer has become a most deadly and devastating disease among the other spectrum of chronic diseases across the globe and is the second highest leading cause of death in SriLanka[2].The sheer potential for suffering from cancer can be a horrifying experience for anyone bearing this diagnosis, while pain is probably one of the most frightening of all cancer symptoms for patients and their families [3].Despite advanced knowledge and pain management methodologies, 70–80% of cancer patients with advanced disease are experiencing uncontrolled painin moderate-to-severe intensity due to poor and ineffective pain management [4].Suboptimal pain management is meaningless and can significantly reduce the quality of life. Although a very poor prognosishas been experienced by many of these patients, needless suffering can be prevented by prompt and effective pain management. This may account to enhance the quality of patient'slives, and may leads to prevent developing feeling of helplessness and desperation.

Management of Cancer Pain: Severe pain can be influenced by proper physical rehabilitation, proper nutrition and mobilization. Depression is a common diagnosis among notable number of cancer patients. Therefore, the pain management has to be aimed at to optimize the quality of life of patients while preventing adverse effects of drugs used in pain control [5]. Though many guidelines have been developed for management of pain due to cancer, guideline introduced by WHO [6] is the most frequently used one for many years. This is called "Three step analgesic ladder" modified to facilitate and standardize pain management in cancer care and provide better pain management protocol for all physicians in world wide. This treatment modality has showed good to satisfactory results in combating pain in 88% of diagnosed patients with cancer over a ten years' period of observation [7]. Despite having many opportunities to treat cancer pain effectively it is still remaining untreated or partially treated due to various barriers which may include fear of opioid addiction, unavailability of needy medicines, cultural factors and socio economic conditions. Successful control of cancer pain need comprehensive pain assessment as an initial step. It has been identified that in every clinical examination pain has to be evaluated and should be considered as the "fifth vital sign" [8]. Ideally, the severity, duration, quality, and location of the pain has to be considered in the initial pain assessment [9].

Pain Assessment : Various pain assessment tools are available worldwide to assess the cancer pain [10].It is evident that multidisciplinary approach in cancer pain management has showed more successful results using combination of treatment modalities[11].The guideline developed by WHO for management of cancer pain is the most widely accepted tool as an international standard and has been incorporated the latest and advanced knowledge that created worldwide.In the mid-decade of 1980 the WHO introduced a cancer pain management programme which emphasis a scientific methodology for management of pain caused by cancer.

The three-step analgesic ladder introduce pain control in terms of intensity of pain. By referring to drug classes, rather than specific drugs, the ladder maintains a level of flexibility that allows clinicians to work within the regulations and limitations employed in their respective countries. Mercadante&Fulfaro, [12] highlighted that: the fundamental aim of the WHO analgesic ladder was to justify the prescribing of strong opioids for cancer pain, which had previously been problematic due to fears of addiction, tolerance and illegal use(1).

Justification: World Health Organization has announced cancer as a global health issue and increasing incidence of cancer has been reported in all countries irrelevant to their economic development. The incidence of cancer reported increased from 12.7 million to 14.1million in year 2008 to 2012 according to the World Cancer Report 2014. This trend has been projected to rise a number of new cases up to 75% and this would bring the number close to 25 million during next two decades. Cancer is the second leading cause of mortality in Sri Lanka [13] and one of the important cause of morbidity in Sri Lanka. In 2008, a total of 16,511 new cancer cases were diagnosed in Sri Lanka. This a considerable increase from the 2007 figure which was 13, 635. The World Health Organization (WHO) emphasized that 5.5million cancer patients with advanced disease still suffer every year moderate-to-severe pain [14]. However, this therapeutic guideline has contributed lot to improve the management of cancer pain, yet most of developing countries including Sri Lanka, were not able to adopt this WHO analgesics ladder therapeutic guideline to our healthcare system. Appropriate use of opioids in each step of the analgesics ladder is essential to obtain maximum benefits. Clear objectively selection of drugs according to the pain assessment is the first basic step use in analgesics ladder. Yet, none of the cancer units in Sri Lanka have adopted the WHO analgesics ladder guideline in scientific manner as recommended by the World Health Organization. Objectives of this study were to determine the factors affecting prescribing practices of opioids analgesics in cancer patients at oncology units, Teaching Hospital, Kandy and assess the level of pain score of patients admitted. Also we assessed the level of satisfaction of cancer patients on services provided by the hospital.

II. METHODOLOGY

This was a descriptive cross-sectional study conducted in oncology units at the Teaching Hospital, Kandy (THK), in the Kandy district of Central Province of Sri Lanka. THK is a 2400 bedded large-size hospital that serves more than one million patients annually. From January to June 2018, total admission to two oncology units was 4682, the average number of admission to that unit was 823 per month. There are three Consultant Oncologist and one Consultant Pediatric Oncologist attached to the THK. All cancer patients with pain who were admitted to two selected oncology units, Teaching Hospital, Kandy for a period of two months were selected for the study. Patientsaged above 13 years at the date of data collection and patients who were diagnosed with any cancer condition and related pain as morbidity were considered as inclusion criteria. Cancer patients with severely ill or impaired cognitive functions were excluded from the study.

Study Methods: An interviewer administered questionnaire was used to identify the patients' understanding of palliative care, quality of care in services provisions, perception of availability of analgesics, continuous supply of narcotics drugs, misuse of narcotics drugs at different levels, etc. the questionnaire was developed after a literature survey and discussion with an expert panel. The final questionnaire was translated into the native languages of the patients. The questionnaire consisted of two parts including basic socio-demographic characteristics and information on morbidity patterns, detailed information from patients regarding opioids usage, and identify the weakness in service provisions. Key Informant Interviews (KII) andFocus Group Discussions (FGD) were used as study methods to gather information regarding prescribing practices.Medical administrators, medical specialists, and pharmacists of the Teaching Hospital, Kandy were interviewed in KII and medical officers and nursing officers of the oncology units were used to FGDs.Based on the results of the FGD another FGD was conducted for the same group.Experts from the field of Oncology, Pharmacology, and anaesthesiology were invited to participate in the expert committee for the development phase.

Pain Assessment: It has been brought to notice that any oncology units of the Teaching Hospital, Kandy were not using any type of pain assessment tool for cancer patients with pain to assess their level of pain status before commencing analgesics. According to the literature survey, few validated pain assessment tools have been used in different countries in the world since the last decades for pain management. These includedNumerical Rating Scales (NRS), Visual Analogue Scales (VAS), categorical scales, Wong-Baker Faces Scale and Pain Rulers. Currently, it is recommended that pain should be measured using a Numerical Rating Scales (from 0–10, where 0 indicates no pain and 10 indicating the worst imaginable pain) [16]. In current study, the numerical rating scale was selected as the pain assessment tool considering many factors with the expert committee. Further based on the findings and considering the WHO recommendations, the WHO three-step analgesic ladder was selected to introduce for pain management of cancer patients who are admitting to oncology units of THK.

Qualitative data analysis was conducted using Grounded Theory Model (GTM) which was introduced in 1967 by Glaser and Strauss [15]. Quantitative data analysis was performed using the Statistical Package for Social Science (SPSS) statistical software by the principal investigator. Descriptive statistical methods and Chi square test were used in analysis of data. Administrative clearance was obtained from Director, THK and Ethical clearance was obtained from the ethics review committee of the THK.

III. RESULTS

Socio – demographic characteristics

Table 1: Distribution of cancer patients with pain according to the age and sex

"Table 1" shows distribution of cancer patients with pain according to the age and sex. According to the table majority (84.6%) of patients were in the age more than 45 years and 57.7% of patients were males.

Variable	Frequency	%
Age in years		
15 – 24	8	7.7
25 – 34	2	1.9
35 – 44	6	5.8
45 – 54	26	25
55 – 64	24	23.1
65 – 74	34	32.7
>75	4	3.8
Mean ± SD =56.7±14.5, Min/Max=16/81 years		
Sex		
Male	60	57.7
Female	44	42.3
Total	**104**	**100.0**

Table 2: Distribution of cancer patients with pain according to the ethnicity, religion and civil status

"Table 2" shows the distribution of cancer patients with pain according to the ethnicity, religion and civil status. According to the table, majority of respondents 84 (80.8 %) were Sinhalese and 74 (71.2 %) were Buddhists. Sixty six respondents (63.5 %) were married.

Variable	Frequency	%
Ethnicity		
Sinhalese	84	80.8
Sri Lanka Tamil	6	5.8
Indian Tamil	2	1.9
Moor	12	11.5
Religion		
Buddhist	74	71.2
Hindu	10	9.6
Islam	12	11.5
Christianity	8	7.7
Civil status		
Single	24	23.1
Married	66	63.5
Divorced	4	3.8
Separated	2	1.9
Widowed	8	7.7
Total	**104**	**100.0**

Table 3: Distribution of cancer patients with pain according to the level of education and employment category

"Table 3" shows the distribution of cancer patients with pain according to the level of education and employment category. According to the table, majority of respondents 48 (46.2 %) were educated up to the ordinary level and 36.5% of the sample was unemployed.

Variable	Frequency	%
Level of education		
No schooling	8	7.7
Grade 1 – 5	22	21.2
Up to Ordinary Level	48	46.2
Up to Advanced Level	20	19.2
University and above	6	5.8
Employment category		
Teacher	6	5.8
Clerical	6	5.8
Businessman	6	5.8
Armed services	2	1.9
Farmer	7	13.5
Laborer	6	5.8
Unemployed	38	36.5
Retried	16	15.4
Other	10	9.6
Total	**104**	**100.0**

Table 4: Distribution of cancer patients with pain according to the level of income

"Table 4" shows the distribution of cancer patients with pain according to the level of income. According to the table majority of respondents 56 (53.8 %) were not responded while 12 (11.5%) respondent's family income were belong to less than SLR. 10000.00 category.

Level of income (SLR.)	Personnel		Family	
	Frequency	%	Frequency	%
<10,000.00	8	7.7	6	11.5
10,000 – 20,000	18	17.3	8	15.4
20,001 – 30,000	14	13.5	6	11.5
30,001 – 40,000	4	3.8	2	3.8
40,001 – 50,000	2	1.9	2	3.8
>50,001	2	1.9	2	3.8
Not responded	56	53.8	26	49.2
Total	**104**	**100.0**	**52**	**100.0**

Clinical characteristics: The study sample consisted of cancer patients who had been admitted to oncology units, Teaching Hospital, Kandy and the response rate was 100%. The majority of respondents 48 (46.1 %) experienced pain at the one year or before one year from the diagnosis of cancer. Twenty six (25%) of patients developed pain on or before six months from the diagnosis. Further 10 (9.6%) of patients have experienced pain after four years. Almost all patients 100 (96.2%) developed pain gradually and only few 4 (3.8%) patients got acute onset pain. Patients were educated regarding opioid drugs by various health care workers and therefore multiple responses (126) were obtained. Majority of respondents 54(43%) said that doctors informed about nature of the opioid drugs. Nursing Officers (NO) 44(35%), pharmacists 10(7.9%), friends 9(7.1%), media 4(3.2%) and others 4(3.2%) have contributed to make aware the cancer patients about opioid drugs. Majority of respondents 58 (55.8%) said that side effects of analgesics drugs were not discussed by the prescribers. The majority respondents 50 (48.1%) were in moderate pain category. Further 42(40.4%) of patients were categorized as severe pain whereas 12(11.5%) of patients found to be mild category. Intensity of pain in each category of pain has assessed using NRS pain assessment tool. In mild, moderate and severe categories mean pain score obtained as 3.33, 5.72, and 8.48 respectively. Finally overall pain score for all categories of pain was 6.56. Out of 104, majority 94(80.4%) respondents were satisfied; somewhat satisfied 70 (67.3%) or satisfied 24(23.1%) about the clinical care services of the oncology units.

Focus group discussions with medical professionals: In the first step we gathered data on prescribing practices, perceived issues, and broad expectations of healthcare professionals. Medical officers (n=10) shared the same perceptions regarding current practices and issues in cancer patient's care.

Medical officers: When inquired on how the analgesics were prescribed for the cancer patients with pain, it was revealed that medical officers prescribe drugs based on their respective consultant's advice and instructions. Non availability of certain drugs in the hospital pharmacy, issuing drugs for only four weeks for the clinic patients and opioid vials are issued only for three days were the other logistic issues related to dispensing. Frequent quality failure of drugs and fear in opioid drugs handling were also affected the prescribing practices of doctors. Non availability of oral Morphine or even Tramadol in private sector has influenced for continued pain control. Lack of adverse event reporting system and non-opportunity to participate in Drug and Therapeutic Committee (DTC) were the other factors that medical officers have faced that leads to poor pain management.

Nursing officers: There were 16 nurses. Two focus group discussions were held by inviting 8 nurses per session. From the discussion with nurses it was revealed that issuing Opioid vials for only three days from the indoor pharmacy is a hindrance to the continuity of patient care. They also claimed that their experience and knowledge in opioid management is very low. The nursing Officers were unaware of any tools on pain assessment and when inquired about the possibility of its implementation. Nurses said that: Due to inadequate staff and heavy work load we have no time to educate patients on pain management and on side effects of drugs (2). Nursing Officers also agreed that quality failure of drugs interrupts the continuity of patient pain management.

Oncologists : Oncologists said "morphine are being delivered to the ward only for three days and also pointed out that sometimes the nurses in the ward do not comply with the instructions being given. Other Oncologists stated that this is due to lack of knowledge in palliative care among staff and at the same time the irrational authoritative attitudes of them. Further he said that: Burning issue is there are no sufficient medical officers in the units due to annual transfer list, special list and post graduate training and ultimately losing of trained officers(3).

IV. DISCUSSION

This study was carried out based on the assessment of current practices of medical officers, nurses, and other support groups in the palliative care setting at the TH Kandy, and further, patients who were admitted and are attending to oncology units were assessed. The growing nature of NCD all over the world, the importance of pain management of cancer patients was highlighted by many researchers and WHO. However, in Sri Lanka, has not prepared yet to face the challenges of NCD care; palliative care subject and the use of opioids in pain management are not popular among most health care professionals. Pain assessment tool (NRS) and WHO 3 step analgesics ladder pattern were adopted to this study to identify gaps. Similar studies were done in most of the developed countries and few in developing countries.

Pain assessment: A similar study was done at the medical oncology clinic of Akdeniz University between August 2009 and January 2010[17]. Same methods and materials were used in this study and Pain perception levels were assessed bynursers asking patients to report their pain intensity using self-administered Visual Analog Scale (VAS) on a range of zero to ten. In our study pain evaluation was done by medical officers as our nurses were not trained for pain management than doctors. We used NRS instead of VAS in the Sri Lankan setting. As per the instruction given in WHO analgesic ladder theory was applied with the participation of the specialist oncologist and anaesthesiologist who are attached to TH Kandy. Same results were achieved in both studies, and side effects were managed properly. Another study was performed in Europe in 2002, for cancer patients who were in pain and getting treatment from community centres [18]. In this study intensity ofpain was assessed using 0 – 10 (NRS) and found that mean pain score was 6.4. In our study, the mean pain score was 6.56.

Barriers to pain management : Another study had been done by [19] to assess knowledge, practices, and perceived barriers to cancer pain management among physicians and nurses in Korea. The study subjects were the physicians and nurses involved in the care of cancer patients. Practices, knowledge, and perceived barriers to cancer pain control, and processes perceived as the major causes of delay in opioid administration were the areas assessed. It was revealed that nurses performed pain assessment and documentation more regularly than physicians even though physicians had better knowledge of pain management than nurses. This evidence is contradictory to the results gathered in Teaching Hospital Kandy, Sri Lanka as consultant oncologists stated that it was the nurses that were reluctant to give adequate Opioids to the patients despite the doctor's recommendation. Any way this physicians and nurses study in Korea too claims a discrepancy in knowledge and practices for cancer pain management among the medical professionals though the direction of the discrepancy is paradoxical to this

study in Sri Lanka. Further all health care professionals agreed that heavy work load, lack of adequate staff and lack of knowledge on pain assessment have continued to be a barrier in pain management of cancer patients[21] revealed that geography, limited resources, legal restrictions,lack of physician education and failure to follow existing guidelines played major role in pain control and prescribing practices. Patients fear addiction, drug tolerance, and side effects also identified as contributing factors for prescribing practices in his study. Manolo in the Philippines had been researched by medical students in 2008[20]. Among several hindrances, to pain management, the main issue has been identified as the medical professional's lack of knowledge about cancer pain and negative attitudes towards opioids. About 35% were not confident with morphine use. The main three reasons stated as limitations in the choice of opioids for cancer pain were fear of addiction, lack of adequate knowledge and experience, and fear of side effects and complications. The findings reveal a need to incorporate a training program that will enable all students to graduate with basic competency in pain management and palliative care in the medical curriculum. This strategy may be very important in the sustainability of cancer palliative care with greater emphasis on adequate pain management in the Sri Lankan context too.

Logistic Issues: Continuous supply of drugs has also played a prominent role in determining prescribing practices and Oncologists and other medical officerssaid "It is impossible to assure the uninterrupted pain management, because there were instances when certain drugs in the hospital pharmacy were not available, for an example sometimes even the basic analgesics like Paracetamol, Tramadol capsules, Morphine SR 30 mg tablets and advanced opioids analgesics like Fentanyl 50 mcg patches. Not only that issuing drugs for four weeks for the clinic patients was restricted by the Ministry of Health; it leads to the interruption in pain control in cancer patients extensively. As a result, they tend to visit the clinics more frequently and or admit to units frequently results deprive the quality of care". Frequent quality failures of opioid drugs, lack of adverse event reporting system and non-opportunity to attend important meetings were mentioned as other determinants. This kind of resource gaps and system deficiencies have broadly contributed in determining prescribing practices among medical officers.

Satisfaction with the service provision : However large majority 94(80.4%) of patients who were treated in TH, Kandy, were at least somewhat satisfied 70 (67.3%) or satisfied 24(23.1%) with the services provided by the hospital. This has been a common finding in many studies because the most intractable cancer pain could be minimized in treatment at many health care settings. Study done by Boujemaa EL MarnissiI,FouadAbbass [22] in Spain found that 90% of patients declared being satisfied with the given treatment.

V. CONCLUSION

In conclusion, lack of continuous supply of opioids, frequent quality failures of opioid drugs, lack of adverse event reporting system, lack of knowledge in palliative care among staff, irrational authoritative attitudes, non-opportunity to attend important meetings, heavy work load, lack of adequate staff and lack of knowledge on pain assessment were the contributing factors which affect the prescribing practices of health care professionals. Further 94% of patients were satisfied with the given care, could be due to relief of terrifying intractable pain which most cancer patients would suffer. Introduction of cancer pain management protocol including pain assessment method and incorporation of pain assessment into the in-service training curriculum of medical officers would be a successful remedy in cancer pain management. Further other logistic issues like lack of staff, unavailability of opioids and administrative issues have to be solved for smooth functioning.

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