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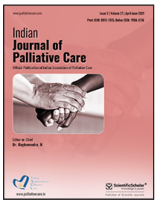

Original Article

Incidence of Different Characters of Neuropathic Pain in Cancer Patients Coming to Tertiary Care Centre in North India Over A Period of 1 Year – An Observational Study

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ABSTRACT

Objectives: Pain is classified as nociceptive, neuropathic, or nociplastic. Neuropathic pain presents as variable phenotypes (characters) based on specific aetiology and pathophysiology. This study aimed to find out among cancer patients the incidence of different phenotypes of neuropathic pain and form specific phenotypic clusters based on the underlying neurophysiology and association of sensory profile with various organ systems – A prospective observational study.

Materials and methods: The Institutional Ethical Committee clearance (IEC code: 2020-49-MD-EXP-15) https://ctri.nic.in/Clinicaltrials/showallp.php?mid1=44886&EncHid=88651.15716&userName=CTRI/2020/09/027964 approval was obtained. After written and informed consent, patients of age group 18–80 years, registering in the pain and palliative outpatient department or radiotherapy department with complaints of pain and not taking any anti-neuropathic pain medications, were enrolled. They were assessed using Leeds assessment of neuropathic symptoms and signs (LANSS) pain score, and a score of >12 was eligible for assessment of neuropathic pain phenotypes.

Results: Out of 210 cancer patients complaining of pain, a neuropathic component with LANSS >12 was found in 73 (34.76%). The most predominant phenotypes, allodynia> tingling> pricking = burning, were found in 72.60%, 56.16%, and 43.84% of patients, respectively. Phenotypes were clustered into Nodes 1 and 2 based on clinically significant separation of phenotypes. Node 1 had neuropathic pain of spontaneous origin found predominantly in gastrointestinal tract (GIT) and genitourinary tract (GUT) cancers. Node 2 had stimulus-evoked negative and positive characters which occurred in head and neck, thoracic, and spinal metastatic cancers.

Conclusion: Careful patient assessment reveals the incidence of neuropathic pain in 34.76%; allodynia and tingling astable the most prominent phenotypes. Broadly, sensory characters were clustered into spontaneous and stimulus-evoked sensations with GIT and GUT cancers presenting with Node 1 symptoms.

Keywords: Neuropathic pain, Phenotypes, Cancer pain, Neuropathic pain treatment

INTRODUCTION

Approximately 70–80% of cancer patients suffer from pain during their course of illness. The nature of pain is purely neuropathic in 20% (range: 9.4–28.4%) of patients and mixed (nociceptive and neuropathic, also known as nociplastic) in 40% of cases.[1] Pain in cancer may arise due to the invasion of tissue by cancer cells, treatments including chemotherapy, radiotherapy, and surgery, or coexisting comorbid diseases.[2-4] Neuropathic pain is caused by injury to the somatosensory system, resulting in pain with various presentations. These pain-related sensory characters, also known as phenotypes, can be broadly classified into three categories: (a) spontaneous (non-evoked) characters, for example, tingling, burning, pricking, and paroxysmal like shock and electrifying sensation, (b) stimulus-evoked positive symptoms such as allodynia, hyperesthesia or hyperalgesia and (c) stimulus-evoked negative symptoms like numbness. These sensory phenotypes form different patterns of sensory profiles in different disease pathologies, based on which they can be grouped or clustered together.[5,6] There have been

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many studies emphasising the importance of differentiating neuropathic cancer pain from nociceptive as the prior has worse pain outcomes.[7] There is no clear consensus for targeted drug management of cancer-related neuropathic pain. Different analgesics act through different mechanisms and act on different molecular targets. Most of the patients end up getting multiple drugs for their pain in the hope of getting some pain relief.

Our study assumes that prioritizing research on cancer pain assessment and clustering them into sensory phenotypes can help in recognising the pathophysiological basis, which may help in the targeted management of cancer neuropathic pain, without exposing them to side effects of unnecessary high doses of multiple drugs eventually affecting the patient's quality of life.

The primary objective was to find out the incidence of different characters/phenotypes of neuropathic pain in cancer patients.

The secondary objectives were as follows:

- To group different characters/phenotypes of neuropathic pain in cancer patients into phenotypic clusters
- To find out the association of phenotypes with organ types (type of cancer)
- To find out the neuroanatomical distribution of pain and its association with treatment.

MATERIALS AND METHODS

Design

This was a prospective observational study.

After ethical clearance from the Institutional Ethical Committee (IEC code: 2020-49-MD-EXP-15, dated 3 March 2020) and study enrolment in the Clinical Trials Registry – India https://ctri.nic.in/Clinicaltrials/showallp.php?mid1=44886&EncHid=88651.15716&userName=CTRI/2020/09/027964 This prospective observational study was conducted in the Department of Anaesthesiology, SGPGIMS, Lucknow, UP. Cancer patients coming to the outpatient department of the pain and palliative clinic and radiotherapy department in our institute over one year from September 2020 to September 2021 and fulfilling the inclusion and exclusion criteria were included in the study.

After written and informed consent, cancer patients between the ages of 18 and 80 years with sound mental condition (using mini-mental status examination with a score between 26 and 30 as normal), complaining of pain arising due to cancer or its treatment and willing to participate in the study were enrolled [Figure 1]. Patients who had difficulty in communication were already on anti-neuropathic medications, or had pain unrelated to cancer were excluded from the study. The enrolled subjects underwent assessment using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale.[8,9] Patients with a score >12 were further assessed and asked to fill out a performa, which included:

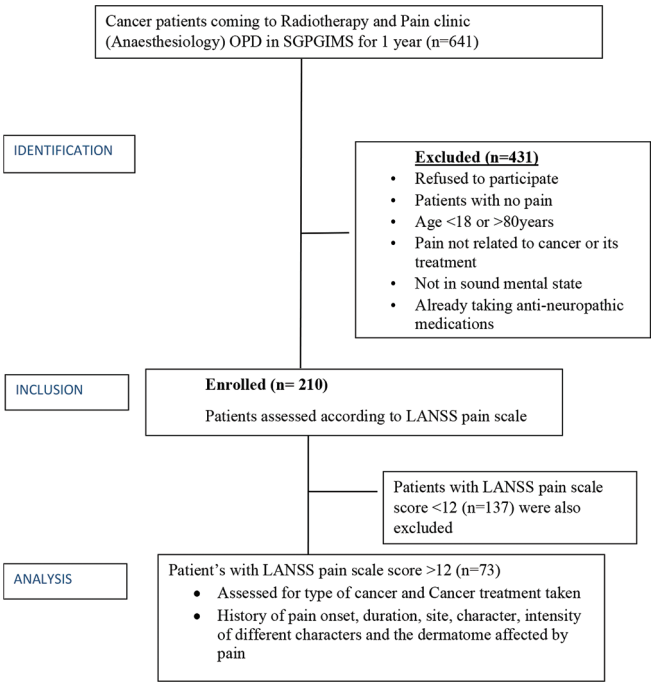

Figure 1: Enrolment of cases in the study. SGPGIMS: Sanjay Gandhi Post Graduate Institute of Medical Sciences, LANSS: Leeds Assessment of Neuropathic Symptoms and Signs.

- Patient demographics: patient's name, age, and gender
- Diagnosis and cancer treatment taken
- History of pain onset, duration, site, character, intensity of different characters (using numeric rating scale 1–3: mild pain, 4–6: moderate pain, and 7–10: severe pain) scale and the dermatomes (if applicable) affected by pain.

The data collected were then evaluated to find out the incidence of different characteristics of pain, group them into phenotypic clusters based on pain-related sensory characteristics, and find out the association between different phenotypes with organ types [Table 1].

Sample size estimation

We assumed that 30% of patients with cancer pain who visit the pain and palliative clinic and radiotherapy department suffer neuropathic pain. At a minimum, two-sided 95% confidence interval and 7% margin of error in the given incidence, the estimated sample size required was 165. After taking 20% data loss due to any reason, an estimated 198 patients with pain need to be screened for neuropathic pain (LANSS score >12). Finally, 210 patients were enrolled. The sample size was estimated using the software Power Analysis and Sample Size Version-16.

Statistical analysis

Categorical variables were expressed in frequency (%). The chi-square test/Fisher exact test (when in any cell, the

Table 1: Phenotype versus organ type cross-tabulation.

Variable's	HN	Thorax	GIT	GUT	Miscellaneous	Total
Allodynia						
Number	8	10	20	12	3	53
% within phenotype	15.1	18.9	37.7	22.6	5.7	100.0
% within organ type	26.7	25.6	18.5	21.1	21.4	21.4
Burning						
Number	2	0	19	7	1	29
% within phenotype	6.9	0.0	65.5	24.1	3.4	100.0
% within organ type	6.7	0.0	17.6	12.3	7.1	11.7
Electric shock-like						
Number	4	6	12	8	2	32
% within phenotype	12.5	18.8	37.5	25.0	6.3	100.0
% within organ type	13.3	15.4	11.1	14.0	14.3	12.9
Numbness						
Number	2	3	5	3	2	14
% within phenotype	13.3	20.0	33.6	20.0	13.3	100.0
% within organ type	6.7	7.7	4.6	5.3	14.3	5.6
Pain evoked by cold temperature						
Number	0	1	4	1	0	6
% within phenotype	0.0	16.7	66.7	16.7	0.0	100.0
% within organ type	0.0	2.6	3.7	1.8	0.0	2.4
Pricking						
Number	3	5	12	5	0	25
% within phenotype	12.0	20.0	48.0	20.0	0.0	100.0
% within organ type	10.0	12.8	11.1	8.8	0.0	10.1
Pins and needles sensations						
Number	2	4	16	7	3	32
% within phenotype	6.3	12.5	50.0	21.9	9.4	100.0
% within organ type	6.7	10.3	14.8	12.3	21.4	12.9
Shooting pain						
Number	1	0	4	1	0	6
% within phenotype	16.7	0.0	66.7	16.7	0.0	100.0
% within organ type	3.3	0.0	3.7	1.8	0.0	2.4
Squeezing pain						
Number	1	1	1	0	0	3
% within phenotype	33.3	33.3	33.3	0.0	0.0	100.0
% within organ type	3.3	2.6	0.9	0.0	0.0	1.2
Stabbing pain						
Number	0	1	2	1	0	5
% within phenotype	0.0	25.0	50.0	25.0	0.0	100.0
% within organ type	0.0	2.6	1.9	1.8	0.0	1.6
Tingling						
Number	7	8	12	11	3	41
% within phenotype	17.1	19.5	29.3	26.8	7.3	100.0
% within organ type	23.3	20.5	11.1	19.3	21.4	16.5
Twisting pain						
Number	0	0	1	1	0	2
% within phenotype	0.0	0.0	50.0	50.0	0.0	100.0
% within organ type	0.0	0.0	0.9	1.8	0.0	0.8
Total						
Number	30	39	108	57	14	248
% within phenotype	12.1	15.7	43.5	23.0	5.6	100.0
% within organ type	100.0	100.0	100.0	100.0	100.0	100.0

Chi-square test P=0.956. HN: Head and neck, GIT: Gastrointestinal tract, GUT: Genitourinary tract

expected frequency was <5) was used to test the association between two categorical variables (such as organ types and phenotypes). The conceptual framework was used to present the selection of the patients in the study. Classification and regression trees (a method of decision tree analysis used to discriminate/classify the characteristics between the groups)[10] are used to present the distribution of phenotypes in different types of organ types in the form of a graph. From the five organ types, its distribution was presented between two phenotype groups divided based on the heterogeneity of the distribution of the organ types called Node 1 (included shooting pain, burning, pain evoked by cold temperature, Twisting + pain, Pins, and needleless sensations, pricking) and Node 2 (squeezing pain, stabbing pain, numbness, allodynia, electric shock-like, and tingling).

Further, the distribution of the organ type was compared between these two nodes and presented in percentage and significance levels. A bar diagram was used to present the incidence of different characters of neuropathic pain in cancer patients. $P < 0.05$ was considered as statistically significant. Statistical analyses were carried out using the Statistical Package for the Social Sciences version 23.0 software.

RESULTS

Out of 210 cases experiencing pain, 73 (34.76%) patients had neuropathic pain [Figure 1].

The majority of patients belonged to the 4th (31.51%), 5th (23.29%), and 6th (17.80%) decade of life, with 53.43% females and 46.57% males [Table 2].

Of the 73 patients analysed, 53 presented with allodynia (72.60%), 41 had tingling sensations (56.16%), and 32 had pins and needles or shock-like sensations (43.84%). The incidence of various phenotypic characters is demonstrated in the horizontal bar graph [Figure 2].

We did a decision tree analysis wherein the computer-generated algorithm made two groups, namely Node 1 and 2, based on the clinically significant separation of phenotypes into two clusters [Figure 3]. Node 1 had spontaneous (non-stimulus evoked) sensory characters, which were mainly seen in the gastrointestinal tract (GIT) and genitourinary tract GUT) systems, whereas Node 2 had predominantly stimulus-evoked negative and positive characters, which occurred in head and neck, thoracic, and spinal metastatic cancers.

The distribution of phenotypic characters according to the organ system has been tabulated in Table 1. Patients suffering from head and neck, thoracic, and GUT cancers presented mostly with allodynia followed by a tingling sensation.

Patients suffering from GIT cancers presented mostly with allodynia and a burning sensation.

Patients with gallbladder cancer and cervical cancer patients mostly suffer from burning and electric shock-like pain.

The miscellaneous group comprised patients with spinal metastasis with unknown primary. These patients mostly presented with allodynia, electric shock, pins and needles, and tingling sensation in equal prevalence.

Table 2: Demographic data of the cases.

Variable's	No. of patients (n=73)	Percentage
Gender (n=73)		
Male	34	46.57
Female	39	53.43
Age in years (n=73)		
Mean±SD	52.28	12.92
Age groups		
18–30	3	4.11
31–40	10	13.70
41–50	23	31.51
51–60	17	23.29
61–70	13	17.81
71–80	7	9.58

Data are presented in number (%). SD: Standard deviation

Overall, 61.64% (45/73) of patients received treatment for cancer. The neuroanatomical association was found in 82% (37/45, $P < 0.001$) of patients who received cancer treatment and in 85% (24/28, $P < 0.001$) of those who did not receive cancer treatment. Thus suggesting that receiving cancer treatment (including surgery/chemotherapy/radiotherapy) did not affect the neuroanatomical distribution of pain [Table 3].

DISCUSSION

The incidence of cancer neuropathic pain (purely neuropathic and mixed neuropathic pain) in this study was found to be 34.76%. Allodynia > tingling > pricking = burning were found in 72.60%, 56.16%, and 43.84% of patients, respectively. Phenotypes were clustered into Node 1 and 2 based on clinically significant separation of phenotypes. Node 1 had neuropathic pain of spontaneous origin found predominantly in GIT and GUT cancers. Node 2 had stimulus-evoked negative and positive characters which occurred in head and neck, thoracic, and spinal metastatic cancers.

LANSS was used to find out the incidence of neuropathic pain. LANSS is a validated tool to diagnose neuropathic components for cancer pain, which includes five clinical questions and two clinical examinations**.** It is validated to identify the neuropathic component of cancer pain.[9] The maximum score on the LANSS pain scale is 24, of which 16 points are from sensory description and 8 points are from sensory dysfunction as experienced by the patient.[8,9] Our result is comparable to the systematic review by Bennett *et al*. in 2012, who found its prevalence as 39.1% (28.9–49.5%).[1] This similarity can be attributed to the fact that both studies were conducted on cancer patients.

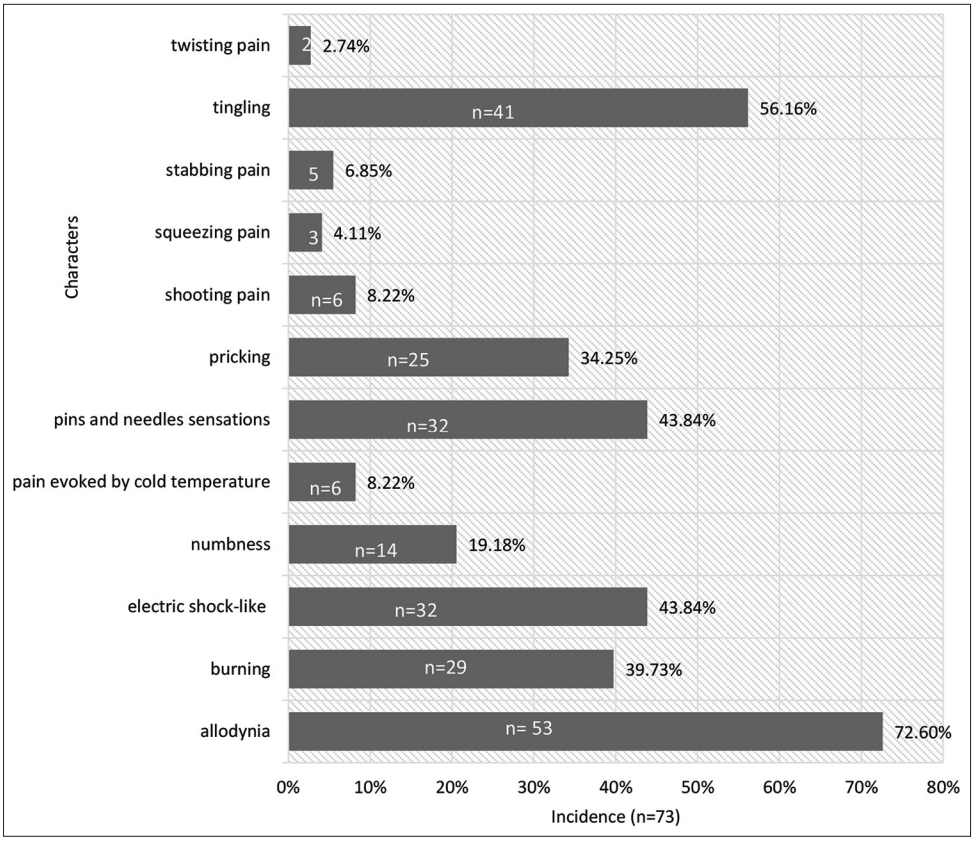

Figure 2: Incidence of different characters of neuropathic pain in cancer patients.

Table 3: Neuroanatomical distribution of pain.

Total Patients with pain (*n*=73)		
Patients who received cancer treatment=45 (61.64%)	Chemoradiotherapy=39 (53.42%) Surgery=6 (8.22%)	Pain was significantly associated neuroanatomically to site of cancer=37/45 (82.22%, *P*<0.001)
Patients who did not receive cancer treatment=28 (38.36%)		Pain was significantly associated neuroanatomically to site of cancer=24/28 (85.71%, *P*<0.001)

In the neuropathic pain cohort, allodynia (72.60%) was the most common character, followed by tingling (56.16%), pins and needles sensations (43.84%), and electric shock-like (43.84%) pain. Allodynia predominated in head and neck, thoracic, and gastrointestinal cancers, whereas allodynia and tingling were found to have equal incidence in genitourinary cancers.

IASP has concluded that a new classification for various neuropathic pain syndromes, especially cancer pain, should take into account subgroups of patients with different sensory profiles.[11,12] Sensory phenotyping can improve potential treatment responders and might lead to a stratified treatment approach, ultimately leading to personalised treatment and optimising patient outcomes.[13] Sensory phenotypes can be broadly divided into spontaneous (non-stimulus evoked) stimulus-evoked positive and negative presentations.[5]

Spontaneous neuropathic pain is caused due to partial injury of sensory afferents, resulting in hyperexcitability and ectopic action potential generation due to the upregulation of sodium and potassium channels. This group of patients may show benefit from Na channel blockers (oxcarbazepine) ± tricyclic anti-depressants (TCAD) (amitriptyline) or serotonin nor-epinephrine reuptake inhibitors (duloxetine).[5,13]

Stimulus-evoked positive symptoms such as allodynia, mechanical or thermal hyperalgesia, and hyperesthesia occur due to increased expression or upregulation of receptors and channel proteins such as TRPV1. These patients may benefit most from Gabapentinoids for evoked pain and anti-depressants for central pain. Stimulus-evoked negative symptoms are caused by damage to the somatosensory system, resulting in cell death and compromised transduction,

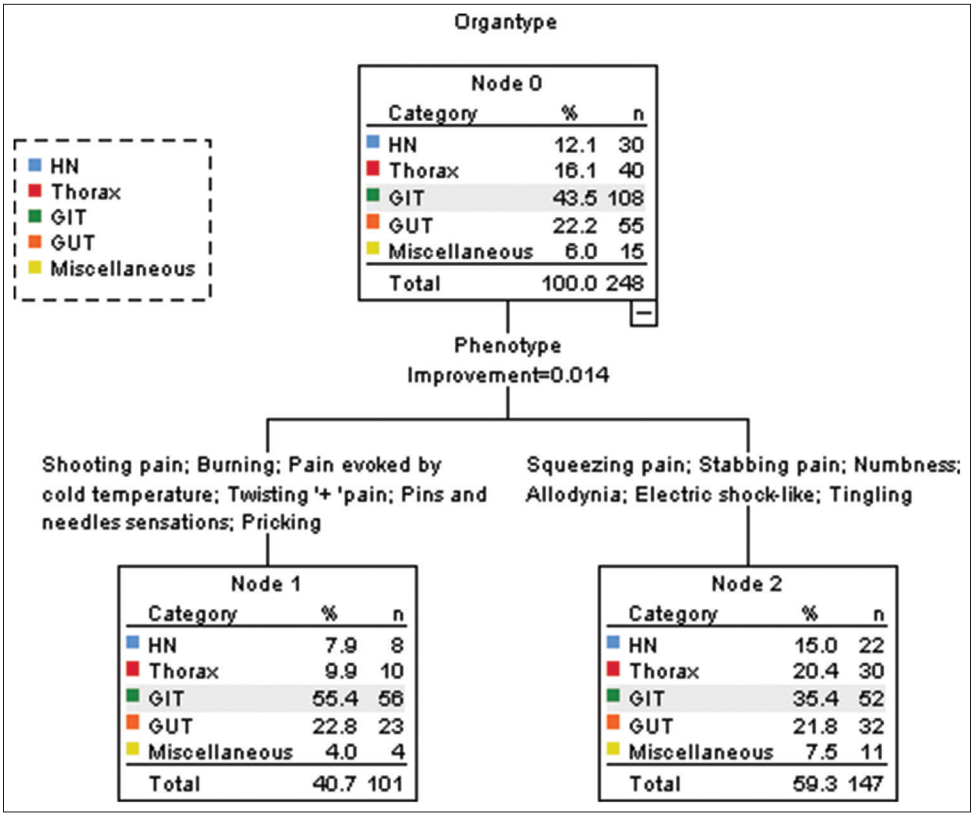

Figure 3: Phenotypic clusters formed using classification and regression trees (decision-tree method) HN: Head and neck, GIT: Gastrointestinal tract, GUT: Genitourinary tract.

conduction, and/or transmission. These cases also respond to Gabapentinoids or benefit from cognitive behavioural therapy (CBT), transcutaneous-evoked neurostimulation, or visual illusion.[5,14]

Based on decision tree analysis of our patients, we formed 2 clusters that grouped symptoms into Node 1 and Node 2. Node 1 had a cluster comprising shooting pain, burning, twisting, pricking, pin and needle sensations, and pain evoked by cold temperature. All these phenotypes, except pain evoked by cold temperature, can be grouped under spontaneous neuropathic pain. Hence, it may be advisable to try Na channel blockers ± TCAD or SNRI for neuropathic pain in these patients. We found that patients suffering from cancers of GIT and GUT systems mostly presented with this cluster of symptoms.

The cluster Node 2 comprised allodynia, numbness, squeezing, stabbing, tingling, and electric shock-like paroxysmal pain. We found that cancers of the head and neck, thorax and miscellaneous group presented primarily with Node 2 sensory characters. Approximately 60% of patients with neuropathic pain were categorised in Node 2. These patients may benefit most from gabapentinoids, CBT, and transcutaneous-evoked neurostimulation.

As far as literature is concerned, this classification is being documented for the 1st time, although the response of medications based on these nodal presentations has not been studied, which becomes a question to be answered in future research.

We cross-tabulated organ type and phenotype and found that the majority of head and neck, thoracic cancers, and miscellaneous groups presented with allodynia > tingling > electric shock-like sensation.

Gastrointestinal cancer presented with allodynia > burning > pins and needles sensations.

The genitourinary system presented with the widest sensory profile, including allodynia and tingling in equal prevalence, followed by burning > electric shock-like = pins and needles sensations > pricking > numbness > pain evoked by cold temperature = shooting pain = stabbing pain = twisting pain.

Although certain phenotypes were predominantly present in some organotypes, overall, there was no statistically significant association between the two ($P = 0.956$) [Table 1]. Similar studies have also been conducted on cases of chronic regional pain syndrome, spinal cord trauma, post-herpetic neuralgia, and peripheral nerve injury patients in which incidence of sensory phenotypes have been identified, whereas targeted drug therapy has been studied in patients of diabetic polyneuropathy and spinal cord trauma.[15-19]

One of the interesting findings of our study was that out of 73 patients who had cancer pain, 45 (61.64%) received treatment, and 28 (38.0 %) did not receive any treatment.

Both these groups had a comparable neuroanatomical correlation between pain distribution and organ cancer (82.22% vs. 85.71%, respectively).

Limitations of the study were that we did not incorporate NeuPSIG[20,21] and quantitative sensory testing, which could have identified the aetiology and sensory profiling objectively and would have been a value addition to the study.

CONCLUSION

In our study, 34.76% of patients with cancer pain suffered neuropathic pain. Allodynia and tingling were the most prevalent phenotypes. Patients were segregated into two groups, Node 1 and 2, based on clinically significant clusters of sensory phenotypes with the help of the decision tree method. Node 1 had predominantly spontaneous sensory phenotypes, and Node 2 had predominantly stimulus-evoked positive and negative phenotypes. Gastrointestinal and genitourinary cancers had clinically significant patients belonging to Node 1, whereas head and neck, thoracic cancer, and patients with spine metastasis belonged to Node 2.

Ethical approval

The authors declare that they have taken the Institutional Ethical committee and the approval number is (IEC code: 2020-49-MD-EXP-15, dated 3 March 2020).

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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