An Observational Research Study to Evaluate the Impact of Breakthrough Cancer Pain on the Daily Lives and Functional Status of Patients

Abstract:

F Twomey[1], T Oâ Brien[2], M O'Reilly[3], C Bogan[4], J Fleming[5]
[1]Department of Palliative Medicine, Milford Care Centre, Castletroy, Limerick
[2]Department of Palliative Medicine, Marymount University Hospice, Curraheen, Cork
[3]Department of Palliative Medicine, Our Ladyâ s Childrenâ s Hospital, Crumlin, Dublin 12
[4]Sligo General Hospital, Sligo
[5]Department of Palliative Medicine, Wexford General Hospital, Wexford

Abstract

Breakthrough cancer pain (BTcP) is common, resulting in significant physical and psychosocial morbidity. We assessed the impact of BTcP on 81 cancer patients attending Irish specialist palliative care services. BTcP occurred up to twice daily in 24 (30%) and 3-4 times daily in 57 (70%) of cases. Median scores for the â worstâ and â leastâ pains in the previous 24 hours were 7 and 2/10 respectively. Pain lasted <15 minutes in 19 (23.5%), 15â 30 minutes in 25 (30.8%), 30â 60 minutes in 18 (22.2%) and > 60 minutes in 19 (23.5%) of patients. BTcP had a negative impact on general activity, mood, walking ability, work, relations with others, sleep and overall enjoyment of life. BTcP increased anxiety, depression, anger, isolation, financial difficulties and an inability to undergo cancer treatments. Systematic assessment of BTcP should form an integral part of every oncology/palliative medicine assessment. Once identified, BTcP should be managed assiduously.

Introduction

Fifty years ago this year, Cicely Saunders described how terminal cancer patients with intractable pain typically experienced a â steady background painâ and intermittent exacerbations.[1] More recently in 1990, Portenoy and Hagen first suggested that the transient increases in pain experienced by a cancer patient, with otherwise stable background pain should be defined as breakthrough pain.[2] In in the intervening period, the term breakthrough pain has been used to describe a variety of clinical entities,[3] perhaps reflected in the wide range in the reported prevalence of breakthrough cancer pain from 24% to 95%.[4] In an attempt to bring clarity a 2009 task force of the Association for Palliative Medicine of Great Britain & Ireland proposed the following definition: â A transient exacerbation of pain that occurs either spontaneously, or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background painâ [5]. Based on this definition, breakthrough cancer pain specifically excludes those patients with inadequately controlled background cancer pain. A typical breakthrough cancer pain episode is of rapid onset, is often severe in nature, rapidly reaches peak intensity and lasts approximately 30 minutes.[4,6] Breakthrough cancer pain is associated with significant physical, psychosocial and economic burdens on patients and their carers. Such patients report being less satisfied with their analgesic therapy, describe decreased functioning and may also experience increased levels of anxiety and depression.[6,7] This is the first multi-centre study conducted exclusively in the Republic of Ireland to explore and describe the range of impacts due to breakthrough cancer pain on the daily lives and functional status of patients with cancer referred to specialist palliative care services the Republic of Ireland.

Methods

Following an invitation from the principal investigator to all specialist palliative care services in Ireland to participate, five services agreed to take part in this multi-centre study. The local investigator at each site invited suitable patients to participate in the study. Eligible patients were those aged over 18 years with a diagnosis of cancer and could provide written informed consent. Patients who had stable background cancer pain and were maintained on around the clock strong opioid analgesia, despite which they experienced up to four episodes of BTcP in a 24-hour period could be recruited from one of a variety of settings including specialist palliative care inpatient unit (hospice), acute general or specialist hospital and community-based specialist palliative care settings. In order to limit the burden on participating patients to the greatest possible extent, this multi-centre observational study utilised a single assessment including a questionnaire designed specifically for the study. The first section of the questionnaire involved a series of screening questions to ensure that all relevant inclusion and exclusion criteria were satisfied. Basic demographic data, location of primary tumour and functional status as measured by the ECOG score were recorded.[8]

The next phase involved a series of questions relating to breakthrough cancer pain. The final part of the assessment involved the completion of the Brief Pain Inventory (short form) version 0.2. (Copyright 1991, Charles S Cleeland, PhD, Pain Research Group). Patients who satisfied strict inclusion criteria were recruited opportunistically rather than sequentially in each of the settings where specialist palliative care is delivered, the inpatient (hospice) unit, the acute hospital and in the community. In the clinical context, making an absolute distinction between poorly controlled background pain and true breakthrough cancer pain can be challenging. Every effort was therefore made to exclude those patients with inadequately controlled background pain, specifically those subjects reporting more than an average of four breakthrough cancer pain episodes per 24 hours. Subjects who, in the investigatorâ s opinion, had any concurrent medical condition precluding the patientâ s ability to participate in the research study were also excluded. The study was approved by each local research ethics committee and was conducted in accordance with all relevant national and international guidelines for the conduct of clinical research. Each patient was provided with an information sheet and only those who met all of the inclusion criteria and who gave written informed consent were recruited. Statistical analysis was undertaken by the Health Research Board (HRB) Clinical Research facility at the National University of Ireland, Galway.

Results

Eighty-one subjects were enrolled in the study. Fifty-two percent were female. The median age of female subjects was 58 (39 â 80), and of male subjects was 68 (38 â 83). The primary sites of cancer as presented in Table 1 are broadly consistent with the incidence of invasive cancers amongst the general Irish population.[9] Performance status Performance status was assessed using the Eastern Cooperative Oncology Group (ECOG) score for each subject. Subjects reported varying degrees of functional impairment as represented by ECOG scores of 0 in 1.2%; 1 in 23.5%; 2 in 35.8%; 3 in 33.3% and 4 in 6.2% of patients. It is noteworthy that only one patient in the group had a normal score of 0 indicating that they were fully active and able to carry out all activities without restriction. Details of BTcP Twenty-four patients (29.6%) reported experiencing an average of 1-2 episodes per 24-hour period, whilst 57 patients (70.4%) reported experiencing 3-4 episodes on average per 24-hour period. Over half reported that their lasted for less than 30 minutes. The duration of breakthrough cancer pain episodes is presented in Table 2.

Sixty-nine subjects (85%) had experienced breakthrough cancer pain on the day of the assessment. They described a median score for the for BTcP â right nowâ and for pain in the previous 24 hours of 2, and a median score for the worst BTcP in the past 24 hours of 7/10. Impact of BTcP The majority of subjects reported having to limit or stop work, with associated financial implications for some. Over three quarters had to limit their usual social contacts. Subjects also reported high levels of anxiety, depression, anger and isolation. A more detailed analysis of the practical and emotional implications of breakthrough cancer pain is presented in Table 3. Patients reported that breakthrough cancer pain had a significantly negative impact on a range of life activities and functions including general activity, mood, walking ability, work (in the home and outside), relations with other people and sleep. Measured on an 11 point numerical rating score where 0 signifies â does not interfereâ and 10 signifies â completely interferesâ , the median score for interference with overall enjoyment of life was 7 (Table 4). Seventy-two patients (88.9%) reported feeling that their healthcare professionals understood their pain. Patients were

also invited to describe in their own words the experience of suffering uncontrolled breakthrough cancer pain. This analysis will be the subject of a separate report.

Discussion

This is the first study of its kind to focus exclusively on the burden and impact of breakthrough cancer pain in Irish specialist palliative care. As pain is a complex and unique and subjective experience[10] we set out to give cancer patients who were experiencing BTcP a voice. We sought neither to apply statistical significance to their descriptions nor to demonstrate any cause-effect associations between the presence of breakthrough cancer pain and any self-reported consequences. We simply documented the patientâ s individual account of his or her experiences and their conclusions drawn from them. We let the patients speak and the studyâ s validity rests in their narrative. The majority (70.4%) of our study population reported experiencing 3-4 BTcP episodes on average per 24 hour period. Not surprisingly, an increased frequency, severity and/or duration of these pain episodes had a profoundly negative impact across a range of domains, representing compromise of each individualâ s quality of life. The typical duration of a BTcP episode in our study is quite short with 54% reporting that their pain resolved within 30 minutes of onset. In a survey of 1000 European oncology patients from 13 countries (including Ireland), Davies et al reported a median duration of BTcP of 60 minutes (< 1 minute â 360 minutes).[11] BTcP was rated as severe by our patient group as evidenced by a median score for the â worst pain in the past 24 hoursâ of 7 (0 â 9) while in the Davies study, 62% patients rated their pain as â severeâ .

Breakthrough cancer pain is associated with a multiplicity of negative practical, social and financial consequences for patients in addition to impacting on their ability to endure cancer treatments. In our study the emotional distress was manifested as anxiety, depression, anger and isolation. When one considers these additional and potentially avoidable stressors on an already heavily-burdened population, it is self-evident that this phenomenon requires far greater attention and a more urgent focus from physicians and other healthcare professionals alike. One interesting finding of our study was that seventy-two patients (88.9%) reported that their healthcare professionals understood their pain. This is a surprisingly high figure when one considers the evident burden of uncontrolled pain in the same population. The early pioneers of hospice and palliative care services focused attention on the burden of uncontrolled pain in cancer. In 1980 the Working Group on Terminal Care noted that â pain is a major problem among terminal cancer patientsâ and made the astute observation that â most of the pain is unnecessary and due to poor medical managementâ .[12] Over the past three decades, we have made great strides in our understanding of the nature and pathogenesis of cancer pain. Sadly, many patients in Europe and indeed across the world, still experience inadequate cancer pain management because of excessive restrictions on the availability and accessibility of opioidsâ .13 As in all situations in medicine, unless we recognise this problem, we are unlikely to be in a position to correct it. In this instance, we have the tools that we need and simply need to apply well published principles consistently and rationally.

As a starting point, we must ensure that we include a detailed assessment of cancer pain for all patients attending for review in both hospital and community settings. Unless and until we routinely record the presence and severity of pain, both background and breakthrough, it seems unlikely that we will make significant progress. Though we took care to exclude patients with poorly controlled background pain and select only those with â pureâ BTcP, we acknowledge that in the clinical context these distinctions are not always clear. We recruited patients in an opportunistic or convenience sample, in part to avoid adding additional burden to an already heavily-burdened (and fatigued) population. Our data did not enable an attempt to be made to distinguish between spontaneous breakthrough cancer pain and incident pain. Our patients, recruited from specialist palliative care settings, may represent a sub-group with more advanced and progressive disease atypical of all cancer patients in the population. In conclusion, BTcP is burdensome across a range of physical and emotional domains and is associated with impaired enjoyment of life. Systematic assessment of breakthrough cancer pain should form an integral part of an oncology or palliative medicine assessment. Once identified, breakthrough cancer pain should be actively and skilfully managed.

Correspondence: F Twomey
Department of Palliative Medicine, Milford Care Centre, Castletroy, Limerick
Email: f.twomey@milfordcarecentre.ie

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