Italian Oncological Pain Survey (IOPS): A Multicentre Italian Study of Breakthrough Pain Performed in Different Settings

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Abstract: OBJECTIVE: A survey of breakthrough pain (BTP) was performed in five palliative care units (PCU), seven oncology departments (ONC), and nine pain clinics (OPC).
METHODS: A standard algorithm was used to confirm the diagnosis of BTP of patients referred to different settings. RESULTS: 1,412 evaluable cancer patients were enrolled. 53.9% were males and the mean age was 63.7±13.1 years. The mean intensity of background pain was 2.8±0.73. Patients reported 2.4±1.1 BTP episodes/day with a mean intensity of 7.37±1.28. 80.6% patients reported that the BTP had a significant negative impact in everyday life. The majority of patients reported a fast onset of BTP, which was predictable in 50.7% of cases, while BTP with a gradual onset (>10 min) was less predictable (29%) (P=0.001). PCU patients were older, had lower Karnofsky levels, a lower number of BTP episodes/day, a slow onset of BTP onset, and a less predictable BTP. Cancer diagnosis was performed a mean of 23.5 months (SD±32.8) before the assessment. The mean duration of background pain was 3.5 months (SD±3.5), and the mean duration of any analgesic treatment was 2.5 months (SD±3.3). BTP started a mean of 2.2 months (SD±1.9) before the assessment. Characteristics of BTP were influenced by the course of disease, as well as the duration of background pain and initiation of BTP. Most patients took rapid onset opioids and were satisfied with the treatment. BTP diagnosis was prevalently made by ONC and OPC physicians, and rarely by GPs. CONCLUSION: This survey performed by an Italian observatory expert review group, has confirmed that the BTP represents a clinically relevant condition with a negative impact on the patient’s quality of life. BTP was detected in all settings involved. A number of factors are associated with the BTP. Also factors regarding the course of disease and setting of care have been assessed. This information may help in stratifying patients or predicting the risk of development of BTP with specific characteristics.

Strengths: Large multi-center study with 1412 participants in 3 different settings. Only included patients with well controlled background pain as defined by ≤ 4/10 and less than 4 episodes of BTP per day, and used a well-defined BTP diagnostic algorithm.

Weaknesses: Opioids used were not the same as our local practice, with most patients using SR oxycodone +/- naloxone, or transdermal fentanyl for background pain, and transmucosal fentanyl for BTP.

Relevance: The prevalence of BTP is reported as 40-80% in cancer patients with pain, and in this study, 80% of patients said BTP impacted their everyday lives significantly. Unsurprisingly, rapid-onset BTP episodes were more often incident pain (50%) than gradual-onset episodes were (29%), and BTP episodes in palliative care units were of lower intensity, likely due to a less active patient population. The increase in the number of BTP episodes with greater background pain highlights the need for individualization of pain control and the flaws with an absolute cut-off definition of controlled pain. Clinically, it may be useful to be aware that patients with longer-standing pain are more likely to report rapid onset of BTP and a longer duration of each episode. Transmucosal fentanyl may be suited to the fast onset and short duration of BTP, but is expensive (30-day cost of $200-1200) and is not currently recommended by guidelines, despite patient satisfaction in this study.