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Prospective analysis of safety and efficacy of medical cannabis in large unselected population of patients with cancer

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Abstract

Background

Cancer is a major public health problem as the leading cause of death. Palliative treatment aimed to alleviate pain and nausea in patients with advanced disease is a cornerstone of oncology. In 2007, the Israeli Ministry of Health began providing approvals for medical cannabis for the palliation of cancer symptoms. The aim of this study is to characterize the epidemiology of cancer patients receiving medical cannabis treatment and describe the safety and efficacy of this therapy.

Methods

We analyzed the data routinely collected as part of the treatment program of 2970 cancer patients treated with medical cannabis between 2015 and 2017.

Results

The average age was 59.5 ± 16.3 years, 54.6% women and 26.7% of the patients reported previous experience with cannabis. The most frequent types of cancer were: breast (20.7%), lung (13.6%), pancreatic (8.1%) and colorectal (7.9%) with 51.2% being at stage 4. The main symptoms requiring therapy were: sleep problems (78.4%), pain (77.7%, median intensity 8/10), weakness (72.7%), nausea (64.6%) and lack of appetite (48.9%). After six months of follow up, 902 patients (24.9%) died and 682 (18.8%) stopped the treatment. Of the remaining, 1211 (60.6%) responded; 95.9% reported an improvement in their condition, 45 patients (3.7%) reported no change and four patients (0.3%) reported deterioration in their medical condition.

Conclusions

Cannabis as a palliative treatment for cancer patients seems to be well tolerated, effective and safe option to help patients cope with the malignancy related symptoms

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Nabiximols for opioid-treated cancer patients with poorly-controlled chronic pain: a randomized, placebo-controlled, graded-dose trial.

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Abstract

Patients with advanced cancer who have pain that responds poorly to opioid therapy pose a clinical challenge. Nabiximols (Nabiximols is the U.S. Adopted Name [USAN] for Sativex [GW Pharma Ltd, Wiltshire, U.K.], which does not yet have an INN), a novel cannabinoid formulation, is undergoing investigation as add-on therapy for this population. In a randomized, double-blind, placebo-controlled, graded-dose study, patients with advanced cancer and opioid-refractory pain received placebo or nabiximols at a low dose (1-4 sprays/day), medium dose (6-10 sprays/day), or high dose (11-16 sprays/day). Average pain, worst pain and sleep disruption were measured daily during 5 weeks of treatment; other questionnaires measured quality of life and mood. A total of 360 patients were

randomized; 263 completed. There were no baseline differences across groups. The 30% responder rate primary analysis was not significant for nabiximols versus placebo (overall P = .59). A secondary continuous responder analysis of average daily pain from baseline to end of study demonstrated that the proportion of patients reporting analgesia was greater for nabiximols than placebo overall (P = .035), and specifically in the low-dose (P = .008) and medium-dose (P = .039) groups. In the low-dose group, results were similar for mean average pain (P = .006), mean worst pain (P = .011), and mean sleep disruption (P = .003). Other questionnaires showed no significant group differences. Adverse events were dose-related and only the high-dose group compared unfavorably with placebo. This study supports the efficacy and safety of nabiximols at the 2 lower-dose levels and provides important dose information for future trials.

PERSPECTIVE:

Nabiximols, a novel cannabinoid formulation, may be a useful add-on analgesic for patients with opioid-refractory cancer pain. A randomized, double-blind, placebo-controlled, graded-dose study demonstrated efficacy and safety at low and medium doses.

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