Characterizing the Use of Nabiximols (Delta-9-tetrahydrocannabinol/cannabidiol) Buccal Spray in Pediatric Patients

Lianne Hagg, B.Sc.(Pharm.); Sarah Leung, B.Sc.(Pharm.), ACPR; Roxane Carr, B.Sc.(Pharm.), PharmD, ACPR

Background

- There is a lack of trials examining the use of medicinal cannabinoids in children
- Cannabinoids with known pharmacologic effects are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)
- THC is believed to have euphoric, analgesic and antiemetic properties, whereas CBD is believed to have anticonvulsant and anxiolytic properties
- The concentration and ratio of THC to CBD determines the therapeutic effects
- A lack of quality assurance and unknown composition of many medicinal cannabinoid products makes it challenging to assess efficacy and safety
- Nabiximols (Sativex®) is a commercially available, plant-derived cannabinoid buccal spray containing 2.7 mg THC and 2.5 mg CBD per spray. It is Health Canada approved in adults for indications of cancer pain and spasticity or neuropathic pain related to multiple sclerosis
- Currently, there are no published studies examining the use of nabiximols in children

Objectives

Primary Objective:

- To describe use of nabiximols in children

Secondary Objectives:

- To describe perceived effectiveness of nabiximols by the healthcare team and patient/caregiver
- To describe adverse events of nabiximols

Methods

- **Design:** Retrospective single cohort study
- **Inclusion:** Pediatric inpatients, aged 0 to 19 years, at BC Children's Hospital who received at least one dose of nabiximols
- **Study Period:** January 2012 to August 2018
- **Analysis:** Descriptive statistics
- **Adverse Events:** All events with a Naranjo score of ≥ 3 were reported (possible to definite likelihood)

Results

Table 1. Patient Characteristics

	N = 34
Age, years [median (range)]	14 (0.6-18)
Weight, kg [median (range)]	50 (7.4-81.9)
Male [n (%)]	16 (47)

Figure 1. Indications for Use

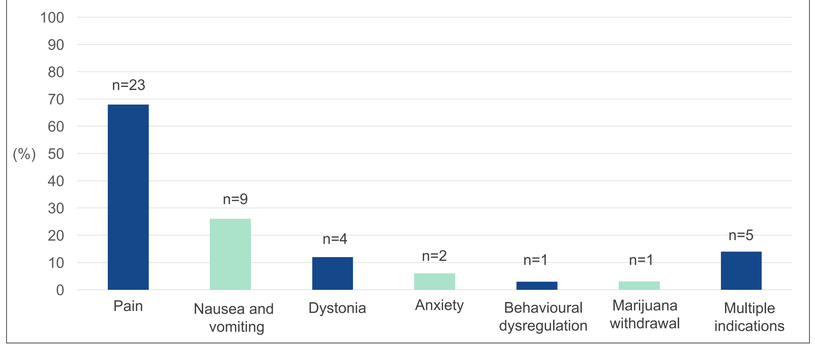

Table 2. Nabiximols Use

	N = 34
Dose [median (range)]	1.9 (0.3-10.8) sprays/day
Duration of therapy [median (range)]	3.8 (1-213) days
Number of admissions nabiximols received [mean (range)]	1 (1-4)
Changes in prescribed dosage [n (%)]	18 (53)
Discontinued in hospital* [n (%)]	11 (32)
Prescribed on discharge** [n (%)]	13 (38)
Prescriber specialty	**n (%)**
Pain	17 (50)
Palliative care	6 (18)
Oncology	5 (15)
Pediatrics	3 (9)
Psychiatry	2 (6)
Hematology	1 (3)
Multiple prescribers	2 (6)

*3 patients had subsequent admissions where nabiximols was not discontinued
**2 patients were prescribed nabiximols on discharge multiple times

Figure 2. Perceived Effectiveness

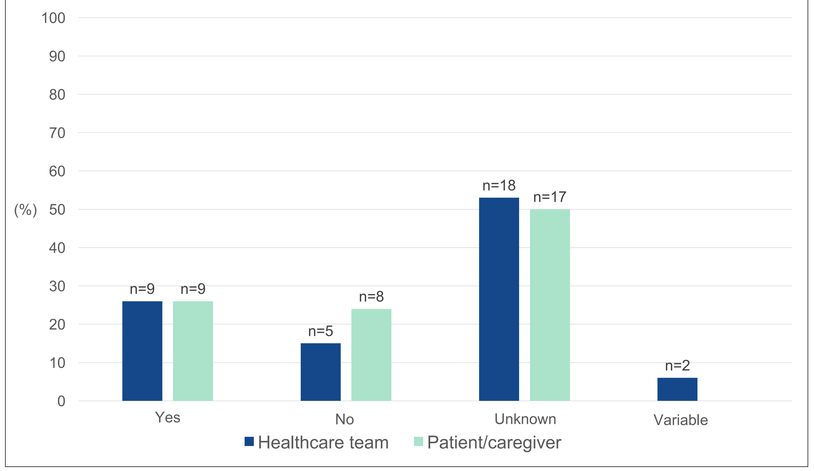

Table 3. Adverse Events

	N = 34 n (%)
CNS effects	3 (9)
Euphoria or "feeling high"	1 (3)
Behavioural changes	1 (3)
Vision changes	1 (3)
Mouth burning	2 (6)
Bradycardia	1 (3)
Tachycardia	3 (9)
Hypertension	1 (3)
Vomiting	1 (3)
Patients with > 1 adverse event	2 (6)

Limitations

- Lack of objective data documented to determine effectiveness and safety
- Small sample size

Conclusions

- Nabiximols were most often prescribed for adolescents for pain and nausea/vomiting
- Dosages received and durations of treatment were variable
- Further study needed to determine effectiveness and safety