Assent of a 16-17 Year-Old to Participate in Cannabis Research Study

Introduction

With the recent legalization of Cannabis, and observed increased use of cannabis by our OS sedation population, we have been evaluating a Pre-Sedation Cannabis Use Score (PCUS) questionnaire to delineate cannabis use and stratify the patients accordingly. We noted also that some adolescents do acknowledge cannabis use also on the routine pre-sedation evaluation. We have previously reported increased sedation needs with our on-going PCUS research study and felt that we would like to explore the prevalence and extent of cannabis usage within the adolescent population also. Of note, cannabis usage can be associated with adverse effects during sedation for dental procedures. We decided to add adolescent patients (16-17 years) to the recruitment protocol with an IRB amendment.

Also the stratification of patients according to their Cannabis use appears to be useful in determining the appropriate sedation dosing and adjunct sedation medication use.

AIM of the study: Create a consent process that allows us to recruit adolescent patients for participation in this study.

Methods

Although cannabis use is legal for adult recreational use in NY state, obtaining consent for information concerning an adolescent's (legally a Minor) use of marijuana was challenging. This required discussion with the IRB and careful preparation of the consent process to ensure that both the parent/guardian and the adolescents' wishes were considered. Figure 1 shows the two step process we used for the consent process. Parents were asked for parental permission (1A) for the adolescent to complete the questionnaire and then if they would need to see the results of the questionnaire (1B). The adolescent was asked if they would participate (2A) and then if they mind if their parents see the questionnaire after completion (2B). This results in 6 possible recruitment outcomes, in three

of these outcomes (green) then recruitment is possible. We also continued to recruit for the previously approved component of this study, alongside. This was achieved using the 25 item questionnaire (Figure 2) that was completed before the IV was placed. Procedure details, sedation requirements and outcomes were recorded from the sedation record.





Results: Adolescent and Overall Recruitment

We have recruited a total of 130 patients so far, with 14 in the new adolescent group. The USER groups and Categories (Never, Past/Occasional. Moderate, Heavy), as defined by the full PCUS are shown in Table 1. There was no significant difference between the Categories with respect to demographic data (Tables 2/3), but there were a few between the Adolescent / adult groups. In the Adolescent sub-group: the average age is 16.5 years, average BMI is 22.8. Only 1 of the adolescents acknowledged drug use during the routine pre-sedation questionnaire, however, 4 participants acknowledged cannabis use when electing to complete the survey questionnaire (Table 3). There have been no refusals to participate / consent so far by either the parent or the adolescent. One of the important findings so far in the PCUS study has been the different sedation needs demonstrated by the different USER Categories. The summary of the sedation administration required is shown in Table 4. As the use of cannabis increase so do the total dose and number of doses given for the three sedative agents used. The average adolescent dosing is consistent with only one patient using cannabis. Using the baseline dosing planned against actual dosing gives a better indication of the difference in dosing with respect to the User Categories. When the effect of all three dosing changes are reviewed (combined) this is most notable in the Moderate and Heavy categories (Figure 3).

Table 2. Demographic		*p < 0.05 c/w adult				
ADULT	NO. OF PATIENTS	PCUS	AGE (years)	WEIGHT (kg)	BMI	
OVERALL (average)	116	45.6	19.1	70.2	24.2	
USERS 0 (average)	37	0.0	18.9	69.5	24.1	
USERS 1-2 (average)	21	23.6	18.7	71.6	25.6	
USERS 3-4 (average)	34	57.4	19.3	68.8	23.5	
USERS 5-6 (average)	24	117.6	19.5	73.6	24.9	
ADOLESCENT	NO. OF PATIENTS	PCUS	AGE (years)	WEIGHT (kg)	BMI	
OVERALL (average)	14	20.3*	16.5 [*]	67.7	22.8	
USERS 0 (average)	10 [*]	0.0	16.3	65.8	22.5	
USERS 1-2 (average)	1	42.0	17.0	89.5	26.5	
USERS 3-4 (average)	2	50.6	17.0	66.9	21.8	
USERS 5-6 (average)	1	141.0	17.0	66.7	23.7	

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USE GROUPS	DESCRIPTION
USERS 0	Never Used
USERS 1	Score < 20 / Not for a year
USERS 2	Score 21-30 / Not for 6 months
USERS 3	Score 31 to 60
USERS 4	Score 61 to 90
USERS 5	Score 91 to 120
USERS 6	Score 120+

Discussion

Recruitment for both groups was successful. The consent assent process using the consent algorithm was very smooth with no cases of parental – child confrontation arising from this possibly sensitive topic. In case there is a problem both the anesthesiologist and oral surgeon have had a lot of experience dealing with this sensitive issues in the past.

The majority of adolescents, 10 of 14, patients reported no use of marijuana (PCUS of 0), however 2 of the 4 reported marijuana users had a PCUS average of over 50. 1 of the 4 adolescents had PCUS of 141 due to extensive cannabis use. Both adult and adolescent groups appear to show similar effects with increasing sedative requirements when cannabis use is heavy. This is statistically significant for the adult patients, and maybe will become so for the adolescent patients when we have recruited more cases. Failure to report cannabis was also prevalent in both the age groups, this is important as sedation dosing may be directed by the extent of cannabis use.

Table 4. Overall Sec	dation Use a	and Exces	s Use comp	areed to p	planned do	sing					
ADULT	MID TOTAL (MG)	NO. MID DOSES	FENT TOTAL (MCG)	NO. FENT DOSES	PROP DOSE (MG)	PROP DUR (MINS)	PROP RATE (MCG/KG/MIN)	MID XS	FENT XS	PROP XS	ALL XS
OVERALL (average)	5.4	2.8	109.9	3.1	165.2	20.2	127.4	1.3	1.1	1.2	1.8
USERS 0 (average)	4.4	2.3	98.6	2.9	159.0	20.9	119.0	1.1	1.0	1.1	1.2
USERS 1-2 (average)	5.3	2.8	100.0	3.0	164.8	21.1	125.6	1.3	1.0	1.1	1.5
USERS 3-4 (average)	5.3	2.8	112.5	3.1	160.8	19.2	131.4	1.3	1.1	1.2	1.8
USERS 5-6 (average)	7.0	3.5	133.3	3.6	185.2	19.8	137.5	1.7	1.3	1.2	3.0
ADOLESCENT	MID TOTAL (MG)	NO. MID DOSES	FENT TOTAL (MCG)	NO. FENT DOSES	PROP DOSE (MG)	PROP DUR (MINS)	PROP RATE (MCG/KG/MIN)	MID XS	FENT XS	PROP XS	ALL XS
OVERALL (average)	4.8	2.4	98.2	2.9	157.1	19.8	126.6	1.2	1.0	1.1	1.3
USERS 0 (average)	4.6	2.3	97.5	2.9	159.5	20.8	127.0	1.2	1.0	1.2	1.3
USERS 1-2 (average)	5.0	2.0	100.0	3.0	200.0	20.0	119.3	1.0	1.0	1.1	1.1
USERS 3-4 (average)	6.0	3.0	100.0	3.0	127.5	16.0	122.6	1.5	1.0	1.1	1.6
USERS 5-6 (average)	4.0	2.0	100.0	3.0	150.0	17.0	137.9	1.0	1.0	1.2	1.2



Conclusion

Recruitment with the adolescent group has been successful. The consent process, although more complicated, appears to be appropriate as we have not had any patient or adolescent patient decline to take PCUS questionnaire. Further data collection and analysis is ongoing as the population group still remains small. Adolescents who partake in cannabis activity require a differing sedation method compared to those who do not partake. Cannabis users, overall, have longer recovery time as well as differing regimen of sedation medication. Further data collection and analysis is ongoing.

Table 3. Dem	ographics 2				
ADULT	% FEMALE	% USE PREOP	% USERS DENY	% ETOH	% PSYCH MEDS
OVERALL	57.8	42.2	43.5	19.0	12.9
USERS 0	55.6	0.0	NA	8.3	5.6
USERS 1-2	75.0	5.0	95.0	15.0	15.0
USERS 3-4	50.0	71.9	28.1	28.1	15.6
USERS 5-6	54.2	95.8	4.2	29.2	20.8
ADOLESCENT	% FEMALE	% USE PREOP	% USERS DENY	% ETOH	% PSYCH MEDS
ADOLESCENT OVERALL	% FEMALE	% USE PREOP 7.1*	% USERS DENY 75	% ETOH	% PSYCH MEDS 7.1
ADOLESCENT OVERALL USERS 0	% FEMALE 64.3 60.0	% USE PREOP 7.1* 0.0	% USERS DENY 75 NA	% ETOH 0.0 0.0	% PSYCH MEDS 7.1 10.0
ADOLESCENT OVERALL USERS 0 USERS 1-2	% FEMALE 64.3 60.0 0.0	% USE PREOP 7.1* 0.0 0.0	% USERS DENY 75 NA 100.0	% ETOH 0.0 0.0 0.0	% PSYCH MEDS 7.1 10.0 0.0
ADOLESCENT OVERALL USERS 0 USERS 1-2 USERS 3-4	% FEMALE 64.3 60.0 0.0 100.0	% USE PREOP 7.1* 0.0 0.0 50.0	% USERS DENY 75 NA 100.0 50.0	% ETOH 0.0 0.0 0.0 0.0	% PSYCH MEDS 7.1 10.0 0.0 0.0
ADOLESCENT OVERALL USERS 0 USERS 1-2 USERS 3-4 USERS 5-6	% FEMALE 64.3 60.0 0.0 100.0 100.0	% USE PREOP 7.1* 0.0 0.0 50.0 0.0	% USERS DENY 75 NA 100.0 50.0 100.0	% ETOH 0.0 0.0 0.0 0.0 0.0	% PSYCH MEDS 7.1 10.0 0.0 0.0 0.0