ACCEPTANCE OF SEDATION GUMMY BEARS: A CONTINUATION STUDY

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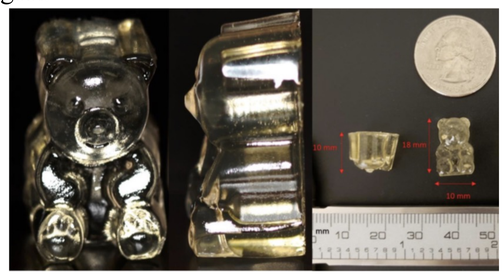
INTRODUCTION

- Oral sedation medications have challenges of large volume and bitter taste.
- An alternative delivery approach is being tested in the form of midazolam and hydroxyzine taste masked in gummy bears.
- Midazolam is ultimately the drug of choice for sedations at NSU. It is used more frequently as it has a slight anterograde amnesia effect, a fast onset short duration of action, and a reversal agent making it very safe compared to other alternatives.
- Hydroxyzine is mainly used if the desire is to increase the length of the sedation. Hydroxyzine however requires a much larger volume to be consumed making it harder for the patient to ingest.



Hydroxyzine is an H1 receptor antagonist.

- It has antiemetic, antispasmodic and anticholinergic effects. Hydroxyzine may be used as the sole sedative, but it is commonly used in combination with other drugs such as midazolam.
- It may enhance depression of the central nervous system.
- Doses studied for the use of sedation in the pediatric population range from 0.5-1mg/kg, resulting in a large volume of suspension for a pediatric patient to ingest.
- No reversal agent

Midazolam: is a selective CNS depressor and acts by opening GABA mediated chloride channels.

- Dose 0.3-1.0 mg/kg
- It is reliably & rapidly absorbed with a half-life of about one hour in a child for moderate sedation.
- Reversal: flumazenil

OBJECTIVES

- The aim is to determine the acceptability of midazolam & hydroxyzine gummies for sedation and to measure sedation parameters of sedation gummies by oral route when compared to oral suspension.
- This study is the continuation of two previously approved studies that were performed by NSU pediatric dental residence in 2019.

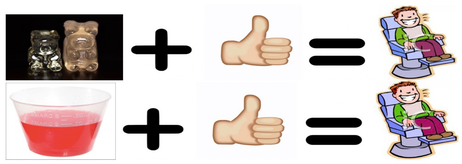
METHODS

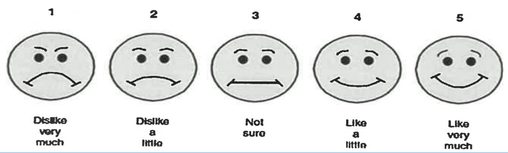
Midazolam gummies used on a convenience sample of 30 medically healthy pts. & 15 pts. with autism were scheduled for mild/moderate oral sedation at NSUs clinics.

Observational data was gathered in regard to pt. taste acceptability, level of sedation, time of onset of the gummies by the patient.

The ability of the gummy to sedate the patient was compared to prior sedations done in the previous year that used the same medication and dose in liquid form.

- This study is divided into 2 components: one portion focused on children with ASD and the other focused neurotypical children.
- This study utilized compounded gummy bears containing 2.5 mg of midazolam or 5.0 mg of hydroxyzine optimized for taste masking and compounded at the NSU pharmacy, given to attain moderate oral conscious sedation.
- Observational data was collected regarding the acceptability of the drug delivery method/ the hedonic response. I
- Efficacy of the sedation was monitored.
  -Acceptability was assessed among all patients using a 3-point Likert scale.
  -The neurotypical children also used a 5- point hedonic response scale.
  -Comparison was made between the same drugs in the liquid suspension form previously used for sedations at NSU.





INCLUSION CRITERIA

- Patients met the standards of NSU Pediatric Dentistry's pre-sedation check list & qualified as a candidate for oral conscious sedation
- Patients were English speaking only
- Patients were ASA I and II only

STATISTICS

- Descriptive statistics of the independent variables were calculated.
- The patients (N=30) were predominately male (N=27, 90%), with a mean age of 6.60 (SD= 1.71).
- The sample consisted of 7 neurotypical patients and 23 patients with a reported diagnosis of ASD.
- Patients ranged in age from four to ten. Fifteen patients were assigned to the group that received the gummies, and the data for the remaining 15 patients was extracted from our axium patient database.
- To serve as a comparison, previous sedations performed using the same medications in suspensions form were examined.

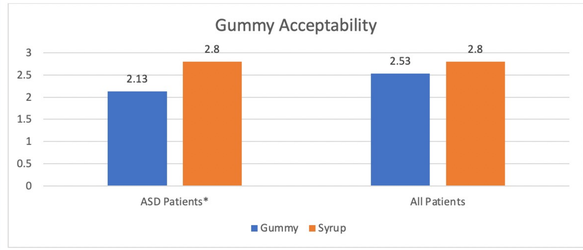
Patient Characteristics (N=30)
Mean age: 6.60 (SD=1.71), Range 4-10

Variable	N	%
Gender		
Male	27	90%
Female	3	10%
ASD Diagnosis		
Yes	23	76.7%
No	7	23.3%

- In order to determine the acceptability of midazolam and hydroxyzine gummies for sedation by all the patients (N=30), an independent samples t-test was conducted to compare the scores on the 3-point Likert's scale [Dose not taken=1; Dose partially taken=2; Dose fully taken=3]; the higher the Likert scale score, the greater the medication acceptability.
- Those who received the gummies for sedation had a mean Likert scale score of 2.53 (SD=0.83), as compared to the mean of the control group patients (2.80, SD=0.41).

RESULTS

Although the mean acceptability score of the control group was higher than the group receiving the gummies, the difference was not significant (P=0.28), indicating that among the whole sample, the use of the gummies did not produce better results.



CONCLUSIONS

Pros

- Volume of hydroxyzine reduced with concentrated gummy bear versus liquid
- Doesn't break NPO status with consumption
- Potential for future use: patents pending

Cons

- Most children consume the gummy bears: midazolam
- N is small. Clinical trial continues
- No preservatives = 2-week shelf life

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