Real-world Survey of Clinical Experience using Dexmedetomidine Sublingual Film for Acute Agitation in over 200 Adults with Schizophrenia or Bipolar Disorder

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Purpose

- Agitation is a common symptom in patients with schizophrenia (SCZ) or bipolar disorder (BPD).
- Acute agitation associated with SCZ or BPD may escalate to verbal or physical aggression, requiring pharmacologic management.
- Alpha-2 agonist, IGALMI™ DSF (dexmedetomidine sublingual film) reduces norepinephrine and is approved to treat acute agitation associated with SCZ or BPD in adults.

Objective

To characterize clinical experience with DSF in the treatment of over 200 patients with acute agitation associated with SCZ or BPD

Methods

- 80 clinicians from 30 institutions with DSF experience were invited to participate in 2 separate web-based anonymous surveys with a total of 35 questions
- No incentives were provided to participants
- Closed-ended, multiple choice, ratings, or forced ranking items
- Data included: DSF utilization, institution & patient characteristics, desired and observed treatment outcomes, efficacy and safety, clinical satisfaction, clinician-rated patient satisfaction, and product features.

Results

- 22 respondents - Overall response rate 27.5% treating over 200 patients in multiple clinical settings
- Most important DSF feature was **targeted mechanism of action**
- DSF starting doses of 180-mcg and 120-mcg were equally given with 33% administered multiple times weekly
- Impaired patients were treated
- Most patients receiving DSF self-administered
- Only 20% used agitation protocols and 10% agitation severity tools
- No additional patient monitoring required by 92% of respondents
- Patient response time ≤10 minutes in 66% of respondents
- Outcomes of DSF were rapid treatment response and decreased IM injections, staff injury, physical restraint use, treatment-related adverse effects, and benzodiazepine use
- Compared to **oral** benzodiazepines & antipsychotics, 75% rated DSF treatment speed as much better or somewhat better.
- Compared to **injectable** benzodiazepines & antipsychotics, 53% rated DSF treatment speed as much better or somewhat better
- 90% of clinicians were satisfied or very satisfied with DSF response

Respondent Demographics (N=22)

50% Pharmacists

27% Psychiatrists

13% Nurses

10% NP/PA

35 questions in 2 web-based surveys

Top Three DSF Features:
- Targeted Mechanism of Action
- Not an Injection
- Inability to Spit Out, or 'Cheek'

80% didn't require or follow a clinical pathway for agitation

92% didn't require additional patient monitoring for DSF

Top Three Observed Outcomes:
- Prompt/Efficient Treatment
- Reduced Physical Restraint Use
- Reduced Staff Injury

Figure 1: Observed Outcomes

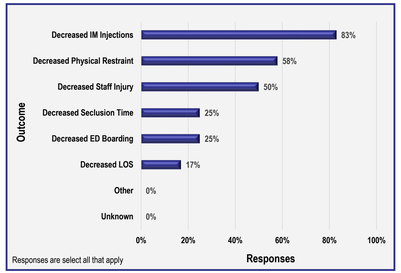


Figure 2: Observed Patient Benefits

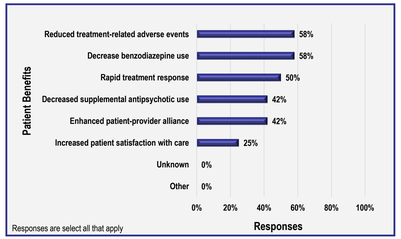
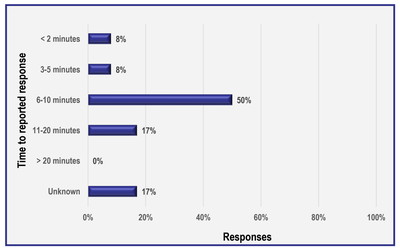


Figure 3: Time to Reported Efficacy Response



Outcomes

- Top 5 highest reported **Observed Outcomes** were (**Figure 1**) were decreased IM injections, decreased physical restraint use, decreased staff injury, decreased seclusion time, and decreased ED boarding
- Top 5 highest reported **Observed Patient Benefits** (**Figure 2**) were reduced treatment-related adverse events, decreased benzodiazepine use, rapid treatment response, decreased supplemental antipsychotics, and enhanced patient-provider alliance.
- **Time to Reported Efficacy Response** (**Figure 3**) was <10 minutes by 66% of respondents

Patient Characteristics

- Responses around use of DSF in patients was variable but when given, patients were impaired with methamphetamines, opioids, alcohol, cannabis, and other substances

Important DSF Features (Figure 4)

- The force ranked DSF product features were 1) Targeted Mechanism of Action, 2) Not an Injection, 3) Inability to Spit Out ("Cheek"), 4) Not a Controlled Substance, and 5) No REMS

Clinical Experience

- With a 5-point Likert-type scale, clinicians rated DSF experience in 2 areas (Speed of Treatment and Patient Acceptance/Safety) compared to alternative therapies: oral benzodiazepines (Oral BZD); oral antipsychotics (Oral AP) injectable benzodiazepines (Inj BZD); injectable antipsychotics (Inj AP); combination (Inj BZD + Inj AP):

  Efficacy: Speed of Treatment (Time inclusive of prescriber decision to treat, drug acquisition, and through patient response) (Figure 5)
  - Compared to Oral BZD or Oral AP, DSF was rated somewhat better or much better by **75%** of clinicians surveyed
  - Compared to Inj BZD, Inj AP, or combination, DSF was rated somewhat better or much better by **53%** of clinicians surveyed

  Patient Acceptance/Safety (Figure 6)
  - Compared to Oral BZD or Oral AP, **80%** of clinicians surveyed rated DSF as somewhat better or much better
  - Compared to Inj BZD, Inj AP, or combination injectables, **90%** of clinicians surveyed rated DSF as somewhat better or much better
  - Moderate agitation severity level most appropriate for DSF

Satisfaction (Figure 7)

- 90% of clinicians were satisfied or very satisfied with the clinical response to DSF
- 77% of patients were satisfied or very satisfied with DSF

Figure 7: Clinician & Patient Satisfaction

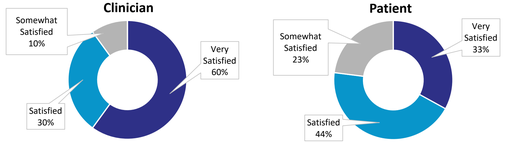


Figure 4: Important DSF Features

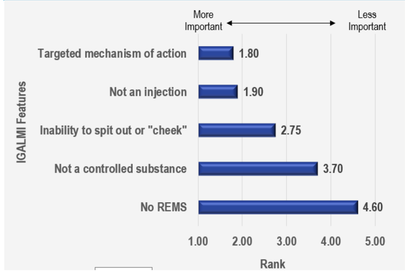


Figure 5: Efficacy: Speed of Treatment

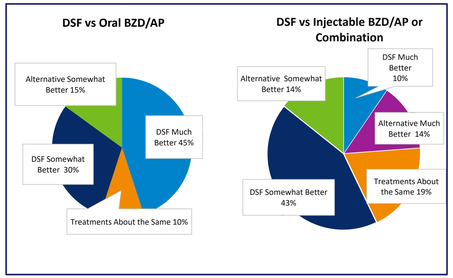
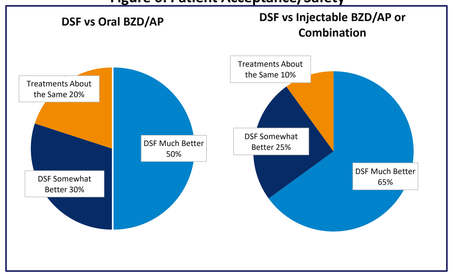


Figure 6: Patient Acceptance/Safety



Conclusions

- These two pilot surveys reported early clinical experience with DSF for agitation in over 200 adults with schizophrenia or bipolar disorder in inpatient psychiatry and emergency settings.
- Most institutions didn't require agitation management protocols (80%), didn't use agitation severity assessment tools for dose selection (90%), and didn't require additional patient monitoring over other treatment options (92%).
- Frequently observed DSF treatment outcomes aligned with desired outcomes, such as rapid treatment response, and decreased IM injections, staff injury, physical restraint use, and benzodiazepine use.
- The most important DSF product features in descending order were, Targeted Mechanism of Action, Not an Injection, and Inability to Spit Out ('Cheek').
- Starting doses of 180-mcg and 120-mcg were equally administered with patient response ≤10 minutes in 66% of patients and most patients self-administering.
- Both DSF speed of treatment and tolerability were rated favorably compared to common oral and injectable treatments
- In the absence of published real-world data using IGALMI™ DSF (dexmedetomidine sublingual film), these early experience surveys in over 200 patients may provide helpful decision-making information to clinicians.

Limitations

- Survey results are descriptive in nature and based on a limited number of respondents, so may not be generalizable to broader populations
- Because all respondents voluntarily completed the survey, voluntary response bias may exist, and survey results may over-represent organizations with higher interest in implementing new treatment strategies.