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Introduction

- 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
- When behavioral de-escalation interventions are unsuccessful, pharmacologic management may be required
- Dexmedetomidine sublingual film (DSF, Igalmi™) is an alpha-2 adrenergic receptor agonist FDA approved to treat acute agitation associated with SCZ or BPD in adults

Objective

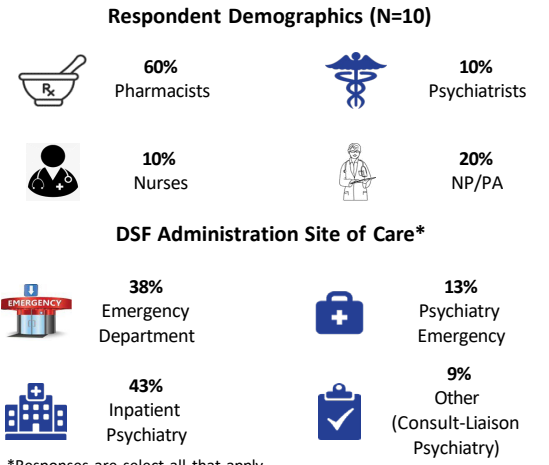
To characterize early clinical experience with DSF in the treatment of acute agitation associated with SCZ or BPD

Methods

- 20 clinicians from 10 institutions who had treated ≥ 3 patients with DSF were invited to participate in an anonymous, 20-question web-based survey
- 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

Results

- 10 Clinicians responded (50% response rate)
- 80% of respondents do not require a clinical pathway or protocol for the management of acute agitation associated with SCZ or BPD
- 90% of respondents reported no formal assessment tool use for rating agitation severity
- 30% reported that 25-50% of patients were impaired or under the influence of alcohol or illicit drugs
- 90% of clinicians were satisfied or very satisfied with DSF clinical response



20 question web-based survey

Site of care primarily emergency department and inpatient psychiatry

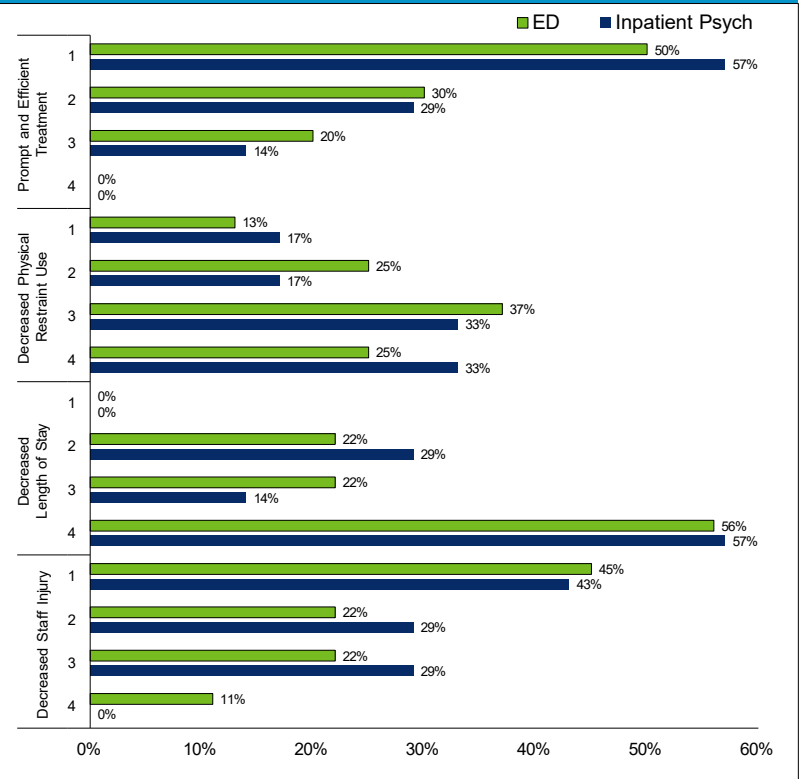
70% identified moderate agitation as the most appropriate patient

90% of clinicians were satisfied or very satisfied with DSF clinical response

Top three observed outcomes:
 - prompt/efficient treatment
 - reduced physical restraint use
 - reduced staff injury

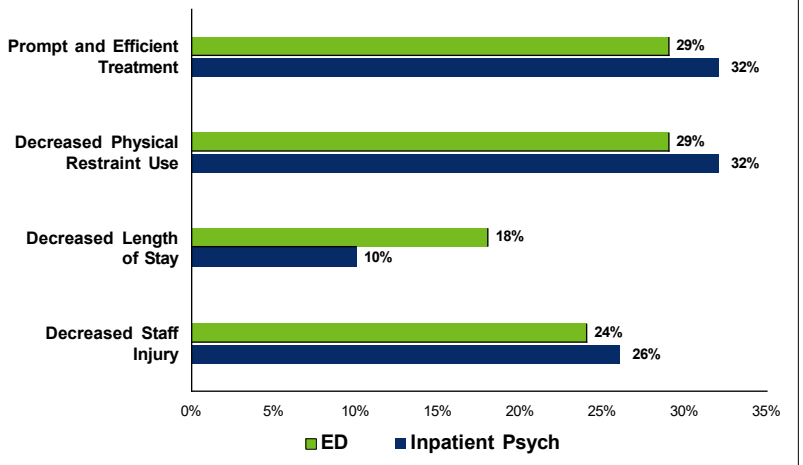
Desired Outcomes*

Top 2 forced ranked desired outcomes for DSF in both inpatient psychiatric and ED settings were prompt and efficient patient treatment and decreased staff injury



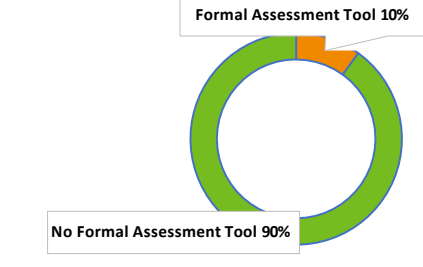
*Responses are forced rank: 1=Most Desirable; 4=Least Desirable

Observed Outcomes*

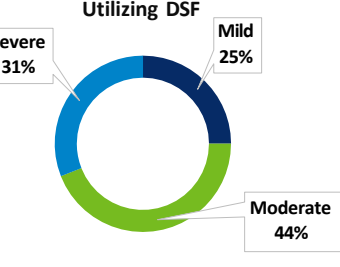


*Responses are select all that apply

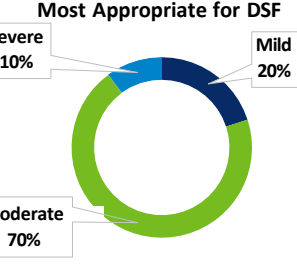
Assessing Agitation Severity



Agitation Severity Level Utilizing DSF



Agitation Severity Level Most Appropriate for DSF



Clinical Experience

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

Efficacy: Speed of Treatment (Time inclusive of prescriber decision to treat, drug acquisition, and through patient response)

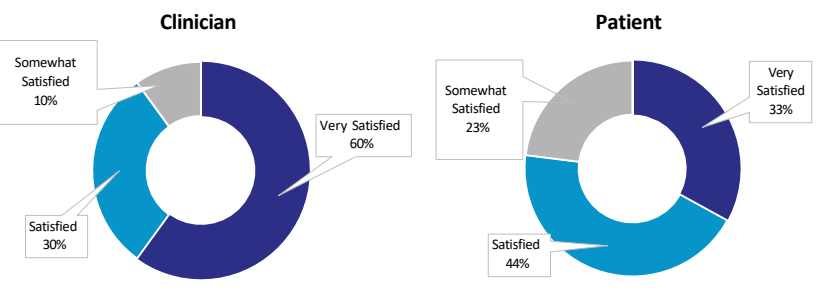
- Compared to Oral BZD or Oral AP, DSF was rated somewhat better or much better by **75%** of clinicians surveyed
- Compared to Inj BZD, Inj AP, or combination, DSF was rated somewhat better or much better by **53%** of clinicians surveyed

Patient Acceptance/Safety

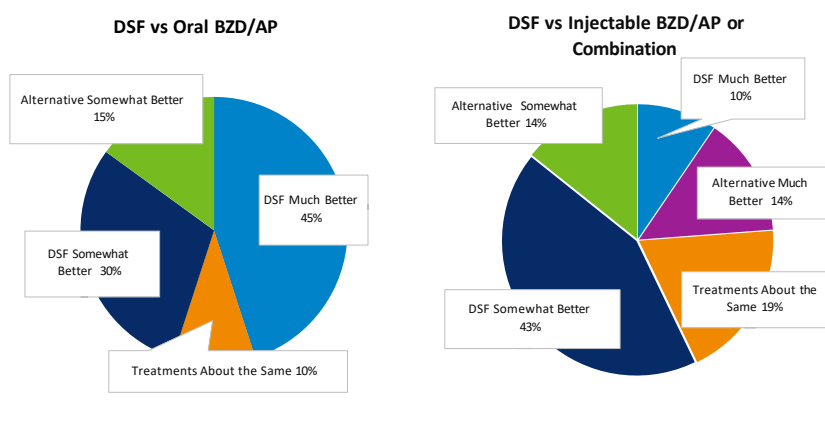
- Compared to Oral BZD or Oral AP, **80%** of clinicians surveyed rated DSF as somewhat better or much better
- Compared to Inj BZD, Inj AP, or combination injectables, **90%** of clinicians surveyed rated DSF as somewhat better or much better

Satisfaction

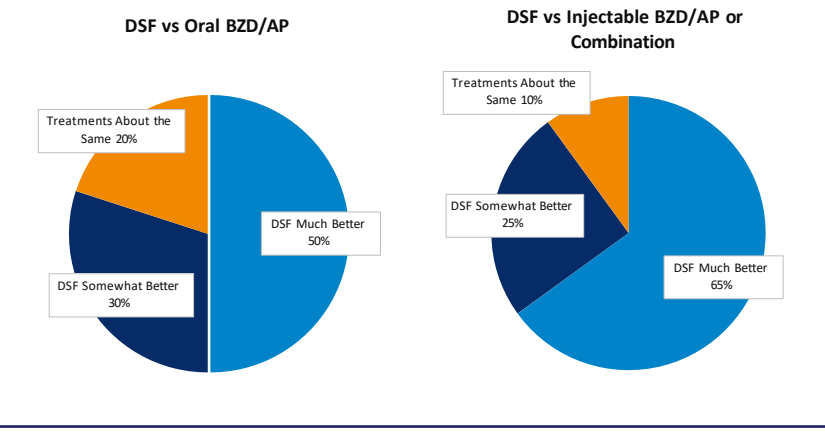
- 90% of clinicians were satisfied or very satisfied with the clinical response to DSF
- 77% of patients were satisfied or very satisfied with DSF



Efficacy: Speed of Treatment



Patient Acceptance/Safety



Conclusions

- This small pilot survey reported early clinical experience with DSF for agitation in adults with schizophrenia or bipolar disorder in inpatient psychiatry and emergency settings
- Most institutions did not require agitation management protocols (80%) and did not use agitation severity assessment tools for dose selection (90%)
- Frequently observed DSF treatment outcomes aligned with desired outcomes:
 - prompt and efficient treatment
 - decreased physical restraint use
 - decreased staff injury
- Both DSF speed of treatment and tolerability were rated favorably compared to common oral and injectable treatments
- Majority of clinicians (90%) and patients (77%) were satisfied or very satisfied with DSF
- Early experience using DSF may provide helpful decision-making information to clinicians in similar settings

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 strategies to manage acute agitation associated with SCZ or BPD